Public Written Comments

Submitted to PCAST

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SCIENTIFIC ECONOMY NORTH AMERICA [and FURTHER, INTERNATIONAL ?]

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SCIENTIFIC ECONOMY NORTH AMERICA [and FURTHER, INTERNATIONAL ?]

Ref. : 1) [redacted]
2) John Holdren's Report on GLOBAL WARMING;
3) Yesterday's IMF CHIEF's PRIZE TALK ON CURRENT RBI's GOVERNOR ON HIS UTTERANCES in '2008' year;
4) Mr. MODI'S [PRIME MINISTER of INDIA] UTTERANCES THAT SCIENCE is international whereas ECONOMY is a COUNTRY AFFAIR;
5)
6)
7)
. . .

It is MY yesterday's EARLY MORNING CONCEPT;

LET THE thoughts PREVAIL.

This is UNDER the *SPECIFIC* REVIEW and ATTENTION OF THE CHIEF EXECUTIVE HIMSELF for this AUGUST MATTER.

OUR ORGANIZATIONS ARE :::

1. **www.rambabu.741.com - - - FOR INTRODUCTION and FRONTAL PAGE DESCRIPTIONS;**
2. **http://drsridhrraocentrmgmt.bloombiz.com/**

(JWALA and Dr. Sridhar Rao Center for Management);

3. **http://www.Medi-e-HEALTHCARE.0catch.com/ [the electronic HEALTH ESTABLISHMENT OF**

(JWALA and Dr. Sridhar Rao Center for Management)

additional e - ADDRESS IN CASE : [redacted]

SCIENTIFIC ECONOMY NORTH AMERICA [and FURTHER, INTERNATIONAL ?]

From: "Devalraju Rambabu" [redacted]
Date: Thu, March 19, 2015 1:10 am
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SCIENTIFIC ECONOMY NORTH AMERICA [and FURTHER, INTERNATIONAL ?]
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Sponsored by: Committee for Economic Development Council on Competitiveness National Science Foundation Science Commons University of Michigan

Selected papers from the conference are available as a special issue of First Monday.The Internet grew rapidly as a general-purpose enabling infrastructure, upon which controls had to be superimposed in an ad hoc manner. Advanced knowledge infrastructure, by contrast, is human-centered and optimized for particular resources and communities. Cyberinfrastructure offers a vision of advanced knowledge infrastructure for research and education that integrates diverse resources across barriers of geography and time – and across the subtle and complex barriers of discipline, community, sector, and jurisdiction. Because it aspires to provide human-centered access to diversely controlled resources, cyberinfrastructure must be open and sensitive to institutional, legal, and cultural context, especially mechanisms and procedures for collaborative research and innovation. This is critical not only for optimizing the productivity of particular research communities and initiatives but in developing public policy for advancing knowledge and innovation in an IT-enabled world.

Thanks to digitization, enabling technology, globalization, and the rise of collaborative research and innovation, knowledge is generated, organized, and used in a multitude of new ways. Todaycyberinfrastructure provides a driving vision for advanced knowledge infrastructure in a complex, vastly expanded, and nearly borderless economy – a customizable, human-centered environment that can be tailored to any task, enterprise, or field of study.

The Internet is the paradigmatic example of enabling infrastructure, founded on nonproprietary technology and minimally regulated. Virtually free of controls, private or public, the Internet spread quickly as a generic technology platform that anyone was free to use and build on. Universal global accessibility has been the default; limits and boundaries had to be engineered in. Controls for service priority, privacy, copyright, and security have been slow to develop, not only they are unsupported in the underlying infrastructure but because they are perceived as departures from the open architecture of the Internet. At the same time, legal regimes for controlling data, information, and knowledge have been enhanced and expanded in response to assertions that stronger protections are needed to encourage greater use and spur investment.

Although enabling technologies and legally based controls often appear to work at cross-purposes, in practice voluntary means have emerged to mediate between the two. These include a variety of mechanisms, practices, and institutions that bridge enabling technology and controls prescribed by law, market conditions, community practice, and culture. Some are driven by technical or user communities; others are business or legal responses to perceived problems in innovation and commercialization. (See sidebar.)

These mediating mechanisms have evolved in ways that are unique to information management, software, and information technology. At the same time, they appear to be especially important in advancing these fields. For example, the development of standards is an essential ongoing process in support of emerging markets. Open source software development and distribution is practical because it is Internet-enabled. Open access publication depends on the commodity infrastructure of the World Wide Web. University-based technology transfer has worked very differently for software than for biotechnology because much software is non-resource-intensive, targeted to academic use, or supported by users.

Information technology and infrastructure have a powerful two-way enabling relationship with collaborative innovation, especially for fields in data-intensive science and technology. Each expands the value and potential of the other. Cyberinfrastructure offers a rich, multidimensional infrastructure extending up the stack and across all fields of science and technology – accompanied by an expanding repertoire of practices and strategies for overcoming the barriers to collaboration between individual researchers, research teams, disciplines, institutions, firms, and sectors.

Building on the Internet

Both the NSFNET of the 1980s and today's vision of cyberinfrastructure were motivated by the need to share costly high-end computing resources efficiently. In the case of the NSFNET, the need for low-end sharing and communications among a growing universe of users became the driving force behind privatization and commercialization. Although high-end needs still drive advanced connectivity and collaboration technology, cyberinfrastructure trades the "high performance computing and communications" vision of the NSFNET for a vision of human-centered, software-integrated knowledge infrastructure.

As information infrastructure has evolved from standalone databases to email to the multifunctional Internet to a content-linked, transaction-based World Wide Web, expanding capabilities have elicited fresh concerns and sometimes new controls. In the late 1970s there was an outcry over databases containing private and sensitive information, all of which might easily escape the location and jurisdiction where it was collected. This led to the OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data (1980), yet similar concerns arose in the context of distributed electronic commerce 20 years later. The functionally sophisticated and ubiquitous Internet also presented challenges for copyright, so new controls were added in the Digital Millennium Copyright Act.

Cyberinfrastructure inherits all of the legal and policy challenges of the Internet and the Web – and adds to them. The challenges initially appear more manageable because of the relatively cloistered, noncommercial nature of scientific research. However, the cyberinfrastructure vision extends explicitly to education and underrepresented groups, and to practical implementation of collaboratories, virtual organizations, and human-centered infrastructure. What was styled in early 1990s as the National Research and Education Network emerged as open and ubiquitous – by no means limited to research and education. As long as cyberinfrastructure, too, remains open to the world, it confronts fundamental issues of access, ownership, control, and consent.

The ultimate success of the Internet and browser technology, both of which were supported by NSF, lay in their widespread commercialization, including the immense variety of proprietary applications and services they spawned. It is increasingly expected that the results of publicly funded research should lead to further development, application, and commercialization. Today, these economic payoffs provide a strong argument for increased public investment in information technology and infrastructure.

The Internet spawned the development of a vast array of proprietary products and services, in part because the basic technology was fully nonproprietary, and anyone could build on it without seeking permission. However, the proliferation of software patents and broad "business method" patents (including patents on tools and infrastructure for education and research) has led to a mixed environment, in which it may be difficult to determine what permission is needed and from whom. At the same time, mechanisms to preserve and pool knowledge as a common resource have emerged, sometimes in reaction to perceived problems of overpropertization and proprietary control.

The report of the National Innovation Initiative frames the problem and the opportunity for accommodation:

[O]pen and proprietary IP models should not be seen as mutually exclusive; rather, the IP framework must enable both approaches. Because collaborative innovation is relatively new, however, the structure and processes to accommodate ownership, openness and access are evolving. New creative models are emerging across sectors. (Innovate America, Council on Competitiveness, December 2004, p. 44)

In collaborative environments with few participants, there may be little need for controls, let alone mediating mechanisms. Shared norms and a few readily understood rules may do the job. However, as environments grow in scale, scope, and significance, they naturally become more heterogeneous, less governable, and less secure. More capabilities are demanded, but common understandings become harder to express and enforce as barriers to the outside fall, and the rules of the market and public law take precedence.

Cyberinfrastructure must grow and mature at a level and time when controls are stronger and more pervasive, more divisive, and more controversial. Deep industry differences have stalled patent reform legislation in the U.S. The U.S. and Europe have taken conspicuously different approaches to control of personal data, ownership of databases, the scope of patentable subject matter, and the research exemption to patent infringement. These differences persist despite common enabling infrastructure, common concern for promoting innovation, and a shared commitment to international harmonization.

Yet as cyberinfrastructure expands, it can draw on a growing menu of mechanisms, institutions, and strategies for reconciling enabling infrastructure and rights-based controls. Optimizing these tools to support research and innovation requires better understanding the social and economic forces surrounding the processes of science and technology. It requires a disinterested, empirically grounded perspective on how tensions between enablement and control are addressed and mitigated in practice. Experience with expanded infrastructure should tell us much about the ecology of knowledge and innovation in a world of porous boundaries and immensely powerful tools. This, in turn, may help us rethink and redefine laws and policies inherited from simpler times and circumstances. For further information contact Brian Kahin, kahin@umich.edu.

Mediating Practices / Mechanisms / Institutions

Open standards are critical to the development of infrastructure at all levels and to the development of complementary products and services, proprietary and nonproprietary.

Proprietary platforms often encourage interconnection by producers of complementary products and services by publishing specifications and not requiring royalties

Open source software spans a number of different approaches to collective enterprise, including use of copyright and licensing to define and enforce a commons (copyleft). Open source software can also be viewed as a complex, highly defined standard that enables the development of complementary products and sources

Patent pools have emerged in a new semi-open form for aggregating rights needed to implement complex IT standards such JPEG, MPEG, DVD players, and GSM

Information and knowledge commons aggregate voluntary contributions. While Wikipedia is the best-known example, such commons are also used to avoid proprietary bottlenecks in research (e.g., the SNP Consortium and HapMap project).

Reciprocal licenses and non-assertion covenants are used to create assurance that firms will not assert rights against users of standards except against those who assert intellectual property rights in the standard.

Collaborative research projects often involve pooled access to "background" rights that may be needed to conduct research, along with allocation of access ownership interests in any outcomes of the research.

Open access publishing may offer free availability after a limited period of exclusivity.

Cross-licensing is common among IT firms as a means of maximizing freedom of action and simplifying accounting for patents.

Cross-sector technology transfer: Bayh-Dole is the dominant paradigm for public funding of university research and subsequent patenting and licensing to industry, but it may be more appropriate for biotechnology than for software.

Simplified enabling licenses such as the Creative Commons that encourage reuse under a limited variety of simple, easily understood terms.

Access management systems: Technology-based systems that limit access to qualified and authenticated members of a project or community

Important New Technology for our Country

From: "Mark Rosen" [redacted]
Date: Thu, March 19, 2015 9:54 am
To: "PCAST" <pcast@ostp.gov>
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PCAST,

I have attached what may be a critically important paper outlining a potential new property of the electron. I deliberately kept this paper simple and very short – in the spirit of many papers in the history of physics. This is a legitimate (and logical) re-interpretation of the discovery of the positive electron in 1932. If correct, it would have profound implications for physics as well as many critical real world problems (energy, nuclear proliferation [eliminates need for reactors], electrical grid [not needed], water [desalination], a possible battery replacement, etc.). It would be new physics – a "**game changer**".

Mark David A. Rosen

[redacted]

www.GAP-s.net

A Little about Me:

I spent 11 years at Harvard. I left academic life because I felt basic physics research would not have any impact on near term solutions to real world problems (like the energy shortage at the time). I went on to solve some of the toughest real world problems (in highly classified and proprietary R&D).

Transforming an Electron into a Positron: A New Paradigm for Physics

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Since the discovery of the positive electron (positron) in 1932, physics has ignored the more plausible possibility that charge is not a fixed property of subatomic particles. Instead of looking for the conditions under which this property might be altered, it has become dogma that the same particle with different charge states are distinct entities solely based on the negative energy solutions of the Dirac equation (formulated in 1928)[1] with its strange negative energy sea of electrons construct (with "holes") in 1930) [2]. It is about time to consider the alternate more logical interpretation – that under certain conditions, an electron can be transformed into a positron. Recent experimental evidence of heat transport along a quantum Hall edge seems to support the formation of a positively charged entity (positron) that can conduct heat in the opposite direction to negative electron flow.[3] A relatively simple experimental test for verifying this new electron behavior is presented in the hope of advancing this line of research.

INTRODUCTION

Lee Smolin in his book "The Trouble with Physics" points out the quandary in which physics finds itself:

"The story I will tell could be read by some as a tragedy. To put it bluntly—and to give away the punch line—we have failed. We inherited a science, physics, that had been progressing so fast for so long that it was often taken as the model for how other kinds of science should be done. For more than two centuries, until the present period, our understanding of the laws of nature expanded rapidly. But today, despite our best efforts, what we know for certain about these laws is no more than what we knew back in the 1970s. How unusual is it for three decades to pass without major progress in fundamental physics? Even if we look back more than two hundred years, to a time when science was the concern mostly of wealthy amateurs, it is unprecedented. Since at least the late eighteenth century, significant progress has been made on crucial questions every quarter century."[4]

Usually a situation like this indicates a mistake may have been made in the past – **that some basic physical assumption may be wrong**.

One possibility may be the idea that the sign of electric charge ("-") is a fixed property of the electron (and other sub-atomic particles). We have been extremely successful at using and manipulating the electron – it is the technological foundation of our civilization.[5][6][7][8][9] The electron may have one more property for us to exploit. A re-interpretation of the discovery of the positive electron ("positron") could indicate that the charge state of the electron can be manipulated as well (i.e., transforming an electron into a positron) – something that could have an extraordinary impact on physics and profound implications for present day problems.[10] [11]

HISTORY OF THE NEGATIVELY AND POSITIVELY CHARGED ELECTRON

The electron was discovered in 1897 by J. J. Thompson.[12][13] He determined that it was a negatively charged particle and calculated its mass to charge ratio. The charge was measured by R. A. Millikan in 1909 using oil drops in the electric field between two parallel plates.[14] In 1932, a positively charged electron (positron) was discovered by C. Anderson in the high energy collisions of cosmic rays recorded in cloud chamber photographs.[15] There are two possible ways of interpreting this positive electron. Either it is a separate distinct entity or it is an alternate charge state of the electron implying that the charge (sign) of the electron can be changed. It seems the latter was never really considered because of the previous theoretical work of P.A.M. Dirac (1928) [1]. He developed an equation describing the electron's behavior incorporating relativistic effects. Instead of discounting the negative energy solutions for this equation, an interpretation that eventually morphed into a positive electron was proposed. The subsequent discovery of the positive electron supposedly corroborated the theory and the interpretation was set – the positive electron has been a distinct, separate entity ever since (the birth of the "antiparticle"). Interestingly, Dirac wrote in his 1928 paper [1][p. 612]:

"One cannot do this on the quantum theory, since in general a perturbation will cause transitions from states with W positive to states with W negative. Such a transition would appear experimentally as the electron suddenly changing its charge from –e to e, a phenomenon which has not been observed." [W = energy][1]

Halpern and Thirring in their quantum mechanics book

[1] Just because it had "not been observed" does not mean it could not happen under certain circumstances. The discovery of the positive electron in 1932 was not initially universally accepted.[16]

(1931) also noted:

"Dirac's system of equations refers to particles of charge +e as well as to those of charge –e; … this signifies that according to Dirac's theory the electrons can change their sign. …" (they felt the negative solutions should be ignored until the problems with them can be resolved) [16][p. 150]-- the only statement found that is close to what is claimed in this paper.[2]

It seems more logical to treat the discovery of a positive electron as indicating that the sign of electric charge is not a fixed property. It was unfortunate that this discovery appeared to justify the Dirac equation's negative energy solutions with their strange interpretation (infinite negative energy sea of electrons) – this has misled physics ever since.

EVIDENCE FOR TRANSFORMING AN ELECTRON INTO A POSITRON ($e^- + \text{strong B (or E)} \rightarrow e^+$)

Since its discovery in 1982, the Fractional Quantum Hall Effect (FQHE) has given birth to the concept of "fractionally" charged "quasiparticles" or "composite fermions". [17][18][19] This phenomenon involving a two dimensional electron system (2DES) occurs at extremely low temperatures in the presence of a strong perpendicular magnetic field. A simpler approach than fractionally charged quasiparticles (or composite fermions) might be to actually assume that the charge state of a fraction of the electrons present has actually been changed (i.e., the net negative charge has been reduced). This would be consistent with the experimental facts. Recent experimental work at Harvard measuring the heat flow under conditions necessary for the FQHE may be the first real evidence supporting the idea that positive electrons (positrons) are being formed.[3]

What was discovered at Harvard was that under conditions necessary for the FQHE, heat is not only transported downstream with the electron flow but upstream as well. Based on the fact that no charge is seen to be transported upstream, "Neutral Modes" have been invoked as a scheme to explain this unexpected heat transport upstream.[3][20][21][22] A much simpler and more logical explanation is that, under the given experimental conditions, electrons are being transformed into positrons. Just like electrons carry the downstream heat, positrons would carry it upstream. No charge transport would be measured upstream since a positron would annihilate with an electron before any detection were possible. This simple idea explains everything without resorting to complex theoretical constructs. An easy test to see if this is happening is to look for the gamma ray signature of electron-positron annihilation. The formation of positrons would also resolve the "unknown microscopic origin" of the FQHE.

If the charge state of the electron can be manipulated, then the next obvious question concerns determining the conditions under which it can be changed.

PROPOSED CONDITIONS FOR $e^- + \text{strong B (or E)} \rightarrow e^+$ TO TAKE PLACE

Based mainly on the heat transport work and the FQHE, the possible conditions needed to alter the charge state (sign) of a low (kinetic) energy electron can be stated as:

- **Have either a one or two dimensional electron system (1 or 2 DES)**. Although the FQHE is at extremely low temperatures, it is felt that this transformation can occur at room temperature or higher (refer to discussion below in Excess Heat Produced in Electrochemical Cells).-- (this would still be a situation of relatively low electron kinetic energy)

- **Apply a strong magnetic (or electric) field** (of sufficient strength to cause the charge state to change).
At the extremely low temperatures associated with the FQHE (low kinetic energies of the electron), strong external magnetic fields may be sufficient to cause the charge state of the electron to flip. It is felt that very strong electric fields are both easier to produce and effective in transforming an electron into a positron at much higher temperatures. This is based on the two phenomena discussed below.

OTHER POSSIBLE PHENOMENA RELATED TO $e^- + \text{strong E or B} \rightarrow e^+$

Over the last 30 years new phenomena have been observed that might be correlated with such an effect. Two possibilities are

1. **High Temperature (High T_c) Superconductivity** – High T_c materials have a layered planar structure. This implies a situation for a 2DES – a potential necessary condition for changing the charge state of the electron. The electric field strength in these layers would be high, but obviously not uniform. The electron could find itself "flipping" back and forth between negative and positive states as it moved within the layer. This might be a

[2] Conservation of Charge is a fundamental guiding principle in physics. Physicists have been looking at the theoretical consequences if it were not conserved as well as searching for charge violating decay schemes [28] [29] If the transformation of an electron into a positron requires an external applied electric or magnetic field, then the process does not violate this concept (refer to section on hypothesized conditions for changing the charge state).

sufficient condition by itself to allow lossless charge transport without needing pairing (or it could possibly be a mechanism for pairing, if needed, as in the BCS theory and current ideas about High T_c materials [23]). Pressure would obviously alter the electric field between the layers and give rise to changes in the critical temperature T_c. that have been observed.

There is no theory at present to explain High Tc Superconductivity.[24] If the charge state of the electron can be changed, this presents a new property of the electron that could help to understand the superconductivity in these materials.

2. **Excess Heat Produced in Electrochemical Cells –** The electrochemical production of excess energy has been firmly established by many groups active in this area**.**[25][26] The question is "what is the mechanism?" An important clue to this mystery comes from the fact that a prolonged incubation period (possibly 100's of hours) is seen before excess heat is produced. During this period, electrochemical deposition can alter the morphology of the electrode surface causing a 3-dimensional nano-texture, the perfect geometry for creating a 1 or 2 DES.[27] This is one of the two proposed requirements needed to flip the charge state of the electron. The other is a very strong magnetic or electric field. In this case, a very strong electric field would be produced between the cations in solution and the electrons in the anode (at least 10^9 N/C, based on the two charged species being separated by about 10 Å). If positrons are subsequently created, then the energy producing mechanism would be electron-positron annihilation.

   This is especially important. Transforming an electron into a positron at room temperature is critical to practical applications of this concept.

EXPERIMENTAL VERIFICATION

It is relatively easy to experimentally verify whether electrons are being transformed into positrons in any of the above physical processes. The annihilation reaction of the electron and positron creates a unique gamma-ray signature of either 2 photons around .511 MeV (180 degrees apart -- normally what would be expected) or 1 photon twice that in energy. Placing gamma ray detectors around the sample to detect this radiation signature would be needed (the intensity in most cases would be very low). Sufficient shielding to eliminate the background radiation is critical.

If the presence of positrons is confirmed, then experiments are needed to delineate the precise physical and external applied (electric) field conditions needed to cause this transformation.

CONCLUSION

While new physics phenomena continue to be discovered, our ability to explain them lags far behind. Usually the underlying reason for such a situation is that there may be something wrong with some past fundamental assumption(s). Mainstream physics seems to be "thriving" on complexity and extremely speculative ideas that are in stark contrast to the simplicity that has marked past progress and understanding. A simple experimental fact is that the electron exists in at least two charge states, negative and positive (there is a good chance that there is also a neutral electron – anyone thinking neutrino?[3]). But because of a mathematical equation with a really strange interpretation invented to explain its negative energy solutions, physics failed to consider whether the electron's charge state could be manipulated – a very simple plausible idea. To an experimentalist, math is just a tool like anything else in the lab to give understanding and insight into our physical world. The discovery of the positive electron was unfortunately a serendipitous and misleading "confirmation" of a theoretical assumption that does not make a lot of sense (Dirac's infinite negative energy sea of electrons construct).

If the electron can be transformed into a positron, the consequences are incredibly profound. For one, it simplifies particle physics. It would imply that the preferred state is normal matter, with antimatter (really antiparticles) being just another state of normal matter. The "mystery" of why we exist (i.e., the imbalance between matter and antimatter) is solved. Having another property of the electron to exploit also gives us an additional tool in which to possibly understand things like high temperature superconductivity – but this is just the beginning. Being able to easily and cheaply (hopefully) create positrons for annihilation is a potential solution to our critical energy needs as well as a boon to the economy. It also would be the solution to many other critical problems (would not need an electrical grid or nuclear power plants [stops nuclear proliferation]; replaces the battery; makes desalination feasible; changes foreign policy, etc.).[10]

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Initial Data is Out

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Date: Thu, March 19, 2015 9:51 pm
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Paper: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0120012

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Patrick F. Terry | [redacted]

From: Michael d'Amato [redacted]
Subject: Re: Confirmation Required: March 27, 2015 PCAST Meeting: Oral Public Comment Confirmation
Date: March 27, 2015 at 12:56:14 PM GMT+1
To: Laura Sosa [redacted]

Laura,

I am very sorry to say that Dean will not be able to attend this morning. He was representing me because I have had a newborn, and he now has become consumed in other life priorities. I'm sorry for the late notice, but I just learned of the change.

I have written a letter with my comment that hopefully can be shared with PCAST in my absence. I will be able to watch the Webcast, so I look forward to seeing the committee today.

With great respect and appreciation, I attach my comment to PCAST.

All the best,
Michael

March 27, 2015

Michael d'Amato, CEO
A&G Medical Solutions, Inc.
[redacted]

President's Council of Advisors on Science and Technology
National Academy of Sciences (NAS)
2101 Constitution Avenue, NW
Washington, DC
Lecture Room

PUBLIC COMMENT TO PCAST:
"Funding for small businesses to develop antibiotics that bacteria can't resist"

Dear PCAST:

I regret that I am not able to join you in person this morning. I have had a newborn baby and am not able to attend.

I am the CEO of A&G Medical Solutions, Inc. A&G is developing antibiotic products that bacteria cannot resist.

We are using non-thermal plasma to treat water, solutions, ointments, and hydrogels; creating products that achieve greater than 7 log reduction in planktonic and biofilm cultures, promote endothelial cell growth, and are stable for at least two years. Since the mechanism involves reactive oxygen and reactive nitrogen species (as our immune cells do naturally), it is unlikely that antibiotic resistance will develop.

A&G believes that developing a broad spectrum of antibiotic products utilizing our technology will contribute to combatting the problem of antibiotic resistant infections.

Our message to PCAST is, "Thank you!" We sincerely appreciate your efforts to bring attention and resources to this problem of antibiotic resistance, and we intend to leverage all that you put in place as we work together to solve the problem.

Sincerely,

Michael d'Amato
CEO
A&G Medical Solutions, Inc.

Important Comment on what is an outbreak
From: "Kevin Kavanagh" [redacted]
Date: Fri, March 27, 2015 10:34 am
To: [redacted]

Are you going to redefine the definition of an “outbreak” so it is actionable? Currently the definition is above a “baseline” which is not quantitative and has led to confusion and under reporting by facilities.

This has been a problem in Kentucky and one of the probable root causes of the not reporting of CRE. See enclosed news article and quote below. Larura Ungar is now a reporter with USA Today.

2014, Mar. 15. "Currently, neither Kentucky nor the federal government tracks individual cases. Hospitals must only report “outbreaks” of greater than- expected numbers of cases, leaving it to hospitals to interpret what that means."

2014, Feb. 3. "It’s difficult to compare the success of universal screening to other infection-control strategies, since most hospitals don’t release MRSA rates. The state only requires hospitals to report outbreaks and has no standard definition of what that means."

2013, Apr. 15. "Currently, they must only report “outbreaks” of greater-than-expected numbers of cases, leaving it to hospitals to interpret what that means. In an email to Kavanagh, a CDC official said her agency agrees with the need to define what constitutes an outbreak of CRE."

Enclosed is also an email from Dr. Denise Cardo from the CDC (director of the Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious) where she states:

"We appreciate and agree with your feedback regarding the need to define what constitutes an outbreak of CRE. "

Kevin T. Kavanagh, MD, MS
Health Watch USA
[redacted]

Kevin Kavanagh <kavanagh.ent@gmail.com>

CRE Covered Front Page Louisville Courier Journal - Health Dept Engagement Questioned

Cardo, Denise M. MD (CDC/OID/NCEZID) [redacted] Thu, Mar 28, 2013 at 6:46 PM
To: Kevin Kavanagh <[redacted]

Kevin,

Thank you for bringing this article to our attention.

We agree with your concern about the threat of CRE throughout healthcare facilities. We published the Vital Signs report as a call-to-action for healthcare administrators and providers to take immediate steps to ensure that CDC infection prevention measures are aggressively implemented in an effort to protect patients and stop the spread of these organisms.

We appreciate and agree with your feedback regarding the need to define what constitutes an outbreak of CRE. We are currently working with the Council of State and Territorial Epidemiologists to standardize approaches for tracking and reporting CRE. This will help to inform the work that all states are doing to monitor CRE infections. At this time, at least six states have moved forward with making CRE a reportable condition (CO, ND, OR, TN, WA, WI) and others are putting steps in place to make this possible. Additionally, we are working with the HAI coordinators in each state to better address HAI prevention efforts, including CRE prevention.

We appreciate your continued collaboration in HAI prevention, particularly your work to raise awareness about these issues.

Denise.

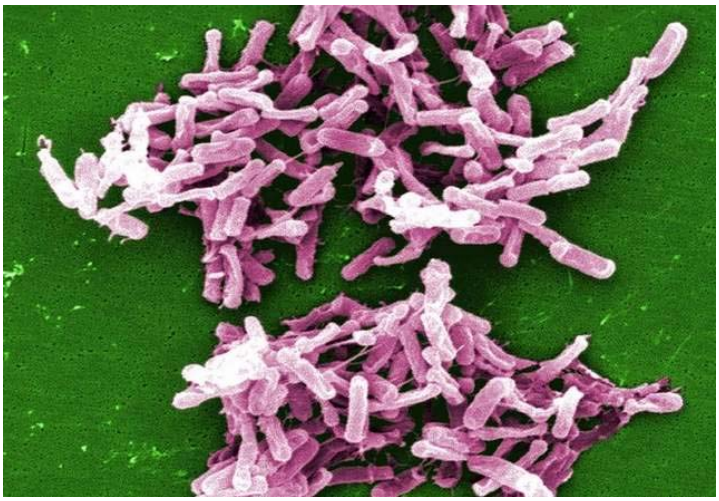
From: Kevin Kavanagh [mailto:[redacted]
Sent: Monday, March 25, 2013 10:47 AM
To: Cardo, Denise M. MD (CDC/OID/NCEZID)
Cc: Thomas R. Frieden (CDC)
Subject: CRE Covered Front Page Louisville Courier Journal - Health Dept Engagement Questioned

[Quoted text hidden]

CRE: Mandatory reporting of 'superbug' sought

Written by Laura Ungar The Courier-Journal
Apr. 15

courier-journal.com



C. difficile bacteria

Superbugs 101

A state legislator from Louisville and the leader of a national watchdog group are calling for a new rule that hospitals report all CRE “superbug” cases to the state — a measure they say would better control the potentially deadly bacteria.

After reading a story in The Courier-Journal last month about the rise in CRE locally, state Rep. Tom Burch, D-Louisville, sent a letter to Gov. Steve Beshear seeking support for mandatory reporting of CRE bacteria, and he plans to introduce a bill on the subject in next year’s General Assembly.

He’s working with Dr. Kevin Kavanagh of the Somerset, Ky.-based nonprofit Health Watch USA.

“This is a problem that if it gets out into the community, it can cause great harm,” Burch said Thursday.

CRE, short for carbapenem-resistant Enterobacteriaceae, strike hospitalized patients and kill as many as half who get bloodstream infections. Cases of infection from these superbugs must be reported in at least six states — Colorado, North Dakota, Oregon, Washington, Wisconsin and Tennessee, according to officials at the U.S. Centers for Disease Control and Prevention.

Burch’s letter asks that a state regulation be changed to add CRE infection or “colonization” of the body to the list of conditions requiring urgent notification of the state health department by hospitals and other health care facilities.

Under that proposed regulation change, the public wouldn’t get to see a breakdown of cases by facility — only a total statewide number.

But Burch said his bill would require public reporting by facilities.

Currently, they must only report “outbreaks” of greater-than-expected numbers of cases, leaving it to hospitals to interpret what that means. In an email to Kavanagh, a CDC official said her agency agrees with the need to define what constitutes an outbreak of CRE.

“We have better data on farm animals and how many farm animals we have in each county than we do on infections,” Kavanagh said. “It’s a sorry state of affairs.”

Beshear spokeswoman Kerri Richardson said her office could not immediately comment. The Kentucky Department for Public Health released a statement saying it is “actively looking at ways to enhance surveillance and infection control efforts in Kentucky health care facilities ... (and is) considering clarifications that could be made to the definition of an outbreak to emphasize reporting requirements related to CRE without requiring a regulatory change.”

Growing threat

Proponents of mandatory case reporting say it helps make health care facilities and professionals accountable for preventing and controlling health care-associated infections — which can be curbed through measures such as hand-washing, room cleaning and using antibiotics more wisely.

In March, the CDC issued a strong warning about CRE, saying “action is needed now to stop these deadly infections” that were treated in nearly 200 U.S. hospitals during the first half of 2012.

Officials at local hospitals told a Courier-Journal reporter last month that they have seen a growing number in recent years.

“As reported in the Courier-Journal article, approximately 20 cases have been treated in the Louisville hospitals over the past two years. However, the Kentucky Department (for Public) Health has received only one report of an outbreak,” Burch wrote in his letter to Beshear.

Doctors said it’s difficult to know where CRE infections originate, since virtually all occur in vulnerable, sick patients undergoing serious medical care.

Dr. Marion Kainer, an infectious diseases physician at the Tennessee Department of Health, said one CRE patient in that state visited nine health care institutions around the time the infection was reported — highlighting the need for all facilities to practice good infection control to prevent CRE from spreading throughout a region.

Burch emphasized this issue in his letter, writing: “Since patients are currently being transferred between institutions with CRE, health department engagement is required to fully investigate the source, prevent these potentially deadly bacteria from developing a foothold in Kentucky, placing our population at risk.”

Burch also enclosed an email to Kavanagh from Dr. Denise Cardo, acting director of the CDC’s office of science, epidemiology and laboratory services. Cardo wrote that she agrees with the concern about the threat of CRE in health care facilities, and said her agency is working with the Council of State and Territorial Epidemiologists to standardize the tracking and reporting of CRE.

Reporting controversial

But mandatory reporting remains controversial.

Officials of KentuckyOne Health, which includes Jewish Hospital & St. Mary’s HealthCare and Saint Joseph Health System, released a statement saying they already report every case of CRE, and “transparency is simply the right thing to do when it comes to matters of public health.”

Dr. Paul Schulz, Norton system epidemiologist, has said the idea of being watched may spur health care workers to be more vigilant about measures such as washing their hands.

But Ruth Carrico, an infection preventionist and associate professor at the University of Louisville, has said so much effort goes into reporting infections that it threatens to drain resources.

Mandatory reporting also requires significant time on the part of state health officials, and an investment in the public health infrastructure, Tennessee’s Kainer said.

Kainer said reporting must be coupled with measures such as room and equipment cleaning, hand-washing

and appropriate use of antibiotics, which prevents germs from becoming resistant and reduces the emergence of superbugs.

Reporting " is one of the tools in our toolbox," she said. "It's important to recognize you have a problem in order to deal with it."

Reporter Laura Ungar can be reached at [redacted]

VA Hospital finds ways to tame

MRSA

SUPER BUG

Advocates urge other facilities to follow example

By Laura Ungar

[redacted]

The Courier-Journal

Before 2007, the potentially deadly super bug MRSA stalked patients at the Louisville Veterans Affairs Medical Center — with infection rates 20 times higher than they are today.

That was before the VA began screening every patient admitted or moved from one unit to another, to see if they unknowingly carried the antibiotic-resistant and highly contagious bacteria, and then, if they found it, taking extra care to ensure it wouldn't spread.

The result? MRSA infections have fallen to 0.09 infections per 1,000 "bed days of care," or days patients stay in a bed, compared with 1.89 infections per 1,000 in 2008.

"We don't see many patients getting MRSA when they're in the hospital any

See MRSA, Page A7

THINKSTOCK

Article Continued Below

See MRSA on Page A007

MRSA: VA hospital finds way to tackle contagious super bug

Continued from Page A1

more," said Dr. Raul Nakamatsu, an infectious disease physician.

Some local and national infection- control advocates say more hospitals should follow the VA's lead.

Dr. Kevin Kavanagh, a Somerset physician who runs a watchdog group called Health Watch USA, recently told the Kentucky House Health and Welfare Committee that he'd like to see all Kentucky hospitals routinely screen like that for MRSA.

Lisa McGiffert, director of the Safe Patient Project at Consumers Union, a national consumer protection organization, pointed out that five other states require hospitals to conduct at least some MRSA screening.

"All hospitals should be doing this," she said. "It's a strategy that's proven to work."

Not everyone agrees. While some studies show screening helps reduce MRSA rates, other research indicates that hospitals do better with different strategies, such as "decolonization," or reducing MRSA with antibiotics and anti-infective cleansing cloths **.**

Officials at Louisville hospitals outside the VA said they don't screen every admitted patient — partly because of the cost, which is about $55 per screening, and partly because they consider other infectioncontrol methods at least as effective.

Norton Healthcare, for instance, stresses washing hands, isolating patients with MRSA, and wearing gowns and gloves while caring for them.

“In general, we have not done surveillance screening. It’s somewhat of a controversial topic,” said Dr. Paul Schulz, an infectious disease specialist with Norton. “We do all we can do that makes the most sense.”

It’s difficult to compare the success of universal screening to other infection-control strategies, since most hospitals don’t release MRSA rates. The state only requires hospitals to report outbreaks and has no standard definition of what that means.

Hospital officials said they do report what they believe are outbreaks — beyond the normal number of cases — and no MRSA outbreaks in hospitals were reported to the state last year.

Organizations such as the U.S. Centers for Disease Control and Prevention don’t require or recommend routine MRSA screening, although the CDC provides some guidance on such strategies as washing hands and educating doctors and nurses.

Attacking a killer

People can carry MRSA, or methicillin-resistant Staphylococcus aureus, without being infected, meaning it is on their skin or in their noses or intestinal tract. But the bacteria also can infect patients, causing serious skin, wound or blood infections, or pneumonia, which can be deadly.

Chronically ill people or those who have been in a hospital or nursing home are among the most likely to become infected. National studies have shown a recent decrease in invasive MRSA infections, but a November study in the journal JAMA Internal Medicine said there were still more than 80,000 infections in 2011.

Nakamatsu said MRSA first arose as a serious problem for VA hospitals about 2000. Veterans are generally older, and in many cases sicker than the general population, making them particularly vulnerable.

In 2007, the VA put in place a nationwide effort called the “MRSA bundle.” It included using a nasal swab to screen patients admitted or moved from one unit to another. Nakamatsu said patients can refuse the procedure, but most do not.

Marvin Meyerhoffer, a 76year-old Army veteran from eastern Louisville and longtime VA patient, said he hasn’t been admitted to the hospital in recent years but would be fine with getting screened.

“If they feel it’s best for the patients and consider it for their own good, I’m all behind it,” he said. “Other hospitals should follow their lead.”

The VA program also stresses washing hands, “contact precautions” such as gowns and gloves for those working with patients testing positive for MRSA, and emphasizing that infection control is everyone’s responsibility. Nurses and others are continually educated about the program and trained in screening techniques, and visitors are also told about the need to wash hands.

“It’s a continuous process,” Nakamatsu said. “I don’t think we can stop educating people on how to do these things.”

Nakamatsu said the transmission rate in his hospital has declined with the infection rate since the program began, dropping from 4.84 transmissions per 1,000 bed days of care in 2008 to 2.31 in 2013.

A 2011study in The New England Journal of Medicine, whose authors included Dr. Martin Evans at the Lexington VA Medical Center, examined the results of the program nationally. Researchers found that MRSA infections dropped from 1.64 per 1,000 patient days in October 2007 to 0.62 per 1,000 in June 2010 in intensive care units.

In non-ICU settings, infection rates dropped from 0.47 to 0.26. A study this month in the American Journal of

Infection Control found similar results in long-term-care facilities, which saw a 36 percent decrease in MRSA infections over 42 months.

“It seems to be having a good effect for us,” said Evans, who is in charge of a national MRSA program for the VA. “If a facility is having an issue with MRSA, then adopting the bundle we have may be very, very useful.”

McGiffert agreed, saying treatment for severe MRSA infections can be grueling for patients, with costs ranging from $20,000 into the millions.

“It’s a cost to the patients, as well as the system,” she said.

The Kentucky General Assembly considered but did not pass a bill in 2008 that would require routine screening as well as reporting of MRSA cases. According to McGiffert’s research, Pennsylvania, Illinois, New Jersey, California and Washington now require screening of targeted populations of high-risk patients.

Kavanagh said he would love to see such a law in Kentucky, but he believes its chances are slim — so he’d at least like to see hospitals voluntarily adopt the practice. “If you have one facility that’s not doing a good job at controlling these infections,” he said, “it can affect the whole community.”

A different tack

Officials at area hospitals outside the VA say they are controlling the super bug without screening all admitted patients. Although they wouldn’t provide MRSA rates, they said they are doing better than in years past.

Connie Barker, vice president of quality and clinical services for Baptist Health Louisville, said her hospital stresses hand-washing and gowns and gloves, along with private rooms for all patients, which slows the spread of the bacteria. With high-risk patients, they clean MRSA from the skin with an antiseptic normally used in preparation for surgery.

“We do not do universal screening. ... The challenge with that is it’s expensive,” not just because of the screening test but also because up to 8 percent of people are carriers, which would trigger additional precautions, she said.

“And,” she said, “it hasn’t been demonstrated that doing that works any better.”

Barker said she’s read the studies evaluating the VA program, and improvements in MRSA rates “could just be a heightened awareness (of MRSA) and changes in their overall practices.”

Officials at Jewish Hospital and Sts. Mary & Elizabeth Hospital say they also have many precautions in place to reduce MRSA. Jewish and Sts. Mary & Elizabeth, for instance, both identify appropriate pre-operative patients and treat them with antibiotics. And at Jewish, patients undergoing high-risk surgical procedures undergo MRSA screening.

Officials at University of Louisville and University of Kentucky hospitals said their infection-control programs also include MRSA screening, but only for patients admitted to the ICU.

“These are the sickest patients,” said Dr. Forest Arnold, hospital epidemiologist at U of L.

“We have thought about expanding (screening),” said Dr. Derek Forster, medical director for infection prevention and control for UK HealthCare. “We’ve reviewed clinical cultures from outside areas, and up to this point, we haven’t felt the need to expand it further.”

Doctors and officials pointed to academic articles supporting methods other than universal MRSA screening, such as a 2010 article in the International Journal of Infectious Diseases that said MRSA screening programs and others focusing on a single germ are not as effective at reducing antibiotic-resistant germs in general as

broad programs targeting all those germs.

Like officials at other hospitals, Forster said they keep up with the research and are willing to change their infectioncontrol strategies if they find good evidence that one works much better than another.

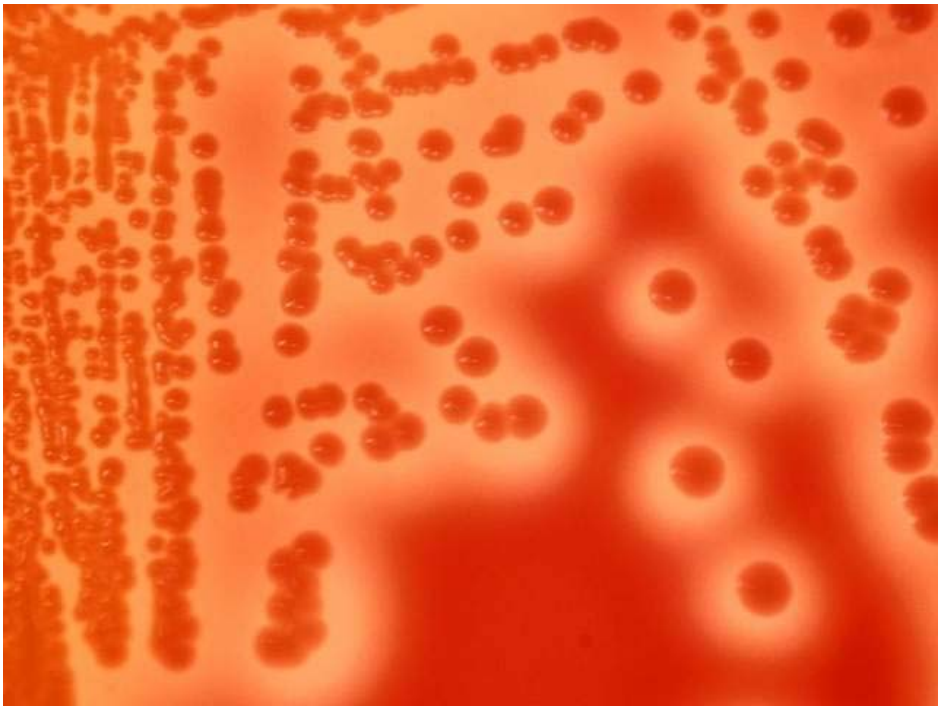
“We always keep an open mind,” he said.

Reporter Laura Ungar can be reached at (502)582-7190. Follow her on Twitter@lauraungarcj.

Janice Lattus, associate chief nurse at Louisville's Veterans Affairs Medical Center, shows registered nurses how to swab for MRSA on volunteer David Hickey, a fellow RN, during a recent training session. MRSA, or methicillin-resistant Staphylococcus aureus, can infect patients, causing serious skin, wound or blood infections, or pneumonia, which can be deadly. MATT STONE/THE COURIER-JOURNAL

Kentucky step closer to requiring hospitals to report superbugs

Mar. 15, 2014 | 1 Comment



Written by
Laura Ungar
The Courier-Journal

FILED UNDER

Business

A health watchdog group fighting to reduce superbug infections is in talks with Kentucky health officials, hoping to hammer out rules that would require hospitals and nursing homes to report cases of the dangerous bacteria CRE to the state.

“We would like to see this deadly and virtually untreatable bacteria to be publicly reported,” said Dr. Kevin Kavanagh, board chairman for Health Watch USA, a Somerset-based nonprofit. “We’re pursuing regulatory and statutory means of doing that.”

Kavanagh said discussions with representatives of the state Cabinet for Health and Family Services are preliminary, and no regulation has been finalized, although “we’ve been told nothing is off the table.”

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At the same time, the group continues to push for legislation in the General Assembly, sponsored by state Rep. Tom Burch, D-Louisville, that would require reporting of all cases and rates of various types of healthcare-associated infections. House Bill 460 is currently in the House Health and Welfare Committee, which Burch chairs.

But Burch said he won't push the bill forward if they manage to iron out a regulation.

"I would rather do it with a regulation," Burch said. "I want to make it as strong as possible."

CRE, short for carbapenem-resistant Enterobacteriaceae, is a family of more than 70 bacteria that are a normal part of people's digestive systems but can cause infections when they get into other areas of the body, such as the bloodstream or bladder. They often strike hospitalized patients and kill as many as half who get bloodstream infections.

Experts say the problem is fueled by the overuse of antibiotics and gaps in infection control in hospitals and long-term care facilities — the same problems that give rise to other superbugs such as MRSA and C. difficile.

The Courier-Journal first reported last March that CRE cases were on the rise locally, with about 15 cases in Louisville hospitals in the first part of 2013. Shortly after the story ran, Burch called for a new rule requiring all CRE cases to be reported to the state.

Currently, neither Kentucky nor the federal government tracks individual cases. Hospitals must only report "outbreaks" of greater-than-expected numbers of cases, leaving it to hospitals to interpret what that means.

But Elizabeth Cobb, vice president of health policy for the Kentucky Hospital Association, said hospitals are reporting CRE — even one case sometimes, especially if it's a hospital's first case — because it is "a new, emerging pathogen" that the KHA has been educating hospital officials about.

She said her organization is glad to work with the cabinet to improve regulations on healthcare-associated infections, but "we don't feel that it's necessary to lift individual diseases into mandatory reporting."

Cobb also said her organization opposes Burch's bill because it's unnecessary. She said hospitals are already reporting healthcare-associated infections through federal channels, and the data is available to the public on Hospital Compare website.

"We are concerned about CRE," Cobb said. "We are very much on alert."

Cabinet spokeswoman Jill Midkiff said officials are working with

Louisville's Montrezl Harrell responds to criticism of Russ Smith
Mar 08, 2014

PHOTO GALLERIES


Kentucky at Arkansas


New Louisville Men's Basketball Uniforms

Kavanagh and the Kentucky Hospital Association on a compromise to include in any proposed regulation, “if one is promulgated.”

Kavanagh, who has pushed failed bills on the topic in the past years, said he may finally get somewhere through the regulatory route.

“I’ve learned up in Frankfort not to be optimistic about much of anything,” Kavanagh said. “But I’m hopeful.”

Reporter Laura Ungar can be reached at (502)582-7190. Follow her on Twitter @lauraungarcj.

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OSTP, PCAST & Fwd: Nature's recent investigative article and NSF's excessive overhead payments

From: "Lloyd Etheredge" [redacted]
Date: Fri, March 27, 2015 6:03 pm
To: [redacted]
Cc: [redacted]

Dear Dr. Holdren:

I enclose, for your attention, a letter based on a investigative article in Nature, and a confirming discussion with Charlie Ziegler of the NSF professional staff, concerning the discovery of substantial waste and mismanagement in NSF payments for indirect costs to colleges and universities. My letter discusses several formal steps that I believe you and the Obama Administration should take in the light of these disclosures.

This is good and exciting news! Prompt action to solve this waste/overpayment and mismanagement problem can redirect substantial funds in the current NSF budget to pay for rapid learning systems for economics and other social sciences and to pay the direct costs (and legitimate indirect costs) of more, vitally important, scientific research across all fields.

Lloyd Etheredge

Dr. Lloyd S. Etheredge Project Director
Policy Sciences Center
[redacted]
URL: www.policyscience.net; [redacted]

Please reply to: [redacted]

[The Policy Sciences Center, Inc. is a public foundation that develops and integrates knowledge and practice to advance human dignity. It was founded by Harold Lasswell, Myres McDougal, and their associates in 1948 in New Haven, CT. Further information about the Policy Sciences Center and its projects, Society, and journal is available at www.policysciences.org.]

THE POLICY SCIENCES CENTER, INC.

Project Director: DR. LLOYD ETHEREDGE
[redacted]

March 27, 2015

Dr. John Holdren, Director – OSTP and Co-Chair, PCAST
Eisenhower Executive Office Building
[redacted]

Dear Dr. Holdren:

I write with good news concerning the discovery of substantial waste and mismanagement in NSF payments for indirect costs to colleges and universities. [The discoveries are documented in the enclosed article by Heidi Ledford, "Keeping the Lights On" that appeared in Nature, 20 November 2014 (vol. 515), pp. 326-329. I have confirmed my interpretation of the overpayment problem by a written inquiry to the NSF Office of Budget, Finance, and Award Management and a telephone discussion with Charlie Zeigler (703-292-4578) who supervises NSF payments in this area.] The good and exciting news is that, by prompt action to solve this waste/overpayment and mismanagement problem, substantial sums in the current NSF budget can be redirected to pay for rapid learning systems for economics and the other social sciences and to pay the direct costs (and legitimate indirect costs) of more, vitally important, scientific research across all fields.

The problem is straightforward. HHS negotiates, for each college and university, a maximum and provisional grant reimbursement rate for indirect costs. It is a number that is used in initial grant applications and – for example – the federal government's policy is not to reimburse for cost overruns above the HHS negotiated rate. However, at HHS, their actual payments are determined by a later audit of the indirect costs. The enclosed article in Nature (p. 329, column 1, second paragraph) reports that the average negotiated grant application/maximum rate is 53% v. HHS's average post-audit reimbursement rate of 34%.

At NSF, the policy is to use the higher HHS overhead rate for NSF grants to colleges and universities (*ibid.*, p. 329, column 3, paragraph 2). NSF, however, simply writes a check for the HHS maximum overhead without audits or the audited adjustments. We do not yet know the cost of NSF's overpayment resulting from a "Maximum reimbursement! No audit!" tradition. However the best available evidence from HHS (53% v. 34%) is that, with a $7.8 billion/year budget, and across many years, NSF's largesse probably adds up to a very large amount of waste and mismanagement of public funds. (You may find that NSF's overpayment is even larger than it seems from these numbers. NIH has a $30 billion/year budget: HHS is negotiating, and is later paying, its high overhead rates for biomedical research and at universities with medical schools.)

I believe that you should correct this problem. And also notify OMB for a review of these issues with NSF, HHS, and other scientific agencies. All colleges and universities use consultants to maxim

ize overhead. The extraordinary growth in NSF applications (expected to be 50,000+ next year) and staff workload suggest that there may be a growing institutional awareness of the profitability, to general university funds, from NSF grants. The loophole that is being exploited at NSF also may be used elsewhere.

- NSF policies and their oversight are the accountability of its Director and the National Science Board. There are grounds for legal, public integrity, and ethical alarm that you may wish to refer to the Department of Justice for professional evaluation. These positions of public trust are substantially populated by administrators and former administrators from research universities who, it now appears, are among the major beneficiaries of NSF's waste and mismanagement. Even if a policy review is never on their public agenda, it is reasonable to assume that senior university officials who serve on the National Science Board will be aware of the maximum, no-audit rate of overhead reimbursement that can be obtained by NSF policies (v. HHS).

Concerning the good news: With the documentation in the Nature article, I also enclose a letter of March 17, 2015 to Dr. Faye Cook, NSF's Assistant Director for the Social, Behavioral, and Economic Sciences, and her SBE advisory committee discussing three exciting opportunities – each in the $100 million mid-range – for new advisory systems, leadership, and rapid learning in areas of vital national interest.

Yours truly,

Lloyd Etheredge

Dr. Lloyd S. Etheredge Director

Enclosures:
- Heidi Ledford, "Keeping the Lights On," Nature, 515 (November 20, 2014), pp. 326-329.
- LSE, Letter to March 17, 2015 to Dr. Faye Cook and Dr. Emilio Moran, NSF-SBE

KEEPING THE LIGHTS ON

Every year, the US government gives research institutions billions of dollars towards infrastructure and administrative support. A *Nature* investigation reveals who is benefiting most.

BY HEIDI LEDFORD

Last year, Stanford University in California received US$358 million in biomedical-research funding from the US National Institutes of Health (NIH). Much of that money paid directly for the cutting-edge projects that make Stanford one of the top winners of NIH grants. But for every dollar that Stanford received for science, 31 cents went to pay for the less sexy side of research: about 15 cents for administrative support; 7 cents to operate and maintain facilities; 1 cent for equipment; and 2 cents for libraries, among other costs.

The NIH doled out more than $5.7 billion in 2013 to cover these 'indirect' costs of doing research — about one-quarter of its $22.5-billion outlay to institutions around the world (see 'Critical calculations'). That money has not been distributed evenly, however: research institutions negotiate individual rates with government authorities, a practice that is meant to compensate for the varying costs of doing business in different cities and different states. Data obtained by *Nature* through a Freedom of Information Act request reveal the disparities in the outcomes of these negotiations: the rates range from 20% to 85% at universities, and have an even wider spread at hospitals and non-profit research institutes. The highest negotiated rate in 2013, according to the data, was 103% — for the Boston Biomedical Research Institute (BBRI) in Watertown, Massachusetts. Under financial duress, it closed its doors that same year.

Faculty members often chafe at high overheads, because they see them as eating up a portion of the NIH budget that could be spent on research. And lack of transparency about how the money is spent can raise suspicions. "Sometimes faculty feel like they're at the end of the Colorado River," says Joel Norris, a climatologist at the University of California, San Diego. "And all the water's been diverted before it gets to them."

Nature compared the negotiated rates, as provided by the US Department of Health and Human Services, to the actual awards given to more than 600 hospitals, non-profit research institutions and universities listed in RePORTER, a public database of NIH funding (see 'Overheads under the microscope'). The analysis shows that institutions often receive much less than what they have negotiated, thanks to numerous restrictions placed on what and how much they can claim. Administrators say that these conditions make it difficult to recoup the cash they spend on infrastructure.

In addition, new administrative regulations have meant that universities have had to increase their spending, even as federal and state funding for research has diminished. "We lose money on every piece of research that we do," says Maria Zuber, vice-president for research at the Massachusetts Institute of Technology (MIT) in Cambridge, which has negotiated a rate of 56%.

But many worry that the negotiation process allows universities to lavish money on new buildings and bloated administrations. "The current system is perverse," says Richard Vedder, an economist at Ohio University in Athens who studies university financing. "There is a tendency to promote wasteful spending."

CRITICAL CALCULATIONS

What are indirect costs?

Indirect costs — often called facilities-and-administrative costs — are expenses that are not directly associated with any one research project. This includes libraries, electricity, administrative expenses, facilities maintenance and building and equipment depreciation, among other things.

The United States began reimbursing universities for indirect costs in the 1950s, as part of a push to encourage more research. An initial cap was set at 8%, but that had risen to 20% by 1966, when the government began to allow institutions to negotiate their rates. Institutions were assigned to negotiate with either the US Department of Health and Human Services or the Office of Naval Research, depending on which supplied the bulk of their research funding. And the agreed rate holds across all federal funders, irrespective of where the negotiations took place.

A common misconception is that indirect-cost rates are expressed as a percentage of the total grant, so a rate of 50% would mean that half of the award goes to overheads. Instead, they are expressed as a percentage of the direct costs to fund the research. So, a rate of 50% means that an institution receiving $150 million will get $100 million for the research and $50 million, or one-third of the total, for indirect costs. But there are multiple caps that lower the base amount from which the indirect rate is calculated, or that limit the amount of money that a research institution can request. So very few institutions receive the full negotiated rate on the direct funding they receive. H.L.

GLOBAL DISPARITY

Reimbursement for overheads is dealt with differently around the world. The United Kingdom calculates indirect costs on a per-project basis. Japan has a flat rate of 30%. And last year, to the dismay of some institutions, the European Union announced that it would no longer negotiate rates and instituted a flat rate of 25% for all grant recipients in its Horizon 2020 funding programme (see *Nature* **499,** 18–19; 2013).

The comparatively high overhead reimbursement in the United States has generated envy, and at times controversy. About 20 years ago, government auditors found that Stanford was using funds for indirect costs to cover the depreciation in value of its 22-metre yacht moored in San Francisco Bay, and to buy decorations for the president's house, including a $1,200 chest of drawers.

Other universities — including MIT and Harvard University in Cambridge — soon came forward to correct overhead claims that they feared would be perceived as inappropriate. In the end, Stanford paid the government $1.2 million and accepted a large reduction — from 70% to 55.5% — in its negotiated rate. But the damage was done. The government layered on new regulations, including an explicit ban on reimbursement for housing and personal living expenses, and a 26% cap on administrative costs, although only for universities.

Two decades later, researchers still worry that the system carries the taint of impropriety. Administrators say that changes at some institutions — such as increased transparency about spending and how indirect costs are calculated — have allayed faculty concerns. But not everywhere. "People often think this is about secretarial staff and bloating the mid-level research administration," says Tobin Smith, vice-president for policy at the Association of American Universities in Washington DC. "The faculty doesn't often think about all the other costs: the lights are on, the heat is on, you're using online services the university provides."

Despite the high level of scrutiny for universities, they did not top the chart for negotiated rates in the data that *Nature* collected. Few universities have rates above 70%, and they would probably face an outcry from faculty if they raised rates too high, says Samuel Traina, vice-chancellor for research at the University of California, Merced.

No such threshold seems to exist at non-profit research institutes: more than one-quarter of the 198 institutes for which *Nature* obtained data negotiated rates above 70%. Fourteen of them have rates of 90% or higher, meaning that their indirect costs come close to equalling their direct research funding. According to Robert Forrester, an independent consultant in Belmont, Massachusetts, who helps institutions to determine their indirect costs, these institutes need to negotiate higher rates because the entire facility is dedicated to research, whereas universities and hospitals also use facilities for other things, such as teaching, that generate funding and must share the burden.

Comparisons of negotiated rates against the RePORTER data mined by *Nature* come with caveats. For example, many smaller institutions negotiate a provisional rate with the NIH that is later adjusted to match actual overhead costs,

OVERHEADS UNDER THE MICROSCOPE

In 2013, the US National Institutes of Health (NIH) awarded more than US$5 billion to research institutes for indirect costs: shared overhead expenses such as lighting, heat and maintenance. Institutes negotiate the rate at which they will be reimbursed, and it is expressed as a percentage of the direct costs for research in a grant. Data obtained by *Nature* reveal the disparity in the outcomes of these negotiations and show that the amount received is usually much lower than that negotiated.

UNIVERSITIES
Received $3.9 billion, at an average rate of 31%

NON-PROFITS
Received $611 million, at an average rate of 38%

HOSPITALS
Received $550 million, at an average rate of 38%

*Institutes can seem to receive higher than their negotiated rates for various reasons. Institutions sometimes negotiate higher rates for specific projects, for example.

TOP 10 EARNERS

The 10 universities that get the most money from the NIH together received more than $1.1 billion towards their indirect costs. Their negotiated and calculated rates were slightly higher than the average for all universities.

	INSTITUTION	TOTAL FUNDING	INDIRECT COSTS (%) NEGOTIATED	INDIRECT COSTS (%) CALCULATED
1	JOHNS HOPKINS UNIVERSITY	$574,844,637	62	43
2	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	$501,656,900	60	41
3	UNIVERSITY OF WASHINGTON	$454,274,167	57	40
4	UNIVERSITY OF PENNSYLVANIA	$451,194,908	57	39
5	UNIVERSITY OF MICHIGAN	$412,016,862	57	38
6	UNIVERSITY OF PITTSBURGH	$396,728,993	56	37
7	UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL	$383,752,058	55	35
8	UNIVERSITY OF CALIFORNIA, SAN DIEGO	$362,004,733	55	32
9	STANFORD UNIVERSITY	$357,812,990	53	32
10	DUKE UNIVERSITY	$350,249,092	52	32

NATURE.COM
For an interactive version and details on the methods used, see: **go.nature.com/j9nefd**

so some grants in RePORTER seem to have a reimbursed rate that exceeds the negotiated value. A change to the negotiated rate in the middle of a year can also cause a disconnect between the data *Nature* obtained and the rates given in RePORTER.

But overall, the data support administrators' assertions that their actual recovery of indirect costs often falls well below their negotiated rates. Overall, the average negotiated rate is 53%, and the average reimbursed rate is 34%.

The shortfall is largely due to caps imposed by the NIH on some grants and expenditures, says Tony DeCrappeo, president of the Council on Governmental Relations (COGR), an association in Washington DC that is focused on university finance. Some training grants, such as 'K' awards for early-career investigators, cap indirect costs at 8%. The NIH also does not award money for conference grants, fellowships or construction. And it has placed limits on specific categories, such as costs associated with research using genomic microarrays.

Such restrictions can make it hard to make ends meet, says Eaton Lattman, who heads the Hauptman-Woodward Medical Research Institute in Buffalo, New York. The institute negotiated a rate of 94%, but received just 52%. Although it does not incur some of the costly administrative burdens of hospitals or universities, it still fails to recoup its full investment on research, Lattman says.

The increasing competition for NIH grants is a major factor in that. Because funds used to support researchers who lose grants or have yet to win one cannot be reimbursed as indirect costs, Hauptman-Woodward must draw from its endowment to keep them working until they can support themselves. "If you don't want to kill their research career, you have to provide bridge funding," Lattman says.

The BBRI faced similar strains. The institute was dependent on NIH funding, and could not cope when the NIH budget tightened and faculty members brought in less grant money (see *Nature* **491,** 510; 2012). "The general cost of operating the organization did not diminish as fast as the direct dollars," says Charles Emerson, former head of the institute and now a developmental biologist at the University of Massachusetts Medical School in Worcester. "So we were able to negotiate a higher rate at the end of our time there, just to keep the operation going."

By 2012, the BBRI's negotiated rate had swelled to 103%, the highest for any organization in the data provided to *Nature*. But it ended up recouping just 70%, or $2.4 million on $3.4 million in direct funding.

Although non-profit institutes command high rates, together they got just $611 million of the NIH's money for indirect costs. The higher-learning institutes for which *Nature* obtained data received $3.9 billion, with more than $1 billion of that going to just nine institutions, including Johns Hopkins University in Baltimore, Maryland, and Stanford (see 'Top 10 earners'). At 38%, the average rate for these nine institutions is about 4% higher than that for all institutions with available data. But the range for higher-learning institutions was wide, with one receiving 62% (York College in Jamaica, New York), and one receiving just under 3% (Dillard University in New Orleans, Louisiana).

SOURCES: US DEPARTMENT OF HEALTH AND HUMAN SERVICES; NIH REPORTER DATABASE

SHORT CHANGE

Even if universities did receive the full, negotiated rate, it would still be less than the actual costs of supporting research, says DeCrappeo. The cap on administrative costs that emerged in the wake of the Stanford scandal has remained unchanged even though administrative burdens have swelled. COGR members maintain that their actual costs are about 5% higher than the cap, says DeCrappeo. The rest of the money must come from other revenue, such as tuition fees, donations and endowments.

> "THE RESEARCH BUREAUCRACY HAS INFLATED WILDLY IN UNIVERSITIES AND IT IS EXPENSIVE."

The best solution, according to Barry Bozeman, who studies technology policy at Arizona State University in Phoenix, is not to raise the cap, but to cut costs by getting rid of administrative rules and regulations that are simply wasting time and money. "The research bureaucracy has inflated wildly in universities and it is expensive." That inflation, he says, is evident in grant applications. Thirty years ago, administrative requirements associated with grants were relatively low. "Nowadays, the actual content of the proposal — what people are going to do and why it's important — is always a small fraction of what they submit," he says.

As an illustration of the growing bureaucracy, DeCrappeo says that when the COGR began to keep a guide to regulatory requirements for its members in 1989, the document was 20 pages long. Now it is 127 pages. And Bozeman says that he has to fill out forms relating to the care of laboratory animals when he applies for grants, even though he has never used animals.

The regulatory burden can be particularly high for medical schools, which must adhere to regulations for human-subject research, privacy protection and financial conflicts of interest, among others. The Association of American Medical Colleges in Washington DC says that 70 of its members have spent $22.6 million implementing conflicts-of-interest reporting guidelines that came into effect this year.

Other funders place strict limits on their reimbursements. The US Department of Agriculture, for example, caps many of its reimbursements at 30%. Many philanthropic organizations do not reimburse for overheads at all, and those that do often pay less than the government rate (see *Nature* **504,** 343; 2013). As a result, some institutions are reluctant to allow researchers to apply for such grants — providing another source of friction between faculty members and the administration.

Tight budgets and fierce competition for federal grants mean that faculty members are keenly sensitive to anything that might affect how much money they receive, says Lattman. Recipients of grants from the National Science Foundation (NSF) are particularly rankled, he says, because the NSF allocates money for indirect costs — at the federal negotiated rate — from the total grant awarded. In other words, researchers told that they will receive a $1-million NSF grant might see only 60% of the money. The NIH, by contrast, typically gives faculty members the full $1 million and then reimburses indirect costs in a separate payment to the university.

Even so, would-be NIH grant recipients often fear that a high indirect-cost rate at their institution will hurt their chances of getting a grant funded, despite the lack of evidence supporting any such trend. Others are troubled by the lack of transparency at many institutions as to how the indirect costs are calculated and the funds distributed. Because indirect-cost revenue is considered a reimbursement for money the university has already spent, much of the cash received from the government disappears into a university's general fund. "Faculty have always been somewhat in the dark," says Edward Yelin, who studies health policy at the University of California, San Francisco.

Although the payout for indirect costs is high, officials at the NIH say that the proportion of the NIH budget dedicated to overheads has held steady for more than two decades. When a 2013 report by the US Government Accountability Office warned that indirect costs could begin to eat up an increasing proportion of the NIH's research budget, the NIH countered that this was unlikely.

DeCrappeo is hopeful that regulations due to come into effect in December will rein in the proliferation of caps on indirect cost rates. The regulations will require officers at agencies such as the NIH to have any new caps on overhead reimbursement approved by the head of the agency and provide a public justification for the change. DeCrappeo says that this could lead to a more transparent process.

And for those who fret about where this money is going, DeCrappeo urges them to look beyond their own research programmes. "If all you're concerned about is the direct costs, it won't take long for your facilities to deteriorate," he says. "You can't do research on the quad." ■

Heidi Ledford *writes for* Nature *from Cambridge, Massachusetts.*

THE POLICY SCIENCES CENTER, INC.

Project Director: DR. LLOYD ETHEREDGE
E-ma[redacted]

March 17, 2015

Dr. Faye Cook, Assistant Director - Social Behavioral and Economic Sciences
Dr. Emilio Moran – Chair, SBE Advisory Committee
National Science Foundation
4201 Wilson Blvd., Room 905 N
Arlington, VA 22230

Dear Assistant Director Cook, Advisory Committee Chair Moran, and SBE Advisory Committee Members:

I write to suggest that you create three NSF Advisory Committees to plan two NSF rapid learning data systems and a joint methodology/data investment in content analysis. Each NSF Advisory Committee will design a planning process (for example, involving several conferences with commissioned papers) to build new R&D data and analysis systems in the NSF investment mid-range, about $100 million each.

This strategic planning process for SBE Big Data systems implements the successful NIH model for biomedical research and physical health. The exciting research opportunities are too large and complex to rely upon an application from one individual or institution alone. Part of a solution, in all cases, is likely to involve a large N, pre-populated, inclusive, curated, R&D data system maintained at public expense. It will be open to all researchers and capable of rapidly testing a universe of competing theories, and with additional ("Everything Included") variables and sub-samples for data exploration. Privacy safeguards will be part of the design. Cloud storage and online analysis tools will democratize access. Sub-samples can develop jointly with NIH's (N= 1,000,000 participants) system to explore genetics, brain, and other physiological mechanisms. With assistance from new machine learning algorithms, 21st century SBE discovery can move at the speed of thought (rather than the speed of an NIH or NSF grant application process).

Parts of the new R&D data systems that you design also may involve competitive grants to individuals, institutions, public-private partnerships, or academic consortia. These grant applications will emerge in a broader planning context in which the reviewers can see the wider architecture rather than faulting each component for its limitations.

My suggestions for high priority NSF Advisory Committees for Big Data planning are:

1.) Changing American Society and Economic Opportunity for Kids. Destructive trends, termed by Robert Putnam the "cursed course of our society," apparently produce (unexpectedly) a limited future

for many children in America born to parents with a high school education or less. His analysis of changing (and eroding) societal norms and closing doors of opportunity in Our Kids: The American Dream in Crisis (NY: Simon and Schuster, 2015) is chilling. The results add to other alarms (e.g., Charles Murray, Coming Apart: The State of White America, 1960-2010). These analyses suggest that we should urgently devote our best brainpower and social science resources to add critical data, understand causation, and illuminate choices that our society can make, and the options and role for government policy. The unraveling of two-parent families in the working class illustrates one of the important, harmful (to children and their futures), poorly understood, and unpredicted trends. How did this happen? Comparative and cross-national data systems might play a critical role to illuminate causal pathways and creative options.

This is a rapid learning investment – concerning children, economic opportunity, and family values - that will have strong bipartisan support. (Charles Murray, for example, is a scholar at the American Enterprise Institute. I enclose a review of Putnam's book by the conservative New York Times columnist David Brooks, "The Costs of Relativism," March 10, 2015 – e.g., "The profiles from high-school educated America are familiar but horrific.") The new NSF appropriations request is about $7.8 billion, and it is time to begin rebalancing the government science portfolio, between the social and physical sciences, to support traction in the SBE disciplines. NSF-supported R&D data systems are about the only way that we, as a society, are going to make rapid progress to stimulate thinking and discovery.

2.) A G-20 Rapid Learning System for Macroeconomics. Earlier, I brought to your attention a (draft) rapid learning strategy for macroeconomics to improve economic recovery and sustainable growth in a changing world.[i] The logic of applying the best available scientific methods to this problem is compelling. I hope that a prestigious NSF Advisory Committee for Rapid Learning Economics can produce a brilliant, generously funded, and rapidly implemented plan for new R&D data systems for the SBE sciences in the $100 million range. [Even if there is an American political case to delay the analysis of a subset of data in the new R&D data systems (because it would be critical of government policies or be cited in partisan debates), we at least should be deploying the metrics, and capturing the missing data, now.] The G-20 variations can yield urgently needed improvements for those (e.g., EU) countries with a political agreement to test competing theories and improve their policy choices quickly.

As an illustration of new and competing paradigms, recommended by serious and capable researchers, I enclose two discussions of confidence-related variables and their role in Recovery Economics and sustained growth. My conceptual discussion ("'Animal Spirits' and Fast Economic Recovery: Reading the Lessons Correctly," enclosed) points to several new metrics. I also enclose a recent Op Ed by the current President of the American Economic Association and Nobelist, Robert Shiller, with a much wider inventory of possible – as yet, unmeasured in standard economic behavior datasets - variables that inhibit confidence, recovery, and long-term growth ("Anxiety and Interest Rates: How Uncertainty is Weighing on Us," The New York Times, February 7, 2015). I hope that you can design and activate planning mechanisms, and create R&D data systems, so that his ideas, mine, and all other theories can be tested quickly. We are losing too much data and too much time. The future of billions of

people can be improved as soon as the NSF SBE Directorate can get us better data and answers. We do not, as a nation or in the G-20, have mechanisms to make these links from conceptual discussions to new R&D data systems automatically.

An NSF Advisory Committee for Rapid Learning Economics should include members from the private sector.

3.) Content Analysis. Computer-assisted content analysis is a research tool whose time has come. The early 20th century pioneers were limited by technology to simple frequency counts and ratios. Even these applications were fiercely expensive: input had to be coded by hand and entered on punch cards. The software was primitive and the memory capacity of early mainframe computers was too limited to "understand" input by the sophisticated statistical analysis of huge databases for each domain that Google (for example) uses to refine its search queries.

Today, content analysis can be a worldwide research tool, across all major languages. There will be hard work ahead for many disciplines, notably computer science. However, machine-assisted translation can work well, based on fast and sophisticated statistical analysis of word usage in specific domains. (Google News shows what can be done for current events.) As soon as the new NSF Advisory Committee on Content Analysis can do its work, social scientists can monitor trends across a tidal wave of daily input from many countries. Human analysts will continue to be needed to interpret data – just as we want individual physicians to make diagnoses of patients, even when they use a universe of lab tests – but content analysis of large media data systems can save the time of social scientists. It can create indexes of events (e.g., civil unrest or strikes), capture changes in mood, and follow (quickly) the change of cultures and sub-cultures (e.g., youth cultures, ISIS) on a global scale. In the 20th century, content analysis of stress levels informed historical studies of crisis decision making in international relations and helped to produce breakthroughs for the new practice of slow motion "coercive diplomacy" (rather than threats, ultimatums, and crisis decisions.)

How these capabilities might evolve and be applied will be one of the tasks of the NSF Advisory Committee on Content Analysis. Early 20th century pioneers dreamed of the day when sophisticated computer-assisted content analysis, able to "understand" subjectivity, could provide a continuous flow of data that would be the equivalent, for all of the other social sciences, of the national income accounts invented for macro-economic modeling in the 1930s.

An initial step probably is for the NSF Advisory Committee on Content Analysis to meet with companies like Google and government institutions like NSA. They can help to plan (and perhaps contribute) public, cloud-based, Reference Datasets, software, and analysis tools. New capabilities for indexing pictures and video, and recognizing speech, might be included to assist the study of television programs and social media in this international Big Data R&D system. A public domain, open, analysis engine for textual, voice, and video data – similar to SAS for quantitative data – might be one goal for the NSF Advisory Committee.

Yours truly,

Dr. Lloyd S. Etheredge

Enclosures:

- David Brooks, "The Costs of Relativism," The New York Times, March 10, 2015.
- Lloyd Etheredge, "'Animal Spirits' and Fast Economic Recovery: Reading the Lessons Correctly." October 20, 2014.
- Robert Shiller, "Anxiety and Interest Rates: How Uncertainty is Weighing on Us," The New York Times, February 7, 2015.

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[i] A reference copy is online at www.policyscience.net.

The Cost of Relativism

MARCH 10, 2015. By David Brooks. The New York Times.

One of America's leading political scientists, Robert Putnam, has just come out with a book called "Our Kids" about the growing chasm between those who live in college-educated America and those who live in high-school-educated America. It's got a definitive collection of data about this divide.

Roughly 10 percent of the children born to college grads grow up in single-parent households. Nearly 70 percent of children born to high school grads do. There are a bunch of charts that look like open scissors. In the 1960s or 1970s, college-educated and noncollege-educated families behaved roughly the same. But since then, behavior patterns have ever more sharply diverged. High-school-educated parents dine with their children less than college-educated parents, read to them less, talk to them less, take them to church less, encourage them less and spend less time engaging in developmental activity.

Interspersed with these statistics, Putnam and his research team profile some of the representative figures from each social class. The profiles from high-school-educated America are familiar but horrific.

David's mother was basically absent. "All her boyfriends have been nuts," he said. "I never really got to see my mom that much." His dad dropped out of school, dated several woman with drug problems and is now in prison. David went to seven different elementary schools. He ended up under house arrest, got a girl pregnant before she left him for a drug addict.

Kayla's mom married an abusive man but lost custody of their kids to him when they split. Her dad married a woman with a child but left her after it turned out the

child was fathered by her abusive stepfather. Kayla grew up as one of five half-siblings from three relationships until her parents split again and coupled with others.

Elijah grew up in a violent neighborhood and saw a girl killed in a drive-by shooting when he was 4. He burned down a lady's house when he was 13. He goes through periods marked by drugs, clubbing and sex but also dreams of being a preacher. "I just love beating up somebody," he told a member of Putnam's team, "and making they nose bleed and just hurting them and just beating them on the ground."

The first response to these stats and to these profiles should be intense sympathy. We now have multiple generations of people caught in recurring feedback loops of economic stress and family breakdown, often leading to something approaching an anarchy of the intimate life.

But it's increasingly clear that sympathy is not enough. It's not only money and better policy that are missing in these circles; it's norms. The health of society is primarily determined by the habits and virtues of its citizens. In many parts of America there are no minimally agreed upon standards for what it means to be a father. There are no basic codes and rules woven into daily life, which people can absorb unconsciously and follow automatically.

Reintroducing norms will require, first, a moral vocabulary. These norms weren't destroyed because of people with bad values. They were destroyed by a plague of nonjudgmentalism, which refused to assert that one way of behaving was better than another. People got out of the habit of setting standards or understanding how they were set.

Next it will require holding people responsible. People born into the most chaotic situations can still be asked the same questions: Are you living for short-term pleasure or long-term good? Are you living for yourself or for your children? Do you have the freedom of self-control or are you in bondage to your desires?

Next it will require holding everybody responsible. America is obviously not a country in which the less educated are behaving irresponsibly and the more

educated are beacons of virtue. America is a country in which privileged people suffer from their own characteristic forms of self-indulgence: the tendency to self-segregate, the comprehensive failures of leadership in government and industry. Social norms need repair up and down the scale, universally, together and all at once.

People sometimes wonder why I've taken this column in a spiritual and moral direction of late. It's in part because we won't have social repair unless we are more morally articulate, unless we have clearer definitions of how we should be behaving at all levels.

History is full of examples of moral revival, when social chaos was reversed, when behavior was tightened and norms reasserted. It happened in England in the 1830s and in the U.S. amid economic stress in the 1930s. It happens through organic communal effort, with voices from everywhere saying gently: This we praise. This we don't.

Every parent loves his or her children. Everybody struggles. But we need ideals and standards to guide the way.

A version of this op-ed appears in print on March 10, 2015, on page A21 of the New York edition with the headline: The Cost of Relativism. Order Reprints| Today's Paper|Subscribe

Anxiety and Interest Rates: How Uncertainty Is Weighing on Us

By Robert Shiller. The New York Times. February 7, 2015.

Anxiety and uncertainty are weighing on individuals even where the overall economy is growing.

Some of this angst is the fallout from advances in information technology. The Internet, ubiquitous computing, robotics, 3-D printers and the like are wonderful advances, yet they may also be personal threats: For some, the technologies may eliminate our jobs or potential future jobs, or make them less lucrative. For others, they may bring new riches.

Even people with moderately high incomes have reason to be uncertain. Some college professors, tenured or not, might lose their jobs in the face of massive open online courses, while others prosper from them. Lawyers might find less demand for services that can be supplanted by computerized legal research tools. News and entertainment media have already faced huge technology-related job losses.

Along with this enormous problem is the psychic cost of growing income inequality. Poor people, who see themselves slipping further and further behind, are hurting, of course. What's less obvious is that yawning inequality also seems to be preoccupying the rich. For example, an Oxfamreport issued last month, "Richest 1 Percent Will Own More Than All the Rest by 2016," was the focus of many nervous conversations at the recent World Economic Forum in Davos, Switzerland, which I attended. Davos is a gathering of the global elite yet even many of those in such rarefied circles are wondering whether they and their friends and loved ones will lose their privileged status in the future.

Such fears are not measured by the usual consumer confidence indexes. The University of Michigan Consumer Sentiment Index reached its highest level since 2004 in January. But this index, and others like it, look ahead only into the short term and report about perceived aggregate conditions rather than individual risks.

I suspect that there is a real, if still unsubstantiated, link between widespread anxieties and the strange dynamics of the economic world we live in today — a link that helps to explain why it's not just short-term interest rates that are very low,

but long-term rates, too. Understanding long rates might also help explain why stock market prices are so high in some countries and why real estate prices have come up in many places since the financial crisis.

In the United States, for example, the 30-year Treasury bond yield hit a record low on Jan. 30 of 2.25 percent, and the 30-year fixed-rate home mortgage reached 3.59 percent as of Feb. 5, also a very low level. The rate for 30-year Treasury Inflation Protected Securities was just 0.52 percent on Jan. 30. These unusual rates cannot be attributed entirely to the Federal Reserve, because it stopped quantitative easing in October, and rates have dropped since then. While other central banks certainly are affecting global interest rates, something else is going on.

One puzzle is that many people are willing to lock up their savings at these paltry rates for decades. When rates are this low, there may seem to be very little incentive for people to save. Yet according to the Bureau of Economic Analysis, personal saving as a fraction of disposable personal income stood at 4.9 percent for the United States in December. That may not be an impressive level, but it's not particularly low by historical standards. The answer may be that all this uncertainty impels them to do that.

In a classic 1978 paper, "Asset Prices in an Exchange Economy," a University of Chicago economist, Robert Lucas, presented a mathematical model that shows that increased uncertainty about future incomes can indeed push up all asset prices and push down expected returns, even in perfectly efficient markets.

When there is unusual uncertainty about the future, and if not enough new business initiatives can be found to increase the supply of good investments, people will compete to bid up existing investable assets. They may go so far in bidding up prices that even though the assets may have horrible prospects, people will still want to hold them because they feel they have to save somewhere.

There is a great deal that we don't know about market movements. Interest rates and prices generally reach extreme levels when there is an unusual confluence of many precipitating factors, like anxiety, and others as well. We are usually puzzled by this multiplicity.

And, because markets are really not very efficient, the effect of these varied factors tends to be amplified through emotional feedback. For example, when people start to see rates or prices changing, some of them take action: They are enticed into the market when prices are rising, and often leave when prices fall. We then are typically surprised by the extent of apparent market overreaction to precipitating factors that we didn't think were really on everyone's mind.

At the moment, anxiety does not seem to be the basis of much public discussion of asset pricing. That's understandable: There may be no real benefit from bringing up the effect of these diffuse fears on market strategy with your tax preparer, lawyer or financial adviser, who surely will not have an authoritative opinion on what to do about them.

Anyone can tell you that there is no certainty about the effect that new technologies will have on job security in coming decades: There is a risk, but it is hard to quantify for general categories of jobs, and nearly impossible to calculate for individuals. Yet these concerns have effects on investor decision-making through the emotional component of our actions — what John Maynard Keynes, the great British economist, called our animal spirits.

Uncertainties about individual economic fortunes can affect asset prices through an important indirect channel, government policy, which is swayed by popular concerns. Raghuram Rajan, governor of the Reserve Bank of India, in his book "Fault Lines: How Hidden Fractures Still Threaten the World Economy" (Princeton 2010) argued that governments were more tolerant of excessive credit expansion when their citizens were upset about rising inequality. Governments, he said, use expanded credit in a desperate effort to placate a dissatisfied electorate. Credit expansion can create housing bubbles and an illusion of wealth for many people, for a while, at least. The idea is: "Let them eat credit."

But with rising anxiety about our economic lives and about the state of the markets, we need something more substantial than credit expansion to help us. We all need to think hard about the underlying mechanisms producing individual uncertainty and inequality, and we need to devise financial and insurance plans to help us to deal with whatever looms ahead.

"Animal Spirits" and Fast Economic Recovery: Reading the Lessons Correctly

by Lloyd S. Etheredge <1>

Keynes believed that economic growth occurs when a free society permits its natural "animal spirits" to flourish and create the economic future. This insight can guide us to better policies for fast economic recovery if we connect the idea to the reality it described and read the lessons correctly.

Keynes' phrase was commonly used of British students in boarding schools in late Victorian and Edwardian England. Their "animal spirits" and an inherent optimism (not derived from cold, rational calculations) found natural expression in the competitive freedom of the playing field and, sometimes, in an irreverent, youthful independence and instinct for challenging the rules that enjoined vigilance by headmasters. The energy of freedom and team competition carried forward to free, competitive markets to build the wealth of Britain and a global empire.

Next, academic economists began to craft their science by turning the observation of animal spirits and a passion to win at cricket into their own mathematical equations that modeled human beings as rational, profit-maximizing robots. Today, they recommend public policies that are based on these equations. The equations captured important truths - cricket players want to win and rationality helps to create winning strategies. However, in current circumstances, economic health requires that we reconnect, directly, to the touchstone psychology of the playing fields.

What are the correct lessons? Current political rhetoric reminds us that there are different diagnoses that we can draw about these animal spirits and remedies to restore economic health. Yes, it is easy to see how totalitarian dictators, intrusive regulators, and bureaucrats could intrude and take control of youthful athletic competitions and suppress natural enthusiasm. And it also would weaken competitive games if - as Mitt Romney believes about America - teams somehow can use political influence to be awarded easy "welfare state" bonuses to their scores, and become dependent on these political strategies for winning. But I think that today's psychological challenge of economic recovery is larger, and it requires that we restore confidence by repairing a catastrophic moral breakdown and failure of institutions.

Returning to the playing fields of Eton: "Animal spirits" actually thrive in a larger moral context, a background of rules and values that Keynes and his British readers took for granted.

Current rhetoric aside, "regulation" does not always destroy sporting contests: The games are *defined* by rules and social norms, the presence of honest umpires who enforce the rules, an understanding of game-enhancing zones for strategy and deception and the boundaries for cheating, the social sanctions against cheaters. The contests are shaped by the code of sportsmanship and respect. They honor a basic human equality: Traditionally, each player takes a turn at bat and teams compete only with their own skill and the same equipment as everyone else. [We should observe, too, that the motivating scores in athletic games are made-up numbers. It is an insight worth remembering: players and teams may have "profit maximizing" motives about scoring, but they were not paid in money.]

By this diagnosis, the missing agenda to restore economic confidence is to restore a moral order, confidence and trust in government and other major institutions. Some of the world's most trusted institutions - banks and financial institutions, government regulators, and even Presidents - unexpectedly and catastrophically betrayed or failed their trust. The "risk shifting" players gained fabulous wealth, damaged the lives of billions of people worldwide, and added public debts that will limit other expenditures in almost every country for at least a generation. They have not gone to jail, paid reparations to the victims, apologized to the victims, or agreed to play by the rules in the future. Today, the wealthy are becoming wealthier while the mass of the public already has paid a fierce price, is being left to repay the huge burdens of public debt for recovery, and with limited ways to play by the rules of the market system and win.

Thus, the Federal Reserve wastes hundreds of billions of dollars by using its equations and believing that the way to restore confidence is by low interest rates and easy money to buy cricket bats and balls. But catastrophic institutional failure and betrayal on the current scale are only partly corrected by monetary policies or by fiscal policies. [Today, governments have been throwing trillions of dollars at the problem of economic recovery. Earlier, it worked. Now, it doesn't.] Confidence has not been restored because major institutions and leaders have not restored confidence in themselves.

Happily, a rapid solution may be possible. I see three steps that would be part of a strong package.

I.) An (Assigned) Wealth Tax. The G-20 nations (at their summit next month in Australia) can agree to an annual tax of 2% - 3%/year on wealth, for individuals worth more than $5 million, that will continue until the full debt incurred as part of the recovery process has been amortized. Any further sums needed for recovery will be added to the total for repayment. This

restores moral order and it pays for the recovery. As a stand for justice: it assures that debts incurred for recovery will be paid without being a further burden on the vast majority of the world's people who have paid enough, as victims. The wealthy will continue to earn a positive return (everything on their first $5 million and above 2% - 3% on the rest) - they just will become wealthier more slowly. Imposing the tax in all countries will limit opportunities for cheating. The ear-marked wealth tax sends important deterrent and incentive-creating messages to the wealthiest members of society that they will share in the responsibility for rapid recovery and future accountability of banks and financial managers who they control.

Also: the wealth tax is a political test. Passing the wealth tax will help to restore confidence in governments and elected politicians who are (rightly) suspected to be dependent on campaign contributions by the wealthy. To pass the tax, political parties must shake lose from this dependency, rethink their priorities and, with their own confidence, reassert control.

A. Rebalancing the Scales of Justice

A proposal for a wealth tax can raise moral arguments. Is it fair, or just, to impose a 2% - 3% annual wealth tax, ear-marked for recovery, on a class of wealthy people? In part, this is a question of whether it is fair to impose *any* tax and it is not unique to this proposal. More specifically, the question is whether there should be detailed moral calculations, like the BP cleanup settlement process imposed by the Obama Administration, linking specific payers and their acts of wrong-doing or negligence and payees who could be fully compensated for damages to their lives and livelihoods and to the public treasury to amortize recovery debts?

The first answer to these objections is that I am making an argument about *justice* in paying the costs incurred for *economic recovery*, and a public process to establish a sense of moral order for the future, not also attempting a full moral and economic rebalancing of historical acts of negligence or calculation leaded to the economic crisis, like the BP settlement. It might be an even better moral solution to secure a larger BP-like settlement, but it strikes me as complex, although worth considering if somebody proposes a way to do it.

A second answer to these objections is that there may be a case, based on the historical record, to extend a wealth tax beyond individuals to include the many holders of wealth (e.g., retirement and endowment funds) whose hired agents speculated, or who were directly negligent in failing to self-police the financial sector and who may have benefitted from the generous profits of investing in what they knew, or should have known, to be asset bubbles. This extension of the G-20 wealth tax can be considered, but institutional investors can be agents for many

smaller holders (e.g., in retirement accounts). It is more straightforward and fairer to tax wealth as it is owned, ultimately, by individuals with assets over $5 million.

A political judgment about justice involves a scale of justice with weights and considerations on both sides. Given that the costs of recovery must be repaid, I am suggesting 1.) a way to pay them that is *more* just than the current mechanism of shifting the burdens of repaying debts to mass publics who have been disproportionate victims and who are less able to pay. 2.) a *practical* way to pay them that speeds economic recovery by also using a simple, assigned wealth tax to restore a sense of moral order. (And 3.) when it does speed recovery, the wealthiest, too, may come out even further ahead than if nothing is done.)

B. The Politics of a Just Solution

The reader might, at this point, believe that I am living in a political fantasyland even to suggest a 2%-3%/year tax on the world's wealth Establishment. Yet in democracies the vast majority of the victims, and the beneficiaries of using the wealth tax, have a vote! Any political candidate or party in G-20 democracies that supports the wealth tax initiative should win the next election with an overwhelming majority - and if everyone is paying, even a subset of wealthy people may support the solution. In America, Mitt Romney knows that there has been a breakdown in the moral order, that trust must be restored, and- if he will deliver a wealth tax - that Republicans can sweep to victory. Democrats, too, know that a wealth tax is a good political solution.

II. Improving the Moral Gamesmanship of Wall Street

To achieve a vibrant global capitalist system a second set of direct steps can improve the moral gamesmanship of Wall Street. For example: a.) End the tax benefits for the wealthy unless they produce honest game scores in the real economy. We give capital gains tax benefits for "investing" in the stock market but only a fraction of this money actually invests in new plant and equipment and economic growth. Large fractions of so-called "investments" are buying and selling to play the market or outsmart other players. As Clayton Christensen recommends, only venture capital and "buy and hold" investment, that is used for business growth in the real economy and held for several years, should be publicly rewarded with tax benefits. A further step? b.) Recognize moral priorities by a new 10% luxury tax on gambling, including the profits secured by hedge funds for their clients.

III. Messages for Young People

Another lesson from reading Keynes correctly is that society should send stronger messages to

young people that we do want youthful “animal spirits” to migrate directly from sports competition into the economy. Too many students, in America and elsewhere, imagine a future of being hired by somebody else and today's large numbers of unemployed youth have few options. The current economic theory and societal message is that they should focus on their STEM education. The new (US) Common Core for public education can be quickly expanded to rebalance imaginations and add skills so that young people, naturally, also think about the option to join with friends to start and build their own companies. The traditional curriculums in other G-20 countries can be rebalanced to encourage self-starting motivation rather than authority-oriented instruction. (A visionary organization, the World Academy of Art and Science, has recommended such international rebalancing to support personal growth and goal-setting, project planning and management, leadership, and related psychological shifts and skills.) We give loans for college education: What about, in the G-20 countries, experimenting with $10,000 seed money loans to graduates to join with others to start their own businesses?

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A Proposal for the Government to Support a Universal Patient Medical Record.
From: "Michael R. McGuire" [redacted]
Date: Thu, April 30, 2015 5:25 am
To: pcast@ostp.gov

With personalized medicine and the greater use of the genome in medicine. I propose that the US Government provide support for a Universal Patient Medical Record the combines a patient's medical records and provides a place to store genomic information.

Personalized medicine will result in super specialization, with "centers of medical expertise" that provide specialized medical care that few medical organizations can provide. The center of medical expertise may later have to work with a patient's principal medical organization to provide follow-on care. The patient's complete medical history should be available to both organizations.

A Universal Patient Medical Record providing a combined medical record and medical history could be created without changing the functionality of current electronic medical record (EMR) systems. Services could be provided to accredited EMR systems over a secure healthcare network that could provide a summary of clinical information for a patient including past encounters, current medications, significant health problems and other summary information. For a particular encounter, a physician could request medical records for the encounter in which case the information could be retrieved from the EMR system for the medical organization.

Large medical organizations may have their own EMR systems, while other medical organizations would have EMR system capabilities through service providers providing EMR services similar to the way electric utilities provide electricity to customers.

In order to implement this approach, there would need to be government support: Perhaps to control development of the services, to require EMR systems to incorporate the services and encourage development of utility EMR systems.

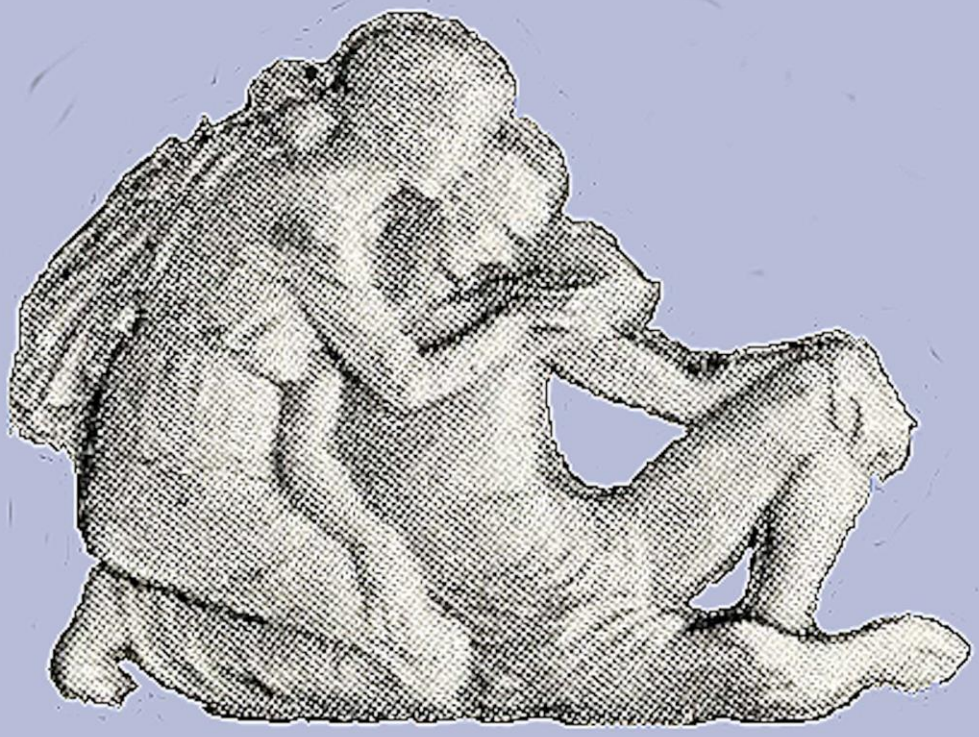
I have just published a Kindle eBook that describes in detail how to accomplish this task. The book is titled "Disruptive Medicine: An Educated Patient's Perspective". I will send an excerpt of the book to anyone who requests it.

Independent of personalized medicine and the use of genome information in medicine, creation of a Universal Patient Medical Record would greatly improve medical care.

Michael R. McGuire
[redacted]

Disruptive Medicine:

An Educated Patient's Perspective



Michael R. McGuire

Disruptive Medicine

An Educated Patient's Perspective

MICHAEL R. MCGUIRE
[redacted]

Preface

Disruptive medicine I define as “changing medicine in a dramatic way to greatly improve the way medicine is currently practiced”. I believe that part of disruptive medicine is changing patient care so it is no longer centered around a physician or medical organization, but centered around the patient—this enables the long-term, as well as the short-term, care of patients to be the primary thing that is improved. Therefore, I think it is entirely appropriate for me as a patient, rather than a physician, to describe how this improvement of medical care could be done.

I am not a medical doctor. However, I do have experience in the area of medicine, developing clinical software systems for a very large Health Maintenance Organization. This involved interviewing many physicians, nurses and ancillary support personnel. I also served as a patient advocate for my paraplegic wife, and I am, of course, sometimes a patient myself. These experiences, I trust, qualify me as an “educated patient”.

All medical examples in this book are taken from my experiences as a patient or patient advocate, from mini med school lectures I have attended at UCSF, from educational course videos I have viewed, and from peer-reviewed scientific articles I have read. Some of the information presented in this book is based upon early research and theoretic ideas that may or may not turn out to be useful in the future prevention, treatment or diagnosis of disease.

Because I am not a physician, none of the examples, suggestions, figures or tables in this book should be used for diagnosis, treatment or prevention of any disease. The reader should consult with medical professionals for all medical-related decisions instead.

This book is *not* meant to be the *end all, be all* on how to improve medicine but the *start of a discussion*.

1. Some Problems with Medicine and How They Can be Fixed

Current medicine suffers from the following problems:

1. **Comprehensive recording of patient care:** There is no combined patient medical information recording care in all medical organizations.
2. **Patient/physician communication:** Communication between physicians and patients is inadequate.
3. **Coordination and continuity of care:** Care is given one encounter at a time with little coordination and continuity of care.
4. **Measuring quality of care:** Information is lacking to evaluate quality of medical care.
5. **Utilization of medical resources:** Medical resources (other physicians, pharmacies, clinical laboratories, nurses, etc.) are inefficiently utilized.
6. **Managing patient medications:** Patients may be taking inappropriate medications.
7. **Quality of life:** Sometimes preserving and restoring quality of life is more important than attempted cures or prolonging life.
8. **Early treatment diseases:** Currently, medicine is not organized to take care of the likely possibility that some diseases will need to be treated before there are clear symptoms of the disease.
9. **Personalized medicine:** The current medical infrastructure may be inadequate to support personalized medicine.
10. **Public health information:** Public health information is not efficiently used for medical care.
11. **Protecting patients:** There is no one to protect patients from bad medical decisions.
12. **Security:** Patient information may be vulnerable to hacking.

13. **Using existing solutions to solve problems with medicine:** An analysis of the problems with medicine should be done first before developing solutions to the problems. Just because a solution currently exists does not mean it is the best solution, or even a good one, although it may be.

In order to fix these problems there must be additional computer systems and the way medicine is currently practiced must change without being burdensome to medical personnel.

1.1 Comprehensive Recording of Patient Care

A patient's medical information may be scattered across many medical organizations. There is likely no complete medical history for a patient.

Many medical organizations are implementing electronic medical record (EMR) systems. I propose that a summary of a patient's medical information be collected from these systems, which I call a *clinical summary*, which would include information such as all significant medical problems, all current medications, and all past encounters.

For each encounter, medical record documents for the encounter could be retrieved for view from a medical organization (or from some other storage location).

I propose that EMR system manufacturers would still have their own systems, but they could use services available over a *secure healthcare network* to provide information for the clinical summary and retrieve information from the clinical summary for use in their EMR system.

Large medical organizations could have their own EMR systems as they may require such systems to interface with their own specialized encounter (hospital and outpatient) systems, pharmacies, clinical laboratories, internal referral systems, and other clinical systems. All other medical organizations, large, small or medium, would have the capability to use EMR systems that would serve like an electric utility, each such EMR system providing EMR services to many medical organizations. See figure 1.1.

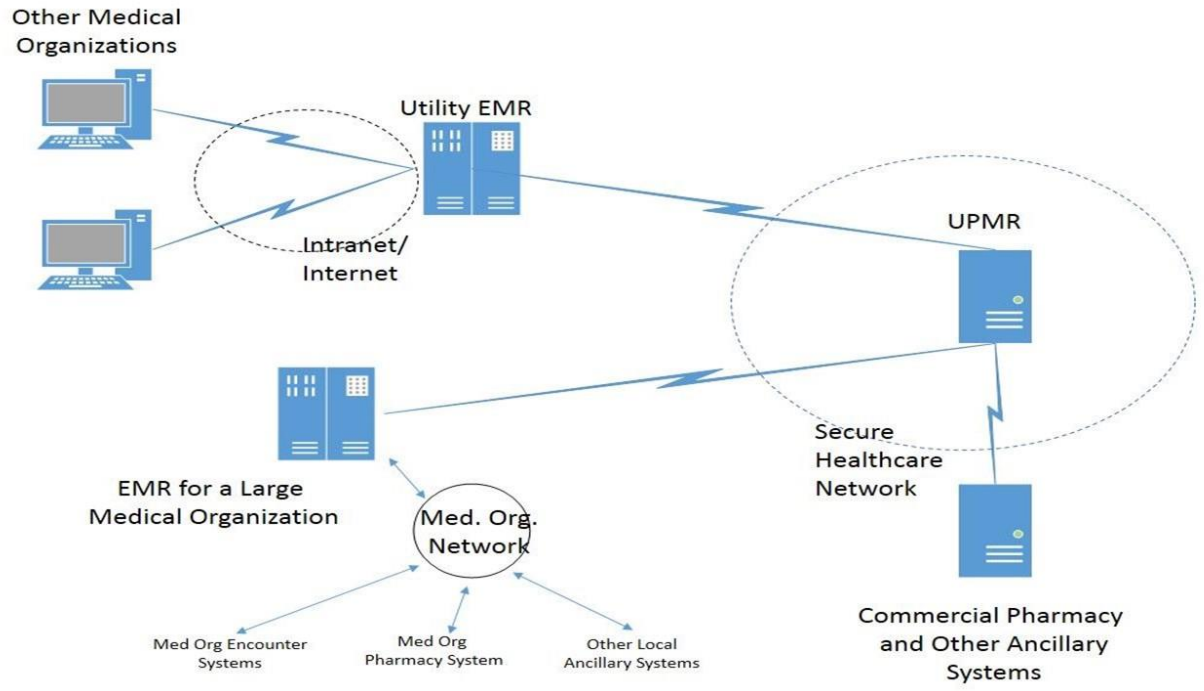


Figure 1.1 **Large organization and utility EMR s**ystems

The clinical summary available through the secure healthcare network would be the only reliable complete source of certain types of medical information. For example, the clinical summary would be the only reliable source for all the current medications a patient was taking, and thus, this information would enable comprehensive checking of drug-drug interactions when a new prescription is made for a medication.

Capabilities provided through the secure healthcare network described here have been termed a *Universal Patient Medical Record (UPMR)* [1,2]. **The UPMR is a general and flexible way of providing the interoperability of EMR systems.**

Other capabilities described later in this chapter may also be part of the UPMR. The UPMR is also a logical place to store information on a patient's genome where it could be stored once and be available to all medical organizations through their EMR systems.

1.2 Utilization of Medical Resources

There is inefficient utilization of the many medical resources that exist.

Most medical organizations do not currently have the ability to make orders and referrals directly to outside medical organizations. Services that could be provided through the secure healthcare network could include the ability to order medications through outside pharmacies, to make outside referrals, to schedule a clinical laboratory test that has been ordered by the physician, and to initiate other orders to outside medical entities. Results, such as notice of fulfillment of a prescription or the results of a clinical laboratory test, could later be returned through the secure healthcare network.

In addition to ordering and referral capabilities, the secure healthcare network could also provide controlled scheduling of outside resources. Medical organizations having special medical expertise or excess capacity of equipment such as MRIs could make available schedules of time when consultation time or equipment time is available for other medical organizations.

This scheduling of outside medical services I predict will become increasingly important in the future, as with the increased complexity of medicine there will be more medical organizations that provide very specialized services. I call these organizations, *centers of medical expertise*. For example, one medical organization has successfully cured some forms of macular degeneration by the use of embryonic stem cells, which requires very specialized medical expertise. [3]

Other better utilization of resources does not involve computer systems. Physicians often serve as dictators, especially when it comes to nurses. Many nurses, especially home healthcare nurses, see patients on a continuing basis not just intermittently like the physician does and have a different perspective on care and outcomes than the physician. This expertise should be utilized by the physician. For example, a home health wound care nurse has a better perspective on the prognosis for a pressure ulcer than physicians.

1.3 Measuring Quality of Care

Quality of care is currently not measured well.

One way of evaluating physicians, evaluating the effectiveness of major medical procedures and providing information for the prognosis of a disease is described here:

For a patient's medical condition, later associated medical conditions, procedures and other interventions (such as medications) and patient-determined outcomes (based upon disability measures) are recorded, together producing what I will call a "disease history". This disease history would most often be recorded over a long period of time.

For example, an individual was in a motor cycle accident where bones in his knee were fractured. He had an operation to repair the knee. For a number of years, his life returned to what it was before with no disability, but over time he could not run anymore, later he developed arthritis, later he walked with a limp, later he took narcotics to ease the pain, later he had a knee replacement that essentially cured his arthritis, and shortly thereafter he had to have another surgery to fix problems with the knee replacement.

In order to "connect the dots" between the medical condition, later medical condition outcomes, patient-identified outcomes, and interventions, I propose that after each encounter, a physician would be asked by the EMR system if a new medical condition or intervention is associated with the original medical condition or a preceding medical condition or procedure. Along with the patient-identified outcomes for the medical condition recorded periodically, this would develop the required disease history.

Using the disease history, bad outcomes as a result of interventions could be identified. This would (1) enable physicians to be identified who have a significant amount of bad outcomes as result of procedures they performed, (2) enable different interventions for the same medical condition to be evaluated and compared based upon later outcomes, and (3) provide information that could be combined with other patient information to enable more accurate prognoses for medical conditions.

The book *Unaccountable* [4] describes how identifying poor outcomes for major procedures in medical organizations has successfully resulted in medical organizations improving their medical practices.

1.4 Coordination and Continuity of Care

Care is now given a single encounter at a time, with little coordination and continuity of care.

The book *From Chaos to Care: The Promise of Team-based Medicine* [5] identifies a problem with current patient care where a patient is seen by one physician who develops a care plan or diagnosis and then sees another physician who develops a completely different—possibly contradictory—care plan or diagnosis for the same medical problem. No one physician was taking responsibility for the care of the patient, and no physician was doing a thoughtful analysis to determine proper care. There was no coordination and continuity of care. Described here is an approach to overcome this problem.

I propose that two data structures be developed, a *case* and an *episode of care*. The purpose of these structures is to contain the following information:

- Medical condition or procedure for a patient
- Managing physician for the medical condition or procedure
- Care plan for the medical condition or procedure
- Encounters where care is given for the medical condition or procedure.

After a trusting relationship is established with the patient, a managing physician would take responsibility for the care of the patient for the medical condition or procedure. He or she would develop a care plan for the medical condition or procedure that would be applicable until it is changed, possibly lasting over many patient encounters, or in the hospital changing many times during an encounter. All other physicians caring for the patient would be obliged to follow the care plan of the managing physician except in case of emergent situations.

A non-managing physician could also sometimes serve as a physician providing a second opinion. In such a case, this information would be sent to the managing physician for evaluation along with the patient of what to do: incorporate the ideas into the care plan of the case or episode of care or to disagree with the analysis. Referring a patient to a specialist is one way for a non-specialist managing physician to get a second opinion.

A patient may choose to drop or change the managing physician at any time.

The difference between a case and episode of care is that a case would be for a long lasting or chronic condition, whereas an episode of care is for a condition that is expected to reach a resolution. For a case, there may be long periods of time where there is no managing physician, such as for the patient with a knee fracture who has no problems for a long time after recovery from his initial surgery.

A case or episode of care would insure consistency and coordination of care with one managing physician taking responsibility for care of a patient's medical condition. Other physicians could express alternative opinions that would be communicated back to the managing physician who then may or may not change her plan of care.

Cases and episodes of care could also be used to identify what I call *virtual organizations.* Physicians often recruit physicians in other specialties, who they may not necessarily commonly work with, to jointly provide care for a patient. For example, a patient may have developed septicemia from a deep pressure ulcer which goes all the way down to the patients' hip. The patient is admitted to the hospital, where the attending physician assigns a surgeon to remove the infection in the bone. A physician specializing in identifying microbes is assigned to identify an antibiotic to be administered to the patient. The patient is put on IVs both to raise his blood pressure and to administer the antibiotic. Because of the access of fluids, the patient has too much fluid in his lungs and finds it hard to breathe. The attending physician later orders a procedure to remove fluid from the patient's lungs. This virtual organization could be represented by a hierarchy of cases. See figure 1.2.

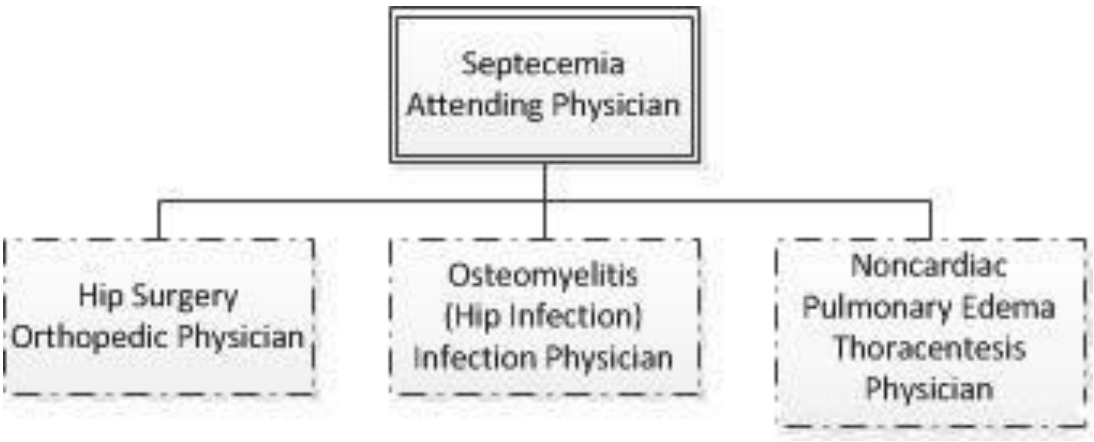


Figure 1.2 Episode of care hierarchy for a virtual organization.

Each physician, including the attending physician, would have a care plan for his episode of care. Although not replacing direct communication between physicians, when there is a change in the overall care of the patient, the other physicians may be informed. Conversely, when there is a change occurs in a lower level episode of care, the attending physician would be informed.

Virtual organizations could potentially also be used for care for a patient where the physicians are in different medical organizations. For example, as mentioned earlier, one medical organization uses stem cells to treat some forms of macular degeneration [3]; when a patient returns to her home medical organization, follow-on care done at the home organization could be supervised for a while by members of the medical organization where the procedure was performed.

For some high utilizers of medical care, there could be an *overall case* for all of a patient's medical care with a manager who may not be a physician. The purpose of such a case is to control costs of care for that patient while providing equal or better health outcomes. Whenever the patient comes in for care, no matter at what medical organization, the manager would be informed. This overall case could support Accountable Care Organizations.

1.5 Patient/Physician Communication

Patient/physician communication is often inadequate.

When a patient comes in for care, he usually receives advice. The patient may remember the advice for a long time or forget it the next day.

Conversely, when a patient describes her medical problem or herself, she may forget or be unable to tell the physician about important details that may affect her care. For example, when she is asked for a list of medications, she may not remember them all. If she creates a personal health record or lists her health problems on an information sheet, she may forget important information.

I propose three vehicles to enhance this communication between a patient and his physician:

- ***An analytic summary:*** Crucial information that a physician should know about, with a physician being informed at the start of an encounter (e.g., the patient is a T5 paraplegic).
- ***A Clinical summary*****:** The clinical summary as described earlier would be developed from information entered in the EMR systems and thus be more reliable than a personal health record or information sheet filled out by the patient. The clinical summary could be available both to the patient and physician providing care and thus enhance communication for both.
- ***A Self-care Checklist*****:** For an individual with a major but manageable chronic medical problem (such as paraplegia), it is much more productive to take measures to avoid medical problems than to treat them. A self-care checklist could identify a list of things the individual should do to avoid a medical problem (e.g., for a paraplegic to do lifts every couple of hours to avoid pressure ulcers) and could describe what to do when there is red flag (e.g., if there is redness of her skin indicating the start of a pressure ulcer to contact the physician).

The self-care checklist was an outgrowth of Atul Gawande's idea of having surgical checklists prior to surgery to insure that the surgeon does not forget do anything prior, during or after the surgery [6].

1.6 Managing Patient Medications

Patients are prescribed medications with little later review of whether the medications are still necessary or are causing problems.

A patient may be taking the wrong medications, unnecessary medications, the wrong dosages of medications, or medications that cause the patient harm. I propose that there be a *consulting pharmacist* who would review a patients' medications.

The consulting pharmacist would meet periodically with all patients taking a large number of medications. A physician could also refer a patient to the consulting pharmacist when a drug interaction or side effect is suspected. In conjunction with meeting a patient, the consulting pharmacist would be able to review the patient's clinical summary and associated medical record documents.

As another capability, when a prescription is made for a patient for a transient health problem, the physician could associate the medication with the health problem. When a physician identifies that the health problem went away, the prescribing physician could be informed, and the physician could consider "unprescribing" medications for that health problem.

1.7 Quality of Life

For psychological reasons, legal reasons and financial reasons, most physicians attempt to aggressively treat a patient's every disease and to prolong the patient's life. Most attempted cures or attempts to prolong life have down sides also and sometimes may not be necessary because the body has its own mechanisms for controlling disease.

One big down side of many treatments is that they may temporarily or permanently disable the patient, in essence removing the patient from living a normal life. Some physicians—in particular geriatric physicians [7,8]—rather than trying to cure every disease are instead attempting to preserve or restore the ability of the patient to function normally in life. I term this *functional medicine*.

Physicians should consider quality of life more and more often practice functional medicine. It could save money and may often be better for the patient.

Part of functional medicine may be “watchful waiting”, keeping track of a detected disease that has the property of being slow developing if it does progress. This requires establishment of a baseline and remembering to check on the status of the disease at later times. This is not possible without continuity of care.

1.8 Early Treatment Diseases

Today diseases are treated once symptoms become obvious. This may be too late to effectively treat some diseases.

It is likely that there are some diseases that cannot be treated once symptoms are obvious—Alzheimer’s may be one. Other diseases are treatable with serious complications for the patient if they are discovered when there are obvious symptoms. In the future, a diagnostic test might be developed to diagnose the disease at an earlier stage together with a successful treatment that could be used at the early stage.

If such is the case, then there could be several potential problems, including the following:

1. **Timing:** The timing of the diagnostic test and treatment may be critical for their success; for example, if the diagnostic test is done too early, then no useful results may result, while if the diagnostic test is done too late, then the treatment may be unsuccessful.
2. **Diagnostic test complications:** The diagnostic test might potentially cause complications.
3. **Treatment complications:** The diagnostic test might cause false positives, and the treatment may cause complications.

This situation complicates care: High risk individuals may have to be selected and others excluded so risks of the test and treatment do not result in overall poorer health of the community of patients. The individual must give his consent to the test and treatment. The individual may need to be brought in at the right time for the diagnostic test and treatment.

For each such disease, an algorithm must be developed to schedule and control these events, which might include selection of candidate patients, consent or non-consent of the patient, scheduling to bring in the patients at the right time for the diagnostic test and treatment.

1.9 Personalized Medicine

With molecular biology we may discover that a disease that we consider to be one disease is actually a number of different ones. Molecular diagnostics is the basis for personalized medicine in that it allows an individual to be treated for the precisely diagnosed disease [9].

In order to accommodate this more precise diagnosis and accompanying treatment, (1) current coding for disease diagnosis may have to be changed and (2) greater specialization of medical care may be required to provide for more complex diagnoses and treatments.

Disease Codes Disease codes we use today may be inadequate for personalized medicine. In the future, we may need additional biomarkers, which I call *disease biomarkers*, to describe the disease so the correct treatment can be selected. This is currently the case with breast cancer: Breast cancer is categorized as to whether the tumor is estrogen positive or negative, progesterone positive or negative, and HER2 positive or negative with different treatments for each [10].

As another example, frontotemporal dementia is known to have three different disease pathways. It is then possible that in the future there could be three different treatments for the disease [11].

Super specialization Because of personalized medicine and the resulting greater complexity of diagnosis and treatment, there is likely to be a greater number of "centers of medical expertise" needed, each supporting diagnosis and treatment of a particular disease. Such medical care, more often than today, would include care in a different medical organization or even in a different geographic location in the

country or world. Referrals, scheduling and follow-up care would become more complicated, being across medical organizations.

Some of the ideas presented here may help support these changes: outside medical organization referrals and scheduling; and virtual organizations.

1.10 Public Health Information

Public health and medicine need to more quickly exchange information.

Using medical information sent to the UPMR by physician entrance of diagnoses at EMRs, public health agencies could record the incidence of selected diseases by geographic location of the patient (home address, work address, school address). In turn a physician could be alerted about any patient who comes in for care who resides or frequents an area with a high incidence of one of the selected diseases. For example, asthma might be considered as a differential diagnosis in a patient with respiratory problems who resides near a port area where there is a high incidence of asthma.

1.11 Protecting Patients

Patients are not protected against medical mistakes.

The following bad things could happen to a patient:

1. A physician makes a medical mistake
2. A patient makes a decision based upon emotions that is not in his best interest
3. A family member makes a decision that is not in the best interest of the patient.

Advice directives and POLSTs are made to protect against the latter. The physician has a responsibility for the second, informing the patient of the consequences of her decision. How can a patient be protected against physician mistakes?

I propose that whenever a patient enters the hospital with a critical illness that the patient have the option of having a patient advocate. A *patient advocate* is “a person who serves as a liaison between a patient and that patient’s healthcare providers in order to improve or maintain a high quality of healthcare for the patient”[12]. A patient advocate should have some knowledge of medical care.

Ideally a patient advocate would be a member of the patient's family, but if none is available or none with the requisite medical experience, I propose that there be an independent group of volunteer patient advocates, perhaps medical students or retired nurses.

1.12 Security

With the hacking of the Internet, patient information that is available through the Internet is vulnerable to being stolen. The following is my approach for insuring the security of a patient's combined medical information.

An EMR system will use services provided by the secure healthcare network to get a patient's combined medical information. Only certified EMR systems would have access to the network.

Through an EMR system, a physician or consulting pharmacist caring for a patient will have access to the patient's combined medical information. At the time of an encounter, a patient may get a printout of her combined medical information, which the patient may or may not then choose to share with a patient advocate or others; a parent of a minor should also be able to get this printout, possibly excluding information restricted by law (e.g., information on abortions); the patient would not have on-line access to the EMR system.

A medical organization may, if it chooses, provide a member of its medical organization with selective access to the member's medical information over the Internet, with the responsibility for security entirely up to the medical organization. This would be the only public access to patient information and the only point of vulnerability to outside hackers.

1.13 Using Existing Solutions to Solve Problems with Medicine

The solutions to problems with medicine presented here were developed by me going through a process of requirements analysis. I define *requirements analysis* in the current context as (1) identifying how medicine currently functions, functions badly, and could function better; (2) identifying how medicine is likely to change in the future; and (3) using this information to determine future best practices. Only then should solutions be developed to implement these best practices, as currently existing solutions

(e.g., EMR system to EMR system interoperability) may not be the best or even good solutions, although they may be!

To truly identify improvements to medicine, this process of requirements analysis should not be done by one person, but by the medical community, governments, patients, public health, researchers and other interested parties as a whole. They should start from scratch in their analysis and determine the best solutions, not necessarily the existing ones!

To paraphrase Robert F. Kennedy, "There are those that look at things the way they are . . . I dream of things that never were . . ." [13]

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