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Sanford Journal of Public Policy

Volume 3  Spring  2012

Mission
The Sanford Journal of Public Policy (SJPP) was created in 2009 as a forum for public policy students and professionals to contribute to the current policy discourse through insightful analysis and innovative solutions.

About
The SJPP is run by the graduate students of the Sanford School of Public Policy at Duke University and is published online on an annual basis. The SJPP solicits articles across the spectrum of public policy in a variety of formats, including policy research and position papers, issue briefs, opinion pieces, reviews of recently published books, and interviews with policy professionals. The accompanying website is designed to be a place where public policy students and practitioners can stay connected to current policy discussions and express their own views on today’s policy challenges.

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Sanford Journal of Public Policy

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No endeavor is achieved without the assistance of many people, and the SJPP is no exception. The Sanford and Duke communities provided us with a great deal of support in bringing this issue to print, and we are particularly grateful to the following individuals and organizations.

We want to thank our faculty advisor, Elizabeth Frankenberg, for her continued leadership and support for the Journal. From its inception through this publication, Dr. Frankenberg has provided critical and consistent advice and leadership and her commitment is a key reason for the Journal’s continued success.

We are also grateful for Saleem Reshamwala, who helped us create and maintain the new website. Mr. Reshamwala’s guidance ensured a sleeker, more user-friendly and manageable website and we thank him for all his efforts.

We owe a great debt to last year’s Journal staff—particularly Matt Tonkin ’11, Sofía Baliño ’11 and Gray Wilson ’13, for their guidance, advice and encouragement throughout this process.

Several members of the Sanford School administration offered us key support along the way including Helene McAdams, Rita Keating and Stan Paskoff. We are also grateful to the Sanford Student Council and the Duke University Graduate and Professional School Student Council (GPSC) for their generous funding, without which the Journal could not have been published. We also thank the people at Zebra Print Solutions for printing our final product.

We want to thank all of the authors who submitted articles for consideration, especially the four authors whose articles we selected for publication. Their flexibility and commitment to working with our editing staff resulted in improved versions of their great work, and we hope they are as proud as we are of their final products.
Finally, we are grateful for our fellow students and colleagues—the graduate students at the Sanford School. Their support and enthusiasm have kept the idea of the Journal alive and encouraged us to bring this edition to its final fruition.

To all, thank you.
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Dear Readers:

We are pleased to present the third edition of the Sanford Journal of Public Policy. The SJPP is a forum for public policy students and professionals to share their views on a wide range of current policy issues. Our goal for this year was to continue the progress made in previous editions to establish the SJPP as a reputable and interesting source for policy analysis. Our staff worked hard to elicit a more diverse range of submissions and to grow our online footprint.

The SJPP is composed of a print publication and the accompanying website: http://www.sjpp.sanford.duke.edu. This year we expanded and improved the content on the website, incorporating long and short form blog submissions from our staff editors. Our goal was to develop a new discussion space where readers can engage with important policy issues as they arise, while attracting new audiences through the use of strategic linking and social media networks. The website continues to contain all the material published in the print journal.

The quality and quantity of our submissions was impressive this year, making the selection process extremely interesting as well as challenging. Ultimately, we selected four articles for publication based on the relevance of the issues they addressed as well as the fine writing and research each contain. These articles address pertinent and crucial matters within the current policy world, including the possibilities and obstacles surrounding health information exchanges; the future and potential for social impact bonds; an analysis of how the World Bank may address revolutions and coups d’etat; and methods for increasing the number of high quality new molecular entities that are available to the public.

We are grateful for the hard work and commitment of everyone involved with the Journal. Our staff editors provided us with high quality content for the website throughout the year, as well as thorough editing of the final four articles selected for publication. Our business team, headed by Lauren Hungarland gave us steady guidance and ensured we had sufficient funds to see the Journal through to publication. Submissions Coordinators Jamie Attard and Anna Kawar worked tirelessly to expand the scope of our submissions, and are primarily responsible for the increase in quality we saw across the
board in all the articles we reviewed this year. We are also indebted to Greg Callanan, our Layout Manager, who made sure the final SJPP product has an appearance worthy of the content within.

Our Senior Web Editors, Blake Holt and Evan Krasomil were innovative and thoughtful in their stewardship of the website and policy blogs. TJ Lowdermilk, our Managing Editor, provided guidance during stressful moments and oversaw innumerable small details that were necessary to keep the Journal moving forward. We are grateful for our Senior Print Journal Editor, Jenny Orgill, whose talent and diligence are primarily responsible for the smooth and successful editing process that went into refining each article.

Finally, we are thankful to the Sanford faculty, staff, students, and administration, whose support and guidance have consistently ensured the Journal's publication.

We welcome you to visit our website and join the discussions around policy issues. We are proud of everything the SJPP produced this year, from the blogs to this final publication, and we know the Journal has a strong future ahead. Enjoy!

Sincerely,

Mike Burrows
Ellen Whelan-Wuest
Editors-in-Chief
Articles
THE FEASIBILITY AND FUTURE OF SOCIAL IMPACT BONDS IN THE UNITED STATES

Beth Bafford‡

Abstract

Social Impact Bonds were recently introduced as a new, innovative way to strengthen social service delivery, improve government spending, and develop impact measurement. While there is potential for this structure to be effective, the excitement surrounding this innovation needs to be managed to provide ample space for experimentation and failure. Without setting reasonable expectations, this product will disappear as quickly, and with the same fervor, as it arrived.

Impact investing, the concept of leveraging private funds for a blended social and financial return, has become a hot topic in the world of social impact and entrepreneurship over the past few years. Collaboration and interest among large banks, foundations, governments, private investors, universities, and venture funds have elevated the field, which has set the stage for the creation of a more supportive financing ecosystem for social entrepreneurs.

Under the impact investing umbrella, one new vehicle that has garnered attention is the social impact bond (SIB), launched in the UK in September 2010. This structure, which is only a bond in name, raises private capital to fund social interventions focused on prevention instead of cure to create government savings. While many countries are experimenting with SIBs, this paper will focus on the steps the US needs to take to lay a strong foundation

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for the successful implementation of social impact bonds.

SIBs have the potential to shift the government funding cycle, creating a system centered on prevention and measurable outcomes instead of one focused on remedial interventions and inputs. This market-driven solution to the inefficiencies found in government spending and social services, if successful, could catalyze large-scale social change.

But SIBs are far from a silver bullet. There are many challenges that need to be addressed before SIBs can be implemented effectively.

While challenges and risks exist in all links of the SIB value chain, the four core issues are:

- Managing public expectations and creating space for failure,
- Attracting commercial capital,
- Identifying “SIB-ready” social services and providers, and
- Preparing the ecosystem to enable the adoption of a new contract type.

As the players in the US attempt to create social impact bonds in a domestic context, they will need to innovatively attack these barriers to unleash the potential of this new financing structure.

**The Social Impact Bond**

Social impact bonds were created to identify and scale proven social interventions to serve vulnerable populations in a more cost-effective way, something that existing systems fail to do. Currently, the only actor incentivized to provide effective social interventions is the government, but it does not have the resources or risk tolerance to find and scale the right social intervention models. The SIB structure was created to address this gap.

SIBs align the interests and incentives of all necessary actors to create an ecosystem that allows for social innovation, measurement, and widespread adoption.

The relationships and cash flow between each entity are described in Figure A. Before any money is allocated, concurrent contracts are written between the intermediary (or the Social Impact Bond Intermediary Organization, the SIBIO) and four parties: the investors, the affected government agencies, the
service providers, and a third party evaluator. The main provisions of the contracts will define:

- The social problem they are trying to address,
- The service model(s) with which to address it,
- The outcome and output metrics they would like to achieve,
- The measurement of outputs and outcomes,
- The relationship between the outcomes and public savings (dollar amounts), and
- The allocation of government savings when realized.

**Figure A**

Once the terms are finalized and the contracts are established, private investors commit capital to the SIBIO, allowing them to draw down funds over the life of the intervention period. When drawn, the funds go through the SIBIO to the participating service providers to fund the interventions. At the end of the defined intervention period, if the interventions are successful,
the government savings are split between three parties, (1) the government agency, (2) the investors (who get both their principal plus an agreed upon annual rate of return), and (3) the SIBIO, which gets a management fee for structuring the deal and providing oversight throughout the life of the SIB. If the intervention does not achieve the agreed upon outcomes, the investors are not repaid.

While various SIB structures may exist in the future (see Appendix A for a list of SIB activity around the world), the Peterborough Social Impact Bond, named for the HMP Peterborough Prison in the UK, is the only one currently on the market.

**The only SIB on the market: The Peterborough Social Impact Bond**

Social Finance in the UK, the organization that created and launched this fledgling product, decided that the first social ill they wanted to attack was adult recidivism among short-sentence prisoners. They saw both a problem – 60 percent of male prisoners released were reoffending within one year – and an opportunity, as these prisoners were not receiving any support upon their release. Social Finance, as the intermediary (or SIBIO), gathered the necessary parties to sign the first SIB contract in 2010.

The story of the SIB structure is more easily told through the eyes of each participating party.

i. **The Service Providers: The ONE* Service**

The ONE* Service is a coalition of service providers, including St. Giles Trust, Ormiston Trust, and the YMCA (among others), which have had success in helping recently released prisoners reenter society effectively in different phases of the reentry life cycle. While their interventions work, they lack the capital and flexibility to scale their operations and impact. The upfront, guaranteed capital over the life of the SIB provides them with the flexibility and incentive to provide their services most effectively – and in coordination with each other.

ii. **The Public Agencies: The Ministry of Justice and the Big Lottery Fund**

The Ministry of Justice is the government agency that will accrue savings if the interventions prove effective. If the ONE* Service
team is able to reduce the reoffending rates of short-sentence prisoners, the money saved on these prisoners – in the form of reductions in the prison stay itself, the legal costs, and the law enforcement resources – can be reallocated. The Big Lottery Fund also signed on to help the Ministry of Justice make these payments should the interventions prove successful. These public entities get both improved social outcomes and public savings, without having to pay for the risks associated with scaling.

iii. The Intermediary/SIBIO: Social Finance
Social Finance is a non-profit financial institution founded in 2007 that created the SIB structure. To run the operations of the Peterborough SIB, it created a separate legal structure called the Social Impact Partnership, which is the Social Impact Bond Issuing Organization for the Peterborough SIB. Success is important for Social Finance for two reasons, (1) to implement more SIBs in the future (and thus create a larger impact), it needs to prove that the model can be successful, and (2) it receives a fee for managing the project. For the organization to be self-sustaining, it must structure and manage multiple bonds concurrently to bring in the necessary income.

iv. The Private Investors: Foundations and High-Net-Worth Individuals
There are seventeen private investors in the Peterborough Bond. The majority are foundations and high-net-worth individuals. These investors stand to gain socially by leveraging their capital to provide better support to vulnerable populations. They also stand to gain financially from the agreed-upon annual return if the SIB is successful. In addition to the return, this structure is attractive financially because it is not correlated with traditional asset classes and can therefore reduce overall portfolio risk. In the case of the Peterborough project, investors can receive up to a 13 percent annual return on their investment, but stand to lose everything if the interventions fail. While this project’s return was attractive for these foundations and individuals, the ability to attract commercial capital remains uncertain.
v. The Measurement Organization

In order to determine the effectiveness of the model, a reputable third-party evaluator must track and measure the success of the interventions. If the outcome metrics are hit, the investors get repaid their principal along with an annualized return. If not, the investors lose their investment. The organization that acts as this independent assessor enters into a contract with the intermediary and is paid for its services.

vi. The Target Population: 3,000 Recently Released Short-term Prisoners

The population receiving services needs to be clearly defined so the service providers cannot cherry-pick a population that is most susceptible to reform. There also needs to be either a control group or a projected baseline with which to compare the improvements. In the case of the Peterborough SIB, the interventions are focused on 3,000 male, recently released, short-term prisoners. The control group is a similar group of short-sentenced male prisoners across the UK pulled from the Police National Computer. The target population benefits from better support given by well-resourced social service providers who care about the recipients’ future and success.

The Peterborough Social Impact Bond completed its first year in November 2011. While the first year’s report showed progress and anecdotal impact, there are three more years of intervention before any results are calculated and reported. However, other countries and jurisdictions are not waiting for the results; they are moving ahead with their own experiments, as evidenced by the activity and excitement in the US.

Social Impact Bonds in the US

The social impact bond concept was introduced in the US in 2011 under two names. The Fiscal Year 2012 Federal Budget released by the Obama Administration included funding for a similar structure, but called them “Pay for Success” bonds. A few days after the Budget was released, a Social Finance office was opened in Boston and expressed its intent to create Social Impact Bonds across the US. Since 2011, there have been numerous states and cities intrigued by this model and attempting to develop their own SIBs. As of the
writing of this paper, it appears that Massachusetts will be the first state to conduct a SIB, with other states, such as New York, Minnesota, Rhode Island, and California, close behind.

**SIBs are needed in the US to shift the government funding cycle**

The public sector in the US, much like the UK, is stuck in a spending trap that focuses on emergency interventions. This leaves minimal public dollars available for prevention or early intervention spending that would reduce the costs to both the government and society. SIB models in the US are meant to address this “negative spending cycle.”

There are two main reasons why this funding trap exists in the US: (1) early interventions are risky and typically require large amounts of up-front capital to implement, a risk that the government is not willing to take with tax-payer dollars; and (2) spending focuses on inputs instead of on measurement of results to decide where funding is best spent. This translates into government spending that is reactionary, unplanned, and often wasted on interventions or services that are unproven and do not work.

Social Impact Bonds are intended to: inject private capital into social service providers to absorb the risk needed to discover and scale proven interventions; increase the integrity of non-profit data collection and metrics through competition for funds; measure the success or failure of these programs; and prove and collect government savings to return to investors, all while creating a learning laboratory for the government to adopt the best programs to grow and scale.

**Pay-for-Performance models in the US have set a foundation from which to launch successful SIBs**

While the SIB structure was considered new when announced, the backbone of the SIB structure, the pay-for-performance contract, is not as novel. The history and success of pay-for-performance programs have helped pave the way for the social impact bond model to gain broad acceptance in the US, and they provide strong examples for interventions that may work well within the SIB structure.

Pay-for-performance programs have gained traction in the past decade as local, state, and federal government budgets search for ways to improve services while maximizing cost effectiveness. While the majority of these programs have resided in the health care delivery and prevention field, others
are finding innovative ways to put quality, evidence-based mechanisms to work in other service areas to save scarce government resources.

The state program that seems most closely aligned with the Social Impact Bond concept is the Maryland Opportunity Compact founded in 2005. The Compact solicits private investment for seed capital to implement a new program, proves the program works and saves public dollars, then reinvests the savings to expand the program to broaden its reach. While the model is slightly different from SIBs because the investors provide grants without an expected return and the savings are recycled back into the programming, the motivations are aligned. The Compact website states that it “aims to break the inefficient cycle of last resort spending by targeting resources to proven strategies that strengthen vulnerable families, move them to self-sufficiency and prepare them to lead productive lives, all while saving tax dollars.”

### The Introduction of US SIBs, the “Pay for Success” bond

The Fiscal Year 2012 and 2013 Budgets released by the Obama Administration included $100 million and $109 million, respectively, for Pay for Success (PFS) bonds. The FY 2012 budget introduces the PFS structure, stating that it is “designed to promote innovative strategies to reduce the aggregate level of government investment needed to achieve successful outcomes and impose minimal administrative requirements on service providers, so as to allow for maximum flexibility to improve efficiency and effectiveness.” The language in the provision also emphasizes the contractual specifications needed in future funding awards, including:

- Disbursement of public funds only after outcomes have been achieved,
- Objective outcome-measurement methodologies,
- Payment schedules based on the estimated return on investment and the probability of achieving benchmarks,
- Use of funds for other Pay for Success projects should some fail to meet outcome criteria

The FY 2013 budget language shows the progress that was made over the last year:

“Over the course of 2012, the Administration is launching a small number of Pay for Success pilots in criminal justice and workforce
development. The President’s 2013 Budget reserves a total of up to $109 million to test this new financing mechanism in a broader range of areas including education and homelessness. If successful, Pay for Success projects offer a cost-effective way to replicate effective practices and support continuing innovation as Federal resources become more constrained.viii

With limited state and federal budgets, there has been excitement and enthusiasm around SIBs/PFS structures from both sides of the aisle, but despite the momentum and push from the Administration, the funding was not included in the federal budget written in Congress for FY 2012. It remains unclear whether it will be included in FY 2013.

Understanding and addressing the key challenges

While the social impact bond model has been well received since its introduction in the US, there are still major barriers to setup and implementation. The four main challenges are:

- Managing public expectations and creating space for failure,
- Attracting commercial capital,
- Identifying “SIB-ready” social services and providers, and
- Preparing the ecosystem to enable the adoption of a new contract type.

While these present barriers to adoption, they are not insurmountable. With each challenge, there are potential solutions that can help mitigate the risks involved.

Managing public expectations and creating space for failure

The most important challenge is managing the expectations of the first few SIBs in the US. The excitement around this new product has brought with it a heightened level of scrutiny and pressure for it to succeed – and succeed quickly.

But this is not a structure that can be launched overnight. Gaining buy-in from the government, investors, and service providers will take considerable time and energy from the SIBIO, which plays the convener and moderator
role in this process. Once all parties understand the risks involved, writing the contracts will take months of negotiation to get all parties to agree on the parameters. In the UK, this process took at least a year to complete. Once the contract is signed and the SIB is officially launched, there is typically a year allowed for setup, three to five years of intervention, and a year of evaluation and wrap-up. Patience will be required should the first (or first few) SIBs fail to hit their predetermined metrics so that the model is not struck down before it has a fair chance to prove its potential.

Transparency and information flow will be critical. Organizations like the Nonprofit Finance Fund and the Rockefeller Foundation, which have set up an unbiased “learning hub” for SIBs, can help by releasing periodic reports on the progress of the SIBs operating across the country. These reports would offer a realistic snapshot of the work, highlighting the day-to-day challenges of providing these services. The hope is that with this information widely disseminated, judgments will shift from a binary choice of success or failure to a more nuanced assessment. If the question can be reframed from “does this model work?” to “how can we learn from early failures to refine and improve the model?” SIBs will have a much better chance at long-term success.

In the end, it is the responsibility of all parties involved – particularly the intermediary, investors, and government agencies – to remain cautiously optimistic about the potential of the SIB and manage the expectations of other stakeholders to limit disappointment should the SIB fail.

**Attracting Commercial Capital**

The SIB structure relies on the availability of commercial capital to open the social services market to a much larger source of funding than is currently accessible to nonprofit organizations. Without this new influx of private capital, the only innovation is the outcome measurement and reward, a combination that has already been introduced in the US through aforementioned pay-for-performance contracts.

In the Peterborough SIB, foundations and high-net-worth individuals stepped in to play the investor role. While there is a budding interest among social investors in vehicles with blended returns, the amount of money from individual investors and foundation program related investments (PRIs) in the US is inadequate.

- Individual Investors. A Hope Consulting report that surveyed individual investors to gauge interest in “impact investing” showed
that 45 percent of respondents were interested in “investment with a social bonus,” and 35 percent were interested in a “business solution to a social issue.” Both could be used to describe SIBs. But when asked how much they were willing to invest in this space, 95 percent of respondents said less than $25,000.ix These results do not indicate a current willingness of private investors to put the necessary amounts of money into a long-term SIB contract.

• Program Related Investments (PRIs). While foundations are starting to look more closely at PRIs, the PRI market is still fairly small. According to the Foundation Center, foundations made $310.5 million in PRIs in 2006, but the majority of this was concentrated in a few major foundations.x Foundations are generally wary of using PRIs because the funds are tied up for a long period of time, increasing the risk of default or loss. The current scarcity of PRI activity does not provide much hope for large-scale foundation involvement in SIBs, unless one of the major foundations, such as Rockefeller, Gates, or Ford, decides to take the lead to help prove the model.

The current structure relies on these sources of capital because of the risk of full principal loss. Because of this risk, the SIB is not an attractive vehicle for private, commercial investors. Any structure developed in the US needs to mitigate this risk in order to make the first SIBs attractive to commercial investors and to set the precedent for future interest by institutional impact investors.

Potential ways to protect the principal of the investment include:

• Creating a separate, grant-raised loan loss reserve to act as a principal guarantee should the SIB intervention fail.
• Layering the capital structure of the SIB to leverage the different intents of the investors. For example, a foundation could provide the “base/first loss” layer, high-net-worth impact investors could provide the second layer and accept lower returns, while commercial investors could provide the final, preferred layer and receive returns with a reduced risk.
• Bundling the SIBs into a mutual fund-type instrument once the market starts to grow so the risk can be diversified across multiple
projects.

If SIBs are to reach their potential scale and impact in the US, commercial viability is essential. All efforts should be made to construct the SIB in a way that is feasible for prudent investors to place money into this structure.

Identifying “SIB-ready” Social Services and Providers

As seen in the UK and through potential interventions in the US, not all social ills can be solved through SIBs. There needs to be a clear problem, identifiable control group, measurable outcomes, and easy-to-define, short-term savings generated for the government to make these work. Therefore, choosing the first interventions in the US on which to test the model is extremely important to prove to investors, public officials, and the general public that the model is feasible.

The federal government and the Massachusetts government, the two entities that are pushing for SIBs in the US this year, have chosen the following intervention areas that they think fit these criteria:

- Criminal justice (juvenile and adult)
- Workforce development
- Homelessness
- Education

The federal government is focusing on all of these interventions, while Massachusetts has zeroed in on homelessness and juvenile justice. These interventions – and their potential to become strong SIB programs – are evaluated along a matrix of required elements:

<table>
<thead>
<tr>
<th>Field of intervention</th>
<th>Problem definition</th>
<th>Desired outcome</th>
<th>Target population</th>
<th>Output or Outcome metrics</th>
<th>Potential for returns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workforce development</td>
<td>Un- and under-employment of US workers</td>
<td>Increased full time employment, higher wages and quality benefits</td>
<td>The un- and under-employed in a certain region</td>
<td>Jobs, wages, quality and type of benefits, hours worked per week</td>
<td>Yes, large savings from reduced unemployment insurance and other welfare benefits</td>
</tr>
<tr>
<td>Field of intervention</td>
<td>Problem definition</td>
<td>Desired outcome</td>
<td>Target population</td>
<td>Output or Outcome metrics</td>
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</tr>
<tr>
<td>Homelessness</td>
<td>Chronically homeless individuals who rely on a large number of “cure” social services</td>
<td>Permanent housing and access to necessary health care</td>
<td>Chronically homeless individuals, mainly in US cities</td>
<td>Placements in permanent housing, Medicaid spending, ER visits</td>
<td>Yes, large savings from more efficient health care delivery and reduced costs from temporary housing</td>
</tr>
<tr>
<td>Juvenile Justice</td>
<td>Juvenile offenders who are more likely to spend part of adulthood in jail</td>
<td>Reduced recidivism rates for juveniles and successful reentry into society</td>
<td>Recent or soon to be released offenders in a certain region</td>
<td>Reduced recidivism rates, employment and education rates</td>
<td>Yes, savings from variable per-prisoner costs, law and enforcement costs, and eventually closed cells/prisons</td>
</tr>
<tr>
<td>Education</td>
<td>Lack of quality public education that is not adequately preparing students</td>
<td>Higher achievement levels and outcomes for K-12 children</td>
<td>K-12 children in public schools</td>
<td>Test scores, HS and college graduation rates, employment rates, income levels</td>
<td>Yes, but long term and harder to track and attribute to one intervention.</td>
</tr>
</tbody>
</table>

Of these, education faces the greatest challenge because using student educational interventions for the initial SIBs could invite controversy over metrics and outcomes that might raise legitimacy claims about the model. The constant debate on how to measure educational achievement and teacher quality could distract from the core ideas of the SIB structure. Therefore, education is better addressed after the model is proven through less politicized interventions.

**Preparing the Ecosystem**

Currently, most budgeting contracts from the state or federal government do not span more than one year because of appropriations laws. As the law stands, most funds are only made available to agencies for a one to two year period, and if unused, they automatically get re-routed to the Treasury Department. If sufficient funds cannot be allocated by the government over the longer-term life of the SIB, investors will perceive more risk in the future cash flow, undermining the effectiveness of the structure.

In order to facilitate longer-term contracting and provide a level of comfort for the investors, one of two changes needs to occur. One option is to pass “full faith and credit” legislation at the state and federal level to allow
for contracting that can promise funding in five to ten years’ time, should the intervention prove successful.

Another option is for each department that receives Pay for Success funding to amend their appropriations language to provide an exception to the law as currently written. The new law would include a statement that “any funds obligated for such projects shall remain available for disbursement until expended, notwithstanding 31 U.S.C. 1552(a)”, which states, “Provided further, any de-obligated funds from such projects shall immediately be available for Pay for Success projects.” In order to attract investors, these changes should be implemented before SIB contracts are written with federal or state dollars.

The second infrastructure requirement is the level of measurement and data analysis of participating service providers. The SIB model depends heavily on identifying providers that can implement an intervention to create the intended, measurable outcomes that will translate directly into government savings. This requires sophisticated tracking, measurement, and data collection that is not typically found in non-profit organizations. Past studies have shown that most non-profit organizations, even those who claim to have a focus on outcome measurement, do not have the sufficient infrastructure in place to effectively measure their impact.

While not all non-profits are inept at measuring outcomes, for the SIB model to succeed, they must place more emphasis on outcome measurement, reporting, and standards. This is particularly important for the initial bonds created, as proven interventions with solid data will be essential to raise private capital.

Model and Intervention Risk

The risks highlighted above are specific to SIB adoption and implementation in the US, where social impact bonds do not yet exist. In addition to these categories of risk, there are multiple risks associated with the model itself, including assumptions that:

- The intervention works as intended and produces the agreed upon outcomes,
- The control group remains untouched and reliable as a counterfactual,
- The government, private investors, and service providers agree upon metrics so the savings can be accurately calculated and
allocated.

• These risks are inherent to the structure and will be a factor regardless of location.

Conclusion

Innovation in social services and government spending is rare, which is why Social Impact Bonds have attracted interest and garnered so much attention from different stakeholders. This structure, developed by a small organization in the UK, has the potential to change how public agencies and service providers interact and measure their success.

In addition, the excitement around the field of impact investing has caused the SIB structure to spread like wild fire and created a daunting space for itself under a global magnifying glass.

At the end of the day, the social impact bond is complicated and requires a lot of large, embedded systems to coalesce around its structure. Because of these challenges, there needs to be sufficient caution around its potential to achieve large-scale change, its ability to attract commercial capital, the availability of relevant social services, and other barriers to implementation until the model is proven.

In order for the US to create a supportive environment for these bonds, the following steps need to be taken concurrently:

i. All parties involved need to manage expectations around the timeline and potential impact of this product and suspend judgment until multiple SIBs have succeeded. Transparency and constant communication is critical to achieving this goal.

ii. The structure of the product needs to mitigate the risk of full principal loss through a guarantee or first loss pool to attract and comfort commercial investors.

iii. The intermediary and government need to be selective about which interventions will work with the model, focusing on proven social interventions in homelessness, juvenile justice, and workforce development that provide short-term, realizable public savings from an easily identifiable population and can be scaled effectively.

iv. The state and federal government need to pass or adapt appropriations
laws to allow for a long-term contract with the intermediary, reducing the risk to future cash flows.

v. Social service providers need to develop more robust measurement procedures to prove they are capable of achieving and proving the desired outcomes.

If these steps are taken, SIBs will have a much greater chance of success at achieving their potential for large-scale social impact in the US.

Appendix A: Global activity of Social Impact Bonds

**United Kingdom**

<table>
<thead>
<tr>
<th>Agency/Government</th>
<th>Intervention Focus</th>
<th>Launch or Announcement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK Department of Justice</td>
<td>Adult recidivism</td>
<td>November 2010</td>
</tr>
<tr>
<td>Manchester City Council</td>
<td>“Looked after” children and young people (foster children)</td>
<td>March 2012</td>
</tr>
<tr>
<td>Greater London Authority and Department of Communities and Local Government</td>
<td>“Rough sleepers” (chronically homeless)</td>
<td>March 2012</td>
</tr>
<tr>
<td>Scotland’s Department of Work and Pensions</td>
<td>At-risk youth</td>
<td>March 2012</td>
</tr>
</tbody>
</table>

**Australia**

<table>
<thead>
<tr>
<th>Agency/Government</th>
<th>Intervention Focus</th>
<th>Launch or Announcement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New South Wales</td>
<td>Juvenile justice, families at risk, disability services</td>
<td>March 2012</td>
</tr>
</tbody>
</table>

**United States**

<table>
<thead>
<tr>
<th>Agency/Government</th>
<th>Intervention Focus</th>
<th>Launch or Announcement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massachusetts State government</td>
<td>Adult recidivism</td>
<td>November 2010</td>
</tr>
<tr>
<td>Manchester City Council</td>
<td>“Looked after” children and young people (foster children)</td>
<td>March 2012</td>
</tr>
<tr>
<td>Minnesota State government</td>
<td>“Rough sleepers” (chronically homeless)</td>
<td>March 2012</td>
</tr>
<tr>
<td>New York City government</td>
<td>At-risk youth</td>
<td>March 2012</td>
</tr>
</tbody>
</table>
Endnotes


vii. Ibid.


x. http://www.philanthropyjournal.org/resources/special-reports/finance-accounting/program-related-investments-provide-needed-relief


TO DISBURSE OR NOT TO DISBURSE?

Strengthening the World Bank’s Response to Revolutions and Coups d’Etat

Georgia Harley‡

Abstract

How does the World Bank respond when one of its partner governments is overthrown in a coup d’etat or revolution? Such power transitions remain frequent in the developing world. Their occurrence gives rise to vexing challenges for the Bank, whose mandate prohibits it from considering politics in its decision-making. To disburse, or not to disburse? That is the question.

The paper analyzes the Bank’s policy for responding to this question. Operational Policy OP7.30 outlines the circumstances under which the Bank may suspend disbursements under existing financing agreements to governments that have changed power through coup d’etat, revolution or other means outside that country’s constitution. The policy lacks clarity, precision and guidance. Recent practice suggests that the policy is not being applied faithfully and that extraneous issues are being considered, including political considerations in contravention of the Bank’s Articles of Agreement.

The paper proposes four recommendations to strengthen the Bank’s policy. The Bank should (1) issue a clarification reconciling the Bank’s Articles of Agreement with OP 7.30; (2) publish its decisions and rationale for suspending disbursements to de facto governments; (3) amend OP 7.30 to clarify the effective control test; and (4) amend OP 7.30 to authorize the Bank to consider the views of relevant organizations in its decision-making. While these recommendations will not resolve all outstanding issues, their adoption would strengthen the effectiveness and legitimacy of Bank decision-making in this challenging area.

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Strengthening the World Bank’s policy on de facto governments

i. The World Bank and de facto governments

a. The World Bank

In 2010, the Bank committed more than $72 billion in assistance to partner governments in the developing world for the purposes of economic development and poverty alleviation.1 In conducting its operations, the Bank’s mandate is governed by the International Bank for Reconstruction and Development Articles of Agreement, which prohibits the Bank from having regard to political considerations in its decision-making.ii The Articles of Agreement requires that ‘the Bank and its officers shall not interfere in the political affairs of any member; nor shall they be influenced in their decisions by the political character of the member or members concerned. Only economic considerations shall be relevant to their decisions, and these considerations shall be weighed impartially.’iii To date, 187 Bank Member States have ratified the Articles of Agreement, making it one of the most widely endorsed treaties in the world.

Despite this, the World Bank has long been accused of being a tool of its developed country shareholders.iv Empirical studies have shown positive relationships between the Bank’s lending practices and recipient countries’ voting behavior in the UN.v Yet, there has been little scrutiny or scholarship on the role of political considerations in Bank decision-making after a lending operation has been approved. Focusing on scenarios where disbursements have begun to flow, researchers can control for a range of pre-approval factors, including political considerations that may be masked during the pre-approval phase. Further, there is a paucity of academic scholarship on the Bank’s decision-making regarding the suspension of disbursements under existing financing operations to de facto governments.vi This article takes a step toward addressing that void.

b. De-facto Governments

A ‘de facto’ government is one that arises by means outside of that country’s own system of political governance. De facto governments may come to power following a coup d’etat or revolution, or by usurpation, abrogation or suspension of that country’s constitution.2vi They need not come to power through the use of armed force or violence (though often they do), and they can arise in countries of any political governance (whether democratic,
authoritarian, theocratic, etc.). What characterizes these governments is the fact that they arise outside of the rule of law, but in actuality govern the country.

De facto governments frequently arise in the developing world. In the last decade alone, more than 30 coups d’état were attempted in over 20 countries, mostly in sub-Saharan Africa. The Bank had existing financing arrangements with the overwhelming majority of those countries.

c. Implications of dealing with de-facto governments

Political instability is closely linked with the Bank’s goals of poverty and economic under-development. Among the predominant causes of coups d’état and revolutions are low income and slow growth.\textsuperscript{viii} Political crises can also jeopardize a country’s economic stability, as investors flee and the local currency fluctuates, economic growth is often stunted, pushing people (further) into poverty. For these and other reasons, countries that experience de facto governments are more likely than other developing countries to need assistance from the Bank.

However, de facto transitions of political power are the realm of high politics – that place where Bank officials fear to tread. When one of those countries has an existing agreement with the Bank, the Bank can find itself squarely in the middle of a contested and controversial space. This is amplified when, as is often the case, the Bank is a large donor in the country.

Continuing disbursements may lend confidence and legitimacy to a de facto government, signaling stability and trustworthiness, and increasing the likelihood that other countries and organizations will recognize the legitimacy of the new government. Continuing disbursements can also strengthen the government’s ability to conduct state functions and further entrench its control over territory. Whereas, suspending disbursements may deal that government a fatal blow in terms of confidence, legitimacy and finance. Further, the Bank often plays intermediary and donor coordination roles in the countries, conferring on it considerable informal influence with donor governments, international organizations, and NGOs.

d. Parallels with broader governance challenges facing the Bank

Parallels may be drawn between the Bank’s approach to dealing with de facto governments, and the Bank’s approach to dealing with governance and anti-corruption challenges more broadly.

For much of its history, the Bank had been silent on issues of governance
and corruption because it deems them ‘too political’. By the late 1980s, evidence of the relationship between governance and economic development had strengthened. Lessons were emerging about the failure of macro-centric structural adjustment policies to cater for the prevailing governance and institutional environment in recipient countries. By the mid-1990s, governance and institutional quality were squarely on the agenda, and the Bank’s longstanding hesitancy to address governance concerns gave way to increasing engagement with corruption, financial accountability, and civil service reform. Two decades on, criticism persists that the Bank’s work in governance is overly selective and that the Bank is ‘forever chasing its own tail, in an effort to remove the political form of its work on institutions, accountability, legal reform, increase participation and so on.’

Like in the broader governance debate, the Bank appears wedged on this issue between its Articles of Agreement and the evolving directions of economic development policy.

**ii. The Bank’s policy on suspending disbursements to de facto governments**

In 2001, the Bank adopted *Operational Policy 7.30: Dealing with De Facto Governments* (OP7.30), which outlines the conditions under which the Bank shall either continue or suspend disbursements under existing operations to a de facto government. OP7.30 stipulates that the Bank may not unilaterally suspend disbursements under existing loans, provided that the Bank is satisfied that the situation meets the following five criteria:

- Criterion A - holds effective control of the country;
- Criterion B - recognizes the country’s past international obligations;
- Criterion C - states it is willing and able to assume all of its predecessors’ obligations to the Bank;
- Criterion D - ensures the continued implementation of Bank projects and programs;
- Criterion E - authorizes a representative for the purpose of withdrawals.

OP7.30 is supported by Bank Procedure (BP7.30), which requires that immediately upon a change of government power, staff must ‘gather all relevant information about the status, policies, and public acceptance of the new government,’ and initiate an internal process to determine whether to continue or suspend disbursements. If, upon analysis, the policy criteria above are met, the Bank is obliged to continue disbursements under its existing
agreement. The decision to continue or suspend is made by the relevant Regional Vice President, in consultation with the Country Director, the Legal Vice President and the Credit Risk Group.

a. Lack of clarity and guidance in OP7.30

OP7.30 fails to provide Bank officials with the necessary guidance in responding to de facto governments.

Criterion A, effective control, is vague and imprecise. The term ‘effective control’ has overlapping meanings under international law. Under the laws of armed conflict, it refers to the circumstances when a belligerent armed force is in control of a hostile territory such that their forces become obliged to provide certain minimum guarantees to civilians in that territory as an occupying power.\textsuperscript{xv} Under human rights law, the term refers to whether a State operating extra-territorially has sufficient control over an individual such that it must protect their rights.\textsuperscript{xvi} In a third context, the UN Secretary General has used the term to specify which of two rival governments, ‘exercises effective authority within the territory of the State and is habitually obeyed by the bulk of the population.’\textsuperscript{xvii} It is not clear whether Criterion A of OP7.30 refers to one of these concepts or to an internal concept of the same name.

Criteria B and C, assuming obligations, and Criterion D, ensuring implementation, are difficult to apply in practice. These criteria emphasize that the policy’s primary concern is the solvency of the Bank’s investment. This suggests that financial risk is indeed more relevant than political considerations in Bank decision-making. Though this prioritization may draw its critics, the focus on lending is faithful to the Articles of Agreement and the Bank’s traditional ‘economics first’ approach. However, a de facto government’s commitment to international obligations and Bank projects and programs cannot be known \textit{ex ante}. As a result, much of the Bank’s assessment under OP7.30 requires prediction and conjecture by Bank staff about the credibility and veracity of the new government’s statements. This introduces subjectivity to the policy, and creates potential space for extraneous considerations, including political considerations.

Lastly, Criterion E, authorizing a representative, is a formality: it merely requires that de facto governments nominate a payee for the disbursement of checks.

In all, OP7.30 provides Bank officials with little objective guidance on the precise meaning of the five criteria, creating wiggle room for the Bank to
continue or suspend disbursements in a given case.

b. Lack of transparency in applying OP7.30

OP7.30 and BP7.30 are publicly available. However, they include a caveat that they are ‘not necessarily a complete treatment of the subject,’ without referring to additional guidelines or documents to elucidate a more complete treatment. Bank officials, including advisers and decision-makers, as well as observers and de facto governments themselves, are all thus left with an incomplete framework for the Bank’s decision-making.

Further, the Bank does not disclose its decisions or deliberations, and is selective in addressing the issue in the media. It is thus difficult to discern the Bank’s exact practice. Not knowing how these decisions are made reduces accountability, hinders experiential learning and limits the ability of the Bank and other actors to improve the Bank’s practice in dealing with de facto governments over time. Further, the opacity does not align well with the Bank’s stated commitment to transparency and its track record as a leader in access to information and open development.xviii

iii. OP7.30 in practice

The author has collated over a dozen case studies of de facto governments that have arisen over the last five years. Below are some illustrative examples of the application of OP7.30 in those cases, based on the limited publicly available information.

a. Recent case studies of the Bank’s application of OP7.30

i. Coup d’etat in Honduras, 2009

The Bank’s suspension of disbursements in response to the 2009 coup d’etat in Honduras appears at odds with OP7.30. When a military coup replaced then-President, Manuel Zelaya, with Congressional President, Roberto Micheletti, the new government quickly gained control of the territory and functions of government, including economic policy. In response, the Inter-American Development Bank (IADB) suspended all loans and the Organization for American States (OAS) suspended Honduras’ membership. The Bank suspended $250 million in loans. In explaining the position, Bank President Robert Zoellick noted that the Bank was ‘working closely with the OAS and looking to the OAS to deal with its handling of the crisis under its
‘democratic charter’. When asked under what conditions the Bank would consider resuming lending, Zoellick stated that the situation was ‘in flux and fluid’ and that the Bank was ‘trying to play a supportive role with the region and its overall goals to restore democracy’. No mention was made of any OP7.30 criteria, such as the government’s effective control or its ability to meet Bank commitments. Zoellick’s statement suggests that the position of regional organizations, such as the OAS and the IADB, factored into the decision-making process, along with overarching considerations of democracy and the rule of the law.

ii. Election stand-off in Cote d’Ivoire, 2010

The Bank’s suspension to Cote d’Ivoire during the 2010 post-election stand-off is also difficult to reconcile with OP7.30. In early December 2010, the Bank and the African Development Bank (AfDB) issued a joint statement expressing concern over the post-election crisis, in particular concerns about governance, peace and stability. In late December, the Bank suspended all disbursements to Cote d’Ivoire, stating that it ‘supported ECOWAS and the AU in sending the message to President Gbagbo that he lost the elections and he needs to step down’ in favor of President-elect Alassane Ouattara. The international community’s response has been described as ‘a remarkably united international coalition intent on cutting funds’ to Gbagbo.

However at that time, Gbagbo maintained control throughout Cote d’Ivoire, including the government and business capitals. Meanwhile, Ouattara was confined in an Abidjan hotel and the militia groups that ultimately seized control were only just beginning to mount in the north of the country. Further, applying Criterion C, there is little to suggest that Gbagbo’s economic policies had changed since before the election, when he was the de jure government and funds were flowing, nor that his government had changed so drastically to render the Bank’s existing projects and agreements unworkable. Lastly, applying Criteria B, there is little indication that Gbagbo would not honor the obligations his government had assumed during the previous 10 years of his presidency. In April 2011, Ouattara’s forces defeated Gbagbo and formed a government, at which time the Bank and other donors immediately reactivated disbursements.

iii. Tunisian Revolution, 2011

The Bank’s continued disbursements to Tunisia during the Jasmine Revolution in 2011 also appear at odds with OP7.30. There, a popular uprising led to the ouster of President Ben Ali and the appointment of an Interim
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Authority, pending democratic elections. Within a week the Interim Authority had gained authority throughout the country and enjoyed broad support. Donors appeared eager to engage with the Interim Authority, whose stated goals of development, growth and governance aligned well with those of the donor community. The Interim Authority stated publicly its willingness to honor the international obligations of the previous Ben Ali government. Like others, the Bank did not suspend disbursements, an outcome which appears consistent with OP7.30.

However, there is also evidence to suggest that the Bank took into account extraneous factors in its decision-making, including democracy promotion and political expediency. In a statement in February 2011, Bank Vice President Akhtar stated that the root cause of political turmoil in North Africa is ‘fatigue with long-standing authoritarian rule and weak political and economic governance as confirmed by public concerns regarding issues of voice, social justice, fairness, accountability and access to public services.’ xxiv The Bank highlighted the importance of ongoing support to the Interim Authority and has since fast-tracked programs and increased lending fivefold to ‘build on the revolution’s achievements in breaking from past practices, including increasing transparency, social accountability, citizen’s participation and social and economic inclusion.’xxv These statements suggest that the nature of the revolution, including its democratic goals, may have also factored into Bank decision-making.

iv. Mali, coup d’état, 2012

The Bank’s suspension to Mali during the 2012 military coup d’état is also difficult to reconcile with OP7.30. Applying Criterion A, the coup leaders would probably not have satisfied either form of the ‘effective control’ test. Indeed, the coup was precipitated by an ongoing rebellion in the north of the country. In the chaotic aftermath of the coup, the Tuareg ethnic group appeared to gain control there and sought to proclaim independence. Application of this criterion would have been sufficient to suspend disbursements. Within one day of the coup, the Bank and the AfDB issued a joint statement suspending disbursements to Mali.

While this outcome appears superficially consistent with OP7.30, there is again evidence to suggest that the Bank considered extraneous factors in its decision-making.xxvi In its five-sentence statement, two sentences referred to democratic governance in Mali. A further sentence confirmed that the Bank was ‘join[ing] the African Union and ECOWAS in condemning the military coup’. No reference was made to any OP 7.30 criteria, such as the
lack of effective control. A plain reading of the Bank’s statement thus suggests that the non-democratic nature of the transition and the views of regional organizations may have factored into the Bank’s decision-making.

b. Analyzing the divergence between the Bank’s policy and its recent practice

The examples above suggest that the Bank’s decisions are coordinated with the international community and, in particular, with the regional organizations and major bilateral donors operating in a particular country. In cases where disbursements were suspended in Cote d’Ivoire, Honduras and Mali, the Bank stated publicly that it was following the lead of others, or at least closely considering their views. This practice is curious for two reasons. First, consideration of the views of regional organizations and donors is not a criterion under OP7.30 for deciding whether to suspend disbursements under existing agreements to partner governments (though it is a criterion for considering new lending). Second, regional organizations and donors often make politically motivated decisions, unencumbered by the Bank’s rules prohibiting political considerations. In spite of OP7.30, the Bank consistently arrives at the same conclusions as political organizations, while generally perpetuating the idea that it bases its decisions on non-political criteria.

The examples may also suggest that the Bank is less likely to suspend disbursements to countries that are geo-politically or strategically important. While the world watched revolutions unfold in North Africa in 2011, the Bank was quick to reinstate disbursements to Tunisia and did not suspend disbursements to Egypt. Meanwhile, after coups d’état in less prominent countries like Mauritania, Mali and Niger, the Bank was quick to suspend disbursements. This trend of differential treatment based upon geo-political status suggests that the Bank takes into account political considerations in contravention of its Articles of Agreement.

iv. Policy recommendations to strengthen OP7.30

The recommendations below aim to strengthen the Bank’s policy to deal with de facto governments, by improving the consistency and quality of Bank decision-making and ensuring compliance with the Articles of Agreement.
a. Aligning the Bank’s Articles of Agreement and OP7.30

Presently, the Bank is exposed, as its policy and practice in the public domain would appear at odds with its founding Articles of Agreement. Theoretically, the option exists to amend the Articles of Agreement to broaden the Bank’s capacity to consider political governance when dealing with governments. However, such a proposal would be highly unlikely to gain support, given popular critiques that the Bank is already overly politicized, and given the technical and logistical challenges of amending such a large multi-lateral treaty.xxvii

More likely, the Bank could issue a legal opinion clarifying a modern day interpretation of the Agreement that aligns the Bank’s practice with the Articles of Agreement. Such a clarification was issued by the Bank’s General Counsel in the 1990s to support the Bank’s work in governance.xxviii Another was issued in 2006 to support the Bank’s work in human rights.xxix A clarification on dealing with de facto governments could reconcile the apparent inconsistency by enabling the Bank to consider the de facto government’s institutional quality and governance arrangements, while still prohibiting the political color of the regime from being itself a consideration.

b. Improving transparency of decision-making under OP7.30

The Bank should also publish the results and rationale of the decisions it makes to suspend disbursements under OP7.30. Publishing decisions could significantly improve accountability and predictability in the Bank’s dealings with de facto governments, and would encourage experiential learning and precedential guidance. Like the Bank’s other knowledge generation efforts, publication of Bank decision-making under OP7.30 may enhance the Bank’s influence by encouraging other international organizations, donor governments and non-governmental organizations to follow the Bank’s policy and practice. The Bank’s policy and practice has previously influenced other organizations in this area, and publication of these decisions could reasonably be expected to have a similar effect.xxx Publication would also give guidance to potential emerging de facto leaders and rival governments in the event of a political transition. Such a policy would seem to align well with the Bank’s existing commitment to transparency and open development.

As with the publication of any material, the publication of decisions to suspend or continue disbursements poses the risk that such decisions may be criticized. That risk would need to be managed carefully during the period
leading up to each decision, in consultation with the legal and public affairs departments of the Bank. However, the risk could be expected to decline over time as consistency and experiential learning improves.

c. **Amending OP7.30 to clarify the scope of the ‘effective control’ criterion**

The policy should be amended to clarify that the scope of the effective control test used in Criterion A is an objective assessment of the extent to which the de facto government is in actual control of the territory, using the same as that applied under the laws of armed conflict.

Adoption of this test would best align with the Bank’s existing framework as an inter-governmental body that deals primarily with countries rather than individuals. By comparison to other tests, this test provides the most clarity and precedents, thus providing the Bank with maximum guidance. This test is not foolproof, and may continue to give rise to some divergence of views. However, that divergence would be narrower than the contestation and ambiguity that prevails under the existing policy.

Further, application of this test would avert the need for the Bank to consider whether a particular government is ‘habitually obeyed by the bulk of the population’, which could raise concerns that the Bank is considering democratic governance and politics in contravention of its Articles of Agreement.

d. **Amending OP7.30 to authorize consideration of the views of relevant organizations**

The Bank should amend OP7.30 to add a criterion that authorizes Bank officials to ‘consider the views of relevant international and regional organizations when determining its response to a de facto government. Such an amendment to OP7.30 would not require the Bank to follow the views of relevant international or regional organizations, but would enable the Bank to consider those views in a given situation. The Bank could thus align its practice with that of key international and regional organizations when it considers doing so is appropriate, while still enabling the Bank to ‘go it alone’ if deemed necessary by decision-makers.

The policy on new lending to de facto governments already enables the Bank to consider the views of relevant international organizations. As a result,
amendment to this policy would align the two policies that deal with de facto governments. Recent practice suggests that the Bank already considers these views in its decision-making. This amendment would merely align policy with prevailing practice and thus improve policy coherence and streamline decision-making.

Adoption of this amendment may promote greater coordination and consistency among donors working in politically unstable environments. Gaining consensus for a common voice on this issue is in the Bank’s interest for several reasons. First, decisions to suspend or disburse funds may be more impactful when organizations and governments maintain a coherent and consistent line with the recipient government. Second, the process of securing consensus may enhance the Bank’s coordinating role and convening power among organizations and donors. It would also be consistent with the Bank’s role as a UN agency.

Adoption of this amendment poses the risk that the Bank would follow the politically motivated views of others, rather than deciding the appropriate use of its own funds under an existing binding loan agreement. A further downside is that the Bank could be perceived as following regional opinion rather than providing global leadership. However, that risk balances favorably against that of the current practice: considering those views without express authorization under OP7.30.

**Conclusion**

The Bank is in a difficult position, wedged between its Articles of Agreement, the evolving realities in economic development and the decisions and opinions of others. This paper has proposed four recommendations, both substantive and procedural, to strengthen the Bank’s policy for dealing with de facto governments. The Bank should:

i. **clarify the policy’s consistency with the Articles of Agreement**;

ii. **publish its decisions under OP7.30**;

iii. **amend clarify the effective control test**; and

iv. **amend the policy to authorize the Bank to consider the views of relevant organizations. Adoption of these recommendations could ensure that the Bank’s work in these challenging environments is more effective,**
legitimate, and consistent with its founding principles.

Endnotes


iii. Article 4 Section, Articles of Agreement.


vii. OP7.30, paragraph 1.


Prior to 1994, the World Bank lacked any stated policy on dealing with de facto governments. In 1994, the Bank adopted an initial policy on dealing with de facto governments, but it was sparse and few official records of it are available. The 2001 policy elaborates and replaces the 1994 version.

OP7.30, paragraph 1. It is also worth complimenting the Bank for having a policy on dealing with de facto governments. Many international and bilateral organizations do not, and they base their decisions on whether to suspend programs, or pull out of countries, on an ad hoc basis.


See for example, the case of Al-Skeini v the United Kingdom, where the European Court of Human Rights held that UK forces had sufficient control over civilians and prisoners in Basra, Iraq, that they were obliged to ensure and protect their human rights. Available at http://cmiskp.echr.coe.int/tkp197/view.asp?action=html&documentId=887952&portal=hbkm&source=externalbydocnumber&table=F69A27FD8FB86142BF01C1166DEA398649.

UN Secretary General Trygvie Lie, Memorandum on the Legal Aspects of the Problem of Representation in the United Nations, 1950, UN Doc S/1466.


http://news.bbc.co.uk/2/hi/americas/8127503.stm

http://www.reuters.com/article/2009/06/30/idUSN30445897


http://web.worldbank.org/WSITE/EXTERNAL/COUNTRIES/AFRICAEXT/CDIVOIREEXTN/0,,contentMDK:22795867~menuPK:50003484~pagePK:2865066~piPK:2865079~theSitePK:382607_00.html. The Bank must necessarily have applied OP7.30 and assessed that Gbagbo’s refusal to step down amounted to an assumption of power by extra-constitutional means. On this rationale, Gbagbo and his team became a de facto government, without the de jure authority of a democratic electoral process. Presumably, the Bank then also assessed that Gbagbo’s team did not satisfy the criteria outlined in OP7.30.

continues.


xxx. The Bank’s policy on dealing with de facto government’s has already influenced other agencies to develop their own policies. See for example, the policy of the International Fund for Agricultural Development, available at http://www.ifad.org/pub/basic/governments/defacto_e.pdf. The Asian Development Bank took a similar approach in deciding whether to deal with a de facto government in Fiji. See http://developmentasia.org/Documents/Economic_Updates/FIJ/in43-11.pdf at page 4.
High quality new molecular entities (NMEs) are drug therapies that provide the most value to the public and are the measure of innovation within the pharmaceutical industry. However, these drugs are not the most profitable for the industry and the pipeline appears to be slowing. Thus, high quality NMEs represent a positive externality in the pharmaceutical market. In this paper I examine the status quo and two policy alternatives: creating a Translational Research Center within the National Institutes of Health to directly increase the number of high quality NMEs, and changing regulations at the Center for Drug Evaluation and Research to incentivize industry to increase the number of high quality NMEs. Due to the complexities of research and development as well as the pharmaceuticals market, I recommend that the federal government create a Translational Research Center.

Introduction

High quality new molecular entities (NMEs) are drug therapies with novel chemical formulations that offer more effective or less harmful treatments than previous therapies—including effective therapies for previously untreated diseases. The most profitable drugs for the pharmaceutical industry, however, are generally not novel chemical formulations. Because NMEs do not provide the greatest benefit for the pharmaceutical industry but do provide a benefit beyond their market valuation, high quality NMEs represent a positive externality in the pharmaceuticals market.

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The pharmaceutical industry chooses what diseases and treatments to pursue based largely on the state of research and how it perceives consumer demand. This varies by firm, both in terms of their research capabilities and market studies. There is no discernible trend over the last thirty years, but there are typically at least 50 non-NMEs approved each year. Most of these are reformulations or new-use approvals for existing drugs. New formulations of existing drugs are awarded an additional three years of patent protection under the 1984 Hatch-Waxman Act. This incentivizes firms to continue investing in existing drugs to extend their profitability instead of making larger investments on NMEs in a research and development (R&D) gamble.

Pharmaceutical R&D is costly and time consuming. On average, it takes 11.8 years and between $500 million and $2,000 million (typically $868 million) for a drug to be brought from discovery to approval. Moreover, R&D expenditures are rising as a result of the increasing costs of running clinical trials and the increasing rates of failure. Pharmaceutical industry R&D spending has increased roughly 5 percent per year from 1980 ($5.5 billion) to 2003 ($17 billion). As of 2008, the market share for generic drugs (off-patent therapies with nonproprietary names) has increased to 58 percent. As a result, R&D investment is expected to decrease, since manufacturers pursue drugs primarily based on expected revenue returns.

Pharmaceutical companies cannot predict which NMEs will be high quality, let alone generally efficacious or harmful. They also cannot predict which ones will receive Center for Drug Evaluation and Research (CDER) approval. This may partly explain the variation (currently a downward trend) in the number of high quality NMEs produced by the industry: the proportion of high quality NMEs to other NMEs has dropped from 14.8 percent (annual average 1989-2000) to 10.7 percent (annual average 2000-2004). Furthermore, CDER received fewer NME applications in 2010 than it has in any of the previous fifteen years, illustrating a continuous downward trend.

The industry is increasing its focus on novel therapies to treat rare diseases. There are several difficulties inherent to creating a medication for a rare disease, regardless of the disease itself. Mainly, having a disease with fewer patients means a much smaller population to get a good sample size for study, which can severely hamper attempts to prove a medication’s efficacy or hide potential confounders and side effects.

NMEs (high quality or not) are not necessarily the most profitable drugs for the pharmaceutical industry. The industry earns a large proportion of its
profits from follow-on drugs, such as Nexium, that provide extremely similar therapies to drugs already in use. The industry also profits from extending the patents on existing successful medications through reformulations, new dosing, and discovery of new uses. This difference in preferences indicates a potential market failure as NMEs present a positive externality: the potential benefit to society is greater than the market incentives for industry to produce them. This suggests that government intervention would benefit consumers.

In comparing two alternatives to the status quo, I first address policy goals and impacts, followed by the criteria I use in my analysis. The next section examines the status quo, a Translational Research Center (TRC) within the National Institutes of Health (NIH), and restructuring CDER rules. The paper concludes with my recommendation.

**Policy Goals and Impacts**

The policy alternatives proposed are specifically intended to increase the number of high quality NMEs available to consumers without affecting safety and efficacy regulations. The policy alternatives are evaluated on the following criteria:

- Increase the number of NMEs submitted to CDER. Increasing the total number of NMEs submitted increases the likelihood of developing high quality NMEs.
- Diversify the research and development of new drugs with an emphasis on novel treatment of rare diseases. A simple increase in the number of NMEs produced by the industry will not address the externality if they do not provide treatment for a wider array of conditions.
- Minimize costs to the consumer. This improves accessibility to beneficial drugs, including potentially life-saving treatments.
- Ensure political feasibility. Feasibility is dependent on industry acceptance, political opinions, and costs to taxpayers. Industry acceptance is particularly important because of the strength of the pharmaceutical lobby.
Alternative 1: Maintain the Status Quo

Overview

The pharmaceutical industry researches, designs, markets, and manufactures a wide variety of therapies to treat numerous diseases. Firms are heterogeneous: they vary in size and differ in capabilities in terms of discovery, R&D, marketing, legal staff, etc. The scope of this paper is to look at the industry as a whole, trends within it, and how potential policies may affect it. The relational picture of changing profits, R&D investment, and industry NME output is complex, but seems to point to a recent decline in innovation.

This section seeks to provide a base to be compared with the two alternatives, where applicable. The policy goals and impacts are not so much departures from the status quo as they are improvements in the market from the current state – status quo realities may contain trends or mechanisms that will correct the market to achieve these desired goals and impacts.

Number of NMEs

The industry is submitting fewer NMEs for approval. It remains to be seen how this trend will affect the number of approved NMEs over the next several years. In 2010, the pharmaceutical industry submitted 23 applications, the second lowest in fifteen years (range: 22 in 2002 to 45 in 1996). There is an overall downward trend in the numbers of NMEs submitted for approval each year. Not all drugs submitted to the approval process are approved; CDER has approved an average of 22.9 NMEs per year over the last 15 years. Many of the drugs that are approved require post-marketing studies; it is impossible at this point to say how many will be higher quality than competing therapies.

Gross industry profits are strongly correlated with R&D investment. As the industry is becoming less profitable – many of the industry’s top-selling drugs are coming off patent and will face direct competition from generic drugs at lower prices – we can reasonably expect R&D expenditures to lower in response. Some analysts argue that the effects of insurance (hiding the true cost of drugs from consumers, leading them to over utilize drugs) and marketing (creating demand) have caused the pharmaceutical industry to misread profits as consumer demand and overinvest in non-NME R&D as a response.
Research and development of novel therapies

Basic research – the foundational research at the root of discovery – is typically done by biotechnology firms, universities, NIH, ethnobotanists, etc. These discoveries are then released to or purchased by the pharmaceutical industry, which translates that basic chemical discovery into applications. NMEs are created wholly within the pharmaceutical industry. These drugs tend to generate more revenue than their externally discovered counterparts but are substantially less likely to be innovative or “respond to unmet medical needs.”

Cost to consumers for newly approved NMEs

Cost to consumers is based on R&D, manufacturing, marketing and other costs, threats of government regulation, world market fluctuations as well as consumer willingness-to-pay and price tolerance studies in some cases. An NME for a previously untreated disease can be viewed essentially as a monopoly, as there are no competing or substitutable therapies. Under these conditions, firms have full control of consumer prices.

Prices charged to consumers for a newly approved NME vary by therapy, but tend to be expensive for first-in-class life-saving medication. An extreme example of this is Alexion Pharmaceutical’s Soliris which treats paroxysmal nocturnal hemoglobinuria (a disease which affects only 8,000 Americans). It is the most expensive drug currently on the market at a consumer cost of $409,500 for a year of treatment. There are now over nine drugs that cost over $200,000 per year.

Political feasibility

It is typically acceptable to maintain the status quo for a variety of well-studied political and economic reasons, none of which this paper will discuss. Each alternative will have a discussion of the apparent political feasibility to move away from the status quo.

Alternative 2: Create an NIH Translational Research Center

Overview

This alternative creates a Translational Research Center (TRC) within the National Institutes of Health (NIH) with the mission of researching and
developing new therapies. Specifically, it would develop therapies that industry will not produce due to slow uptake of new techniques and basic research discoveries of NIH or to unwillingness because of the size of the potential market. This division would thus translate basic research into applied research to minimize the time from discovery to dissemination of new medicines. The TRC would decide which diseases to target based on its assessment of the needs of the populace, the state of basic research as it relates to a potential therapy, and whether the industry is pursuing a similar medication. The TRC would consist of new or repurposed labs at NIH campuses and the materials and personnel to fully utilize them. Additionally, the TRC would coordinate already existing grants and university-based translational research work being done with NIH in order to form complementary capabilities across multiple partners.

The TRC would not manufacture the drugs it designs. Instead, manufacturing would be contracted out to the industry to avoid large startup costs. It would also provide industry with R&D assistance and funnel them partial discoveries. This process could be complicated and would require rules that govern how the TRC interacts with industry in terms of both collaboration and staff bleed-over. The TRC would maintain control of patents in order to keep authority over drug distribution as well as to ensure it follows the same testing standards as the industry.

**Number of NMEs**

The TRC would increase the number of NMEs by developing its own without detracting from the number of therapies that industry produces. However, the extent to which the TRC will directly increase the number of high quality NMEs available to consumers is uncertain because pharmaceutical R&D cannot produce guaranteed results. Because the TRC will focus on novel therapies for untreated or undertreated diseases, any successes would provide to consumers NMEs that are high quality by definition.

The mission of the TRC is consistent with creating medications to combat diseases that have a low demand-to-R&D-cost ratio, which tend to be low-incidence diseases. As such, diseases the TRC targets will be unlikely to have competing therapies within the industry, as those medications would not be commercially viable. Some therapies the TRC develops would likely be substitutes for existing medications, but otherwise the center and industry would not compete. Therefore, industry would largely continue to submit
the same number of NMEs to CDER and all TRC submissions would be an increase in the total number of NMEs submitted for approval.

The mission to translate basic research into clinical research will involve sharing some research and discoveries with the industry. The NIH already conducts much of the basic research that goes into pharmaceutical development, and the new division would continue these ties. Further developing the NIH’s basic research before giving it to industry should speed the industry’s efforts to create NMEs.

**Research and development of novel therapies**

The TRC’s primary focus would be to develop NMEs available for patients with rare diseases. The TRC will research and design new drugs and therapies that have either not been pursued by the pharmaceutical industry or that the industry has otherwise failed to produce. Additionally, it will supply industry with semi-developed research to open the pipeline of drugs for these patients over and above the industry’s increasing focus on therapies for relatively rare and small-market diseases.

**Cost to consumers for newly approved NMEs**

Establishing the TRC should yield drug costs substantially lower than what industry would charge. The TRC would determine pricing of NMEs, as it would maintain control of the relevant patents and the manufacturing and distribution process. As the TRC would be a public entity that has a primary objective of creating NMEs, center administrators would decide the cost to consumers, and therefore it would reflect actual development costs rather than profit-seeking.\(^{xxv}\)

**Political feasibility**

Political opinion on the TRC is uncertain. Spending is an issue in the current budget climate, but the impetus to rein in pharmaceutical costs and increase the number of NMEs may outweigh these concerns. The TRC may be at least partially funded by consolidating current government R&D programs and reducing grants. It will be attractive if it requires little new funding, though budget implementation would be in the hands of NIH and Department of
Health and Human Services (HHS) chiefs as well as Congressional stakeholders.

Upfront costs to taxpayers would be roughly $1.3 billion for startup facilities, personnel, and materials. Part of this would come from consolidation of current government-sponsored pharmaceutical research, most likely much more than the $378 million spent in 1993. While this startup cost is high, it is comparatively little next to the average cost of industry NME development. Additionally, investing in the process should prove more efficient than investing in individual industry projects as this has proven difficult in the past.

Creating a new NIH division will present many difficulties, including hiring a staff of researchers, maintaining a steady funding source from Congressional stakeholders and other NIH and HHS administrators, acquiring the appropriate equipment and materials, and deciding what diseases and therapies to pursue. The costs of initial inefficiencies inherent in the creation of such projects are difficult to project at this time.

Industry acceptance of the TRC is ambiguous. The industry and the TRC will not be direct competitors; the TRC will most likely develop therapies for underserved markets while industry will continue to focus on the most profitable therapies. It should be noted that if the TRC creates a drug with market potential, the industry would likely put money into R&D for a substitute or follow-on medicine in order to capture potential consumers. In this case, the industry would directly compete with the TRC and would use resources to create therapies that treat the same disease instead of the intended novel therapies for untreated or undertreated diseases. The creation of the TRC is a boon to the industry as a whole: it effectively takes R&D a step further before handing it over to pharmaceutical firms. However, firms doing translational research may view it as unwanted competition. This policy alternative will not change the power or rights of the patent holding entity, as FDA rules will be unaffected and the TRC will put its drugs through the same testing process as the industry.

The pharmaceutical industry relies on outside research for drug discovery – universities were responsible for roughly 31 percent of novel drug discoveries between 1998 and 2007. Thus, it would be likely to accept further help from non-industry sources.
Alternative 3: More Stringent CDER Regulations

Overview

A second alternative to the status quo would be to change CDER regulations to require that drugs submitted for approval have high quality or, for drugs that cannot be assessed without post-marketing studies, at least demonstrate strong indications of high quality. In other words, they must be more effective or less harmful than an already existing therapy.

CDER’s main task is to use physician, statistician, chemist, pharmacologist and other scientist expertise to evaluate studies of drugs that pharmaceutical companies submit for approval. This process requires studies to demonstrate that a drug’s health benefit outweighs its known risk. However, there is a major weakness in CDER’s basic mission that must be addressed to increase the supply of high quality NMEs. Namely, a drug must only be proven more beneficial than harmful (i.e., it must show more effectiveness than a placebo), not that it must be more beneficial or less harmful than already existing therapies.

There are other problems with the CDER drug approval process: the companies that have a stake in the results often conduct the studies, surrogate measures are often approved (e.g. reducing a risk factor, but not requiring proof that this reduces the incidence of the targeted disease), and there is weak enforcement of required post-marketing studies.

Number of NMEs

This policy change should increase the proportion of high quality NMEs to other drugs by not allowing less effective or more harmful (compared to an existing therapy) NMEs onto the market. By nature, if an NME is a novel therapy, it will be considered high quality. Thus, firms will be more likely to research and develop NMEs if their chances of approval are higher.

Research and development of novel therapies

Follow-on drugs are more often the result of a development race than imitation: in the 1990s, 88 percent of as yet unapproved first-in-class drugs had follow-ons in the same class in Phase 3 clinical trials. The mechanisms by which a development race (or imitation research) start is unclear. As such, it is not possible to predict whether this policy would discourage direct competition.
from follow-on drugs or merely result in further studies to differentiate a follow-on drug from the first-in-class therapy. Weighing the approval process in favor of novel therapies should incentivize pharmaceutical companies to pursue NMEs that would serve previously untreated or rare diseases.

**Cost to consumers for newly approved NMEs**

Costs to consumers may increase slightly because this alternative increases the value of NMEs over already approved compounds, and it will require more R&D to discover a larger number of NMEs. Consumer cost of drugs will continue to depend on industry willingness-to-pay studies and the nature of the diseases treated, such as the efficacy of the current treatment if one exists and how many people are afflicted with it. Such a policy may increase industry reliance on biomedical companies and universities, which discovered about 56 percent of scientifically novel NMEs (35 percent of all NMEs) from 1998 to 2007. This reliance could either increase or decrease costs, depending on the discovery efficiency of pharmaceutical companies as compared to biomedical companies and universities.xxxiii

**Political feasibility**

The political feasibility of this policy change is difficult to predict. The rule change itself should not incur a major administrative cost on the government. The pharmaceutical industry has a very strong lobbying presence and would fight the change because it would make approval for non-novel therapies significantly harder to obtain.

This policy change would likely increase the value of a drug patent as it would make drug approval harder to obtain, particularly for follow-on drugs. Follow-on drugs would have to go through further studies to demonstrate increased effectiveness over the first-in-class drug, either overall or for specific populations. This would increase the value of the first patent by the cost of additional studies, perhaps inciting a race to application for the CDER approval process. In some cases where first-in-class drugs and their follow-ons have similar efficacy across all patient groups, that particular race would be winner-take-all.

This policy alternative would require no additional up-front cost to taxpayers from the status quo. Additionally, this policy would be a substantive rules change that would require no difference in technical expertise of CDER
personnel from the status quo, so administrative costs should remain the same.

**Recommendation**

I recommend that Congress create a Translational Research Center within NIH. A consolidated, government-run Translational Research Center would both provide high quality NMEs directly to the market at lower costs than industry and funnel discoveries into industry. This would benefit both the population and the drug industry.

**Endnotes**

i. New Molecular Entities are drugs that contain no active moiety that has been approved by the FDA


viii. CDER is a division of the US Food and Drug Administration (FDA)


xi. Conway, B. “Big Pharma Reassesses Orphan Drug Sector.” *Genetic Engineering &
Biotechnology News, March 1, 2011


xxiv. Undertreated refers to a disease whose therapy is of limited effectiveness or causes excessive harm.

xxv. Additionally, most follow-on drugs are researched simultaneously with the first-in-class therapy and not purely as a response to a successful first-in-class drug (DiMassi, 2011).

xxvi. It is plausible that the industry and the TRC may compete over talent. However, if the industry downsizes its R&D departments as is implied by this analysis, there will be an oversupply of researchers and support staff for just the industry to hire.

xxvii. Pricing could be used to offset some portion of the production cost or we could consider a pricing system under which the federal money is considered a direct subsidy and consumers/insurance pay the rest. Pricing will depend on the fiscal security of the TRC. That said, unlike industry it will not be trying to earn a profit, so at most
NMEs developed by the TRC will be priced an amount related to the research and production cost.

xxvi. Ibid


Abstract

Health Information Exchanges (HIEs) are regional, state-wide, or federal systems designed to exchange patient health information across providers and treatment episodes. HIEs have the potential to dramatically alter the nation’s public health landscape by giving providers unprecedented access to patient health histories while enabling innovative new applications for state and federal public health agencies. The legal landscape has matured considerably, and legal conditions at the federal level are quite favorable for the establishment of HIEs. Recent amendments to the Health Insurance Portability Accountability Act (HIPAA) have increased the viability of HIEs, and historic new patient protection measures should go a long way in allaying consumer concerns. However, state laws are an inconsistent “patchwork” in need of reform. Until the federal government drives states to adopt minimum technological and usage standards, HIEs will remain state-specific silos of invaluable patient health histories. To realize the true potential of HIEs, federal and state governments should choose opt-out consent models, educate patients about advances in legal privacy protections, and coordinate regulatory efforts to ensure that HIEs are interoperable and functional across states.

Introduction

Health Information Exchanges are a quickly emerging reality. In 2009,
Congress passed the $780 billion American Recovery and Reinvestment Act, which includes the Heath Information Technology for Economic and Clinical Health Act (HITECH). Congress allocated $20 billion in an effort to drive nationwide adoption of Health Information Technology (Health IT or HIT) and provided $2 billion to the Office of the National Coordinator for Health Information Technology (ONC) to support Health IT. As a result of these federal initiatives, states across the nation are in the midst of planning and initiating state-wide HIEs. This technology promises cost and quality of care advances that should prove attractive to both providers and patients. Providers that are able to access patient health histories will be empowered to make better clinical decisions. As a result, patients will avoid adverse drug interactions, experience fewer repeated tests and fewer hospital readmissions. These benefits could lead to enormous cost savings if HIE technology is adopted across the nation. The technology may provide one solution to dealing with America’s exploding cost of healthcare.

Despite promising substantial cost and quality improvements, HIE policies require further reform if the envisaged National Health Information Network is to be realized. This paper will first examine how potential HIEs may work. Next, public health benefits and potential applications will be examined. An analysis of consent models and their policy implications will follow. Then, legal impediments to viable HIEs will be discussed. Lastly, the focus will turn to recommendations to overcome the legal and implementation hurdles that will pave the way for an effective National Health Information Network.

What are Health Information Exchanges?

HIEs promise to revolutionize the healthcare industry by providing patient health histories and personal health information (PHI) in an electronic format. HIEs promise substantial benefits in terms of cost and quality. Through the digitization of patient records, providers will be able to avoid unwanted drug interactions and reduce repeated tests, among other quality of care improvements. HIEs will offer the opportunity for an authorized user, most often a health care provider, to electronically exchange information with other users. States will need to decide which entities will be given user privileges, but foreseeable users include medical providers and health plans. Some states might consider special access for “unauthorized” users during an emergency situation. More contentious user privileges include whether health plans, research organizations, or public health agencies should have access to the HIE. States may also decide to create patient portals wherein patients can
log in and see the instances where their information has been accessed.\textsuperscript{iv}

In application, providers will have access to patient histories of varying comprehensiveness depending on each state’s decision on which functions to include. Some states will elect to retroactively input previous patient histories, while others might choose to start collecting patient histories at the beginning of the statewide HIE. Once the system is in place, providers will have access to information such as which doctors have treated a particular condition and what drugs have been prescribed from the pharmacy for particular symptoms. Access to such information promises to improve medical outcomes and reduce medical errors. For example, HIEs could identify potential adverse drug interactions.\textsuperscript{v} The key innovation for Health Information Exchange is that it promises to reach all providers, rather than specific provider networks. This attribute ensures that a patient’s health history follows the patient, regardless of which provider he or she chooses. If HIE technologies are compatible across states, then patient histories will follow the patient across states as well. HIEs will then ensure that providers have access to a patient’s history anywhere in the country.

Benefits and Public Health Applications

HIEs offer several broad public health benefits. First and foremost, quality of care will improve. Access to PHI will enable providers to better serve the patient by enabling a more complete picture of patient health. The provider can ensure that treatments do not interact adversely. If a patient forgets which medications he or she is taking, HIEs will ensure that a provider has access to that information and can prescribe new drugs without adverse drug interactions.\textsuperscript{vi}

Quality and cost of care will be impacted by decreasing rates of duplication. For example, the patient’s history of test results will be available to a provider, thereby reducing the need for repeated x-rays and lab tests. This will reduce patient exposure to harmful tests while providing cost savings.\textsuperscript{vii} Additional benefits include access to information during emergencies, when a patient may not be able to explain certain health conditions. During such emergencies, providers will be able to quickly access information about the patient’s medications, treatments, health issues, and tests, which will allow the provider to make better decisions.\textsuperscript{viii} Furthermore, in the case of a natural disaster paper records might be destroyed, whereas HIE information will remain protected. Paper records are also more vulnerable to physical theft, wherein HIE data
may allow for increased protections, including the ability for a patient to view incidences of access to his PHI via web portal.

**Specific Public Health Use: Public Health Registries**

Public Health departments around the country already collect population-wide data, most frequently in the form of public health registries. These registries track public health threats, such as flu, bio-terrorism related diseases, or diabetes. Divisions of Public Health have often created relationships with hospitals across their respective states and come to an agreement to track specific diseases. For example, North Carolina’s Division of Public Health and the North Carolina Hospital Association agreed to create NC Detect to identify bio-terrorism threats, but have since expanded to track a number of issues, including hospital infections. With the onset of HIEs, the scope of data tracking could be expanded immensely.

Another potential public health application of HIEs will be to mandate reporting of laboratory and physician-based diagnoses. Public Health Agencies already collect data-sets from state laboratories and HIEs will broaden the source and substance of the information collected. Electronic laboratory results are already directly transmitted to state public health divisions, and this reporting allows for vital public health functions such as tracking communicable disease outbreaks in a state. However, in states where there have not been strong investments in lab reporting, difficulties in mapping of disparate systems and codes can occur due to varying technology vocabularies. HIEs would prove beneficial by standardized mapping for clinical exchanges and state reporting purposes; these standardizations would increase the efficiency and quality of public health surveillance by providing accurate, population-wide data.

For example, in many states physicians are required by law to report some diseases to local health departments, specifically communicable diseases such as HIV. However, physician compliance with these requirements is tenuous. Again, if all providers tap in to a state-wide HIE system, the issue of inconsistencies in reporting will be largely eradicated. State and federal public health agencies will also gain vast new population-wide data, which will increase the scope for tracking many more diseases. Physicians will no longer be tasked to report; rather the HIE technology can automatically take care of this burden, leading to increased accuracy and efficiency. Diseases and pathogens that are currently not under bio-surveillance will provide new options for treatment and research. The potential for public health tracking is truly unprecedented.
and so are the quality, research and treatment implications. Never before have public health agencies had potential access to real, population-wide data sets.

**Other Uses: Syndromic Surveillance and Population-level Quality Monitoring**

Another specific and high potential public health benefit is syndromic surveillance, which uses population health indicators to monitor the health status of a community. Antibiotic resistant organism surveillance is an example of a potential syndromic surveillance capability, which can aid public health agencies in their fight against these deadly organisms. In this application, microbiology culture resistance patterns could potentially be sent through the HIE system directly to the health department. This information could then be used to construct community-wide antibiograms that could help focus antibiotic selection in target areas based on local resistance patterns. Additionally, HIE technology could notify clinicians when a patient with a previously diagnosed antibiotic resistant organism becomes present. This would potentially decrease the spread of antibiotic resistant organisms by localizing infected patients and alerting attending providers. An average hospital-acquired antibiotic-resistant infection can cost up to $30,000 per incidence, and this application demonstrates the potential benefits of investing in real-time syndromic surveillance technologies. This concept could be extended to flu, bioterrorism related incidences, and other emerging communicable diseases, providing state epidemiologists with unprecedented access to population-wide data.

Population-level quality monitoring will enable state and federal public health agencies to target conditions such as diabetes, obesity, and heart disease that have taken on epidemic-level proportions. National campaigns have been started that are aimed at prevention. Community-wide monitoring could arm state and national agencies with population and community-wide data to improve disease prevention initiatives. The information could also be used to target specific communities with higher incidences of testing to better control costs and ensure that quality of care is not affected by over-testing. State and national leaders can maximize the impact of prevention efforts by using these population-wide data sets to customize and target specific communities.

**Models of Consent**

States must choose to adopt either an “opt-in,” “opt-out,” or “no consent”
model for HIEs. “Opt-in” is the preferred choice for states with strong consumer protection concerns because it grants the greatest level of patient privacy.\textsuperscript{xvii} In this model, no patient’s health information is included in the HIE until the patient proactively gives consent. Upon consenting, the patient’s complete health data is included.\textsuperscript{xviii} In an “opt-in with restrictions” model, patients must give consent and can select which sub-sets of data are included.\textsuperscript{xix} However, the health provider community largely prefers the “opt-out” model. “Opt-out,” models include all patient health information automatically, but the patient can then choose to opt out of the system completely.\textsuperscript{xx} Finally, “no consent” models automatically include all health information, and patients are not given the choice to opt out.\textsuperscript{xxi}

In choosing a consent model, states must carefully consider the implications of each approach. Choosing a model with the option to restrict sub-sets of data can be clinically deceptive. For example, if a state decides that the patient can choose to withhold STD information, all such information must be purged from the record, including drugs that are specifically targeted at treating STDs. Yet providers across the country want access to the most complete possible patient history. Withholding certain subsets of information might actually confuse the provider into thinking that the patient is not affected by those conditions. For example, if a patient withholds a subset of mental health information the provider may mistakenly assume that the patient has no mental health history. The treatment could, therefore, be less effective or have adverse implications.

**Legal Challenges to Implementation**

There are a number of laws that complicate the successful implementation of HIEs, some at the federal level and many at the state level. A patchwork of state laws that protect privacy and sensitive health information creates a challenging and complex legal landscape. In many circumstances, there may be a need to change the legal landscape through legislative methods. Adapting state and federal law will ensure that HIEs protect patients’ privacy, while federal interoperability standards will ensure that the technology is useful on a nationwide scale.

**Patient Privacy Concerns: HITECH’s Expanded Civil Penalties and Enforcement**

Effective deterrents to fraud and abuse are essential for HIE’s to gain the public’s support. If patients do not trust that the technology will secure
their personal health information, they will choose not to participate and the benefits of HIEs will be compromised. Previously, HIPAA, the federal law designed to protect patients’ privacy during the transfer of personal health information, was criticized for civil penalties that were too low to be a truly effective deterrent. HIPAA civil monetary penalties, ranging from $100 to $25,000, will be amended under the HITECH Act. A tiered penalty structure based on the nature of the HIPAA violations will be instituted.\textsuperscript{xi} HITECH will also allow DHHS to consider new evidence regarding the nature and extent of harm resulting from a violation in DHHS’ penalty determination\textsuperscript{xiii}. Whereas previous penalties were based solely on the existence of a violation, the new rules create a tiered penalty structure ranging from $100 to $1,500,000 for violations.\textsuperscript{xiv} Moreover, HIPAA covered entities (including providers, health plans, and healthcare clearing houses) can no longer plead two affirmative defenses (a tactic to mitigate damages) that were previously available pre-HITECH.\textsuperscript{xv} A covered entity can no longer claim that it did not have knowledge of a HIPAA violation as a strategy to minimize culpability. Additionally, a covered entity cannot claim that its violation was due to reasonable cause, not willful neglect.\textsuperscript{xvi}

HITECH also expands enforcement incentives to the DHHS’ Office of Civil Rights (OCR). Most of the civil penalties collected under HIPAA privacy or security violations must now be turned over to OCR to expand enforcement efforts.\textsuperscript{xvii} Furthermore, HITECH grants explicit authority to state attorneys general to enforce HIPAA privacy and security rules, which adds another layer of enforcement.\textsuperscript{xviii} They may bring actions to enjoin violations and obtain statutory damages, although there is a $25,000 yearly damages cap.\textsuperscript{xix} While the ability for attorneys general to enforce HIPAA was arguable implicit in that law, HITECH gives explicit authority for this added layer of enforcement.

Increased enforcement is a welcome addition to HIPAA, since lax enforcement of HIPAA might undermine the security of HIEs. The threat of substantial penalties, especially for repeat offenders, and the prospect of enforcement by state attorneys general will ensure that HIE operators will protect patient privacy. Hefty civil penalties will force providers and health plans to be careful with PHI and ensure that breaches are minimized. These added penalties should also allay patient concerns, especially concerning accountability.
Interoperability: HIPAA and State Laws

A patchwork of state laws will make compliance quite difficult for potential HIEs and RHIOs. In particular, laws that protect sensitive health information, such as those regarding STDs, HIV/AIDS, mental health, and substance abuse are often preempted by state laws that are more stringent than HIPAA regulations. Each state will need to carefully weigh policy considerations while determining which types of information to include in an HIE. Providers usually favor a robust exchange with the most complete patient medical histories. Sequestering specific information may result in an incomplete record. If patients are given the choice to exclude sensitive health information there can be important implications for treatment. For example, without knowing a patient’s mental health history, a provider might prescribe a drug that could negatively affect the patient’s mental health.

Policy considerations must be made in light of existing state laws. There may be a need to reform those laws to achieve the goals of a state’s HIE, especially for states that pursue opt-out consent models. An example of the interplay between state objectives and existing laws can be found in North Carolina. In this state, some laws were more stringent than HIPAA and proved to be challenging to the state’s HIE policy. Specifically, NC GS 130A-143 posed a major challenge to the implementation of policy goals. The statute states that all information and records “whether publicly or privately maintained, that identify a person who has AIDS virus infection” will be kept strictly confidential, although an exception exists when the patient is receiving medical treatment.

In effect, the statute implies that communicable disease information in North Carolina should be kept confidential unless it meets the criteria for certain exceptions. HIEs would provide health information upon receiving written consent from the person or persons identified. From the standpoint of many providers, “opt-out” consent features are most desirable because they ensure that a maximum number of people are enrolled in an HIE. Due to these policy concerns, North Carolina decided to pursue legislative changes that would bring G.S. 130A-143 more in line with federal HIPAA regulations. Thereby, the optimum policy goal of “opt-out” consent could be achieved while also keeping patient histories as complete as possible.

The example of North Carolina demonstrates the patchwork of laws that permeate various states. Depending on the policy objectives of each state, obstructive laws could require legislative changes to ensure that HIEs operate
effectively. Those state laws that are more stringent than HIPAA are not preempted by the federal regulation. The DHHS Secretary has determined that state laws related to the privacy of individually identifiable health information would escape preemption. This implies that states will have to solve the legal patchwork problem themselves. This might pose problems for interoperability of HIEs, leading to incompatible standards and hindering a Nationwide Health Information Network (NHIN).

Perhaps the most challenging legal aspect of HIEs will be coordinating with other states and their laws. Mental health and substance abuse disclosure laws, for instance, vary from state to state, creating legal hurdles for the exchange of PHI across states and the establishment of a NHIN. Records must be interoperable in content, technology and legal compliance. Uniform laws will ensure that patient histories are exchanged across states without requiring adjustment to specific state laws. However, reconciling PHI across state boundaries will present huge challenges. Consequently, there must be national leadership on this crucial issue. True interoperability will expand the scope of HIEs and achieve the vision of a nationwide NHIN.

Recommendations

The issue of interoperability between records is becoming the defining challenge in creating a nationwide health information network due to the wide variety of policy choices being made by states. Each state is devising unique exchanges. States must first make the choice of adopting opt-in, opt-out, or mixed consent models. They then must decide on a timeline for setting up the exchange and decide on what types of information to include. They must decide which entities should have access to the information, whether public health officials or health plans. They must decide on a technology vendor and what if any special technology solutions should be provided to consumers, such as patient portals. The huge amount of discretion that states exercise threatens to derail the vision of a uniform, nationwide interoperable standard.

Consent Recommendations

In terms of an “opt-in” consent model, while such a model affords a great deal of patient control it also diminishes the potential benefits of a state-wide HIE, simply because the success of getting population-wide data depends on the HIE’s ability to convince patients to give consent. If the HIE is unsuccessful in convincing patients it will not achieve its true cost and quality potential. “No
“consent” is most favorable in achieving HIE’s potential, yet this model can seem draconian and create public and political outcry. Ultimately, HIEs will be subject to the political process and must be practical enough to survive public scrutiny. These considerations point to the “opt-out” model as the most favorable. With opt-out, consumers who have deep privacy concerns are given the opportunity to forgo the benefits of the system. Providers gain access to complete patient histories. State and federal agencies can access population-wide data since the whole state population will be in the system, and it may be unlikely that many patients will proactively opt out.

Privacy Recommendations

Patients may have innate fears that their sensitive conditions will become public. To allay these and general privacy concerns, patients must be educated about the protections provided by HIPAA. In particular, they should receive instruction on HIPAA’s new, stricter enforcement capabilities and its enhanced penalty system. They should also learn about changes to the HIPAA Security Rule, which will ensure that minimum technological safeguards are in place. Most importantly, they need to understand how HIEs will affect their lives by reducing over-treatment and adverse drug interactions. When a patient understands that he or she will be able to avoid duplicate tests, he or she will understand the argument that HIEs will cut costs in the healthcare system. He or she will understand that he or she will personally benefit from the technology. Most patients will likely “buy in” to the innovative new applications of HIE information. A strong education and marketing campaign will be a requisite part of any HIE effort because the system will fail without patient “buy in.”

Interoperability Recommendations

Apart from consumer outreach and education, the national government has important work to do to achieve its envisioned nationwide NHIN. The federal government needs to push states to adopt standard technologies so that records can be made compatible across states. HIE policies are being planned. Many HIEs are moving into the implementation stages and next, states will award huge contracts to technology vendors. The national government has paid for policy creation thus far and may aid in funding the creation of this technology in the future. It is currently the chief source of funding for this endeavor and has the power of the purse. It needs to fervently push the adoption of standards that will result in interoperability. The national
government should also push states to reform laws that will lead to uniform legal compliance across the country, ensuring that a provider can access a patient’s history anywhere in the country. In order to ensure compliance by states, the federal government should consider minimum guidelines attached to future federal healthcare grants. In the current economic context, states will likely continue to depend on federal funds to invest in HIE technologies. Stringent minimum guidelines regarding legal reforms and technology compliance will ensure that state efforts are not fragmented and that records move towards interoperability. Lastly, the federal government should push all states to grant local, state and federal public health agencies access to HIE information. The resulting applications will revolutionize public health and create tremendous improvements in cost and quality. State policies are currently being created. The federal government needs to take the lead and act urgently and ensure that its vision of this technology is fully realized.

Conclusions

Ultimately, the current federal legal landscape greatly favors the creation and adoption of HIEs. HIPAA and recent changes enacted in the HITECH act allow, even encourage, the freer flow of health information. The federal government has committed unprecedented funds to initiate this process. However, at the state level, the situation can be described as chaotic at best. There remains a patchwork of state laws that threaten to impede the creation of interoperable health records - records that could potentially pave the way for a Nationwide Health Information Network (NHIN). State laws concerning communicable diseases, mental health, and substance abuse histories are particularly fragmented and in need of state-level reform. NHIN envisions the ability to access records anywhere in the country and also to give federal public health agencies access to nationwide health data. For this to happen, the federal government should make a stronger push for ONC to set interoperable standards and also to clarify minimum requirements for state HIEs. Moreover, the ongoing policy debate concerning individual privacy concerns must be resolved. To truly harness the potential of HIEs, patient privacy concerns should not keep HIEs from adopting opt-out models - models that would provide public health agencies with unprecedented volumes of PHI. With a concerted education campaign, which would explain HIPAA protections and the benefits of HIE, patient concerns can be allayed and the true potential of HIE realized.
Endnotes


ii. Ibid.


v. Ibid.


vii. Ibid.

viii. Ibid.


x. Centers for Disease Control and Prevention, “Nationally Notifiable Infectious Diseases” (June 2007).


xvi. Ibid.


xviii. Ibid.
xxvii. 45 C.F.R. § 164.302
xxviii. Ibid.
xxxii. Ibid.
xxxiii. Ibid.
xxxiv. NC G.S. 130A-143
xxxv. NC G.S. 130A-143
xxxvi. Ibid.
xxxviii. 45 C.F.R. §160.203