Stakeholder Rulemaking: A Model for Implementing Evidence-Based Medicine

By David L. Weimer

Organ transplantation offers many people greater longevity and higher quality of life. In cases of liver failure, transplantation is the only treatment to forestall death. In the case of kidney failure, transplantation provides a more desirable and less costly way to extend life. Unfortunately, the supply of organs from deceased people that are available for transplant falls far short of number needed to provide appropriate transplants. Consequently, the rules for the allocation of these cadaveric organs literally have life and death implications. In 1984, the National Organ Transplant Act delegated authority for determining the substance of these rules to the Organ Procurement and Transplantation Network (OPTN), a nongovernmental organization consisting of those who have a stake in the outcome, including transplant centers, laboratories that determine the compatibility of donor organs and potential recipients, organ procurement organizations, professional societies, and patients. Based on my review of the history of the OPTN and direct observation of its proceedings over a dozen years, I was impressed with the extent to which rule changes were based on the best available medical evidence and took explicit account of the various values at stake. Indeed, I believe it offers a model of medical governance that may be desirable in other contexts, such as in rationalizing the use of surgical procedures funded by Medicare.

My initial motivation for studying the OPTN was what seemed to be a puzzle: Why would Congress delegate this important task to a private organization? Very quickly it became apparent to me that most members of Congress did not want to be drawn into questions about what constituted medically appropriate allocation rules, which would almost certainly happen if the substance of rulemaking were delegated to a federal agency. In view of the great shortage of transplant organs, any rule change that favored some patients would inevitably disfavor others. As people tend to view losses as more salient than comparable gains, members of Congress would likely garner more blame than credit whenever the agency changed the rules.

As I began observing the OPTN, a more interesting research question emerged: How does its rulemaking compare to what we would expect from rulemaking in traditional agencies? To answer this question, I studied the history of changes to liver allocation rules, which erupted in public controversy in the late 1990s, and the evolutionary changes in kidney allocation rules that have been occurring since the initial rules were made. My answer, set out in detail in Medical Governance: Values, Expertise, and Interests in Organ Transplantation (Georgetown University Press, 2010), is that the OPTN makes extensive use of both scientific evidence and...
the tacit knowledge of transplant professionals to improve rules incrementally to promote more efficient and fair allocation of scarce organs in ways that would not be likely to occur through agency regulation.

Features of Stakeholder Rulemaking that Facilitate Effectiveness

Assessment of rulemaking by the OPTN suggests that eight features promote desirable, evidence-based evolution of rules. Efforts to apply the OPTN model in other contexts should seek to replicate these features.

First, stakes should be meaningful. The stakeholders with scarce expertise typically have high opportunity costs in terms of time and energy. These experts, or their employers, are more likely to be willing to bear the costs of participating in governance when they perceive the stakes to be meaningful. For the stakes to be meaningful, they must involve something of value. Further, stakeholders must believe that they can influence the allocation of the thing of value through their participation in governance. Participation must connect stakeholders in some direct way to outcomes. Clear delegations of authority to organizations for the development of particular aspects of policy do so. In the case of the OPTN, members can influence access to scarce transplant organs by contributing to network governance.

Second, the stakes should be sufficient to engage those with relevant professional expertise. Rulemaking by the OPTN relies heavily on the participation of transplant professionals who bring expertise to the table. The norm of promoting patient welfare, as well as a shared understanding of science, helps shape deliberations about allocation rules that are based on evidence and take explicit account of relevant values.

Third, there should be continuity in rulemaking. Continuity enables the OPTN committees to deal effectively with many inherently complicated issues by providing an opportunity for members to learn about them during their two-year terms. The opportunity to learn is most important for those who do not have directly relevant expertise, but it is also essential for enabling those who do have such expertise to relate it directly to problems with existing policies and proposed alternatives for addressing the problems. Learning about the other committee members through mutual participation may increase trust in the information that each provides. When major changes in policy are being developed, often during an extended period, committees may be allowed to grow in size so that existing members who have accumulated issue-specific knowledge can be reappointed and new members added.

Fourth, voting rules should be used to provide a means of making decisions. Voting in the OPTN serves the very important instrumental purpose of allowing decisions to be made in the absence of consensus. In the development of complex policies, voting may also be useful in facilitating, at least temporarily, the specification of components needed to assemble a complete proposal and therefore move toward a final decision. Although voting can sometimes be sophisticated in the sense of people voting against their true preferences at the early stages of the process to obtain a more favorable final outcome, the proportions voting for and against a proposal generally convey information about the degree of consensus on the proposal.

Fifth, policy development should employ specialization with consultation. Policy development often involves a tension between expertise and the representation of the full range of relevant values. Designing policies that can be effectively implemented in complex circumstances and predicting their consequences generally requires the tacit knowledge of specific experts. If these experts share very similar experiences, then they may also hold similar values. Consequently, it is usually valuable to broaden the policy design process to include a wide range of knowledgeable participants who may bring values to the process that might otherwise be ignored or only surface during controversy over the ultimately proposed policy.

The OPTN does this through committees that specialize in specific organ systems. These committees consult regularly with other committees, including those that have “jurisdictions” over aspects of transplantation generally, such as patient affairs, minority affairs, and ethics. Consultation among committees occurs through a number of mechanisms, including representatives from these general jurisdiction committees serving as members of the organ allocation committees, presentations to these committees by members of the organ allocation committees, sharing of information and analyses, and requests to the general jurisdiction committees for comments on specific proposals.

Sixth, the process of rulemaking should be transparent. Some degree of transparency in governance is a prerequisite for accountability and perhaps for legitimacy. The OPTN deliberates about policy in public. With the exception of meetings to handle membership issues, anyone can attend committee meetings as observers. Although there is some variation by committee, meeting summaries and reports to the board of directors are routinely posted on the OPTN website as are executive summaries of the minutes of board meetings. Those interested in participating in OPTN policy development can add their names to an e-mail list of people who are sent requests for comments on proposed policies. The transparency of OPTN governance prevents stakeholders from being surprised by policy decisions and gives them many avenues to influence it.

Seventh, investment should be made in data for creating relevant evidence. The Scientific Registry of Transplant Recipients (SRTR) created to work with the OPTN is an exemplary clinical database. It includes a near universe of transplant candidates and it follows transplant recipients over an extended period.
time—until their death. The OPTN contributes to the quality and appropriateness of the data in the registry through the policies it sets concerning reporting by transplant centers. Analyses using the data, primarily statistical and simulation models developed by SRTR staff, play an important role in policy development and evaluation efforts of the OPTN committees—the data provide systematic evidence to complement the broad knowledge of their members. Arguably, because of these data and their use by the SRTR and the OPTN, organ transplantation is at the forefront of evidence-based medicine.

Eighth, government oversight should be strategic rather than tactical. Congress created the OPTN as a distinct entity but made it subject to oversight by the Department of Health and Human Services (HHS). The oversight role of HHS with respect to organ procurement and allocation policies was initially ambiguous, but eventually HHS asserted its authority over making OPTN rules binding, establishing a distinction between de jure rules that have the force of law and de facto rules that actually govern transplantation. After a period of intense controversy over liver allocation in the late 1990s, HHS has engaged in what might be termed “strategic oversight”—sparing and selective interventions to guide or direct the OPTN and SRTR. The HHS rule that ultimately emerged from the controversy requires review of allocation rules in terms of general goals, but it does not specify how those goals are to be met. Most importantly, HHS has not attempted to formalize or overturn any of the OPTN substantive allocation rules, but rather allows these rules to operate de facto. In contrast, it has acted to make OPTN rules concerning data reporting by transplant centers and organ procurement organizations legally binding so that OPTN efforts to ensure compliance with them have the force of law.

Application: Rationalizing Medicare Surgery

In the United States, surgeries are numerous and expensive. They often lack solid evidence regarding their efficacy, and usually they have not been assessed in terms of their cost-effectiveness. Extrapolating from evidence on expenditures in Medicare, the total surgical bill in the United States in 2005 was probably about $120 billion.

Assessing the appropriateness of the large annual expenditures on surgeries requires knowledge about the efficacy and cost-effectiveness of the various types of surgeries in the contexts in which they are used. Unlike new pharmaceuticals, which are regulated by the Food and Drug Administration, surgical procedures do not require “well controlled studies” to demonstrate their effectiveness and safety before they enter mainstream practice. As noted by Alan Gerber and Eric Patashnik in their account of arthroscopic surgery to treat osteoarthritis of the knee, at least since the 1970s, medical critics have noted the weak level of evidence that is typically advanced in support of new surgical procedures; there is both a lack of research on the effectiveness of even widely adopted surgical procedures and failure of the surgical professions and the Medicare program to make use of the evidence that is available.

How could an entity like the OPTN be designed to make surgery more evidence based, thereby reducing its financial burden on the federal government and improving health outcomes of beneficiaries? For ease of reference, I label my proposal for such a system as the Medicare Surgery Assessment Volunteers for Effectiveness (MedSAVE).

Basic Requirements for an Effective Evidence System

Like the OPTN, MedSAVE would be created through legislation, with the objective of assessing the effectiveness and cost-effectiveness of surgeries. The stakes would be made meaningful for participants by having an overall annual budget cap for surgical services paid through Medicare Part B. Effectiveness also requires that MedSAVE be given the authority to set payment rates for specific surgical services through majority voting by a board of directors. Membership would be open to organizations representing surgeons and the surgical specialties, other organizations representing those concerned about specific diseases and the elderly, medical ethicists, and interested individuals drawn from the general public, patients, and the professions. And, funding would be provided to support a full-time staff, a companion registry of surgeries like the SRTR, and participation expenses for individual members of MedSAVE through a small surtax on surgeries paid for by Medicare.

Participants and General Governance Structure

MedSAVE would require explicit and systematic representation of the surgical specialties. The board of directors, which would have responsibility for approving surgical payment schedules, would be broadly representative but also include members selected by a number of interested specialty groups, such as the American College of Surgeons, the American Academy of Orthopaedic Surgeons, and so on. Other organizations representing the medical professions, those interested in specific diseases, the elderly, taxpayers would be invited to nominate people to participate in MedSAVE committees and the board of directors. For example, the Centers for Medicare and Medicaid Services (CMS) might be empowered to appoint an equal number of board members, choosing representatives of broader medical and societal interests.

MedSAVE would create standing committees to advise the board of directors with recorded votes. Some of these committees would likely focus on specific surgical specializations while others would address cross-cutting issues, such as standards for evidence, ethical concerns, and the development of coherent fee schedule proposals. A professional staff, funded from a surgery surtax, would support the work of the committees and the board of directors. The surtax would also provide funds for a sister organization, like the SRTR in the organ transplant example, that would assemble a database to help assess surgical effectiveness, analyze data as MedSAVE committees requested, and make the database available to researchers generally.

HHS would exercise strategic oversight in several ways. First, CMS would appoint the non-surgical specialists to the board of directors. Second, CMS would have ex officio
representation on the board of directors and the committees, and it would be responsible for ensuring that decision-making within MedSAVE remained transparent. Third, the HHS secretary would have the option of overruling the fee schedule adopted by MedSAVE and forcing across-the-board reductions. This default arrangement would be a serious penalty should MedSAVE fail to carry out its responsibility to promote efficacy and efficiency in the provision of surgery to Medicare patients.

Money on the Stump: The Surgical Budget Constraint

Public policy scholar Joseph White argues that health-care systems around the world have used four types of targets to control costs: price, volume, capacity, and appropriateness. MedSAVE would employ three of these targets. A combination of price and volume targets would set a “global” maximum on expenditures for surgical services similar to the one employed for all physician services under Medicare Part B. With such a cap on expenditures, the members of MedSAVE would have an incentive to assess the appropriateness of types and circumstances of surgeries and discourage inappropriate surgeries through the fee schedule. Such a budget cap would implement the advice once offered by Alice Rivlin, the first director of the Congressional Budget Office: “[T]he best rule for politicians for dealing with generals, admirals, and doctors may be this: put the money on the stump and run.”

Beginning in 2002, the sustainable growth rate target for physician fees adopted by Congress required across-the-board reductions. The 5.4 percent reduction called for in 2002 was actually implemented. However, in each of the following years Congress intervened to block the implementation of reductions, instead allowing small increases in total expenditures to occur.

While this approach has had serious shortcomings, it is instructive to ask why the sustainable growth rate system has been ineffective in controlling the growth of expenditures. From the perspective of the individual physician, gains from over-provision of services are larger than losses due to the contributions of those services to the overall fee reduction. Of course, this is just a tragedy of the commons, a classic common property resource problem in which individuals base their decisions on their private marginal benefits and costs, ignoring the contribution of their decisions to the average costs to all users of the resource. The most familiar approaches for countering the over-consumption of a common property resource are regulation and self-governance. With respect to the Medicare expenditure problem, regulation involves CMS taking steps to limit service use that have been largely ineffective and often elicit political opposition, especially from the medical profession. Self-regulation involves the resource users—physicians who receive Medicare payments—taking actions to limit their collective over-utilization.

MedSAVE would provide governance arrangements relying in part on self-governance, in which at least the surgical professions would have an incentive to self-regulate. The primary incentive would be imposing a separate sustainable growth rate for surgeries. Such a surgery-specific sustainable growth rate would be implemented by calculating current total payments for surgeries under Medicare Part B as the starting point. When calculated, the sustainable rate would yield new expenditure targets for surgery. Subject to MedSAVE’s adjustments designed to discourage inappropriate procedures, actual expenditures in excess of the target amount would trigger proportional reductions of all subsequent surgical payments. This threat of across-the-board reductions in surgical fees combined with the ability to affect the determination of inappropriate surgeries would provide meaningful stakes to encourage voluntary cooperation with MedSAVE by the most relevant stakeholders, the surgical specialties.

Authorities: Payment Rates and Data Requirements

In short, the primary authority of MedSAVE would be to apply downward reductions in the resource-based fee schedule for surgeries currently employed in the Medicare Part B prospective payment system. MedSAVE could reduce the full payment to signal uncertainty about the effectiveness of a surgical procedure, or reduce it to zero to remove it from Medicare coverage entirely. MedSAVE would have the authority to specify the conditions necessary for full payment. With angioplasty as an example, MedSAVE could choose to specify that the full payment would be made in the case of stable angina patients only if moderate or severe ischemia is documented through a stress test prior to the procedure, as the relevant medical societies currently recommend.

MedSAVE would also have the authority to require that specific data be collected before and after surgery as a condition of full payment. This authority could be employed to produce data to provide better assessments of the effectiveness and safety of surgical procedures. Data requirements would be potentially very useful in assessing common procedures of questionable effectiveness and in providing a basis for assessing new procedures before they become common.

Finally, MedSAVE would have the authority to use some of the financial resources it receives from the surtax on surgeries to fund research on surgical procedures. The research funded could include both controlled experiments and observational studies based on administrative and required data. These studies would create evidence to support decision-making by MedSAVE.

Potential Benefits (and Risks) of MedSAVE

If MedSAVE functioned as well as the OPTN, the benefits could be substantial. Most importantly, by tapping surgeon knowledge and creating incentives for the development of effectiveness data, MedSAVE would provide a framework for implementing evidence-based surgery. It would enable the scalpel to be used to cut out inappropriate surgeries so that the hatchet applied to fees across the board could be avoided. As such, MedSAVE offers the potential of controlling the growth in a substantial component of Medicare Part B spending.

Moreover, if successful, MedSAVE would likely produce a number of desirable spillover effects. Reductions in unnecessary, ineffective, and dangerous surgeries would reduce both Medicare-covered hospitalization and physician costs. Many private insurers would take advantage of fee schedule adjustments made by MedSAVE in setting their own reimbursement.
rates and coverage. MedSAVE could be a model for efforts to tie appropriate medical practice to expenditure controls in other categories of physician services.

Adopting MedSAVE would not be without risks. While the OPTN formalized an existing network of a community of transplant surgeons with experience voluntarily sharing organs among their transplant centers, MedSAVE would require cooperation across heterogeneous surgical specialties rather than within a single surgical community. The liver allocation controversy that engulfed the OPTN shows the potential vulnerability that MedSAVE would face if it failed to accommodate powerful surgical specializations.

Perhaps the most relevant difference between MedSAVE and the OPTN is the scarcity constraint that creates the high stakes. MedSAVE would require the imposition of a budget constraint, while OPTN has the natural constraint of a limited number of cadaveric organs. Moreover, MedSAVE would be legislatively created and therefore subject to legislative change. Can Congress credibly commit to a fixed budget for surgery or for any other set of medical services for which we seek to induce evidence-based assessment? If the answer is no, then the various interests may put resources into lobbying Congress instead of implementing evidence-based medicine. Indeed, rather than conflicting with the promotion of good medical practice, more stringent cost control may actually be a prerequisite for more effective evidence-based medicine.

**Conclusion**

Some observers recognize the advantages of insulating governance to some extent from interference. However, it is not clear how agencies can be kept independent in the face of lobbying by various stakeholders. We have at least one example of governance—stakeholder rulemaking of organ allocation rules—in which isolation has been generally effective, contributing to the implementation of evidence-based medicine in an area of extremely high stakes. No governance arrangement is perfect, and one can easily find instances in which the OPTN moved slowly or erred in changing organ allocation rules. Nonetheless, its implementation of evidence-based medicine is substantial, sustained, and consequential.

I have sketched MedSAVE, a form of stakeholder governance that could potentially control costs and induce evidence-based medicine for Medicare surgery. The prerequisite for an effective MedSAVE is creating meaningful stakes through delegated authority to allocate a scarce resource. The meaningful stakes, in turn, can secure continuous professional and other stakeholder engagement, providing both expertise and the possibility of keeping rulemaking isolated from legislative politics. A rich internal committee structure facilitating specialization and consultation, the reliance on majority rule voting to make decisions and move proposals forward, and creation of databases to produce evidence facilitate the effective use of expertise. Transparency and strategic oversight would provide democratic accountability. ✶
Using Brain Scans to Understand Links between Economic Status and Cognition

By Barbara Wolfe

A large body of research documents a tie between income and health, and shows a clear health disadvantage for those at the bottom of the income distribution. Among children, the gap between rich and poor has grown, and the gap widens as they get older. But just because a relationship is observed consistently across time and countries does not mean the link is causal or that we understand the nature of the tie. It could be that low income causes poorer health; that those with poor health have lower earnings and spend more on health so that poor health increases the risk of poverty; or that other factors could explain both. In the belief that children’s health is more likely to be influenced by their families’ income than vice versa, researchers use a variety of techniques focusing on children to better understand the nature of this crucial linkage.

Several researchers, including my colleagues at the University of Wisconsin–Madison, have begun a somewhat different approach: we use biomarkers to study whether poverty gets “under the skin.” This use of biomarkers in the study of health disparities between the rich and poor provides insight into how environmental hardship and stress may affect the human body. Biomarkers such as cortisol and plasma samples have provided clues into the causal mechanisms underlying the socioeconomic gap in health status. More recently, cognitive neuroscience approaches have been used to understand the role of these socioeconomic disparities in cognitive, socioemotional, and physical development. Such approaches may take the form of behavioral experiments motivated by an understanding of the brain or involve physiological measurements such as magnetic resonance imaging (MRI).

In this article, I provide a brief overview of this approach, including some of our work using MRI scans to attempt to understand how poverty “gets under the skin” or, in this case, gets into the brain. Our approach is to ask whether any evidence shows that children growing up in poor families have differences in brain areas important for control of behavior and important cognitive processes, compared to children from higher income families and whether these brain differences predict differential performance on cognitive tests. Is there a rich vs. poor difference in the pattern of brain growth in regions that matter to health and cognitive ability. We view the brain as a bridge between biology and the environments in which poor, middle-income, and rich children grow up; we hypothesize that a child’s environment affects brain development.

Clear evidence in non-human animals that parts of the brain respond to the environment suggests we may find this link in humans as well. Experimental manipulation of the environment of nonhuman animals can provide strong causal evidence that helps us understand poverty’s effects. We hypothesize that parental socioeconomic status is tied to factors such as children’s nutritional intake, brain stimulation, stress, and adequate sleep, so we expect a link between these environmental factors to areas of the brain that develop as a child ages. These areas are likely to influence the development of cognitive ability and behavior, and ultimately adult health. Finding systematic differences between socioeconomic groups in the growth of regions of the brain means we will have identified a route by which parental socioeconomic status influences children’s cognitive ability and health. Once such differences are identified in children, then the next steps are to learn more about interventions that might limit the negative effects of poverty on brain development. Our research at this point is only the first step in this process.

Functions of Brain’s Regions

A bit of background on the brain. In terms of brain circuitry likely affected by poverty, regions such as the prefrontal cortex, hippocampus, occipital lobe, and cerebellum are our major interests. These regions may be vulnerable to environmental experience due to the long childhood and adolescence period over which they develop after birth, as suggested by nonhuman animal research. The prefrontal cortex has one of the longest development trajectories in humans. A large body of research has found the prefrontal cortex is important for emotion regulation and executive functions such as inhibitory control, cognitive flexibility, working memory, and sustained attention. All of these functions are likely important for understanding socioeconomic-status-related deficits. This region, which comprises important subregions, including the dorsolateral and ventral-medial prefrontal cortices, is believed to develop into early

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The hippocampus is a region uniquely affected by stress and post-natal experience, such as environmental complexity. Similar patterns have been found in the occipital lobe, with a large body of research showing responses of this brain area to environmental conditions. We study the cerebellum because of recent reports examining genetic and environmental contributions to brain development that provide evidence that the cerebellum is the region least related to genetic factors.

The research is possible due to the availability of a unique data set collected on behalf of the National Institutes of Health's MRI study of brain development. This large, two-part, multisite longitudinal study involves brain imaging, assessment of neuropsychological function, screening, and a large battery of questionnaire data on a sizable cohort of participants. The National Institutes of Health developed this public-access database to aid in understanding the course of normal brain-behavior development. In brief, clinical/behavioral and neuroimaging metrics were acquired at multiple research centers across the United States from a sizable cohort of children and adolescents ages 4 to 18 years (initial n=431) and a smaller cohort ages 9 months to nearly 4 years. Participants were followed over time; for the older sample, scans were made in two-year waves, for approximately seven years. MRI scans were acquired using General Electric or Siemens 1.5 Tesla scanners.

Part of the research is to "read" the scans and to access the absolute and relative size of our key selected regions. Without this important step, there is no outcome variable for the analysis. Thus we worked with psychologists and neuroscientists who used multiple methods to ensure reliability in reading the scans. (We also note here that there are two core types of scans: anatomical, which we use, and functional or fMRIs.) In brief, reading the scans and measuring the regions of interest is complicated and has the following steps: First, images are checked for scanner artifacts. Second the scans are segmented into different core elements—gray matter, white matter, and cerebral spinal fluid. White matter helps connect parts of the brain, gray matter executes specific actions, and cerebral spinal fluid helps support the brain. This segmentation of the scans used the age and gender distributions of the full sample. Third, a structural neuroimaging expert checks the accuracy of each subject’s segmentation. Then each subject’s tissue segments are compared to a template with quantified “normal” brain regions. This comparison allows researchers to quantify how an individual subject’s MRI differs from the template. Amounts of gray or white matter are then summed in each regions of interest and used in our analysis.

After processing neuroimaging data from each subject we conducted a random effects regression analysis that controlled for the wave of the MRI scan, the total volume of the brain, the child’s age, the child’s sex, and interactions between age and sex. We did this for all of our regions of interest of the brain including the hippocampus, prefrontal cortex subregions, the occipital lobe, and the cerebellum. We estimate the influence of socioeconomic status on specific regions of the brain. Our baseline measure of socioeconomic status is tied to household income. We average income levels for each child and divide the children into three groups: low income (families with income below $35,000), middle income (families with incomes between $35,001 and $100,000), and high income (families with incomes over $100,000).

Our Findings
Although the hippocampus has been implicated in long-term memory functioning, it has also been tied to learning, control of neuroendocrine functions, and moderation of emotional behavior. We are particularly interested in the hippocampus because evidence suggests environment and stress affect it.

Our analysis finds evidence of a significant association between the size of the hippocampus and family income. These results clearly suggest that for children in higher income families the hippocampus is larger than among those in lower income families. The findings suggest a deprivation difference; that is, a child in a low-income family has a hippocampus that makes up smaller part of her/his brain compared to middle and higher income children. This difference in the hippocampus, perhaps due to stress tied to growing up in poverty, might partially explain differences in long-term memory functioning and, in particular, differences in learning, control of neuroendocrine functions, and moderation of emotional behavior.

The prefrontal cortex is considered to be central to attention, inhibition, emotion regulation, complex learning, and mental processing. This region comprises many important subdivisions that are central to cognitive control and emotion regulation. The area known as the superior prefrontal cortex is crucial in...
attention, working memory, and cognitive control processes. Neuroscience research has found that this region plays a role in emotion regulation, is involved in the perception of spatial relationships among objects and working memory, and it activates during inhibition of irrelevant stimuli (the separation of wheat from chaff, so to speak). The area known as the ventral medial prefrontal cortex is primarily involved in valuation of stimuli and emotion regulation. Damage to this brain region has been linked to problems in controlling behavior and responding to emotions. Neuroscience studies involving imaging point to this sector of the brain more generally as supporting behaviors such as appropriate responses to other people’s moods and self-regulation of social-emotional behavior.

Again we find evidence of statistically significant differences in the proportion of the brain allocated to gray matter in one component of this critical region of the brain, the dorsolateral prefrontal cortex, which is crucial in attention, working memory, and cognitive control processes. The significant association between income and the dorsolateral prefrontal cortex suggests that children from poor families have smaller portions of their brains allocated to the dorsolateral prefrontal cortex than do children from middle or higher income families. Hence, we expect that children in low-income families may be more likely to exhibit impairments in planning, goal attainment, and problem-solving ability. The dorsolateral prefrontal cortex may also influence visuospatial working memory and the ability to pay attention in school. We do not find this pattern for the ventral medial prefrontal cortex.

The occipital lobe is central to visual-cognitive processes. This brain region is responsible for pattern recognition and visual mental imagery, translating visual images into more abstract representations of object shape and identity, and reciprocally translating visual memory knowledge into mental images. It is the region of the brain that allows us to look at something, to recognize it, and use it in the future to recognize similar images.

Our analysis of the size of this region suggests an income gradient rather than deprivation pattern. Here results suggest a statistically significant difference by income group with the lowest and middle-income groups both having a statistically significant smaller share of their total brain volume devoted to occipital gray matter. The implication is that children in lower-income families may receive less complex visual input, leading to alterations in this brain region. Such brain changes may slow down translation of visual stimulation into mental images and lower cognitive ability more generally. Our results also suggest that middle-income children are not exposed to the same complexity of images as higher income children.

Research examining neurocognitive functioning finds strong relationships between socioeconomic status gradient and differences in language functions. For example, poverty has been associated with poor language abilities and decoding skills, limited vocabulary and poor syntax. The original collectors of the National Institutes of Health imaging data found a link between socioeconomic status and performance on tests of cognition and achievement. The evidence on relationships between income gradients and health is extensive.

Tying the sizes of the regions of the brain to socioeconomic outcomes of children is new work. Further studies will provide insight into what might be taking place in the “black box” linking income to health and cognition. Eventually we have to determine what is causing these differences in critical parts of the brain between children from different income levels. We hope to identify the role of stress in the family, in the neighborhood, or school in children’s brain development. Research is needed to help delineate the effects of environmental stimulation (including, for example, talking with a child or reading to a child), stress, and other variables related to poverty to aid in understanding the neurobiological correlates of poverty. The evidence here does suggest that one component of the “black box” linking socioeconomic status to health and, more generally, to human capital is the influence of socioeconomic status on the relative size of critical components of a child’s brain. Without interventions to modify this influence, poverty is limiting many children’s potential.

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Reconsidering Agency Capture during Regulatory Policymaking

By Susan Webb Yackee

Images of the U.S. public bureaucracy tend to be polarized. By one account, government agencies are made up of public servants who are among the best in the world and promote the public interest. These bureaucrats strive to be non-political actors motivated by their aspirations to serve citizens. In contrast, the other image of the bureaucracy is much less sanguine. Here, narrow, self-serving interests capture government agencies with the result being inefficient, ineffective, or even undemocratic public decisions.

Scholars, politicians, and the media frequently employ the second image, that special interests control government agencies, even though we lack definitive proof of “agency capture.” A number of recent studies suggest that agency capture may exist in banking, criminal justice, and consumer protection, and that it may subtly occur within government agencies. Other studies question the widespread existence of agency capture. Nevertheless, many observers urge elected officials to design public agencies and develop policy solutions so as to diminish agency capture in the modern bureaucracy.

In this article, I define agency capture as the control of an agency’s policy decision-making by a subpopulation of individuals or organizations external to the agency. Although in principal any subpopulation may capture agency decision-making, most people concentrate on the potential for nefarious influence by business or economic interests on regulatory outputs to the detriment of the “public interest” or the “public good.”

Rulemaking—the political and policymaking process by which government agencies formulate rules—offers one opportunity to determine whether agency capture exists, identify when it takes place, and find whether groups have a relatively strong effect on rules that regulatory agencies issue. Key public policy battles in the United States often involve the decisions bureaucrats make about the legally binding rules and regulations that government agencies propose and issue to fill in the details of congressionally passed statutes. Rulemaking is how we specify standards for automobile emissions, clean water, and workplace safety. Forthcoming rules may set requirements for state health insurance exchanges and capital bank standards. These federal agency rules, mandated after a two-step process that allows for public comment, have far-reaching effects.

The Administrative Procedure Act of 1946 (APA) guides federal agency rulemaking, which typically unfolds across two stages. The first stage is a pre-proposal stage, where agency officials gather information and decide which stipulations and requirements to include in a draft rule. Some rules use an Advanced Notice of Proposed Rulemaking to begin the pre-proposal stage. In an Advanced Notice, the agency indicates how it may regulate or deregulate on a topic and asks for public comment. In theory, the information generated in this first round of comments informs the draft rule, formally called a “Notice of Proposed Rulemaking.” In accordance with the APA, each Notice of Proposed Rulemaking must be publicly announced and then be open for a public comment period before it can be finalized as a legally binding “Final Rule.” During the second stage, the notice and comment period, the APA requires that most Notices of Proposed Rulemaking be opened for public comment. Only after considering any public feedback will agency officials decide whether to issue a legally binding Final Rule.

The quantitative rulemaking literature provides numerous accounts of who participates and who influences during the notice and comment period, and it is through these accounts that our understanding of agency capture during rulemaking may be inferred. For instance, my earlier research provides evidence of participation by subpopulations—often interest groups—and tracks influence during notice and comment. Using content analysis on a sample of more than 30 rules, my coauthor and I find that business interests participate during the notice and comment period at a higher rate than other commenter types and hold more influence over Final Rule content.

Other research, including my own, suggests that interest group influence may be more important during the pre-proposal stage than during the notice and comment period. My studies demonstrate an agenda-setting and agency-blocking role for organized interests during this early stage; however, the patterns of influence across different types of interests have yet to be investigated.
In this article, I focus on defining and measuring agency capture during the rulemaking process. Our current lack of knowledge surrounding the concept of agency capture stems in large part from a blurry distinction between subpopulation influence on agency decision-making and subpopulation capture of agency decision-making. I argue that influence is a necessary condition for agency capture, but influence alone does not signify capture. Thus, if one uncovers evidence of policy influence by an interest group, then one must take the additional step of evaluating agency decision-making to understand whether that group wields merely influence, or, more powerfully, undue influence, or even control over agency decision-making.

I first identify which types of subpopulations—again, often interest groups or interest group types—tend to participate in rulemaking and to what degree. If business or other interests have captured rulemaking, then they will not simply influence rulemaking. Rather they will be able to consistently move regulatory policy decision-making in their preferred direction. For example, if capture exists, then consistent influence will likely occur across the different stages of the rulemaking process and across lobbying tactics. Moreover, if agency capture is a widespread phenomenon, then I expect to see these patterns across most rules, regardless of the agency; if capture is specific to particular agencies, then I expect to see these patterns across all rules promulgated by a particular agency.

I determine whether influence and agency capture exist during regulatory policymaking by focusing on 36 U.S. Department of Transportation (DOT) rules completed from 2002 to 2005. Each of these 36 rules used an Advanced Notice of Proposed Rulemaking document to begin the pre-proposal stage; thus, I am able to study rulemaking participation patterns across the pre-proposal stage, as well as during the notice and comment period. To draw my conclusions, I rely on content analysis of government documents and a sample of the public comments taken from each stage of the rulemaking process. I coded information from the 36 DOT rules at each stage of the rulemaking process, for a total of 59 points of evaluation. Additionally, I completed 15 background interviews in Washington, D.C., with the agency officials who worked on these rules. For 19 rules, I also implemented a telephone survey of the public commenters. Finally, to assess implications generated through my analysis, I used 2004 survey information drawn from agency heads in all 50 American states and across all policy areas.

Results

One of the top rulemaking agencies, the U.S. DOT regulates across a diversity of controversial policy areas, including standards for school bus safety, English language requirements for flight attendants, and bridge inspection standards. Moreover, numerous administrations within U.S. DOT are active rule-writers. In this study, nine agencies are represented: the Federal Motor Carrier Safety Administration was the largest rulemaking entity, promulgating nine rules; the Federal Highway Administration contributed eight rules; the Research and Special Programs Administration wrote five rules, followed by the National Highway Traffic Safety Administration (four rules), the Federal Aviation Administration (three rules), U.S. Coast Guard (now part of the Department of Homeland Security; three rules), the Office of the Secretary (two rules), and the Federal Transit Administration and the Maritime Administration with one rule each.

Overall, a good number of DOT rules with Advanced Notice of Proposed Rulemaking are withdrawn before finalization. Eighteen rules were ultimately finalized, and 18 were withdrawn. Eighty-three percent were withdrawn after receiving the Advanced Notice comments, while 17 percent were withdrawn after a later stage. These results imply that the politics during the pre-proposal stage may be just as important to understand as the politics during the notice and comment period. If influence exists—indeed, if agency capture exists—then it may be directed toward stopping unwanted proposals early in the rule formation process.

The Participation of Organized Interests

Regarding the participation of interested parties across rulemaking (see Figure 1), my analysis focuses on three such groups: business interests, government interests, and nonbusiness/nongovernment interests.

The first set of bars in Figure 1 shows the involvement of the three types of commenters during the pre-proposal stage of rulemaking. Businesses interests make up more than 51 percent of total participants, followed by non-business/non-government participants at 26 percent and government interests (including state and local government officials and members of Congress and federal agencies) at 24 percent. Of the business interests, about one-third of the comments came from trade associations, while two-thirds came from individual businesses or corporations. The majority of comments from government interests came from state DOT officials. Among the nonbusiness/nongovernment participants, citizens are the largest participant type, with public interest groups representing 4 percent of the pre-proposal commenters. The second set of bars in Figure 1 displays a similar pattern; however, while business interests again make up most of the participants, the relative participation of nonbusiness/nongovernment and government officials increased during the notice and comment period. Most notably, the percentage of comments from public interest groups nearly doubles during this second stage of rulemaking; however, the relative size of their contribution remains small at 7 percent.

The third set of bars in Figure 1 suggests a different
conclusion with regard to the participation patterns of organized interests. These data come from the telephone survey, which asked respondents: “Outside of your written comment, did you have any communications with federal Department of Transportation officials about this rule? Yes or No.” Forty-nine of the 126 survey respondents answered “yes,” indicating that 39 percent employed some form of informal lobbying, which includes face-to-face meetings, emails, and telephone calls that are outside of the written commenting process. The third set of bars presents the subpopulation participation rates for those using informal lobbying. The largest category here is government interests at 39 percent, with almost all of those informal contacts coming from state DOT officials. Business interests and non-business/non-government interests both participate at the lower rate of 31 percent. The telephone survey also asked about indirect lobbying, which is operationalized on the survey as lobbying through elected legislators. The question was: “Did you contact any Members of Congress about this rule? Yes or No.” Fourteen of the 129 (11 percent) respondents answered in the affirmative. Six of the 14 indirect lobbying participants came from business interests, while six came from nonbusiness/nongovernment interests. Only two government officials reported that they contacted a member of Congress about the rule.

Overall, the results from Figure 1 suggest that business interests have an advantage within the primary form for providing feedback to agency officials—the submission of public comments—across both comment gathering stages of rulemaking. However, this evidence of lobbying is not necessarily equal to agency capture by one subpopulation. Indeed, the survey evidence suggests that subnational public officials frequently charged with implementing U.S. DOT’s rules—state DOT officials—often provide agency officials informal feedback, and nonbusiness/nongovernment interests use indirect lobbying tactics at the same rate as businesses. Furthermore, when looking across this sample of rules, it is hard to conclude businesses dominate other subpopulation voices through the submission of public comments: approximately 50 percent or more of the comments sent to agencies come from nonbusiness interests.

Yet, these descriptive statistics may obscure evidence of agency capture. For instance, business interests may dominant the dialogue surrounding particular rules, or the rule-writing in particular government agencies may be plagued by a near monopoly on participation by business interests.

These data drawn from DOT rulemaking illuminate several conflicting patterns. On the one hand, I find that business interests participate at a rate of 75 percent or higher across numerous rule stages, and this high level of participation can be found across rules that were finalized or withdrawn. On the other hand, there are more stages where business interests participate at a rate of 24 percent or lower than at a high rate. This low rate of business involvement also includes finalized or withdrawn rules. Thus, business participation appears to vary across rules. Although individual rule stages or even entire rules may have high levels of business commenter participation, it is not clear that particular agencies consistently see high levels of business participation across rulemaking efforts. Of the three largest rule-writing agencies in the

Business interests have an advantage within the primary form for providing feedback to agency officials—the submission of public comments—across both comment gathering stages of rulemaking. However, this evidence of lobbying is not necessarily equal to agency capture by one subpopulation.
Interest Group Influence
As for the influence of interest groups on rulemaking, I find in my analyses of these data that the preferences expressed by outside parties that comment on rules do, at times, influence changes that agencies make. Typically, when public commenters desire less government regulation, agencies tend to respond by adjusting policies toward less government regulation. In a similar but more muted fashion, agencies move rules toward more government regulation when commenters agree on the need for more government regulation. Small sample sizes and the use of few explanatory variables in the model specifications warrant caution in generalizing the results. However, across both stages, evidence suggests government responsiveness to the desires expressed in the public comments.

As for differences among interest group types, I first look across rule stages at various levels of business interest participation and ask when commenters are most influential. When business participation is high, there is strong and statistically significant (0.73) correlation between what commenters desired, on average, and the change in direction of proposed rules. When businesses make up 50-74 percent of the public participants, the correlation remains significant but moderate (0.50). At business participation rates of 25-45 percent the correlation is 0.34, and at 24 percent or lower, the relationship is -0.20; neither of these last two relationships is significant. Of course, these correlations must be treated with some care, given that they do not control for other rule-level factors likely to influence the relationship between commenter desires and rule change, such as the importance and the complexity of rules, as well as political oversight measures.

The evidence from these correlations allows for the possibility of business influence across some sample rules, but it does not necessarily support the assertion that business interests consistently hold greater influence over the writing of agency rules than other groups. Instead, the results suggest a responsive bureaucracy—as the proportion of business interest comments increases, so too does the abilities of these comments to affect regulations.

A different way to think about subpopulation commenter influence entails moving away from the idea of average commenter success and instead focusing on the fulfillment of the individual desires of commenters. In these analyses, I measure “commenter success,” which occurs when an agency changes a rule in the direction the commenter desired. The correlation between commenter success and a comment being made by a business interest is positive, small, and significant during the pre-proposal stage; however, it is negative and significant during the notice and comment period. This juxtaposition of influence is noteworthy, and on its face appears to suggest that although business interests are influential early in the regulatory process, they are less influential later.

The analysis also suggests potential findings regarding the influence of government interests and nonbusiness/nongovernment interests on rule change. During the pre-proposal stage, there is no relationship between commenter success and a comment coming from a government interest, while there is a negative and significant relationship between commenter success and a comment from a nonbusiness/nongovernment interest. In contrast, during the notice and comment period, government interests appear better positioned to achieve commenter success with a positive and significant correlation, while the relationship for nonbusiness/nongovernment commenters is insignificant. These findings suggest that government interests may be, at times, influential during rulemaking, while providing little evidence of nonbusiness/nongovernment influence.

When taken together, the results from this second set of correlations are mixed. They do not suggest that any interest group type consistently holds greater influence over the writing of agency rules than any other group. While there appears to be some evidence of agenda-setting influence for business commenters—particularly when those business interests are advocating less government regulation early in the regulatory process—this influence may be partially offset by the influence of government officials during the notice and comment period, at least for those rules that are ultimately promulgated as legally binding Final Rules. Thus, these analyses do not provide clear evidence in support of the assertion that one interest group type has more influence over rulemaking than another.

Figure 2 displays information collected from the telephone survey on perceived commenter influence; this information, again, cuts against the expectation of agency capture.
Respondents were asked: “Do you believe that your comment helped to influence the Department of Transportation’s actions on this rule? Yes or No.” A follow-up question asked all affirmative respondents: “On a scale of 1 to 5, with 1 being very little and 5 being a great deal, do you feel that this action affected this rule?” I then combined these questions into a 6-point scale running from 0 to 5. Eighty-two of the 127 (65 percent) respondents answered that their comment had some effect, while on the 6-point scale, the mean response across survey respondents was 1.83, which suggests a low level of influence. Figure 2 uses the six-point scale to display perceived influence patterns by subpopulation type. The figure clearly suggests that government interests—which, in the case of the survey respondents, are mostly state transportation department officials—believe their comments to be the most influential of the subpopulations. Moreover, this finding holds if one looks at all government respondents (column shown in gray) or only survey respondents who also employed informal lobbying tactics (column shown in red). Business interests find themselves the next most influential, followed by nonbusiness/nongovernment interests.

Survey respondents were also asked a more general question about business interest influence during rulemaking. The question was: “Do you feel that big businesses or corporations have an advantage during rulemaking? Yes or No.” Ninety-two of the 127 (72 percent) respondents answered “Yes.” The survey followed up with all affirmative respondents and asked: “Why?” Respondents’ qualitative answers varied; however, two categories stood out. First, 15 of the 92 (16 percent) respondents suggested that businesses have closer relationships with members of Congress that advantaged big businesses and corporations. Second, 81 of the 92 (88 percent) respondents mentioned resources, implying that big businesses and corporations had a resource advantage. One respondent stated, “It is easier for big business to get their voice heard.” Another reasoned, “Large businesses have more knowledge about the industry and the topic of the rule.” Yet, others had a different point of view, stating that “corporations or businesses do not have an advantage,” while another respondent stated that businesses should influence DOT rules because they are likely to be most affected by them. Figure 3 breaks the findings down by interest group type. Government interests were the most likely to agree that big businesses and corporations have an advantage during rulemaking at a rate of 81 percent. Nonbusiness/nongovernment interests were also high at 76 percent; business interests were lowest at 64 percent.

Do Interests Control Rulemaking?

Thus far, I do not find clear evidence of influence across rulemaking; indeed, the findings presented suggest a mixed picture of interest group participation and influence. Therefore we cannot assume business interests control rulemaking or that
they have captured the various U.S. DOT agencies.

Businesses are the largest participants across the sample rules in these data, but business interest lobbying does not dominate across all sample rules, nor does it appear to dominate the rule-making of particular agencies (at least the top three rule-writing agencies studied). Although my two assessments of potential business interest influence are suggestive in nature, the analyses provide evidence that businesses are not consistently influential. Moreover, their preferences appear to be advanced more often when other business-related commenters also participate within a particular rule stage. Put differently, business influence appears to decrease as other subpopulations’ participation increases. The results also suggest that government interests may be a foil to business interests. I find, for instance, that government interests—which in the sample are largely state transportation officials—make up the category of informal lobbying participants. Moreover, they perceive their comments to be the most successful of the interest groups, and correlation analysis suggests that government interests may be well positioned to obtain their desired rule changes at certain times during rule-making. In contrast, nonbusiness/nongovernment interests hold no clear advantage in participation or influence in these data. Given these mixed results, I do not look for evidence of interest group “control” over federal agency decision-making in these data.

To determine whether business interests have captured state officials lobbying for federal policy change, I study data from the 2004 American State Administrators Project that queried state agency heads about the influence of “ cliente groups” on the generation of their rules and regulations. Although cliente groups do not align perfectly with business interests, these data provide the opportunity to investigate whether select interest groups hold high levels of influence over state agency heads, especially state transportation officials. The survey question wording is: “In making various agency decisions it is usually possible to identify and weigh several major sources of influence. Among these are: (1) governor, (2) legislators, (3) state courts, (4) clientele groups, (5) professional associations, and (6) agency career officials. Please indicate below (by circling) the degree of influence each source has on decisions your agency makes in the following decision areas.” Agency heads were asked to respond about multiple decisions, including “Agency Rule/Regulations” on the following scale: 0-None, 1-Slight, 2-Moderate, and 3-High Influence.

When I break out results by nine agency categories (see Figure 4), several patterns stand out. First, among transportation agencies, interest group influence on agency rules and regulations registers closest to “slight” on the four-point scale and is, relatively speaking, much lower than the influence of state legislators, the governor, or career agency officials on rules. Second, when comparing interest group influence across agency types, this influence on state transportation departments ranks near the bottom of all policy areas. Third, patterns in the 2004 data are not an aberration. Survey administrators found consistent patterns on this same question in their earlier survey efforts (in 1978, 1984, 1988, 1994, and 1998). I should note that these data do not rule out the possibility that interest groups or business interests in particular hold excessive influence over some state transportation agencies or some sub-national officials. However, the findings do call into question the generalizability of the argument that business interests control the decision-making by state transportation departments.
**Conclusion**

Business interests often participate in agency rulemaking at a high rate and influence the crafting of particular agency rules. However, this influence is not consistent across rulemaking or agencies. The evidence shows that the participation of state agency officials in rulemaking may provide a foil to business interests and thus deter agency capture. In the end, I do not uncover evidence of wide-scale agency capture. It is especially noteworthy that this conclusion materializes from analysis of a sample of rules completed during a Republican administration, when one might expect business interests to be better positioned to obtain desired regulatory changes.

The data employed here—while rich in terms of knowledge about these 36 federal transportation rules—are limited in several important ways, and thus they restrict the generalizability of the conclusions. I suggest three key limitations here. First, the rules all began with an Advanced Notice of Proposed Rulemaking, which limits the generalizability to federal rulemaking. Second, all nine agencies reside within the U.S. DOT, which may be less prone to agency capture than other agencies, particularly those with an express consumer-oriented mission. Moreover, the U.S. DOT may attract more state officials as lobbying participants than other some other agencies, given the tradition of state transportation agencies playing a role in implementation of federal regulations. Third, businesses often send varied messages in regard to agency rulemaking. A more fine-grained treatment of variations in business interest lobbying may be necessary to capture influence over agency decision-making.

The implications of these findings for the design of regulatory policy and for leaders of regulatory agencies are twofold. First, strategic agency officials may ensure greater legitimacy for their regulatory decisions when they encourage and engage segments of society beyond regulated entities. Indeed, even the appearance of a bias toward business during rulemaking may hold negative consequences for the agency by perpetuating the perception—if not the existence—of agency capture. Thus, attempts to prevent or limit regulatory capture in practice may include reaching out directly to public interest groups and state officials to appraise them of plans for agency policymaking and to encourage their participation via such traditional tools as public meetings and public commenting processes, as well as through new social media tools, including wikis, Twitter, and Facebook. And second, while much has been said about the information asymmetries between regulated entities and other “public” participants during rulemaking, agency officials may wish to use special administrative procedures (such as Advanced Notice of Proposed Rulemakings), to tap “off the record” feedback networks, and to engage other regulatory design features to encourage the participation of knowledgeable subpopulations, such as state and local officials, during regulatory decision-making. Doing so may provide their agencies with a competing source of high-quality information during administrative rulemaking.

**Director’s Perspective continued from page 1**

like to highlight a few notable things that were especially important and interesting (at least to me, admittedly a health economist).

A generally accepted reason for the high cost of health care in the United States is the interaction between health insurance coverage and the adoption of new and expensive medical treatments. Insurance coverage ensures that the demand for expensive treatments, when available, remains high. In turn, the existence of new and expensive treatments leads people to want better and more comprehensive health insurance. One unsettled question is whether public insurance expansions, such as those that will occur under the Affordable Care Act, also will lead to further widespread adoption of expensive technology. If so, the ability of these expansions to lower costs could be limited. In their conference paper, Seth Freedman and colleagues from Indiana University examined Medicaid expansions to pregnant women and children in the 1980s and 1990s to see if these expansions hastened the adoption of neonatal intensive care units (NICUs) by hospitals. They found that, in fact, Medicaid expansions slowed the adoption of NICUs, particularly in states where Medicaid pays substantially less than private insurance. Their findings suggest, to me, that Medicaid expansions under the Affordable Care Act may lead to a slowing of health-care costs by slowing the adoption of expensive treatments.

Another puzzle facing policy and health economists is to explain the substantial differences across regions of the United States in the amount spent on health care. The fact that some areas spend a lot less than others, without any apparent detrimental effect on health, indicates that there is some promise to “bend the cost curve” and reduce what we as a country spend on health care. However, before we can achieve any such cost savings we must determine why we spend so much to begin with. In her innovative paper, Ariel Stern of Harvard University and colleagues surveyed doctors on their beliefs about what appropriate end-of-life care should be and surveyed patients about their preferences. It is often held that we spend so much on end-of-life care because people are willing to incur substantial expense to extend life, especially when individuals are fully insured against that expense. However, this study suggests that doctor’s attitudes, not patient preferences, are what drive excess spending. Doctors’ belief in aggressive treatment, often beyond recommended guidelines, tends to be in areas where excess spending is common.

**Director’s Perspective continued on page 20**
The new administration of Japanese Prime Minister Shinzo Abe has introduced a three-pronged approach to stimulating economic growth in Japan. The components of the plan include increased fiscal stimulus through public works, growth strategies aimed at reinforcing private investment, and an aggressive increase in monetary stimulus through unconventional policies.

The third element of Abe’s program has generated substantial controversy in international policy circles. Two measures promoted by Abe’s choice as governor of the Bank of Japan, Haruhiko Kuroda, potentially have major international repercussions. Kuroda is committed to raising the rate of inflation from zero to 2 percent and driving down longer term interest rates by purchasing government bonds and other assets.

Although government officials have stressed they would not directly intervene in foreign exchange markets to weaken the yen, expansionary monetary policy will inevitably lead to considerable depreciation of the yen, which should spur exports and, therefore, increase economic growth.

In this note, we assess the rationale for Kuroda’s aggressive action, the prospects for success along the international dimension, and potential hazards to the Japanese economy.

The Need for Action

Japan certainly needs to jump-start economic growth. The global economic recession hit Japan hard, and the country had barely recovered when the East Japan Great Earthquake occurred in March 2011. Figure 1 depicts the evolution of gross domestic product (GDP) since 1990. The sharp declines recorded in 2008-09 and in 2011 clearly illustrate the impact of the recession and the earthquake.

At the end of 2012, Japan’s total output was still 2 percent below its peak at the end of 2007, and the nation was barely eking out positive growth. Hence, the need for some sort of change in policy direction is clear. Japan also incurred a substantial and persistent economic burden with the disaster at the nuclear facility at Fukushima in the wake of the earthquake. The government’s subsequent decision to temporarily cease electricity generation based on nuclear power curtailed economic activity and necessitated greater fuel imports. The trade balance thus deteriorated even as economic activity declined. Figure 2 shows this outcome. Each yen used to import fuel is a yen not spent on domestically produced goods or nonfuel imports.

International Prospects for Success

Japan’s economy is highly integrated into the world economy, in some ways more so than the economies of the United States or the European Union. Prior to the global financial recession in 2008, exports plus imports as a share of GDP—a standard measure of openness to international trade—approached 40 percent. As a consequence, what happens to trade will have important implications for Japan’s economic prospects.

Unconventional monetary policy—including quantitative easing by way of additional central bank purchases of securities—and establishment of an inflation target can spur the economy. Each of these measures reduces borrowing costs and loosens credit constraints on firms and households. In addition, expectations of accelerated inflation will lead to a weakened yen. In fact, the yen has already dropped in value since the last quarter of 2012, when Abe took office. Figure 3 depicts the value of the yen against a basket of currencies, after adjusting for inflation.

The question is whether the quantitative easing and resulting elevated inflation will affect exports and imports. Historically, the yen’s value (as well as economic activity at home and abroad) influences the trade balance. As the yen loses value, exports become cheaper to foreigners, while imports become more dear. Growing exports results in higher economic growth.

With the yen about 20 percent weaker than in the third quarter of 2012, should one expect the Japanese trade balance to improve sufficiently to affect output? Estimates published in 2007 concluded that imports are relatively insensitive to price changes, while each 10 percent change in the inflation-adjusted value of the yen induces a 3.4 percent increase in real exports. 2012 estimates suggest the impact is slightly larger, 4.4 percent to 6.1 percent. In our own estimates, we find that Japanese exports will increase by about 5 percent in response to such a drop. A sustained 20 percent depreciation, such as that...
experienced thus far, should result in an increase in real exports equivalent to about 1.3 percent of GDP in the fourth quarter of 2012. This means that after about a year, GDP should be about that much higher. Of course, one can't simply add the 1.3 percent to the level of Japanese GDP. Although the additional exports suggest a boost to income, the resulting additional income will generate an increased demand for imports, offsetting some of this growth.

If we abstract from the effect of higher income on imports, yen depreciation should, in principle, depress the level of imports, as imported goods become more expensive for Japanese households and firms. However, recent estimates indicate little sensitivity of imports to exchange rate changes. Hence, for the moment, to be conservative in our calculations, we assume the impact of the decline in the yen's value to be essentially zero.

A complication is that a large portion of Japanese imports are commodity-based, including mineral fuels (oil, natural gas, and coal). Since oil and natural gas are priced in U.S. dollars, the depreciation of the yen would likely lead to a rise in the yen
value of fuel imports, limiting the increase in Japan’s aggregate demand. In addition, higher energy prices will feed into the general price level, squeezing consumer budgets, unless wages also rise.

Simulations from a computer model of the Japanese economy, conducted by the Organisation for Economic Co-operation and Development, indicate that a 20 percent depreciation (arising from a reduced attractiveness of yen assets) would be consistent with GDP increasing 1.6 percentage points more than otherwise would occur, after about two years.

**Potential Complications**

The foregoing analysis relies upon historical relationships persisting into the near future. Several reasons suggest that the past might not prove a reliable guide. First, analyses that extend to the 1980s are problematic because the nature of Japan’s export industries has drastically changed in the wake of the substantial offshoring that occurred in the mid 1990s. Japan has become inextricably integrated into the East Asia production chain. As a consequence, higher exports require higher imports of components and other inputs. For instance, if about one-third of Japanese exports is composed of imported inputs, then Japanese GDP would only be about 1 percent higher than otherwise because of the policy change. Furthermore, because exchange rates only affect the onshore value added (and not the imported component), one might expect the sensitivity of Japanese total exports to be lower in the 2000s than the 1990s.

The fact that some share of imports is used for exports (for example, oil to manufacture plastic used to make parts that Japan then exports) suggests an explanation for why determining the impact of exchange rates on imports is difficult. A yen depreciation discourages imports and encourages exports that rely upon imported inputs. The two offsetting effects probably explain the small estimated effects on imports detected.

A related issue is that supply chains may be rigid at least in the short term. Japanese manufacturers have gradually increased offshoring in their procurement and production activities. Persistent appreciation of yen for the last few years contributed to increased offshoring. As the yen depreciates, firms may switch their procurement from imported inputs back to Japanese domestic inputs that are now relatively inexpensive. This transition will help the domestic suppliers of such inputs increase their outputs. However, in some situations—where firms have invested in setting up offshore facilities—production activities may not return onshore even if the yen depreciates for only a short period. Hence, much depends on expectations of a lasting yen depreciation; then the return of domestic production will spur Japan’s domestic production and employment.

**Implications**

We have assessed the impact of a policy-induced exchange rate depreciation on Japan’s trade balance and therefore on economic activity. Clearly, exchange rate depreciation that occurs as a consequence of a loosened monetary policy would only go part way to resurrecting the Japanese economy. More expansionary fiscal policy, as well as the monetary policy working through domestic channels (on investment and consumption), are also important in stimulating growth, and may be more important than the effects operating through exchange rate depreciation. However, because the Japanese economy needs all the help it can get, the uncertain—though positive—effects of the proposed unconventional monetary policy measures on Japanese trade and economic growth should be welcomed. ✦

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**Figure 3: Value of Yen against Broad Basket of Currencies**

![Figure 3: Value of Yen against Broad Basket of Currencies](chart.png)

Note: Yen value is log real trade weighted value. Source: International Monetary Fund
In late April, the School held its annual Spring Symposium with this year’s theme being “What’s Next for the Affordable Care Act? The View from Researchers, Regulators, and Providers.” Cosponsored by the Evidence Based Health Policy Project, the gathering brought together academics, policymakers, and practitioners to have a public discussion on ACA implementation and its likely effects.

One topic was Medicaid expansions. A recent study by Amy Finkelstein and her coauthors was discussed. They conducted an experiment in Oregon in which approximately 30,000 adults were selected by lottery from a waitlist and given the opportunity to apply for the state’s Medicaid program. This type of experiment allows for definitive assessments of the impact of Medicaid coverage on outcomes such as the use of care, financial distress, and self-reported health. The results of this remarkable study were striking: those given the opportunity to apply for Medicaid—the “lottery winners”—used more outpatient and hospital care, but they did not seem to use the emergency department more. These lottery winners also experienced a reduced probability of being delinquent on medical bills and, most interestingly, reported being in better health.

In this same session, Brett Davis, the Wisconsin Medicaid director, presented the governor’s proposals to adjust income eligibility thresholds to qualify for Medicaid for most adults. Currently, parents are eligible for Medicaid up to 200 percent of the federal poverty line (although premiums are required at incomes above 150 percent of the poverty line). Adults without dependent children, however, do not have access to Medicaid in Wisconsin, although about 25,000 receive coverage through the BadgerCare Core Plan. Enrollment into this state-funded plan has been frozen since October 2009. Under the proposal, eligibility for parents would be reduced to 100 percent of the federal poverty line. At the same time, all adults without dependent children up to this same income threshold would be able to enroll into the state health plan.

In discussing the proposal, we touched on the most controversial aspect of it, which is that it does not comply with provisions of the Affordable Care Act that would enable Wisconsin to receive additional federal funding to pay for the expansions to the childless adult population.

In the last session of the day the discussion returned to this topic when Helen Levy of the University of Michigan presented the results of a study that shows that Michigan would save a substantial amount of money by expanding Medicaid (and accepting the federal money).

Health policy will, no doubt, be at the forefront of economic and policy discussions for years to come. The La Follette School and its faculty will continue to be involved with evaluating and developing health policy for the state and the nation.

Thomas DeLeire