ABSTRACT

Atrial fibrillation (AF) is the most common abnormal heart rhythm, affecting nearly 2% of the world’s population at a cost of $26 Billion in the United States annually, and incalculable costs worldwide. AF causes no symptoms for some people. However, others with AF experience uncomfortable symptoms including palpitations, breathlessness, dizziness, and fatigue. AF can severely diminish quality of life for both AF sufferers and their loved ones. Beyond uncomfortable symptoms, AF is also linked to congestive heart failure and stroke, both of which can cause premature death. Medications often fail to control AF, leading patients and healthcare providers to seek other cures, including catheter ablation. To date, catheter ablation has yielded uneven results, but garners much attention in research and innovation in pursuit of a cure for AF. This dissertation examines the historical development and contemporary practices of AF ablation to identify opportunities to improve the innovation system for the disease. First, I trace the history of AF and AF ablation knowledge from the 2nd century B.C.E. through the present. This historical look identifies patterns of knowledge co-development between science, technology, and technique, as well as publication patterns impacting knowledge dissemination. Second, I examine the current practices of AF ablation knowledge translation from the perspective of clinical practitioners to characterize the demand-side of knowledge translation in real-world practice. Demand-side knowledge translation occurs in nested patterns, and requires data, experience, and trust in order to incorporate knowledge into a practice paradigm. Third, I use social network mapping and analysis to represent the full AF ablation knowledge-practice system and identify opportunities to modify research and innovation practice in AF ablation based on
measures of centrality and power. Finally, I outline six linked recommendations using raw data capture during ablation procedures and open big data analytics, coupled with multi-stakeholder social networking approaches, to maximize innovation potential in AF ablation research and practice.
ACKNOWLEDGMENTS

I am deeply grateful to my dissertation committee for providing an intellectual sounding board that was accommodating, challenging, and supportive in equal measures. I owe them many thanks, collectively and individually.

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Along with Clark, I am indebted to Andra Williams whose special gift of cheerleading has been a comfort and inspiration.

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>LIST OF TABLES</th>
<th>ix</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIST OF FIGURES</td>
<td>x</td>
</tr>
<tr>
<td>LIST OF ABBREVIATIONS</td>
<td>xi</td>
</tr>
</tbody>
</table>

## CHAPTER

### 1 THE PROBLEM OF ATRIAL FIBRILLATION AND ABLATION

- INNOVATION .............................................. 1
  - The Problem of Atrial Fibrillation .............................................. 1
  - The Problem with AF Ablation .............................................. 3
  - Patient Perspective .............................................. 6
  - Societal Perspective .............................................. 13
  - Constructing this Project .............................................. 20
  - Methods .............................................. 21
  - Related Work .............................................. 32
  - Reflexive Note .............................................. 33

### 2 AF PRIMER: ARRHYTHMIA AND THERAPIES .............................................. 36

- Epidemiology .............................................. 36
- Physiology and Pathophysiology .............................................. 38
- Clinical Care of Patients with AF .............................................. 41
- Summary .............................................. 55

### 3 THE HISTORY OF ABLATION FOR ATRIAL FIBRILLATION .............................................. 56

- History of AF Catheter Ablation (or, How AF Became a Killer... vi

...
CHAPTER  Page

Without a Cure.................................................................56
Contemporary Practices, Variation, and Controversies in AF Catheter

Ablation.................................................................73

Co-Development of Knowledge in AF Ablation.........................86

Power in AF Ablation......................................................103

Implications for Innovation Recommendations.........................113

4 KNOWLEDGE-PRACTICE PARADIGMS IN AF CATHETER

ABlation.................................................................116

Moving Knowledge to Practice..............................................117

Individual Paradigms.......................................................121

Group/Team Knowledge Paradigms and Practice Patterns..............139

Field Paradigms...........................................................147

Implications for Innovation...............................................155

5 KNOWLEDGE SYSTEMS................................................160

AF Ablation Knowledge System...........................................164

Social Network Analysis as a Critical Tool................................199

AF Ablation Knowledge System Analysis..............................202

Opportunities for System Innovation and Optimization..............223

6 INNOVATION RECOMMENDATIONS IN THE U.S. HEALTHCARE

SYSTEM CONTEXT.....................................................230

Research Findings.......................................................231

Innovation Recommendations...........................................239
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Actor Type Classification, Grouped by Individual, Institution, and Technology</td>
<td>25</td>
</tr>
<tr>
<td>2. Thematic Coding Framework for Historical Literature Analysis</td>
<td>92</td>
</tr>
<tr>
<td>3. Actor Types in the AF Ablation Knowledge System</td>
<td>182</td>
</tr>
<tr>
<td>4. Formal Actor Network Density</td>
<td>206</td>
</tr>
<tr>
<td>5. Formal Actor Network Centrality</td>
<td>208</td>
</tr>
<tr>
<td>6. Informal Actor Network Density</td>
<td>212</td>
</tr>
<tr>
<td>7. Informal Actor Network Centrality</td>
<td>212</td>
</tr>
<tr>
<td>A-1. Coding Scheme for Historical Documents</td>
<td>313</td>
</tr>
</tbody>
</table>
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Normal Electrical Function and Atrial Fibrillation</td>
<td>38</td>
</tr>
<tr>
<td>2.</td>
<td>Year-by-Year Count of AF Ablation Articles Indexed in PubMed</td>
<td>58</td>
</tr>
<tr>
<td>3.</td>
<td>Non-Fractionated and CFAE Electrograms</td>
<td>75</td>
</tr>
<tr>
<td>4.</td>
<td>Voltage Map and CFAE Map of Left Atrium</td>
<td>76</td>
</tr>
<tr>
<td>5.</td>
<td>Triple Helix Structure</td>
<td>90</td>
</tr>
<tr>
<td>6.</td>
<td>Models of Knowledge Translation and Co-Development</td>
<td>93</td>
</tr>
<tr>
<td>7.</td>
<td>Graphical Example of Knowledge Co-Development in AF Ablation</td>
<td>94</td>
</tr>
<tr>
<td>8.</td>
<td>Rotor Sites and Conventional Ablation Sites</td>
<td>103</td>
</tr>
<tr>
<td>9.</td>
<td>Knowledge Density in the Knowledge-Practice Paradigm</td>
<td>119</td>
</tr>
<tr>
<td>10.</td>
<td>Individual Knowledge-Practice Paradigm</td>
<td>122</td>
</tr>
<tr>
<td>11.</td>
<td>Group or Team Knowledge-Practice Paradigm</td>
<td>140</td>
</tr>
<tr>
<td>12.</td>
<td>Field-Level Knowledge-Practice Paradigm</td>
<td>148</td>
</tr>
<tr>
<td>13.</td>
<td>Formal and Informal Knowledge (Sub)Systems in the AF Ablation Knowledge System</td>
<td>165</td>
</tr>
<tr>
<td>14.</td>
<td>Watchman Left Atrial Appendage Occlusion Device</td>
<td>195</td>
</tr>
<tr>
<td>15.</td>
<td>Formal Knowledge System Map</td>
<td>205</td>
</tr>
<tr>
<td>16.</td>
<td>Informal Knowledge System Map</td>
<td>211</td>
</tr>
<tr>
<td>17.</td>
<td>Dendogram Showing Similarity Among Clinicians Performing AF Ablation</td>
<td>214</td>
</tr>
<tr>
<td>18.</td>
<td>Full Knowledge System Map</td>
<td>218</td>
</tr>
<tr>
<td>19.</td>
<td>Multiplex Matrix Data</td>
<td>221</td>
</tr>
<tr>
<td>20.</td>
<td>Graphic summary of recommendations for knowledge system innovation</td>
<td>240</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td>AdvaMed</td>
<td>Advanced Medical Technology Association</td>
<td></td>
</tr>
<tr>
<td>AF</td>
<td>Atrial fibrillation</td>
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</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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</tr>
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<td>AV</td>
<td>Atrioventricular</td>
<td></td>
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<td>BRCA</td>
<td>Breast cancer susceptibility gene</td>
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<td>BS</td>
<td>Basic scientist</td>
<td></td>
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<tr>
<td>CARD</td>
<td>Non-electrophysiology cardiologist</td>
<td></td>
</tr>
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<td>CCDS</td>
<td>Certified Cardiac Device Specialist</td>
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<td>CDRH</td>
<td>Center for Devices and Radiological Health</td>
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</tr>
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<td>CEPS</td>
<td>Certified Electrophysiology Specialist</td>
<td></td>
</tr>
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<td>CFAE</td>
<td>Complex fractionated electrogram</td>
<td></td>
</tr>
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<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
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<td>CSPO</td>
<td>Consortium for Science, Policy &amp; Outcomes</td>
<td></td>
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<td>DALY</td>
<td>Disability-adjusted life-years</td>
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</tr>
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<td>Department of Health and Human Services</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<td>EP</td>
<td>Electrophysiology/Electrophysiologist</td>
<td></td>
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<td>EPRN</td>
<td>Electrophysiology laboratory nurse</td>
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<td>EPT</td>
<td>Electrophysiology laboratory technologist</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FHR S</td>
<td>Fellow of the Heart Rhythm Society</td>
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</tr>
<tr>
<td>FIRM</td>
<td>Focal impulse and rotor modulation</td>
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<tr>
<td>Acronym</td>
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<td></td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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</tr>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>HRSA</td>
<td>Health Resources and Services Administration</td>
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<tr>
<td>HRS</td>
<td>Heart Rhythm Society</td>
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<tr>
<td>ICD</td>
<td>Implantable cardioverter-defibrillator</td>
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<td>IR</td>
<td>Industry representative</td>
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<td>MD</td>
<td>Doctor of Medicine</td>
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<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
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<tr>
<td>M&amp;M</td>
<td>Morbidity and mortality conference</td>
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<tr>
<td>NCATS</td>
<td>National Center for Advancing Translational Sciences</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NOAC</td>
<td>Newer oral anticoagulant</td>
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<td>NP</td>
<td>Nurse practitioner</td>
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<td>NSF</td>
<td>National Science Foundation</td>
<td></td>
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<tr>
<td>NTL</td>
<td>Non-thought-leader electrophysiologists</td>
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<td>PA</td>
<td>Physician assistant</td>
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<td>PHI</td>
<td>Protected health information</td>
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<td>PhRMA</td>
<td>Pharmaceutical Research and Manufacturers Association</td>
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<tr>
<td>PMA</td>
<td>Premarket Approval</td>
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<td>PS</td>
<td>Professional society senior manager</td>
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<td>PVI</td>
<td>Pulmonary vein isolation</td>
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<td>RF</td>
<td>Radiofrequency</td>
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<td>Abbreviation</td>
<td>Description</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>QT</td>
<td>Ventricular repolarization segment of the cardiac electrical cycle</td>
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<td>RFID</td>
<td>Radiofrequency identification</td>
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<td>RO</td>
<td>Regulatory official</td>
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<td>SEK</td>
<td>Swedish Krona</td>
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<tr>
<td>STS</td>
<td>Science and technology studies</td>
<td></td>
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<td>TL</td>
<td>Thought-leader electrophysiologists</td>
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<tr>
<td>UIC</td>
<td>Unique identifier code</td>
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<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>U.S.</td>
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<td></td>
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<tr>
<td>USD</td>
<td>U.S. Dollars</td>
<td></td>
</tr>
<tr>
<td>WACA</td>
<td>Wide area circumferential ablation</td>
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<td>YODA</td>
<td>Yale Open Data Access</td>
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<td>£</td>
<td>British Pounds</td>
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</table>
CHAPTER 1

THE PROBLEM OF ATRIAL FIBRILLATION AND ABLATION INNOVATION

“When the pulse is irregular and tremulous and the beats occur at irregular intervals, then the impulse of life fades; when the pulse is slender [smaller than feeble, but still perceptible, thin like a silk thread], then the impulse of life is small.” – Huang ti nei ching su wen: The Yellow Emperor’s Classic of Internal Medicine (Veith, 2002, p. 159-160)

The Problem of Atrial Fibrillation

Since the 2nd century, people have been trying to describe, classify, and treat atrial fibrillation (AF), the irregular heartbeat that plagues tens of millions of people worldwide, causing uncomfortable symptoms, disabling strokes, and immeasurable emotional distress. In the United States (U.S.) alone, AF treatment costs more than $26 billion annually\(^1\) (Goren, Liu, Gupta, Simon, & Phatak, 2013), or nearly the annual budget of the National Institutes of Health (NIH). Population projections estimate that AF will continue to grow in prevalence, swelling to afflict 8 million Americans (Colilla et al., 2013; Naccarelli, 2009) by 2050, or nearly 2% of the projected U.S. population (Passel & Cohn, 2008).

In my practice as a nurse practitioner in cardiac electrophysiology since 2001, I have cared for many people as they enter the labyrinth of diagnostic tests, medications, \(^{1}\)In 2009 USD.
and invasive procedures to treat AF, typically abbreviated to a-fib, or “fib,” in the parlance of healthcare providers. AF is most often a chronic disease, exerting complex effects on other aspects of health and daily living beyond the discomforts associated with the arrhythmia itself. Although a prevention-based approach would seem ideal, prevention does not address the suffering of those who already have AF. Moreover, existing knowledge about AF remains quite limited. We know that AF is associated with scarring of heart tissue, weakened and enlarged hearts, high blood pressure, obesity, and an overactive thyroid gland. However, not all obese people have AF, and most people with high blood pressure do not have AF. We know that AF runs in some families, but not in others. We also know that substances like caffeine and alcohol can trigger AF in some people, but not in others. As such, we have some ideas about things to avoid in order to prevent AF. But for some patients who already keep a healthy lifestyle – avoiding excess alcohol and caffeine, and maintaining a healthy body weight with low blood pressure – we are at a loss to explain their AF, let alone prevent it. Given that medication approaches may help to alleviate patient symptoms, the burden of daily medications poses an imperfect therapy, as it introduces additional costs and stressors – essentially trading the burden of the disease for the burden of the treatment. Therefore, in the absence of a genomic solution, a curative device-based approach would seem to offer the most promising solution to alleviating the burden of AF at all levels – the individual patient, the system of healthcare providers, and society writ large.
The Problem with AF Ablation

One of the tools that we have available for treatment— and scientific discovery— related to AF is catheter ablation. In 2016, as I write this, catheter ablation is widely considered the most advanced and promising therapy for AF. But ablation is not perfect, and does not assure a patient that his or her AF will improve, let alone be cured.

Since the early days of ablation procedures for AF, coinciding roughly with the start of my clinical career, there has been a steady stream of new technologies and techniques for identifying, locating, isolating, and destroying the electrical signals that cause AF. Each innovation promises enhanced accuracy, improved efficiency, and greater success with AF ablation. As clinicians, we monitor the ever-growing body of clinical research literature that compares new techniques to old, reports on new catheters and mapping systems, and suggests a burgeoning role for AF ablation for treating AF.

Yet in closed-door conversations, clinicians often question the wisdom of our seemingly pervasive push to perfecting AF ablation. We have a sense that it works to reduce AF for some people, but not always predictably, and almost always yields to recurrent arrhythmia within a few years. Therefore, we adopt new variations in our technical approach to AF ablation, sometimes involving new intracardiac mapping systems, new catheters, or new areas of targeted destruction in the heart tissue. These variations are sometimes guided by small clinical trial findings published in medical journals that we incorporate along with our existing approaches. Sometimes we rely on clinical acumen, or a hunch, to guide our techniques. No two electrophysiologists perform AF ablation in exactly the same way, and most electrophysiologists do not even
perform AF ablation in exactly the same way for every patient. Often, the published experience from so-called thought-leaders in AF ablation fails to account for real world experiences and practices of the much larger group of non-publishing AF ablation practitioners, or non-thought-leaders. However, this literature informs the formal knowledge system for innovation. We hope that we can find the so-called holy grail of AF ablation that will cure the arrhythmia forever, but we acknowledge that for now, AF ablation is unlikely to reach that goal, partly as a function of the wide variety of experience and limited successes of existing literature and technologies.

Still, for patients who continue to have AF episodes despite medication treatments, or those who suffer troublesome side effects with medications, we have a sense that AF ablation is better than the alternative approach, in which we completely disconnect the patient’s heartbeat so that they are dependent on an implanted pacemaker. Although this pace-and-ablate approach yields nearly complete resolution of AF symptoms with minimal complications, the notion of making a person dependent on a pacemaker for their most basic physiologic function can be troubling. If it is possible to accomplish the goal of controlling AF without destroying the natural heartbeat, it feels like that is a better, safer, more desirable therapeutic approach. So, we struggle with

---

2 This terminology of non-thought-leaders is not intended to suggest that these individuals who are not thought-leaders are not thoughtful. Quite to the contrary, this work will show that the AF ablation innovation system is limited by not capturing the deep thoughtfulness of these so-called non-thought-leaders, who could rightfully be termed thoughtful non-leaders.

3 I recall talking with colleagues in 2002 about the need for a trial to compare AF ablation to the older ablate-and-pace approach, in which the patient’s atrial and ventricular electrical systems are disconnected at the atrioventricular (AV) node using the same technology as the AF ablation this project addresses. However, in the case of AV node ablation, the technique applies ablation energy in a different area of the heart than in AF ablation.
knowing when and how to determine that AF ablation isn’t going to work for a patient, and whether we should recommend it once, twice, or not at all. And for our patients who do undergo AF ablation and have recurrent arrhythmia, when should we press ahead to try just one more thing? Or when should we make the decision to stop trying to eradicate AF and just focus our attention on preventing a stroke? As clinicians, we press on, accumulating informal knowledge via experience and conversation to inform our practice along with the growing, yet fundamentally incomplete, formal literature. We do our best to make decisions with and for patients, as we engage with the ever-developing landscape of AF ablation technologies to adopt and adapt the new innovations that continue to appear like new arrows in our ablation quiver. But I am left with the feeling that there must be a better way to capture the expert knowledge that develops from experience treating and living with AF ablation, yet never makes it into the literature because it does not come from recognized thought leaders in the field. If the informal knowledge system

ablation. At the time, we concluded that a comparative study would likely never be done, as the potential findings were not solidly in the interest of either the catheter companies or the pacemaker companies that would be able to provide the resources necessary to fund a trial of sufficient magnitude to provide statistical power to answer the comparison question. In the intervening 12 years, we still await that trial; our formal knowledge, vis à vis the scientific literature, remains incomplete.

At the time of this writing from 2014-2016, a major clinical trial is underway to compare the effectiveness of AF ablation with antiarrhythmic medications. As with a direct comparison between so-called curative ablation and permanent pacing, this issue transcends the interests of any pharmaceutical or medical device company. Indeed, only the National Institutes of Health – an industrially agnostic body – can sponsor this research. It is telling that more than 5 years after the launch of this trial, scarcely three-quarters of the 2200 targeted subjects were enrolled, despite 124 active centers enrolling patients in 10 countries (CABANA Trial, 2016). The difficulty finding patients to enroll might be surprising, given the ever-growing burden of AF worldwide. However, clinical practice related to AF is characterized by making clinical recommendations about new technologies, despite relatively incomplete knowledge in the formal literature to guide our decision-making. Therefore, the drive to treat and innovate does not necessarily entail a drive to do formal clinical research.
could be understood along with the formal knowledge system, perhaps innovation around
AF ablation could be more productive, and yield better outcomes for patients with AF.

In light of the therapeutic and scientific goals and limitations, it seems worthwhile
to accelerate and improve innovation for AF ablation. This project seeks to identify
opportunities to innovate within the existing AF ablation knowledge system in order to
better support innovation to ultimately find a better way to relieve the burden of AF for
individuals and society. First, I will characterize the burden of AF and AF ablation for
individuals and society. Then I will describe the approach to constructing this project.

**Patient Perspective**

The main driver to spur innovation in AF ablation is the patient who must live
with the experience and consequences of AF on a daily basis. It is helpful, therefore, to
briefly review common patient experiences with AF.

**Symptoms of AF**

Patients describe a range of symptoms, including palpitations, shortness of breath,
lightheadedness, fatigue, or no symptoms at all. For some people, AF symptoms are
distinct; they know exactly when they go into the arrhythmia. One of my patients, a
recently-retired high school history teacher, knows exactly when his AF starts and stops.
He adjusts his medications accordingly, taking an extra dose of his antiarrhythmic drug
when he is in AF. For others, symptoms are vague; they think that they might be out of
rhythm, but they aren’t sure. Another of my patients is an 86-year-old woman who falls
into this category. At a recent visit to my office she said, “I think I’ve been in and out of it [AF] for about the past month, but I’m not really sure.” Rarely, AF causes heart rates so fast that the patient loses consciousness. Some people are essentially unable to complete their daily activities of living when they are in AF, putting social and professional plans on hold until their symptoms subside and their energy returns.

AF episodes can be triggered by a variety of variations in everyday life, including food, stress, and activity. I take care of a 46-year-old man who frequently goes into AF after his favorite vigorous treadmill workout at the gym. Another of my patients is a 54-year-old man who predictably goes into AF after a weekend alcohol binge in the midst of coping with a tumultuous romantic relationship. Yet another is a 71-year-old man who, with his wife, has been caring for two young grandchildren while his daughter has been on bed rest with another pregnancy. After active days of babysitting, they have been stopping at a restaurant for dinner, too tired to cook for themselves at home. The salty restaurant food has caused his blood pressure to be higher than usual, and he has been suffering with more AF for the past month, making him even more tired. When we drew this connection during a recent clinic visit, he was flabbergasted. He said, “I had no idea that what I eat could make me go out of rhythm.” These types of lifestyle impacts on AF are common, but not consistent for every patient. Therefore, living with AF entails a significant period of uncertainty as each patient must piece together their particular puzzle of AF triggers.
Medications: Impact on Daily Living

Patients with AF often take multiple medications to try to control the rhythm and decrease the risk of stroke. Many of these medications must be taken with food in order to avoid stomach upset or gastric bleeding, or to increase the absorption and effectiveness of the medication in the body. Many medications must be taken with more or less precise timing – 12 hours apart or 8 hours apart – in order to ensure that a steady dose of medication remains in the body to keep arrhythmias at bay. This means that a patient’s daily life and meals must be organized around medication dosing times with little room for flexibility, lest a breakthrough arrhythmia occur.

Some medications, notably the blood thinner warfarin, require frequent blood tests (sometimes weekly or more often) to ensure that the drug levels are maintaining the patient’s blood at just the right thinness. Too much warfarin can cause dangerous bleeding, and too little warfarin can increase the risks of a blood clot forming that can cause a stroke.

Many medications for AF interact with other medications or foods, causing problems with medication levels in the bloodstream, or even raising the risk of other life threatening arrhythmias. In many cases, the interactions with heart rhythm medications are with antibiotics and antifungal medications, limiting the treatment options available for patients who develop infections. In addition, many people with AF must monitor their diet for arrhythmia triggers. Others must maintain strict control over their daily vegetable intake in order to regulate Vitamin K levels that interfere with the blood thinner that helps to protect against a stroke.
Many medications that are prescribed to control the heart rate in AF, or even to control AF itself can lower the blood pressure, causing fatigue, lightheadedness, or even fainting. Many of these same medications can also cause the heart rate to slow down so much that people feel sluggish, out of breath, or lightheaded. Sometimes the heartbeat can slow so much that the person faints; in many of these cases, a patient must have a pacemaker implanted in order to maintain a normal heart rate with the medications that are helping to control AF.

**Risks of Stroke and Heart Failure**

During AF, the atria do not contract normally; they fibrillate, or quiver. This quivering motion of the heart walls does not pump blood effectively through the atria. Rather, blood is more stagnant than usual, and tends to pool and form clots, particularly in the left atrial appendage, an ear-like projection of the left atrium. Blood clots that form in the left atrium may eventually travel from the atrium through the left ventricle and be pumped out of the heart into the general circulation of the body, including the brain where a blood clot will eventually lodge in a smaller blood vessel, blocking blood flow – and thus oxygen – to that area of the brain. When a part of the brain is deprived of oxygen, it effectively dies, akin to the section of a heart muscle affected by a heart attack. Just as the affected part of a heart muscle no longer beats properly after a heart attack, the affected part of the brain no longer functions properly after a stroke. Depending on the area affected by a stroke, a person may lose the ability to speak, remember new information, move part of their body, or even breathe. People with AF have a five-fold
increase in stroke risk compared to the rest of the population (Wolf, Abbott, & Kannel, 1991).

The risk of stroke related to AF increases with other types of heart disease. For people who have no other heart disease, the annual risk of stroke with AF is higher than that of the general population, but still quite low – about 0.84% per year (Camm et al., 2010). For people who have other stroke risk factors, including diabetes, high blood pressure, congestive heart failure, or blood vessel blockages, the risk of stroke related to AF is much higher. Risks are also higher with advancing age, and significantly higher if the person has had a prior stroke or mini-stroke. For a person who has every risk factor for stroke: a woman over the age of 75 who has high blood pressure, diabetes, a weakened heart, artery blockages, and a history of mini-strokes, the annual risk of stroke with AF is estimated at 18.2% (Camm et al., 2010). This means that each year, this woman has a nearly one-in-five risk of having a stroke unless she takes medications to thin her blood, or has a separate procedure to insert a clot-blocking device or surgically remove the left atrial appendage.

**Psychological Impacts to Patient and Loved Ones**

One of my patients is a vibrant and articulate 50-year-old woman who has been plagued by AF, which she tracks sometimes using an app on her iPhone. I asked her once if she would like to participate in a clinical trial using a more sophisticated monitor. She considered it for a few weeks, and ultimately declined. She told me, “I want to help you with your study, but I just don’t want to have to think about my a-fib every day. It [thinking about a-fib] makes me feel bad.”
AF exerts significant impacts to quality of life for patients, with studies demonstrating significantly lower health-related quality of life for patients with AF (Kang & Bahler, 2004; McCabe, 2010; Suzuki & Kasanuki, 2004; Thrall, Lane, Carroll, & Lip, 2006). In addition to impacts from direct symptoms of AF, multiple studies have shown that having AF is associated with significant levels of physiological stress for patients due to direct discomfort from troublesome symptoms, as well as anxiety related to the possibility of recurrent symptoms for patients with paroxysmal AF (Gehi et al., 2012). Indeed, many patients have told me that they have avoided or canceled travel because they are afraid that they might have a-fib episodes. The effects of AF, therefore, pervade the lives of many patients, even if the arrhythmia itself is held at bay with medications. In addition, AF causes significant stress to patients’ loved ones with nearly the same level of emotional distress as patients experience directly (Bohnen et al., 2011).

**Financial Costs of AF**

AF is a costly condition, both for society at large and for patients individually. Individual costs may vary significantly for patients in countries with private versus national medical systems. Patients in countries with nationalized health systems have heavily subsidized prescription plans with annual maximum caps for prescription medications. For example, in the United Kingdom (UK) an annual prepaid prescription plan costs 104£ (163.16 USD on 28 June 2015), and no Swedish citizen pays more than SEK2,200 (263.17 USD on 28 June 2015) for medications annually (National Health Service, 2014; Sweden, 2015). In contrast, Americans can spend thousands of dollars per month for prescription medications. Even for patients with significantly subsidized
private medication plans, newer medications can cost up to $40 per month after the insurance subsidy. For older Americans with Medicare prescription plans, there is an annual out-of-pocket spending limit similar to other national health plans. However, the 2016 spending limit for Medicare patients is $4,850 – more than 18 times more than Swedes pay, and nearly 30 times more than Brits pay for prescription medications annually.

In addition to medication costs, patients may incur significant expenses for testing, and procedures to treat AF. These costs may vary dramatically between regions, and even between facilities within a single region. For example, at one private health system in Harrisburg, Pennsylvania, the average out-of-pocket cost for cardioversion was $3,831 for patients with no insurance, $2,619 for patients with employer or commercial insurance, and $864 for patients with Medicare (PinnacleHealth, n.d.). At Mayo Clinic Hospital in Phoenix, Arizona the patient cost for an elective electrical cardioversion is $1,342 (Mayo Clinic, 2014). At another hospital system in Palo Alto, California, the out-of-pocket cost for an ECG – the standard test to diagnose a patient’s heart rhythm status that may be performed several times in a single hospital visit – is $202 (El Camino Hospital, 2016). The average self-pay cost to the hospital for catheter ablation in the state of Arizona in 2009 was $66,723 (Arizona Department of Health Services, 2011), though most hospital billing departments note that they will work with patients and may offer a discounted rate for those who do not have insurance coverage or other resources. Overall, the costs of AF care are typically higher for patients who opt for a rhythm control approach in order to alleviate AF symptoms, whether by medications or interventional procedures.
On top of the out-of-pocket costs for medications and procedures to treat AF, patients often have costs related to missed work. These costs, of course, vary widely depending on profession and type of employment. However, it is important to note that the Medicare population — older adults — are increasingly likely to be in the workforce due to significant discrepancies between Social Security income and actual living costs in 2015. Other costs to the patient include transportation to medical appointments and procedures, and costs of missed work for family members who attend appointments or procedures, or who must accompany patients to hospital outpatient procedures that involve administering sedation (and thus require that the patient be accompanied by a responsible adult to assume care in the post-anesthesia period).

**Societal Perspective**

In addition to thinking about the myriad impacts that AF has on patients and families at the individual level, we need to consider the impacts that AF has at the societal level.

**Costs of AF Care**

Medical costs of cardiovascular disease have grown by 6% annually from 2001-2011, and compose 15% of the increase in annual health spending in the U.S. Direct costs of all cardiovascular disease in the U.S. is predicted to triple between 2010-2030 from $273 billion to $818 billion dollars (in 2008 USD). In addition, indirect costs of
cardiovascular disease are expected to increase 61% over the same timeframe from $172 billion to $276 billion (Heidenreich, 2011).

AF costs represent a significant minority of all cardiovascular disease costs in the U.S. In 2009, AF was estimated to cost $8705 annually for each of the 3.03 million Americans with AF for a total of $26.4 billion\(^4\) (Goren et al., 2013), or nearly the annual budget of the NIH; between half and three-quarters of that cost was related to hospitalizations (Coyne et al., 2006). There is a trend toward increased hospitalizations for AF, correlating with an increase in hospital-based procedures and pharmaceutical approaches used to treat AF. People with AF have markedly higher rates of healthcare resource use compared to people without AF, including 43% higher rates of outpatient healthcare provider visits, and more than twice the rate of ER visits and hospitalizations (Goren et al., 2013).

Indirect costs of AF are more difficult to quantify. However, a 2010 U.S. study in the showed that people with AF missed nearly twice as many days of work annually as individuals without arrhythmias (Rohrbacker, 2010). A 2007 European study found that people with AF missed between 2-6 weeks of work annually due to AF (Ringborg et al., 2008).

**Cost Considerations of AF Ablation**

The data related to cost and cost-effectiveness of AF ablation is varied. AF ablation costs to the hospital may vary significantly as a function of the variety of ablation technologies available to physicians may result in a three-fold cost differential

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\(^4\) In 2009 USD.
($7,000 to $22,000) depending on the particular configuration of mapping, catheter, and ablation energy technologies used in a single ablation case (Winkle, Mead, Engel, Kong, & Patrawala, 2013). Some of these costs may be passed along to insurance companies or consumers, but this is not the case universally. A study of ablation procedures from 2006-2011 demonstrated that ablation procedures with higher costs typically yield a small improvement in patient outcomes, but also have higher rates of complications (Perino et al., 2015).

In a 2006 U.S. cost effectiveness study, AF ablation was found to be cost effective (in 2004 costs) when examined for the endpoint of stroke risk reduction for patients at moderate risk of stroke, but not cost effective for patients with low risk of stroke (Chan, Vijan, Morady, & Oral, 2006). It is worth noting, however, that those patients at low risk of stroke tend to be younger and more active, and in many cases more symptomatic with arrhythmia. Therefore, the patient population for whom ablation was less cost effective may be more motivated to pursue curative therapy in order to avoid a lifetime of medications. A more recent European study of cost-effectiveness found AF ablation to be cost effective for younger patients with paroxysmal AF, but not for older patients or those with longer-lasting AF (Aronsson et al., 2015). This difference may reflect changes in ablation effectiveness, or national differences in costs due to structural features of U.S. and European healthcare systems. Finally, a novel approach to assessing costs of AF ablation found that the costs of AF care are lower for patients who have undergone ablation compared to patients who do not undergo ablation, with ablation costs recovered after 50 months and costs of lost productivity recovered after 18 months.
(Kleinman, Rohrbacker, White, March, & Reynolds, 2011), lending support for AF ablation as a long-term cost-beneficial solution.

**Timing and Costs of Innovation: Research and Regulatory Pathways**

In the U.S., the Food and Drug Administration (FDA) regulates medical devices through the Center for Devices and Radiological Health (CDRH). Devices associated with AF ablation are generally considered Class II medical devices, as they are used in the body and confer moderate risk of morbidity and mortality if they malfunction. This is contrast to Class I devices that are used outside the body and confer minimal risk, and Class III devices that confer high risk to the individual in the event of malfunction. Most Class II devices are evaluated via the 510k pathway, which is considered a streamlined evaluation process for devices that are substantially similar to existing technologies already approved for use. De novo Class II devices and all Class III devices are regulated via the PMA (Premarket Approval) process, which does not use an existing technology as the basis for evaluation. In response to criticism that regulatory processes are cumbersome and stifle innovation, the FDA has been making a public-facing (as opposed to intramurally-focused) effort to encourage innovation. The FDA’s Innovation Initiative, founded in 2011, seeks to improve upstream guidance for medical device companies in order to address study design questions early in the development and research process in order to facilitate and thus contract the typical timeline from innovation to FDA clearance for commercial marketing of products (CDRH, 2011).

Although the process and costs of device development are generally considered to be quicker and less costly than that for pharmaceuticals, it is estimated that the
development time from concept to market for medical devices may range from 3-7 years with stringently prescribed standards for the types of experimental data required to demonstrate safety and efficacy. This is compared to the estimated 12 years and $800 million investment from molecule to market for a novel pharmaceutical agent (Fargen et al., 2013). Therefore, device companies must be judicious about which technology innovations they will pursue. In light of the financial constraints posed by regulatory processes, even the FDA’s effort to improve their innovation pathway still does not effectively afford broader access to the medical device innovation pipeline.

A recent trend in the device industry is for individuals or small firms to pursue venture capital funding to develop a technology through the FDA pipeline then be acquired by a larger company (e.g. Biosense Webster, St. Jude Medical) around the time of FDA approval. Topera and TactiCath technologies are good examples of this phenomenon.  

Topera was an American firm founded in 2008 by Sanjiv Narayan and Ruchir Sehra (Bloomberg Businessweek, 2014), who quickly engaged a seasoned device industry professional as the CEO of the company. After progressing through the patent process and FDA pipeline and securing 510(k) clearance of its first generation mapping system in 2012, Topera went through several rounds of venture capital funding totaling $31.52 million. Topera was purchased by Abbott Laboratories, a major corporation in the medical device industry, in October 2014 for over $250 million.

5 I will return to describe the technical aspects of Topera and TactiCath in Chapter 3.
6 The 510k pathway establishes that a new medical device is substantially equivalent to a device that is already commercially available. This regulatory pathway is considerably less costly and burdensome than the PMA pathway that is required for a device that is entirely novel.
TactiCath also followed this development pathway. In 2003 the pressure-sensitive catheter ablation technology was developed by the Swiss firm Endosense, who filed patents and conducted initial European clinical trials with the financial backing of multiple European venture capital firms until 2013 when it was purchased by St. Jude Medical for $170 million, with an additional $160 million payment contingent on meeting regulatory milestones. Like Abbott Laboratories, St. Jude Medical is another major player in the medical device industry.

In both the Topera and the TactiCath cases, development of the technology required significant investment of time and capital to reach the point of clinical study and eventually commercial use by a widespread field of healthcare providers to impact patients with AF. As subsequent chapters show, broad use of new technology is critical to the innovation process, and to scientific understanding more fundamentally. The Topera and TactiCath cases illustrate the high barriers that must be overcome to engage the innovation system in order to progress toward curing AF. I return to these technology cases in Chapter 3 to illustrate the ways in which AF ablation knowledge emerges and progresses over time, and in Chapter 4 as examples of the ways that new technology knowledge transitions into practice.

**Healthcare Workforce**

Healthcare workforce studies have predicted a shortage of physicians, nurses, and other providers to meet the healthcare needs of the aging U.S. population (Bodenheimer, Chen, & Bennett, 2009). Some estimates have indicted that there are similar shortages in cardiology and electrophysiology (Rodgers et al., 2009), though the 2008 economic
collapse in the U.S. resulted in a decline in procedure volume, and thus the workforce gap diminished so that by 2014, a gap no longer seemed as dire (O'Gara, Cooper, & Fry, 2014). There is still need for cardiovascular providers, but that need is felt more keenly in geographical regions that many cardiologists consider less desirable, including rural and underserved populations. In addition, increasing use of communication and information technologies, including telemedicine, has virtually increased the reach of cardiovascular specialists so that fewer providers are able to provide care for more patients. However, this virtual reach does not extend to interventional procedures, which still require a live team of physician and allied professional staff with specialized training in the complex AF ablation procedure.

Electrophysiologists responding to a 2009 Heart Rhythm Society survey stated that they felt competition in the workforce, and noted that referring physicians (mostly cardiologists, but also primary care providers and emergency room physicians) were the primary source of 95% of patients, with only 5% of patients self-referring (Deering et al., 2010). However, even in the event of a currently competitive market, the nature of AF impacting older adults and particularly older adults with other structural heart disease, suggests that there will continue to be an increasing population of Americans requiring care for AF, with double the cases of AF in 2050 as in 2013 (Ball, Carrington, McMurray, & Stewart, 2013). As evidence grows to support rhythm control and interventional device-based therapies, it is reasonable to expect that the workforce requirements for electrophysiology will continue to grow to meet the needs of a growing AF patient population. In light of the population age inversion that is occurring in the U.S. as a function of improved survival and increased lifespan, it is not clear how these
workforce demands for AF will be met, let alone demands for workforce to care for people with other chronic diseases associated with an aging population, like diabetes and Alzheimer’s disease (Rice & Feldman, 1983). Therefore, if the field can advance AF therapies to eliminate the chronicity of the disease, it may be possible to effectively relieve population health burdens to focus scarce workforce resources on other worthy areas.

**Constructing this Project**

With individual and societal impacts of AF in mind, I have approached this project with a goal to characterize the relationships between knowledge, practice, and innovation around AF ablation in order to propose changes to improve the innovation system for AF ablation. The findings and recommendations from this study will be focused on innovation in the context of the practice and regulatory environment around AF catheter ablation in the U.S. However, the core findings may be relevant to innovation for a broad variety of biomedical technologies – and other types of technologies – used in the U.S. and internationally.

**Theoretical Framework**

I use three major theoretical constructs to build the framework for this project. In Chapter 3, I demonstrate that the knowledge of and about AF catheter ablation is co-developed by three distinct and interrelated types of knowledge that operate within a broader healthcare environment that enables and constrains the developing knowledge in multiple ways. This co-development model characterizes the ways that individual sources
and streams of knowledge impact, and are impacted by, interaction with one another to yield a novel understanding. Recognizing AF catheter ablation as a co-developed system highlights the types and sources of knowledge that are important to consider, in order to ensure that the system is complete.

Next, in Chapter 4, I show that knowledge and practice paradigms in AF catheter ablation are formed and shift at multiple similar nested levels, recalling broad observations about fractals and self-similarity (Mandelbrot, 1977). Understanding the patterns by which individuals, groups, and fields take up knowledge and translate knowledge into practice raises additional useful insights to inform innovation practices.

Finally, in Chapter 5, I show that AF ablation is developed and used in the context of a complex adaptive sociotechnical system comprising individuals, institutions, and technologies that continually interact to with a variety of goals and approaches to leverage ablation technology. The complex and adaptive nature of the AF ablation knowledge system poses a set of attributes and insights that critically impact innovation in the field. 

### Methods

This research uses a mixed-method qualitative approach, including literature search, historical analysis, ethnographic fieldwork methods, and social network analysis.

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7 In medicine, knowledge systems exit within innovation systems and perform two simultaneous functions: innovation and social control of medical practice. This project focuses on innovation functions. Future work will turn to examine the knowledge system as an instrument of social control.
Literature Analysis

I use literature analysis to demonstrate the phenomenon of co-production in AF catheter ablation. I first identified a body of key articles in the peer-reviewed literature representing the work of thought leaders in AF catheter ablation. These articles include seminal studies on pulmonary vein isolation and areas of contemporary controversy in AF ablation practice; consensus statements from major professional societies; and review articles from the peer reviewed literature. I read each of these articles closely, and coded each one based on content related to science, technology, technique, or a combination of these meta-codes. I also noted the presence of domesticated knowledge, or the individualized use of a technology, as well as the patterns of citation that each of these key articles employed. I then performed ancestry searching from each of these key articles to identify historical references undergirding the published work. This approach yielded over 630 articles in the medical literature from 1850 to 2015, representing the major formal knowledge system of AF catheter ablation.  

I analyzed each of these articles to determine whether it represented knowledge of science, technology, or technique, or a combination of these meta-codes based on title, abstract, and key words. I then performed historical analysis to map the co-development of knowledge through the history of AF catheter ablation to the present practice paradigms. My findings from historical literature analysis are discussed in Chapter 3.

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8 This 630-work corpus is a subset of the full body of indexed peer-reviewed literature directly related to AF ablation, consisting of 9,558 articles since 1980, as of a PubMed search on September 30, 2015.
**Ethnographic Fieldwork**

I used ethnographic techniques of participant observation and interview (including semi-structured and unstructured interview techniques) to conduct fieldwork in order to build a model and understanding of AF catheter ablation as a complex adaptive actor-network system. I used the same ethnographic fieldwork to explore the phenomenon of knowledge and technology uptake in the system. In some ways, I have been working as a participant-observer for the past 16 years as I moved from being a nurse practitioner student to early career professional to a named leader in the field of cardiac electrophysiology. However, my deliberate participant observation and interview fieldwork, approved by the Institutional Review Board at Arizona State University, began in December 2013. My clinical career experience has afforded me a framework of extant knowledge, as well as a dense network of colleagues, that has enabled me to streamline my ethnographic fieldwork for this project.

I conducted participant observation in public settings, including three large international scientific meetings held in the U.S.: Heart Rhythm Scientific Sessions 2014, American College of Cardiology Scientific Sessions 2015, and Heart Rhythm Scientific Sessions 2015. I conducted participant observation at a fourth smaller international scientific meeting held in the U.S.: the 12th Global CardioVascular Clinical Trialists Forum in 2015. I also conducted participant observation at two semi-public events: an invitation-only research forum (Heart Rhythm Society Research Forum on the Treatment and Prevention of Atrial Fibrillation) and an industry-sponsored educational dinner. I have also been a participant-observer at multiple private events, including three AF ablation cases in two different electrophysiology (EP) labs, direct patient care
experiences, and many meetings as part of my leadership role as a Trustee of the Heart Rhythm Society and, to a lesser extent, a health policy subcommittee member in the American College of Cardiology.

In addition to participant observation, I conducted semi-structured and unstructured interviews with 31 individual informants representing nodes in the network. These interviews included face-to-face, telephone, and e-mail communication. When feasible, interviews were recorded and transcribed, in addition to handwritten interview notes. My informants were all engaged in some way with AF ablation in the United States, and included 3 thought-leader electrophysiologists (TL), 6 non-thought-leader electrophysiologists (NTL), 5 electrophysiology nurse practitioners and physician assistants (NP/PA), 2 EP lab nurses (EPRN), 2 EP lab technologists (EPT), 3 industry representatives (IR), 4 regulatory officials (RO), 3 professional society senior managers (PS), 2 basic scientists (BS), and 1 non-EP cardiologist (CARD). Throughout the manuscript, I will refer to informant interviews using the letter code, followed by a number (e.g. NTL-1). I will discuss my classification criteria in chapters 3, 4, and 5, particularly as it applies to the thought-leader designation.

Network Coding

In order to construct and analyze the AF ablation knowledge system, I used social network analysis techniques including coding for existing flows of communication, in order to assess for existing sites of centrality as well as structural holes. I approached network construction by reviewing participant observation field notes and interview transcripts to identify nodes in the network. A variety of individuals and institutions
contribute to the diagnosis and ongoing management of AF, representing all phases from fundamental bench research to regulating and marketing medical technologies to direct face-to-face patient care.⁹ Although there is some variation in the activities and arrangements of individuals and institutions in different local and national settings, there are broad similarities across the field. I constructed nodes using a regular equivalence approach, as described in social network analysis methods (Borgatti, Everett, & Johnson, 2013), to understand individual actors and actants (including institutions and communication technologies) in their archetypal forms based on the professional licensing and scope of practice established by local and national regulations, task allocation in the work environment, or institutional employment patterns. For example, I grouped all thought-leader AF ablation electrophysiologists into a single node for the purposes of building the network. I used this classification approach to identify interview respondents confidentially, in addition to constructing the network.

Table 1

*Actor Type Classification, Grouped by Individual, Institution, and Technology.*

<table>
<thead>
<tr>
<th>Actor Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thought-leader EP (TL)</td>
<td>Physicians who perform AF ablation and are recognized as thought-leaders in the peer-reviewed literature and professional meeting presentations. TLs are prominent nationally or internationally and are typically actively engaged in directing new clinical research including industry-sponsored research and independent research.</td>
</tr>
<tr>
<td>Non-thought-leader EP (NTL)</td>
<td>Physicians who perform AF ablation but do not contribute as thought-leaders in the peer-reviewed literature and professional meeting presentations. NTLs may be prominent in local communities among physicians, but are not prominent nationally or</td>
</tr>
</tbody>
</table>

⁹ In addition to describing these institutions as actor types in the table that follows, I will describe the individuals and institutions in the context of AF care in Chapter 2.
<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>internationally, and are not typically engaged in directing new clinical research, though they may participate as a site in industry-sponsored clinical research.</td>
<td>Thought-leader non-AF ablation Physicians who are thought-leaders in the field of cardiac electrophysiology but do not perform AF ablations.</td>
</tr>
<tr>
<td>Media professional</td>
<td>Professional writers, editors, publishers of mainstream, medical, and social media publications distinct from peer-reviewed publications.</td>
</tr>
<tr>
<td>EP lab registered nurse (EPRN)</td>
<td>Registered nurse participating directly in AF ablation cases.</td>
</tr>
<tr>
<td>EP lab technologist (EPT)</td>
<td>Technologist (including Cardiovascular Technologist [CVT], Radiology Technologist [RT], and clinical engineers) who are employed by the hospital and participate in directly in AF ablation cases.</td>
</tr>
<tr>
<td>Industry Representative in EP lab (IR)</td>
<td>Industry-employed field personnel who perform sales and clinical support services directly for AF ablation procedures.</td>
</tr>
<tr>
<td>Industry business manager</td>
<td>Industry-employed professionals who are focused on business, rather than clinical aspects of AF ablation technologies and procedures.</td>
</tr>
<tr>
<td>Industry engineer</td>
<td>Industry-employed engineers who are focused on new technology development.</td>
</tr>
<tr>
<td>Basic scientist (BS)</td>
<td>Typically PhD-prepared scientists who are employed by universities or hospitals and conduct pre-clinical research, including computer modeling, in-vitro experiments, and animal lab experimentation.</td>
</tr>
<tr>
<td>EP nurse practitioner/physician assistant (NP/PA)</td>
<td>Non-physician heart rhythm specialist typically involved in the clinical care of patients in inpatient and outpatient settings. May be involved as an assistant to the physician in the EP lab during the AF ablation procedure.</td>
</tr>
<tr>
<td>Non-EP cardiologist (CARD)</td>
<td>Cardiology provider (including physicians and non-physician providers) who are part of the cardiovascular care team for the AF patient, but do not directly lead the heart rhythm care.</td>
</tr>
<tr>
<td>Family including patient as subject of care</td>
<td>This node represents patients and their family members (including non-related loved ones and advocates) who are engaged in decision-making regarding the AF care. This node is distinct from the patient as a physiological object of ablation.</td>
</tr>
<tr>
<td>Primary care provider</td>
<td>Primary care provider (including physicians and non-physician providers) who are part of the patient’s healthcare team but does not typically lead</td>
</tr>
</tbody>
</table>
cardiovascular care, and does not direct heart rhythm care.

<table>
<thead>
<tr>
<th>Institutional Actor Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital administration</td>
<td>Individuals and institutional mechanisms that control staffing and purchasing decisions in the hospital.</td>
</tr>
<tr>
<td>Insurance provider</td>
<td>Public and private organizations providing insurance coverage to patients undergoing AF ablation. Insurance providers make decisions to cover (or not cover) AF ablation procedures based on national coverage determinations (for public insurance) and typically mirroring national coverage determinations (for private insurance). Insurance providers determine the patient’s individual deductible or co-pay cost, as well as payments to hospitals and physicians for ablation services.</td>
</tr>
<tr>
<td>FDA (RO)</td>
<td>Food and Drug Administration. Approves medical devices for use in the United States on the basis of safety and efficacy through the Center for Devices and Radiological Health (CDRH) via established regulatory pathways for new and modified medical devices.</td>
</tr>
<tr>
<td>CMS (RO)</td>
<td>Centers for Medicare and Medicaid Services. Makes national coverage determinations for medical procedures, and sets regional and national payment rates for physicians and hospitals.</td>
</tr>
<tr>
<td>Professional society (PS)</td>
<td>Organization comprising and representing medical professionals. The major professional societies in the United States for heart rhythm professionals are Heart Rhythm Society and the American College of Cardiology. There are other smaller professional societies also engaged with heart rhythm care. Professional societies typically engage in education and advocacy activities, including producing annual scientific meetings, publishing peer-reviewed journals, and serving as advocacy representatives to governmental and non-governmental agencies.</td>
</tr>
<tr>
<td>Patient advocacy organization</td>
<td>Patient-directed organizations typically focused on a single disease state. The major AF patient advocacy organization in the United States is StopAfib.org.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Communication Technology Actant Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer-reviewed journal articles</td>
<td>Articles appearing in peer-reviewed journals indexed by PubMed.</td>
</tr>
<tr>
<td>Non-peer-reviewed journal articles</td>
<td>Articles appearing in journal publications that are not peer-reviewed. These articles may or may not be indexed by PubMed.</td>
</tr>
<tr>
<td>Government-regulatory</td>
<td>Official documents from government agencies</td>
</tr>
<tr>
<td>dispatches</td>
<td>including FDA and CMS.</td>
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<tr>
<td>Private insurance coverage decisions</td>
<td>Published coverage decisions from private insurance companies.</td>
</tr>
<tr>
<td>Traditional media – central sources</td>
<td>Publications from media professionals with content written mainly by media professionals. Traditional media may be print or online, including video presentations.</td>
</tr>
<tr>
<td>Social media – de-central sources</td>
<td>Media content that is generated by individuals other than media professionals. May include blogs, discussion boards, chat rooms, or video content. Social media sites may be publicly available or restricted to members meeting some criteria for participation.</td>
</tr>
<tr>
<td>Meeting presentations</td>
<td>Official content composing the program of a professional scientific meeting. The major meetings in the United States related to AF ablation include the annual scientific sessions of the Heart Rhythm Society, the American College of Cardiology, and the American Heart Association, along with the Boston AF Symposium (renamed in 2014 as the International AF Symposium after relocating from Boston to Orlando).</td>
</tr>
<tr>
<td>Conference abstracts-posters</td>
<td>Peer-reviewed original research or case presentations in the form of a poster or short oral presentation as part of a scientific meeting. Conference abstracts are typically published in a supplemental issue of the professional association’s major peer-reviewed journal (e.g. <em>Heart Rhythm, Journal of the American College of Cardiology, Circulation</em>).</td>
</tr>
<tr>
<td>Industry publications</td>
<td>Educational and marketing materials published by industry. These are not peer-reviewed publications, nor are they considered non-peer-reviewed journals, as the content is typically specific to a single company’s products.</td>
</tr>
<tr>
<td>Industry meetings-dinners</td>
<td>Educational and marketing programs produced by a device company. These include satellite symposia associated with scientific meetings that typically feature a panel of thought-leader speakers, as well as local programs that are typically organized by a single field sales team and feature local physician speakers. The content for industry meetings is typically created by industry personnel and presented by physicians who are directly compensated for the presentation. Industry</td>
</tr>
</tbody>
</table>
Educational and sales programs are discrete entities, regulated by AdvaMed\textsuperscript{10} rules in terms of the content that can be discussed. Federal law requires that companies report all physician speakers and advisers, along with physician attendees at industry events, along with the value of the meal, which is counted as physician income from industry in a national database.

<table>
<thead>
<tr>
<th>Patient as object of ablation</th>
<th>This node represents the patient as a physiological structure on whom AF ablation is performed. This patient node is distinct from the patient as a sentient being and independent decision-maker regarding AF care.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab technologies</td>
<td>Catheters, mapping, and ablation systems used in performing AF ablations.</td>
</tr>
<tr>
<td>Procedure notes</td>
<td>Official documentation of the AF ablation procedure that becomes part of the patient’s permanent medical record.</td>
</tr>
<tr>
<td>Standard operating procedures</td>
<td>Document containing the official procedures, including equipment, for an AF ablation procedure. These documents are specific to each EP lab, and are typically approved by hospital administration bodies and protocols.</td>
</tr>
<tr>
<td>Meeting sidebar conversation</td>
<td>Off-the-record conversation occurring at a scientific meeting. Meeting sidebar conversations may be overheard by individuals not directly involved in the conversation.</td>
</tr>
</tbody>
</table>

Network ties between nodes represent the presence or absence of direct communication between nodes. I used a binary coding approach to provide a simple illustration of communication flows. It would be feasible and likely informative to conduct future research using a graded analytical schema based on the strength or other quality of communication ties. However, a graded approach exceeded the scope of this initial mapping study. I assessed the presence of direct communication based on directed

\textsuperscript{10} AdvaMed is the Advanced Medical Technology Association, a U.S.-based global trade organization of medical technology companies. AdvaMed oversees marketing transparency for medical device companies. The corollary oversight body for pharmaceutical corporations is the Pharmaceutical Research and Manufacturers of America (PhRMA).
written or oral communication between individuals as in a face-to-face conversation, a phone conversation, or an individualized e-mail. I also assessed direct communication ties between communicators and communication technologies (e.g. conference abstracts or meeting presentations and NTLs), and between communication technologies and their targets (e.g. peer-reviewed articles and NTLs). There were some cases when individual nodes engaged in multiple communication methods. For example, TLs communicate directly with NTLs via a phone conversation, but also through the intermediary communication technology of peer-reviewed journal articles. In other cases, when direct communication between individual nodes almost always occurs via some communication technology, the direct tie between individuals was judged to be absent; only the ties between individuals and the communication technology were coded as present. For example, there is not a direct tie between the FDA and NTLs. Rather, the FDA and NTLs are connected through regulatory dispatches.

In this network, the directionality of communication is also important. Therefore, I used a directed (rather than symmetrical) matrix approach to code and analyze data. Network graphs, therefore, represent unidirectional communication such as regulatory dispatches to NTLs as thin red lines, distinct from bidirectional communication such as between NTLs and EPRNs as thicker blue lines. Recognizing that each node represents multiple individuals with the capacity for independent communication, I accounted for the presence of intranodal ties in the network, represented as a present communication tie on the matrix diagonal. These intranodal ties are graphed as a bidirectional curved blue arrow on the network graphs. For example, in the formal knowledge system, TLs talk amongst themselves.
Throughout my fieldwork, I observed that so-called typical practices comprise a range of experiences. In order to construct a legible network for analysis, I assessed the most common patterns of practice and portrayed these in the network. By collapsing nodes and nodal ties into representative demonstrations via regular equivalence, I inevitably lost some data at the level of the individual lived experience. For example, there is one patient who is a prominent patient advocate and a frequent speaker at professional meetings, thus contributing directly to the formal knowledge system. However, this is an outlier experience and is not reflected in the network map for this project. Although this project seeks to represent and analyze the usual condition of AF ablation, I took care to capture the unusual cases, particularly as they might serve as a seed crystal for innovative processes in the future.

**Network Analysis**

Using fieldwork data as described above, I performed data analysis using UCInet software (Borgatti, Everett, & Freeman, 2015) and constructed separate network matrices representing the formal knowledge system and the informal knowledge system. I understood the formal knowledge system to comprise organized research, peer-reviewed publication, and regulatory activities. By contrast, I understood the informal knowledge system to comprise clinical care delivery processes not related to research or peer-reviewed publication. I analyzed each network for multiple centrality measures, as well as structural holes.

I joined the formal and informal matrices using the Join Matrices function, and transformed the joined matrix to a multiplex graph for analysis of common nodes and
ties, centrality measures, and structural holes. Network analysis findings will be discussed in Chapter 5.

**Related Work**

Others have engaged similar questions of inadequate solutions to health problems and examined the systems of healthcare knowledge and practice with regard to innovation. For example, the case of peptic ulcer treatment saw a decades-long effort for Australian medical researchers Barry J. Marshall and Robin Warren to contest the long-held idea that stomach ulcers were caused by acid imbalance in the stomach. Their work to prove that stomach ulcers are caused by bacteria and treatable with antibiotics, rather than antacids, was excluded from the formal knowledge system by the medical community for decades, before their novel therapy was taken up and they ultimately received the Nobel Prize in medicine in 2005. Similarly, fecal bacteriotherapy (sometimes colloquially termed transpooesion) represents a case of relevant therapeutic knowledge slow to enter the innovation system. However, in each of these cases, the ultimate uptake of new knowledge occurred through existing formal pathways of peer-reviewed publication. This project seeks to explore alternatives to the formal publication pathways that presently do not adequately capture the body of relevant knowledge to inform innovation in AF ablation.

Epstein (1996) has examined the phenomenon of challenges to the structure of the formal knowledge system in the context of AIDS research, particularly with regard to the role of patient activists as formal advocates. Although the focus of this project is not
centered on patients per se, the observations related to successful strategies for gaining acceptance and power in apparently entrenched systems for medical innovation are relevant. In addition, Christensen (1997) has examined the notion of disrupting the extant system as an innovation strategy, though his work has recently been contested by Lepore (2014) and others. Contestation aside, the concept of offering an alternative solution outside of existing dominant systems is valuable for this project, particularly as I consider ways to perturb the existing knowledge system for AF ablation.

**Reflexive Note**

I have been an active practitioner in cardiac electrophysiology since 2001. By some accounts, I am even considered a thought leader in the field, particularly with regard to patient-centered treatment considerations and outcomes related to AF. I continue to maintain an active clinical practice encompassing all segments of adult cardiac electrophysiology (albeit with a reduced patient load at present, compared to earlier points in my career). I also have an active portfolio of ongoing clinical research, and contribute to the formal knowledge system as an invited speaker at international gatherings of heart rhythm professionals. In the past, I have served as a consultant and speaker for multiple device and pharmaceutical corporations, and served on the medical advisory board for a start-up ambulatory device monitoring company. At present, I am a co-investigator for several industry-sponsored clinical trials as part of my clinical practice, but I do not maintain an active consultancy with any corporations. I am an appointed committee member of the American College of Cardiology, and a Trustee of
the Heart Rhythm Society, two of the largest professional advocacy organizations for heart rhythm professionals in the U.S. In many ways, I am the type of outlier in the AF ablation system that my own network mapping approach would exclude.

Practitioners in the field of AF ablation tend to be entrenched in particular epistemologies associated with the so-called biomedical model that centers on performing diagnostic and therapeutic activities to eliminate diseases and return diseased bodies to normal ways of functioning (Engel, 1977). Partly as a function of historical atrocities at the hands of medical charlatans, and partly as a function of the desire to practice in ways that stand up to legal scrutiny in an era of litigious healthcare, practitioners tend to treat research publications as reverential signposts that guide practice. Moreover, there is a tacit knowledge hierarchy, wherein a few prominent physician-researchers are recognized and explicitly labeled as thought-leaders in the field of AF ablation, akin to Collins’ and Evans’ core set of experts (Collins & Evans, 2002). The notion of a complex sociotechnical system is not foregrounded in thinking about AF ablation, and questions of power as a function of communication patterns does not cross the collective mind of those engaged with AF ablation on a daily basis. I entered the social sciences as a healthcare practitioner with a sense that many of the seemingly intractable problems in healthcare may benefit from interrogation by social scientists alongside the ongoing work that clinical scientists do. My goal in this work, and in my future career, is to bridge the clinical and social sciences so that they might augment one another, rather than remaining in disciplinary silos. In essence, I am trying to engage the clinical and social sciences in a complex adaptive system with permeable boundaries between disciplines in order to
collectively address the wicked problems facing society with health and healthcare in the 21st century.

With this background in mind, I have approached this dissertation research as an exercise in reflective practice (Schön, 1983), including the processes of problem framing, reflection-in-action, and reflection-on-action. I have not attempted to bracket my accumulated experience in the field. But I am not relying wholly on my extant expertise to frame the problem or form the data for analysis. Rather, I am using my existing and constantly growing body of practice as a critical lens to inform, refine, and test the knowledge that emerges from this research endeavor. I acknowledge that this approach will undoubtedly yield a nuanced view that other researchers with a single disciplinary approach might not similarly reach. For example, I might observe a shift in tone or terminology in one member of an ablation team that could go unrecognized by an ethnographer without a long history in the field. However, I trust that by maintaining active and ongoing reflection, a truthful and useful contribution will emerge in the end.
CHAPTER 2
AF PRIMER: ARRHYTHMIA AND THERAPIES

Before delving into a close examination of the AF ablation knowledge system, it may be helpful to have a crash course in AF and its treatments in order to better understand how ablation technology and practices fits into the bigger picture of AF therapy. AF is the most common heart rhythm disorder worldwide, affecting people with a range of troubling symptoms and associated conditions including heart failure and stroke. As the Yellow Emperor observed (Veith, 2002), AF is characterized by an irregular heartbeat pattern, as electrical signals cause the heart’s upper chambers to become chaotic and cause the heart’s main pumping chambers to squeeze in an unpredictable rhythm. We refer to AF as being irregularly irregular. In fact, we will see that this characterization holds true not only for the physiological phenomenon of AF, but for the knowledge and innovation system that is working to address the disease. Before delving into the problem of the AF ablation knowledge and innovation system, some background related to AF and ablation will be helpful.

Epidemiology

AF is the most prevalent arrhythmia in the U.S., impacting an estimated 5.2 million Americans and 33.5 million persons internationally (0.5% of the world’s population) in 2010, with a prevalence of 596/100,000 males and 373/100,000 females internationally across all age groups, and consistently increased prevalence with older
groups (Alonso, 2009; Chien et al., 2010; Colilla et al., 2013; Heeringa et al., 2006; Kannel, Wolf, Benjamin, & Levy, 1998; Lip et al., 1997; Lloyd-Jones et al., 2004; McManus, Rienstra, & Benjamin, 2012; Miyasaka et al., 2006; Phillips et al., 2001; Stewart, Hart, Hole, & McMurray, 2001; Wolf, Kannel, Baker, D’Agostino, & Mitchell, 1996). Prevalence has increased over the past two decades of available statistical data from 1990-2010, and is expected to continue to increase with an estimated incidence of over 8 million cases in the U.S. by 2050 (Colilla et al., 2013; Naccarelli, 2009). For individuals reaching the age of 40, there is 25% lifetime risk of developing AF (Lloyd-Jones et al., 2004). AF causes significant morbidity, including contributing to the development of congestive heart failure and stroke. Measured disability-adjusted life-years (DALYs) were 18.8% higher in individuals with AF (Chugh et al., 2014). AF mortality is higher in females, and nearly doubled in males and females from 1990-2010 (Chugh et al., 2014). AF treatment costs billions of dollars annually in the United States and is practically incalculable worldwide, including the direct costs of medical therapy, and the indirect costs of lost productivity related to illness and comorbid conditions (Coyne et al., 2006). AF is reflective of a growing national and international epidemic of cardiovascular diseases, including hypertension and coronary artery disease, that are rising in prevalence as a consequence of the Western diet, sedentary lifestyle, and prevalence of obesity in the developed world (Laslett et al., 2012). The cardiovascular disease epidemic is also spreading to the developing world, and with it, increased prevalence of AF in low- and middle-income countries (Laslett et al., 2012).
Physiology and Pathophysiology

The human heart consists of four chambers that contract in sequence to efficiently move blood throughout the body (Figure 1). The right and left upper chambers are called atria. They are thin-walled structures that mainly serve as a conduit to the lower chambers, the right and left ventricles. The ventricles have thick, muscular walls, and are the main pumping chambers of the heart. The heart’s chambers are separated by valves that work as one-way swinging doors to prevent blood from flowing backward through the system. The pumping function of the heart is mediated by the heart’s electrical activity, which normally maintains a steady and organized rhythm that responds to the body’s oxygen demands by causing a faster or slower heartbeat.

*Figure 1. Normal electrical function (left) and atrial fibrillation (right). Source: iStockPhoto.*
Normal electrical function in the heart, or sinus rhythm, initiates in the sinus node high in the right atrium and spreads cell to cell throughout the atria, causing the atria to contract in a regular manner (Figure 1, left). This contraction helps to propel blood from the atria into the ventricles, and contributes approximately 10% of the cardiac output with each normal heartbeat. The electricity reaches the atrioventricular node in the low right atrium, and travels through the specialized conduction tissue that electrically connects the atria with the ventricles. Once the electrical signals reach the ventricles, they cause the ventricles to contract in order to squeeze blood from the heart through the circulatory system. The ventricular contraction is responsible for 90% of the cardiac output of a normal heartbeat. In a normal heart, with no muscular damage and normally-functioning valves, approximately 60% of the blood in the heart is pumped out with each heartbeat.

In a normal heart, most cells have membrane channels that allow for the passage of charged particles, or ions, in and out of the cell. This ionic movement confers relatively higher or lower electrical charge to the interior of the cell, compared to the cell’s immediate environment. When the charge differential passes a specific threshold, the cellular membranes shift to allow rapid movement of ions in and out of the cell, generating electrical current. The current activity from one cell influences adjacent cells, thus propagating electrical activity throughout the heart tissue.

AF occurs when the electrical activity in the atria becomes chaotic, no longer responding to an electrical impulse from the sinus node (Figure 1, right). This electrical chaos causes the atria to flutter, rather than contract in a regular pattern. Chaotic fluttering causes inefficient movement of blood through the atria, which can lead to clot formation and potentially a stroke. The fluttering activity also reduces the effectiveness
of the blood pumping activity, directly reducing the cardiac output by approximately 10%.

Although the mechanism of AF onset is not completely understood, it is generally accepted that primary AF – AF that is related to a change in heart tissue and not directly caused by an external factor – is the result of anisotropy, or a mismatch in the electrical activity potential between cells. Anisotropy can result from scar tissue or stretching of the atrial muscle due to high blood pressure, heart muscle weakening, a leaky heart valve, or complications of longstanding lung disease. Secondary AF – AF that is directly caused by an external condition – may be the result of hormone imbalance (e.g. hyperthyroidism, hypertestosteronism), trauma, simulant medications, or surgery.

Two main theories exist to explain the initiation and propagation of AF: trigger initiation and wavelet maintenance. One theory holds that inside the pulmonary veins, which drain blood from the lungs into the left atrium, anisotropy at the junction of vein tissue and atrial tissue causes electrical potentials to develop in the atrial cells inside the pulmonary veins. These electrical potentials spread cell-to-cell, and activate the left atrium outside of the normal pattern of sinus rhythm, thus triggering AF. The second theory describes organization of AF signals into rotational patterns – rotors – that propagate the abnormal signals throughout the atria along wavefronts in a continuous manner. According to the rotor theory, AF is sustained by electrical signals encountering multiple rotor processes throughout the atrium that serve to maintain the abnormal electrical patterns indefinitely. In truth, AF is most likely not a discrete disease explainable by any single theory, but rather a sign and symptom of many different pathophysiological mechanisms that converge on a single result with fibrillating atria.
As the atria fibrillate, cellular remodeling occurs, impacting both electrical and mechanical functions. Over time with persistent fibrillation, mechanical remodeling occurs when the replacement of regular contractions with fibrillations leads to a loss of muscle tone, just as with disuse of skeletal muscles. This results in “flabby” atrial muscle that tends to stretch, thus propagating anisotropy and electrical remodeling that causes atrial cells to remain in a fibrillatory state. The arrhythmic effects of mechanical and electrical remodeling are described by the adage: a-fib begets a-fib. From a therapeutic perspective, mechanical and electrical remodeling cause the atria to resist therapies to restore normal rhythm. Thus, AF becomes harder to control the longer it persists.

AF is classified based on its propensity to stop and start without external intervention. Paroxysmal AF stops and starts on its own, either with or without long-term medications to help maintain a normal rhythm. Persistent AF is defined as AF lasting longer than 7 days, and requiring an external intervention (e.g. electrical cardioversion) to restore normal rhythm. Permanent AF is defined as AF that fails to revert to a normal rhythm even with electrical cardioversion.

**Clinical Care of Patients with AF**

A multidisciplinary team of healthcare professionals, researchers, engineers, and industry representatives contribute to the care of patients with AF in a variety of institutions including hospitals, outpatient clinical practices, medical device companies, regulatory agencies, and public and private payers. The patient and care team must navigate this complex healthcare system in the process of diagnosing and treating AF.
Multidisciplinary Healthcare Team

Individuals. The center of the AF care experience, and arguably any healthcare experience, is the patient, surrounded by loved ones and advocates. The patient interacts most directly with healthcare providers, including physicians, nurses, and technologists. Most people considering AF ablation have a primary care provider and general cardiologist in addition to the heart rhythm specialist physician, the cardiac electrophysiologist. The cardiac electrophysiologists typically works with a team of specialist nurses and technologists for the AF ablation procedure itself, as well as a team including nurses and advanced practice providers (NP and/or PA) who coordinate and manage care outside of the EP lab. Heart rhythm clinicians are typically employed by hospitals, universities, or private practice groups. During the ablation procedure, heart rhythm clinicians are typically joined by one or more industry representatives who assist the heart rhythm team with the mapping and ablation technologies manufactured by their respective companies.

Outside of the clinical care team, bench and animal researchers and industry engineers engage in pre-clinical scientific and technology research. Basic researchers are typically employed by universities, hospitals, or private research organizations. Industry engineers are employed by medical device companies. Much clinical technology research is conducted by clinicians working in concert with industry research. Media professionals can also be peripherally involved with AF ablation, particularly when new technologies are released.
**Institutions.** Individuals involved with AF ablation operate within and in concert with many types of institutions focused on the spectrum of activities from basic research to clinical care to regulation and advocacy. Clinical institutions directly engaged with AF ablation are mainly represented by hospitals that typically control the equipment and staffing for ablation procedures. Insurance providers including public (e.g. Centers for Medicare and Medicaid Services, CMS) and private providers (e.g. Blue Cross/Blue Shield, Aetna, United Healthcare) control patients’ access to particular physicians and hospitals, as well as reimbursement to physicians and hospitals for AF ablation services.

Medical device corporations (i.e. Industry) conduct much of the research and development activity for AF ablation technologies, in addition to sales and clinical support for marketed technologies. Industry engineers typically function in research and development roles within medical device corporations. Industry representatives typically function in field sales/marketing roles as well as providing clinical support for AF ablation technologies. The research and sales divisions do interface within a corporation, but regulatory guidelines in the U.S. require distinct firewalls between research and marketing activities within corporations.

Regulatory institutions vary nationally, but broadly include bodies that oversee medical technology safety, medical procedure payments, scope of practice for healthcare providers, and business transparency for medical device and pharmaceutical corporations. In the U.S., key regulatory institutions impacting AF ablation include the FDA (oversees drug and device safety and provides clearance for marketing), CMS (determines payments for medical procedures), private insurance providers (typically follows CMS
guidance for determining payments), state boards of medicine and nursing (determine scope of practice for physicians and nurses), and AdvaMed.

Outside of the direct clinical and regulatory institutions, a variety of media and advocacy institutions interact with AF ablation, including traditional and social media sources, professional advocacy organizations, and patient advocacy organizations. These media and advocacy institutions typically interact with particular institutional and individual target audiences in a variety of formal and informal roles.

**Initial Clinical Assessment**

**Diagnosing AF.** In many cases, AF is first detected as an abnormal sensation of an irregular heartbeat, often described as palpitations. AF can also cause symptoms of breathlessness, unusual fatigue, dizziness, or lightheadedness. For some people, AF does not cause any unusual symptoms and may go undetected until it is incidentally discovered on a routine medical examination.

Several technologies are used to assess heart rhythm by measuring the heart’s electrical activity. The most commonly used technologies to diagnose AF involve electrodes placed on the chest in particular configurations to capture cardiac electrical signals around the heart. These recordings include a short rhythm strip, a single view of the heart for a few seconds to minutes, or a 12-lead electrocardiogram (ECG) that provides more detailed data about the heart’s electrical conduction for a shorter time, usually less than 1 minute. However, a longer 12-lead ECG may be captured at the time of a treadmill stress test that may last for several minutes. These recordings are typically
captured in the clinical setting, and represent a short snippet of time from the patient’s life.

Other external monitors including Holter monitors (typically worn for 24-48 hours) and external 30-day loop monitors (sometimes called event recorders) provide a longer monitoring period for patients who may not be experiencing symptoms during a clinical visit. For patients whose symptoms occur less frequently than daily-to-weekly, an implantable monitor can be surgically placed under the skin of the chest, and provides a 3-year opportunity for monitoring automatically-detected and symptomatic events. Implied loop recorders are rarely used for the initial diagnosis of AF, though they are becoming more widely used for possible AF detection following a cryptogenic stroke (cerebrovascular accident of unknown origin). In addition, implanted loop recorders are sometimes used for long-term rhythm monitoring following invasive ablation procedures intended to treat AF.

Consumer-grade ambulatory and wearable devices are offering opportunities for rhythm monitoring without a prescription from a healthcare provider, and are incorporating algorithms for automatically detecting AF (e.g. AliveECG [AliveCor, Inc.], Heart Rhythm app [SoftRobo], AfibAlert [Cardiostaff Corporation]).

Assessing other related conditions. When a diagnosis of AF has been made, structural assessment of the heart is important to gauge risk of stroke and to guide treatment approaches. The three major categories of assessment include cardiac structure, cardiac function, and arterial disease. Cardiac structural assessment encompasses the size and geometry of each chamber, as well as the shape of heart valves. Chambers that are
enlarged are less likely to respond to rhythm control therapies, and valve malformations are likely to create unusual blood flow patterns and pressures that may make rhythm control efforts unsuccessful.

Heart valves are also assessed as a component of cardiac function. Even normally shaped valves may be stiff or overly pliant so that blood flows in a restricted or regurgitant pattern, exacerbating abnormal chamber pressures or wall stretch and thus AF. In some cases, functional assessment identifies the need for surgical or catheter-based intervention to correct the abnormality and improve the chances for atrial rhythm control. Cardiac functional assessment also includes the contraction strength and pattern of the ventricles. Weak ventricular contraction poses higher risks of stroke related to AF, contributes to worsening AF, and also limits the types of antiarrhythmic medications that can be used for rhythm control. Similarly, coronary arterial disease limits the types of antiarrhythmic medications that can be used for rhythm control and may exacerbate AF and lead to weak ventricular function.

Other conditions that impact AF and must be assessed include blood pressure, thyroid function, lung disease, diabetes, and peripheral vascular disease. In addition, a history of stroke or mini-stroke strongly predicts future strokes related to AF. Certain types of other cardiac electrical abnormalities (e.g. long QT syndrome, Wolff-Parkinson-White syndrome) may also impact therapeutic choices, and must be assessed before any therapies are begun.

**Assessing risk.** Based on the structural and functional assessments of the heart and other comorbid conditions, patients are analyzed for risk of stroke related to AF
using the CHADS$_2$-VA$_2$Sc score (January et al., 2014). This scoring mechanism assesses heart function, blood pressure, age, diabetes, stroke history, vascular disease, and gender to assign a relative annual risk of stroke related to AF. The relative risk of stroke is balanced against the risks associated with blood-thinning medications, and the resulting scoring system is used to make a risk-guided recommendation regarding blood thinning medications for individual patients.

Along with the stroke risk scoring, patients for whom blood thinning is recommended are assessed for risk of abnormal bleeding using the HAS-BLED scoring system (January et al., 2014). In this assessment, patients are assessed for high blood pressure, abnormal liver or kidney function, history of stroke, history of internal bleeding (typically in the intestines or head), history of difficulty maintaining stable blood thinning medications in the past, advanced age, and excessive use of drugs or alcohol. A patient with three or more of these conditions is deemed to be at “high risk” of excessive bleeding, and caution is advised with regard to use of blood thinners. There is significant overlap between factors raising the risk of a stroke and factors raising the risk of bleeding from medications designed to prevent a stroke.

Finally, patients with new AF that stops and starts without an external intervention are evaluated for their risk of AF progressing to a persistent state that requires electrical cardioversion or another external intervention to restore a normal rhythm. This is accomplished using the HATCH score, assessing for high blood pressure, advanced age, history of stroke or mini-stroke, lung disease, and history of heart failure (weak cardiac function) (de Vos et al., 2010). Patients with more of these risk factors are deemed to be at higher risk of having progressively worsening AF, and thus merit more
aggressive treatment to maintain normal rhythm and prevent worsening arrhythmias and other related conditions. As with the other relevant scoring systems, there is a significant overlap between factors that increase the risk of a stroke, factors that increase the risk of bleeding problems on blood thinners, and factors that increase the risk of worsening AF.

**Therapeutic Management of AF**

**Therapeutic goals.** The primary goal for managing AF is to prevent morbidity and mortality related to stroke resulting from the arrhythmia. The secondary goal is to avoid weakening of the heart muscle due to abnormally fast heart rhythms in AF. Once those two priorities are controlled, therapeutic attention can turn to the arrhythmia itself, with goals related to minimizing symptoms from AF and preventing long-term remodeling that may lead to worsening heart function and related symptoms.

**Therapeutic approaches: A primer.** In general, the approach to treating AF follows the ordering of goals as described above. The therapeutic goals of symptom management may be addressed concomitantly with safety goals, but would not be undertaken without first addressing safety.

**Stroke prophylaxis.** Presently, there are three available approaches to prevent a stroke related to AF. The most common approach is using blood-thinning medications. Until 2010, warfarin was the only FDA-approved medication available in the U.S. to prevent blood clots from forming in the atrium to prevent stroke related to AF. Warfarin is a vitamin K antagonist, and therefore interacts with many foods and medications,
impacting the dose required to accomplish effective blood thinning. Warfarin dosing is assessed and managed by blood tests, and some patients may spend more than a third of the time outside of a therapeutic blood thinning range (Ezekowitz et al., 2010), either failing to prevent a clot from forming, or thinning the blood too much so that internal bleeding is a risk.

In 2010, the first of four available non-warfarin anticoagulants, so-called NOACs (newer oral anticoagulants) was approved for use to prevent stroke with nonvalvular AF in the U.S. (U.S. Food and Drug Administration, 2013). These medications impact a different part of the blood clotting mechanism than warfarin, and are generally not reactive with most foods and medications. They do not require blood testing or dose adjustment in most cases, and have equivalent or superior rates of stroke prevention and less adverse bleeding when compared to warfarin in clinical trials.

The second approach to stroke prophylaxis is surgical removal of the left atrial appendage, the section of the left atrium where blood clots tend to form during AF episodes. This procedure requires open heart surgery, and is typically only undertaken in conjunction with another necessary surgery, such as valve replacement or bypass surgery.

The third approach to stroke prophylaxis similarly targets the left atrial appendage. However, rather than excising the structure, the third approach uses a mechanical device to block the entrance to the left atrial appendage, thus preventing any blood clots from escaping into the rest of the circulatory system. Although the left atrial appendage occlusion or exclusion devices do not require open heart surgery, they are still invasive procedures and carry some risk. Therefore, appendage exclusion devices are
presently recommended only for patients for whom long-term blood thinning is deemed to be excessively risky.

**Removing secondary causes.** In cases where AF is caused by another reversible condition, the primary therapeutic approach (after stroke prevention) is to remove or alleviate the problematic condition, whether an endocrine disorder or an exacerbating substance. The most common endocrine disorder that stimulates AF is an overactive thyroid, which can be treated with medications to quell the thyroid activity. Other endocrine disorders have also been known to cause AF, and may be treated using medications or surgery.

Stimulants, either as prescription medications, over-the-counter preparations, or illicit drugs are known to cause and exacerbate AF. In many cases, simply removing these chemicals effectively resolves the condition. It should be noted, however, that this is not always possible due to the prevailing therapeutic needs of competing comorbid conditions. For example, an individual with severe lung disease may require the use of stimulant medications in order to breathe properly. Therefore, it would not be possible to remove the medications that are causing or exacerbating AF.

Rarely, a tumor or other foreign body inside or around the heart may cause AF. When this occurs, the tumor can be surgically removed, typically with good effect. In some cases following surgery, the surgical trauma itself may cause irritation and anisotropy in the atrial tissue, leading to AF. When this occurs, medications often are successful at controlling the arrhythmia until the surgical healing process is complete.
Although it is not always the case, the irritation from surgical trauma often resolves, along with the attendant AF.

**Rhythm control.** Rhythm control approaches to restore and/or maintain sinus rhythm include pharmacological therapies, electrical cardioversion, and ablation procedures using a variety of energy sources and techniques via catheter or surgical approaches. Rhythm control strategies may be used alone or in combination.

*Antiarrhythmic medications.*\(^{11}\) Antiarrhythmic medications include a range of drugs that modulate the movement of ions across the cell membrane to better stabilize atrial tissue preventing spurious electrical activity. These medications may be used alone, or in combination with other medications more commonly used to treat high blood pressure. Antiarrhythmic medications may be used intermittently to treat arrhythmia recurrence, or may be taken on a regular basis to help maintain a normal rhythm. Antiarrhythmic medications are typically successful at treating AF by maintaining sinus rhythm approximately 30-50% of the time (Zimetbaum et al., 2012). In cases where one type of medication does not work to maintain a normal rhythm, a higher dose or another medication type might be more successful.

Some antiarrhythmic medications used to treat AF may cause other arrhythmias, including slow heart rhythms that might require a permanent pacemaker, or life-threatening ventricular tachycardia. The risk of ventricular tachycardia related to

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\(^{11}\) It is telling that in order to discuss rhythm control therapies in the context of AF and AF care, we have reached a fifth level of organizational headings. This deep layering typifies the complexity of AF and its therapies, and we will see that this intrinsic complexity characterizes the system in which AF therapy is developed and delivered, as well.
medications is pronounced in patients with coronary artery disease or heart failure. Therefore, the available medications to treat AF are limited for these patients.

*Electrical cardioversion.* For patients with persistent AF that does not convert to a normal rhythm spontaneously or with medications, electrical cardioversion may be used to restore a normal rhythm. Electrical cardioversion is accomplished by placing patches or paddles on the chest and/or back to deliver a single shock of electricity across the heart. This single electrical shock effectively overwhelms the AF signals, allowing the normal impulses from the sinus node to once again control the heart rhythm. This cardioversion shock is timed to be synchronous with the heartbeat in order to avoid initiating a life-threatening ventricular arrhythmia. Electrical cardioversion does raise the short-term risk of stroke if there is not adequate blood-thinning. In addition, electrical cardioversion is quite painful, and patients are usually medically sedated for a cardioversion procedure.

Electrical cardioversion is highly effective for restoring a normal rhythm, but is not curative and does not help to maintain sinus rhythm. In most cases, electrical cardioversion is used as an adjunctive therapy to antiarrhythmic medications. Electrical cardioversion does not damage the heart muscle, and there is no limit to the number of electrical cardioversions that one may undergo.

*Ablation.* AF ablation most commonly uses radiofrequency energy to create thermal injury – burns – at critical locations in the atria. These burns are thought to isolate the triggers for AF thus preventing their propagation to the rest of the atria, or destroy the tissue responsible for propagating atrial signals via rotors thus preventing triggers from becoming a sustained arrhythmia. Ablation techniques may include trigger
isolation and rotor elimination techniques alone or in combination. We will review areas of contemporary controversy regarding AF ablation technology and techniques in Chapter 3. For now, I describe general principles of AF ablation.

AF ablation may be accomplished using a transvenous catheter approach, where thin wires are inserted into the large blood vessels in the groin and threaded through the circulatory system to reach the heart. The physician manipulates the catheters using a variety of steering techniques from the groin insertion site, and monitors the catheter position using a combination of real-time x-ray, ultrasound, magnetic, and electrical signal imaging. Catheter ablation carries up to a 13% risk of serious complication (Calkins et al., 2007), including damage to a major blood vessel, a hole in the heart requiring surgery to drain, a hole between the heart and esophagus that could be life threatening, or narrowing of the pulmonary veins that cause damage to one or both lungs.

AF ablation may also be accomplished using a surgical approach, either “minimally invasive” through a small incision in the left side between two ribs, or via open heart surgery typically in conjunction with another heart surgery. Early surgical approaches to AF ablation sought to minimize the contiguous area required for propagation of AF. Therefore, the earliest surgical approaches incorporated physically cutting the atria into pieces and stitching it back together so that it resembled a patchwork quilt. More contemporary surgical approaches use radiofrequency energy to accomplish a similar effect, and may additionally incorporate trigger isolation and/or rotor elimination techniques as well. The risks of surgical AF are similar to those of catheter ablation, and include infection, a hole in the heart requiring drainage of blood from around the heart, and stroke. Minimally invasive surgical ablation confers an additional risk of
complications associated with collapsing the left lung, and a risk of requiring a pacemaker following the surgery. Surgical ablation has a lower risk of pulmonary vein narrowing and resulting lung damage compared to catheter ablation, and is not typically associated with a hole developing between the heart and the esophagus.

Catheter ablation is performed by specially trained cardiologists – cardiac electrophysiologists. Surgical ablation is performed by cardiac surgeons. Success rates of catheter and surgical approaches are variably reported, with some centers claiming a 90% rate of success treating AF. In some centers, electrophysiologists and cardiac surgeons collaborate to perform a hybrid procedure incorporating both catheter and surgical approaches.

**Rate control.**

*Medications.* When rhythm control approaches are ineffective, a rate control approach may be used to ensure that the heartbeat is neither too fast nor too slow in AF. Most often, rate control is focused on slowing down fast heart rates that, if unchecked, could lead to weakening of the heart muscle. This is primarily accomplished by using medications to slow the heart rate.

*Ablate-and-pace.* Sometimes, medications may be ineffective for slowing the heart rate, or may cause the blood pressure to be too low, resulting in uncomfortable side effects. When this occurs, an ablate-and-pace approach may be used. This entails using catheter ablation to destroy the normal road of electrical conduction between the atria and ventricles (the atroventricular node, Figure 1, left), and implanting a permanent pacemaker to control the ventricular heartbeat. This ablation approach is irreversible, and
the patient is permanently dependent on the pacemaker. However, the vast majority of people using this approach are free from adverse symptoms associated with AF. Often, the ablate-and-pace method is viewed as a cure for AF. However, even when a pacemaker controls the heart’s pumping rhythm to alleviate irregularity and symptoms, the atria still fibrillate and patients are still at risk of a stroke. In addition, permanent pacing itself can be detrimental to the heart’s function, leading some patients to develop weakening of the heart muscle that ultimately becomes heart failure, requiring a more complex pacemaker (and sometimes defibrillator) to help alleviate the symptoms of heart failure and prevent sudden death. In essence, the ablate-and-pace approach offers a solution for one aspect of AF by trading an irregular heart rhythm for regularity at the cost of a weakened heart pump and another attendant set of problems.

Summary

In summary, AF is a complex syndrome that exerts myriad significant costs to individuals, institutions, and society in terms of physical and emotional discomforts, time, and money. Though we continually try to understand and manage the complexities of AF, our limited knowledge resigns our relationship with this syndrome to reflect AF itself as irregularly irregular. As we turn to examine the knowledge that informs our understanding of AF and AF ablation in Chapter 3, along with the ways that practitioners use and communicate AF ablation knowledge in Chapters 4 and 5, we will see the themes of irregularity and complexity again and again.
CHAPTER 3
THE HISTORY OF ABLATION FOR ATRIAL FIBRILLATION

The current practice of AF ablation did not spring forth fully formed, as Athena from the forehead of Zeus. What kinds of knowledge undergird the practice of AF ablation? And how did the contemporary understanding of AF and the practice of AF ablation develop? Many practitioners of AF ablation would name French cardiologist Michel Haïssaguerre as the critical innovator – the bellwether of modern AF ablation. However, such a reductionistic explanation seems out of place in the history of a complex sociotechnical system like AF ablation. Instead, I will use the historical literature in AF ablation to show that three distinct threads of research focused on science, technique, and technology interact to constitute the knowledge that informs contemporary AF ablation practice. These knowledge threads constituting AF ablation practice have co-developed in conversation with the surrounding context of medical science and practice. Therefore, after reviewing the internal development of AF ablation knowledge, I turn to ask what are the social forces within and outside the field of AF ablation that shape – and have been shaped by – AF ablation? Finally, I examine the implications of these internal and external forces on the AF ablation knowledge system in terms of future innovation.

History of AF Catheter Ablation (or, How AF Became a Killer Without a Cure)

Before delving into a critical analysis of the knowledge informing AF ablation, I will briefly sketch the history of AF ablation from the earliest recognition of the disease
to present-day approaches. Because AF ablation is deeply complex, this historical overview will provide a foundation for understanding the ways in which different types of knowledge inform current approaches and controversies.

In order to tame the body of nearly 10,000 articles published in the peer-reviewed literature related to AF ablation, I selected a core set of articles authored by thought-leaders in the field. I queried the PubMed database of the National Library of Medicine to identify consensus documents from the major professional associations relevant to atrial fibrillation ablation (i.e. Heart Rhythm Society, American College of Cardiology, American Heart Association, Canadian Cardiovascular Society, European Heart Rhythm Association, European Cardiac Arrhythmia Society, and Society of Thoracic Surgeons) and recent review articles, including catheter and surgical AF ablation. I also identified areas of ongoing controversy that have not yet achieved technological closure, and identified major papers from thought-leaders in each of these areas (i.e. Cox, Haïssaguerre, Jais, Oral, Natale, Pappone, Narayan, Kottkamp). These individuals are explicitly labeled by the community of AF ablation researchers as thought-leaders in scientific meetings, and are co-authors in field-wide scientific consensus statements. Each of them is a recognized leader related to one of the dominant catheter and surgical ablation techniques (i.e. surgical, pulmonary vein isolation [PVI], complex fractionated atrial electrograms [CFAE], and rotors) or technologies (i.e. including mapping systems, robotic navigation, imaging systems, and cryoablation catheters). Therefore, their papers

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12 Influential researchers and practitioners in AF ablation – and the EP field more broadly – are colloquially termed thought-leaders. This label is roughly akin to the core set that Collins and Evans (2002) describe in their third wave of science studies. I discuss this further in Chapter 5 in the context of the AF ablation knowledge system.
represent the dominant thinking in the field. This initial search yielded 47 relevant articles of a total 9,558 (on September 30, 2015) articles related to the catheter and surgical ablation of AF since 1980 (see Figure 2). I analyzed each of the key articles for its content, noting mention of particular technologies and domesticated knowledge, as well as the relationships between science, technology, and technique portrayed. In addition, I performed ancestry search for each of the 47 original papers to identify relevant published history. This yielded more than 630 articles representing the knowledge pedigree for the dominant approaches to contemporary AF ablation (Appendix A).\textsuperscript{13}

\textbf{AF Ablation Publications in PubMed by Year}

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*As of 30 September 2015

\textit{Figure 2}. Year-by-year count of AF ablation articles indexed in PubMed from 1 January 1981 through 30 September 2015. Note that there are significant increases in indexed publications in 2002, 2008, and 2013. Although this project did not seek to uncover the cause of these changes, this may be a relevant focus for future research.

\textsuperscript{13} This approach admittedly fails to trace the history of technologies and techniques that have not achieved success in the landscape of AF ablation. That project remains a worthy topic for future research. In this project, however, history is written – or at least informed – by the victors.
From Early Recognition to Experimental Studies (100 B.C.E. – 1980 C.E.)

AF was recognized first as signs and symptoms of an irregular heartbeat by early physicians including the Chinese Yellow Emperor in the late 2nd century B.C.E. (Lip & Beevers, 1995), and the Spanish Jewish philosopher-physician Moses Maimonides in the late 12th century C.E. (Maimonides, 1989). In the modern era, 17th century British physician William Harvey observed fibrillation of the atria in animals just before death (Harvey, 1957), and the 18th century French physician Jean-Baptiste de Sénac connected the elevated atrial pressures associated with a stiff mitral valve with AF (Sénac, 1783). de Sénac noted that although the symptoms might be uncomfortable, fibrillation was itself harmless. This characterization of harmlessness would remain the prevailing paradigm regarding AF for more than 200 years. But we will see that by the 21st century, AF had been recast as a killer.

Over the ensuing centuries, physicians and anatomists continued to discover the interactions between mechanical and electrical structures in the heart via early anatomical studies (e.g. Lower, 1968; Nothnagel, 1876) and finally aided by the invention of a critical technology, the electrocardiograph, by Willem Einthoven in 1900. The electrocardiograph allowed scientists to create a visual representation of the electrical activity in the heart and preserve the visualization for future study and comparison. The first electrical recording of AF was published in 1906 (Einthoven, 1906), and was definitively linked to gross anatomical observations of fibrillation by Sir Thomas Lewis in 1909 (Lewis, 1909).

In the late 19th and early 20th centuries, medical scientists built on the earlier work of anatomists to conduct active experiments rather than just passive observations of
human anatomy and physiology in order to better understand AF. The first of these experiments explored the notion that AF was initiated by focal triggers – discrete areas in the heart that fire off aberrant electrical signals to cause the chaotic electricity of AF. The focal trigger hypothesis was joined by the idea that the heart requires a critical minimum mass of electrically-contiguous tissue to sustain the chaotic electrical signals of AF. The minimum mass theory derived from observations that AF triggered in one area of the heart did not continue when that triggered area was clamped off from the rest of the heart (Garrey, 1914). Within a few years, experimental studies of AF demonstrated that the electrical chaos tends to organize to a reentrant circuit in some areas of the heart, particularly around heart structures like valves that do not conduct electricity (Lewis, 1920). These experimental observations supported theories of circus movement, the idea that electrical signals can occur in rapid, abnormal, and repeating patterns. Thus, early surgical approaches sought to create scar tissue throughout the atria to limit the mass of contiguous conductive tissue for sustaining AF (e.g. Williams, Ungerleider, Lofland, & Cox, 1980).

**The Nature of AF (1783 – 2015)**

For centuries, AF was characterized as a nuisance, causing symptoms of palpitations or fluttering as individuals experienced an irregular heartbeat. In the 18th century, French physician Jean-Baptiste de Sénac reported that AF was transient and not an illness in itself, with no sequelae (Sénac, 1783). This characterization of AF as a mere nuisance persisted for nearly two centuries, even once AF was recognized as an electrophysiological abnormality and distinct disease. In 1978, however, data from the
Framingham Heart Study revealed that AF was associated with an increased incidence of stroke (Wolf, Dawber, Thomas, & Kannel, 1978). Shortly after, Cox began his work to develop a surgical cure for AF in 1980, leading to the development of catheter ablation techniques in the 1980s and 1990s that afforded relatively expanded access to AF treatment procedures. Over the next two decades, epidemiological work related to AF progressed as well. In 1998, just as AF catheter ablation techniques were gaining acceptance, new data from Framingham revealed that AF itself exerted a long-term mortality risk (Benjamin et al., 1998). This notion of AF as a potentially dangerous condition contrasted sharply with the centuries-old notion of AF as a troublesome but benign condition. By 2002, AF was characterized as a life-threatening condition in its own right (Stewart, Hart, Hole, & McMurray, 2001; Wattigney, Mensah, & Croft, 2002).

As a life-threatening condition, AF merited a turn of clinical attention away from mere symptom management toward obliterate treatment in order to remove the threat to life.¹⁴

By 2007, the thought-leader community noted in its expert consensus statement on AF ablation that the primary justification for AF ablation should be symptomatic improvement for quality of life (Calkins et al., 2007). However, the increased risk of death with AF was also cited as rationale to consider AF ablation (Calkins et al., 2007). These rationale and justification grounds were reiterated in the 2012 update to the consensus statement (Calkins et al., 2012). In order to put patients at risk of serious complications with a procedure conferring results that are middling at best, the risk of the

¹⁴ This perceptual change from nuisance to threat constituted a sense of crisis, prompting a shift in the treatment paradigm of AF, consistent with the notion of scientific paradigm shift (Kuhn, 1962). This idea will be addressed in detail in the next chapter.
disease must be greater than the risk of the procedure itself. Therefore, the characterization of AF as impacting mortality seems to bolster the move toward a risky, invasive therapy. One informant, who began performing AF ablation in 2010 after several years of busy interventional EP practice that did not include AF ablation, said, “The timing of a-fib becoming a lethal condition strikes me as unusual” (NTL-1, August 22, 2015). This observation from a non-thought-leader outside the formal knowledge system highlights friction between the perspectives of thought-leaders and non-thought-leaders. We will see other examples of this friction shortly.

A 2013 article from a prominent AF patient advocate in a non-peer-reviewed professional publication characterized AF as fatal (True-Hills, 2013). This portrayal in a pseudo-formalized publication from an individual clearly outside the contributory expert community of physicians and scientists echoes the lethality move of the formal knowledge system. This individual was invited to participate as an expert panelist on AF at the 2015 American College of Cardiology Scientific Sessions. Her patient-focused website was cited as “wonderful” in a formal presentation by a thought-leader (Prystowsky, 2015) and she had informal sidebar conversations with several other thought-leaders with whom she had established relationships in the past. She was the only such non-clinician non-researcher included in the conference presentations around AF at the 2015 American College of Cardiology Scientific Sessions. However, she bolstered the message delivered by thought-leaders that AF is life-threatening, and merits efforts toward an interventional cure. Every stakeholder group in AF ablation has an interest in establishing AF as a deadly disease that needs a cure.
Early Surgical Ablation (1980 – 1990)

Early attempts at a surgical treatment for AF caused very slow heart rates by interrupting the normal pattern of electrical conduction between the sinus node (the heart’s natural pacemaker) and the AV node that shuttles electrical signals from the atria to the ventricles, the heart’s pumping chambers (Guiraudon, Campbell, Jones, McLellan, & MacDonald, 1985). This approach to blocking the electrical signals that cause AF by segmenting the atria also slowed the heart, causing an unintended altered rhythm. In addition to slowing the heartbeat, surgical approaches that created a patchwork quilt of the atria in an effort to create non-conductive scar tissue also reduced the pumping force of the atria. Without effective muscular pumping, much of the blood in the atria was stagnant. Atrial blood stagnation, whether the natural result of AF or the surgical result of atrial segmentation surgery, was linked to two major effects. First, there was a loss in the heart’s overall pumping power. Second, and more significantly, stagnant atrial blood formed clots that could travel from the heart to the brain to cause a stroke (Wolf et al., 1978). This discovery linking AF and stroke revised the earlier understanding that AF was generally harmless. AF was now understood to be more than a nuisance, and indeed a dangerous condition. Moreover, its surgical treatment caused the same danger of stroke as AF itself. Therefore, approaches to maintain atrial contractility and sinus node conduction and function became key priorities in the ongoing evolution of surgical technique (Cox et al., 1991a).
From Surgical to Catheter Approach (1982 – 1998)

As surgical techniques were maturing to address AF in the early 1980s, catheter ablation procedures to obliterate the AV node were developed by Scheinman (1982). Scheinman’s approach used intracardiac electrogram recordings and direct current electricity to deliver a destructive explosion of heat to the AV nodal tissue in order to destroy conduction between the atria and ventricles. AV node ablation destroyed the natural heartbeat and required pacemaker implantation. This procedure was the earliest version of the ablate-and-pace approach to AF rate control described in Chapter 2. For many, the idea of destroying the natural heartbeat in order to rely completely on a pacemaker is troubling. However, this catheter-based approach did not require open heart surgery with its attendant risks. Even in the most experienced hands, open heart surgery requires weeks to months of time to recover from having one’s breastbone sawed in half and being placed on a heart-lung bypass machine for hours to allow the surgeon to carve the heart apart and stitch it back together. Moreover, AF surgery often caused a slow heartbeat that would require pacemaker implantation, even in the absence of a directed AV node ablation. Therefore, given the effectiveness of the AV node ablation procedure, with a relatively lower level of invasiveness to the patient compared to open-heart surgical techniques, some clinical research efforts turned to using catheter ablation for AF ablation.

Throughout the 1980s, most catheter ablation attention focused on other arrhythmias linked to discrete anatomical structures in the atrium, such as AV nodal reentrant tachycardia and accessory bypass tracts. Although the safety and efficacy of these catheter ablation procedures quickly ascended with the development of
radiofrequency energy delivery to replace direct current, efforts to treat AF using catheters in a similar way languished in the absence of a discrete anatomical ablation target within the atria. Noting the existing conventional wisdom regarding atrial segmentation from the surgical experience, interventional cardiologists attempted to replicate the Cox Maze\textsuperscript{15} surgery pattern using a radiofrequency catheter-based approach to create scars in the atria. Cardiologists focused the catheter ablation approach primarily in the right atrium due to its relative ease of access through the vascular system and low risk for complications (e.g. Calkins et al., 1999; Elvan, Pride, & Zipes, 1994; Ernst et al., 1999; Haïssaguerre et al., 1994; Jaïs, Shah et al., 1998; Swartz, Pellersels, Silvers, Patten, & Cervantez, 1990). These right-sided ablation efforts met only modest success, particularly noted in rare patients with a distinct focal trigger for AF impulses (Haïssaguerre, Marcus, Fischer, & Clémenty, 1994). However, catheter ablation approaches yielded new insights about the electroanatomic nature of AF (Chen et al., 1999; Gerstenfeld, Sahakian, & Swiryn, 1992), along with the need for novel catheter design and mapping systems for more complex electroanatomic mapping and energy delivery (Ben-Haim et al., 1996; J. L. Cox, 1985; Lavergne et al., 1997).

From Maze to Pulmonary Vein Isolation (1998 – 2015)

By 1998, French cardiologist Michel Haïssaguerre was already recognized as a thought-leader in the burgeoning field of AF catheter ablation. Along with his colleague

\footnote{Medical procedures are frequently named for their innovator, like the Whipple procedure (pancreaticoduodenectomy), Fontan procedure (congenital heart defect repair), and Cox Maze surgery for AF. This common practice reinforces the notion of the thought-leader, as well as the myth of the hero innovator in the face of a far more complex set of actors and activities that contribute to innovation.}
Pierre Jaïs, Haïssaguerre’s Bordeaux lab had been publishing broadly on their efforts – including successes and failures – to cure AF using a catheter ablation approach. In 1998, Haïssaguerre published a single paper that is widely recognized to have revolutionized the practice of AF catheter ablation (Haïssaguerre et al., 1998). Through electrical mapping observations during multiple procedures to ablate AF using a Maze\textsuperscript{16}-like approach, Haïssaguerre traced the initiation of AF by following the electrical signals back to the point of earliest activation. In the majority of cases, he found that AF was initiating from focal trigger points within the pulmonary veins, the conduits that drain freshly oxygenated blood from the lungs back to the heart for circulation throughout the body. The anatomy and histology of the pulmonary veins, and particularly the connection with the left atrium, was already well known in the scientific literature, having been described three decades earlier (Nathan & Eliakim, 1966). Inside the pulmonary veins, there is a transition zone where electrically inert venous cells meet electrically active atrial cells. Based on the anatomical knowledge, others went on to describe the physiological travel of electricity between the atrium and thoracic veins, and the electrical properties of the pulmonary veins themselves (Spach, Barr, & Jewett, 1972; Zipes & Knope, 1972). Areas of anisotropy with electrical mismatch between cells, like the transition zone, were prone to triggering abnormal electrical activity. Haïssaguerre’s paper suggested that rather than attempting to interrupt or isolate existing wavelets of AF activity already in progress, catheter ablationists could simply obliterate the focal trigger points for AF in the pulmonary veins to cure the disease.

\textsuperscript{16} The Cox Maze procedure is frequently abbreviated to Maze, retaining the capitalization.
Following Haïssaguerre’s paper in 1998, several prominent electrophysiology centers in the U.S. and Western Europe began to practice an AF ablation technique focused squarely on the pulmonary veins. Catheter ablation had become established as a safe and reliable technique for curing other arrhythmias by this point, including precise targeting and obliteration of the complete AV node, accessory bypass tracts, and the slow pathway of the AV node. In contrast with AF, these arrhythmias occur in discrete and predictable heart structures in the right atrium (the lower pressure side of the heart that carries less risk of stroke associated with invasive procedures). Drawing on this experience, ablationists attempted to apply a similar approach by mapping and obliterating the precise focal AF triggers within the pulmonary veins, often creating dozens of burns within a single vein in an effort to destroy all aberrant electrical activity (e.g. Gerstenfeld, Guerra, Sparks, Hattori, & Lesh, 2001; Haïssaguerre, Jaïs et al., 2000; Mangrum, Haines, DiMarco, & Mounsey, 2000). This technique was met with some clinical success, but centers began to notice an unusual pattern of lung disease in some patients. Ultimately, several of these patients were found to have narrowing (stenosis) of the pulmonary veins (Robbins et al., 1998; Scanavacca, Kajita, Vieira, & Sosa, 2000; Yu et al., 2001). Pulmonary vein stenosis obstructed blood flow from the lungs to the heart, causing blood pressure in the lungs to increase, and ultimately destroying lung tissue. Researchers realized that the stenoses were caused by scar tissue that had developed from ablation, thus proving that the focal ablation approach, previously thought to be benign, could actually cause dire complications (Ernst et al., 2003).

Around this time, ablation catheter technology was developing based on an increasing understanding of the biophysics of radiofrequency ablation, allowing for
longer and larger contiguous lesion delivery (Jaïs, Haïssaguerre et al., 1998; Jaïs et al., 1998; Kasai, Anselme, Teo, Cribier, & Saoudi, 2000; Lavergne et al., 1997; Macle et al., 2002; Tsai et al., 1999). Technology development with new energy sources also made it possible to move from a spotwise approach to lesion creation to being able to effectively “draw” lines of ablation by dragging the catheter in the heart (Jaïs et al., 1999). In addition, new circular mapping catheters branded as Lasso17 catheters were developed with electrodes in a circular pattern to allow for simultaneous recording around the circumference of the pulmonary vein (Haïssaguerre et al., 2000). Simultaneous mapping with the Lasso catheter allowed a measure of control by measuring the whole pulmonary vein, compared to linear catheters that could not account for multiple paths of electricity. Catheter technology advances afforded a change in approach for ablation lesions from targeting a single cell or group of cells for ablation to ablating around an entire anatomic structure, effectively isolating it from surrounding tissue. Using the new Lasso catheters, electrophysiologists could effectively encircle the pulmonary veins by ablation, so that any electrical triggers inside the veins could not transmit electricity to the atrial tissue to spur AF (Pappone et al., 2000). This encircling technique also allowed for ablation just at the opening of the pulmonary veins, therefore avoiding the development of scar tissue to cause stenosis and lung damage. Thus, the pulmonary vein isolation (PVI), rather than pulmonary vein trigger ablation, technique was underway.

17 The Lasso name recalls the cowboy-explorer myth of the American West, embodying bravery, adventure, and risk-taking. In medicine, physicians who do risky procedures are often called “cowboys.” In the early days of AF ablation, the procedure was only practiced by a few leading electrophysiologists. Thus, the Lasso seemed to be the appropriate tool for this new electrophysiology frontier.
Some discrepancies and challenges remained with the PVI technique. Some thought-leaders used a segmental isolation approach, ablating only along the course of electrical signal travel from the interior pulmonary vein to the atrium (Gerstenfeld et al., 2002; Haïssaguerre, Shah et al., 2000; Marchlinski et al., 2003). Others used a wide-area circumferential ablation (WACA) approach, completely encircling the pulmonary veins with a line of ablation (Pappone et al., 2000). With both techniques, many patients still experienced recurrent AF, detracting from the notion that PVI represented a definitive cure for AF and suggesting that AF is a complex problem that is not amenable to a simple solution from a single discipline, or knowledge stream18 (Klein, 2004), understanding sectors as science (anatomy and physiology), technique (medical science), and technology (engineering). Simply improving technology, technique, or scientific knowledge will not result in a cure for AF. Still, the basic concept underlying PVI has persisted as the so-called standard technique for AF ablation, recognized by thought leaders in the formal knowledge system in both published formal consensus documents (Calkins et al., 2007; Calkins et al., 2012), expert domestication reports19 (Haïssaguerre

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18 The word “discipline,” meaning a branch of knowledge, can be understood in many ways in the AF ablation case. Science, technology, and technique in this case are distinct branches of knowledge, and may rightfully be considered disciplines. However, electrophysiology is a discipline. Nursing is also a discipline. When we speak of interdisciplinary collaboration, we typically refer to disciplines as those fields of scholarship that are established in the academy. Therefore, in an effort to avoid confusing my discussion of distinct knowledge types with a more academic view of disciplines, I will refer to knowledge streams (i.e. science, technology, technique).

19 One of the challenges associated with AF ablation is the critical importance of technique, or the hands-on use of technologies, for the success of a procedure. For most practitioners, there is limited opportunity to be coached in the practical technique once the formal training years have passed. In a field that is constantly evolving with new technologies and technical approaches, there is a constant need to update one’s practical
et al., 2000; Pappone & Santinelli, 2004; Pappone & Santinelli, 2005; Saad et al., 2003) and presentations at major international meetings (Calkins, 2015). Later in this chapter, I show that a small cohort of physicians represents the whole of the field in the peer-reviewed literature, resulting in a very fine filter to admit knowledge of AF ablation into the innovation system.

The Notion of a Cure

Alongside the evolution of understanding AF as a dangerous arrhythmia, the nature of AF ablation evolved with regard to its potential as a cure. The notion of AF ablation as a cure for AF first appeared with the Cox group in the 1980s (Cox et al., 1991a) and persisted through early catheter ablation attempts (Swartz et al., 1990), pulmonary vein isolation (Haïssaguerre et al., 1998), wide-area circumferential ablation skill and learn from others’ experiences domesticating existing technologies or techniques for their own use (Silverstone & Hirsch, 1992). Therefore, the peer-reviewed literature offers an opportunity to learn technical approaches through detailed description from others with more practical experience using a particular technique or technology. However, only a small sliver (<1%) of the AF ablation community is represented in peer-reviewed publications as a mechanism for disseminating their own accumulated knowledge. There is another theoretical pathway for disseminating domesticated knowledge via conference abstracts. However, only a small minority of domesticated knowledge reaches this modality, as the abstract review criteria prioritize experimental design rigor or unusually provocative case reporting over more mundane or incremental observational reporting. As a result, the vast majority of domesticated knowledge communication occurs only via individual face-to-face communication. Due to the practical constraints of individual-level conversations as a dissemination mode, this means that the vast majority of domestication knowledge is never captured by the formal knowledge system, and is therefore functionally silent. Professional organizations like the Heart Rhythm Society have made efforts to establish discussion board forums to afford information sharing along the lines of domesticated knowledge. However, concerns related to time, ease of access, and confidentiality for patients, providers, and institutions, have curtailed the success of these digital efforts. Therefore, it may be worthwhile to explore alternative mechanisms to accomplish domestication information sharing.
approaches (Pappone & Santinelli, 2004), and even an allusion to a surgical cure in the first major expert consensus document on AF ablation (Calkins et al., 2007). In 2008, responding to a growing body of evidence about the deep complexity of AF and the limited ability of current interventional procedures to eliminate the arrhythmia, Calkins (lead author of the consensus statement) published an editorial in a leading electrophysiology journal in 2008 arguing that the notion of a cure was not accurate to describe AF ablation procedures at this time (Calkins, 2008). Calkins mentioned that the 2007 consensus statement recommended against referring to catheter ablation for AF as a cure. It is interesting to note, therefore, that in the 2012 consensus statement (Calkins et al., 2012), the term “cured” was in quotation marks with regard to early surgical papers in a shift from no quotation marks in the 2007 consensus statement, and there was language shift to refer to catheter ablation procedures for treatment of AF (rather than for a cure). Moreover, throughout the peer-reviewed literature following the 2008 Calkins editorial, references to AF ablation as a cure virtually disappeared from the formal literature. However, attention to AF ablation has continued to grow in the peer-reviewed literature, even as the notion of a cure has eroded (see Figure 4). This effect parallels the experience with ventricular assist devices, where despite the poor clinical outcomes associated with early systems, researchers continued to believe in the constructed technological paradigm

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20 It is important to remember that although the ablate-and-pace approach (described in Chapter 1) offers a permanent solution to AF symptoms, it is a rate control approach only, and does not obliterate the AF itself. Therefore, although a pacemaker may relieve many of the overt symptoms of AF, it does not cure the pathophysiological effects of the disorder including stroke risk and the potential for heart failure. Unfortunately, this distinction is often overlooked in the popular media, particularly with regard to the newest generation of leadless pacemakers that are portrayed as a treatment for AF (Maminta, 2015).
(Bijker, 1995; Morlacchi & Nelson, 2011). In the case of the ventricular assist device, the power of the successful technological paradigm, fed by the promise of a successful heuristic, enabled rapid progress and eventual clinical success. In the AF ablation case, where the promise of a cure has collapsed, the heuristic power of the technological paradigm may be, as van den Belt and Rip (2012) describe, more illusory.

Outside of the formal peer-reviewed literature, however, the notion of a cure – in some cases as hope for the future and in others as marketing hype for AF ablation programs – persists, providing another illustration of friction between thought-leaders and non-thought-leaders in the AF ablation knowledge system. As of September 2015, the Cleveland Clinic’s website for AF surgery states, “Cleveland Clinic surgeons have the nation’s largest experience in the ablation (cure) for atrial fibrillation” (Cleveland Clinic, 2015). This claim stands in contrast to another statement on the Cleveland Clinic’s website that states, “There is currently no cure for afib” (Cleveland Clinic Heart & Vascular Team, 2015). These conflicting messages in the public sphere are echoed by prominent patient advocacy groups including stopafib.org, whose website states, “Catheter ablation and surgical maze procedures cure atrial fibrillation for many patients” (StopAfib.org, 2011). In my own clinical experience, I have witnessed colleagues as recently as 2013 describing AF ablation to patients as a procedure that has a 90% chance of curing AF. Clinician references to a cure in the sphere of routine clinical practice have declined since 2012 around the time of the second consensus statement publication. However, in 2015 I do still hear patients refer to AF ablation as a cure, signaling that the notion of a cure has not entirely met its end, and indicating that the power of the formal knowledge system to drive real-world practice has limitations.
The changing perception of the nature of AF as a threat to health gave rise to the development of invasive and potentially risky techniques to treat AF, including AF ablation. In turn, the practice of AF ablation has reshaped the public understanding of AF from a threat to health that must be chronically mitigated with medications and devices to a threat to health that can be conquered through the use of ablation technology.

**Contemporary Practices, Variations, and Controversies in AF Catheter Ablation**

Although a WACA approach to PVI is currently considered the standard practice, high recurrence rates of AF signal that the existing state-of-the-art is suboptimally effective. As a result, researchers and practitioners search for better ablation approaches to treat AF. Because knowledge of AF remains fundamentally incomplete, efforts persist to identify new opportunities with anatomical targets for ablation (scientific knowledge to afford technique) as well as new tools for ablation (technology). There are four major areas of variation and controversy in clinical practice, coupled into themes of technique and technology. These four areas: complex fractionated atrial electrograms (CFAE), rotors, energy sources, and catheter design, are the predominant foci of new research in AF catheter ablation. I review the present state of literature and practice surrounding each of these controversies to illustrate some of the ways in which AF ablation has not yet achieved closure (Bijker, 1995). These multiple streams of simultaneous innovation contribute to the fundamental complexity of the AF ablation knowledge system as multiple interdependent components are in flux.
The review of contemporary controversies that follows illustrates two significant points. First, multiple types or streams of knowledge contribute to the development of AF ablation. Second, AF ablation is fundamentally complex and adaptive as a result of the complex nature of AF, the heart, and the heart’s response to ablation. The intrinsic complexity of AF ablation is echoed by the multiple knowledge streams that co-exist, interact, and change one another to ultimately yield AF ablation. Each of these points will contribute to a set of recommendations to improve innovation processes for AF ablation.

**Controversies in Technique**

The ongoing struggle with achieving complete resolution of AF via PVI has prompted the notion that critical sources of AF lie outside the pulmonary veins, directly in atrial structures. Perhaps the failure of AF ablation is due to inadequate knowledge of the arrhythmia itself, and thus inadequate techniques to identify and obliterate the source of AF. Thus, researchers have explored techniques beyond PVI to identify and obliterate these additional foci. These techniques are particularly pursued in patients with longstanding persistent or chronic AF, as these forms of AF tend to be less responsive to PVI than does paroxysmal AF.

**Complex fractionated atrial electrograms (CFAE).** The first major approach to AF ablation beyond the typical PVI lesion set was motivated by researchers who used electroanatomic mapping technologies to afford new physiological knowledge, showing

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21 I address the complex adaptive system nature of the AF ablation knowledge system more fully in Chapter 5.
that there was not consistent conduction throughout the atria during AF (Jaïs, Haïssaguerre, Shah, Chouairi, & Clémenty, 1996). Further investigations used spectrographic analysis to identify that AF triggers often arise from areas in the atrium with CFAEs at baseline (Pachon et al., 2004; Sanders et al., 2005).

*Figure 3.* The top panel shows non-fractionated electrograms with crisp signals. The bottom panel shows fractionated electrograms with high-frequency, low-amplitude signals consistent with fibrosis.

CFAE regions have electrical activity resembling that of heart tissue that has previously been scarred from a heart attack (Figure 3). However, such scarring was typically thought to reside in the ventricles – the main pumping chambers of the heart that are primarily affected by heart attacks – not in the thinner atrial chambers. Further investigation afforded by magnetic resonance imaging (MRI) scanning and spectral analysis technologies revealed that the atria of people with longstanding persistent or permanent AF were full of fibrotic tissue that carries the same electrical characteristics as
scar tissue, including a tendency toward electrical excitation due to anisotropy, or an electrical charge mismatch between adjacent cells (Figure 4). Therefore, extra aberrant heart signals can arise at the border between fibrotic and healthy tissue in the atria. This electrical mismatch in CFAE regions recalls the electrical mismatch between in transition zones in the pulmonary veins.

**Figure 4.** In the left panel, areas not in purple have been identified as scar according to electroanatomic voltage mapping. Grey dots indicate points where the cardiac tissue has been ablated. In the right panel, areas not in purple have been identified as areas of fibrosis according to complex fractionated electrogram measurements. Areas noted in red represent more fibrosis. Note that the image on the right is tilted ~20 degrees to the left, compared to the image on the left. Thus, it is possible to see rough correlation in areas of scar and fibrosis using the two mapping techniques. Source: ondemand.hrsonline.org/media/HRS2014AM_15/Documents/Abstracts/images/g6662_1.png

Borrowing from the anatomical isolation approach of the WACA lesion set where ablation lines are drawn to electrically separate the pulmonary veins from the atria, some
electrophysiologists have begun to map the atria directly for electrical signals indicating CFAE regions (see Figures 3 and 4). The goal of CFAE mapping is to identify areas of fibrosis that can be isolated from surrounding healthy atrial tissue with a circumferential line of ablation, just as circumferential ablation is used around the pulmonary veins. CFAE isolation is thought to be helpful as an additional ablation strategy for patients with long-lasting persistent AF. This form of AF that does not stop on its own without an electrical cardioversion does not typically respond robustly to the typical PVI approach (Nademaneet al., 2004). Therefore, additional ablation seems to be needed for these patients. CFAE mapping and ablation require additional use of imaging and image integration mapping technology, as well as time for the ablation procedure, whether performed before the ablation procedure or during the ablation. CFAE mapping can be performed using either MRI or electrical signal mapping (Konings, Smeets, Penn, Wellens, & Allessie, 1997; Mahnkopf et al., 2010; Nademaneet al., 2004; Oakes et al., 2009). MRI mapping is done prior to the ablation procedure (typically one or more days in advance), with the MRI image integrated into the electrophysiology mapping system to guide the ablation procedure (Dong et al., 2006). Electrical signal mapping is done with intracardiac catheters at the time of the ablation procedure, with mapping integrated into the extant electrophysiology mapping system that already uses similar electrical inputs.

Data regarding the effectiveness of CFAE ablation are mixed. Early published literature suggested that CFAE mapping improves ablation outcomes compared to PVI alone for patients with longstanding persistent or chronic AF (e.g. Oral et al., 2007; Oral et al., 2009; Porter et al., 2008). However, the STAR-AF study published in 2015 comparing three different techniques for AF catheter ablation in patients with
longstanding persistent AF (including PVI only, PVI plus additional linear lesions based on anatomy, and PVI plus CFAE ablation) showed no difference in freedom from AF for PVI plus CFAE compared to PVI alone. The only significant difference was an additional hour of procedural time required for CFAE lesions, compared to PVI alone (Verma et al., 2015). In the context of a procedure that typically takes 3-5 hours, the additional time is not extraordinary. As a result, CFAE mapping continues to be done by many electrophysiologists, but its utility remains uncertain.22

**Rotors.** In 2009, Sanjiv Narayan and colleagues at the University of California-San Diego23 published a paper that revisited the early 20th century notion of wavelets of AF activity (Krummen, Peng, Bullinga, & Narayan, 2009). The wavelet theory postulated that AF is propagated and sustained by multiple wavelets of self-sustaining electrical circuits. For much of the 20th century, the wavelet theory was linked to the Cox Maze approach aimed at segmenting the atrium to prevent wavelets from forming and sustaining. However, the multiple wavelet theory had not been examined for relevance to catheter ablation. Narayanan and colleagues recast the wavelets as discrete rotors of electrical activity that propagate AF. As with the CFAE approach, the focus on rotors seeks an explanation for why AF ablation procedures don’t work well, by identifying another anatomical target for the basic ablation technique. Narayan built his new

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22 It is interesting to note that on an international panel of AF experts at the Cardiovascular Clinical Trialists forum in December 2015, Hugh Calkins, an AF ablation thought-leader, referred to this single study as proof that CFAE ablation does not work (field notes, December 5, 2015).

23 In 2014, Narayan moved to Stanford University, largely to take advantage of the innovation culture there.
approach to the wavelet theory on a history of doing voltage spectral mapping via direct
electrophysiologic catheter measurement, and combined this with novel computational
techniques based on his prior expertise in computer science. He designed a novel
mapping technology that could localize rotational electrical circuits in atrial tissue,
thought to be sites of AF initiation and propagation.

In order to achieve simultaneous wide area mapping of atrial tissues, Narayan
employed a rarely used basket-shaped catheter that fit inside the atrium for measuring the
site and pattern of aberrant electrical activity throughout the whole atrium. This early
work led to the development of a novel mapping system – Topera – to identify the sites
of atrial rotors as ablation targets beyond the pulmonary veins. Clinical trial results
described the technique’s effectiveness for terminating AF even without performing PVI
ablation (Narayan et al., 2012). Rotor mapping and ablation is done while a patient is in
AF. In many cases during clinical trials, rotor ablation terminated AF without doing PVI
ablation. This emerging knowledge about ablation technique reinforced the notion of
rotors as a critical source of AF outside the pulmonary veins. Moreover, by
demonstrating that rotor ablation could terminate AF, it challenged the primacy of
pulmonary vein sites as the source of most AF. In 2013, Narayan published a paper
noting that many of the common sites of rotor ablation in the left atrium correspond
largely to atrial sites that are included in the typical WACA lesion set (Narayan,
Krummen, Clopton, Shivkumar, & Miller, 2013). Therefore, in many cases, some rotors

24 Narayan holds graduate degrees in medicine, neuroscience, and software engineering.
25 Narayan co-founded Topera with Ruchir Sehra in 2010. They sold the company to
industry giant Abbot Medical in 2014 for more than $250 million.
may be inadvertently ablated even without targeted mapping. However, as WACA is only done in the left atrium, Topera mapping and ablation is thought to exert a significant advantage for right atrial rotors. However, there remains skepticism in the community that a rotor-based AF approach holds the key to a cure for AF.

As Topera cleared the FDA approval process and entered regular commercial use in the EP community outside of clinical trials, formal feedback has been limited. Because the purchase of a novel mapping system and catheters is a considerable expense, many centers have been reluctant to make the investment, particularly in a national environment of strained healthcare expenses. Topera has a 3-month trial program available in an effort to entice future purchasing. However, many physicians find that this is an inadequate time period to gain comfort with the catheters and mapping system (TL-1, June 25, 2015). Moreover, a 3-month time horizon is insufficient to allow for a meaningful assessment of procedural success via patient outcomes, given that AF recurrence is common in the 3-month healing process immediately after ablation, even for procedures that ultimately prove to be successful at eliminating AF. Therefore, Topera is sparsely used and the community as a whole remains skeptical about the role that rotor mapping should play in AF ablation. This skepticism both stems from and limits the type of widespread use and experience that is necessary to build robust experience and knowledge about rotor mapping and the Topera technology. As a result, knowledge of rotor ablation remains incomplete without hope of achieving closure.

26 I will revisit this idea of inadvertent rotor ablation with more technical detail in Case 3 later in this chapter.
27 In Chapter 4, we will further examine the factors that facilitate translation of knowledge into individual practice.
At the 2015 Heart Rhythm Scientific Sessions, for example, there were 38 abstract presentations related to rotor mapping for AF ablation out of nearly 800 abstract presentations related to AF ablation (<5%).\textsuperscript{28} Thirty-three of these abstracts were generally positive toward the notion of rotor mapping and ablation as a useful approach, particularly for persistent AF. Six of these positive abstracts included Narayan as an author, signaling his continued activity in the field, and marking his ongoing belief in rotor ablation as a useful technique. One additional positive abstract included an original investor in Topera. Of note, one abstract specifically noted limitations in the basket catheter technology available for effective mapping (Kuklik et al., 2015), illustrating the critical relationship between technology and technique knowledges. Although technology afforded the rotor ablation technique, further limitations in the technology remain.

Two of the rotor abstracts were directly contradictory; both examined long-term follow-up data regarding freedom from arrhythmia. The original investigation group (Narayan’s research group) reported effective freedom from AF in long-term (1-2 year) follow-up (Narayan, Krummen, Donsky, Swarup, & Miller, 2015). Another center that had not been part of the early trial reported no freedom from AF in a similar group of patients (Gianni et al., 2015). This second abstract was remarkable, in that it is rare to see an entirely negative outcome published from any type of trial.

Overall, the abstract presentations at the 2015 Heart Rhythm Scientific Sessions demonstrated relatively little independent research on rotor ablation. However, I observed

\textsuperscript{28} It is worthwhile noting that while many published articles were initially presented as abstracts at major electrophysiology meetings like the Heart Rhythm Annual Scientific Sessions, only a small percentage of the hundreds of abstracts at such meetings are further developed for manuscript publication in peer-reviewed journals.
much informal sidebar conversation during poster sessions about the divergent abstracts presenting long-term follow-up data. The overriding response of attendees interested in AF ablation technologies was significant interest in and healthy skepticism about the possibility of rotor mapping and ablation, but not enough to either support the purchase of new Topera systems or dismiss rotor ablation entirely. More experience, and thus more knowledge, may help to encourage uptake of the technology and technique into widespread clinical practice. Widespread uptake, in turn, can generate new knowledge from lived experience that will help to move the community to achieve closure.

Controversies in Technology

Just as the CFAE and Topera cases illustrated the search for improved AF ablation outcomes through improved technique with additional ablation targets, other efforts to improve AF ablation have sought to innovate around the technologies used to do the ablation. Perhaps AF ablation outcomes could be improved if the technologies used to perform AF ablation were more effective. Two major foci of technology innovation are the type of energy used for ablation, and the design of ablation catheters.

Energy sources. Although radiofrequency is the dominant energy source for performing AF catheter ablation, concerns about tissue heating (particularly related to atrial-esophageal fistula – a hole between the heart and the esophagus that is usually deadly) have led researchers to investigate alternative energy sources for catheter ablation. The alternative most commonly used in clinical practice today is freezing, or cryoablation, particularly via the Cryoballoon catheter (Medtronic, 2013). The
cryoballoon tends to yield shorter procedure times (Andrade et al., 2013; Packer et al., 2013a). However, long-term AF recurrence rates are relatively higher than for radiofrequency ablation (Packer et al., 2013b; Vogt et al., 2013), and there have been cases of atrial-esophageal fistulae even with the cryoballoon that was thought to be safer than radiofrequency, with less likelihood of damaging the esophagus (Metzner et al., 2013).

Ultrasound and laser are also under investigation by industry actors working through thought-leader research physicians as alternative energy sources that may improve safety and efficacy. High-frequency ultrasound has been investigated for its potential to deliver effective ablation lesions without blocking off the pulmonary vein (Okumura et al., 2009). Laser has been used in concert with direct endoscopic visualization technologies to allow for direct visualization of the heart tissue before and during ablation (Evonich, Nori, & Haines, 2007). As recently as the 2015 Heart Rhythm scientific sessions, findings from a clinical trial of the laser balloon were presented (Reddy et al., 2015), demonstrating safety and efficacy endpoints for the device, which is under investigation in the United States at the time I write this in February 2016. In addition, the trial findings demonstrated that physicians without prior experience using the laser balloon were able to develop proficiency within 15 cases. This short, steep learning curve is significant, as operator proficiency is considered by practitioners to be an important, if grossly unaccounted, component of AF ablation success. Yet, as a function of limits imposed by the FDA regulatory system, the vast majority of electrophysiologists do not use ultrasound or laser ablation technology. Therefore, the opportunities to develop broad understanding of these technologies is currently limited.
**Catheter design.** Catheter technology development for AF ablation has focused on two primary areas: geometry and lesion feedback. Catheter geometry is thought to impact the time course and success of an ablation procedure by impacting the ability of the operator to reach critical anatomical structures to deliver effective ablation lesions. Concern regarding operator technical proficiency is pronounced for centers with less experienced and less technically gifted ablationists.\textsuperscript{29} In addition, the transseptal access required for left atrial ablation raises concerns about the number of catheters required to cross the interatrial septum, and the attendant risks of clots and stroke that increase with additional hardware introduced into the left atrium. Therefore, efforts have been made to develop basket-shaped (e.g. Topera) or balloon-type (e.g. Cryoballoon, laser balloon) catheters with easy maneuverability to the pulmonary veins that allow for signal recording (mapping) as well as ablation energy delivery from a single catheter without frequent requirements to maneuver and reposition multiple catheters. However, limitations of these geometric catheter approaches have been noted, particularly with regard to adequate full-atrial mapping for rotor identification given the variation in atrial size and shape from person to person (e.g. Kuklik et al., 2015).

The other notable area of catheter technology development stems from observations that many arrhythmia recurrences following AF ablation with PVI stem from areas of incomplete or healed lesions around the pulmonary veins. Indeed, in many cases, new left-sided atrial flutters appeared in patients after undergoing what were apparently initially successful ablations. This observation led to mapping studies that

\textsuperscript{29} This concern about operator proficiency is voiced by thought leaders who caution against the expected replicability of their own AF ablation outcomes by others (e.g. Oral et al., 2002, Oral et al., 2006, Pappone et al., 2003, Piccini & Daubert, 2011).
revealed many ineffective lesions, despite operators’ confidence that their ablations were indeed effective (Kuck et al., 2012). As a result, new pressure-sensitive catheter technologies were developed to give operators real-time feedback regarding pressure from tissue contact during lesion delivery, so that in the event of less effective tissue contact, energy could be delivered for a longer time period to afford an effective lesion (Kuck et al., 2012; Natale et al., 2014). For some operators, the notion of catheter feedback regarding lesion quality may pose a threat to the judgment or skill of the operator as the most important component of the ablation procedure (participant observation, July 6, 2015). For others, the opportunity to improve outcomes and prevent the need for additional procedures is the most salient feature of this catheter (participant observation, June 19, 2015; NTL-3, June 17, 2015). One respondent noted that the use of this catheter provides additional comfort in allowing fellows (physicians in training) to do more direct catheter manipulation (and thus gain more direct ablation experience) without fear of perforation due to the real-time feedback of catheter pressure against the heart tissue (NTL-2, June 17, 2015).

A recent systematic review and meta-analysis of pressure-feedback catheters found evidence for significant reduction in AF compared to standard ablation catheters without adding time to ablation cases (Afzal et al., 2015). This evidence is compelling to the community of practitioners who perform AF ablation with limited access to direct evidence of the procedure’s technical effectiveness. As a result, there is little way to identify the factors contributing to AF recurrence (i.e. technical failure with the right

\(^{30}\) As of February 2016, St. Jude’s TactiCath and Biosense Webster’s SmartTouch are the two commercially available pressure-sensitive catheter technologies in the U.S.
targets, or technical success with the wrong targets). In fact, several of my informants espoused the value of using the novel catheters. However, the new catheters add a significant financial cost to the case, and require the use of proprietary systems to incorporate lesion quality feedback with the electroanatomic mapping data to guide the ablation. The choice to use a pressure-feedback catheter, therefore, entails some tradeoffs in terms of other technologies available to use in a given AF ablation case.

Co-Development of Knowledge in AF Ablation

Having sketched the historical and contemporary landscape of AF ablation, I now turn to examine the complex knowledge that constitutes clinical practice and controversy in AF ablation. Complexity refers to construction from multiple interactive parts that affect one another in a functioning system. Knowledge of complex subjects is critically built or co-produced from the interaction of multiple knowledge streams, particularly in the case of so-called wicked problems that are too complex for a single stream (Klein, 2004). Medical sciences are particularly noted to be complex and to require multiple knowledge stream inputs (Turner, 1990). Within the medical sciences, electrophysiology itself is inherently complex, as it is a hybridized subfield of electronics (physics) and cardiology (anatomy and physiology) with critical requirements for human manipulation of specialized technologies. As such, it is logical that AF, as a specific focus of electrophysiology, would require a multi-stream knowledge approach in order to untangle such a complex problem. I refer to this multi-stream knowledge approach as co-
development. This is a fairly standard part of technology development with other complex technologies (e.g. airplanes, transistors).

Discrete streams of knowledge intersect and interact to produce the body of knowledge that informs practice of AF ablation. In essence, three discrete streams of knowledge – science ([patho]physiology), technology, and technique – collaboratively develop (co-develop) the integrated body of knowledge that informs AF ablation. Each stream of knowledge retains its distinctive character, just as an organ system retains its

31 It is useful to distinguish co-development from co-innovation, which is typically conceived as a contiguous process in time and space. Co-innovation has been described as a business management approach to innovation that involves multiple parties from inside and outside the innovation firm working together according to principles of engagement, co-creation, and shared experience (Lee, Olson, & Trimi, 2012). Co-innovation is also relevant to the AF ablation case. However, particularly when knowledge systems are composed of a large number of individuals working in discontinuous environments, it is helpful to employ a flexible understanding of person and place to reveal opportunities for co-innovation, as with co-development processes, in complex systems. Because the work of knowledge co-development and co-innovation in AF catheter ablation is done in the space of the knowledge system, it is important to activate or leverage the full knowledge system in order to yield the most complete knowledge in the relevant space. This observation informs the priority goals of this project to activate the full knowledge system around AF catheter ablation, and the approaches to designing interventions toward this goal.

Similarly, I take the process of knowledge co-development to be distinct from the notion of co-evolution (Morlacchi & Nelson, 2011) that suggests a more organic or natural process of knowledge development as knowledge emerges in response to its extant environment, as has been explored in the biological case (e.g. Darwin, 1859, Webb, 1994). Rather, the term co-development suggests a more active and constructed process through which new knowledge emerges by mobilizing other streams of knowledge in its environment. Similarly, the term co-development seems more specific for this case than co-creation (e.g. Regeer & Bunders, 2009) as co-creation suggests an act of de novo ideation, whereas co-development suggests the work of an ongoing process with a story that has already begun. In truth, all four terms: co-innovation, co-evolution, co-creation, and co-development embody similar values of intersectoral and transsectoral work, making the distinctions – and choice of term between the four – a finely-tuned selection that could easily be nudged toward a different path without a significant alteration in meaning.
distinctive characteristics in the body, but the interaction yields a distinct knowledge and understanding unlike any of the three individual streams. Moreover, intersections among the streams exert influence on inquiry within streams, while building the combined body of knowledge.

The AF ablation case illustrates how to cope with increasingly complex systems of knowledge and work in a variety of settings in and beyond healthcare. By analyzing the AF ablation literature through a co-development lens, the importance of multiple knowledge streams emerges, and reinforces the notion that each knowledge stream must be incorporated to build the full knowledge system. Any effort to improve the AF knowledge system in order to yield improved patient outcomes must account for the multiple constituent knowledge streams of AF ablation.

**Science, Technology, and Technique**

In the case of AF catheter ablation, three streams of knowledge: science, technique, and technology, interact to co-develop knowledge of AF ablation, and AF more broadly. Science knowledge in AF ablation is the structural and cellular physiology and pathophysiology of AF. Science knowledge describes intrinsic characteristics of the human body and natural world including anatomy, physiology, biophysics, and biochemistry.

Technology encompasses the technologies directly associated with AF ablation itself (e.g. mapping systems, ablation catheters), as well as adjunctive technologies including imaging, computing, and spectral analysis technologies that electrophysiologists use to accomplish, facilitate, and advance the AF ablation procedure.
Technology often acts as a critical affordance between knowledge in the streams of science and technique.

Technique includes the manipulative approaches used by the cardiac electrophysiologist to accomplish AF ablation, including where and how to deliver lesions in the heart. Technique knowledge encompasses the ways that electrophysiologists choose to use technology based on an understanding of the science of AF. Technique also represents the skill with which the electrophysiologist manipulates the technologies used to perform AF ablation. \(^{32}\)

Throughout the history of AF ablation, knowledge in one stream has affected, and been affected by, knowledge in the other two streams in a perpetual dance of mutual transformation (Figure 5). Therefore, the constitutive science-technology-technique framework of AF catheter ablation paints a useful portrait of both constitutive and interactional work that has underscored technology and practice innovation to date, and may offer critical insights to inform changes for an improved innovation process in the future. \(^{33}\) Although this type of knowledge co-development framework is not novel, it is a critical component to innovation in AF ablation that is not facilitated in the present innovation system. Therefore, it merits foregrounding here.

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\(^{32}\) Langdon Winner (1986) referred to Plato’s technē, or practical art, to describe the ways that one uses knowledge of politics to practice statecraft. This term is a relevant component of technique for AF ablation, as physicians use knowledge of science with the tools of technology to exert craftsmanship in the practice ablation.

\(^{33}\) The science-technology-technique model is also similar to the triumvirate of descriptive, prescriptive, and tacit knowledges that informs engineering practice (Vincenti, 1990).
Figure 5. Triple helix of co-developed AF ablation knowledge comprising science, technology, and technique. Like the collagen triple helix structure from which this model is adapted, each sectoral thread retains its essential character, but continually and repeatedly interacts with each of the other sectoral threads, adapting over time in response to the complex interactions. Image source: https://upload.wikimedia.org/wikipedia/commons/9/94/1K6F_Crystal_Structure_Of_The_Collagen_Triple_Helix_Model_Pro-Pro-Gly103_04.png

Innovation economists have addressed a similar triple helix of critical knowledge required for medical practice to evolve (e.g. Morlacchi & Nelson, 2011 with the left ventricular assist device). These innovation studies provide an explicit critique of a prevailing linear bench-to-bedside view of medical practice progress that continues to inform research structures and funding, despite NIH and FDA programs suggesting more integrated approaches to innovation (i.e. CDRH, 2011; NIH, 2015). One of the ways that the NIH has moved toward more integrated approaches to innovation is through an active
focus on translation, stemming from the observation that translation of scientific concepts to clinical practice does not occur naturally. However, the NIH’s translation approach is focused on the supply side of translation from molecular concept to clinical application. There is little attention to clinical uptake of innovation or its attendant domestication practices – the ways that users adopt and adapt technologies for their individual purposes. Moreover, there is no formal feedback mechanism from uptake or non-uptake of clinical applications to inform any re-examination of the knowledge and knowledge flow related to innovation. In addition, it is valuable to consider the possibility that even a triple helix approach to integrating multiple streams of sectoral knowledge (i.e. science, technology, technique) may fail to overcome the reductionistic linear notions of normal science that are preserved within each stream’s typical approach (Funtowicz & Ravetz, 1993).

**Analytical methods.** To analyze my historical literature sample for components and directional influence of scientific knowledge, technology, and technique, I used a mixed deductive and inductive coding approach at the level of the individual article (Table 2). I began with an overarching coding scheme based on deductive categories of science, technology, and technique. As the text analysis process continued, I induced subthemes within each meta-theme in order to allow for more detailed concept mapping within and between major thematic categories using a map-analytic technique to capture the direction of concept relationships as depicted in each paper (Carley, 1993).
Table 2

*Thematic Coding Framework for Historical Literature Analysis*

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<th>Meta-Theme</th>
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**Examples of Complexity and Co-Development in AF Catheter Ablation**

Although a description of the history of AF ablation can paint a linear picture of discovery and innovation, close examination of the literature reveals significantly more complexity in the ways that scientific, technical, and technological knowledge interrelate to inform AF ablation. Distinct from a classical bench-to-bedside conception of knowledge translation, or even a more modern circular model of biomedical innovation knowledge, the AF ablation case illustrates how translational knowledge afforded by new technique or technology, coupled with active domestication, afforded new scientific understanding of AF over time, creating complex loops in the flow of biomedical innovation (See Figure 6).
An overarching example illustrates the co-development of technology, technique, and science knowledge in AF ablation (Figure 7). AF was long understood to comprise abnormal electrical conduction throughout the atrium by large or small circuits or wavelets of electricity. However, the source of AF, in terms of a discrete focus or trigger that initiates the arrhythmia, was unknown. Therefore, there was not a clear target for catheter ablation to eliminate the onset of AF. The observation that cellular transition zones between atrial tissue and venous tissue in the pulmonary veins were the focal source of some AF (1: *science*) provided a discrete target for catheter ablation (2: *technique*) and led to the development of looped catheters to allow for the simultaneous measurement of electrical signals throughout the internal circumference of the pulmonary
vein (3: technology) in order to perform pointwise ablation of electrical triggers within the pulmonary veins (4: technique). That technical approach, however, led to the observation that intra-venous ablation causes scar-related narrowing of the pulmonary veins and resultant lung damage, which led to a change in ablation technique to ablation outside the pulmonary veins (5: technique) using geometrical mapping (6: technology) to ensure safe positioning of the ablation catheter. This shift to a complete atrial vein isolation procedure (7: technique) meant that recurrent AF must be coming from sites outside of the pulmonary veins (8: science). This hypothesis led to the development of basket-type catheters (9: technology) to allow for simultaneous mapping of an entire atrium (10: technique), along with the development of novel computational algorithms (11: technology) in order to identify rotors of electrical activity in atrial tissue (12: science).

Figure 7. Graphical example of knowledge co-development in AF ablation.

I will present three cases drawn from historical literature analysis to further illustrate the co-development story between technology development, technique development, and scientific understanding of the pathophysiology of AF. Many of the
actors and scenes in these cases will be familiar, as we met and examined them in our linear historical accounting at the beginning of this chapter. Now, we return to those old friends with a new set of labels to see how their knowledge has woven together to form the marled fabric of contemporary AF ablation. These cases show how knowledge streams representing technology, technique, and science have created a feedback process to help advance one another in the context of the AF catheter ablation knowledge and practice system. These cases demonstrate how the practice of AF catheter ablation requires particular combinations of technology and technique, coupled with operator skill, in order to effect clinical success at ameliorating AF. Moreover, literature review illustrates that while the understanding of AF – in terms of scientific pathophysiology as well as ablation technology and technique – remains incomplete, ongoing co-development between the three constituent knowledge streams illuminates emergent knowledge that might not be obvious from following any one of the individual component system elements in isolation. For example, simply pursuing catheter technology design (technology) in an effort to achieve a more complete PVI ablation line without reflecting on the pathophysiology of recurrent AF (science) would not reveal the presence of rotors in the atria (science) that contribute to AF. Therefore, it is important to incorporate continuous interaction between knowledge streams, in order to effect a cure for the disease.

Case 1: Experience with technique affords scientific knowledge. In the early 1990s, non-surgical cardiologists grew frustrated with the limited success of using medications to control AF. They observed the surgical AF treatments that began in the
1980s (Cox et al., 1991b), which were based on physiological research conducted in the early-to-mid 20th century (Garrey, 1914; Lewis, 1920; Mines, 1913; Scherf, Blumenfeld, & Schaffer, 1953; Scherf, 1947; Winterberg, 1907) and the resulting wavelet theory of AF that postulated that AF requires a critical mass of electrically contiguous tissue to sustain the arrhythmia (Boineau, Mooney, & Hudson, 1976; Boineau et al., 1980; Moe & Abildskov, 1959; Moe, Rheinboldt, & Abildskov, 1964; West & Landa, 1962).

Cardiologists were intrigued by the Cox Maze surgery designed to divide the atrium into small electrically-isolated segments in order to prevent wavelet conduction. This was something that medication could not achieve. Cardiologists merged the surgical isolation concept with the idea of catheter ablation that was developing from early experience targeting the AV node (Scheinman, 1982), along with growing knowledge of techniques and technologies for making electrical measurements inside the heart using intracardiac catheters and new energy sources (Allessie, Lammers, Bonke, & Hollen, 1984). Non-surgical cardiologists began to explore radiofrequency catheter ablation techniques to treat AF.

Initially, catheter ablation techniques tried to replicate the Cox Maze lesion set, first in the right atrium (Calkins et al., 1999; Elvan et al., 1994; Gaita et al., 1998; Haïssaguerre et al., 1994; Swartz et al., 1990) and then in the left atrium as Cox had done with surgery (Haïssaguerre et al., 1996). Throughout the early to mid 1990s, researchers observed effects of radiofrequency ablation on heart tissue (Bauer et al., 2006; Cheema et al., 2007; Feld, Yao, Reu, & Kudaravalli, 2003; Fenelon & Brugada, 1996; Pappone et al., 2001; Tada et al., 2002; Tanno et al., 1994; Taylor, Kay, Zheng, Bishop, & Ideker, 1996).
and particularly the effects on AF itself after ablation (Haïssaguerre et al., 1996; Sih, Berbari, & Zipes, 1997).

One of the key observations during the late 1990s was that AF seemed to initiate from trigger sources within the pulmonary veins, rather than in the atrium itself (Haïssaguerre et al., 1998). This observation led to the pulmonary vein-focused approach rather than atrial segmentation, representing a major break from AF surgery. Over the next several years, as pulmonary vein isolation (PVI) became the dominant technique for catheter ablation, researchers made further observations about the nature of AF based on arrhythmia recurrence after a successful PVI procedure. Some of these observations exposed flaws in ablation technique such as incomplete lines of ablation, signaling the need for improvements in ablation technique or technologies (e.g. Gerstenfeld, Callans, Dixit, Zado, & Marchlinski, 2003; Haïssaguerre, Hocini, Sanders, Sacher et al., 2005; Jaïs et al., 2006; Lemola et al., 2004; Nathakumar et al., 2004; Pappone et al., 2004; Sawhney, Anousheh, Chen, & Feld, 2010). Other observations from evolving AF ablation techniques using new technologies led to new understanding of the physiology of AF itself, at structural and cellular levels of the heart (Bauer et al., 2006; Chugh et al., 2005; Gerstenfeld et al., 2004; Gerstenfeld, Callans, Sauer, Jacobson, & Marchlinski, 2005; Haïssaguerre et al., 2004; Haïssaguerre et al., 2006; Hocini et al., 2000; Hocini et al., 2010; Hsieh et al., 1999; Hsieh et al., 2006; Kottkamp et al., 2004; Lazar, Dixit, Marchlinski, Callans, & Gerstenfeld, 2004; Lemola et al., 2006; Lin, Beldner, Vanderhoff, Pulliam, & Siddique, 2004; Rostock et al., 2006; Verma et al., 2005).

This case provides three major observations about AF ablation knowledge. First, the three streams of AF ablation knowledge (i.e. science, technology, technique) support
advancements in one another in a variety of patterns, such that contemporary knowledge would be incomplete if any one of the streams was missing from the conversation.

Second, knowledge advancement as codified in the peer-reviewed literature is not completely linear with respect to time. For example, Haïssaguerre’s 1996 paper describing biatrial ablation predates Gaita’s 1998 paper describing right atrial ablation. This observation raises two well-known points about the development and codification of formal knowledge: it takes a long time to assemble robust empirical scientific evidence, and the peer-reviewed publication system does not afford real-time knowledge communication.34 Third, a few names dominate the literature landscape (i.e. Haïssaguerre, Gerstenfeld) for a given concept among several other authors, supporting the notion that a few thought-leaders may be disproportionately represented in the literature compared to the full body of thinkers in the field.

None of these observations is novel. However, their presence highlights a persistent limitation in the knowledge dissemination system for AF ablation. The present system of peer-reviewed publication as the core method for knowledge dissemination is subject to resource limitations that constrain real-time access to new knowledge that may be a critical component for new knowledge development.

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34 My informants mentioned this time lag with peer-reviewed publication several times in participant observation and interviews. One physician recalled a six-month lag between performing a first-in-human procedure and the eventual publication of the single case report in a peer-reviewed journal in October 2015 (NTL-1, November 17, 2015). The time dilation stretches to years in the case of more complex publications from multicenter randomized controlled trials.
Case 2: Technique failure and the use of new technology to investigate old scientific ideas lead to new scientific knowledge, new techniques, and a new focus on the patient. Case 2 shows how a new technology that was developed to do a specific kind of tissue analysis identified the presence of particular types of electrical signals as targets for catheter ablation. This discovery led to an understanding about how atrial tissue conducts electricity and insights regarding the impacts of a patient’s lifestyle and other heart disease on AF. This case begins at roughly the same knowledge point as case 1, as researchers grappled with the physiological mechanisms of AF that occurred following what was believed to be a successful PVI procedure. In some cases, AF recurrence was due to failure of the ablation line to prevent electrical conduction from the pulmonary veins in the months following the ablation (Haïssaguerre, Sanders et al., 2005). However, in other cases, particularly in the setting of persistent or permanent AF, arrhythmia recurrence arose from sites outside of the pulmonary veins (Chugh et al., 2005; Gerstenfeld et al., 2003; Haïssaguerre, Hocini, Sanders, Takahashi et al., 2005; Lazar et al., 2004; Lin et al., 2004; Shah, Haïssaguerre, Jaïs, & Hocini, 2003; Stabile et al., 2003).

These observations about non-pulmonary vein sites recalled a parallel line of investigation regarding AF mechanisms that held aloft early 20th century theories about atrial wavelets and other arrhythmia foci outside of the pulmonary veins (Garrey, 1914; Lewis, 1920; Mines, 1913; Moe & Abildskov, 1959; Scherf, 1947; Winterberg, 1907). More recently, researchers had been using novel technologies to characterize the electrophysiological characteristics of AF in different heart structures. This effort supported the early 20th century theories about wavelets and particular areas of AF foci.
outside of the pulmonary veins with additional observations related to electrical signal variations and tissue changes (Berenfeld et al., 2000; Gerstenfeld et al., 1992; Jaïs et al., 1996; Jaïs et al., 1997; Jalife, Berenfeld, Skanes, & Mandapati, 1998; Kottkamp et al., 1999; Liu et al., 2003; Mandapati, Skanes, Chen, Berenfeld, & Jalife, 2000; Sarmast, 2003; Shah et al., 2002; Shah, Haïssaguerre, Jaïs, & Clémenty, 2002; Skanes, Mandapati, Berenfeld, Davidenko, & Jalife, 1998; Spach & Boineau, 1997). Using newer technological approaches to analyze the atrial tissue than had been available in the early-to-mid 20th century, including biochemical analysis (Boldt et al., 2004), electroanatomic mapping (Kalifa et al., 2006; Monir & Pollak, 2008; Nademanee et al., 2004; Everett et al., 2006), spectral analysis (Pachon et al., 2004), and MRI (Khurram et al., 2014; Oakes et al., 2009), researchers found that areas of the heart producing abnormal electrical signals linked to AF (CFAEs) correlated to areas of tissue fibrosis or scarring. This link suggested that the presence of scarred tissue enables the formation of the electrical impulses that become AF. Based on this finding, afforded by the critical merger of knowledge in science, technology, and technique, thought leaders developed new ablation techniques to target CFAE sources in an effort to obliterate AF (Hunter et al., 2010; Kumagai, Muraoka, Mitsutake, Takashima, & Nakashima, 2007; Nademanee, Schwab, Porath, & Abbo, 2006; Nademanee et al., 2008; Oral et al., 2007; Oral et al., 2009; Scherr et al., 2007; Schmitt et al., 2007; Van Belle et al., 2009; Verma et al., 2010; Willems et al., 2006).

As CFAE ablation gained favor in the AF ablation community, attention turned to efforts to understand how CFAE areas arise in the heart, both from a cellular level
(Atienza et al., 2011) as well as from the perspective of the whole person (Kottkamp, 2014; Medi et al., 2011; Platonov et al., 2011; Teh et al., 2012; Yokokawa et al., 2012). This turn to identify person-level causes for CFAE regions marks a critical point in the knowledge of AF ablation, raising factors associated with lifestyle as impacting the performance and outcome of AF ablation for the first time in the peer-reviewed literature. For the first time in the AF ablation literature, the patient as a cognizant and autonomous actor became an object of the clinical gaze (Foucault, 1973) rather than merely the vessel providing the anatomical targets of clinician’s attention for catheter ablation. This transformation will be important for interpreting the knowledge network around AF ablation and planning ways to improve AF ablation innovation. I will return to this in Chapter 5.

Case 3: New technique and new technology unseat empirically-“proven” science. This case presents two separate instances of a similar phenomenon wherein empirical knowledge held as truth in AF ablation is unseated by new research afforded by novel technologies to evaluate new catheter ablation techniques. In the first instance, the creator of the eponymous Cox Maze surgery for AF conducted a series of experiments to simplify his surgical procedure in order to make it more accessible to other surgeons. Cox’s experiments demonstrated that only a few surgical lines were required to separate

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35 It is interesting to note that the authors of this paper (Atienza et al., 2011) refer to fractionated electrograms as though they are a physiological finding in their own right, rather than simply a technology-afforded representation of cellular activity. Indeed, the body does not consist of electrograms. Rather, the body produces electrograms that we can measure in order to represent the body. This physiological characterization by the authors recalls the varieties of body representation by subspecialists (Mol, 2002).
two critical structures in the right atrium and two critical structures in the left atrium in order to obliterate AF. This experimental finding led him to promote the theory that AF occurred via a single large electrical circuit. Over the years, Cox conducted multiple additional experiments to confirm this theory. In a 2000 paper, Cox reflected that although his single electrical circuit theory was proved false by Haïssaguerre (1998) and others, his empirical experimental findings remained intact (Cox & Ad, 2000). This observation about the durability of experimental findings despite contravening evidence supports the value of a recursive approach to knowledge development with periodic reexamination of so-called scientific truths under the lights of new techniques and technologies.

In the second instance, Sanjiv Narayan, creator of the Topera rotor mapping system, reflected on the contravening evidence regarding PVI success in light of his findings related to atrial rotors in an effort to connect the body of knowledge around AF ablation. In a 2013 paper, Narayan noted that the most common sites of rotors in his experimental findings coincide with areas that are already targeted in a typical wide-area circumferential ablation (WACA) approach to pulmonary vein isolation (Narayan et al., 2013, see Figure 8).
Figure 8. Rotor (also called Focal Impulse and Rotor Modulation [FIRM]) sites coincide with typical WACA sites. Image from Narayan et al., 2013.

With this observation, Narayan postulated that the success of the WACA approach may be due in part to coincidental elimination of atrial rotors. In other words, PVI as a strategy for AF ablation was supported by experimental data, but driven by the wrong scientific theories. As with Cox above, Narayan’s observation highlights the need to maintain a recursive approach to knowledge that incorporates the three streams of science, technology, and technique.

**Power in AF Ablation**

Historical analysis of the AF ablation literature reveals three major observations. First, the contemporary understanding of AF and AF ablation relies on the continual interaction of three streams of knowledge as described above. Second, the nature of AF as a target for therapy has changed over time. Third, the knowledge formally captured in
peer-reviewed literature is contributed by a narrow group of a few dozen individuals, relative to the much larger community of the thousands of clinical experts who engage in the practice of AF ablation. Therefore, knowledge is created and codified by thought-leaders without direct participation by non-thought leader physicians and other healthcare professionals from the formal knowledge community.36

Jasanoff’s (2010) framework of co-production is built on the notion that “scientific knowledge…both embeds and is embedded in…the social” (Jasanoff, 2004, p. 3). Co-production has been used to describe the relationship between science and social structures or frameworks for regulating science. For example, the notion of climate change is embedded in not only scientific descriptions of what the climate is, but equally in socially held notions of what the climate ought to be (Jasanoff, 2010). If Jasanoff’s framing of co-production allows us to understand the ways that science and society co-constitute in order to shape knowledge and identities, then a co-production frame leads to asking how the knowledge comes to be created such that some individuals are involved in the knowledge creation and others are excluded. Co-production allows us to ask why the thought-leaders are recognized as thought-leaders, including by what mechanisms, and with what authority.

Bibliometric Power

Formal power in the knowledge system is embodied in the thought-leaders, through their representation in peer-reviewed literature, including direct authorship as well as publication citation that yields bibliometric power. Bibliometric power is a self-

36 I will be discussing the notion of the formal knowledge system further in Chapter 5.
reinforcing enterprise characterized by ethnocentric patterns of peer engagement and power delegation (Pritchard, 1969). Although formal quantitative bibliometric power calculations including bibliographic coupling and co-citation exceed the scope of this project, qualitative literature analysis reveals a few relevant high-level observations.

The publishing community in AF ablation is quite small, representing a limited sample of all those who engage with AF catheter ablation. Within this small publishing community, there is a tendency to preferentially cite from one’s own academic group, including peers in one’s home institution. There is also a strong pattern of thought leaders entering the publishing community as a function of being trained in the lab of an older thought-leader and being included on peer-reviewed publications with the senior thought-leader. This phenomenon reflects the typical apprenticeship training pattern, and a type of bibliometric ethnocentrism.

In addition to considering the innate human tendency toward ethnocentrism, auto-citation may also be driven by the external publishing structure of impact factor. For decades, professional and scholarly journals have employed a grading schema at the journal level, based on citations to articles in that journal. The number of citations from other journals is used to assign a score, termed the impact factor (Garfield, 1955). Over the years, the impact factor has come to represent power, and impact factor scores have been extended from journals to authors. A high impact factor score elevates the publishing author to thought-leader status. Therefore, the impact factor structure

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37 I observed similar enthocentric citation behavior in formal presentations at the Heart Rhythm Society Atrial Fibrillation Research Forum in December 2013 (Washington DC), and in invited presentations on AF ablation at the American College of Cardiology Scientific Sessions in March 2015 (San Diego, CA).
privileges those who publish in high-impact journals, as practitioners particularly note
high-impact journal articles as a key source of knowledge.

The impact factor scoring approach has been appropriated for use in a variety of
ways, including prestige, advertising value, tenure assessment, and academic promotion.
As a result, the publishing community, including thought-leaders, has adopted behaviors
designed to impact the impact factor, including preferential citation patterns based on
author and publication. Such behaviors have been widely regarded as detrimental to
scholarship with calls in the science policy community to abolish traditional journals in
favor of open access publishing in an effort to avoid publication bias based on impact
factor (Coats & Shewan, 2015; Seglen, 1997; Simons, 2008). Despite growing criticism
of the impact factor, pervasive belief in the impact factor as a representation of power
persists. This phenomenon was evident in my fieldwork as informants across all
categories specifically and reflexively mention journal articles as a key source of
knowledge, whether or not they actually refer directly to peer-reviewed journals in the
course of their own knowledge seeking for AF ablation.

External structural influences of peer-reviewed publishing like the impact factor
shape AF ablation by affecting the flow of knowledge into and through the constituent
knowledge system. Given that knowledge flows affect research choices, these social and
structural forces in the historical literature offer considerations for assessing the AF
ablation knowledge network and planning interventions in that network to improve
innovation, as well as a valuable site for future investigation. Moreover, because
knowledge is contingent on the context and patterns of communication, it is relevant to
revisit historical knowledge – including theory and data – as novel contexts emerge to afford new opportunities for interpretation over time (Consoli & Ramlogan, 2008).\(^{38}\)

Money is a key affordance to entering the innovation system in the context of the U.S. regulatory structure, as innovation in the AF ablation space is very expensive. Most research and development activity in biomedical technology innovation is funded through public grants, venture capital, or industry investment activities. In most cases, grant applicants must demonstrate a strong record of relevant peer-reviewed publication in order to secure financial backing for research and development projects. Therefore, bibliometric power is a key tool for accessing more public and private grants and venture capital funding in the credibility cycle of biomedical technology innovation (Latour & Woolgar, 1979; Rip, 1988). In other words, although there are other modes of practical knowledge transmission available, biomedical technology regulation in the U.S. and Western Europe requires significant formal publication presence as the ticket to innovation resources. In effect, bibliometric power is money.

In the next section focused on knowledge system implications, I present a critique of the credibility cycle that relies on peer review publication, and an alternative to it, using AF ablation as an empirical foundation. AF ablation offers a case where the extant credibility cycle resulted in premature closure of an unsettled technology and impediments to rich communication among strands of the knowledge triple helix as two key constraints to effective innovation.

\(^{38}\) As I was completing the final draft of this doctoral dissertation in March 2016, I stumbled across a review article that takes a similar historical approach to examining AF therapies (Heijman et al., 2015).
**Knowledge System Implications**

Formal peer-reviewed publication is the primary currency of knowledge exchange for innovation and regulatory pathways. However, the overarching goal of this project aims to identify new opportunities to improve the AF ablation knowledge system to better support innovation. Having reviewed some of the asymmetries in knowledge and power evident in the historical AF ablation literature, it is helpful to use a symmetrical approach to consider what might be gained or lost in future knowledge system arrangements that do or do not privilege thought leaders in knowledge creation and codification. Thought-leader privileging may occur by two predominant means: bibliometric power, and availability of time and workload capacity allowing participation in the publishing exercise.

**What do we gain in the present system of publishing mainly by a small group of thought-leaders?** By limiting inputs to the knowledge system, we limit complexity in the knowledge, which lends greater availability for controlled scientific scrutiny and thus knowledge production according to the privileged status of controlled experimentation as producing fact or truth. In essence, fewer knowledge inputs are simpler to manage and render legible through the commonly accepted processes of scientific inquiry and peer review. In turn, a smaller and legible body of peer-reviewed knowledge can be effectively communicated to busy clinicians, and thus translated into clinical practice.

This idea has recently been advanced as the primary role of the peer-reviewed publication system. Valentin Fuster, editor-in-chief of the *Journal of the American College of Cardiology*, has recently countered an argument proposed by three prominent
cardiovascular researchers in an editorial of the *British Medical Journal* for clinical medicine to adopt a pre-review publication model akin to that commonly practiced in mathematics and physics (Lauer, Krumholz, & Topol, 2015). Fuster argues that the role of peer-reviewed publication is precisely to offer clarity to the practitioner and public, who lack the time and sophistication to make use of raw data and unevaluated scientific claims (Husten, 2015).

Fuster’s interpretation of peer review contrasts somewhat with Chubin and Hackett (1990), who argue that peer review is intended to evaluate scientific work in order to “certify the correctness of procedures, establish the plausibility of results, and allocate scarce resources” (p. 2). Peer review, however, is not intended serve the role of interpretation and clarification to make science more accessible to a broader public, whether the general public or a specialized public of non-thought-leader AF ablation practitioners. That role falls to the drive toward science communication and public engagement, separately from the peer review process.

In light of the complex association between AF and AF ablation, limiting the volume of new ideas renders greater possibility for attention to be focused on one idea at a time. Therefore, each idea can be explored more thoroughly rather than many concomitantly circulating ideas that cannot gain the traction of focused research attention. With focus, each idea can be vetted through the scientific process in order to understand its relative merits and shortcomings.

**What do we lose in the present system of publishing mainly by a small group of thought-leaders?** With limited inputs to the publishing system, we lose detail
representing the full experience of practice in real-world conditions. This may limit knowledge of the variety of ways that AF may manifest itself, or the ways that AF ablation may work in heterogeneous patient bodies and performed by heterogeneous ablationists. Given the complexity and heterogeneity of AF itself, the loss of heterogeneity in the AF knowledge system can have significant ramifications for medical interventions. This phenomenon has occurred many times in the pharmaceutical field. For example, in the cases of drugs including Fen-Phen, Seldane, and Vioxx, controlled scientific study revealed safety and efficacy data that merited FDA approval. However, these drugs were later shown to be dangerous for at least some people in real-world conditions compared to the controlled circumstances of drug trials, and were ultimately removed from the public market. Some AF ablation thought-leaders have alluded to the limitations of homogeneity in articles reporting their technique knowledge, warning that the results that they achieve in their labs should not be understood to be necessarily replicable in the hands of a less experienced ablationist (Pappone et al., 2003). The loss of heterogeneity means that the real-world safety and effectiveness of AF ablation techniques or technologies may not be well established or well communicated.

Limiting the publishing community also limits the potential inputs to the innovation system, as fewer individuals garner the bibliometric power that affords experimentation on new technologies and techniques. In some respects, loss of heterogeneity may allow selected AF ablation approaches to develop increased reliability, as with modern tomatoes that have been bred for selected qualities. However, loss of heterogeneity can also lead to increased susceptibility to unanticipated challenges, as the Dutch Elm population was decimated by a fungal infection spread by the bark elm beetle.
In the AF ablation case, loss of heterogeneity means that fewer new ideas will be explored in clinical practice. Given the complexity of AF and AF ablation, this may mean that potentially effective technologies or techniques never reach evaluation and the field remains without effective ways to treat AF.

In addition to limiting knowledge and ideas, when we limit publishing to a small group of thought-leaders, we lose transparency and a measure of popular control that is ceded to the thought-leaders comprising the peer-review process. By virtue of recognizing and privileging thought-leaders in the knowledge system, a sort of representative intellectual democracy emerges, rather than a directly democratic knowledge system. Journal editors promoting pre-review publication approaches note that transparency and legibility need not be a zero-sum game, as pre-review publication does not replace or supersede the peer review process. Rather, the exclusion of pre-review publication in favor of limiting publication to the post-peer-review process excludes potentially valuable data and knowledge from entering the system.

**What do we stand to gain from including the full community of AF ablation professionals in the knowledge system to inform innovation?** We potentially gain the full knowledge of practice experience to better understand the complexity and behavior of the AF ablation procedure in a variety of circumstances including variation in anatomy, technology, and technique. We also gain new ideas that may lead to innovation and novel knowledge that would not otherwise be able to gain traction in the present system where barriers to entering the knowledge and innovation systems are very high in terms of money and time. Thus, opening the knowledge system to inputs from individuals
who are not thought-leaders has the potential to increase the bibliometric power base, affording a greater diversity of input into the innovation system. Understanding that the AF ablation knowledge system is a complex system, including a greater diversity of inputs in the system would strengthen the robustness and resilience of the system, according to complex systems theory (Axelrod & Cohen, 2008).

Organized practice registries, such as those operated by the American College of Cardiology (American College of Cardiology: National Cardiovascular Data Registry, n.d.), purport to gather and yield broad data regarding real world practice by increasing inputs to the knowledge system. However, registries are constrained by their limited data reporting fields, and afford no mechanism for meaningful idea contribution beyond quantitative data. Therefore, the registry system does not offer a meaningful mechanism to achieve full community inclusion in the knowledge system. Still, registries or other real-world observational experiences partially address the limitation posed by the current regulatory paradigm that privileges randomized controlled trial evidence. Although randomized controlled trials provide organized and legible scientific scrutiny of a single hypothesis, they fail to capture the complex and dynamic nature of complex technologies and interventions (Morlacchi & Nelson, 2011). For AF ablation, which is intrinsically complex and dynamic, full community inclusion provides the innovation system with a variety of inputs and testing opportunities.

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39 Present-day clinical registries function as simple searchable databases populated by information reported by clinicians. In Chapter 6, I suggest ways to mobilize newer data capture and computational technologies to improve the registry system.
What do we stand to lose from including the full community of AF ablation professionals in the knowledge system to inform innovation? When we include the full community of AF ablation professionals in the knowledge system, we potentially lose clarity and organization of knowledge in the face of an overwhelming number of ideas without resources available to fully explore each. By opening the knowledge system to dramatically more inputs, it becomes impossible to subject each new idea to rigorous scientific testing and broad application for observation and learning in practice. We lose verifiability and reliability of knowledge when a lack of clarity and organization impedes or prevents knowledge from being evaluated via the formal scientific process. These losses would hinder the ability to draw conclusions according to the existing mechanism of controlled scientific investigation that presently forms the foundation for regulating health technologies. As a result, we risk cultivating an environment that is rich for observation but cannot evaluate the safety and effectiveness of new technologies and techniques. This may result in patients being exposed to therapies that range from highly effective but poorly understood to ineffective and even dangerous. Moreover, we may lose the opportunity to validate or refute existing paradigms with new empirical data, as new data may not accumulate to generate a stable, and thus testable, hypothesis.

Implications for Innovation Recommendations

During literature ancestry cataloguing and coding with a map-analytic approach, I noted two levels of knowledge transformation. First, knowledge may be leveraged between publications, traced across the progression of publications firmly seated in a
given knowledge stream (i.e. science, technology, or technique). Second, knowledge may be transformed within an individual publication so that it crosses boundaries between science, technology, and technique. These integrated knowledge artifacts could be more directly powerful to influence individual innovation than distinct “binned” publications that adhere to classical knowledge-practice boundaries. Such knowledge integration may help to dislodge the approach to treating AF from its present residence in the annals of so-called normal science directed by a limited set of thought-leaders who pursue a precise, classical solution to an inherently complex problem. Rather, an integrated knowledge approach may afford AF a postnormal science approach that acknowledges the inherent complexity in AF and incorporates a wide network of contributory stakeholders (Funtowicz & Ravetz, 1993). This is worth exploring further in future bibliographic research to analyze the relative impact of single-stream versus transitional publication, and may be a target point for future recommendations about research and communication to support and promote innovation. More immediately, these observations about integrated knowledge suggest that the AF ablation knowledge and innovation systems must explicitly include knowledge from multiple streams.

Literature analysis demonstrating complex interactions between science, technology, and technique is not novel, but it does reaffirm that innovation with regard to AF ablation is co-developed by multiple streams of knowledge. One pillar of my recommendations to improve innovation, therefore, will be to create different types of research funding calls from major granting agencies (e.g. NIH, National Science Foundation [NSF], Health Resources and Services Administration [HRSA]) to acknowledge the value to science that is afforded by clinical experience. The path of
discovery does not fit cleanly into the paradigm of basic research leading to translational research that results in clinical application (See Figure 5). Rather, it is important to understand that the notion of translation can be understood from technology and technique, back to scientific discovery (See Figure 6). I will propose a new system to afford and understand scientific discovery related to AF ablation.

Finally, the observation that a slim minority of practitioners has access to contribute domestication knowledge to the field-wide knowledge system for AF ablation implies that new mechanisms for knowledge system inputs are needed. Such mechanisms should afford opportunities for peer review, but may reflect nontraditional priorities for assessing the value of an idea for publication.

With this understanding about how AF ablation knowledge develops in the formal literature and in the context of the larger medical landscape, I next examine the factors that affect AF ablation knowledge uptake into clinical practice. These coupled lenses on AF ablation knowledge development and use will help to shape recommendations for improving the innovation system for AF ablation.
CHAPTER 4

KNOWLEDGE-PRACTICE PARADIGMS IN AF CATHETER ABLATION

In Chapter 3, I used historical literature review to show that AF ablation knowledge progresses through complex interactions between three streams of literature representing knowledge in science, technology, and technique or practice. We also saw that the formal knowledge informing AF ablation – the codified backbone of the formal knowledge system – was presented in the peer-reviewed literature by a small contingent of the AF ablation practice community. However, the historical literature does not illuminate how the formal knowledge of peer-reviewed publications enters practice at the level of patient care. In medical science, there is currently a major focus on translation with nearly $700 million annual investment in the National Center for Advancing Translational Sciences (NCATS) as a new center of the NIH. NCATS was founded in 2012 to “translate scientific discoveries into new, more effective, and safer health interventions…by reduc[ing], remov[ing], or bypass[ing] costly and time-consuming bottlenecks to speed development and delivery” (NCATS, 2016). NCATS focuses on supply-side translation along the classical bench-to-bedside research model (See Chapter 3, Figure 5). This effort is laudable to overcome the observed lag in translating new discovery into practice. However, the NCATS effort and federal investment does not acknowledge the demand side of translation. How do individual practitioners and practitioner groups decide which sets of knowledge to translate from clinical research into their real-world practice paradigm? We have seen that many products of clinical
research are not translated to practice. Therefore, my investigation focuses on the
demand-side translation story.

Moving Knowledge to Practice

In the practice system of AF ablation, there are three nested levels or sites of
knowledge-to-practice translation: the individual, the group, and the field. Within each of
these levels, there is a general knowledge paradigm\textsuperscript{40} that informs the practice of an AF
ablation procedure. That knowledge paradigm is formed from the same basic ingredients
at each level: data, trust, and experience. This self-similar pattern recalls Mandelbrot’s
(1977) observations about fractals as nested patterns occurring in nature. Rather than true,
identical fractals, these nested levels of AF ablation practice more closely resemble
Russian nesting dolls. In some cases, all of the dolls in a set are identical. In others, the
dolls are themed, but not identical. As a child, my favorite was the 5-doll set that depicted
the Wizard of Oz. The largest doll was the Cowardly Lion, who contained Dorothy, who
contained the Tin Man, who contained the Scarecrow, who contained the littlest doll:
Toto. Like the Wizard of Oz dolls, the specifics of the knowledge-to-practice paradigm
formation are slightly different at every level of the AF ablation system, but they are
closely related and must be taken together to form the full set. Before presenting a
detailed examination of each level, I will sketch an overview of the framework.

\textsuperscript{40} It is important to acknowledge the contributions that Thomas Kuhn (1962) made to the
contemporary scientific understanding of a paradigm. However, I am using the term in a
broader sense to describe an understanding that informs the basis for practice, rather than
adhering to Kuhn’s notion of a scientific paradigm with its specific commitments.
Each individual practitioner approaches the ablation procedure with an established knowledge-practice paradigm that informs the order and process of the AF ablation procedure. This paradigm is constituted by a combination of fundamental scientific knowledge established through educational and training, knowledge transmitted from trusted sources including individuals and publications, and lived experience. The knowledge paradigm forms the core of practice. However, practice occurs in the context of emergent conditions that do not necessarily fit into the existing paradigm. For example, a patient may have an unexpected response to a medication, thus departing from the expected set of conditions for a therapy. For example, during one ablation I observed, the patient began to show signs of distress. In response, the physician modified the procedure by omitting a medication that may have exacerbated the distress. In its place, he performed an additional pacing maneuver to elicit proxy data in the absence of the missing drug (field notes, June 17, 2015). Due to the emergent nature of practice, the density of the knowledge-practice paradigm fades at the edges where the emergent conditions of practice challenge, defy, and contribute to the extant knowledge (Figure 9).
Based on the outcomes from these emergent experiences, the practitioner incorporates new knowledge that augments and eventually modifies the knowledge-practice paradigm. The individual’s knowledge-practice paradigm can accommodate significant variability in experience, akin to the range of normal values that is widely understood in medical science. However, accumulated small variances may reach a tipping point for change to the paradigm. For example, I watched an experienced nurse coaching a newer staff member about preparing the patient and equipment for an AF ablation. She explained that over the years, she has learned to stack the various cables in a particular configuration on the patient’s abdomen in order to prevent the weight of one unwieldy component from disconnecting the other equipment (field notes, August 31, 2015). Or, a single major variance may achieve a tipping point for an individual to reevaluate the knowledge-practice paradigm in light of the new information. For example, one physician in my sample stopped using a particular technology abruptly after
a single patient experienced a severe adverse outcome while he was using the technology (field notes, June 19, 2015).

Dewey (1909) describes that in response to an observed difficulty or challenge presented to the status quo, expert practitioners accumulate new information through the complementary processes of inductive and deductive reasoning. In AF ablation, clinicians and technicians employ inductive and deductive reasoning in every procedure, undergirded by accumulated lived experience and learned expertise that enables the judgment necessary for rigorous thinking related to AF ablation. In practice, a challenge to the status quo may come from new knowledge in the peer-reviewed literature, word-of-mouth, or an unexpected outcome in a procedure.

A similar pattern of knowledge-practice paradigm formation and shifting occurs at the group level in AF ablation practice. An AF ablation procedure requires several individuals from different disciplines, including physicians, nurses, technicians and industry representatives. Each individual contributes their individual knowledge paradigm to the shared experience of AF ablation procedures to form group practice paradigms. Group paradigms include both formally codified understanding and tacitly shared behaviors (EPRN-1, April 27, 2015; EPT-1, June 2, 2015; EPRN-2, October 2, 2015; field notes June 17, 2015, June 19, 2015, August 31, 2015). As group paradigms emerge from shared experiences, individuals and groups find ways to communicate between themselves to form voluntary communities of practice (Wenger, 1998) around shared interests in AF ablation. The communities of practice, in turn, inform paradigm formation at the field level.
A similar pattern occurs at the field level in terms of the paradigm established on the basis of knowledge and shared experience. However, at the field level, the standards for knowledge to be admitted to the paradigm are more formalized than at the individual level. Lived experience also has a slightly different role at the field level than at the individual and group levels. At the field level, lived experience is shared through sidebar conversations in the community of practice formed by thought-leaders in AF ablation. The experiences from sidebar conversations establish and inform the conventional wisdom that leads to priority setting and eventually paradigm formation at the field level.

The AF ablation system at every level is open to the emergence of new circumstances and solutions. In this way, AF ablation research and practice is consistent with Popper’s (1959) notion that the ultimate goal of scientific research is not to possess knowledge, but rather the quest for more knowledge. Scientific openness, represented by the fading density of existing knowledge at the edges of practice (Figure 9), helps to ensure that the AF ablation system can accommodate emergent conditions to inform new knowledge.

**Individual Paradigms**

Individuals practicing AF ablation rely on three things to build the knowledge paradigm that they use to guide their decision making around technique and technology: 1) formal data in the peer-reviewed literature generated from scientific observation and experimentation, 2) recommendations from trusted individuals (through formal or informal communication), and 3) tacit knowledge from personal experience (Figure 10).
Formal Literature

Every physician informant told me that formal data published in leading medical journals provides a layer of information that drives their use (or rejection) of a new technique or technology. This privileging of highly ranked journals reinforces the notion that journal impact factor exerts a measure of power in the practice setting. One thought-leader in AF ablation said of his decision to use a new technology, “Obviously it depends on the…clinical data.” He prioritized data over informal word-of-mouth, saying, “Just because someone else says something’s great doesn’t mean it’s really great. So I think the proof’s in the pudding” (TL-1, June 25, 2015). Not every physician informant communicated such heavy prioritization of published data over individual recommendation. In the next section, I describe a distinction between thought-leaders and non-thought-leader physicians on this count.

Non-physician informants reported variation in their direct personal use of the peer-reviewed literature. A clinical engineer reported that he relies on direct
communication more than reading journals (EPT-1, June 2, 2015). An EP lab nurse echoed this practice, saying that she doesn’t think that most lab-based nurses and technicians usually read journals directly. Rather, they rely on physicians and industry representatives to provide major journal highlights (EPRN-2, October 2, 2015).

Individual Communication and Recommendations

Every informant told me that in addition to formal literature, they also incorporated recommendations from trusted individuals to guide their decisions around adopting new technologies or techniques. Non-thought-leaders said that published data were important for their practice. But they prioritized individual reports from thought-leaders’ experience as being more influential to their individual practice than published data. In contrast, thought leaders themselves prioritized published data as the critical driver of their practice patterns, particularly with regard to new knowledge. One informant who is not a thought-leader in AF said that the primary motivation for him to use a new technique or a new technology is the communicated experience from thought leaders.

That’s probably the most…the strongest impetus to do something is you hear somebody present it at a meeting. As opposed to, I don’t know, reading about it’s okay too, but you want to…see that the big guys are doing…the experts and what their approach is. (NTL-3, June 17, 2015)

Multiple informants shared the notion of thought leaders as having privileged information as a result of their access to a broad range of technologies. One informant said, “This guy has tried all the different things and this…is his approach now” (NTL-3, June 17, 2015). Another informant mentioned that he surveys former colleagues from his
training institution for guidance as to the latest in technology, “Just because they get the first dibs for where they’re at, you know…they get the chance to try it. Whereas in the private sector, you know, I’m not as much [getting to try the new technologies]” (NTL-4, September 16, 2015). Thought-leaders themselves, though, did not necessarily perceive that they had unfettered access to new technologies. One prominent thought-leader at an elite academic medical center explained that hospital budgeting did not allow for extensive hardware purchasing. Therefore, he perceived that he was constrained with regard to accessing new technologies (TL-1, June 25, 2015). This thought-leader’s report about access to experience with new technologies is directly opposite the perceptions that other informants hold about thought-leaders and new technology access, including perceptions about this thought-leader specifically.

Every informant noted that attending professional meetings, including the Heart Rhythm Society Annual Scientific Sessions, was an important source of expert information from thought-leaders in the field. Informants reported attending formal presentations by thought-leaders, as well as holding informal sidebar conversations with colleagues. One thought-leader described the role that meetings play in his individual practice.

I go to the Boston A-Fib meeting every year…I go to every single talk. ….And then everyone there is really interested in a-fib ablation so during sidebar conversations or whatever, you learn more…just talking to colleagues from Europe or whatever about, you know, how this is really working. (TL-1, June 25, 2015)

Another informant, who is not considered a thought-leader, also mentioned the value of sidebar conversations, but from a peripheral perspective. He said, “Sometimes where I’m
at an HRS [Heart Rhythm Society] meeting and I overhear some guys talking about something they’re using, and I always try to listen” (NTL-3, June 17, 2015).

Individual communication at annual scientific meetings also produces group sentiment (Durkheim, 1915). I recall an informal conversation in 2011 with a physician who would ultimately become an informant in this research. Our conversation centered on the notion that participating in the annual scientific meetings imbues a feeling of being part of something bigger, so that we felt inspired to return home and do new research. This feeling in the practitioner community is similar to the feeling of inspiration described after a scientific community retreat (Parker & Hackett, 2012). Although the annual scientific meetings are not explicitly designed to capitalize on the micro-level experiences as with Parker and Hackett’s scientific retreats, they do recreate a similar macro sensation of flow (Csikszentmihalyi, 1997). Moreover, deliberate group identification has been shown to increase empathy and trust in experiments (Hein, Silani, Preuschoff, Batson, & Singer, 2010), suggesting the importance of building an active sense of group belonging by participating in shared events like field-level meetings and holding shared accolades like the title of Fellow in a professional society (e.g. FHRS: Fellow of the Heart Rhythm Society).

Trust

At the American College of Cardiology 2015 Scientific Sessions, Nassir Marrouche, MD, opened his presentation on AF ablation technique by saying, “I’m going to try to convince you that fibrosis is becoming a treatment target” (field notes, March 14, 2015). He is a thought-leader at a major international cardiology meeting, using data and
personal experience to try to build the trust to accomplish individual paradigm shift. Trust is a necessary condition to afford scientific collaboration and paradigm formation (Knorr Cetina, 1999; Parker & Hackett, 2012), particularly in the case of scientific work that contravenes prevailing paradigms in a given scientific community (Kuhn, 1977). Similarly, trust is a critical currency to afford knowledge transfer (Levin & Cross, 2004). Implicit trust in socio-technical systems is a necessary precondition for risk taking and innovation that, in turn, requires more explicit trust in particular knowledge to enable practice (Lucas, Leith, & Davison, 2015; Luhmann, 1988).

**Trust in data.** In the AF ablation practice community, trust is a major component of an individual’s choice to adopt or reject informal, and even formal knowledge. One informant described the problem of trust in people and data.

The problem with AF data is, you know, you don’t know what you can have confidence in, and you don’t know what you can’t have confidence in. And it seems like a lot of the thought leaders that we see giving us the formal guidelines that eventually go to inspire innovation, are not necessarily the ones who are participating in day to day management of this…of atrial fibrillation. …some of those names don’t even ablate a-fib. So that’s why you get a little bit, um, disheartened, or skeptical of who is formally now considered a thought leader. (NTL-4, September 10, 2015)

There is a critical tension between a sense of trust in data and skepticism in the motives and veracity of the thought leaders who provide the data that informs formal AF ablation knowledge.

**Trust in individual clinicians.** Individual expertise in performing AF ablation procedures contributes to the notion of trust in AF ablation. Although a track record of
peer-reviewed publication is foregrounded as a quality that describes a so-called thought-leader, physician informants – thought-leaders and non-thought-leaders alike – identified an individual’s experience and track record with AF ablation procedures as the qualities that define an AF ablation expert (TL-1, NTL-1, NTL-6, November 18, 2015).

Accordingly, individuals often rely on contact with trusted mentors from fellowship training to gauge the value of new technologies or new techniques on the horizon. One informant reported mentor input as very important to his ongoing practice, based on his mentors’ experience at a leading center for AF ablation in the U.S. But he does not rely exclusively on his mentors to guide his decision to adopt a therapy. He said, “I take it [their input] with weight, but not necessarily. You know, I’d have to see some data before I adopt it.” But, he noted some skepticism with regard to data, as well. “You know, you can’t really tell if this is clean or true data.” He mentioned one of his mentors from fellowship training, a noted thought-leader in the field. “I’ve never seen anybody as skilled in the lab as he is.” He continued, lowering his voice.

But I don’t know if I can trust the [thought leader’s] data that much. I think there’s a lot of cherry picking. I think there’s a lot of, you know, this is what we’d like the answer to the hypothesis be – let’s work on the data. (NTL-4, September 10, 2015)

This is an instance of trusting data as a paradigm of scientific practice, but having that trust eroded to some degree by distrust of the individual who generates the data. This essential tension between trust in data and trust in people who generate data is another factor reflected by the phenomenon of core knowledge density fading at the edges of practice in response to new information that challenges the solidity of the paradigm core (Figure 9).
Another informant also discussed trust in individuals, and particularly trusting the data from specific thought-leaders, as a significant component guiding his decision to adopt a new technology and technique in AF ablation. He referred to a combination of study data and reputation of the researchers. He named one researcher in particular as “the guy I respect,” based on an established track record of conducting and publishing highly rigorous studies, as driving his confidence in the technology. He said, “If it was the numbers [study data] on their own, I wouldn’t believe it” (NTL-1, January 26, 2015). In this case, trust in the specific researcher inflated the practitioner’s trust in the published data, rather than detracting from his trust in the data, as with the previous case.

In an example to illustrate failure to adopt a novel technique in the absence of individual-level trust, several of my informants were aware of an innovative approach to avoid using x-ray fluoroscopy throughout the AF ablation procedure. One non-thought-leader physician developed a technique with a mapping catheter designed for use inside the heart. Instead, he positioned the catheter inside the patient’s esophagus. This allowed him to visualize the patient’s esophagus on the mapping system, along with the heart structures, without the use of x-ray, so that the patient and staff would be exposed to less radiation and would not have to wear heavy lead-lined garments throughout the procedure. He had begun to use this novel technique for all AF ablation procedures in

41 One of the biggest risks associated with AF ablation is damage to the esophagus, which lies adjacent to the left atrium near the pulmonary veins. The esophagus is not a rigid structure, and tends to move. Therefore, it is important to know its precise location in order to avoid causing esophageal damage with ablation. Typically, the position of the esophagus relative to the heart is tracked with x-ray. As an additional safety measure, esophageal temperature is monitored using a specialized probe. If the esophagus heats up, the physician can stop ablating immediately in order to avoid damage.
order to improve some margins of safety and convenience, primarily for staff in the procedure and secondarily for the patient. He used his lived experience to domesticate\textsuperscript{42} a well-known technology in an unexpected way to some recognizable benefit (Scott, 1998). However, my informants did not consider the innovative physician to be a trusted advisor. As a result, although there was widespread sharing about the innovative technique, other practitioners did not adopt the innovation. One informant noted that widespread discussion of the innovation in his center drew many comments predicting that this technique, while clever and potentially useful to improve some aspects of the AF ablation procedure, may eventually lead to a negative outcome for a patient (NTL-1, June 26, 2015). One of the concerns was that the individual who pioneered this technique was colloquially believed to have a mediocre track record with AF ablation, such that this individual did not fulfill the broadly shared criteria of AF expert in terms of procedural outcomes. Therefore, others did not trust the source of the innovation and did not adopt it into their practice.

\textbf{Trust in industry representatives.} Multiple informants mentioned that they rely on industry representatives to provide information about technique and technology use in other centers. However, clinician informants, including physicians and non-physicians, universally mentioned that they were skeptical of the information they received from industry representatives. One informant said, “I suspect their primary driver is business driven; it most likely biases the information they choose to share” (NTL-1, June 26, 2015). Another said that he sometimes asks industry representatives about the practices

\textsuperscript{42} I discuss domestication more fully later in this chapter.
of other local electrophysiologists whom he trusts. However, he noted, “Everything they tell me as far as technological information and success and whatnot, I take with a big grain of salt because I think it’s coming from a sales bias” (NTL-4, September 10, 2015).

Similarly, a clinical engineer noted that he communicates information that he learns from industry-sponsored meetings “with a grain of salt” (EPT-1, June 2, 2015). He continued:

I usually say…I heard there’s another lab that’s using this technology. Of course, I don’t know anything about the technology. Or, um, I heard they’re using this technique. But I don’t know what any of their results are because it’s not published or anything like that. (EPT-1, June 2, 2015)

In the case of industry-communicated information, brackish tension between reliance on industry representatives and skepticism in the information creates a barrier to immediate uptake of industry-provided information into practice without additional published data or lived experience.

**Trust in technology.** Trust is also significant at the level of the technology. In a formal webinar presentation of the European Society of Cardiology, a prominent thought-leader mentioned that he trusted a novel automated mapping technology more than manual human mapping, because the novel technology could measure and analyze many more points than manual human mapping could cover (field notes, April 7, 2015).

Similarly, one of my informants commented that the use of pressure-sensitive catheters confers a level of safety that helps him in the process of training fellows to perform ablations.

It makes me feel more comfortable. You know…when the fellow’s [physician in specialty training] moving the catheter, I probably let them move it more now than I did in the past because, again, safety and also they might not have been
getting good contact before. Now we can tell, hey, you know, you’re not moving
the catheter the right way. You’re not getting contact. (NTL-2, June 17, 2015)

Trust in the technology confers trust in the physicians-in-training.

Conversely, another informant who did not use the pressure-sensitive catheters in
AF ablation characterized the technology as “hocus pocus,” instead trusting his own

技术 as providing an optimal ablation outcome. Interestingly, this informant

mentioned the Topera rotor mapping system, saying that if it is proven to improve
ablation outcomes, he would use it. This sentiment contrasts with his assessment that the
data demonstrating improved outcomes with the pressure-sensitive catheter was

“nonsense” (NTL-5, July 6, 2015). I perceived that this physician’s contradictory views
of the newer technologies aligned according to the perception that the technology
challenged his own technique or competence at ablation.43 The pressure-sensitive
catheters were developed based on the notion that most operators do not deliver
uniformly effective ablation lesions, and thus the pressure-sensitive technology can

reinforce the operator’s own technique. Therefore, using that catheter technology
amounts to an admission of inexpert technique. In contrast, the Topera mapping
technology was developed to augment an operator’s existing technical ability, and does
not suggest any measure of inexpertise. This difference may explain his variance with
regard to new technology adoption.

43 Incidentally, this informant uses a unique technique for ablation, delivering all lesions
using a catheter-dragging technique rather than delivering individual point-by-point
lesions. Although his technique is widely known among physicians in the local EP
community, no other physician emulates his technical approach, perhaps conveying that
he is not a trusted peer in the AF ablation community.
Lived Experience and Tacit Knowledge

As the final ingredient in paradigm formation, individuals incorporate their own lived experience into their individual practice paradigm. One informant, a thought-leader and innovator in AF ablation, said “There’s always a big difference between what has been spoken of and what people are doing in real practice” (TL-2, March 14, 2015). Another thought-leader said, “Everything has to ultimately be something that you validate with your own hands, in your own lab, with your own patients” (TL-1, June 25, 2015). The observations from individual lived experience form tacit knowledge that contributes to individual practice paradigms (Collins, 2012; Dewey, 1909; Polanyi, 1967; Zuboff, 1988).

Direct interactional experience with new technologies and techniques leads to the development of new knowledge through local adaptation, drawing on Silverstone’s (1994) notion of domestication as use-based knowledge distinct from the formal research-based knowledge system and transmitted informally by direct observation or word-of-mouth. Domestication, therefore, refers to the ways in which users deploy a technology in practice differently than the technology was or originally designed to function. In the classic science and technology studies (STS) case of domestication, early users of the Model T automobile put the wheels up on blocks and used the engine to power household machinery, domesticating the Model T in a way that it was not intended to be used (Kline & Pinch, 1996).

In AF ablation, domestication occurs via the variety of particular configurations of technology and technique that may be used in practice. Most ablationists and clinical staff report that when they begin to work with a new technology or technique, they
initially adhere to recommended or reported procedures – whether from the formal
literature or from word-of-mouth description by industry representatives. Several
physicians told me that in their first few cases using pressure-sensitive catheters, they
used settings as recommended by official product labeling. However, over time, they
adjusted the system settings to facilitate their own individual technical style (NTL-2, June
17, 2015; field notes, June 17, 2015, August 31, 2015).

One clinical engineer told me that tacit knowledge developed from his personal
experience guides the recommendations that he makes to physicians regarding particular
technologies and technical approaches to use during a case.

Depending on the case I can offer up suggestions. Whether to use a decapolar (10-
electrode) or a duodecapolar (12-electrode) catheter…mostly from my
experiences and my experience with other physicians and what I find other
physicians prefer, so I have some experience as to what other physicians like, so I
can add some, some idea that another physician might like it as well. (EPT-1,
June 3, 2015)

Physicians told me that they use the same approach to every case, including the
order in which they isolate the pulmonary veins. I observed this to be the case in multiple
ablations. In addition, non-physician staff told me that each physician executes AF
ablations in the same way each time. As one EP lab nurse said, “Some docs are fixed.
They’re like, ‘I know what I like; I know what I don’t like.’” However, she noted that one
of the physicians she works with frequently “is always trying new stuff.” She said, “He’s
the only one who will [say], ‘Do my usual.’ And we’ll joke, the Tuesday usual or the
Wednesday usual?” (EPRN-1, April 27, 2015).

The so-called usual, however, is often modified in response to an unexpected
finding during an individual case. For example, one physician shared that he has recently
begun to use a two-step approach to rotor ablation based on a recent experience. The usual approach to rotor mapping and ablation takes place once during an AF ablation, prior to PVI. Rotor mapping requires that the patient be in AF during the mapping and ablation. When a rotor is successfully ablated, the AF often changes or stops altogether. Similarly, sometimes AF stops after PVI is complete. In other cases, an electric shock (cardioversion) is required to stop AF and restore a normal rhythm. This physician’s individual knowledge-practice paradigm gauges an AF ablation case as successful if the AF terminates as a direct result of ablation, and the patient does not require cardioversion to terminate the AF. In a recent case during which the AF persisted even after rotor ablation followed by PVI (the usual pattern according to prevailing practice at the field level), he returned to rotor mapping once again in an effort to find some source of the continuing AF. He ultimately found another rotor and eliminated it, along with the AF. Based on this lived experience, he has developed a new practice heuristic incorporating a two-step rotor mapping process before and after PVI in every case. He explained that he thinks that there may be multiple competing rotors in the atrium that suppress or mask one another, and thus may not be apparent with initial mapping. He is not a thought-leader in the field, but has been tracking his experience with this approach in hopes of contributing to the literature. He told me that he is planning to contact a thought-leader with specialized expertise in rotor ablation and computational models in order to explore this idea further (NTL-1, September 17, 2015). This vignette highlights the notion that expert systems require users to interpret knowledge in the context of particular culture or

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44 This experience-driven theory is an example of technique affording scientific discovery, as described in Chapter 3.
technological frame (Bijker, 1995; Collins, 2012). In this case, tacit knowledge and commitment to a heuristic that measures AF ablation success by directly terminating AF with ablation, led the physician to deviate from the existing culture of rotor mapping, and resulted in the formation of a new individual practice paradigm.

In an example of counter-domestication, a physician had been using a robotic ablation system to perform AF ablation as part of his individual ablation paradigm until he had a negative outcome in one case. A patient’s heart was perforated and the patient became critically ill, requiring a lengthy stay in the intensive care unit. Based on this negative experience, the physician shifted his individual paradigm and stopped using the robotic system, eliminating the technology from his lab altogether (NPPA-3, September 29, 2015).

I observed another case – this one of temporary domestication – when an unusual physiological finding at the end of the case motivated the physician to deviate from his usual technique in order to avoid potentially exacerbating a problematic physical response to the AF ablation procedure (field notes, June 17, 2015). However, that physician resumed his usual practice in subsequent procedures (field notes, June 19, 2015).

More pervasive than the example of domesticating a single new technology or technique, the expectation for AF catheter ablation practice is increased customization of the procedural experience – including technology and technique – at the level of the individual clinician. Customization can even extend to the level of the individual patient. Compared to domestication, which is a significant deviation from usual practice, customization is fine-tuning within the spectrum of what is expected. Customization is a
mild, or partial version of domestication. This observation at the individual clinician level was reflected in the comments from individuals who work with multiple physicians on a regular basis. One experienced EP lab nurse recounted the various approaches taken by the four different physicians who rotate through her lab. She listed the different sets of technologies, including mapping systems, mapping catheters, ablation catheters, ablation generators, and transseptal needles, along with the different techniques and expected case flow for each of the four physicians individually.

One uses Cryo [freezing] initially but RF [radiofrequency; burning] on re-do...the other three don’t use Cryo at all. Um, of the three RF guys, two use a transseptal puncture, or a double transseptal [two separate holes poked between the right atrium and left atrium for catheter introduction]. One uses a single [hole poked between the right atrium and left atrium], and he tends to be more conservative. (EPRN-1, 27 April 2015)

A single transseptal puncture is thought to confer less risk to the patient, but a double transseptal puncture is easier for catheter manipulation by the physician. This vignette illustrates the expectation that each physician develops and individual practice by customizing the suite of available technologies and techniques to perform AF ablation.

Lab technicians recounted a similar set of stories for each of the physicians who routinely work in their labs. One experienced radiology technician recounted particular ways that different physicians use the same technology. For example, one needle designed for performing transseptal punctures is packaged with a plastic stylet designed to provide additional guidance support to the needle and to avoid needle shear through the catheter sheath.45 The nurse noted that only one of the three physicians who routinely

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45 In the case of needle shear, small bits of the plastic sheath that houses the needle catheter are shaved off and enter the bloodstream with the possibility of lodging in small blood vessels, thus affecting blood flow to those locations and causing a stroke.
work in her lab leaves the stylet in the sheath to withdraw the needle, as the other two feel that they can maneuver the needle adequately without the sheath. She noted, though, that this resulted in significant damage to the plastic sheath when it was withdrawn from the patient, suggesting that bits of plastic have entered the blood circulation with the potential to lodge in small blood vessels in the brain, with the potential to cause small strokes (EPT-2, June 17, 2015). An industry representative in the lab during this encounter concurred, “A lot of people use the Brock[enborough needle] without the stylet. But that’s it’s entire purpose [to avoid plastic shear with embolization to the brain]” (IR-2, June 17, 2015).

Similarly, industry representatives from mapping technology companies described the variations in technique that they observe as they travel from hospital to hospital within a sales region. Industry representatives recounted that physicians and staff frequently ask them about the approaches that other centers, and particular physicians in other centers, are using in their ablation cases. In this respect, industry representatives act as the conduit for cross-fertilization communication between physicians. Industry representatives noted, however, that physicians rarely appear to adopt the technique modifications that they describe, or rarely adopt the techniques right away. One representative told me, “Docs like to know what others are doing, but don’t necessarily do those things” (IR-3, June 19, 2015). Another industry representative echoed this sentiment, saying, “I think they [physicians] don’t experiment enough [with new technologies]” (IR-1, May 14, 2015).

Recognizing and labeling domestication, therefore, is useful to examine the variety of ways that biomedical technologies, particularly those requiring significant
technical skill, are deployed in the clinical setting by individual users who have generated novel experiential knowledge. This variety of informal domesticated knowledge highlights the development of new knowledge distinct from codified knowledge in the formal system of peer-reviewed literature. There is some recognition of use-driven domestication knowledge within the formal knowledge system, particularly in peer-reviewed journal articles and scientific conference presentations describing first-in-human experiences with a novel technique or technology. However, review of the literature as discussed in Chapter 3, revealed that the majority of these domestication publications are limited to the small cadre of individuals already recognized as thought-leaders in the field. As a result, the majority of informal domestication knowledge related to AF catheter ablation remains uncaptured, uncodified, and never disseminated via the formal knowledge system. Thus, most domestication knowledge is silent, using the construct as understood by feminist theorists (Fishkin & Hedges, 1994). The silent majority of domestication knowledge, therefore, does not directly affect innovation in the present AF catheter ablation system because it exists mainly outside of the formal evidence and does not encounter the rigor of experimental validation to impact thinking at the field level. Therefore, there is an opportunity to unmask this silence in the AF ablation knowledge system in order to capture the tacit knowledge that domestication yields. I will return to further examine communication, silences, and the AF ablation knowledge system in Chapter 5.
Groups of AF ablation professionals go through similar processes of group paradigm formation with similar inputs as individual clinicians. Groups comprise individuals from different disciplines with different disciplinary practice frameworks and different roles contributing to an AF ablation. For example, AF ablation groups typically include physicians, nurses, technicians, and industry representatives who make up the clinical team in the EP lab. This lab team is joined by advanced practice providers (NPs and PAs) who contribute directly to patient care from outside the lab. In AF ablation practice groups, individuals do not necessarily share actual knowledge, but rather correlated tacit understandings of a particular phenomenon (Metcalf & Ramlogan, 2005). In other words, although different disciplinary professionals may each possess different shades of knowledge about a patient’s AF, their individual knowledge components and understanding combine to form a common group understanding when they are caring for the patient. Group paradigms emerge from the interdisciplinary accumulation of multiple individual paradigms, along with shared personal experience among the group forming tacit group-level knowledge, and shared trust in sources (Figure 11). Group paradigms translate into shared practices and practice patterns, and form a sense of belonging to a community of practice that reinforces practice standards and behaviors within groups (Wenger, McDermott, & Snyder, 2002).
Figure 11. Group or Team Knowledge-Practice Paradigm

Shared Experience

At the group level, trust is built through shared experience that contributes to the formation and shifting of group-level paradigms that emerge from accumulated individual practice paradigms. Shared experience is also noted to build trust in scientific research communities (Parker & Hackett, 2012) and facilitate the organization of a professional network by incorporating standardized routines (Langlois & Savage, 2001).

Shorthand. This process of organization was evident in the extensive use of shorthand in dialogue during cases. For example, at the beginning of each case, the scrub technician would ask the physician which catheters he (I only observed male electrophysiologists) planned to use. About half of the time, the question was posed...
without even using the word “catheter” as in, “What would you like today?” The physician would respond by listing the catheters he preferred. In some cases, the physician called them by name: “SC-1, small Agilis, Sound, Bayliss” (field notes, June 17, 2015). In other cases, the physician called them by a series of numbers only. One EP lab nurse described that the support staff in the lab typically knows each physician’s preferences regarding technology. She routinely works with four different electrophysiologists, and was able to describe all of the equipment choices that each physician typically makes for each case (EPRN-1, April 27, 2015). In another EP lab, staff members maintain a binder with a record of each physician’s preferences for equipment. Staff members consult the binder before every case (field notes, June 17, 2015; EPRN-2, October 2, 2015).

**Choreography.** Shared experience was also evident in the pattern of movement and conversation during each case. For example, the procedure to don a sterile gown requires the assistance of a second individual to hold the edge of a cardboard tab attached to the sterile tie that secures the gown around the body. Among the team members with extensive shared experience, this choreography was accomplished seamlessly without explicit signaling. In most cases, the sterile gowning process occurred in the midst of chatting about a different subject, and did not even require a break in the cadence of the dialogue.

I witnessed similar cueing with established shared experience during the process of building voltage maps to sketch the shape of the left atrium and pulmonary veins at the beginning of the ablation procedure. In the cases I observed, this was accomplished by
the physician and the industry representative, who managed the computer for electrical mapping and ablating. In most labs, with the exception of a few academic medical centers that may employ a nurse, technician, or engineer who is expert at mapping, an industry representative is present for every AF ablation case. During the beginning of the mapping process, which had been accomplished many times by each respective physician-industry representative dyad, the industry representative or physician often called out just a few words such as “got it” or “left superior” or “a little more posterior” to indicate progress through the intricate dance of building a picture to represent the patient’s heart on the computer screen. This lack of verbal communication signaled the exercise of a cumulative shared experience that allowed the actors to anticipate one another’s needs and behaviors without explicit explanation. Several physicians, technologists, and nurses mentioned to me that individual physicians preferred to work with a specific industry representative for mapping, reinforcing the preference for shared experience and trust among team members.

Dialogue cues. Dialogue cues signaled the cumulative experience at the level of the entire team as different stages of the ablation case proceeded. Most ablations take place with a background of conversation unrelated to the direct case at hand. Topics range from music to weekend plans to new technologies and ablation research. However, this background conversation ebbs and flows throughout the case in response to the stage of the ablation that is underway. One notable ebb occurs invariably during the transseptal puncture, when the physician uses a needle to poke through the thin membrane that divides the right atrium, where catheters are introduced into the heart, from the left
atrium, where the main work of AF ablation is done. During this puncture process, an inadvertent slip of the needle could create an unwanted hole through the heart wall that could be life threatening. In every case I observed, the background conversation stopped during the transseptal puncture stage. There was never a verbal signal; no one ever stated, “We’re crossing the septum now.” Rather, the team members in the room demonstrated their accumulated shared experience by eliminating background distractions to allow for more intense focus during that portion of the procedure.

The failure to participate in shared team behaviors and thus garner trust results in exclusion from the team. One informant told me about an industry representative who repeatedly failed to accommodate the ebb in extraneous activity during the transseptal puncture, instead taking the break in conversation as an opportunity to promote her company’s catheter.

We had a company who was bringing in a new transseptal catheter. And um, was really pushing it and really pushing it. And really it was just a matter of sitting in the back behind the nurse’s station and making comments about, “You could try this catheter… It was getting really blatant to that point where he [the physician] was having a hard time crossing [the interatrial septum] and she [the industry representative] would shout out from the nurse’s station, “Well, you could always try this catheter!” which was her new catheter. …That’s probably the most stressful point of a procedure is when they’re crossing the septum, obviously. Everything is right there. Your aorta’s sitting right there, your… I mean everything’s sitting right there. So it’s not really the time to be shouting out and to be joking and to be pushing a product. And so we asked if she would go. (EPRN-1, April 27, 2015)

The industry representative was excluded from the lab for future cases; she was no longer part of the team.

The differences were clear when a new team member was being introduced to the lab during an ablation case. I observed two separate ablation cases where a new scrub
technician was being oriented into the particular lab environment and with the particular physician. In case with each new scrub tech, there was significantly more verbal communication among the team, including more questioning about whether certain tasks had been completed. This demonstrated increased reliance on explicit knowledge in the absence of established trust that would allow tacit knowledge to prevail. In one case with a new scrub tech, the physician narrated his actions nearly continuously, and repeatedly questioned whether tasks had been completed, such as flushing catheters and needles with heparinized saline. On a few occasions during this case, the tech had not performed the flush, or did not have a particular solution ready to administer. Although the physician did not overtly admonish the tech for these errors, I noted that the mapping system industry representative, an established team member, performed some of the tasks that would normally be done by the scrub tech, such as handing off sterile gloves and assisting with tying the sterile gown. Her status as an established team member took precedence over the usual performative role definition by education and training. During this case, the physician explicitly commented on the representative’s established role with the team. He joked, “I see her [the industry representative] more than I see my own family.” He also alluded to the established norms of their teamwork, saying, “I make [the industry representative] make me earn my dots [indicating a successful burn in the heart, as represented on the computer screen]” (field notes, August 31, 2015).

**Bidirectional Trust**

Bidirectional trust flow is an important basis of group formation (Lucas et al., 2015). Active trust is required for the establishment of group identity beyond passive
belonging that yields trust in name only, rather than as an active decision. In the case of the AF ablation team, passive belonging was enacted by presence in the laboratory and a formal role in the procedure. In contrast, active trust was evident in the non-verbal shared rituals among co-experienced group members. The literature around trust includes experimental evidence that observations of pain and resulting decisions differ between in-group observers and out-group observers. Thus, as with the importance of individual belonging by participating in shared events at the field level like scientific meetings, group-level nonverbal rituals of the AF ablation team are critical to build trust.

Of note, the negative outcome with the robotic system described in the previous section that resulted in a change in one physician’s individual knowledge-practice paradigm also resulted in a shift in the group’s knowledge paradigm and practice pattern. While I was observing a case with the physician and team who experienced the bad outcome with the robotic system, one of the technicians pulled me aside and lowered her voice to tell me that they used to use the robotic ablation technology, but they don’t have it anymore and they don’t talk about it since there was a problem with it in one case. I told her that I had heard about the incident and she nodded, giving me a knowing look to suggest that I was part of that shared group paradigm that does not mention the robotic technology (field notes, June 19, 2015).

**Industry Representatives as Group/Team Members**

The role of the industry representative on the team recalls Shapin’s (1989) invisible technician. Although the industry representative is implicitly and explicitly described by practitioners as a member of the AF ablation team, and performs discrete
components of the AF ablation procedure, the industry representative is not represented in the formal outputs from the team’s work, including procedure reports or other notes in the patient’s medical record (EPRN-1, November 15, 2015; NTL-1, November 20, 2015). Formal position statements from the Heart Rhythm Society discuss the role of the industry representative in EP lab procedures, but decline to specify those roles, instead noting that industry professionals “must function according to clear policies under the direction of the laboratory manager, staff, or physician” (Haines et al., 2014, p. e24). However, the guideline neither delineates what these policies should encompass, and actually contradicts its own guidance later in the same document when it states that industry representatives “must work under the direct supervision of the responsible physician” (Haines et al., 2014). Even the formal codified status of the industry representative role is problematic, affording the invisible status of this team member in the context of the work of AF ablation.

When introducing new technologies into the lab environment, industry representatives create opportunities to accelerate the building of shared experience through educational marketing dinners for lab teams. These dinners feature a semi-formal presentation consisting of slides provided by industry but presented by a physician on the team. The physician presents scientific data from studies of the technology, highlighting its features. This practice reflects a tacit acknowledgement that industry-delivered information may be viewed as less trustworthy than information from a clinician. Thus, the choice to have a clinician present the industry information is an effort to mitigate the inherent distrust in industry. At one of these dinners, the physician presenter glossed over many of the details of the studies, trading on his perceived trust as a leader of the team.
He flipped quickly through the slides, saying, “I won’t go through all of the studies because that would be boring.” However, he called on the group’s shared trust in science. He told the group, “The scientific process was used to establish the technology, and confirmed through multiple studies so that it could be FDA approved” (field notes, February 18, 2015). By the time I observed AF ablation cases in the labs staffed by the teams attending this dinner meeting four months later, the use of the new technology had been incorporated into the group paradigm (field notes, June 17, 2015; June 19, 2015; August 31, 2015).

Field Paradigms

At the level of the field, the knowledge-practice paradigm is driven by accumulated individual and group paradigms that inform priority setting by thought-leaders who construct codified evidence. The pattern of paradigm formation at the field level is similar and nested like individual and group patterns. However, field-level functional constraints result in differently enacted components of trust and experience compared to individual and group levels (Figure 12).

46 In the next section, we will see that shared trust in science is a critical component of field-level paradigm formation.

47 Incidentally, one of the nurses attending the dinner approached me months later when I was conducting an observation in the EP lab. He remembered me from the dinner, and said that he appreciated my comments at that event. He proceeded to welcome me to the EP lab, saying that they were glad to have me there (field notes, August 31, 2015). The shared experience from the industry dinner several months prior afforded me a measure of team status with this group.
Figure 12. Field-level Knowledge-Practice Paradigm

Trust

For the individual, trust is based on tacit knowledge from lived experience and individual relationship observations. Similarly, in group paradigms, trust is based on tacit knowledge from shared experience from individual AF ablation cases and patients. At the field level, trust is built on these themes of shared experience and relationships, reflecting the notion of social trust building from shared individual trust (Job, 2005). However, field-level trust from shared experience is limited by scant opportunities for non-thought-
leaders and their associated groups to communicate accumulated tacit knowledge beyond immediate group boundaries. The existing mechanisms of individual-level sidebar conversations do not accommodate the volume of communication that would be necessary to give voice to the full quantity of tacit knowledge developed in the formal knowledge system. The other significant mechanism to afford meaningful tacit knowledge flow from individual and group levels to the field level is through the industry representative. Although the industry representative could potentially facilitate a greater volume of communication between groups, low trust in the industry representative as a knowledge translator limits the effectiveness of this communication mechanism. Therefore, lived and shared experience alone does not confer trust at the field level.

Moreover, the existing regulatory regime for biomedical technologies requires additional evidence beyond that required at individual and group levels. At the field level, trust in knowledge extends beyond trust at the individual and group levels, along William James’s notion that “to know is one thing and to know for certain that we know is another” (James, 1897). Rather than relying on shared experience built on case-by-case observations, shared experience at the field level is enacted through the use of data driven by shared trust in the scientific process to establish truth that is encoded in the formal literature (Figure 12). There is a shared reverence regarding the validity of data generated by controlled scientific research, and particularly the randomized controlled trial. Multiple informants mentioned their individual reliance on literature and data to solidify
their belief in the rightness of a particular technique or technology. So too does the field rely on data published in the formal literature to determine truth and rightness.⁴⁸

**Trust in data.** At the field level, AF ablation follows suit with clinical medicine writ large in its use of clinical research findings in the peer-reviewed literature to establish knowledge for clinical consensus documents and eventually practice guidelines. These evidence-based consensus and guideline documents (e.g. Calkins et al., 2012) are used as the basis for regulatory decisions, including considerations of legality, payment, and patient access to procedures and technologies. Compared to individual and group paradigms, in the field paradigm trust and lived experience are deprioritized in favor of organized scientific data. Clinical research is graded in its strength according to study design. More rigorous quantified statistical control is believed to confer more exact knowledge, and thus higher quality data that exerts more weight in the pursuit of truth (Jacobs et al., 2013). This grading system emerged from the field of evidence-based medicine that privileges controlled trials and meta-analysis over qualitative or observational studies and expert opinion (Sackett, Strauss, Richardson, Rosenberg, & Haynes, 2000). Explicit reference to this evidence grading system is a featured component of expert consensus statements and clinical guidelines, including the AF ablation consensus statements (Calkins et al., 2007; Calkins et al., 2012). Therefore, at

⁴⁸ The time and financial constraints that limit participation in formal research (Douglas & Wildavsky, 1982) effectively limits inputs to the knowledge system to established thought leaders to the exclusion of broader tacit knowledge from non-thought-leaders. As a result, the existing regulatory regime for biomedical technologies limits inputs to the innovation system and is, therefore, anti-innovative. I will examine this idea further using social network analysis in Chapter 5.
the field level, shared experience is enacted through shared belief in the rightness of an evidence grading system that privileges scientifically controlled, quantified empirical evidence over individual experience to guide practice.

In addition to shared belief in a hierarchy of evidence types that privileges controlled, experimental data, the field level has a more rigorous set of criteria to determine trust than simply shared experience. In addition to grading the strength of evidence on a hierarchy according to research design, individual studies are graded on the quality of the data according to a codified set of criteria to determine how rigorously the study was conducted (Schulz, Altman, Moher, & CONSORT Group, 2010).

**Trust in thought-leaders.** The construction of consensus statement and guideline documents also embodies the notion of trusted sources in the selection of thought-leaders to write the documents. Empirical scientific evidence is increasingly prioritized above expert opinion in consensus statements and guidelines for driving recommendations. However, there is still broad latitude for including comments from the writing group members to articulate their personal opinions, even in the face of evidence of completed science. In professional organizations like the Heart Rhythm Society, an appointed committee tasked with overseeing the development of scientific and clinical documents selects individuals to participate on the writing committee for a new (or updated) document. Committee members propose a slate of individuals whose publication and presentation track record has earned the status of expert in a given topic. One of my informants is a prominent thought-leader in AF ablation, and provided insight into the
criteria used to select individuals to contribute to the 2007 and 2012 consensus statements on AF ablation.

I thought it was critical to have people that have contributed to the literature. So the thought…not only the thought-leaders, but the people who have, that are actively publishing in the field of AF ablation. And I wanted a mix of people who were interventionalists and general cardiologists, people on guidelines, drug people…. We felt it was crucial that we have the thought-leaders on the document, because when we come up with guidelines for endpoints of clinical trials for AF ablation, if we don’t have the thought-leaders there, then there’s no reason at the end of the day that we have any obligation to try to follow these recommendations…. So, you know, a huge number of worldwide highly regarded people are authors of that document. (TL-1, June 25, 2015)

In order for the consensus statement document to carry weight, its authors must be trusted authorities in the field. That trust was established through an established track record of scientific publication in the peer-reviewed literature, which is understood by the field to be a mark of trustworthiness.

**Establishing trustworthiness.** Increasingly, trustworthiness is also tied to the notion of truth as enacted by an expert’s practice of disclosing full data in their publications, rather than excluding some inopportune cases. This concern about the trustworthiness of noted experts was mentioned by multiple informants who are not thought-leaders in AF ablation. One physician said, “You can’t tell if this is clean or true data. I mean, you mentioned [thought-leader], and you know, I’ve never seen anybody as skilled in the lab as he is.” This informant continued on, lowering his voice. “But at the same time, I don’t know if I can trust the data that much” (NTL-4, September 10, 2015).

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49 As of 2015, there have been multiple consensus statements, but there is not yet a clinical practice guideline for AF ablation. A consensus statement update is planned for 2017.
Another informant recalled an occasion at a scientific meeting when a young physician was presenting a first-in-human case of a major complication related to AF ablation. At the conclusion of this presentation, when the young physician reasserted that this complication had never been reported in the literature, a noted thought-leader stood up and declared that he had already had six such complications in his practice (NTL-1, November 5, 2015). This incident illustrates the competing notions of expertise as tied to experience, as well as the concern that experts may not be disclosing their full experience, raising concerns about the trustworthiness of their assertions.

Field-level trust is also increasingly related to the notion of connection to – or independence from – industry interests. This is distinct from individual- and group-level trust, where industry representatives are both viewed with skepticism and included as part of the trusted team in providing patient care. At the field level, efforts to disclose real or perceived conflicts of interest have historically relied on individual self-disclosure of payments received from industry. In light of findings regarding significant industry influences over some physicians’ practice behaviors, the Grassley-Kohl Physician Payment Sunshine Act (2010) mandated the public reporting of industry payments to physicians beginning in 2014.50 One informant, who has responsibility for vetting contributing authors to health policy documents including consensus statements and practice guidelines produced by a professional association, told me that she has begun using Sunshine Act data in the vetting process. “It makes my job so much easier,” she

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50 On October 7, 2015, Senator Grassley introduced a similar bill (S. 2153) to expand Sunshine Act reporting to cover nurse practitioners, physician assistants, and other advanced practice nurses.
said. She noted that there are frequently significant disparities between Sunshine data and physician self-disclosures.

I have to go back to some people and ask them about their payments…a lot of meals and international travel…. I have to wonder how much of the work is for [personal income] revenue and how much of the work is intellectually driven.” (PS-3, October 8, 2015)

The move away from assumed trust to a requirement for proof of trust via transparent disclosure of financial transactions illustrates three points. First, there is a changing set of expectations and burden of proof underscoring the notion of trustworthiness. Second, the effective currency of implicit trust diminishes at the field level as compared to the individual level. Third, there is an emerging assumption in the field that financial compensation is a surrogate marker for non-trustworthiness. I will return to the problematic of financial involvement in the final section of this chapter.

**Suppressed Skepticism**

In addition to shared enactments of trust at the field level, there also seems to be a shared practice of stealth denial (Rowson, 2013), or the backstaging (Goffman, 1959; Hilgartner, 2000) of skepticism in the AF ablation procedure. I have observed backstaged stealth denial of the efficacy of AF ablation among AF ablation practitioners since 2001. Stealth denial, contrasted with public promotion of the developing technologies and procedural approaches to AF ablation, seems to be a necessary condition for the continued practice of AF ablation with the knowledge that the procedure is imperfect in terms of clinical outcomes. A similar phenomenon has been observed with other complex medical procedures (e.g. Morlacchi & Nelson’s 2011 review of the development of the
ventricular assist device). Suppressing field-level skepticism is required for the evolution of medical knowledge writ large that continues to posit scientific truth in formal position statements by thought leaders in the face of imperfect data and clinical outcomes.

In the 35 years since Cox and colleagues began publishing their work related to surgery aimed at curing AF, nearly 10,000 articles have been published in peer-reviewed journals and many more abstracts have been presented at scientific meetings worldwide (but primarily in the U.S. and Europe). Much of the published evidence builds on previous work, but a few of the articles I analyzed are directly contradictory. For example, two examples in Chapter 3 presented the varied messages among the body of abstracts related to rotor ablation that were presented at the 2015 Heart Rhythm Scientific Sessions (Gianni et al., 2015; Narayan, Krummen, Donsky, Swarup, & Miller, 2015), and the recent publication of the STAR-AF trial concluded that CFAE ablation was not an effective adjunct to PVI (Verma et al., 2015), despite multiple previous studies to the contrary (Oral et al., 2007; Oral et al., 2009; Porter et al., 2008). This recent emergence of negative and contradictory studies may herald a trend away from the positive publication bias that has dominated the peer-reviewed literature. In its place, there seems to be a rising tide toward valuing transparency and data, even if the data contradict the prevailing field-level paradigm.

**Implications for Innovation**

Any effort to influence the processes of innovation for AF ablation technology and technique must be sensitive to the critical elements that influence the enacted
demand-side translation of knowledge into practice that results in paradigm formation and shifting at each level in the system. Trust is a critical component influencing data uptake at every level. Trust extends to individuals as well as to the data that the individuals present. For trust in data, transparency regarding study design and data acquisition is key. For individuals, trust is driven by a track record of thoughtful science that is not primarily driven by industry-promoting goals. Association with industry interests detracts from trustworthiness, particularly at the individual level.

However, existing regulatory structures (i.e. FDA approval pathways) result in increased financial investment requirements for biomedical technology innovation that is typically available only to large industry bodies or venture-capital-funded start-up corporations. Either of these cases requires a corporate structure to carry out innovation operations, positioning the work of innovation squarely in the industry space that detracts from trust at individual and field levels. Even universities, which have historically been viewed as separate entities from industry in the health technology space and thus not tainted by concerns about trust, are increasingly creating corporate structures to afford commercialization activities for innovative technologies. The strong connection between biomedical technology innovation and industry creates a problematic catch-22 where pragmatic efforts to move through the innovation regulatory process require adoption of a status that is implicitly and explicitly cloaked in suspicion. Thus, the typical innovation pathway hampers fundamental trust that is necessary for an individual knowledge paradigm shift and a resulting shift in practice patterns.

From a policy perspective, in light of ever-increasing costs of doing rigorous research on complex technologies and procedures in a climate of contracting funds, the
reliance on industry funding injects an inherent perception of bias into the outcomes of clinical research. Therefore, efforts to increase the transparency of research data may help to increase individual trust in research findings and facilitate increased uptake of research knowledge into individual practice (Lucas et al., 2015). At the group level, paradigms develop based on shared experience with the individual paradigms of team members working together. Therefore, building or shifting knowledge paradigms at the group level requires buy-in from all individuals on the team, and a body of shared experience to shape the paradigm. At the field level, paradigms require a critical mass of group paradigms to be in place, supported by a body of data that conforms to shared beliefs regarding data strength and quality according to a set of expectations about what constitutes science, and thus scientific truth. Therefore, increasing research data transparency can facilitate knowledge paradigm development at all levels.

In Chapter 5, I explore the structure and function of the AF ablation knowledge system, including separation between formal and informal components of the knowledge system. I will preview those ideas here, as they lend structure to my observations about knowledge, practice, trust, and innovation. As a result of separated formal and informal knowledge systems, only the small subset of formally encoded knowledge contributes to paradigm shifts at the field level of AF catheter ablation, whereas individual and group subsystems also incorporate informal knowledge to construct practice paradigms. Therefore, paradigm shift at subsystem levels (i.e. individual, group) may happen more frequently with smaller increments (as with the second- and minute-hands on a clock), compared to the full system (i.e. field) that experiences paradigm shifts less frequently, but with larger increments (as with the hour-hand on a clock). Moreover, subsystem
paradigm shifts may occur based on knowledge from demand-side translation that is functionally unavailable to the full system as a result of limited avenues for individuals to communicate their lived experience. This observation highlights the knowledge mismatch between system levels, and will help to frame recommendations to better align knowledge throughout the innovation system.

This project seeks to identify structural holes in the knowledge system and create novel solutions to overcome those holes in order to connect informal knowledge with the formal knowledge system. As such, the novel solutions must be responsive to the fundamental issues of trust in terms of scientific (rather than financial) motivation and scientifically rigorous data in order to yield any meaningful impact toward mobilizing knowledge in the AF ablation system at all levels.

The regulatory environment that undergirds clinical practice in the United States in terms of commercial availability of technologies and, to a lesser degree, reimbursement for interventional techniques, requires the establishment or shift of a field-level paradigm in order to effect a regulatory change to accommodate innovations. However, given the nested pattern of interaction at individual, team, and field levels, individual and group level paradigm shifts from demand-driven knowledge translation to practice are already in place prior to a field level paradigm shift occurring. In other words, paradigm shift at the individual level does not functionally relieve accumulated anomaly pressure at the field level like small earthquakes do along a fault line. Rather, the regulatory system requires a field-level paradigm shift — typically enacted via supply-driven knowledge-practice translation — in order to yield a regulatory change to accommodate new techniques or technologies. To the contrary, accumulated paradigm
shifts at the individual and team levels compound the functional pressure of accumulated anomalies at the field level like a ratchet, as external regulation constrains actual clinical practice and innovation at the individual and team levels. Therefore, a field-level paradigm shift is required to accomplish a regulatory shift and finally relieve the practice-level pressure for the individual and team subsystems to function with the new knowledge paradigm. This functional feature invites examination of the existing regulatory system in order to better align patterns of practice and regulation. I will return to discuss opportunities for knowledge system innovation in Chapter 6.
Chapter 3 examined how three different streams of knowledge – science, technology, and technique – intertwine to create the formal body of knowledge that informs AF ablation. Chapter 4 turned to focus on the key factors that admit formal AF ablation knowledge – along with tacit knowledge based on trust and lived experience – into practice by individuals, groups, and the electrophysiology field writ large. Now, I examine the paths by which formal and informal knowledge move through the practice system, and the ways that knowledge travels those paths. The AF ablation enterprise comprises individuals, epistemologies, and structures engaging in activities that generate and leverage knowledge. Therefore, it is useful to think of the AF ablation system in terms of a knowledge system that functions within a larger innovation system.

The concept of a knowledge system is widely used, but lacks a canonical definition. The Consortium for Science, Policy & Outcomes (CSPO) defines a knowledge system as “a suite of interconnected individual, social, and/or institutional practices by which knowledge claims get formulated…, validated, circulated, and put to use in making decisions” (Miller, Munoz-Erickson & Monfreda, 2010). This definition that includes actors, actions, and connections is particularly useful, as it is broadly

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51 I use Latour’s (Latour, 2005) concept of non-human actors, or actants, as nodes in the network subject to the same activity and analysis as human actors. However, I do not routinely differentiate in the text between actors and actants. Rather, I will refer to both human and non-human actors by the single term: actors.
generalizable across disciplines. Therefore, I represent these knowledge system components as nodes and ties in a network with complex and adaptive communication practices in order to understand how the particular structure and function of the AF ablation system poses innovation constraints and opportunities for improvement.

In addition to understanding how knowledge flows through the AF ablation knowledge system, it is important to understand how knowledge from the practice system traverses the innovation system. Because the practice of AF ablation requires integration of science, technology, and technique knowledge in a unified performance by an interdisciplinary team, division among separate knowledge systems and sequestration between knowledge strands is inefficient and potentially obstructive toward a goal of knowledge integration. Rather, understanding all knowledge as integrally valuable contributions toward the goals of the system alleviates a notion of a false hierarchy of knowledge that could impede (and arguably already does impede) innovation potential in

52 Other organizations have published definitions of a knowledge system, including the Global System for Sustainable Development at Massachusetts Institute of Technology, which defines a knowledge system as:

| An organized structure and dynamic process (a) generating and representing content, components, classes, or types of knowledge, that is (b) domain specific or characterized by domain-relevant features as defined by the user or consumer, (c) reinforced by a set of logical relationships that connect the content of knowledge to its value (utility), (d) enhanced by a set of iterative processes that enable the evolution, revision, adaptation, and advances, and (e) subject to criteria of relevance, reliability, and quality. (Global System for Sustainable Development, n.d.)

In addition, the Sustainability Science Program at Harvard’s Kennedy School describes knowledge systems as consisting of 3 kinds of knowledge: formal knowledge from basic and natural sciences, clinical knowledge from professions (e.g. engineering, medicine), and tacit knowledge from practitioners (Harvard Kennedy School Sustainability Science Program, n.d.). These alternative definitions, which are broadly similar and vary mainly in nomenclature and emphasis, demonstrate that there is not a single canonical definition of a knowledge system. Therefore, this project requires significant attention to empirically constructing boundaries for knowledge system analysis.
the system. In the AF ablation system, the goal is the practical obliteration of AF to eliminate human suffering from the arrhythmia. Given that the component knowledge streams informing AF ablation (i.e. science, technique, and technology) span the realm of fundamental understanding and practical application, it follows that AF ablation innovation is an instance of Stokes’ (1997) Pasteur’s Quadrant. Fundamental understanding and practical application are co-prioritized for use-inspired innovation. However, regardless of the theoretical inputs, the outcome of AF ablation is fundamentally evaluated by the patient’s clinical disposition. Therefore, innovation in AF ablation requires knowledge transfer from the practice system to the formally codified knowledge system. I will show that this knowledge transfer is presently constrained for AF ablation, limiting the innovation potential in the system.

With the paths of knowledge through the practice and innovation systems for AF ablation identified, I examine how the AF ablation knowledge system does and does not work from the perspective of information flow. Two major concepts will be helpful to accomplish this. First, the AF ablation system is complex – consisting of many parts that interact with one another, and adaptive – it changes in response to shifts in the environment, including emerging knowledge and regulations. Therefore, by understanding the AF ablation knowledge system as a complex adaptive system, complex systems theory can offer potential opportunities to change the system in order to maximize information flow by leveraging the intrinsic properties of a complex adaptive system. Second, the AF ablation knowledge system comprises heterogeneous actors who
translate and communicate knowledge in different ways. Therefore, the concept of user types is helpful to characterize actor roles in terms of the ways that different actors transmit or receive knowledge in the system.

In theory, a fully connected social knowledge network would have all actors serving as both transmitters and receivers of knowledge throughout the network, so that all ties between actors in the network are bidirectional. When there is bidirectional communication, translated knowledge can be communicated throughout the system efficiently due to the density of network connections, reducing the potential constraining force of single actors or institutions according to a network flow-type model in the context of social homogeneity. However, this theoretical complete network state poses the potential for cacophony, particularly in larger and more complex systems, as the number of connections increases quadratically with the number of nodes (Weisstein, n.d.). In the AF ablation knowledge network, however, it is important to remember that there is not social homogeneity, but rather particular embodiment and exercise of social capital related to variations in expertise, institutional arrangements, and cultures of practice. Knowledge system actors may be in transmitting or receiving roles, and some actors may act in both roles depending on their user type. For example, a cognizant patient is unlikely to communicate knowledge about technical approaches to maneuvering an ablation catheter. Therefore, the theoretical full-function network state is not realistic. However, the notion of maximizing bidirectional communication according

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53 In truth, AF ablation heterogeneity extends beyond actors to include heterogeneous theories of causation, sites of treatment, and technological approaches. However, for the purposes of this knowledge system communication analysis, I am focusing on actor heterogeneity.
to the potential for each actor role by user type still offers value toward knowledge system optimization based on network theory.

**AF Ablation Knowledge System**

The AF ablation knowledge system consists of two separate, but connected, components (Figure 13). The formal knowledge system comprises the work of generating and certifying research knowledge that informs the field-level paradigm of AF ablation (see Chapter 4). Outputs from the formal knowledge (sub)system include peer-reviewed journal articles, scientific conference presentations from thought-leaders, and regulatory communications that inform the development and use of new technologies and techniques for AF ablation. In contrast, the informal knowledge (sub)system comprises the work of performing AF ablation in clinical practice and incorporates knowledge from lived experience in clinical practice distinct from research activities, as well as inputs from relevant regulatory institutions that enable or constrain practice. Outputs from the informal knowledge system include patient-level clinical outcomes, practice patterns among individuals and teams, and direct communication between actors.

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54 The distinction between thought-leaders and non-thought-leaders correlates with the distinction between contributory and interactional experts (Collins & Evans, 2007). I return to examine this distinction in more detail later in this chapter.
Figure 13. Relationship between formal and informal knowledge (sub)systems in the AF ablation knowledge system. Multiple strongly established flows of knowledge exist from the formal to the informal subsystem, and fewer weaker flows of knowledge from the informal to the formal subsystem.

With AF ablation, there is a mismatch between the foregrounded public discourse of thought-leaders supporting innovation activities via the formal knowledge system, and the backgrounded private discourse of non-thought-leaders whose clinical practice work yields most of the user activity and a robust but largely unaccounted informal knowledge system. Although practitioners engage in local practice innovation within the informal knowledge system, this mismatch between the formal and informal systems prevents the majority of informal knowledge from entering the regulated innovation system. Thus, the formal-informal knowledge system separation and mismatch limits the capacity for innovation to occur based on knowledge generated in the informal component of the knowledge system. The AF ablation technology case allows for examination of the ways that knowledge travels within and between the innovation and practice subsystems. In addition, the work to map and analyze the full knowledge system around AF ablation
contributes to a broader conversation about how to conceptualize knowledge and outcomes related to other emerging and contested medical technologies.

Before I present my approach to mapping the AF ablation knowledge system, a discussion of expertise and authority is warranted. This concept and its attendant mechanisms play active roles in constructing the knowledge system.

**Expertise and Authority**

At several points along this exploration of AF ablation, I have referred to expertise. Expertise, with the closely coupled notion of authority, provides the ticket for knowledge to be admitted to the formal knowledge system. In the case of AF ablation, expertise is paramount and closely related to authority, which facilitates or reinforces expertise status and allows for the translation of expert knowledge to practical action.\(^\text{55}\) Expertise adds both to the transmission and reception of knowledge (or supply-side and demand-side translation) by conferring credibility, legitimacy, and salience. Collins and Evans (2007) describe two main types of performative specialist expertise: contributory and interactional, as well as evaluative meta-expertise. Contributory expertise is the kind of expertise that both outsiders and insiders in the field recognize as making an expert. For example, a scientist who has published a well-researched book about deep-sea fishing in the Bahamas is a contributory expert on the subject. The other type of expertise is interactional expertise. An interactional expert has deep understanding of a subject

\(^{55}\) See Chapter 4 for a discussion of the knowledge-practice transition.

166
through extensive direct experience. An interactional expert can discuss the subject at length. However, an interactional expert is not recognized by field insiders as being an expert. For example, a sport fisherman who has spent years vacationing in the Bahamas with his fishing boat may be an interactional expert. However, our sport fisherman is not included in the core set of experts who define the field. That fraternity is reserved for contributory experts. When the Bahamian government needs advice for writing regulations for reef fishing off the coast of Grand Bahama Island, they call the scientist, not the sport fisherman. The scientist’s contributory expertise grants the authority to take action by facilitating access to regulatory decision makers.

The same is true with medical technology and procedures including AF ablation. Research scientists and a small group of thought-leader physicians make up the core set of contributory experts who frame the formal knowledge system of AF ablation. Thought-leaders are those academic research physicians who have published extensively in the peer-reviewed literature. This group is a small minority of people who interact with AF ablation and is self-reinforcing through the exercise of bibliometric power and monarchical publishing practices, as discussed in Chapter 3. Moreover, thought-leaders are the individuals who are invited to contribute to field-defining consensus and policy statements that exert significant impact on innovation and regulatory systems. This self-reinforcing group of contributory experts is the embodiment of the core set in Collins’ and Evans’ third wave of science studies paradigm (Collins & Evans, 2002).

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56 There is some overlap in the distinction between contributory and interactional expertise and the concepts of explicit and sentient or tacit knowledge (Polanyi, 1967, Zuboff, 1988).
Collins and Evans (2002) described the idea of permeability between interactional experts and the core set of contributory experts in their third wave model of science studies. In the third wave, interactional experts remain outside of the core set of contributory experts, but expertise is shared between the groups in the service of advancing science. In the AF ablation case, however, there is generally a unidirectional barrier between the contributory expert thought leaders of the formal knowledge system and the interactional experts who construct an informal knowledge system. Formal knowledge flows freely from the thought leaders to the rest of the field via the system of formal publication in medical journals. However, informal knowledge from physicians who are not thought leaders does not generally make the reverse trip. Even informal knowledge practices such as sidebar conversations at meetings constitute unidirectional travel of knowledge from thought leaders to eavesdropping non-thought-leaders. In general, the formal knowledge system does not capture the interactional expertise of those outside of the core set. A rare exception to this unidirectional travel of knowledge occurs in the highly diffuse practice of communication among industry professionals whereby industry representatives who work with non-thought-leaders share informal observations with industry business professionals, who in turn communicate these observations to industry engineers. In some cases, these observations inform technology development that proceeds through formal knowledge system structures to enter the innovation system. However, the path from periphery to core set is indirect and lengthy, which compromises the efficiency of the knowledge system. With the understanding that the complex enterprise of AF ablation is taxed by inadequate time and resources to meet population needs for AF therapies, inefficiencies in the knowledge network merit
attention in order to allow more efficient and effective allocation of scarce resources to ultimately serve population health needs.\(^5^7\)

In the context of the AF ablation knowledge system as a complex adaptive system, the communication practices of the core set limits inputs to the knowledge system, constraining potential future innovation opportunities. Moreover, self-reinforcing group behaviors decrease the permeability between system and subsystem nodes and boundaries, which inhibits the optimal functioning of the complex adaptive system.\(^5^8\)

Limited permeability is reinforced by expert authority in the network in three major ways: reinforcing structural holes in the network that limit communication from informal to formal subsystems, limiting the circulation of new participants into the formal network, and self-citing in the formal peer-reviewed literature.

**Reinforcing structural holes.** Outside of the core set of thought leaders, there is a much larger group of physicians and other health professionals who perform AF ablation procedures. These are the interactional experts who are recognized as AF ablation experts by virtue of procedural experience, but are not considered to be thought-leaders. In this case, their expert knowledge never penetrates the barrier from the informal knowledge system to enter the formal knowledge system for capture and codification. As we will see shortly, they are end users, but not designers in the context of

\(^{57}\) The Social Construction of Technology (SCOT) framework (Bijker, 1995) provides another framework for examining technology development by a variety of users in the knowledge system. Further examination of AF ablation against a SCOT framework is merited in future work.

\(^{58}\) Later in this chapter, we will see how decreased permeability between system nodes creates silences and structural holes in the social network, restricting communication and innovation in the network.
building knowledge that may ultimately lead to field level paradigms. There are three major factors reinforcing the barrier between formal and informal knowledge: time, culture, and thwarted efforts to publish.

**Time.** During interviews and observations, many clinicians referred to themselves or others outside of the formal knowledge system as lacking time to do research. According to one thought-leader physician:

> I do think there’s a lot of people you wouldn’t consider thought leaders that may have some really good ideas that it’s hard for them to get them out there…. Either they’re not going to publish because they don’t have a fellow [physician in post-graduate training] or time. And they’re not going to be asked to speak because they’re not considered a famous person. (TL-2, March 15, 2015)

Another thought-leader also lamented time constraints for research. He told me that he frequently does research (as opposed to clinical work) at night and on weekends (TL-3, October 12, 2015).

**Academic culture.** One widely recognized thought leader acknowledged that “private practice non-publishing AF ablationists,” distinguished from the “academic circle” are not represented among the authors contributing to formal statements that represent the current standard of practice for AF ablation (TL-1, June 25, 2015). Only already-recognized thought leaders are included as authors on the position statements that shape the field and contribute to field-level paradigms and regulatory considerations including national coverage determinations that enable the use of technologies and procedures (e.g. 78 FR 48164-69, the national coverage determination for AF ablation).
The private practice guy who works the back end who doesn’t share their knowledge or go to meetings or talk to people or publish…whatever tricks that person may learn will never be learned by anyone else because they have to share them. (TL-1, June 25, 2015)

Therefore, an individual who is not contributing to the peer-reviewed literature or formal conference presentations is effectively outside of the formal knowledge subsystem as far as innovation and regulation are concerned. Such an individual is part of the formal knowledge system only as a recipient of knowledge conveyed by the recognized thought leaders. We will see later that this individual is essentially silent in the formal knowledge system.

Despite being privileged in the knowledge system, not all academic physicians are included equally. One academic physician who jokingly refers to himself and institutional colleagues as “thought followers” or “thought laggards” in AF ablation told me about thwarted efforts to contribute to the formal knowledge system by publishing their institutional experience with a new technology for AF ablation. “The problem is it’s an observational study. It’s like not a randomized [trial]…. We submitted it as an abstract to HRS and it didn’t get accepted. So, you know, I don’t know” (NTL-2, June 17, 2015).59 I asked another colleague from the same academic group about the abstract that wasn’t accepted. He replied, “I couldn’t tell you which one you were referencing because there were several we submitted that didn’t get accepted.” He continued, explaining the typical

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59 This statement reinforces the field-level epistemic culture that values randomized controlled clinical trials over observational case reports as the basis for new knowledge (Jacobs et al., 2013). In addition, formal publishing practices value clinical trials over cases due to the tendency for trials to be more widely cited and thus increasing the impact factor of the journal. Therefore, the editors of peer-reviewed journals prefer to publish clinical trials to the exclusion of case reports in an effort to boost bibliometric ratings (TL-3, October 12, 2015). Thus, publishing practices driven by impact factor limit access for experiential knowledge to reach the knowledge system.
experience of submitting abstracts to the HRS meeting. “It’s not too unusual to have this many rejected…we usually submit four to five abstracts at least. Usually two or so get accepted” (EPT-1, June 2, 2015). Even in this academic medical center, a minority of the knowledge produced from robust observational work ever enters the formal knowledge system. This type of failure of organized knowledge to reach the formal knowledge system represents a structural hole created by socially constructed expertise boundaries in the network. Fundamental epistemic differences between practice and research cultures prevent knowledge from entering the innovation system.

**Patient culture.** Beyond the pale of non-research clinicians, there is an even larger group of interactional experts, consisting of patients who have undergone AF ablation. These individual patients, along with their family and loved ones, have indisputable interactional expertise from the lived experience of considering and undergoing AF ablation procedures. Like the non-publishing healthcare providers, the broader public does not consider these patients to be contributory experts to the field. Even the patient advocacy organization StopAFib.org lists experts as being physicians, not patients (StopAfib.org, 2015). As such, patients’ interactional expertise is not included in the formal knowledge system that is generated by the contributory experts, and does not directly impact innovation.

In a very few cases, patients are invited to participate as subject experts in the formal knowledge system. For example, Melanie True-Hills, a patient who underwent
surgical ablation for AF and started the website StopAFib.org, served as a panelist in a case-based session on AF at the 2015 American College of Cardiology scientific sessions. More often, though, patients are completely excluded from the AF formal knowledge system. Even in the exam room, physicians frequently edit the range of therapies they present to patients with AF. Several years ago, one physician colleague told me that if a patient is elderly with high blood pressure and permanent AF, he deems them to not be a candidate for AF ablation, and won’t even discuss it with them. When physicians do discuss the procedure with patients, they don’t mention particular technologies unless the patients ask them specifically. Physicians estimated that about 20-25% of patients ask about technologies, and most of those inquiries stem from public-facing advertisements either from the hospital or from technology manufacturers, highlighting the use of a new technology at a particular medical center (NTL-1, June 17, 2015; NTL-2, June 17, 2015). In general, patients are – with rare exception – excluded even from the informal knowledge system of AF ablation except as end lay users (or nonusers) of technology use. The one exception to this patient exclusion is to note that patients do communicate with non-thought-leader physicians, NP/PA providers, and EP lab nurses about their lived experience following AF ablation. This communication generally includes symptoms resulting directly from the ablation procedure (e.g. patients

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60 Even though the founder of StopAFib.org is increasingly recognized as a contributory expert in the field of AF writ large, and AF ablation more specifically, the website features a disclaimer removing itself from the realm of expertise and authority: “We here at StopAfib.org are not medical doctors or trained medical personnel and cannot guarantee 100% medical accuracy” (StopAfb.org, 2012). The organization features a Medical Advisory Board that is “made up of some of the world's foremost atrial fibrillation experts,” distinguished from the non-expert patients who make up the constituency of the organization (StopAfib.org, 2015).
tend to have more chest pain after extensive ablating in a particular area of the left atrium) as well as the frequency and nature of recurrent arrhythmia symptoms in the days, weeks, and months following an ablation. To this end, patients are considered a part of the informal knowledge system. However, their contributions to the system are generally limited to their symptomatic experience from AF ablation itself. Therefore, patients who are nonusers of AF ablation remain excluded from the knowledge system.

*Thwarted efforts to publish.* Individuals who are locally recognized as AF ablation experts, but do not occupy a rarified post in the formal knowledge system, expressed the converse experience to those with high bibliometric ratings. One busy ablationist told me about his group’s effort to influence innovation by entering the formal knowledge system. “We wrote an abstract [for the Heart Rhythm Society scientific sessions]. It maybe does or doesn’t get it, depending on who grades it [peer reviewer] and what their personal or professional biases are.” He continued, “If the abstract doesn’t get in, we really have no mechanism to affect innovation” (NTL-1, January 26, 2015).

Indeed, that abstract was not accepted for presentation at the meeting based on the peer review process, and the interactional expert knowledge from that center is not included in the formal knowledge system.

*Communication differences: Case observation.* I observed the differences in communication experience between thought-leaders and non-thought-leaders in sidebar conversations during the American College of Cardiology Scientific Sessions in March 2015. I attended one of the large sessions focused on AF. This session was held in a
convention center room set with a raised dais at the front facing a half dozen round tables with 5 chairs each, and two equal blocks of 168 chairs divided around a central aisle with a few microphone stands to accommodate audience questions. I arrived to the session room about 15 minutes early and easily found a seat in the center of the left-hand block of chairs. I saw a clutch of four physician thought-leaders standing together at the front of the room. Three of these were current or past presidents of the Heart Rhythm Society, and the fourth was a well-known thought leader in AF. As they chatted, Melanie True-Hills, widely considered the leading patient advocate in AF, entered the room and immediately connected with the group, hugging two of the physicians in turn. Their conversation turned to recount their experience speaking at a recent event for Ms. True-Hills’ organization. Meanwhile, the room was filling to about 85% capacity with a few minutes remaining before the scheduled start of the early afternoon session. As the heavily male-dominated audience filled the seats, I noted a small cluster of mid-tier leaders in the Heart Rhythm Society a few rows in front of me, chatting amongst themselves. This group of middle-aged men all hailed from different academic institutions, but were well known to one another. As they chatted, another, newer mid-tier leader in the Heart Rhythm Society entered the room, and was quickly waved over to join the seated group. Looking around, I noticed that other attendees were observing these sidebar conversations among thought-leaders, as I was. However, none of the observers attempted to join a conversation.

With one minute to go before the session began, Hugh Calkins, the immediate past-president of the Heart Rhythm Society and Sanjiv Narayan, inventor of the Topera mapping system, arrived together and took seats at a round table in the front of the room,
joining the current president of the organization. As I watched, I noted that none of these thought-leader physicians engaged with any non-thought-leader individuals prior to the session.

After the session, a few younger physicians approached the thought-leaders as they lingered in the front of the room. As it turns out, these younger physicians were not simply seizing the opportunity to engage with their more senior peers; they were fellows-in-training in the thought-leaders’ hospitals. Their in-person interactions reflected the ethnocentric publishing practices discussed in Chapter 3. The thought-leaders scarcely noticed other session attendees. I personally received a smile and a wave from each, a quick “How are you?” as I glanced up from my field notebook, but I did not seek substantive conversation.

Limiting new participants in the formal network. Perhaps the most straightforward way to identify thought leaders in the field of AF ablation is via the list of authors contributing to the first international scientific document: Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation (Calkins et al., 2007). Of the 27 authors representing 10 countries on 3 continents, each participant was selected by appointed leaders of constituent professional societies and the document chair, who was himself appointed by the leadership of his professional society. Contributor selection was particularly based on each author’s track record of significant contributions to the peer-reviewed literature in order to authoritatively represent the various constituencies that contribute to the enterprise of AF ablation, including catheter ablationists, surgical ablationists, non-ablationists, academic practitioners and private community practitioners.
One participant in the writing group for this expert consensus statement commented on the process of contributor selection.

We felt that it was crucial that we have the thought leaders on the document, because when we come up with guidelines for endpoints of clinical trials for AF ablation, if we don’t have the thought leaders there, then there’s no reason at the end of the day that we have any obligation to try to follow those documents. (TL-1, June 25, 2015)

Therefore, by including recognized thought leaders to the exclusion of those who do not publish in the formal literature, the document carries the authority to influence future practice.

Similarly, the roster of speakers at annual scientific meetings comprises mainly individuals with a track record of delivering confident, coherent, informative, and timely presentations at previous meetings. Speakers are selected by the program committee, an appointed group of experienced volunteers of the professional society that produces the meeting. Members of the program committee are themselves appointed by society leaders on the basis of a track record of strong presentations at previous meetings, echoing the self-reinforcing nature of publication in the formal knowledge subsystem. There is no formal guidance document for speaker selection. Rather, program committee members use a combination of literature searches, collegial contacts, and lived experience in the field to nominate speakers based on “what individuals are known for in the field to demonstrate that they are a thought leader and subject expert” (PS-1 & PS-2, October 1, 2015). One seasoned leader of the Heart Rhythm Society Scientific Sessions program committee said, “The [speakers] that get used the most are the ones that we have heard speak before and know speak well. That being said, we have really been trying to use more new people each year” (NPPA-1, August 30, 2015). This individual also noted that
self-nomination to speaking engagements was rare. “I know there is a way to put your interest in speaking onto the HRS website, but I don’t know that I’ve ever seen that list” (NPPA-1, August 30, 2015). Another former leader of the Heart Rhythm Society Scientific Sessions program committee reiterated that the most common pathway to speaker invitation “is to look at past scientific session speakers and re invite” (NPPA-5, September 1, 2015). She added:

    There was a process where seasoned…members of HRS were emailed by program chairs to ask if they had topics they wanted presented and knew good people who were interested in speaking about those topics from their institution. So recommendations for finding NEW speakers who were interested in getting more involved with HRS. (NPPA-5, September 1, 2015)

For the 2016 Heart Rhythm Society scientific sessions, the majority of invited presenters (78%) are individuals who have previously presented at the conference. Individuals involved with speaker selection noted that this percentage of returning speakers is lower than in previous years, due to a deliberate effort by Heart Rhythm Society leaders to include new early-career faculty in the 2016 meeting (PS-1 & PS-2, October 1, 2015). In effect, the effort to include new faculty to the scientific sessions introduces more active voices to the knowledge network. However, the majority of the existing formal knowledge network remains silent.

    **Self-citation.** As I discussed in Chapter 3, self-citation and citation circles are prevalent in the AF ablation literature. In many cases, thought leaders tend to reference their own papers and those of their local colleagues more than those of colleagues from other programs. For example, the Bordeaux AF ablation group heavily referenced itself in a research article with 14 of 41 (34%) of the references from their own group
In addition, the Milan AF ablation group referenced itself for fully half (8 of 16) references in a review paper on AF ablation (Pappone & Santinelli, 2005). As another example, when I was researching the ancestry of the 2007 Calkins consensus statement, as the final key paper in my dataset, I identified multiple papers from the Marchlinski group that had not been cited elsewhere. I had not previously included any articles from Marchlinski in my core set of manuscripts for evaluation regarding the development of current technologies and techniques in AF ablation, and my expanded bibliography from ancestry search of those core manuscripts did not yield many papers from the Marchlinski group. However, Marchlinski was a member of the writing committee on the consensus statement. It seems, then, that he preferentially included multiple papers from his own lab as references for the consensus statement, that were not widely cited elsewhere. I did not find that papers from other major AF ablation centers (e.g. Bordeaux, Milan, University of Michigan, Mayo Clinic, Cleveland Clinic) had to be added de novo to my dataset.

This observation about self-citation in the formal knowledge system follows with the impact factor strategy, and may have some influence on the structure of the formal knowledge system and its perceived or real barriers to those who are not already recognized as thought-leaders. For example, the strategy of using database queries of the peer-reviewed literature to select conference speakers will privilege authors who have extensively self-cited, thereby reflecting a higher ranking in bibliometric indices, and promoting the self-citing individual as a recognized thought leader in the field. In addition, the practice of self-citation in the context of field-level guideline documents that are heavily cited, further reinforces the cycle of auto-citation increasing one’s
bibliometric rating that in turn influences future selection to contribute to formal
knowledge system activities. This observation may provide a valuable framework for
future knowledge system analysis with opportunities for comparative analysis with self-
citations present and filtered out.

System Composition: Structural Attributes

The AF ablation knowledge system is made of components including individuals,
institutions, and technologies. Each of these components has distinct characteristics and
commitments, resulting from cultural and regulatory constraints that characterize
healthcare research and delivery. In this study, I consider cultural and regulatory
considerations specific to the U.S. experience. Other national experiences may yield
distinct findings, and merit future investigation.

The knowledge system is a network. Latour’s (2005) actor-network model
provides a useful tool for representing the AF ablation knowledge system, as it accounts
for the nonhuman actors, or the institutional and technical components in this
sociotechnical system. Relationship ties represent interaction and communication via
direct and indirect communication methods (i.e. face-to-face conversation, formal peer-
reviewed publication, live presentations, social networking). In the AF ablation network,
communication ties are directional, meaning that the flow of communication from one
actor to another may travel in one direction, but not the other. For example, a thought-
leader physician may give a presentation at a scientific conference that is attended by a
non-thought-leader physician. In this case, the presenter communicates directly to the
audience. However, the non-thought-leader audience member does not communicate directly to the thought-leader. If the two physicians were to carry on a face-to-face conversation after the meeting, then the communication would be bi-directional.

In another example, from Chapter 4, much information is exchanged at scientific meetings during sidebar conversations. For the individuals directly engaged in that sidebar conversation, communication is bidirectional; they are directly transmitting and receiving information from one another. However, for the individual who is eavesdropping on the sidebar conversation, communication is unidirectional only. The eavesdropper is receiving information, but not transmitting directly to the conversation.

**Network actors.** In order to characterize the ways that different individuals, institutions, and communication technologies access and use knowledge in the system, it is helpful to understand the types of actors who compose the knowledge system. Although this actor typology does not affect the construction of the network itself, it will be important to account for actor types when analyzing the findings from social network analysis. I use a regular equivalence approach to define actors (Borgatti, Everett, & Johnson, 2013) based on archetypal professional designations from national regulations defining the scope of professional practice and institutional jurisdiction, functional roles based on fieldwork data (Nadel, 1957), and participation in the formal knowledge system based on fieldwork data and literature review. For example, in the EP lab setting, physicians, nurses, technicians, and industry representatives each have distinct roles, scope of professional practice, and licensing (or lack of licensing). Therefore, they are represented separately in the network. Similarly, although thought leader and non-
thought-leader electrophysiologists both work with the same legal scope of practice and licensing, their functional roles in terms of formal knowledge generation and communication are distinct. Therefore, they are represented by separate nodes in the network (Table 3).

Table 3

*Actor Types in the AF Ablation Knowledge System*

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<tr>
<th>Individual Actors</th>
<th>Clinicians</th>
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<td>Thought-leader electrophysiologists</td>
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<tr>
<td></td>
<td>Non-thought-leader electrophysiologists</td>
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<td></td>
<td>Thought-leader non-electrophysiologists</td>
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<td>EP lab nurses</td>
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<td>EP lab technologists</td>
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<td>EP nonphysician providers (NP/PA)</td>
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<td>Non-EP cardiologists</td>
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<td>Primary care providers</td>
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<td><em>Industry-employed professionals</em></td>
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<td>Industry representatives in the EP lab</td>
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<td>Industry engineers</td>
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<td><em>Nonclinical, non-industry researchers</em></td>
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<td>Basic scientists</td>
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<td></td>
<td><em>Lay individuals</em></td>
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<td>Patients and family members, and friends as sentient actors</td>
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<td></td>
<td>Media professionals</td>
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<th>Institutional Actors</th>
<th>Hospital administration</th>
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<td><em>Industry business</em></td>
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<td><em>Insurance providers</em></td>
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<td><em>Regulatory bodies</em></td>
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<td><em>Professional societies</em></td>
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<td><em>Patient advocacy organizations</em></td>
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<tr>
<th>Technology Actors</th>
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<td>Peer-reviewed medical journal articles</td>
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<td>Non-peer-reviewed medical journal articles</td>
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<td>Industry publications</td>
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<td><em>Private insurance coverage decisions</em></td>
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182
### Traditional (centralized) media sources
- Scientific meeting presentations
- Scientific conference abstracts
- Sidebar conversations
- Industry education/marketing meetings

### Meeting
- Scientific meetings
- Industry education/marketing meetings

### Procedure-related technologies
- Patient (as object of ablation)
- EP lab technologies (e.g. mapping systems, ablation systems)
- EP lab procedure notes
- Standard operating procedures

**Network communication.** I discovered exceptional cases of non-typical communication patterns relevant to almost every node in both the formal and informal knowledge systems. For example, I encountered EP lab technicians who regularly present research alongside physicians at scientific meetings and serve on writing committees for formal consensus documents. I also encountered a leading patient advocate, Melanie True-Hills, who has close relationships directly with several AF ablation thought-leaders, and is a frequent invited speaker at professional meetings. I did not attempt to reflect these exceptional cases in the network map. Instead, I portrayed the more usual case of communication ties throughout the network. This usual case approach will allow for the design of system interventions relevant to the field in general, rather than limited in applicability to the exceptional cases. Still, the exceptional cases should not be ignored altogether. Opportunities arising from such exceptions may continue to contribute, and

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61 In addition to being a technology, traditional media can also be construed as an institution insomuch as it comprises an organized collection of actors with a codified purpose. I will address traditional media both as technology and institution in my analysis.
may ultimately have greater impact in the context of a more wholly robust user-innovation system.

**Users in the AF ablation knowledge system.** User typology is useful to distinguish different ways in which people consume products or services (Casper & Clarke, 1998; Oudshoorn & Pinch, 2003). User typology is drawn from cultural and media studies focused on consumption of products and services in a market context. AF ablation is a service, and though AF ablation does not take place in a true free market where patients can acquire AF ablation as with traditional consumer goods, there are ample similarities with AF ablation as an elective medical procedure to justify the appropriation of user types in the AF ablation context. User types in the AF ablation knowledge system tend to circulate knowledge differently into and out of their respective nodes, based partly on practice scope regulations and partly on practice culture. For example, nursing and technical staff in the EP lab do not communicate directly with a patient’s general cardiologist or primary care provider due to the regulatory expectation that the physician conducts interprofessional communication regarding the procedure, as well as cultural expectations that the physician speaks on behalf of the team. User coding, therefore, gives operational context to networks for mapping and intervention planning based on network analysis. In addition, single users or user groups in a system may enact different roles at varying points in the system, such as a salesperson at one point and a consumer at another point (Lindsay, 2003), and may play mediating roles between other user groups at junctures in the system (Schot & Albert de la Bruheze, Adri, 2003).
In the AF ablation system, *designers* are the scientists whose work focuses on discovery of new knowledge, as well as the engineers and companies that design, test, and market AF ablation technologies. These are companies like Topera and St. Jude Medical, and the engineers who work for them. Designers work closely with end users to test and market technologies. *End users* are physicians who perform AF ablation procedures. This includes thought-leaders who contribute to the formal knowledge system, as well as non-thought-leader physicians who contribute only to the informal knowledge system. End users interact with *end lay users*, including patients and other healthcare providers who do not directly perform the AF ablation procedures. Patient advocates including family members, and professional advocates including professional societies, are *implicated actors* in the user system. They do not have direct experience with AF ablation, but they do interact with end users and end lay users. Insurance companies and regulatory officials are also implicated actors in the AF ablation system. Finally, *nonusers* are patients and others who specifically do not engage the AF ablation system. For some nonuser patients, their nonuser status may be the result of specifically choosing to avoid the AF ablation procedure. Other nonuser patients may have been told that they were not a candidate for the AF ablation procedure, and thus were excluded from the AF ablation system.

User type categorization is helpful to show the patterns of work and role interactions that function in the system. User types are also helpful to guide and refine empirical data collection, particularly with participant observation activities, by

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62 Although end users do contribute as informants to the design process, their role is limited in this respect, as end users do not engage in formal design activities as do engineers and researchers.
foregrounding different types of actors who may not be included in the formal knowledge system. This foregrounding is useful to elucidate silences in the formal knowledge system, and helps to identify novel roles and activities to reconcile and unify the formal and informal knowledge systems in order to improve the innovation system.

In addition, the concept of multiple roles enacted by a single user is particularly useful to understand how physicians may simultaneously act as the purveyor and recipient of various sales techniques consistent with the expectations of the professional expert role in the physician-patient relationship (Freidson, 1970). For example, when a physician engages with an industry salesperson regarding new technology, he is a consumer. However, when a physician counsels a patient about AF ablation, he acts as a salesperson. The patient, then, acts as the consumer who decides whether to have or not have an AF ablation procedure. With this understanding of multiple roles, it is possible to show how individuals may contribute to formal and informal knowledge systems via different actions as they engage in the knowledge system of AF ablation activities. For example, individual thought-leader physicians embody multiple roles as they engage in research and innovation activities in the formal knowledge system in a discrete way from non-research activities in the informal knowledge system. In addition, individual technology nodes also perform in multiple roles. For example, the sidebar conversation functions in the formal knowledge system as a structure that enables bidirectional communication between thought leaders. However, in the informal knowledge system, the same sidebar meeting conversation functions in a unidirectional mode to convey (potentially partial) information from a thought-leader (who may be unaware of their engagement in this transmission) to a non-thought-leader. These multi-role actors, or
boundary spanners, are valuable targets for intervention to coalesce the formal and informal knowledge systems. Such targets are particularly valuable when the multi-roles cross subsystem boundaries, because they provide existing functional anchors between subsystems from which to leverage interventions to accomplish improved knowledge transmission to the innovation system. I will describe such multi-role boundary spanner instances as points of contact in the combined knowledge system later in this chapter. I will also point to structural holes where boundary-spanning roles are needed – either to create a de novo communication pathway, or to relieve a reinforced structural hole by creating and alternative path.

Network ties represent direct communication between nodes that translate information (Latour, 2005). Therefore, individual-individual ties represent a direct communication between individuals, individual-institutional ties represent direct communication between an individual actor and an actor who represents an institution, and individual-technology ties represent situations in which individual actors communicate through a technology in order to communicate with another individual or institutional actor.

**System Properties: Functional Attributes**

**Knowledge flow: Communication.** The major work done by the AF ablation knowledge system is learning. However, the major work that is done within the AF ablation knowledge system is communication, including communication between actors in research and clinical practice, communication between technology and actors, and communication of the body of knowledge itself (via a variety of publications) with actors
and technology to yield new knowledge. In the AF ablation knowledge system, communication occurs in a variety of ways including written, directly spoken in a formal presentation, directly spoken in an informal presentation including a sales transaction, direct demonstration/observation, and tactile experience. Different points of AF ablation knowledge merit different communication modalities – written, spoken, tactile – and different AF ablation practitioners respond to modalities differently. Therefore, many varieties of communication are vital to the knowledge network.

Written communication is more prevalent in the formal system compared to the informal system. Directly spoken communication in informal settings (i.e. non-presentations), direct observation, and tactile experience are the predominant modes of communication output in the informal knowledge system. For example, many non-research clinicians rely on verbal reports from industry representatives present during ablation cases to learn what other clinicians are doing during AF ablations with regard to technology and technique choices. In addition, most of my informants mentioned the high value of individual sidebar conversations with colleagues from other centers while attending scientific meetings. However, spoken communication does not reign alone in the informal knowledge system. Spoken communication often enlists written communication as a source of authority. For example, industry representatives are trained to reference peer-reviewed publications when conversing about new technologies, and frequently present reprints of journal articles to clinicians when discussing technologies.

Non-physician clinicians particularly commented that they learned much from presentations given at industry-sponsored educational events, such as local dinners bringing an outside speaker to talk about a particular technology to clinicians from
multiple local centers. These industry speakers are rarely AF ablation thought leaders. One non-physician characterized industry speakers as “just random people from labs I’ve never heard of,” rather than recognized thought leaders (EPT-1, June 2, 2015). This individual said that he attends industry symposia and brings the information back to his institution “with a grain of salt.”

I also usually say, like, you know, ‘I heard there’s another lab that’s using this technology. Of course, I don’t know anything about the technology.’ Or…, ‘I heard they’re using this technique. But I don’t know what any of their results are, because it’s not published or anything like that. (EPT-1, June 2, 2015)

This characterization reinforces the observation that busy clinicians – high volume ablationists and thus sales leaders who attract industry attention – are not also generally engaging in research towards formal knowledge generation. Therefore, while busy clinicians may be locally prolific in the informal knowledge system, they are not generally contributing to the formal knowledge system. In Chapter 4, I discussed that lived experience, rather than scientific proof, is the key affordance allowing evidence to reach the informal knowledge system. Informant data related to industry-sponsored events shows that despite this tendency, users in the informal knowledge system do maintain a threshold requirement for scientific proof in order to act on informal evidence. Although the barrier to entry for evidence to reach the informal knowledge system is

63 Industry sales representatives use the mechanism of so-called educational dinners as a marketing tool for sales of their technologies. Speakers at these dinners are often selected on the basis of being a sales-prolific user of the company’s technology. Industry speaking engagements are notably lucrative for the speaker. Although engagement as a speaker at an industry dinner is not directly considered a bribe given to the speaker by the company, individual clinicians are required by academic institutions, including universities and professional societies that engage in educational activities, to disclose the nature and monetary value of all engagements with industry. Likewise, medical industry companies are required by law to disclose all payments to U.S. physicians.
very low when compared to the barrier to entry for the formal knowledge system, the barrier for evidence to actually enter use from the informal knowledge remains high.

**Silences.** Feminist theorists describe various causes of silences, including failure to speak, failure to be understood, or failure to be recorded (Fishkin & Hedges, 1994). All of these occur in the AF ablation system. Although Actor Network Theory (Latour, 2005) provides a helpful framework for analyzing the AF ablation knowledge system, it fails to account for actors who do not communicate within the system. Therefore, if an actor is silent, he or she is excluded from the built network. For example, most non-thought-leaders are silent in the formal knowledge system because they fail to speak. In addition, most experiential knowledge is silent in the formal and informal knowledge systems. In general, only a few thought-leaders in the field contribute experiential knowledge to the formal knowledge system. Therefore, majority of experiential knowledge is functionally silent in the informal knowledge system by failing to be recorded, and thus excluded from the typical innovation processes. Non-users – individuals who do not engage in the AF ablation system – are completely silent in the knowledge system. By particularly capturing the silences of non-users, my network analysis includes more actors in the AF ablation system and reveals more structural holes, understood as opportunities to innovate within the innovation process by engaging individuals who have not historically been involved in AF ablation innovation. Such increased involvement and participation may yield improvements in innovation from a structural perspective, with more people able to access AF ablation and relieve their suffering related to AF.
In order to design meaningful structural innovations, I will account for modes of silence according to the three main practices of silence: failure to speak, failure to be understood (or be heard), and failure to be recorded. Considering the field as a whole, patients and nonuser physicians fail to speak in formal and informal knowledge systems. Physicians and most allied professionals fail to be recorded in formal and informal knowledge systems. Those who speak or publish outside of the formal system generally fail to be heard and understood.

Uncovering silences may shift relationships in the AF treatment paradigm by giving voice to historically silent patients in the patient-provider relationship (Katz, 1984). This kind of paradigm shift was realized in the breast cancer movement in the 1970s when women advocated for alternatives to radical mastectomy (Osuch et al., 2012). A further shift occurred in the AIDS treatment experience in the 1980s, when patients and patients’ interests gained a voice in the formal knowledge system for drug development (Epstein, 1996). In the case of AF ablation, such a cultural shift could result in patients selecting their ablation providers based on experience with particular technologies, or with particular patient subpopulations.

Silences in the AF ablation system also exist at the level of technologies. Many technologies are not used in practice – whether by individuals, groups, or throughout the field writ large. For example, every clinician informant mentioned at least one technology that they aren’t currently using in clinical practice. The most prevalent reason for non-use is cost. Most hospital administrations operate with constraints that limiting access to an emerging technology. Thus, clinicians do not have an opportunity to directly evaluate the clinical utility of the technology. This cost constraint was mentioned by thought-leaders
and non-thought-leaders alike. However, non-thought-leaders believed that this constraint was not a factor for thought-leaders. Therefore, non-thought-leaders believe that thought leaders have access to a broader field of lived experience with technologies. Therefore, thought-leaders’ technology selections are colloquially considered to represent the best technological approach to merit exemplar status. This perception-experience mismatch highlights a divide between the informal knowledge system and the formal knowledge system that results in unknowingly incomplete information informing clinical decision-making, and thus potentially limiting therapy to patients. Another prevalent cause of technology silence stems from the proprietary interrelationships between different types of technologies (i.e. mapping systems are designed to work only with particular suites of catheters and ablation systems). Therefore, one physician or hospital’s choice to invest in a particular company’s equipment creates a silence at the level of that EP lab group with regard to other competing technologies not in use.

These technological silences can be understood as undone science, or ideas that have been proposed and prioritized by social groups but never supported through the rigors of scientific inquiry (Frickel, Gibbon, Howard, Ottinger, & Hess, 2010). Therefore, in order to construct and understand the relevant political landscape that informs the research agenda for AF ablation, it is useful to consider the landscape of contributions from thought leaders that are rejected (or significantly modified) in the practice of users in the informal knowledge system of AF ablation. For example, one busy EP lab has invested in the St. Jude Smart Touch system, which has steered them away from using the Topera mapping system because Topera does not interact directly with St. Jude technologies (EPRN-1, April 27, 2015).
**Complexity and adaptation.** The heart is a complex adaptive system that modifies its cellular structure and physiological function including heart rate and pumping power to supply blood and oxygen at levels responsive to the body’s ever changing requirements. Within the complex adaptive system of the heart, AF itself is a complex (mal)adaptive system, with a variety of structural, cellular, genetic, and environmental processes interacting in non-linear patterns both exerting and responding to changes in anatomy and physiology in the constantly changing environment of the heart. For example, fibrillating atria do not contract normally, causing the atrial muscle to become flaccid over time. With the loss of atrial muscle tone, the atria stretch out like a deflated balloon, and stretch further in the presence of high blood pressure that is exacerbated by congestion that occurs as a result of the loss of normal atrial muscle contractions. In stretching, the atrium’s matrix of cellular alignment is interrupted, leading to tissue fibrosis and anisotropy, or cell-to-cell electrical mismatch. Anisotropy, in turn, makes the heart more likely to remain in AF. Therefore, management of the complex condition of AF is not accomplished via a single treatment, but rather a variety of therapies (e.g. treatment of heart rhythm, heart rate, blood pressure, and sleep apnea) to reach a common goal.⁶⁴

AF ablation follows a similar pattern, with a variety of technologies and techniques required in multiple configurations in the effort to ameliorate the arrhythmia.

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⁶⁴ Broadly speaking, the goal is typically a cure for AF. However, the notion of a cure is fraught, owing to the varieties of patient and clinician experiences and expectations, and the constituent body of knowledge that is continually evolving and adapting. Due to the complex adaptive natures of AF and AF ablation, one may conceptualize the therapeutic approach with AF much like William James’s (1897) notion of the varieties of religious experience as many paths up a common mountain.
The complex adaptive system, therefore, is an apt model to understand the behavior of the heart and its treatment, as well as the behavior of heart science. The knowledge system and practice of AF ablation can be understood as a complex adaptive socio-technical system comprising scientific knowledge, technology, and practice technique that interrelate and affect one another’s structure and function in a nonlinear fashion. These effects contribute to self-organization of the complex system. By understanding the AF ablation system as a complex adaptive system, it becomes possible to design system interventions that are more likely to work effectively in the context of the extant system, and to understand the ways that introducing particular system interventions are likely to affect the system.

The AF ablation system includes component parts of social and technological elements that interrelate in order to accomplish the work of the system. The impact of a single ablation procedure relies on the particular marriage of technology, technique, and skill in a single patient with a unique heart. The complexity of AF ablation interacts with the complexity of the disease itself and of the person in which the disease occurs. Ablation is also informed by a constantly evolving body of formal scientific knowledge (discussed in Chapter 3), as well as professional knowledge-practice paradigms (discussed in Chapter 4) in the context of social and institutional norms and expectations. Therefore, there is inherent complexity and uncertainty to the exercise and outcomes of AF ablation at the level of the individual procedure and at the level of the field writ large.

The AF ablation system has complex adaptive system qualities that differentiate AF ablation from other AF-related therapies. For example, the Watchman left atrial appendage occlusion device is a therapeutic intervention for the prevention of stroke.
related to AF (Figure 14). The Watchman device is fixed into the left atrium at the opening of the left atrial appendage in order to prevent blood clots from exiting that part of the heart to cause a stroke. Once inserted, the Watchman device becomes incorporated into the lining of the heart by the process of epithelialization, or the heart’s lining growing over the device. Otherwise, the Watchman device is inert in the heart. The Watchman does not adapt to the heart, nor – beyond epithelialization – does the Watchman cause the heart to adapt its anatomy or physiology. Watchman device therapy is complex, but does not cause adaptation in the system.

Figure 14. Graphic illustrating the Watchman left atrial appendage occlusion device (Watchman device help prevent strokes, 2006).

In contrast, AF ablation causes adaptation in the system. AF ablation introduces new scar tissue into the heart that impacts the ways that electrical signals form and transmit throughout the heart. In some cases, the ablation scar tissue heals and regains the ability to conduct electricity, so that the ablation is rendered ineffective. In other cases, persistent ablation scars change the way that the heart muscle pumps by changing
electrical contraction pathways throughout the heart muscle, or by reducing arrhythmia so that the heart muscle regains the strength and organization that it had lost due to a state of persistent arrhythmia. The physiological outcomes of AF ablation are complex, and do bring about adaptation in the system. AF ablation is itself a system, as a system is an integrated whole of its component parts, rather than a collection of isolated components in simple causal relations (Laszlo, 1996).

In addition to being complex and adaptive, AF ablation is also intrinsically intelligent. AF ablation is performed by individuals who make informed choices about how and where ablation lesions are positioned inside the heart. For example, one informant, who typically performs complete pulmonary vein isolation, curtailed ablation lesions in one patient in order to avoid creating an atrio-esophageal fistula. Therefore, one pulmonary vein remained partially electrically connected to the atrium (field notes, August 31, 2015). One physician who performed additional rotor mapping and ablation (Chapter 4) provides another example of intelligence in the AF ablation system. His technical approach deviated from the usual in response to an unusual finding in one patient, and informed by his prior accumulated ablation experiences. These choices inject intelligence into the AF ablation system. As the choices account for formal literature as well as accumulated lived experience that shifts in response to each new ablation procedure, the informed choices are adaptive. Therefore, ablation for AF is a socio-technical system that may be represented as an intelligent complex adaptive system (Bennett & Bennet, 2004) with relevant subsystems at the level of the individual practitioner, the interdisciplinary team, and the broad professional field. As such, the processes of knowledge creation and communication must be understood in the context
of complex adaptive systems. This framing will afford insights regarding opportunities for interventions to integrate the knowledge system in an effort to improve innovation.

The AF ablation knowledge system is complex and adaptive, just as the phenomenon of AF itself and the AF ablation procedure are both complex and adaptive, as we have seen throughout this section. In turn, any effort to perturb the AF ablation knowledge system with a goal of improving innovation and its resulting outcomes must consider the complex and adaptive qualities of the system in order to effect a meaningful change. Two key emergent properties of a complex adaptive system are that it has permeable boundaries between nodes, and that it operates optimally at the edge of chaos (Bennett & Bennet, 2004). Interventions to the system should be aligned with these emergent properties of complexity and adaptation.

The case of clinical practice registries offers an example of failure to align a system intervention to the system’s properties. Clinical practice registries purport to gather experiential data from across a community of practice in order to inform research and knowledge. Such registries exist for a variety of complex cardiovascular procedures, including angioplasty, bypass surgery, and implantable cardioverter-defibrillators (ICDs, American College of Cardiology: National Cardiovascular Data Registry, n.d.). However, these registries try to capture complex knowledge in simple data fields, and the registries do not adapt to changing contexts. As a result, practice communities are highly critical of registry outputs for inferential research questions. For example, a 2011 paper declared that nearly one quarter of ICD implantations in the U.S. were not evidence-based, according to registry data (Al-Khatib et al., 2011). This paper was deeply criticized as misrepresenting the complexities of real-world practice, and led to criticisms that the
regulatory criteria and practice guidelines fail to adapt to emerging evidence or patient considerations (Hohnloser & Israel, 2013; Kusumoto et al., 2014; Steinberg & Mittal, 2012).

It is also important to acknowledge that complex problems cannot be solved simply by applying more information. Therefore, the AF ablation knowledge system does not simply require more inputs into the extant system. Rather, the structure of the system must be modified to allow complexity to inform the system.

In contrast to the intrinsic intelligent complex adaptive system qualities of AF ablation, the ablation approach itself takes a classical approach to obliterating AF by applying knowledge derived from controlled normal science. The normal science approach effectively isolates the AF condition from other components of the cardiovascular system, rather than taking a systems view that treats AF as an integrated component of the whole cardiovascular system that requires continual management (Laszlo, 1996). Given that AF is inherently a complex and messy problem, the AF ablation approach that attempts to neaten the condition with a single procedure is effectively attempting to apply a normal science approach to a postnormal complex condition. This is an inherently flawed approach to a complex problem, and is doomed to fail (Funtowicz & Ravetz, 1993). Therefore, just as perturbations to the AF ablation knowledge system must align with a systems approach, the AF ablation approach itself should reflect a complex adaptive systems framework.
Social Network Analysis as a Critical Tool

With the structure and function of the AF ablation knowledge system mapped as an actor-network, social network analysis offers a useful approach for evaluating the current knowledge system in order to make recommendations for improving innovation processes. Classical social network analysis takes a local view by mapping social networks on a specific level. In the case of the AF ablation knowledge system, however, local approaches may not yield a meaningful and actionable set of recommendations, particularly as the formal knowledge system exists on an international level, rather than within an individual institution. Therefore, I am using a regular equivalence approach (Borgatti et al., 2013) to social network mapping by creating an aggregate network of nodes based on archetypal professional designations and functional roles (Nadel, 1957) from fieldwork data, and ties elicited from fieldwork data and literature review. For example, rather than mapping individual actors in a single EP lab (e.g. Joe, Mary, Ahmed), I am mapping actors according to their professional role designation (e.g. EP lab nurse, EP lab technician, industry representative, non-thought-leader physician). This approach allows for communication analysis at the level of the professional system in order to make broad recommendations in the context of a simpler, cleaner network, rather than specific recommendations that may be useful in one particular setting but less relevant to the knowledge system as a whole. Defining relationship ties in this way allows the knowledge system network to be mapped and analyzed using social network
analysis technique in the context of an actor-network model. My approach omits some fluidity in understanding complex roles by assigning discrete functional labels to complex human activities. However, I mitigate that omission by acknowledging that a single individual may serve in multiple roles. I accomplish this through regular equivalence modeling, rather than individual-level social network mapping. This choice, in turn, results in the loss of some detail in understanding the full extent of an individuals’ complex set of relationships. However, this level of detail could be elucidated in a secondary mapping exercise in a future research project.

I am using the following professional roles for mapping and analyzing the network: thought-leader electrophysiologists, thought-leader non-ablation physicians, non-thought-leader electrophysiologists, cardiologists (non-EP), basic scientists, industry scientists, industry engineers, non-physician clinicians (EP lab nurses, advanced practice clinicians in EP [nurse practitioners and physician assistants], EP lab technologists), regulatory officials (FDA, CMS), cognizant patients (and family members), patient advocates, insurance providers, industry business entities, industry representatives, and hospital administrators (See Table 3 in this chapter and Table 1 in Chapter 1). Each of these professional and lay roles has relevant regulatory commitments related to practice and privacy.

In the aggregate network, I map directional relationships representing communication in the knowledge system (and lack thereof), and identify measures of centrality that indicate key leverage points in the system (i.e. brokers, highly central

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65 Although social network theory is considered an alternative theoretical approach to actor-network theory for understanding knowledge systems, the analytical tools afforded by social network analysis are not at odds with actor-network theory.
actors) and structural holes representing sites in the system that may provide opportunities for interventions to improve communication throughout the full knowledge system (Burt, 2004; Burt, 1992). There are relevant structural holes in the informal knowledge system as well as the formal knowledge system. Some of these structural hole sites enforce functional silences that have direct implications for advancing the innovation of ablation techniques and technology. Other functional silences are more relevant to broader aspects of the clinical system related to AF, but not related to ablation. For example, in some ways, the patient is silent as an autonomous actor during the ablation procedure. Although this may not be immediately significant for the purposes of the individual ablation procedure, the patient as an object of ablation is functionally silent in terms of the technology innovation system, as the individual patient’s data filters through the reporting lens of the physician and lab report in order to reach the rest of the system. By analyzing the social network analysis data coupled with ethnographic fieldwork data, I can determine whether structural holes lead to silences that are primarily a function of structural arrangements in the network (and thus would be alleviated by a structural intervention), or a deeper cultural barrier in communication that invites a deeper cultural shift in the system. This multilayered analytical approach allows for meaningful recommendations for innovative interventions to give voice where there is presently silence.

As a result of institutional constraints including national and local regulation of professional clinical practice (i.e. scope of practice regulations), data sharing (i.e. Health Insurance Portability and Accountability Act [HIPAA] privacy regulations), and experimental therapeutics (i.e. investigational device regulations), the AF ablation system
can not be a homogenous actor network with the potential for contagion-type flow of communication throughout the full network. Each actor in the network does not have access to all of the same information sources and communication pathways. Instead, each type of actor in the network communicates the portion of information that is available to him, given his professional or lay role and access to communication pathways. As a result, knowledge communication in the network represents coordinated information from multiple actors. A variety of institutional pressures exerted on the network result in a constructed, rather than purely emergent, network. In turn, interventions to the network must be understood in the light of the institutional pressures that undergird the network architecture. For example, although structural hole analysis identifies media professionals as having high power-ratings, the privileged nature of individual patient data and knowledge related to AF ablation does not lend the traditional media role an unfettered path for information flow. Therefore, network analysis findings will be interpreted in light of the particular cultural and regulatory commitments that underscore the structure and function of the network.

AF Ablation Knowledge System Analysis

Formal Knowledge (Sub)System

The formal knowledge system for AF ablation consists of ideas and power enacted in peer-reviewed literature, conference presentations, and regulatory dispatches. This content is generated by a small proportion of professionals who make up a small community of mostly academic physicians among the larger multidisciplinary field of
professionals contributing to the care of patients with AF. The formal knowledge system consists of the ecosystem of deliberate research experience, as opposed to spontaneous observational experience, that is captured and codified in the peer-reviewed literature as journal manuscripts and conference proceedings. Both of these communication forms are regulated by peer-review processes administered by contributory experts, and form the basis of evidence that drives the innovation system for new technologies and techniques. The FDA and CMS in the United States, and corollary European structures (e.g. European Commission, National Institute for Health and Care Excellence [NICE]), rely on this formal knowledge for technology approval and payment coverage determinations. The formal knowledge system also includes experiential knowledge from so-called thought leaders – individuals who are contributory experts to the research processes composing the formal knowledge system. Thought-leader experiential knowledge is conveyed in the peer-reviewed literature as observational case reports of first-in-human experiences, as well as in presentations at professional scientific conferences.

**Formal knowledge network map.** In this map of the formal knowledge system (Figure 15), the network is represented as a binary, directed system. Red arrows represent unidirectional ties between nodes. These ties reflect communication that typically flows in only one direction between nodes. For example, government-regulatory dispatches directly inform the work of industry business professionals, but industry business professionals do not (or, more accurately, should not) directly inform government-regulatory dispatches. Blue arrows represent reciprocal ties between nodes, including reflexive ties within a single node. For example, thought-leader EPs both inform, and are
informed by, the patient as an object of ablation. Similarly, thought-leader EPs both inform, and are informed by, conference abstracts. I constructed the formal knowledge system based on the formal regulatory literature, participant observation, and interviews with thought-leader EP physicians, scientists, non-thought-leader EP physicians, industry professionals, professional advocates, and regulatory officials.
Figure 15. Formal knowledge system map with binary directed data showing unidirectional ties in red and bidirectional ties in blue.
**Formal knowledge network analysis.** There are many unconnected actors in the formal knowledge system network (Figure 15). There is a moderate level of network density within the main connected component of the network, suggesting that there are few critically irreplaceable players in this network (Figure 15). However, considering all of the nodes in the complete AF ablation network, the formal network does not connect many of them as part of the main component. Therefore, the overall density of the formal knowledge system network is fairly low, with only 7% of the possible connections actually present in the system (0.069; Table 4). This low density suggests that a change in a few nodes in this network would yield a significant shift in information flows. Noting the unconnected nodes, there are many silent actors in the formal knowledge system, representing failure of the formal knowledge system to hear these actors.

Table 4

*Formal Actor Network Density, adapted from UCINet*

<table>
<thead>
<tr>
<th>Density</th>
<th>No. of Ties</th>
<th>Std. Dev</th>
<th>Avg Degree</th>
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<tbody>
<tr>
<td>0.069</td>
<td>84</td>
<td>0.253</td>
<td>2.400</td>
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The thought-leader EP has the most individual connections in the formal knowledge network (n=21; Table 5) with the highest number of reciprocal connections (n=8; Figure 15). More unidirectional connections from the thought leader EP are directed outward (3 of 5; Figure 15), suggesting that the thought leader has the ability to inform and impact most of the sources of information that contribute to his deliberate research and innovation activities. However, the thought-leader EP does not allow reciprocal informant information from some of the sources he informs, contributing to
silences in the formal knowledge system. This suggests that thought-leaders form a relatively closed community that is less susceptible to perturbation and change from emergent external factors, compared to other groups that exhibit more inward-directed and reciprocal ties (Douglas & Wildavsky, 1982).

Betweenness centrality reflects other centrality measures in the formal knowledge system. The thought-leader EP has the highest degree of betweenness centrality (96.457; Table 5), followed by the professional society (58.925; Table 5). The professional society has nearly as many connections as the thought leader EP (n=17; Table 5), but fewer reciprocal connections (n=4; Figure 15) and fewer recipients of information, or outward connections (n=7; Table 5). The unidirectional ties with the professional society are equally directed inward and outward to the society. This suggests that the professional society does not have full access to all of the information sources that inform its work as a contributor to the innovation system, nor does the professional society afford open communication access to all of the constituents it informs. Considering the formal system alone, these findings suggest an opportunity for the professional society to increase open communication access to its constituents. However, I am considering the informal knowledge system as well. Therefore, I will return to discuss potential interventions later, in the context of the full system.

Other secondary nodes with relatively high network betweenness centrality in the formal knowledge system include the FDA (34.956; Table 5) and conference abstracts (39.614; Table 5). The FDA has a higher degree of network prestige (indegree centrality = 8) than direct influence (outdegree centrality = 5; Table 5). Conference abstracts have identical measures of prestige and influence (n=6; Table 5). This suggests that conference
abstracts may be a communication modality or technology target that is potentially well positioned for meaningful knowledge communication.

Table 5

*Formal Actor Network Centrality.*

<table>
<thead>
<tr>
<th>Category</th>
<th>OutDegree Centrality</th>
<th>InDegree Centrality</th>
<th>Betweenness Centrality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thought Leader EP</td>
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<td>10</td>
<td>96.457</td>
</tr>
<tr>
<td>Non-Thought-Leader EP</td>
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<td>3.883</td>
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<td>Thought-Leader non-ablation</td>
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</tr>
<tr>
<td>Media Professional</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EP Lab Nurse</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EP Lab Technician</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Industry Rep in Lab</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Industry Business Manager</td>
<td>3</td>
<td>7</td>
<td>5.593</td>
</tr>
<tr>
<td>Industry Engineer</td>
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<td>6</td>
<td>7.112</td>
</tr>
<tr>
<td>Basic Scientist</td>
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<td>3</td>
<td>11.988</td>
</tr>
<tr>
<td>EP NP/PA</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-EP Cardiologist</td>
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<td>0</td>
</tr>
<tr>
<td>Cognizant Patient and Family</td>
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<td>0</td>
<td>0</td>
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<tr>
<td>Primary Care Provider</td>
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<td>0</td>
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<td>Hospital Administration</td>
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</tr>
<tr>
<td>Insurance Provider</td>
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<td>3</td>
<td>0</td>
</tr>
<tr>
<td>FDA</td>
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<td>8</td>
<td>34.956</td>
</tr>
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<td>CMS</td>
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<td>4</td>
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<tr>
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</tr>
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<td>Social Media – De-central Sources</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>Meeting Presentations</td>
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<td>18.481</td>
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<td>Conference Abstracts-Posters</td>
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<td>39.614</td>
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<td>0</td>
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<tr>
<td>Industry Meetings-Dinners</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Patient as Object of Ablation</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Lab Technologies</td>
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<td>5</td>
<td>11.445</td>
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<td>Procedure Notes</td>
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<td>0</td>
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<tr>
<td>Standard Operating Procedures</td>
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<td>0</td>
</tr>
<tr>
<td>Meeting Sidebar Conversations</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Note. Adapted from UCINet. Individual actors are shaded in blue. Institutional actors are shaded in purple. Technology actants are shaded in peach, as listed in Chapter 5, Table 3. OutDegree Centrality is the number of communication ties directed outward from a given node. InDegree Centrality is the number of communication ties directed into a given node. Betweenness Centrality reflects the number of times that a given node connects other nodes in the network that would not otherwise be unconnected.

**Informal Knowledge (Sub)System**

The informal knowledge system for AF ablation exists in concert with the formal knowledge system. Whereas the formal knowledge system is captured, codified, and communicated in the peer-reviewed literature, the informal knowledge system is communicated by direct experience or word-of-mouth only. The informal knowledge system does not include formal research data, but rather consists of experiential and tacit knowledge generated by practitioners in the field who make use of the literature and thought leader inputs by applying and evaluating formal knowledge in practice. These are the physicians and other professionals who practice AF ablation but do not publish their experience, either because of time or access restrictions that prevent them from contributing to the formal knowledge system. For physicians and other clinical professionals, the rigors of daily clinical practice outside of academic settings are generally structured around maximal output of patient care without time built in for conducting research or writing reports for the literature. The informal knowledge system
also embodies the individuals and institutions that enable and constrain the practice of AF ablation.

**Informal knowledge network map.** The informal knowledge system (Figure 16) was constructed based on participant observation, as well as interviews with thought-leader EP physicians, non-thought-leader EP physicians, non-physician clinicians, and industry professionals. The informal knowledge system map uses the same component construction as the formal knowledge system map.
Figure 16. Informal knowledge system with binary directed data showing unidirectional ties in red and bidirectional ties in blue.
Informal knowledge network analysis. In the informal knowledge system, the only unconnected actor is the basic scientist (Figure 16), who is well connected in the formal knowledge system (Figure 15). Otherwise, the informal knowledge system has double the network density than the formal knowledge system (0.136 [Table 6] compared to 0.069 [Table 4]), by including more actors in the main network component and involving more ties (166 [Table 6] compared to 84 [Table 4]).

Table 6

Informal Actor Network Density, adapted from UCINet

<table>
<thead>
<tr>
<th>Density</th>
<th>No. of Ties</th>
<th>Std. Dev</th>
<th>Avg Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.136</td>
<td>166</td>
<td>0.342</td>
<td>4.743</td>
</tr>
</tbody>
</table>

Whereas the thought-leader EP and professional society were the most densely connected nodes in the formal knowledge system (Figure 15), the non-thought-leader EP is the most central actor in the informal knowledge system by every measure of centrality (Table 7), with the broadest diversity of information sources (n=20; Table 7).

Table 7

Informal Actor Network Centrality.

<table>
<thead>
<tr>
<th></th>
<th>OutDegree Centrality</th>
<th>InDegree Centrality</th>
<th>Betweenness Centrality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thought Leader EP</td>
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<td>2</td>
<td>37.083</td>
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<tr>
<td>Non-Thought-Leader EP</td>
<td>16</td>
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<td>333.337</td>
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<td>Thought-Leader non-ablation</td>
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</tr>
<tr>
<td>Media Professional</td>
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<tr>
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</tr>
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<td>Industry Rep in Lab</td>
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<td>65.165</td>
</tr>
<tr>
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<td>7</td>
<td>9</td>
<td>73.198</td>
</tr>
<tr>
<td>Role</td>
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<td>InDegree</td>
<td>Betweenness</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Industry Engineer</td>
<td>4</td>
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</tr>
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<td>Basic Scientist</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EP NP/PA</td>
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</tr>
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<td>4</td>
<td>8.308</td>
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<td>Lab Technologies</td>
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<td>7</td>
<td>34.961</td>
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<td>Procedure Notes</td>
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</tr>
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<td>Standard Operating Procedures</td>
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<td>Meeting Sidebar Conversations</td>
<td>2</td>
<td>2</td>
<td>60.000</td>
</tr>
</tbody>
</table>

Note. Adapted from UCINet. Individual actors are shaded in blue. Institutional actors are shaded in purple. Technology actants are shaded in peach, as listed in Chapter 5, Table 3. OutDegree Centrality is the number of communication ties directed outward from a given node. InDegree Centrality is the number of communication ties directed into a given node. Betweenness Centrality reflects the number of times that a given node connects other nodes in the network that would not otherwise be unconnected.

The highly central non-thought-leader EP physician (Figure 17, #4) is accompanied by a cluster of similarly central actors including the EP lab nurse (Figure
17, #6), EP lab technician (Figure 17, #7), EP NP/PA (Figure 17, #12), and industry representative (Figure 17, #8), along with hospital administrators (Figure 17, #3), who exhibit highly similar connections in the informal knowledge network. All of these actors with similar connections are clinically engaged with the patient and the AF ablation procedure itself.

Figure 17. Dendrogram showing similarity among clinicians directly performing AF ablation, including non-thought-leader EP, EP lab nurse, EP lab tech, EP NP/PA, as well as industry rep and hospital administration.
The patient – both conceived as a cognizant actor along with family members (Figure 17, #15) and as the object of the ablation procedure (Figure 17, #14) – is less similarly connected than the clinicians, and less central than clinicians with regard to indegree and outdegree centrality (Table 7) and plotted location in the network map (Figure 16), even though the patient is the central focus of the ablation activity. Though less central than clinical actors in network analysis, the patient as a cognizant actor has a high degree of betweenness centrality (169.269; Table 7). This finding suggests that the patient, along with family, is a potentially important conduit of information for clinical practice.

The dendogram\textsuperscript{66} also demonstrates a few other sets of nodes with highly similar connections, including professional societies (Figure 17, #32) and private insurance coverage decisions (Figure 17, #23); meeting presentations (Figure 17, #26) and thought-leader electrophysiologists (Figure 17, #2); industry publications (Figure 17, #29), industry engineers (Figure 17, #10), and industry business entities (Figure 17, #9); and cognizant patient/family (Figure 17, #15) and non-EP cardiologists (Figure 17, #13). It is interesting to note that three of these four smaller cliques comprise different actor types (e.g. individual, institutional, and technology). It is also interesting to note that the industry representative (Figure 17, #8) is not situated close to the industry clique actors (Figure 17, #29, #10, #9), suggesting that the industry representative is a particularly unique actor in the network, when accounting for the legal, regulatory, and corporate

\textsuperscript{66} Although a fully symmetrical approach would indicate that a similar dendogram from the formal knowledge system should be analyzed, the formal knowledge system does not reflect AF ablation practice delivery. Therefore, it is not likely to yield meaningful insights for improving the knowledge system and future innovation. With this in mind, I am not including a dendogram of the formal knowledge system in this analysis.
alignments associated with that role. I will return to consider the industry representative’s position in the context of recommendations to improve communication in the knowledge system.

The nonclinical, non-procedural nodes in the informal knowledge network are less densely connected to the network and to one another than the clinical, procedural nodes (Figure 16; Table 7). This suggests that there may not be a robust infrastructure to communicate clinical, non-research information throughout the AF ablation knowledge system outside of the direct EP laboratory environment, or even between EP lab environments. In addition, the input nodes to the majority of the EP lab environment actors (other than the physician, who has a broader diversity of inputs) are industry-sponsored nodes, as opposed to peer-reviewed resources or governmental resources (Figure 16). This suggests that industry has a particularly powerful and influential position to control knowledge in the EP lab clinical environment. This impression, emergent from other observational evidence, is reinforced by formal network analysis. The industry business manager and industry representative in the lab exhibit relatively high betweenness centrality in network analysis (73.198 and 65.165, respectively; Table 7). This finding is problematic, given the potentially conflicting goals of industry nodes where proprietary interests may outweigh the value of scientific knowledge or clinical patient outcomes, except as they explicitly support proprietary goals. Moreover, proprietary goals may explicitly privilege knowledge protection over knowledge sharing, which introduces obstacles to optimal knowledge mobilization throughout the knowledge system. This suggests that industry nodes effectively form a structural hole that invites alternative strategies for knowledge transmission in the clinical component of the
informal knowledge system. As with observations regarding the formal knowledge system, I will return to this point following full system analysis.

**Combined Formal and Informal System**

Using multiplex network analysis, I combined the formal and informal AF ablation networks to yield a graphic representation of the full AF ablation knowledge and practice network (Figure 18). As with the informal knowledge network, the non-thought-leader physician and other clinical actors (i.e. EP lab nurse, EP lab technician, EP NP/PA, industry representative) are highly connected with bidirectional ties in the combined system. Non-clinical actors (i.e. non-peer-reviewed journal articles, insurance providers, and media professionals) are on the periphery of the network with only unidirectional ties.
Figure 18. Full knowledge system, representing joined formal and informal binary directed actor networks as a multiplex graph with unidirectional ties in red and bidirectional ties in blue.
The complete knowledge system graph is generated by multiplex matrix data from the joined matrices of the formal and informal knowledge systems that affords a deeper level of analysis beyond the mere presence of unidirectional and bidirectional ties (Figure 19). The matrix demonstrates whether each possible directed tie was present in either or both of the constituent knowledge systems that compose the full AF ablation system. A small proportion of the possible ties in the network (25 of 1,225: 2%) are present in both the formal and informal subsystems of the AF ablation knowledge system. For example, non-thought-leader EP physicians contribute to conference abstracts in both the formal and informal subsystems of the full knowledge system. The communication paths that already exist in both subsystems provide a potential opportunity to use existing institutional and social structures for a system intervention, so that an intervention would not require a structural system change in order to activate. It may be potentially more attainable to unify systems at these common points.

In contrast to the common nodes in the combined knowledge system, many actors relevant to technology innovation for AF ablation are silent in the formal knowledge system (notated as 0 or 1 in the combined system matrix, Figure 19). In addition to formal literature, the broader professional discourse that contributes to the formal knowledge system includes editorials, conference proceedings, and expert consensus statements. This broad professional discourse typically minimizes or excludes potentially significant relevant user groups including healthcare providers in non-academic settings, patients who do not undergo AF ablation because providers do not recommend the procedure, and patients who choose to avoid AF ablation. Therefore, there remain potentially significant but unquestioned silences in the innovation system for AF ablation.
(represented by 0 on the multiplex network matrix, Figure 19), as well as significant mismatches between included knowledge (represented by 2 and 3 on the multiplex network matrix, Figure 19) and excluded knowledge in the professional innovation discourse (represented by 1 on the multiplex network matrix, Figure 19). As a result, priorities outside of the formal system are not captured, translated, or included in the innovation process in order to improve treatment for AF. This is a particularly significant problem for physicians who are not recognized as thought leaders in the AF ablation system. Given that AF ablation requires specific configurations of technology and technique, coupled with significant individual skill, this silence signals a potentially significant hole in the innovation system. All relevant voices are not uniformly heard and captured throughout the modes of work that characterize the practice of AF ablation.
Many professionals and lay individuals involved in AF ablation are silent in the formal professional discourse and innovation system as a result of structural features of the formal knowledge system. These actor groups (pictured in the formal knowledge system network map, Figure 15, as unconnected nodes) include patients and their advocates, and clinical providers across the spectrum of clinical disciplines.
including non-thought-leader physicians, advanced practice clinicians, industry representatives, nurses, and technicians. This category of silent actors in the formal knowledge system also includes clinical research coordinators, and non-governmental payers who are not portrayed in my mapping, as they do not contribute de novo knowledge or translation of knowledge related to AF ablation. Basic scientists, along with clinical research coordinators, are similarly silent in the informal knowledge subsystem (Figure 16).

Silences in the full AF ablation knowledge system run deeper than the formal and informal knowledge systems accounting of non-connected nodes (Figure 19). The knowledge system map of the full AF ablation knowledge network (Figure 18) shows that every node has at least one inward or outward directed tie. However, careful observation of the AF ablation system reveals nonusers in the system who have only inward ties. They receive communication from the knowledge network, but do not contribute communication to the innovation network, particularly with regard to the AF ablation procedure. Using the feminist framing of silences these non-users fail to speak (Fishkin & Hedges, 1994). With this combined, or full, knowledge system framework portrayed, it is clear that the majority of actors in the informal knowledge system are silent in some way,

Much of the communication in the AF ablation system is unidirectional (red lines on the knowledge map, Figure 18, so that there is non-communication in the opposite direction. For example, non-research ablationists receive communication from academic research physicians via journals and live presentations at scientific conferences. However, research physicians do not receive return communication from non-
researchers, either via journal publications or direct conversations (TL-2, March 14, 2015; NTL-2, June 17, 2015; TL-1, June 25, 2015). Therefore, the relation is unidirectional from thought leader to non-thought leader. Enacted silences like this represent opportunities to enhance communication toward a goal of improving the innovation system.

As a result of the core set of thought leaders effectively dictating to the innovation system to the exclusion of knowledge generated outside of the core set, the lived expertise of the many who compose the informal knowledge system is lost. Therefore, giving voice to silences in the full knowledge system via improved communication pathways may accelerate innovation in ablation technology and technique, to continue the co-development of knowledge toward the goal of obliterating AF. For example, including inputs from non-thought-leaders, non-physician clinicians, industry representatives, and patients may yield valuable insights for exploration. It is also important to acknowledge the potential for cacophony with additional knowledge inputs to the system. Therefore, innovation recommendations must be designed to preserve the clarity and utility of additional knowledge inputs. Moreover, understanding that not all actors in the system share common knowledge, practices, or understanding, innovation recommendations must attend to the need for meaningful interdisciplinary knowledge translation.

Opportunities for System Innovation and Optimization

Understanding the AF ablation knowledge system as a network allows for organized observations about where power and influence resides among actors in the
network, and where silences and holes in the network presently stem communication. Just as the cardiovascular system requires unobstructed flow of oxygen in order to function properly, the AF ablation knowledge system must function without blockages or gaps in the information flow in order to optimize therapeutic gains in the field. The bibliometric observation about AF ablation thought leaders as an elite, self-sustaining, self-referencing group in the formal literature is reinforced in observations of informal communication. Even the non-elites who interacted with thought-leaders at the ACC session were those in formal training programs with the thought-leader elites, and thus poised to benefit from the ethnocentric publishing practices observed in the formal literature. Network analysis shows that elites’ ideas are communicated throughout the network, but the flow of new ideas from non-elite groups is limited.

Moreover, understanding the AF ablation knowledge system as a complex adaptive system affords insights into the ways that existing communication patterns influence the work of the system. These insights, in turn, suggest ways that changes may be helpful to optimize the work of the system according to complexity science. For example, complexity science tells us that a greater volume and diversity of inputs can increase the resilience of the system, and the health of a system is directly afforded by its ability to converse with, and respond to, changes in the environment. Therefore, mechanisms to afford reciprocal or bidirectional communication ties more broadly throughout the network will ultimately strengthen the knowledge system.

Social network analysis offers three approaches to strengthening the knowledge system. First, leverage highly central nodes with high potential for power and influence. Second, highlight points of silence in the network that should be afforded opportunities
for communication. Third, identify structural holes in the network as opportunities to fill the silences, accounting for extant cultural patterns of power and influence that may or may not be already enacted by centrality measures (as noted in the first point above). With this framing in mind, network analysis suggests some opportunities for interventions to improve innovation in the AF ablation knowledge system.

**Individuals**

The team-based suite of clinical professionals who work directly with the technology in practice holds a high degree of inward influence in the network. This group of professionals, therefore, is well positioned to influence technology use and development/innovation. Within this team, there is an opportunity to improve sharing among non-thought-leader clinical teams by instituting a routine debriefing process. Multiple respondents said that although they routinely develop patterns of practice around and during AF ablation procedures, there is no formal procedure to debrief after a case in order to extract learning points from an individual experience. One clinical engineer told me that although his team routinely reflects on the procedure after an ablation case, the practice is not codified or captured. He said, “They’re purely anecdotal, and it would be wonderful conversations [sic] to mine for actual information. But that’s not being collected” (EPT-1, 3 June 2015). Such team-level knowledge capture would facilitate outward communication from the multiple professionals who contribute to the ablation procedure, through the more highly connected conduit of the physician ablationist who is a more central figure in the knowledge network. This would effectively centralize the codification of knowledge at the level of the individual patient, thus placing
the patient (albeit as an object of ablation, rather than the cognizant patient) at the center of the knowledge generation system.

Outside of the direct team in a single institutional setting, it would be beneficial to improve the non-thought-leader communication between institutions. In general, network analysis demonstrates that non-thought-leaders are highly central actors in the full AF ablation knowledge network by every measure of network centrality and structural holes. Therefore, it follows that the knowledge network would benefit from the creation of opportunities to for non-thought-leaders to capture and share their AF ablation knowledge.

One additional finding from individual-level node analysis in the network is that patients as cognizant participants in AF ablation (as opposed to patients as technical objects of ablation procedures) exhibit a high degree of betweenness centrality, suggesting the possible benefit of an increased role potential for the patient to act as a key communicator in the network.

**Communication Technologies**

In the full network analysis, communication technologies did not emerge as being highly central to suggest strong influence or prestige in the network. However, social media sources have a low positive outward Bonacich power score $^{67}$ (114.045) and moderately low positive inward Bonacich score (338.792). These scores suggest the

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$^{67}$ Bonacich scores indicate an actor’s power in a network as a function of the network centrality of the actor’s network associations. Positive scores indicate ties to highly central network actors. Negative scores indicate ties to highly non-central network actors. In this case, the positive scores for social media indicate ties to central network actors.
potential to be a relatively powerful local node for outward communication in the network with a more global role for inward communication. Therefore, there is an opportunity to use social media technologies in order to mobilize the communication that is presently enacted through meeting sidebar conversations and the patient as an object of ablation.

Sidebar conversations – those unprepared, non-presentational comments that reflect lived experience – are highly important at the level of individual AF ablation practice, but presently not captured or codified in the system. Noting that these comments are effectively unprocessed, similar to raw data, there may be value in leveraging data sharing technologies (like social media that presently languishes on the periphery of the AF ablation knowledge network) in order to aggregate these unprocessed experiences, with the potential for future analysis and learning of a robust body of knowledge. Similarly, more granular ablation case-level raw data could be de-identified and aggregated in a bio-information bank to allow for population-level analysis. This is distinct from the present practice of clinician-reported registry data, as raw data may allow for population-level big data discovery that is not apparent at the level of the individual patient.

Finally, conference abstracts and posters appear in all knowledge subsystems as a valued source of information among physicians. This information-sharing modality presents a familiar structure that may be leveraged to facilitate communication in new ways.
Institutions

Social network analysis demonstrates that among institutions engaged in the AF ablation network, professional societies are highly central actors with a particularly high level of in-degree centrality, which confers potentially significant prestige influence in the network. In addition, the professional society has the highest betweenness centrality of any institution in the AF ablation knowledge system, indicating its potential to act as a boundary organization to join different ways of knowing in order to co-produce interdisciplinary actions (Feldman, Khademian, & Ingram, 2006; Guston, 1999; Guston, 2001; Jasanoff, 1990; Miller, 2001). Based on network structural hole measures for the existing practice of AF ablation, thought leader physicians, non-thought-leader physicians, and professional societies have the largest effective size networks with EP nurse practitioners/physician assistants close behind. Physicians and EP nurse practitioners/physician assistants are the largest constituent group of the professional societies, suggesting that the institutional embodiment of these actor groups may offer an opportunity for system change. Professional societies also have a high degree of betweenness centrality in the existing AF ablation network, supporting its potential as a key leverage point.

The other institution that is presently under-used as an institution or a technology is the traditional media, which is presently not cited as a source of influence, but is positioned to be a powerful tool for communication. Along with the professional society, traditional media sources have highly efficient networks based on structural hole analysis. Therefore, social network analysis suggests that there is room to leverage the prestige of the professional society, and use the opportunity to increase the role of traditional media
professionals to facilitate knowledge communication. Professional societies and traditional media together may offer institutional opportunities to improve communication throughout the system.

**Regulatory Context**

In order to pursue knowledge system optimization opportunities in a meaningful way, it is important to consider the extant legal and regulatory environment in which the knowledge system functions. Any recommendations to improve the knowledge system for innovation must either fit into the existing regulatory framework, or address the need for policy changes to legal and regulatory structures in order to accommodate the recommended innovations. Chapter 6 will examine the innovation recommendations from this social network analysis, along with historical literature analysis and ethnography from chapters 3 and 4, in the particular context of the US healthcare system.
CHAPTER 6

INNOVATION RECOMMENDATIONS IN THE U.S. HEALTHCARE SYSTEM

CONTEXT

This project used multiple approaches to study the AF knowledge system. The views from each of these approaches offered a series of findings that, combined, suggest opportunities to improve the AF ablation knowledge system. Knowledge is linked to learning, which is linked to innovation. Each of these components – knowledge, learning, and innovation – can be represented as a system; each theoretical system shares the same components (i.e. actors and communication ties), but with slightly different the aims and outputs for system facet. Nonetheless, by improving the knowledge system, it will be possible to improve learning and innovation in order to ultimately ameliorate AF. This chapter briefly reviews the findings from historical literature review, ethnographic fieldwork, and social network mapping to evaluate ways in which the present practices surrounding AF catheter ablation do and don’t reflect effective innovation cultures. What, then, to make of these findings? Based on the research for this project, and informed by my 15 years in clinical cardiac electrophysiology practice, I have identified sites to intervene in the existing system to make it work better for knowledge, learning, innovation, and ultimately, for patient outcomes. I present six opportunities to support, augment, or change existing practices in order to optimize a climate of innovation in the context of contemporary U.S. healthcare and biomedical technology regulatory policy.
Research Findings

Historical Literature Review

The historical literature review revealed two major findings: AF ablation requires a triple helix of knowledge streams comprising science, technology, and technique; and it is valuable to revisit old data through the lens of new knowledge. First, progress and innovation for AF ablation requires three streams of knowledge: science, technology, and technique/practice. These three streams interact in continuous and nonlinear ways over time with recurrent and dynamic impacts on one another. Therefore, innovation in AF ablation requires continuous and interactive inputs from all three sectoral streams of science, technology, and technique/practice. Moreover, cross-pollination between knowledge streams yields insights and innovation opportunities that would not be realized from a single stream in isolation (Johansson, 2006). Beyond separate intellectual traditions, each stream also works with a unique lens that filters and prioritizes data publication and dissemination in line with its worldview, including disciplinary knowledge interests regarding what is or is not important, along with data interpretation through particular lenses for political gains. As a result, some knowledge is unavailable to other sectors owing to disciplinary filtering and interpretation. Therefore, AF ablation

68 This finding is consistent with the Silicon Valley innovation firm IDEO, which operates with the idea that innovation requires multiple faces, personalities, or approaches to work in concert. One individual does not naturally possess all of the requisite qualities to undertake innovation successfully. Therefore, innovation requires a team (Kelley & Littman, 2005). It is reasonable to extend this concept from understanding the individual as a person to understanding the individual as a sector (i.e. science, technology, technique) such that innovation requires the full team of sectoral thought, rather than progressing via a single sector alone.
innovation efforts should aim to deliberately cross-pollinate knowledge from the three streams, beyond passively including the knowledge streams in the system. An active approach to intersecting and aligning knowledge streams would allow knowledge, learning, and innovation to be aligned between streams, and notably to be aligned with patient outcomes.

In addition to this major finding about knowledge streams, a minor finding – or rather lack of finding – from the historical literature review is that the patient is largely unrepresented in any of the streams that populate the AF ablation knowledge system. This reflects a view of science that has excluded the patient as a source of knowledge for innovation, despite the observation that all AF ablation knowledge is ultimately directed at the patient. By revising the knowledge stream arrangements and expectations for the AF ablation knowledge system, it will be possible to include the patient more explicitly in a system that is available to interdisciplinary learning.

The second major finding from historical literature review is the value in revisiting historical data in light of emerging knowledge to confirm or challenge existing scientific paradigms. We saw this in the case of surgical ablation practices that were empirically effective, but driven by the wrong scientific theory. Therefore, innovation would be supported by mechanisms to capture empirical data in a way that allows future analysis based on new knowledge. Recursive study of empirical data, or data upcycling, would allow researchers to test new ideas against the old empirical data that led to existing paradigms. Beyond offering an opportunity to glean novel insights from new

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69 I am appropriating the term “upcycling,” which refers to the practice of using old objects in new ways. Tree swings made from used tires provide a classic example of upcycling.
knowledge, data upcycling would address a separate, but relevant problem in biomedical technology innovation: the high costs of doing clinical research. By reducing the need for new data collection, data upcycling would effectively reduce clinical research costs. More affordable approaches may expand opportunities for novel hypothesis testing from the current system that is deeply constrained by high costs (Cohen, 2001; Douglas & Wildavsky, 1982).

**Ethnographic Fieldwork**

Ethnographic fieldwork yielded three major findings related to the knowledge-practice transition: trust is necessary to move knowledge into practice, the knowledge-practice transition is similar at every level of the system, and workforce constraints limit research activity. First, trust is a key component in the AF ablation knowledge network and is necessary at every level (i.e. individual, group, and field) to move research-based knowledge into practice. However, trustworthiness is undermined by cultural and institutional arrangements (i.e. core set behavior, monarchical authorship practices, impact factor publishing strategies, workforce time constraints) that give thought-leaders easy access to publishing in peer-reviewed journals, while limiting others’ access. This asymmetry of access to publishing fuels the perception that thought-leaders publish freely to promote their careers, with insufficient concern for the quality of data. In addition, reliance on industry resources to support scientific communications (i.e. industry representatives in the EP lab, industry-sponsored educational programs) may create conflict between scientific and proprietary interests, which further erodes trust. Therefore, there is an opportunity to focus on transparent data in order to buttress the
credibility of individual and institutional knowledge communicators despite potentially competing interests. Opportunities to build trust include using raw data from sensors, and establishing non-industry mechanisms to undertake technological innovation work. One of the key affordances for establishing non-industry mechanisms is funding, which has traditionally restricted non-industry actors’ entrance to the innovation system. Therefore, different types of interdisciplinary and transdisciplinary funding calls from public and private agencies may help to improve access to the innovation system by non-traditional interdisciplinary actors to contribute to the triple helix of knowledge that is necessary for innovation.

The second major finding is that knowledge-practice uptake, or demand-side translation, occurs similarly at individual, group, and field levels. At each level, there is some variation in reliance on a variety of data sources and different approaches to valuing and codifying trust. However, there is a common nested pattern of knowledge-practice uptake with individuals adopting knowledge to practice, leading to group adoption of knowledge to practice, and finally leading to field-level adoption of knowledge to practice. This observation recalls Rogers’ (2003) diffusion of innovation theory, both in terms of observations about innovation diffusion as well as the role of opinion leaders (characterized in the AF ablation community as thought-leaders) to promote innovation adoption. Therefore, it is important to account for all three levels of uptake (i.e. individual, group, and field) in order to make progress in AF ablation innovation.

The third major finding is that workforce constraints limit the capacity to conduct research. This is true for individuals who are primarily practitioners, as well as (somewhat surprisingly) those employed in academic clinical research environments.
Workforce constraints are multifactorial, due to a combination of population increases among the aging segment that represents the largest burden of AF, increased AF diagnosis, increased access to healthcare services afforded by the Patient Protection and Affordable Care Act (2010) and increased burdens of reviewing data from a growing complement of biomonitoring devices (Miller, Ross, Bennett, & Hurlbut, 2016). Declining reimbursements also contribute to workforce constraints by creating smaller economic margins for clinical practice and thus limiting resources to hire additional staff.

Therefore, it is important to create additional and accessible pathways for knowledge contribution. Knowledge contribution pathways must be streamlined to afford robust participation from non-research actors without adding burden to the time and workforce constraints already endemic to clinical practice. The primary existing knowledge pathway for practitioners to contribute exists in the form of clinical registries (e.g. National Cardiovascular Data Registry ICD registry) that are widely used by the electrophysiology community, but are felt by non-research clinicians to be highly cumbersome. For busy practitioners who view the ICD registry as a burden with little impact on practice, the so-called goal of engaging the ICD registry is to complete as little of the data form as possible in as little time as possible. Therefore, data are rarely reported directly by the operating physician. Rather, the clerical duty is often tasked to other team members who may or may not provide accurate data. At present, the National Cardiovascular Data Registry is developing an AF ablation registry (at the request of CMS but without a mandate for participation) that will function similarly to the ICD registry (American College of Cardiology: National Cardiovascular Data Registry, n.d.). As a result many clinical leaders are concerned about limited participation in the registry.
by clinical institutions due to the perceived burden-benefit mismatch, as well as the value of the data that the AF ablation registry will collect. As I write, just prior to the formal launch of the AF ablation registry, few heart rhythm professionals have moved to participate in the new registry.

**Social Network Analysis**

The AF ablation knowledge network can be understood as a complex adaptive system comprising many interconnected parts that exert change on one another and the system as a whole. In complex adaptive systems, resilience is increased by including more inputs into the system. Therefore, by increasing knowledge inputs to the system, resilience in the network should be similarly increased. As the knowledge system is intrinsically a social network, it is logical to use highly central nodes in the network to improve communication. Social network analysis highlighted four major network nodes (or nodal groups) with centrality properties that invite opportunities for system innovation: the clinical care team; the cognizant patient; the professional society and traditional media; and communication technologies.

The clinical care team is directly involved in performing AF ablation procedures in the informal knowledge system. This team includes a heterogeneous mix of interdisciplinary clinicians as well as industry representatives, who are particularly useful conduits for inter-institutional knowledge sharing, though with a caveat of limited trust. Therefore, along with this recommendation to foreground the clinical care team, I recommend a move to codify the industry representative role by establishing a formal set of standards for training, scope of practice, and licensing or registration. Role
codification may help to increase transparency and improve trust in the service of knowledge communication. It is important to maintain open pathways for physician-industry communication in order to advance medical device innovation (Chatterji, Fabrizio, Mitchell, & Schulman, 2008; Gelijns & Thier, 2002). Increased attention to the industry representative role would enhance one such pathway. One possible limitation of increasing the industry representative role in knowledge communication stems from my fieldwork observation that industry representatives typically focus their communication along lines of novel proprietary technologies. This proprietary alignment of data communication may potentially limit learning opportunities by constraining the content of communication throughout the network (Eisenberg & Nelson, 2002; Heller & Eisenberg, 1998). For example, a hospital that only uses St. Jude mapping equipment may not have access to relevant knowledge aligned with Biosense Webster or Abbott Medical technologies. Therefore, it is important to pay attention to these communication structures particularly with regard to proprietary content, because changes in the extant practice environment in terms of technology uptake can affect learning processes (Dosi & Nelson, 2010; Murray & O'Mahony, 2007).

Second, social network analysis indicated that there should be an increased role for the cognizant patient (as opposed to a passive object of healthcare services) as a highly central and uniquely knowledgable actor in the system. The patient’s role in the exercise of healthcare practice has shifted in the last 250 years from being the mere object of the medical gaze in Foucault’s 18th century *clinique* (Foucault, 1973), to the sentient object of a therapeutic effort in Freidson’s relationship with the professional physician (Freidson, 1970). The objectified patient was elevated to cognizant subject
status – albeit a silent subject – in Katz’s study of the doctor-patient relationship (Katz, 1984). Not until the late 20th century crisis of HIV/AIDS bred a generation of activist patients did the patient’s role reach the status of an empowered participant in the healthcare landscape in research, policy, and therapy (Epstein, 1996). Today’s 21st century patient has, therefore, come a long way to her current position as the deliberate center of an interdisciplinary healthcare team that expects her to participate as a team member (Brush et al., 2015).

The healthcare team is highly heterogeneous with regard to technical knowledge and experience. Not all team members possess and use knowledge in the same ways. Similarly, the AF ablation knowledge system is highly heterogeneous representing a wide variety of disciplinary knowledge and technical understanding with complex interactions to inform AF ablation. Just as the EP lab technician may not have the same clinical management knowledge as the NP/PA on the clinical care team, the patient may not have the technical knowledge of the scientists and practitioners in the system. However, the patient has other knowledge gained by lived experience relevant to the ablation procedure. Metcalfe and Ramlogan (2005) proposed that individuals in a knowledge system share correlated understandings, rather than sharing actual knowledge. Therefore, there may be understanding-sharing opportunities to reap by explicitly including the patient as an active learner in the knowledge system.

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70 The AIDS patient activists were preceded by breast cancer activists in the 1970s who paved the way for patient choice to elect therapeutic alternatives to the radical mastectomy (Osuch et al., 2012). Breast cancer activists gave patients a voice that AIDS activists used to achieve participant status in the medical research policy enterprise.
The third group highlighted in social network analysis included the institutions of the professional society and traditional media. These institutions are strategically located to connect multiple actors in the network as boundary organizations. Therefore, professional societies and traditional media should be explicitly leveraged to facilitate communication in the knowledge network.

Fourth, although no communication technologies emerged as highly central actors in the full knowledge network, a few trends suggest opportunities to use three types of communication technologies more broadly. 1) Sidebar conversations were mentioned as key components for individual knowledge exchange, suggesting that unprocessed person-to-person data may be valuable. 2) Social media was not widely utilized, but demonstrated the potential to be a powerful network node. 3) Conference abstracts are well positioned in the formal knowledge system, suggesting that this is a well-established and widely used communication technology.

Taken together, ethnography and social network data suggest that the ability to share unprocessed data and commentary among individuals is useful, and that social media technologies may be a powerful way to accomplish such sharing. In addition, the conference abstract medium is highly valued for formal knowledge sharing among network actors, suggesting that it should be preserved and expanded.

**Innovation Recommendations**

With the above findings in mind, I propose six recommendations for changes to the AF ablation knowledge system to improve knowledge creation and communication,
and enhance AF ablation innovation. Recommendations are summarized in Figure 20 below.

**Figure 20.** Graphic summary of recommendations #1-5 for knowledge system innovation, including the use of unique identifier codes (UIC) to protect privacy concerns of individuals and institutions.

1) **Use Ablation Technologies to Capture Raw Data for Direct Export to a Central Database**

Photographers capture images using raw data in order to preserve the maximum amount of information available for image processing while retaining empirical image data for future reference. Raw data is similarly generated by digital AF ablation
technologies, including mapping and ablation systems. Such raw data, prior to being processed, interpreted, and edited by human actors, may serve as a proxy for so-called real data from an AF ablation procedure. However, raw pre-interpreted data are currently not captured or reported with AF ablation procedures. I propose that raw data can be captured by a common software system that runs on top of proprietary mapping and ablation systems to automatically save and report all measured data from every AF ablation procedure to a common database. These data will create a so-called big data environment representing every AF ablation procedure.

Raw data will provide detailed information about every measured aspect of the patient’s cardiac electrophysiology, along with every action taken by the mapping and ablation team during the procedure. In effect, the granular detail of the case can emerge through raw data, reflecting both the patient’s condition and operator’s technical skill in ways that are not currently captured by reporting systems. Raw data can be used in three ways for the AF ablation case. First, raw data can be included with traditional research publications to demonstrate transparency and improve trust in the data, which may help to improve innovation adoption or knowledge-practice uptake throughout the system. This notion reflects the observation that imperfections in communication and data sharing are often based on imperfect knowledge (Hayek, 1945; Loasby, 1991; Loasby, 1998; Ziman, 1978). Thus, raw data may help to achieve a more perfect set of knowledge for communication and data sharing. Raw data offers advantages compared to registry data

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71 In truth, what I refer to as raw data is not truly raw. The decisions about what to measure and how to measure it, the design of the processing filters used to capture the data, and the particular suite of technologies and settings used to capture and display the data, reflect human choice, design, and intervention.
that undergoes interpretation and filtering by clinicians prior to reporting. By leveraging big data analytics, raw data may yield insights that are not visible from pre-processed clinician-interpreted data alone, as with registry and clinical research data (Moskowitz, Rosenberg, & Gelijns, 1998). Second, automated raw data capture will allow for broadly crowdsourcing inputs from practitioners outside of the formal research system without unduly taxing the already-strained workforce. Third, a central repository of raw data will afford historical data upcycling in light of emerging knowledge in a way that is not currently available.

One significant consideration for this automated capture system is the need to preserve privacy and security for patients, healthcare providers, and institutions. Therefore, a secure privacy system should be incorporated into the root design for the software. This system should include unique identifier codes (UICs) for all individuals and institutions associated with the case. UICs will not be displayed at the point of care, where names will be used as per usual clinical care practices. However, the use of UICs will allow for meaningful individual- and institutional-level data analysis while affording privacy protections in the context of a large multicenter database.

Another significant consideration is that researchers, practitioners, and regulators – the innovation system writ large – will need to be able to make use of the raw data. This innovation will, therefore, require changes in the regulatory bodies to admit, certify, and make use of new types of data in the knowledge and innovation system. This idea merits further attention in future work.
2) Couple Raw Data with a Social Network Where Clinicians Can Add Qualitative Discussions to Their Quantitative Data

Patients Like Me (2016) is an online community that allows patients to share their medical information in a social networking data commons. Data are aggregated to allow patients to identify trends with symptoms and therapies beyond their individual experience, and researchers to study a variety of health conditions using patient-generated real-world data. In effect, Patients Like Me brings a big-data sensibility to the individual patient experience, marrying qualitative and quantitative data so that people can leverage real-world experience beyond their local community to inform their own healthcare decisions.

AF ablation can use the same concept to marry qualitative experiential data to the raw quantitative data using a social networking platform (Figure 20). In effect, the social network will allow participants to add skin to the bones of the raw data. This system will use social media technology to accomplish the qualitative communication that occurs during face-to-face sidebar conversations at annual scientific meetings. However, a social network expands the participants in the conversations to potentially encompass the full complement of those who engage in AF ablation, far beyond the limited scale of the sidebar conversation.

As with recommendation #1 for raw data capture, privacy is a major concern with social networking. Therefore, this communication system, including the point-of-care raw data capture system and social network, should be designed to include security as a central component, including the use of UICs to protect privacy for all individuals and institutions. UICs will be known to the individual but blinded to others; UIC input will be
accomplished via radiofrequency identification ([RFID] or similar) scan that displays individuals’ names at the point of care, consistent with usual clinical care practices. However, the UIC and names will not be directly linkable otherwise through the social network or research platforms, which will display only the codified role name (e.g. nurse, physician, technician, patient, industry representative). In order to ensure privacy protections for patients, clinicians, and institutions, contributions to the social network should be moderated by a multistakeholder group outside of the AF ablation community to ensure that contributed text does not name or otherwise identify particular actors. However, UICs linked to data will allow for multidisciplinary clinicians to contribute to the knowledge. I return to examine privacy implications from a policy perspective later in this chapter.

Given that the usual structure of AF ablation reporting funnels all clinicians’ experiences through the single report of the operating physician, a social network will afford unique inputs from team members that have previously been silent in the procedure reporting system. The social network will be operated by the professional society, which is optimally situated with a high degree of betweenness centrality, particularly between practitioners in the network. As with the recommendation for raw data capture, the social network will afford a single knowledge system encompassing the AF ablation experience. Because of the issues with privacy, as well as a discrete behavior change required for practitioners to engage with the knowledge system, successful implementation of this recommendation will likely require a bigger culture change than recommendation #1. Prioritizing shared values of security and privacy as central design elements will help to facilitate this culture shift (Haudan, 2008).
3) Codify the Role for Industry Representatives Participating in AF Ablation Procedures

Codifying roles will allow the contributions of industry representatives to be captured and counted, both in terms of the healthcare and biomedical technology workforce writ large, and in the proposed UIC set. Including industry representative data will create an additional pathway for physician-industry communication important for innovation processes (Chatterji et al., 2008; Gelijns & Thier, 2002). In addition, making the industry representative role visible in the AF ablation system provides more complete data regarding personnel inputs to assess procedure quality as a function of all its component parts. Codification of the industry representative role also facilitates the creation of standardized training platforms and programs to echo those of other members of the clinical team (e.g. physician, nurse, technologist). Such standardization may reinforce the professional identification of the industry representative, as well as establish a standard level of competency as exists for every other professional engaged in clinical patient care.

There is some precedent for the idea of role codification for industry representatives in the electrophysiology world. For many years, industry representatives for the companies that make implanted devices (i.e. pacemakers and implantable cardioverter-defibrillators) have participated in certification as cardiac device specialists (CCDS) by the International Board of Heart Rhythm Examiners (formerly NASPExam). While this certification is not required for industry representatives, device companies subsidize the test preparation and exam fees for their clinical employees and engineers. These individuals prominently display their CCDS credential on business cards as a mark
of credibility in the field. A similar examination exists for the ablation side of the electrophysiology world. The Certified Electrophysiology Specialist (CEPS) exam is less broadly subscribed. Like the CCDS exam, it is not required for industry representatives, but rather serves as a mark of credibility. Both the CCDS and CEPS credentials are designated for Allied Professionals, including nurses, NPs, PAs, and technicians, along with industry professionals. Therefore, these designations are not truly codifying instruments for the industry representative role.

I recently had a sidebar conversation with an industry business official at a small scientific meeting. His company is preparing a major launch of a new mapping and ablation system for AF. He said that one of his current tasks is to establish a formalized training program for the company’s representatives in advance of the product launch. This has been a significant challenge, as there are no regulations for the representative role, and no base set of competencies across the industry (field notes, December 5, 2015).

In some ways, having an enlarged and more visible role may reduce freedom of action for industry representatives by regulating discrete responsibilities and boundaries for activities. However, the potential losses in mobility are likely outweighed by the gains in trust and communication effectiveness. Compared to the current practice where industry communication is relatively unconstrained but yields little in the way of knowledge-practice uptake between institutions, more tightly regulated industry communication may be more constrained but also more trusted, and thus more effective for achieving knowledge-practice uptake.
4) Include patients in the Social Network with Access to Data in Order to Contribute Their Knowledge

This allows the AF ablation knowledge system to incorporate patients’ lived experience, which is not routinely captured or codified in the formal knowledge system at present. Whereas clinician information reflects observations from the controlled clinical setting particularly centered on ablation procedures, patient experience encompasses the experience outside of the controlled clinical environment. In many cases, patients may have different priorities than clinicians and researchers, as has been shown with BRCA testing and AIDS research (Epstein, 1996; Parthasarathy, 2007). I routinely encounter this phenomenon in my own practice. Some patients who are unlikely to benefit from AF ablation due to underlying anatomy, physiology, or behavioral conditions, are eager to undergo a risky procedure in the unlikely event that it may allow them to stop taking medications to quell their AF symptoms. Other patients who experience severe side effects from medications are unwilling to undergo ablation, even with a strong possibility of improving their AF symptoms. They would rather endure the adverse medication effects than undergo an invasive procedure.

Including patients in the social network also affords the possibility of including patient-generated data (i.e. quantified self) in the data set. Including patient-reported outcomes is consistent with a culture of patient-centered care, and promotes the notion of patient engagement that has been described in the social science literature (Epstein, 1996) and is presently enacted in the funding processes for the Patient Centered Outcomes Research Institute (2013). Patient-driven social networks already exist in multiple formats, including open and moderated discussion boards, as well as more organized
reporting modalities that allow for data aggregation (e.g. PatientsLikeMe, 2016).

However, patients and clinicians have not historically been included in the same social network as data contributors. Rather, clinicians occasionally participate in patient social networks by serving as a so-called expert for question-and-answer sessions, or by mining the patient social network data for research.

By engaging patients in the same social network as clinicians and technology, it is possible to build a more complete understanding of the AF ablation procedure than is afforded by procedure data alone or even by a unified clinician knowledge network. Given the paucity of meaningful outcomes data in the AF ablation peer-reviewed literature, this intervention would provide potentially valuable data for outcomes reporting. Including patients in the social network will require a significant culture shift for some patients – particularly older individuals who are not digital natives and may not have a personal history of social network engagement – as well as for clinicians who are not accustomed to the notion of parity with patients in the context of medical data.

With this novel experience between traditionally separated groups, institutions like professional societies and patient advocacy organizations can collaborate as experience curators for the social network environment. In addition to experience curation, professional societies and patient advocacy organizations can collaborate with researchers to curate knowledge that emerges from network data.
5) Make the AF Ablation Data – Including Raw Data and Social Network Data – Publicly Available

Public access to data for research is consistent with Krumholz’s (2012) argument that unpublished and restricted-access data yield clinical decision making based on incomplete knowledge. In an effort to improve knowledge-based decision-making, his Yale Open Data Access (YODA) Project (2015) opened clinical trial data to researchers beginning in January 2015. AF ablation data do not represent clinical trial data, but rather real-world observational clinical data. However, the same concepts apply in terms of alleviating the bias associated with selectively published or unpublished data. By making AF ablation data publicly available, potential bias due to proprietary restrictions on data access will be alleviated, further affording opportunities for historical data upcycling.

Given the robust data set that raw data capture will create, computer modeling offers approaches for theory testing. Computer modeling may be done by interdisciplinary research teams that combine clinical and computing expertise. There is an existing – and growing – community of basic scientists in electrophysiology who are doing computer modeling at the molecular level. Therefore, this dataset would offer a new opportunity for researchers to work collaboratively at the boundary between basic and clinical research. Computer modeling research on raw data and social network data may yield meaningful knowledge generation at a significantly reduced cost compared to prospective clinical trials that may cost up to $47,000 per patient for a phase 3 device study (Stein, 2015). AF ablation data will not replace prospective clinical trial data completely. However, publicly available AF ablation data may yield model-based knowledge that will enhance the economic and time efficiency of prospective clinical
trials. Moreover, public availability of data will provide a non-industry resource for research data, which may enhance trust in the data.

6) Institute Pre-Publication/Open Access Procedures for Conference Abstracts

Pre-publication or open access approaches to conference abstracts may enhance individuals’ motivation to contribute abstracts to professional conferences with the knowledge that their contributions will be included in an open data commons. The concept of pre-publication conference abstracts is aligned with the contemporary discourse in which a triad of prominent clinical researchers published an editorial in the *British Medical Journal* to argue for pre-review publication in medicine, akin to the customary practice for math and physics papers (Lauer, Krumholz, & Topol, 2015). Proponents argue that pre-publication allows increased access to data and knowledge. Moreover, pre-publication creates a knowledge commons, rather than a separation between clinical practice and scientific results, which has been the traditional role of scientific publications (Consoli & Ramlogan, 2008). Such separations act as a barrier to knowledge inputs into the system, and thus to learning. Therefore, it is important to create opportunities to join scientific and practitioner communities – and adequate metadata to insure sound inference between practice and scientific knowledge – in order to facilitate transitions between scientific knowledge and practice knowledge for use-inspired innovation to occur.

These recommendations for widespread data sharing and pre-publication are in tension with arguments by prominent journal editors, including Valentin Fuster (*Journal of the American College of Cardiology*) and John Jarcho (*New England Journal of*
Medicine), that raw data are useless to the patient and the average practitioner, and that the role of peer review is to simplify cacophony in favor of increased clarity of data (Fuster, 2015; Husten, 2015; Jarcho, 2015). In other words, most people aren’t capable of interpreting data due to intellectual or time constraints, so the core set should do all of the interpretation. This sentiment is in line with a paternalistic view of the doctor-patient relationship (Foucault, 1973; Freidson, 1970; Katz, 1984), and the privileged core set (Collins & Evans, 2002), and discordant with the notion of a complex adaptive system. Fuster and Jarcho are correct that the contemporary practitioner with an overloaded and under-resourced clinical practice does not have the time to interpret mountains of raw data. The peer-reviewed publication does offer a meaningful simplifying service. However, the wholesale exclusion of raw data from view need not be the tradeoff for legibility. Peer review should not disappear to be replaced by raw data. Instead, raw data and peer review should co-exist for two reasons: First, so that researchers can have the opportunity to use raw data for research. Second, so that the availability of raw data can serve as a panopticon of sorts to bolster the accuracy and veracity of researchers’ claims.

My recommendation for pre-publication abstracts will not replace the peer-review function and will not ultimately contribute to the publication impact factor, as they will not be included in formal publication of conference proceedings that will remain limited to those abstracts scored by peer-review to merit formal inclusion. Therefore, pre-publication abstracts need not threaten the extant notion of bibliometric power rewards

Another major journal editor, Stuart Spencer of The Lancet (Spencer, 2015), presented a counter argument to Fuster and Jarcho that there is little evidence that peer review improves quality, and that peer review tends to stifle innovative thinking, more in line with Lauer et al. (2015).
for high quality work to immediately disrupt the existing system. However, pre-publication abstracts will be searchable in the grey literature for those who wish to do so. Pre-publication of conference abstracts would expand the information-sharing capacity of the sidebar conversation by affording broad access to the content that would normally be limited to just a few individuals who participate in a face-to-face conversation.

**U.S. Healthcare and Biomedical Technology Policy Implications**

Healthcare practice and innovation occurs in the context of a particularly regulated national system with regard to clinical, research, and business activities. Therefore, the notion of innovation itself, as well as proposed changes to the knowledge and innovation system, must be understood in this regulatory context. The six recommendations proposed by this project raise three major considerations with regard to regulatory policy: privacy, reimbursement, and data management.

**Privacy**

In many ways, privacy is at odds with the transparency that is critical to building trust. This tension between privacy and transparency raises challenges for the AF ablation system, and for the possibility of improving knowledge systems across every healthcare domain. Privacy considerations arise in two major categories: individual and institutional privacy, and proprietary interests. I will address each of these considerations separately.
**Individual and institutional privacy.** Individual privacy is legislated in the United States by the Health Insurance Portability and Accountability Act (1996), which regulates and limits the sharing of so-called protected health information (PHI). In clinical research, institutional review boards apply the 2003 HIPAA Privacy Rule (2003) that requires data de-identification in order to prevent the inadvertent connection of publicly reported data to a private individual. In the contemporary landscape of social networking, some individuals have effectively waived their healthcare privacy by participating in a variety of online discussion boards, as well as contributing their own health data to social networking structures like PatientsLikeMe (2016). Such participation reflects an overarching trend toward increased patient empowerment in the healthcare system with the changing role of the patient from the inert object of medical observation (Foucault, 1973) to an expectation for a sentient but compliant subject (Freidson, 1970; Katz, 1984), to a more elevated cognizant partner (Epstein, 1996). Social network participation reinforces the notion that patients ultimately own – and should control – their own data. However, this notion is not universally held, particularly in the context of data from clinical trials that are subject to intellectual property considerations, or data from an AF ablation procedure where privacy protections may be understood to extend to the procedure operator and the institution. The privacy considerations in these contexts are ripe for debate in the U.S. and other national legal contexts. Nonetheless, the default mode for public data sharing errs on the side of privacy protection for the patient, and thus should be enacted in the proposed system for raw data capture.

A few highly publicized legal cases have highlighted the steep consequences of HIPAA privacy breaches, resulting in loss of license, multi-million dollar fines, and
extended prison terms (e.g. United States of America v. Joshua Hippler, 2014; Walgreen Co. vs. Abigail E. Hinchy, 2014). These cases have reinforced a culture of privacy protection in the healthcare community such that the notion of public data sharing seems a foreign concept to many, and is met with skepticism and even avoidance. Therefore, it is critical to foreground individual privacy protections in the proposed raw data and social network commons in line with the HIPAA Privacy Rule.

A secondary privacy consideration related to individual patient privacy protection is the notion of provider and institutional privacy. Several times, STS colleagues have answered my bemoaning the positive publication bias in medicine by pointing out that the Morbidity and Mortality (M&M) conference structure exists so that clinicians can share their bad outcomes. This is true. M&M conferences exist at both academic and community hospitals as a forum to review cases with bad outcomes – those that resulted in death or worsening of the patient’s condition. M&M conference might be held in a large departmental conference room or in a small auditorium, attended by a coterie of physicians wearing white coats and clutching paper cups of coffee. There is a screen at the front of the room, projecting a few slides with the patient’s medical history and the plan of care, followed by images to illustrate what went wrong. There may be a chest x-ray showing a collapsed lung or a color photo showing a torn esophagus. As the physician presents the case, his colleagues listen and judge, interjecting a missed detail – “Don’t forget that he had been on amio[darone] for ten years.” – or asking a pointed question – “Did you check a wedge pressure before you gave the fluid bolus?” In some institutions, M&M conference is leveraged as an opportunity to learn and improve at individual and team levels. At other institutions, M&M conference is viewed as a witch
hunt— an opportunity to ferret out unsafe physicians. At every institution, though, M&M conference is protected by patient and institutional confidentiality, which creates a sense of protection against litigation in the event of a bad outcome. Therefore, the potentially valuable discussions that take place during M&M conference will never spread beyond the door of the conference room. As a field, there is much to learn from the M&M experience, but no mechanism to access that learning.

Moreover, there is a general—and appropriate—concern among clinicians about sharing institutionally-identified case information due to the potential for violating patients’ privacy, even with reasonable and proper de-identification procedures in place. However, some patients are exercising their emerging autonomy to proactively share their own health data. There is some tension around this practice, particularly in the case of suspected medical malpractice, so that some institutions make it difficult for patients to access their own medical record and case data. However, there is a burgeoning movement toward open notes, started at Beth Israel Deaconess Medical Center in Boston (Walker, Meltsner, & Delbanco, 2015). The open notes project has resulted in improved outcomes at every measure, including clinical outcomes, patient satisfaction, and provider satisfaction.

Although the open notes movement has not overtaken the healthcare system as of early 2016, incremental changes are evident. For example, in February 2016, the Department of Health and Human Services (DHHS) established limits for charges, including specification that patients should have access to their digital records for free (DHHS, 2016). Although this guidance does not constitute a binding or directly
enforceable regulation, it does signal and expectation that record-sharing will become increasingly prevalent.  

**Proprietary interests.** Another privacy consideration concerns the perspective of proprietary technology and patenting interests. The prevailing culture around industrial technology development has been to limit data sharing in order to protect corporate knowledge from being exploited by competing corporate interests in order to produce financial gain. This culture of corporate data privacy and protection is inconsistent with the notion of maximizing communication throughout the full knowledge system of AF ablation technology. There is a mismatch between the good of the company and the good of the knowledge system. In essence, the basic system of market economics that drives biomedical technology innovation is not completely aligned with the knowledge system on which innovation is based. Recently, American health policy experts like Harlan Krumholz and his YODA Project have argued for revising the prevailing notion of corporate privacy in favor of data sharing to promote the common good through broad research platforms. Participation in the YODA Project by healthcare industry leaders Medtronic and Johnson & Johnson is encouraging. However, as of January 2016, there is

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73 The question of medical record and data ownership is also embedded in the issue of open notes and access to medical records. Although I will not weigh on this issue at length, it is a relevant factor to consider for this project with regard to data management and inclusion in the proposed system. Participation in the proposed system should be voluntary for patients, as participation in healthcare is voluntary, outside of public health emergencies. Should patients be allowed to self-exclude from data capture in this system? Yes, they should, though this would weaken the potential for new knowledge creation and learning about AF ablation. Should providers be allowed to selectively exclude cases from data capture? No, they should not, as this would undermine the learning power of the system that – unless otherwise directed by an autonomous patient – is designed to maximize the body of data captured.
not evidence of broader participation in the data holder category by other drug and device corporations in the year since the YODA Project officially launched.

As the medical device industry comprises for-profit corporations that compete on the basis of transitioning intellectual property through the patenting and FDA regulatory process in the U.S. (and similar regulatory institutional processes in other national contexts) in order to generate profits, there is a prevailing culture of data privacy in the medical device industry. Data privacy is enacted in several ways, including nondisclosure agreements, black-boxed data algorithms, and firewalls separating source code from clinical data. Given the primacy that intellectual property protections hold in the for-profit device industry, it is unlikely that ablation technology manufacturers will be keen to expose their intellectual property to a data commons. Therefore, in order to promote participation in the raw data capture system, the data capture should occur via a software platform that sits outside of firewalled proprietary software, using common standardized data coding (Health Level Seven International, 2016) to ensure consistency of data reporting across corporate platforms.

**Reimbursement**

One of the major, and underdiscussed, concerns related to AF ablation technology is the high cost of the technologies that limits or precludes new technology uptake in most healthcare settings, from thought-leading academic medical centers to smaller community-based institutions. Even in well-funded health systems, hospitals must make purchasing decisions with limited budgets. In addition, ablation technology components are often designed with proprietary-specific hardware connections to force allegiance to a
single company’s system. This limits the individual components that a hospital may purchase due to interoperability issues with existing equipment. Moreover, although AF ablation has its own codes for physician reimbursement as of 2015, there is no mechanism for Medicare reimbursement for new ablation technologies per se as is the case with other new technologies that are implanted into patients (e.g. MitraClip for mitral valve disorders) (Hernandez, Machacz, & Robinson, 2015). In other words, physicians can use new implantable technologies largely without cost consideration, as cost is passed to the patient via insurance coverage for the device itself. However, the cost of non-implantable technologies, like mapping and ablation systems, remain with the hospital. Therefore, physicians require a capital investment in order to acquire and use the technology. As a result, adoption of some newer technologies may be limited by cost (as explained by TL-1 with regard to Topera).

High technology costs are coupled with the rising costs of providing healthcare services in the face of declining reimbursements and increasing population demands for clinical care – including ubiquitous data management – with a stable-to-declining provider supply. Although financial and workforce considerations may seem like distinct issues, the reality is that they are inextricably intertwined. Healthcare workforce activity generates income in the form of reimbursements that are generally set by federal payment policy by CMS. Although CMS only pertains directly to patients with Medicare and Medicaid coverage, it is generally accepted that most private payers use CMS reimbursement as the basis for their payment policies. Therefore, healthcare workforce services yield financial remuneration at predetermined levels that are not necessarily commensurate with the quantity of work required for the procedure. Since 2010, when
many cardiology reimbursements were cut by up to 40%, the technological intricacy and resulting costs of performing AF ablation has increased out of proportion to the payments for AF ablation. As I previously discussed, the rising costs of healthcare delivery have forced many healthcare systems to operate with minimal profit margins that preclude hiring adequate staff for laborious research reporting activities. Moreover, in the face of declining reimbursements, clinicians have been driven to devote more time to revenue-generating activities like seeing patients and doing procedures, and less time to non-revenue-generating activities like collecting research data and writing manuscripts for publication. Therefore, the raw data capture system must be streamlined to work in the background of the usual care systems with little to no requirement for additional workforce time to facilitate data capture and reporting. If not, the realities of contemporary healthcare practice will suffocate even the most well-intentioned and potentially valuable data system. Uptake of this recommendation would be facilitated by inclusion as a Qualified Clinical Data Registry as part of the system that connects registry reporting to CMS payment adjustments to providers and institutions.

Similarly, broad uptake of the social networking platform will be limited by the perceived value of the activity in the face of the required time investment. Therefore, it will be important to establish shared value with a clear common sight line to the goal of the social networking component of the data commons in order to motivate participation (Haudan, 2008; Malloch & Porter-O'Grady, 2009). Additionally, the participation of opinion leaders will be important to promote uptake of this innovation in the knowledge system (Rogers, 2003). It is unlikely that regulations will emerge to mandate participation
in the social network portion of data commons reporting. Therefore, social spread of innovation adoption will be critical for the success of this recommendation.

**Data Management**

**Regulatory considerations.** Implementation of the recommendations from this project have the potential to significantly impact the universe of AF ablation data for the purposes of generating knowledge for innovation. However, the proposed raw data capture system will generate real-world observational data, rather than the randomized controlled clinical trial data that is privileged in the FDA regulatory process. Therefore, if the FDA uses observational data from raw data capture, it may be for post-market surveillance only. In order for raw data capture to directly inform new technology innovation, FDA data expectations for pre-market applications would need to shift to co-prioritize real-world raw data along with controlled clinical trial data.74

Similarly, CMS typically relies on formal clinical trial data in order to make coverage determinations. However, CMS’s recent use of Qualified Clinical Data Registries, and particularly the request to develop a registry for AF ablation, signals the potential for raw data to be used robustly by CMS. Currently, CMS is only using clinical registry data to assess quality practice related to reimbursement in the ongoing transition to a value-based payment system. However, robust data from a raw data capture system

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74 As of 2016, the FDA uses post-market device registries extensively for safety surveillance, but not for new labeling as is common with pharmaceuticals. This reflects the wider variety in use and user experience for medical devices as opposed to pharmaceuticals.
could potentially motivate CMS to use such data to inform coverage decisions in the future.

In the short term, it is unlikely that data captured by the proposed social network would be used by either FDA or CMS to inform regulatory decisions. However, if patient-reported outcomes data continues to gain traction in the clinical trial community, the data commons platform and culture that this project recommends might encourage more extensive use of patient- and multistakeholder clinician-reported data in future clinical research.

**Workforce considerations.** Clinicians are faced with increasing work in a climate of declining reimbursements, and so increased data production may overwhelm the system if clinicians are expected to attend to the robust data that are produced by raw data capture from AF ablations. However, raw data capture will not be used directly in clinical management. Rather, the intended audience for the raw data constitutes a small minority of the workforce (researchers), as these data may be used primarily for research purposes, rather than direct patient care by clinicians. This criticism of ubiquitous data collection and availability has been leveraged by journal editors (Fuster and others), who note it would only benefit a select few researchers who can already access relevant research data.\textsuperscript{75} However, the reality of the present system that relies on industry actors to

\textsuperscript{75} I am writing in the midst of rapid developments regarding expectations for data sharing. In January 2016, new rules were proposed by the International Committee of Medical Journal Editors for authors to share de-identified patient-level clinical trial data at the time of manuscript submission (Taichman et al., 2016). This proposal was met with mixed reactions from the publication community. It is likely that this issue will continue
collect and release clinical trial data for analysis does not constitute ubiquitous data availability that would be afforded by the proposed recommendation for raw data capture and open access. Ubiquitous availability and open access is important to promote transparency and trust with ramifications beyond the pale of the formal knowledge system. Therefore, the greater good is promoted by ubiquitous data availability, regardless of whether it is widely accessed by those outside of the formal knowledge system.

In Chapter 7, I examine opportunities for further study based on the findings and recommendations from this project, including proposed metrics to measure outcomes from the recommendations for knowledge system innovations proposed in this chapter.
CHAPTER 7
REFLECTION AND OPPORTUNITIES FOR FUTURE WORK

This project has been bounded in many ways in order to accommodate time and resource constraints typical of a doctoral dissertation. Like the complex adaptive system of AF ablation knowledge, the boundaries of this project are permeable, offering access points to future paths and sites for further exploration. Here, I highlight a few intellectual trailheads that emerged from each of the major themes explored in this project.

Opportunities for Future Work

Bibliometric Analysis

Interdisciplinary collaboration. The brief bibliographic assessment in Chapter 3 highlights an opportunity for further research to examine publication patterns and impacts on AF ablation knowledge and practice. A variety of bibliometric analysis approaches may reveal insights into publication patterns based on institutional types (i.e. academic medical centers, other university settings, non-academic medical centers, government, industry), individual professional training histories, and other associations based on institutional homes and collaboration patterns. This type of research may yield insights particularly with regard to patterns of interdisciplinary collaboration. Bibliometric
analysis of citation patterns may also yield insights regarding learning patterns in the system evidenced by bench-bedside cross citations.76

Further text coding and event history analysis of the peer-reviewed literature with visual representation of the segmented co-development process may provide another useful approach to identify key qualities of the published literature that contributed to knowledge construction and paradigm shifts over time. For example, literature may be evaluated based on disciplinary content versus interdisciplinary content in the three major streams of knowledge composing AF ablation literature (i.e. science, technology, and technique). Each article could then be deemed a disciplinary, inter-disciplinary or transdisciplinary knowledge artifact according to the degree to which knowledge from individual streams interacts. This approach would allow one to explore the idea that key moments in paradigm construction and shifting are motivated by transitional or transdisciplinary knowledge work in which knowledge from disciplinary streams merge or co-develop one another to constitute new knowledge. This notion holds implications for intentional design approaches to facilitate knowledge construction in the context of a complex adaptive knowledge system.

**Functional analysis framework.** As I discussed in Chapter 3, the particular arrangements of the healthcare system for AF ablation practice motivated the definition of knowledge streams around performative disciplinary characteristics (i.e. science,  

76 There is a robust community of scholars, including Leydesdorff, actively engaged in the project of bibliometric analysis of science and technology research and practice. This growing body of inquiry and scholarship offers a variety of analytical opportunities for future work.
technology, and technique). Examining the historical AF ablation literature through the lens of functional goals of AF ablation (i.e. understanding, representing, and treating the arrhythmia) may illuminate different patterns of knowledge development. New patterns may yield observations that suggest a need to develop and facilitate different communication pathways in the knowledge system compared to the extant pathways arranged according to disciplinary and performative characteristics. For example, a functional frame for analysis may ultimately suggest that basic scientists and industry engineers should communicate more directly, or that cognizant patients should be more explicitly included in regulatory activities.

**Impact factor.** Additional targets of bibliometric analysis may examine impacts of the impact factor in AF ablation publishing, as well as changes in the nature and timing of AF ablation knowledge publication with the rise of open-access peer-reviewed journals, particularly with regard to patterns of emergence consistent with a complex adaptive system.

In the context of the knowledge network built in Chapter 5, bibliometric analysis can be used to further explore the observation that thought leaders in AF ablation practice extensive self-citation in the peer-reviewed literature. It would be useful to understand whether extensive self-citation is mainly practiced by a few particular thought-leaders in AF ablation, or whether self-citation is endemic throughout the formal knowledge network. Formal bibliometric analysis to examine the citation practices of a broad spectrum of individuals in the peer-reviewed literature may help to illuminate this issue. It would also be useful to understand whether self-citation is similarly practiced in fields
outside of AF ablation within the medical sciences, and outside of medical sciences more broadly. Formal examinations of self-citation bias may be valuable to inform the ways that impact factor calculations are understood and used in formal knowledge systems and other professional contexts. If co-development is truly segmented with multiple interacting knowledge streams, then the bias introduced by self-citation does not reflect the function of the larger knowledge system as a complex adaptive system. Citation bias holds implications for future cultural expectations or formal policy in the peer-reviewed knowledge system, particularly noting the construct of the impact factor as a likely source for bias generation. For example, peer reviewers may be instructed to carefully evaluate citation patterns in manuscripts to identify and stem the practice of capricious self-citation.

**Trust**

One of my major findings is that trust is a critical component that facilitates the knowledge-to-practice transition at every subsystem level. Conversely, lack of trust prevents the knowledge-to-practice transition. The focus of this study, in terms of trust, centered primarily on the ways that healthcare practitioners experience and exercise trust. Given the breadth of actors in the system beyond direct healthcare practitioners, it would be valuable to extend the trust investigation to other actor types, including patients, industry, regulators, and media. For example, it is important to know how patients form trust perceptions around data and other information from a variety of media sources. This is particularly relevant if a key recommendation to improve the knowledge system is to leverage the traditional media as a communication technology. It would also be valuable
to understand how patients form trust perceptions related to communication from other patients, from health systems, and directly from healthcare professionals. Similar questions can be asked of trust perceptions in industry, regulatory, and media settings in order to better understand how communication throughout the network may be affected. This research would likely center on ethnographic techniques of participant observation fieldwork and key informant interview.

Beyond the U.S.-based experience that informed this project, further research regarding trust would be relevant in other national cases and non-AF contexts where basic trust cultures may vary from the very specific case of AF ablation in the U.S. Other national and medical contexts would invite additional ethnographic investigation.

The powerful role of the peer reviewer raises an additional aspect for further examination related to trust. Trust is noted to reduce complexity in a system (Lucas, 2014), which is consistent with the role of peer review that journal editors like Valentin Fuster describe. However, my fieldwork reveals a backgrounded lack of trust in the thought-leaders who compose the peer reviewer community for the major journals publishing AF ablation research (e.g. *Heart Rhythm Journal, Journal of Cardiac Electrophysiology, Journal of the American College of Cardiology, Circulation*). Therefore, the reality of distrust undermines the foundation on which peer review is based. It would be valuable to examine the extent to which distrust of peer review is a factor in the knowledge-practice transition in order to inform transparency standards and practices for peer review.

Co-Production and Power
As I mentioned in Chapter 3, there is value in examining the AF ablation case through the Jasanoff co-production lens to examine the exercise of power. Given the understanding that AF ablation relies on a triple helix of knowledge, it would be useful to understand how the three strands of knowledge engage with one another to impact the course of knowledge development. As such, it is important to understand how each strand of knowledge is created and mobilized in the context of the triple helix. This co-production understanding would offer additional insights to understand how the knowledge network and knowledge products are shaped in concert.

Regarding the assumption and exercise of power in the knowledge network, it is important to acknowledge the role that peer-reviewed literature plays in the formal knowledge network that underscores all medical innovation in the U.S. healthcare system. Therefore, the recent discourse among journal editors and researchers regarding a pre-review publication process offers an interesting space for examination. Opponents to pre-publication contend that pre-review publication would be wasted because most people – including patients and non-methodologist clinicians – are unable to critically appraise raw data, and thus require the peer review process to make knowledge legible. Given the level of expertise required to engage in clinical practice, the notion that this expertise does not afford admission to the core set of contributory experts equipped to evaluate clinical science is intriguing and merits testing. This may include designing knowledge assessment queries, as well as an assessment of university and medical training curricula across the spectrum of clinical practice fields (e.g. medicine, advanced practice nursing, nursing, technology specialists, engineering).
Beyond the critique of clinicians, the critique leveled at the patient suggests a weakness in the educational system including educational skills for 21st century living in an age of data. Again, this merits assessment and suggests the opportunity to improve the educational components in basic university, as well as advanced medical, education in order to ensure that the majority of actors in the future knowledge system will possess the ability to assess raw data, thus increasing the exercise of transparency in the system and improving trust to facilitate innovation uptake.

Testing Non-AF Cases

Noting that the knowledge network for this project emerged from the specific case of AF ablation, it would be useful to test the framework of knowledge co-development in a complex adaptive system in other healthcare and non-healthcare cases. For example, neurosurgical ablation procedures may offer another relevant healthcare case with similarities in the basic biophysics of the therapeutic procedure, but critical differences in the culture of the operating room environment and the nature of the health threat that underscores the practice.

Outside of healthcare, a case like the construction of formal educational assessments in a variety of learning environments (e.g. K-12, post-secondary, professional education) may offer similarities in the constitution of formal and informal knowledge settings, but critical differences in the type of science that underscores the field. As the parent of children who are subjected to extensive standardized testing, and the child of a public school teacher, many of the grumblings that I hear about formal educational assessment recall the backstaged criticism of AF ablation in my professional
community. Therefore, educational testing might offer a non-obvious site to test the knowledge co-development framework.

**Assessing the Impact of Innovation Recommendations**

Taking a long-term view of future research, it would be valuable to measure processes and outcomes that occur as a result of implementing the innovation changes recommended in Chapter 6. Specific measures should include the type, volume, and mechanism of inputs to knowledge system; clinical outcomes; and cost impacts at patient, provider, industry, and healthcare system levels. It would also be useful to assess impacts to regulatory efficiency in terms of time and financial expenses associated with technology innovation. In order to accomplish these outcome measurements, the implementation process for each of the changes recommended should include an evaluation mechanism. For example, the UIC system proposed in Chapter 6 would facilitate outcomes evaluation over time and across settings without compromising the privacy of individuals and institutions. Although a central repository would need to hold a master identification list, this type of system would facilitate more robust measurement that neither requires extensive work to obtain individual level consent, nor compromises data quality as a result of excluded or missing data.

One opportunity for assessing outcomes of incorporating raw data capture, as described in Chapter 6, would use a quasi-experimental approach to assess how raw observational findings from real-world practice compare to findings from a randomized controlled trial condition. In other words, how does real-world practice compare to clinical trials? This may yield implications for regulatory data requirements, particularly
with regard to the present preferences for randomized controlled trial data when feasible to inform FDA applications as well as CMS and other coverage decisions in the United States. For instance, if real-world conditions measured with raw data yield significantly different outcomes that affect patients, regulators may mandate real-world raw data monitoring to ensure patient safety. Or, if real-world and randomized controlled trial data are very similar, regulators may opt to include real-world data in FDA applications, which may significantly reduce the costs associated with new device innovation. It is worth noting that European regulatory agencies typically require trial data as well, though with less stringent requirements than American agencies. Therefore, a comparative study of real-world practice data in European settings would also be valuable.

It is also useful to assess the impacts of proposed recommendations on patient and provider satisfaction, including a comparative analysis of provider satisfaction with the raw data capture registry modality compared to standard provider-reported clinical registries. Another measure of provider satisfaction may include the number of abstracts submitted to medical conferences with a pre-publication system in place, compared to abstract submissions in conference cycles that used peer-review only without pre-publication of conference abstracts. Similarly, it would be valuable to assess professional satisfaction among industry representatives in the environment of codified roles for that group using survey data as well as personnel turnover as a proxy measure for professional satisfaction. Patient satisfaction may be assessed using typical survey data, as well as participation in the proposed social network, along with social network reported data.

Another opportunity for study with raw data would involve experiments with a set of raw data. For example, a single set of raw data could be presented to a variety of
stakeholders in the AF ablation system to understand how they may or may not use raw data in research and practice. This type of experiment may yield a new understanding about how new types of knowledge are engaged by the innovation system.

Finally, the initial and overarching motivation for this project was the limitations of present technologies and techniques to ameliorate the problem of AF. Therefore, it would be useful to understand how these recommendations impact the quantity and quality of AF ablation innovations reaching practice. In turn, the ultimate long-term outcome measure would be to assess the societal burden of AF in terms of disease prevalence affected by the use of ablation technology.

International

Although this project examined the practice of AF ablation in the U.S. context, much AF ablation research and practice occurs outside of the U.S. To that end, it is relevant to consider the practice and research contexts in other countries by examining the constructed formal, informal, and combined knowledge networks from this project against non-U.S. experiences. In order to do this, the ethnographic observation and interview activities that informed my findings in Chapter 5 should be replicated in other national settings in order to establish the validity of the network and associated innovation recommendations from Chapter 6 in other national contexts. Relevant research sites would include countries with developed AF ablation practices like France and Italy, those with more restrictive electrophysiology practices like Egypt, and those with nascent electrophysiology practices like Cuba.
Beyond the mechanistic structures and behaviors associated with AF ablation practices in other national contexts, it is important to examine other national practices and regulatory contexts in terms of cultural implications for expertise, authority, and trust that underscore AF ablation practice at every level, as discussed in Chapter 4. Existing international comparative studies (e.g. Jasanoff’s 2005 comparative study of the life sciences in the U.S., UK, and Germany, and Parthasarathy’s 2007 comparative study of breast cancer genetics screening in the U.S. and UK) provide useful models on which to build future international investigation of the AF ablation case. One point of particular attention for international study is the role and political position of industry actors in the knowledge network, as this is highly variable in different national contexts. The AF ablation case is distinctive with regard to industry actors, as industry representatives in AF ablation procedures bear directly on health outcomes by virtue of participating directly in the procedures, whereas industry activities are not directly connected with health outcomes in other cases.

In addition to establishing the validity of the network and innovation recommendations in other national contexts, it is important to understand the regulatory agencies and policies in unique national contexts. Therefore, it will be important to assess the innovation recommendations from this study against the extant regulatory

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77 For example, since the early 2000s, extant culture in the U.S. context has been highly suspicious of industry influence on physician behaviors by providing financial remuneration, or bribes, directly to physicians. As a result, U.S. industry must report all payments of direct (e.g. consulting fees) or in-kind compensation (e.g. meals, travel to conferences) to physicians in a public database. In an effort to avoid any perception of bias, many institutions bar physician employees from accepting any payments from industry, and salespeople are barred from communicating directly with physicians at many hospitals.
environment in relevant countries in order to assess whether the national regulatory agencies might invite changes in structure or policy in order to improve the innovation environment.

Reflection

At the outset of this project, I reflected on my privileged position among the elite healthcare community that I was embarking to study. My professional status afforded me access to the backstage conversations that question the efficacy of AF ablation, drawing this research question in ways that other researchers would not see. As I set out to construct a map of the AF ablation knowledge system, I was fortunate to have easy access to many of the thought leaders in the field due to prior collaborations. In the course of conducting this study, my name has been included as a co-author and co-presenter with many of the thought-leaders I describe, as I continue my clinical and scientific work to conduct and shape the care of people with heart rhythm disorders. I have found myself frequently in a liminal space with one foot inside the formal knowledge system, another in the informal knowledge system, and craning to view them both with a social scientist’s gaze. On several occasions, I have forced a pause to plant my feet as an observer, rather than stepping into the insider role that I have inhabited over the years. Many times, I have been caught in the insider space, and required my mentors to nudge me back toward the outside in order to find a stronger voice to tell this story.

One of the things I noticed in this research is that so many of my own experiences exist outside of the typical. Although I identify myself in the NP/PA role that I map in the
network, the activities that I have come to count as normal in my calendar do not represent the typical experience. Thus, I have taken care to cross check everything that I know – or more accurately, believe – to be true about the experience of participating in the research and practice of AF ablation. This is not to say that I have dispensed with my own lived experience. Rather, I have tried to transform my experiences from statements into questions. Typically, my questions yielded the answers I expected. However, on a few occasions, I was reminded that my professional status is indeed privileged. On those occasions, I have taken care to portray the data from my informants, cataloguing my own experiences separately.

As I now review my catalogue of experiences, I appreciate the points where my path has diverged from the so-called normal. These points of divergence include my privileged insider status in the cardiac electrophysiology community, as well as observer status to that community as an emissary from the social sciences. Two similar events along the scholarly trial helped to highlight these points. The first was at the American Anthropological Association meeting in December 2013, when I presented a small ethnographic study of clinical EP practice to highlight the ways that so-called midlevel providers act as conduits of physician authority. As I prepared for this foray into the world of anthropology, I sought advice from my ethnography professor, Dr. Amber Wutich. She assured me that my status as a healthcare provider would confer instant authority, rather than preserve outsider status in the anthropology community. Indeed, as I stood at the lectern to read my paper to the small but packed room, when I came to the phrase, “In addition to conducting this ethnography, I am also a nurse practitioner in the practice,” there was an audible gasp from the audience. In the group question-and-answer
session that followed the papers, a majority of the questions were directed to me as a voice of authority. I was stunned that Amber was right. My outsider status actually conferred dual insider status, and thus insider credibility.

The second event occurred two years later at the Cardiovascular Clinical Trialists Forum in December 2015, a small gathering of elite researchers and regulators representing North America and Europe. I was invited to participate on a panel of AF experts, and particularly to discuss quality of life and the patient’s perspective in clinical trials. In my prepared remarks, I commented that in addition to being a nurse practitioner and clinical researcher, I am also a social scientist. Once again, there was an audible gasp from the audience of clinical researchers, industry executives, and regulatory officials. This time, rather than being surprised, I almost laughed. Once again, Amber was right. My status as a dual insider affords me a unique voice among elites in the field of heart rhythm care.

I realize that these points where I can simultaneously exercise as a boundary-spanning insider and outsider represent the most significant opportunities to impact policy and practice. To that end, it is valuable for me to continue to cultivate the broad stance that I have developed with feet planted in separate intellectual practice spaces and a knowledge filter that translates observations into research questions. Part of my strategy to maintain that stance will continue to include a strong community of STS and policy colleagues and mentors prone to challenging one another’s ideas.

Looking ahead, I intend to build interdisciplinary knowledge at boundary spanning points, by constructing research questions from multiple disciplinary observations. I will leverage my professional and scholarly experiences to assemble
interdisciplinary research teams that can contribute unique views and interpretations of the world, and build shared understanding of knowledge around answers to the questions that alone we would not know to ask.
REFERENCES


288


Hunter, R. J., Berriman, T. J., Diab, I., Baker, V., Finlay, M., Richmond, L., . . .


292


Lazar, S., Dixit, S., Marchlinski, F. E., Callans, D. J., & Gerstenfeld, E. P. (2004). Presence of left-to-right atrial frequency gradient in paroxysmal but not persistent atrial fibrillation in humans. *Circulation, 110*(20), 3181-3186. doi:10.1161/01.CIR.0000147279.91094.5E


Lower, R., 1631-1691. (1668). De corde, london 1669. England; United Kingdom:


299


pulmonary vein ablation with a modified approach. *Circulation, 110*(19), 3036-3042. doi:10.1161/01.CIR.0000147186.83715.95


303


Sénac, J. B. (1783). *Traité des maladies du coeur / par M. de senac ... ; tome premier*


United States of America v. Joshua Hippler, Criminal No. 6:14cr18 (United States District Court, E.D. Texas, Tyler Division 2014).


Walgreen Co. vs. Abigail E. Hinchy, 49A02-1311-CT-950 (Court of Appeals of Indiana 2014).


APPENDIX A

HISTORY OF DOMINANT APPROACHES TO CONTEMPORARY AF ABLATION
Table A-1

Coding Scheme for Historical Documents

<table>
<thead>
<tr>
<th>Meta-Theme</th>
<th>Sub-Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Science</td>
<td>• Structural SS</td>
</tr>
<tr>
<td></td>
<td>• Cellular SC</td>
</tr>
<tr>
<td></td>
<td>• Predictors for Procedural Success SP</td>
</tr>
<tr>
<td>Technology</td>
<td>• Mapping TyM</td>
</tr>
<tr>
<td></td>
<td>• Ablation TyA</td>
</tr>
<tr>
<td></td>
<td>• Imaging TyI</td>
</tr>
<tr>
<td>Technique</td>
<td>• Ablation Procedure TeAP</td>
</tr>
<tr>
<td></td>
<td>• Complications TeC</td>
</tr>
<tr>
<td></td>
<td>• Domestication TeD</td>
</tr>
<tr>
<td></td>
<td>• Surgery TeS</td>
</tr>
<tr>
<td></td>
<td>• Patient Selection TeP</td>
</tr>
<tr>
<td></td>
<td>• Clinical Management TeCM</td>
</tr>
<tr>
<td>Connectors</td>
<td>• - (indicates multiple sub-themes actively</td>
</tr>
<tr>
<td></td>
<td>mobilized by the manuscript)</td>
</tr>
<tr>
<td></td>
<td>• → (indicates new theme enabled by sub-</td>
</tr>
<tr>
<td></td>
<td>themes in the manuscript)</td>
</tr>
</tbody>
</table>

1850 – 1920\textsuperscript{78} (observational studies)

Marshall, J. (1850). On the development of the great anterior veins in man and mammalia; including an account of certain remnants of foetal structure found in the adult, a comparative view of these great veins in the different mammalia, and an analysis of their occasional peculiarities in the human subject. \textit{Philosophical Transactions of the Royal Society of London, 140}, 133-170. doi:10.1098/rstl.1850.0007  SS


Garrey, W. E. (1914). The nature of fibrillatory contraction of the heart. its relation to tissue mass and form. \textit{American Journal of Physiology, 33}(3), 397-414.  SS

\textsuperscript{78} This reference list is organized by year. Within each year, references are ordered alphabetically. Given the protracted timeframe that is typical from manuscript submission to print publication in peer-reviewed journals, this ordering conveys more-or-less the co-development timeline for AF ablation knowledge, with little additional detail to be gained by a more precise ordering by weekly publication dates within a year.


1947 – 1979 (experimental studies)


1980 – 1989 (AF surgery)


315


1990 – 1993 (AF surgery and Early catheter ablation)  


1994 (Rise of catheter ablation 1994 – present)


flutter: Insights into mechanisms. *Circulation Research, 74*(5), 882-894. doi:10.1161/01.RES.74.5.882  


1995


1996


318


1997


1999 


Keane, D., & Ruskin, J. N. (1999). Linear atrial ablation with a diode laser and fiberoptic catheter. *Circulation, 100*(14), e59-e60. doi:10.1161/01.CIR.100.14.e59  


fibrillation. *The American Journal of Cardiology, 86*(9), K9-K19. doi:10.1016/S0002-9149(00)01186-3 TeAP → TeD


2002


initial clinical experience with high resolution, under blood visualization. *Journal of the American College of Cardiology, 39*(3), 509-516. doi:10.1016/S0735-1097(01)01764-8


Analysis of acute and chronic failures. *Journal of Cardiovascular Electrophysiology, 13*(10), 957. TeAP → TyA


fibrillation. *Circulation, 105*(25), 2998-3003. doi:10.1161/01.CIR.000019585.91146.AB


2003


ostium in patients with atrial fibrillation. *Circulation, 108*(13), 1599-1604. doi:10.1161/01.CIR.0000091081.19465.F1


2004


Lazar, S., Dixit, S., Marchlinski, F. E., Callans, D. J., & Gerstenfeld, E. P. (2004). Presence of left-to-right atrial frequency gradient in paroxysmal but not persistent atrial fibrillation in humans. *Circulation, 110*(20), 3181-3186. doi:10.1161/01.CIR.0000147279.91094.5E


TeCM


TeAP ! SC-TyM ! TeAP


TyM ! SC ! TeAP


TeAP


TeAP ! TeC


TeAP-TeD


SC ! TeAP

TeS ⇒ TyA

TeAP ⇒ TyA

TeS ⇒ TyM ⇒ SC

TeAP ⇒ SC-TeCM

TeC

SC

TyM-TyI ⇒ TeAP

TeAP ⇒ TeC

TeAP ⇒ TeC


2005


2006


radiofrequency ablation. *Annals of Internal Medicine, 144*(8), 572.


359


360


2007


strategy to pulmonary vein antrum isolation improving the outcome of AF ablation. *Journal of Cardiovascular Electrophysiology, 18*(12), 1261-1266. doi:10.1111/j.1540-8167.2007.00953.x


2008


2009


TeP → TeAP


TeP → TeAP → SC-SS


TeAP


TyA → TeAP


TyA → SC → SP


TyA → TeAP


TyI → SC → TeAP → SP


prior to pulmonary vein isolation: A multicenter experience. *Circulation, 126*(21 Supplement), A11126. SC → TyM → TeAP


Ranjan, R., Kholmovski, E. G., Blauer, J., Vijayakumar, S., Volland, N. A., Salama, M. E., . . . Marrouche, N. F. (2012). Identification and acute targeting of gaps in atrial ablation lesion sets using a real-time magnetic resonance imaging system. *Circulation: Arrhythmia and Electrophysiology, 5*(6), 1130-1135. doi:10.1161/CIRCEP.112.973164 TeAP → TyI → TeAP


Electrophysiology, 23(11), 1254-1257. doi:10.1111/j.1540-8167.2012.02324.x


2013


generation balloon. *Heart Rhythm, 10*(9), 1318-1324. doi:10.1016/j.hrthm.2013.07.005


Cardiovascular Electrophysiology, 25(5), 466-470. doi:10.1111/jce.12358  TyA


2015


TeAP