

DIFFUSION OF MEDICAL TECHNOLOGY



# Diffusion of Medical Technology Workshop

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# Acronyms and Abbreviations

Acronym	Definition
ACE	angiotensin-converting enzyme
ACO	accountable care organization
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
BD2K	Big Data to Knowledge
CMS	Centers for Medicare and Medicaid Services
СТ	computed tomography
CTSA	Clinical and Translational Science Awards
FDA	Food and Drug Administration
HCOS	Healthcare Organization Services
HRR	hospital referral region
ICD	implantable cardioverter defibrillator
ICU	intensive care unit
IMS Health	formerly Intercontinental Marketing Services
MRI	magnetic resonance imaging
NCTC	National Conservation Training Center
NICE	National Institute for Health and Care Excellence
NIH	National Institutes of Health
NPI	national provider identifier
PCI	percutaneous coronary intervention
PHN	physician hospital network
PSA	prostate specific antigen
RFA	request for funding announcement
TIN	tax identification number
UDI	unique device identification

# Introduction

The Steering Committee for the three cooperative agreements funded in response to Diffusion of Medical Technology and Effects on Outcomes and Expenditures (U01) RFA-RM-12-023 by the National Institutes of Health (NIH) Health Economics Common Fund Program convened a workshop on November 13-14, 2014 to discuss research on the diffusion of medical technology, network analysis methods, effects on technology adoption of new forms of organization and financing, and opportunities for data development and other resources to advance the field. The workshop consisted of seven presentations by invited participants, project updates from principal investigators of each of the three cooperative agreements, and discussions about improving concepts, data sources, and methods used in the field. The discussion especially benefited from the presence of a diverse group of clinicians, producing a broader perspective on reasons for adoption or non-adoption of new technologies. Though it is still very early in the research, some common themes are starting to emerge from case studies, including a problem of indiscriminate adoption, not concordant with guidelines or the results of trials. These and other findings are relevant to the work of cooperative agreements working on the economics of personalized medicine and prevention, so NIH participants will foster two-way communication among the research groups. This document summarizes the workshop proceedings. The workshop agenda and participant list can be found in the appendices.

# **Challenges and Opportunities**

Discussions throughout the workshop focused on establishing a conceptual framework for diffusion research, identifying and facilitating access to key data sources, and developing improved methodologies.

## **Conceptual Framework**

Workshop participants discussed the benefits to the field of establishing an overarching conceptual framework for the multiple mechanisms of diffusion. Such a framework would support appropriate hypothesis development and model specifications. A multiple-author publication outlining proposed mechanisms of diffusion and challenges in the field could serve to define and disseminate a conceptual framework for the field. The publication could draw on historical case studies to illustrate potential mechanisms of diffusion, including professional networks, organizational characteristics, financial incentives, risk perceptions, and costs and benefits to both patients and physicians. While there is a need for a consistent definition of value, it may be difficult to address conclusively in a concept paper because of the heterogeneity of value, even of a single technology, in different clinical settings.

A conceptual framework for the diffusion of medical technology could also draw on lessons from other fields of research. Some challenges, such as the heterogeneity of value attributions, may be unique to health care diffusion; however, research methodologies developed in the fields of economics, infectious disease, behavior change, big data, and other disciplines may be relevant. Inviting experts from these fields to future workshops might be valuable. Collaboration with the Clinical and Translational Science Awards (CTSA) program, which aims to speed research from discovery to improved patient care, and the Steering Committee for *Determinants of Personalized Health Care and Prevention* (U01) <u>RFA-RM-12-024</u>, another NIH Health Economics Common Fund supported effort, might also be fruitful.

#### **Data Sources**

Timely and affordable access to a range of data sources is critical for successful research on diffusion of medical technology. Participants discussed ways to improve access to the most important extant data sources and identified outstanding data needs. There was some interest in posting links to important resources on a new or existing website so researchers, particularly those new to the field, can quickly learn about and access available data. Referencing such a website in a future concept paper would help raise awareness of its existence.

Data from private sources, such as IMS Health and the American Medical Association (AMA), are useful but can be expensive and difficult to access. There is also a perception that some users receive data faster and for lower cost than others. Participants suggested that NIH help explore possibilities for facilitating data access by its funded researchers.

Participants identified a number of gaps in currently available data. Claims codes, for example, are often not sufficiently detailed to determine the exact device or drug used. The ultimate solution is for CMS and other payers to adopt more precise codes, including unique device identification (UDI) numbers for devices. Alternatively, some researchers have merged multiple datasets, such as claims data and device registries. This strategy is limited because registries exist only for select technologies. Nonetheless, merging disparate datasets may be useful for other purposes. For example, the CMS Open Payments database could be used to identify key thought leaders and then be merged with claims data to study patterns of practice.

Longitudinal data on private insurers' coverage decisions covering a long period of time, along with data on CMS regional commitees' coverage decisions, would be very useful.

More information is needed on characteristics of organizations and providers and on the attitudes and behaviors of physicians. Participants suggested that physician surveys might be the best way to obtain these types of data. While it is possible to field a new survey, adding new questions to an existing survey might yield a better response rate. Participants suggested approaching a variety of organizations that conduct relevant surveys including both government agencies, such as the Agency for Healthcare Research and Quality (AHRQ), and private entities, such as the American Hospital Association (AHA) and the AMA, to ascertain their willingness to collaborate.

Surveys of expert opinion could also be used to develop better definitions and measures of the value of medical technologies in various clinical settings. Attributing value to technology— specifically, value to whom and under what conditions—might also require expert consensus and ranking procedures and as these metrics are collected, they could be shared with other

researchers. The Choosing Wisely initiative<sup>1</sup> used this approach to qualitatively identify potentially low-value tests and procedures. The creation of a quantitative database of high- and low-value technology based on expert opinion would be valuable; one participant suggested a hybrid qualitative approach. This work might be done in collaboration with the CTSAs.

In later discussion, Brent Hollenbeck and Julie Bynum observed that characteristics of a technology relevant to the adoption decision are not only its effectiveness in terms of patient outcomes and its profitability, but also human factors from the standpoint of the provider. A good example is robotic surgery for prostate cancer, which obviates the need for the surgeon to work for a long period in an uncomfortable position.

It is possible to create synthetic datasets that resemble real datasets without sensitive information. While work based on synthetic datasets may not be acceptable for publications in many academic journals, they might be useful for network analysis and other methods development.

### Methodologies

Determining the best metrics for diffusion of new technologies remains a key challenge. The projects presented at this workshop used a variety of metrics. Time and experimentation will likely be needed before the most effective metrics are identified. It may also be useful to communicate with experts from economics, sociology, and other fields that have studied diffusion of innovations generally. One participant proposed development of a diffusion "rate generator" at several levels of analysis that could be used as a common resource.

Several projects employed network analysis to examine patterns of diffusion and there was robust discussion on ways to improve these methods. Since the dominant mechanisms of diffusion are yet unknown, establishing a conceptual framework for diffusion research may help researchers using network analysis to focus on the most important relationships. For example, it may be important to identify key opinion leaders in the network and assign greater weight to their relationships over others. Developing multiple networks with the same nodes and different relationships and comparing them to one another will likely be an important step.

One question is to identify which networks are the most important—those based on common residencies, on current employers, hospital affiliations or geographic locations, etc.

One of the primary critiques of the network analysis studies was that the edges that define each relationship are deterministic and include no measurement of error or distribution of probability. Creating networks with stochastic relationships may yield more compelling results. Incorporating functional analysis into network analyses may also be useful.

<sup>&</sup>lt;sup>1</sup> Choosing Wisely is an initiative of the American Board of Internal Medicine Foundation. More information can be found at their website <a href="http://www.choosingwisely.org/">http://www.choosingwisely.org/</a>.

The hypothesis that adoption of new technologies could change the relationships in a network poses another challenge to network analysis. Bhattacharya suggested that economists have addressed similar problems in general equilibrium models and that collaborating with economists may be useful. Given the complexity of multidimensional network analysis, collaboration with <u>Big Data to Knowledge</u> (BD2K), another NIH Common Fund Program, may inform new methodologies.

Workshop participants briefly discussed potential international comparisons of diffusion. For example, it would be interesting to investigate international differences in clinically appropriate and inappropriate diffusion of new medical technologies. Hollenbeck suggested leveraging empirical work on diffusion funded by the United Kingdom's National Institute for Health and Care Excellence (NICE).

# **Invited Presentations**

### **Can Health Insurance Competition Work? The U.S. Medicare Advantage Program** Jay Bhattacharya, Stanford University

The U.S. Medicare Advantage Program, or Medicare Part C, is an alternative to traditional feefor-service Medicare in which beneficiaries enroll in private managed care insurance plans in a competitive market. The Centers for Medicare and Medicaid Services (CMS) compensate the private insurers on a per enrollee basis and has historically paid private insurers more than the matched fee-for-service costs due to rebates intended to attract enrollees. In the last decade, CMS has carried out a significant experiment with managed competition via the expansion of Medicare Advantage.

In 2006, the compensation structure of Medicare Part C changed from simple capitation rates to risk-adjusted rates based on health scores assigned to beneficiaries at the time of enrollment. This is important because Medicare Advantage beneficiaries are, on average, healthier than beneficiaries enrolled in traditional Medicare. The new payment structure also incorporates competitive bidding and payments. CMS establishes a benchmark that approximates Medicare's expected cost of care for a given insurance market. Private plans offer bids that may be either above or below the benchmark. Enrollees must pay the difference for plans that are more expensive than the benchmark. Plans that are less expensive than the benchmark receive an additional rebate payment from Medicare equal to three quarters of the difference between the benchmark and the bid. The rebate must be passed on to consumers in the form of greater benefits.

Bhattacharya's study addressed the following research questions using data from 2006 to 2011:

- Are there gains from trade in allowing seniors to enroll in private Part C plans?
- Who captures these gains: taxpayers, beneficiaries, or insurance companies?
- How effective is competition? Could it work better with a different program design?

#### **Competition and Pricing**

Most Medicare Advantage plans (93 percent) bid below the benchmark and receive a rebate. Bids appear to respond to changes in the benchmark, increasing about 40 cents for every onedollar increase in the benchmark.

Medicare Advantage plans face competition from other Medicare Advantage plans and from traditional Medicare. Bhattacharya's analysis showed that, on average, a plan that increases its bid by \$20 per enrollee per month would lose 20 percent of its enrollees, with about half switching to traditional Medicare and the rest to other Medicare Advantage plans.

#### **Efficiency and Surplus**

Overall, Medicare Advantage plans appear to be more efficient than traditional Medicare. There is no evidence that clinical outcomes of patients with the same risk score are worse off in Medicare Advantage compared with traditional Medicare, and the estimated average cost of care in Medicare Advantage plans is \$586 per enrollee per month compared to \$675 in traditional fee-for-service Medicare. Nevertheless, the average Medicare payment for Medicare Advantage plans (excluding rebates) is \$681, resulting in a \$95 surplus per enrollee (\$681-\$586) per month for private insurers. Because Medicare also pays an average rebate of \$75 per enrollee per month, the government surplus is *negative* \$81 per enrollee per month.

Rebates are primarily spent on cost-sharing reductions, with the remainder spent on Part D (prescription drug) benefits, premium reductions, and other benefits. One of the primary ways that Medicare Advantage plans save money is by utilizing a smaller provider network, which Bhattacharya estimates costs consumers \$26 per month in value. The effective average surplus for consumers of enrolling in Medicare Advantage plans is therefore about \$49 per month.

In order to meet cost savings goals, Medicare Advantage payments will be reduced by lowering benchmarks. Bhattacharya's analysis predicts that this will make markets more competitive. Private insurers will still have surplus, albeit lower than today, and will likely lose market share to traditional Medicare.

#### Differential Use of Technology

Whether new technologies are used differently in Medicare Advantage plans versus traditional Medicare was not explicitly investigated, partly because detailed utilization data are not available for Medicare Advantage plans. Theoretically, one would expect differences in technology usage between traditional Medicare and Medicare Advantage plans because of the different compensation schemes and incentives for Medicare Advantage plans to provide more cost-efficient care.

#### **Closing Thoughts**

Medicare Advantage is a large and fast growing program that provides an attractive opportunity to study the potential for managed competition in health care markets. Despite being a stated goal, Medicare Advantage has not reduced taxpayer costs. Private plans do appear to realize substantial cost savings when compared to fee-for-service plans and capture a substantial fraction of surplus that is created. Plans can generate markups due to very low enrollee demand elasticity and, to some extent, concentrated market structure. Successful health care competition may depend on fostering more competitive bidding.

#### **The Role of Physician Networks in the Adoption of New Prescription Drugs** Julie Donohue and Hasan Guclu, University of Pittsburgh

Many factors may affect physician prescribing choices, including scientific evidence, influence of payers and pharmaceutical companies, physician characteristics, and peers. The influence of peers is poorly understood yet may play an important role. Physicians form connections with peers during training, working in health care organizations, and through professional societies. They share information, advice, and patients and may influence each other's prescribing habits in significant ways. Social network analysis can provide a theoretical framework and measurement tools to estimate the effects of peer influences on physician prescribing behavior.

Previous research validated the use of administrative claims data to infer social networks of physicians based on their number of shared patients.<sup>2</sup> Because methodological challenges relating to causal inference persist, it is wise to supplement network analyses with other types of data.

#### Adoption of New Drugs in Pennsylvania

Donohue, Guclu, and colleagues are investigating the role of physician networks in the adoption of new prescription drugs in Pennsylvania. Preliminary analyses focused on prescribing of dabigatran, an oral anticoagulant introduced in 2010 as an alternative for warfarin. All anticoagulant prescribers in Pennsylvania were identified from IMS Xponent<sup>TM</sup> data. These prescribers were subsequently linked to a Medicare patient-sharing network using National Provider Identifiers (NPIs). Characteristics of the prescribers were also measured, including age, sex, specialty, practice setting, and prescribing volume.

Initial results of adoption time (measured as time to first prescription) of dabigatran by specialty show that cardiologists were the fastest adopters, followed by primary care physicians. It is not clear what proportion of the primary care prescribers received patients who were already prescribed dabigatran by a cardiologist.

Significant geographical differences in dabigatran adoption times were also observed: adoption was faster in Allegheny County, which includes the city of Pittsburgh, than in Philadelphia County. The two counties have similar provider populations overall. Guclu and colleagues hypothesized that network analysis based on provider characteristics might reveal potential mechanisms to explain the observed difference in adoption rates.

<sup>&</sup>lt;sup>2</sup> Barnett, Michael L, Bruce E Landon, A James O'Malley, Nancy L Keating, and Nicholas A Christakis. "Mapping Physician Networks with Self-Reported and Administrative Data." *Health Services Research* 46, no. 5 (October 2011): 1592–1609. doi:10.1111/j.1475-6773.2011.01262.x.

#### **Network Analysis**

Guclu presented preliminary results in the form of several spatial visualization maps. On each map, the dots, called nodes, represent physicians who prescribe anticoagulants and the lines, called edges, represent relationships between the physicians. The relationships were defined as sharing either at least 8 or at least 20 patients based on Medicare claims data. The analysis considered any shared patients, not just anticoagulant users. For the maps of Allegheny and Philadelphia Counties, nodes were color coded to represent cardiologists, primary care physicians, and other specialists.

Guclu noted that the Allegheny networks were more tightly clustered than the Philadelphia networks, especially at the 20 patient threshold. Many cardiologists share patients with one another and form the core of the network. Clusters of highly connected primary care physicians were also evident in both counties. The relatively greater prevalence of highly connected physician communities in Allegheny County may help explain the faster adoption of dabigatran in Allegheny compared to Philadelphia.

#### Discussion

Workshop participants discussed several ways to improve or extend the analysis. For example, it may be important to identify key opinion leaders in the network whose relationships might be more influential than others'. Those leaders could be identified using other datasets, such as Open Payments from CMS, which connects physicians to payments from pharmaceutical companies. It is possible that key opinion leaders do not provide care for many patients, in which case a network based on shared patient relationships would not be the most meaningful. Relationships could be defined differently, such as by institutional affiliations, to generate alternative networks. Multiple networks could subsequently be combined in a more complex analysis to give a richer picture of the social networks that might influence adoption of new prescription drugs.

# Professional Physician Networks to Study the Diffusion of Implantable Cardioverter Defibrillators

A. James O'Malley and Julie Bynum, Dartmouth College

Implantable cardioverter defibrillators (ICDs) are an excellent technology to study diffusion because they confer heterogeneous benefits to different patient groups and there exists an ICD device registry that allows researchers to discern instances of appropriate and inappropriate use. Thus, researchers can measure both good diffusion and bad diffusion for the same technology. This ongoing study is investigating whether mechanisms of diffusion are the same for both appropriate and inappropriate uses of ICDs based on the theory that physician social networks are a core mechanistic component of diffusion.

It is impractical to directly measure social interactions between physicians. Instead, shared patients as measured from claims data were used to infer professional relationships between physicians. In an attempt to focus on professional relationships relevant to ICD use, shared patients were restricted to those with at least one of four cardiovascular diagnoses: cardiac

arrhythmia, congestive heart failure, coronary heart disease, and peripheral vascular disease. Whether this is the best proxy for relevant physician professional networks remains an open question.

Preliminary results were shared using graphic displays of relationships between all providers in the Boston hospital referral region (HRR). Nodes representing providers were color-coded according to physician hospital networks (PHNs), which are artificially constructed groups of physicians based on the primary hospital to which they bill, refer, or admit patients. The graphics showed that some PHNs are more centralized or have a higher density of professional relationships than others.

Two specific hypotheses will be tested based on these preliminary results: (1) highly centralized PHNs will have slower internal diffusion rates unless the central individuals are the initial adopters and (2) physicians' professional relationships to other PHNs are more important than geographic or organizational closeness to a physician becoming a first-adopter. In the long-term, the research team plans to streamline construction of more flexible physician networks, expand the analysis to cover the entire country, and apply the technique to other technologies and diagnoses.

## **Regional Patterns in Medical Technology Adoption**

Anne Hall, Bureau of Economic Analysis

Misaligned incentives often lead to non-optimal adoption of medical technology. Profitable technologies with questionable medical benefits are often adopted rapidly, and medically beneficial technologies that are not profitable are often insufficiently adopted. Previous research has revealed significant regional variation in health care spending, productivity, and outcomes, but the sources of variation are unclear. Hall sought to determine whether regions that adopt effective medical technologies quickly also adopt ineffective medical technologies at a higher rate than other regions.

#### Principal Components Analysis

Hall conducted a principal components analysis of the rates of use from 2002 to 2008 of seven medical technologies—each with an established medical effectiveness rating (high or low)—to detect patterns in the adoption of all technologies. The seven medical technologies and their medical effectiveness rating are listed below:

Technology	Effectiveness
Mammograms among women 50 and over	High
Colorectal cancer screening among adults aged 50	High
Cervical cancer screening among women aged 18 and over	High
Mammograms among women aged 40-49	Low
Prostate cancer screening among men aged 50 and over	Low
MRI to diagnose causes of back pain <sup>1</sup>	Low
MRI to diagnose cancer <sup>2</sup>	Unknown

<sup>1</sup> Defined as all MRIs for patients with diagnoses of back pain.

<sup>2</sup> Defined as all MRIs for patients with diagnoses of cancer.

Data for adults age 64 and under in 150 large metropolitan statistical areas were analyzed regionally. MarketScan<sup>®</sup> data were used for health care spending and magnetic resonance imaging (MRI) utilization. Behavioral Risk Factor Surveillance System data were used for cancer screening rates.

Three primary components were identified that together explain about three quarters of the total variation. The primary component, high use, accounts for about 47 percent of the variation. All technologies had positive loadings under this component, suggesting that regions that adopt highly effective medical technologies also adopt less effective medical technologies. The second component explains 16 percent of the variation and seems related to MRI utilization because only the MRI technologies had positive loadings. The third component explains only 13 percent of the variation, but is interesting because all high-effectiveness technologies have positive loadings and all low-effectiveness technologies have negative loadings.

#### Technology Adoption and Health Outcomes, Productivity, and Spending

Hall also explored whether the patterns revealed by the principal components analysis relate to health outcomes, productivity, and spending. Health outcome measures included self-reported health status, disability days, and mortality. Controlling for demographic and other factors, a regression on component scores from the principal components analysis showed that only the quality component significantly affects aggregate health outcomes. Hall suggested that the quality factor is correlated with other high quality medical practices that also positively affect outcomes and that these seven technologies do not directly affect outcomes. This interpretation is supported by the fact that cervical cancer screening had a significant negative effect on mortality of men in Hall's analysis.

Health care productivity was measured as aggregate health outcomes divided by per capita medical spending. The high use and MRI components had significant positive effects on productivity based on mortality, but not when adjusted for outcomes that would be predicted by health care spending and utilization. The quality component had a significant positive effect on adjusted productivity based on health status or disability.

Although not presented at the workshop, the full paper includes an analysis of the relationships between technology adoption and education and social capital. The high use component is positively related to education and negatively related to social capital; the quality component has the reverse relationships. Future research will incorporate financial incentives.

#### Discussion

Workshop participants discussed the study methodology. Principal components analysis assumes data are continuous, not bounded, and may not be the most appropriate statistical approach. Principal components analysis may overestimate the number of significant factors. Creating a correlation matrix and using a tetrachoric analysis may be a suitable alternative. A factor analysis with a non-orthogonal rotation was also suggested.

In the present analysis, the effectiveness of technologies was defined based on guidelines in 2002. Workshop participants noted that some of the guidelines have changed over time and different groups of clinicians have different opinions on the efficacy of various treatments. Investigating the use of these technologies in older populations may avoid some of the clinical disagreements. The recommended frequency of some tests is not annual, which may also factor into their effectiveness classification and may have consequences due to recall bias of self-report data. Finally, it is important to adjust for demographics of each region separately because the accuracy of self-report data varies based on demographics and may distort any disparities, especially for measures of education and social capital.

### Accountable Care Organizations and the Diffusion of New Surgical Procedures Brent Hollenbeck, University of Michigan

Value can be conceptualized as two components: benefit to patients and cost. Surgical procedures can be mapped into four quadrants to visualize their value using these parameters as axes. Value may also be heterogeneous within procedures depending on the patient population and clinical circumstances.

Discouraging use of low-value technologies is a priority. Accountable care organizations (ACOs) have novel financial incentives and may be able to influence substitution of low-value technologies and expanded use of high-value technologies. Hollenbeck and colleagues plan to use data from 2012 to 2016 to determine whether groups of providers that become ACOs use low-value technologies less often after they become ACOs. Two key challenges exist: attributing value to procedures and measuring ACOs.

#### Attribution of Value

There are several possible ways to attribute value to procedures. First, researchers could leverage the variation in use of procedures to characterize their degree of discretion. Some procedures are used evenly across health care markets, whereas others have wide variation in rates of use. The implication is that procedures that are used consistently across health care markets are likely more valuable or necessary than those used discretionally. The advantages of this approach are that it is empirical and scalable. The weaknesses are that uncertainty does

not itself imply value and variability of less common procedures might not be a reliable indicator of discretionary decisions.

Another approach to measuring the value of procedures is to survey surgeons. Extant data suggest that surgeons generally agree on which procedures are most necessary and most unnecessary, but agree less on procedures that fall in the middle. The strengths of this approach are its flexibility to account for heterogeneity of value across patient groups and its involvement of the primary stakeholders who determine adoption of procedures. An important weakness is that surgeons are potentially bad agents who may ignore evidence and be motivated by incentives other than benefits to patients. Surveying surgeons may also be impractical.

A third option is a hybrid qualitative approach consisting of a systematic review tabulating costs and benefits that is subsequently presented to an expert panel to adjudicate value into one of the four domains. This flexible approach can adapt to new technologies and changing evidence, can account for heterogeneity across patients, and involves the primary decision-makers. Its primary weakness is reliance on expert opinion to adjudicate value.

#### ACO Measurement

The best way to measure whether ACOs succeed in reducing the prevalence of low-value procedures over time while increasing the use of higher-value procedures would be to use the not-yet-released CMS beneficiary alignment file containing tax identification numbers (TINs) of ACO participants. In its absence, two methods may be used: the Harvard approach and the PHN approach.

The Harvard approach<sup>3</sup> starts with the lists of ACO participating physicians and provider groups published by either CMS or ACOs. Names of physicians and provider groups are then matched with NPIs, which are subsequently matched with TINs using publicly available databases. Once the TINs under which ACO providers bill are matched to ACOs, utilization from claims data can be attributed to an ACO. The strength of the Harvard approach is that it captures the full spectrum of ACOs, which are heterogeneous organizations, and approximates real world experience. The disadvantages are that the method is computationally and labor intensive and it is difficult to work with TINs because each TIN is often associated with multiple NPIs.

The second approach is to use PHNs to define the scope of providers affiliated with ACOs that involve hospitals.<sup>4</sup> There are about 133 ACOs that involve hospitals, comprising about 500 different PHNs. The benefits of this approach are that populations are well defined and the beneficiaries assigned to ACOs approximate CMS methods for the Shared Savings program. The

<sup>&</sup>lt;sup>3</sup> As described by McWilliams, J. Michael, Bruce E. Landon, Michael E. Chernew, and Alan M. Zaslavsky. "Changes in Patients' Experiences in Medicare Accountable Care Organizations." *New England Journal of Medicine* 371, no. 18 (October 29, 2014): 1715–24. doi:10.1056/NEJMsa1406552.

<sup>&</sup>lt;sup>4</sup> As described by Fisher, Elliott S., Douglas O. Staiger, Julie P. W. Bynum, and Daniel J. Gottlieb. "Creating Accountable Care Organizations: The Extended Hospital Medical Staff." *Health Affairs* 26, no. 1 (January 1, 2007): w44–57. doi:10.1377/hlthaff.26.1.w44.

primary disadvantage is that it focuses on ACOs that involve at least one hospital. This is a minor concern especially when studying surgical procedures.

#### Discussion

Workshop participants noted that there might be a long lag time between when ACOs are formed and when it is possible to measure technology utilization outcomes attributable to the ACO. Since ACOs will form at different times, it may be possible to control for early adopters by examining late adopters. ACOs may be initially cautious about implementing changes that may affect revenue. Physicians in new ACOs might retain much of their autonomy and may not fully understand the ACO contracts. On the other hand, new referral patterns, which may be a primary driver of change, have sometimes emerged very quickly such as after the 2012 guidelines on prostate specific antigen (PSA) testing were released. Participants agreed that such rapid changes following the release of new guidelines are relatively uncommon and whether ACO-induced changes will occur quickly is uncertain.

Significant heterogeneity is likely across ACOs in terms of their ability to achieve savings and meet quality measures. It may therefore be useful to investigate potential sources of variation. For example, one hypothesis is that the success of ACOs will be greater in health care markets with high penetration of ACOs due to competition.

# Diffusion of Implantable Cardioverter Defibrillators: Regional Variation and Patient Selection

Nancy Morden, Dartmouth College

The clinical indications for ICDs are evolving and include secondary prevention following resuscitation and primary prevention for patients at risk of cardiac arrest. CMS reimbursement for ICDs for primary prevention began in 2005. Evidence-based guidelines issued in 2006 and 2008 emphasized that ICDs should only be used as primary prevention after patients receive angiotensin-converting enzyme (ACE) inhibitors and beta blockers because these medications can improve symptoms such that as many as two-thirds of patients no longer qualify for ICDs. Morden and colleagues investigated diffusion of ICDs for primary prevention and compared real-world use to optimal use as defined by clinical guidelines. The hypothesis was that early adoption of ICDs for primary prevention would be associated with less appropriate patient selection.

Medicare claims data from 2006 to 2011 were combined with data from the ICD registry to generate a database of registry enriched claims for analysis of population-level ICD rates. A random subgroup (40 percent) with more clinical data from the registry was used to construct a denominator. The main measures were the range and variation of ICDs for primary prevention by HRR in 2006 to 2011, early adoption by HRRs in 2006 and 2007, a comparison of ICD recipients by HRR versus the guideline criteria, and the correlation of early ICD use with guidelines adherence.

Results showed that from 2006 to 2011 about 80 percent of ICDs were implanted for primary prevention. However, many patients who received ICDs for primary prevention did not meet the guideline requirements: more than 50 percent of patients did not receive optimal medication and more than 40 percent did not receive the minimum recommended medication prior to ICD implantation. Both ICD use and the proportion of ICDs meeting guideline criteria varied considerably among HRRs. Preliminary analyses of these data indicate that although adoption rates varied geographically, early uptake of ICDs was not associated with a lower proportion of patients meeting ICD guideline criteria.

Morden and colleagues plan to compare early adoption and specific guideline criteria, differences by subtype of ICD from registry data, and apparent exnovation of ICDs between 2010 and 2011. For greater precision, the authors plan to conduct analyses at the hospital level. They also plan to complete additional modeling studies.

# Health Care Expenditures and Health Outcomes: An Analysis in the Medicare Population

Carrie Hoverman Colla, Dartmouth College

Previous studies comparing health care spending and health outcomes have reached conflicting conclusions. Even when focused on the same outcome—mortality from acute myocardial infarction—results varied based on the specifications of the regression, including outcome metrics, risk adjustment schemes, and patient sets.

Variation in supply factors, such as productivity, expertise, and choice of services provided, has been inadequately addressed in the literature and is important because not all spending is equally productive. Health care services may, for example, be classified as effective (cost effective for most patients), heterogeneous (cost effective for some patients and ineffective for others), or low-value (uncertain or small benefits or potentially harmful). The degree to which a given hospital utilizes effective, heterogeneous, and low-value technologies respectively greatly influences the relationship between spending and health outcomes. To investigate this relationship, Colla and colleagues conducted a cross-sectional analysis of spending and health outcomes by treatments of varying effectiveness for acute myocardial infarction.

Medicare fee-for-service claims from 2007 to 2009 were analyzed at the hospital level and included only hospitals that treated at least 200 patients with acute myocardial infarction. The outcome measures were 3-day mortality, 1-year mortality, and 1-year price-adjusted expenditures. Separate linear models were used for mortality and spending. The analysis controlled for covariates including comorbidities at admission, location of heart attack, and demographics. The models used were not sensitive to risk adjustment schemes. Three treatments from each category of effectiveness were used as independent variables for regressions.

Category	Type of Care	Examples
I	Effective	Beta blockers in first 6 months
		Statins in first 6 months
		Hospital Compare quality measures
II	Heterogeneous	Percutaneous coronary intervention (PCI) in
		first two days
		PCI in following year
		Unique doctors (quartiles)
Ш	Uncertain/Low value	Home health care expenditures
		Double computed tomography (CT) scans
		of the chest
		Feeding tubes in dementia patients

Results of 1-year mortality and 1-year spending showed that effective treatments lead to lower mortality and lower spending while low-value treatments lead to higher mortality and higher spending. The use of heterogeneous and low-value technologies explained a high proportion (more than 40 percent) of the variation in expenditures. In contrast, all variables explained very little (cumulatively less than 15 percent) of the variation in mortality.

Based on the preliminary results, the empirical evidence is consistent with the theoretical model suggesting that the relationship between health care spending and outcomes depends in part on effectiveness of services provided. Limitations of the study include the difficulty of categorizing and measuring categories of health care services by effectiveness and controlling for organizational quality factors. Conducting the analysis at the individual level would mitigate organizational bias, but may introduce other biases. Future work will incorporate a greater number of categorized health technologies and analyze longitudinal data from 1986 to 2009.

# **Cooperative Agreement Project Updates**

## How Do Patents Affect Research Investments?

Heidi Williams, Massachusetts Institute of Technology

Many factors affect health care research investments. Patents are market incentives designed to encourage research investments; however, little empirical evidence supports the perception that patents are an effective way to spur medical innovation. Generating empirical evidence on patents is difficult because public information on specific research investments is scarce and because all patents have fixed 20-year durations. Williams and colleagues have identified new data sources on pharmaceutical research investments and focus on effective patent terms—the difference between the official 20-year term and the duration of clinical trials—which varies substantially by disease.

A preliminary analysis showed that longer commercialization timelines significantly reduce private research investments, but it is not clear that shorter effective patent terms are the causal mechanism. For example, corporations may have excessive discount rates motivated by a desire to demonstrate short-term returns to investors.

In an attempt to provide more direct evidence of the importance of patents, Williams investigated the relationship between effective patent terms and Food and Drug Administration (FDA) approvals of new uses for existing drugs, excluding biologics. While pharmaceutical companies may receive patents for new uses, such patents offer little protection in practice because physicians may prescribe generic drugs for off-label uses. In fact, pharmaceutical companies often do not know for any given patient which indication their drugs are being used for. Differential pricing for drugs by clinical indication is not currently possible. Nevertheless, companies often choose to invest in research for new uses if they believe such approvals will broaden the use of their products.

A comparison of FDA new use approvals and market entry of generics showed that new use approvals are most likely between 5 and 15 years before generic market entry. New use approvals are uncommon after generics are on the market. The average number of approvals for new indications also increases with greater lags between initial FDA approval and the market entry of a generic. In contrast, FDA approvals of new formulations—a common tactic for extending effective patent terms without directly competing with generics—are about equally likely 5 years before and 5 years after the introduction of a generic.

In the long term, this study aims to determine the effects of longer effective patent terms on approvals for new indications and new formulations. The researchers may also pursue new ways to measure off-label use as well as to assign social value to approvals for new indications and formulations.

## **Technology Diffusion Under New Payment and Delivery Models**

Sharon-Lise Normand and Haiden Huskamp, Harvard University

This project aims to identify organizational characteristics associated with the diffusion of selected new technologies and the use of lower- and higher-value services and to estimate the effects of Medicare risk-based reimbursement contracts on spending for the same technologies and services. Data include several public and private sources with information on organizational characteristics, private insurance and Medicare claims, and clinical registries from 2005 to 2015. The research team is evaluating the use of multiple new technologies for cancer, depression, cardiovascular disease, and hip degeneration. Normand and Huskamp presented preliminary results for the diffusion of the cancer biologic bevacizumab and for characterizing organization affiliations using the IMS Healthcare Organization Services (HCOS) database.

#### Diffusion of Bevacizumab

The diffusion of bevacizumab was measured for several cancers as time to first bevacizumab infusion in elderly fee-for-service Medicare beneficiaries with a cancer diagnosis undergoing

chemotherapy between 2005 and 2012. The unit of analysis was the individual patient. Nearly 500,000 cancer patients comprised the denominator for diffusion rates. In the future, characteristics of each provider organization will connect to this analysis based on the TIN associated with the physician responsible for each infusion.

Preliminary results indicated bevacizumab was adopted faster in some diseases than others, likely due in part to different approval dates and designations as a first- or second-line treatment. Colorectal cancer, for which bevacizumab was approved as first-line treatment in 2004, had the fastest initial adoption rate with its slope decreasing over time. Off-label use was apparent for other diseases prior to their respective approval dates. Once approved for brain cancer, the adoption of bevacizumab for that indication rapidly increased. In contrast, diffusion of bevavizumab for breast cancer slowed after 2010 when bevacizumab lost its indication for that disease.

The next steps for the bevacizumab analysis are to model diffusion curves at the organization level and to examine the case of breast cancer post-2010, when bevacizumab can be considered a low-value treatment and exnovation should be observable. Workshop participants suggested that using a measure of new adoptions for each annual cohort might be more meaningful than cumulative adoptions for all cohorts combined, particularly when studying exnovation or comparing adoption by organizations. Participants also expressed interest in linking this analysis to health outcomes, such as survival.

#### **Organization Affiliations**

The research team has begun to explore organizational affiliation data from HCOS. In 2014, 57 percent of providers in the HCOS database were physicians. The top three specialties were internal medicine (15.9 percent), family medicine (11.3 percent), and pediatrics (7.8 percent). The HCOS data provides organization affiliations, such as hospitals and practices, for each provider. These data will be used to create organizational affiliation variables for subsequent analyses.

#### Next Steps

Beyond the bevacizumab and organization affiliation analyses, the research team will identify additional technologies, complete a review of Category III codes, and identify Medicare spending associated with new technologies.

## Technology Diffusion, Health Outcomes, and Healthcare Expenditures

Jonathan Skinner, Dartmouth College

Skinner provided progress updates on three parts of his cooperative agreement: diffusion of intensive care unit (ICU) beds, diffusion of fraud, and exnovation.

#### **Diffusion of ICU Beds**

There are substantial regional differences in the percent increase of ICU beds from 2000 to 2010 normalized to the regional adult population. The percent change in ICU beds per 10,000 individuals plotted on a map of the United States reveals a heterogeneous mosaic; many states

contain regions with positive and regions with negative changes over the same time period. Future research will link these regional differences to health care costs and outcomes.

### Diffusion of Fraud

Fraud is an extreme example of costs incurred with no clinical benefit. One example of fraud occurred in Miami from about 2004 to 2006 where physicians filed thousands of fraudulent Medicare claims for up to 60 immunoglobulin shots per patient per year that cost between \$2,000 and \$3,500 per shot. Nationally, the median rate of immunoglobulin shots is about 1 per 100,000 people. In Miami in 2004 the rate was over 750 per 100,00 people. Typically, a laboratory test is required prior to administering immunoglobulin. Lab tests were not obtained in these cases and, indeed, it is possible that the patients never received the shots.

To investigate whether physicians, laboratories, or other parties drove the fraud, Skinner and colleagues conducted a network analysis of laboratories sharing the same physicians requesting tests for immunoglobulin shots. The result was one highly connected network with several isolated laboratories on the periphery, suggesting that some labs may have been involved in the fraud scheme while others may have not. A future comparison of this network to a network of all laboratory-physician relationships regardless of the purpose of requested tests might reveal whether the pattern of relationships based on immunoglobulin tests is, in fact, abnormal. There is some evidence of possible Medicare fraud with immunoglobulin injection claims in other parts of the country. Similar social network analyses may help reveal whether the alleged fraud was learned from the confirmed fraud scheme in Miami.

#### Exnovation

Skinner and colleagues are also studying exnovation as defined by the patterns of decreased use of a medical technology. Skinner defined exnovation in this context as essentially the opposite of diffusion. For example, surgeons in the United States now perform fewer carotid endarterectomies than in the past. Whether there are regional differences in the exnovation of carotid endarterectomies is unclear. Further, it is uncertain which patient groups benefit from the procedure. It is therefore important to determine whether surgeons performed fewer endarterectomies only on patients who are least likely to benefit from the procedure versus fewer endarterectomies across all patient groups regardless of clinical indications.

# Appendix 1: Agenda

#### Thursday, November 13, 2014

6:30-8:30	BREAKFAST	NCTC Commons
10:00 a.m.	Welcome and Introductions	Jonathan Skinner
10:15 a.m.	Competition and Coordinated Care: The Case of Medicare Part D:	Jay Bhattacharya
10:45 a.m.	The Role of Physician Networks in the Adoption of New Prescription Drugs	Julie Donohue Hasan Guclu
11:15 a.m.	Physician Networks and the Diffusion of ICDs	A. James O'Malley Julie Bynum
11:45 a.m.	Roundtable Discussion on Network Analysis	
12:15 p.m.	LUNCH	NCTC Commons
1:30 p.m.	Regional Patterns in Medical Technology Adoption	Anne Hall
2:00 p.m.	Accountable Care Organizations and the Diffusion of New Surgical Procedures	Brent Hollenbeck
2:30 p.m.	BREAK	
2:45 p.m.	Opening Remarks: Health Economics Research Funding	John Haaga
	Discussion I: Resources for the Study of Technology Diffusion Data Needs Methods Development Training Needs Dissemination of Research	Moderator: Jonathan Skinner
4:15 p.m.	ADJOURN	
5:30-7:30	DINNER	NCTC Commons

## Friday, November 14, 2014

6:30-8:30	BREAKFAST	NCTC Commons
8:30 a.m.	Awardee Project Updates	Heidi Williams Haiden Huskamp Sharon-Lise Normand Jonathan Skinner
10:00 a.m.	BREAK	
10:15 a.m.	Implantable Cardioverter Defibrillator (ICD) Diffusion	Nancy Morden
10:45 a.m.	Healthcare Expenditures and Health Outcomes: An Analysis in the Medicare Population	Carrie Hoverman Colla
11:15 a.m.	Discussion II: Joint Publications and Data Sharing	Moderator: Jonathan Skinner
12:00 p.m.	LUNCH	NCTC Commons
12:45 p.m.	ADJOURN	
1:00 p.m.	Chartered Shuttle to IAD/Dulles	Murie Lodge

# **Appendix 2: Workshop Participants**

### **Steering Committee Members**

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