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The Journal of the Missouri State Medical Association www.msma.org January/February 2015

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Missouri Medicine

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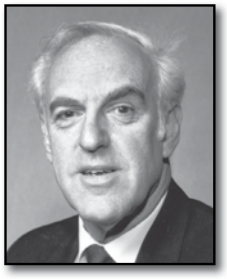
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Bigger But Not Better: Hospital Mergers Increase Costs and Do Not Improve Quality

by Arthur H. Gale, MD

From the very beginning of health system reform, hospitals have done everything in their power to form mergers, create monopolies, and avoid competition. Hospital mergers increase medical care costs and do not improve quality.



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The final verdict on hospital networks is in. Despite all of the self promoting ads in the media, hospital mergers increase costs and do not improve quality. The Federal Trade Commission's (FTC) Director of the Bureau of Economics recently stated that when hospitals merge they face less competition and charge as much 40 to 50 per cent higher prices than if they had not merged or consolidated. The FTC has been challenging hospital mergers in the courts for some time and after a string of failures has won three cases over the past two years. It has also won its first-ever litigated case challenging a health system's acquisition of a physician group.[1] These court wins by the FTC have caused considerable anxiety among hospital executives contemplating mergers.

In 2012 the Robert Woods Johnson Foundation conducted an exhaustive review of studies on hospital consolidation. Their conclusions were:

- ***Hospital consolidation results in higher prices.*** This is true across geographic markets and different data sources. When hospitals merge in already concentrated markets the price increases can be dramatic.
- ***Physician-hospital consolidation has not led to either improved quality or reduced costs.*** Studies find that consolidation was primarily for the purpose of enhanced bargaining power with payers, and hence did not lead to true integration. Consolidation without integration does not lead to enhanced performance.
- ***Hospital competition improves quality of care.*** This is true under both administered price systems such as Medicare and the English National Health Service, and market determined pricing such as the private health insurance market. The evidence is more mixed from studies of market determined systems, however.[2]

A recent study reported in *JAMA* of 4.5 million HMO patients concluded that "Organizations in California that are owned by local hospitals or multihospital systems incur significantly higher expenditures per patient than integrated medical groups and IPAs owned by participating physicians."[3]

America's Health Insurance Plans (AHIP), the lobbying and trade group for health insurers has proclaimed "Consolidation promises greater efficiency, but all that ever materializes is greater costs."[4]

One economist noted that there have been over one thousand health care mergers and acquisitions since 1994. He noted that they "muffled competition and caused higher prices." He also called Accountable Care Organizations (ACOs) an "anticompetitive sham" dominated by hospitals implying that these organizations will further exacerbate spiraling health care costs.[5]

One might ask what took policy makers, scholars, and researchers so long to figure out that hospital mergers would increase not lower costs. The warning signs were present from the very onset of merger mania.

When the former Jewish Hospital of St. Louis merged with Barnes Hospital in 1996 members of the Board of Directors told the medical staff (including myself) that the merger would "improve efficiency through economies of scale." Shortly after the merger it was clear to any interested observer that just the opposite was happening. Barnes Jewish quickly developed a costly administrative bureaucracy, tore down perfectly good buildings replacing them with new often unnecessary lavish structures, spent enormous sums on marketing, and purchased physician practices at above market value on which they lost money.

Now almost two decades after the board told the medical staff about the merger Barnes Jewish Hospital has become BJC Health Care. It owns 12 hospitals, has 26,000 employees, owns 3,378 physicians and has net revenue of approximately $4 billion. BJC is not unique. It is just one of many similar hospital mergers have occurred throughout the U.S.[6]

After the Barnes Jewish merger I wrote a number of articles contending that the basic reason that hospitals were merging was not to improve efficiency and lower costs but to form monopolies and increase prices. I also wrote about how the Federal Trade Commission played a pivotal role in orchestrating this system that allowed hospital monopolies to flourish. These articles were compiled into two books.[7]

Since the FTC has been successful in preventing mergers in only three hospitals, what can be done with all of the hospitals that are already merged? Or as one pundit put it, "What can be done now that the horse has already left the barn?" The answer is probably very little. Hospitals are among the most powerful lobbying groups in the country.

It is quite understandable for physicians to feel little sympathy for the FTC in its fight against hospital mergers. Its actions are too little and too late. Furthermore the FTC has a track record that has been fundamentally hostile to physicians. The FTC successfully sued the American Medical Association in an administrative law court where it acted as prosecutor, judge, and jury and removed one of the AMA's Principles of Medical Ethics so that it could impose its own version of "free market competition" on the medical profession. At that time there were many who said that the FTC "was out to get the doctors."[8]

This harsh evaluation of the FTC was confirmed by the FTC's subsequent actions. The FTC vehemently opposed legislation introduced in Congress and backed by the AMA that would have allowed doctors to collectively bargain. The FTC position on doctors was clear. The FTC stated "Physician collective bargaining leads to higher prices and is unlikely to likely to result in higher quality care."[9]

Finally when clinically integrated physician-owned groups tried to bargain with health insurance companies like hospital integrated systems do, the FTC signed more than 30 consent agreements involving price fixing by groups of physicians, which in its opinion were not properly integrated or engaged in substantial risk sharing. It is not clear what risk sharing is and the AMA tried unsuccessfully to get the risk sharing requirement removed.[10]

When a new drug or a new procedure is introduced into medicine studies are done to determine their effectiveness. Lamentably, the FTC doesn't operate in this fashion. The FTC has based its policies on its own arbitrary, rigid, self-made and often biased rules which carry the force of law. The FTC never conducted studies to determine whether clinically integrated physicians groups might be more cost effective than hospital integrated systems. The recent study in *JAMA* of 4.5 million patients, which showed that hospital-owned organizations have significantly higher costs than physician-owned integrated systems or IPAs fundamentally undermines the FTC position on physician run organizations.[3] The FTC should have undertaken similar studies years ago.

Competition has been the guiding principle in health system reform over the past three decades. The theory was that through competition health care costs would decrease and quality would improve. This theory hasn't been proved or disproved because it hasn't been tried. From the very beginning of health system reform, hospitals have done everything in their power to form mergers, create monopolies and avoid competition.

The United States is under tremendous pressure to reduce health care costs. Now that the truth about hospital mergers as a major driver of health care costs has been exposed we'll have to wait and see if anything is done to correct the problem. It is doubtful that antitrust lawsuits by the FTC alone will have much impact.

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Why Should We Be Politically Active?

by Brian Biggers, MD

The House of Medicine is our profession and the only one who is going to fight for it is us.



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As physicians we have spent much of our lives crafting our trade to help diagnosis and treat patients. As the years pass we encounter more barriers in actual treatment, more time restraints, decreased compensation and less oversight. At the end of the day, many physicians feel that they have little left over to give to additional organizations or even to be politically active.

In recent years several important issues have come up in Missouri. The most concerning and greatest priority is tort reform. Most of us are familiar with the overturn of non-economic caps in the *Watts vs Cox* case. This ruling set the state of Missouri back. Prior to the 2005 ruling to limit non-economic caps there were places in the state which were in dire distress. Certain specialties such as neurosurgery and gynecology had such expensive malpractice premiums that many of these physicians were forced to leave the state. After the cap, many physicians were brought into the state. Since that time 1,000 new physicians were added. This gain in physicians is again threatened if the cap is not returned. Earlier this year a White Coat Rally occurred at the state capitol hosted by our own Missouri State Medical Association. Those attending were able to witness the bill being passed after the third reading in the House of Representatives. Even though the turnout was decent, it is far from what it should have been. I attended, and told many of my colleagues that attending the rally would be much more cost effective than any amount of revenue a physician could obtain from working that day. If you couldn't attend then, plan to attend the next White Coat Rally in spring 2015.

A second concern is the encroachment on our profession by physician extenders. Every year nurse practitioners attempt to gain further strides toward independent practice. Some argue that nurse practitioners can do up to 80% of what physicians do. It is the other 20% that is most concerning. There are many excellent nurse practitioners, as well as, other medical practice extenders. Not all want independent practice.

There are several problems with independent practice. First, the training they receive is far less than a primary care physician. Second, there is no standardization in their training. Third, clinical training is based on the number of hours and not the overall experience. There is not a training period after schooling. Physicians go through residency programs for at least three years after schooling. There should be similar criteria for physician extenders. To give independent practice to anyone straight out of schooling, physician or nurse practitioners, is dangerous.

At this stage the practitioner still cannot appreciate what they still don't know. Nurse practitioners are still governed under the Board of Nursing. This is one issue that there will not be any consolidation. The Board of the Healing Arts and the Board of Nursing

are governed differently. Another point which may make the nurse practitioners stop and think is that they would be under their own malpractice insurance, not under a physician.

Several other important issues are lurking as well including prescription drug monitoring where a physician can look up the amount of narcotics a patient has received. I fail to understand why certain physicians are against this, and by the way, we are the only state in the United States not adopt such a system. As I have said before Missouri is the Show-Me State, but we have showed the U.S. little on this subject. The regulation of pseudoephedrine is being proposed. Once again there has been opposition by certain physicians. Do we not want to stop being known as one of the top methamphetamine-producing states?



Greene County Physicians and supporters lend a hand during the 2014 White Coat Rally Day.

Additionally, we have the lowest tobacco tax in the United States. It is time to get up to speed with the rest of the nation. Those funds could go to support Medicaid which Missouri has failed to support. It is not that most of us are opposed to Medicaid expansion, but that we are opposed the expansion in its current state. There are many patients who need this, but there is also a large amount of abuse present. A system that is government supported, but also makes the patient have a stake in his or her own health would make sense. Even making a patient pay a co-pay of $1 with emergency room or office visits has been shown to change behavior and make patients think about their visit to a physician. Almost all physicians are for expansion once reform occurs.

In 2014, many new challenges exist in medical practice. There are still the multiple problems with the Affordable Care Act. Besides this issue we are being faced with new challenges every day. Recently we have the threat of the deadly Ebola virus on our shores. Recently our president appointed Ron Klain as the Ebola czar. The president's appointee has no health care experience.

So, how can we be more politically active? The first is to join our local and state medical societies. Many physicians fail to see the benefit of these societies. A simple way to see the benefit is to review the legislation that the Missouri State Medical Association supports or fights every year. All physicians receive benefit for the ones who support the fight. Issues, like those mentioned above, keep our colleagues and elected officials in the trenches trying to either get a good bill passed or a poor bill stopped.

Find out who your local elected officials are. Let them know where you stand on the issue and why. The tort reform bill two years ago did not pass. Why? One legislature stated that there were not as many physicians at the White Coat Rally as expected. It did not seem like the issue was that important to physicians, or more would have come to the rally to support the tort reform bill. We have to be present and speak out.

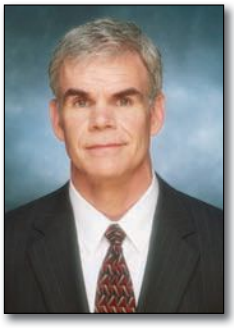
It is also important to contribute. The MSMA has lobbyists just like every other organization. In the past two years the American Association for Justice, (formally known as the Association of Trial Lawyers of America), gave contributions for lobbying of $2,090,000 in 2014 and $3,770,000 in 2013 in the United States. Other special interest groups give as well. One interesting fact is that in 2013 the general assembly received $20,853.97 worth of non-alcoholic beverages from the Missouri Beverage Association. This group lobbies against the regulation on sugary beverages. Interesting information considering we are in a fight against obesity.

As physicians the time is over to sit around and complain about how health care is changing. This is our profession and the only one who is going to fight for it is us. We may not agree on all issues, but there are many we can agree on. I have said before, but I'll say it again, in life you can be one of three things, inactive, reactive, or proactive. Which one are you? **MM**

Accountability: Crossing the Barriers

by Jeffrey G. Copeland, MD

In theory, it is the right thing to do to make life better for our patients, but there are a lot of big barriers. Let's think big.



Jeffrey G. Copeland, MD, MSMA member since 1988, is a plastic surgeon in St. Charles, Missouri, and President of the MSMA.
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I had the fortune to attend the St. Louis Business Health Coalition Annual Meeting in mid-November as one of about three or four independent physicians out of a crowd of about 400 people. That, in and of itself, is a little embarrassing for our medical community, but this meeting is really directed, supposedly, to members of the business community. I paid my way and did not advertise my office with MSMA. I wish more non-system employee physicians had been there. The meeting really had a lot of substance that the medical community should know about and consider.

The keynote speaker was James L Reinertsen, MD, an internist and rheumatologist who now operates a consulting firm and who has extensive experience in health care policy, both in the U.S. and in overseas in England and Scandinavia. He has worked with the Institute for Healthcare Improvement and has been a CEO of health care systems. He has been around. This discussion is derived directly from his talk, but his points were excellent and I think they bear repeating for the wider benefit of the state medical community. In that sense, I am serving as a reporter.

He recounted some very salient thoughts regarding our current health care scenario. One part of this discussion related to the importance of patients having a real stake in their own health care decisions. He recalled his experience with a rural community in another country where the farmers bought "farming insurance," a term with which I was unfamiliar, but I did grow up in an agricultural community, so I could understand that it referred to insurance that was as inexpensive as possible (with a high ceiling before the beneficiary received any insurance benefit) and that the farming families were very interested in the specific costs of the care that they had to cover before getting any insurance coverage. That meant that the local health care services had to prove their value and to have clearly defined costs. One could not explain "transparency" any more clearly (pardon the pun). Also, the concept of entitlement was nowhere to be seen in that world. The community took care of its own, but in a mutually responsible way.

It was noted that patients' principle desires are to know what is happening to them, what the future will likely hold, and if that eventual result can be changed in a positive way by medical care. He

also said that individual physicians, hospitals and teams have different cultures and that those features, which produce quality of care that is better or worse, are much more important that which insurance a patient has. The people taking care of them will provide the same quality they always do, regardless of payer. I will interject that that is the basis on which different physicians and systems should compete, rather than network size or some other business characteristic or relationship. Finally, he said that spending money educating patients about health and health care so they can be smart consumers is more valuable/important than putting money into delivery of care or insurance pockets.

His message was sophisticated, but really boiled down to the fact that when patients are not artificially insulated from costs (as with first-dollar insurance) they are good, thoughtful consumers, and can and will drive down the cost of care. This smacks of market economy. He made the funny comment that health care in our country is like the toy industry where the beneficiary is not the payor. His point was, I believe, that it should be more like the farm community and less what it is like in general.

Dr. Reinertsen also said that you can pick which things you chose to live with. In the case of one Scandinavian country, they decided that no one would face financial ruin from medical care costs. In trade, they gave up some things, but the overall outcome was better. Our country has a high percentage of bankruptcy from those costs, which can ruin lives as well, and our health care in general doesn't always stack up well against that of other countries. (We are the best at many things, but not always at "population care.")

His next points were directed to the elements and challenges of effective leadership. He made reference to a popular TedMed presentation, the "Wonder Woman" talk by Amy Cuddy, a social psychologist, where taking a leadership posture actually promotes leading. This is interesting physiology and has real implications in life. It can even have implications on whether a lawsuit is filed against you.

There was discussion about one of my favorite topics: safety, and what really has an impact on that. A federal OIG study in 2011 revealed that a hospitalized patient has as high a risk of an "accident" as a mountain climber. The harm can be the result of delayed diagnosis, poor care coordination, overuse of care, complex procedures done in facilities with low volume for those procedures, night-weekend-holiday care or culture that de-emphasizes rules and includes failure to speak up. This extended to the EMR. His comment about meaningful use is that it is more about documentation and billing than better, safer clinical care. As has been repeatedly said, the "high fiber" record often obscures or doesn't even include the "story of the patient." This can have a major impact on patient care and outcomes. The metrics we chose to evaluate "safety", or for that matter a wide variety of other aspects of care, are often quite imperfect and can be misleading. As leaders, we need to keep these issues in sight.

Along the same lines, it was noted that "provider consolidation", i.e., acquisition of practices by systems to become larger, rarely has a positive impact on quality of care or costs, but does make it easier for the system to negotiate more lucrative contracts and agreements. This is not something that satisfies the Institute for Healthcare Improvement's "triple aim" of better patient experience, better population health outcomes, and lower per capita costs of care.

Burdensome back-office administrative requirements were also cited as useless in improving care or saving money.

Then there is the issue of costs. There are multiple examples of egregious billing for physician and hospital care, which insurance companies occasionally actually pay As an example, the prosthesis and associate care for a below-knee amputee costs about $80-100,00 in the U.S. but about $13,000 in Belgium. This is crazy and indefensible. And, hospitals and employed physicians receive a substantial premium for the care they deliver, not because it is different, but because they have a higher negotiated or allowed rate.

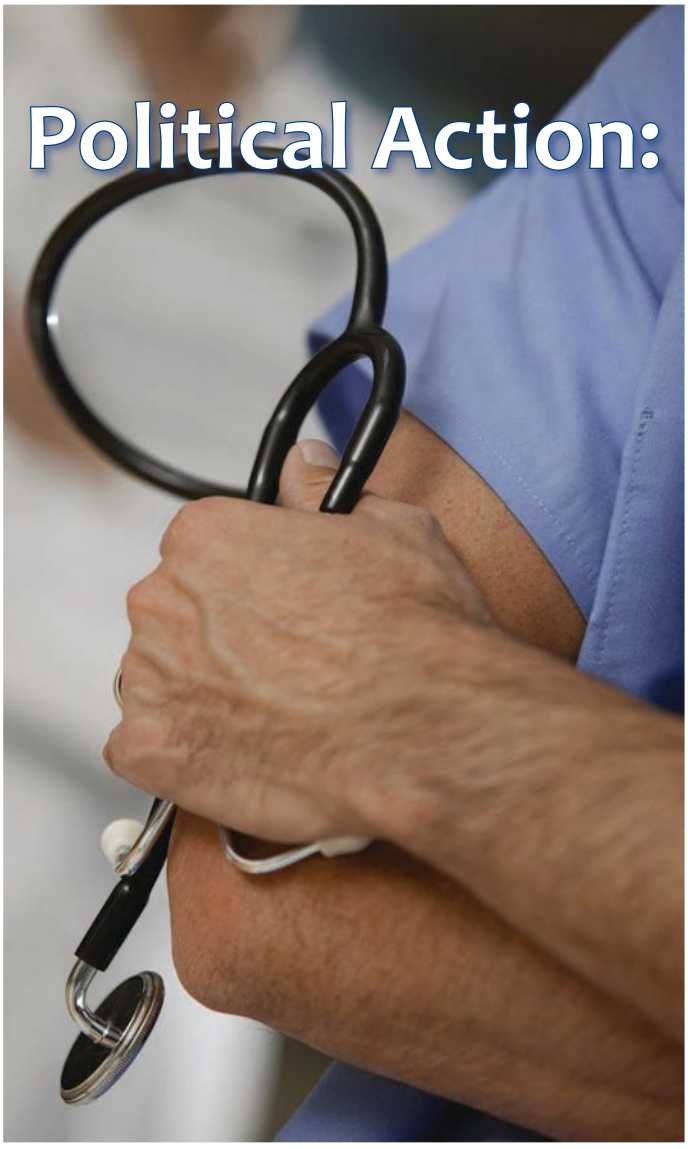
A final observation about a problem with our current situation is that we physicians and others involved in providing care are in the transition zone between getting paid better as we do more volume and getting paid for value, which is where we prosper

when we accomplish good health with less, not more, volume. If we are doing our job, people are healthier and consume less care. This concept is being driven by the current high costs of care which are held to be unsustainable, Obamacare and the associated ideas of value-based purchasing, ACOs, risk contracts and the individual insurance market. It is likely that some of these constructs are fatally flawed, but some may work well. It is a tough concept for us to try so hard to stop doing what we have always worked so hard to do. In this world, hospitals are considered successful if they are empty. In a sense, we are supposed to work hard to put ourselves out of business. It is unrealistic to think that we will completely eliminate most of the need for health care, but I think it is an appropriate goal to work to get the result of making health enough better that we don't need so much capacity. In that situation, we could get along well with less of everything. And along the way, we could shed some major bureaucracy. Good riddance.

It seems clear to me that we must look hard at these issues and embrace the good parts which strive for better patient care. It means major power shifts which are especially hard for those in control. It is imperative that physicians are leaders in this whole business because we have the knowledge of health care that can make this happen. That does not mean that we can cling to old concepts about reimbursement and control. In some real ways, everyone but the patient may have to take some "hits." Hospitals, insurance companies, employers and physicians all have choices to make to either swim upstream or to try to accomplish goals which really are the manifestation of successful provision of care.

If we can re-order priorities and change the culture regarding health care (that's a tough one) we might come out with something of which we are really proud. In theory, it is the right thing to do to make life better for our patients, but there are a lot of big barriers. Let's think big. **MM**





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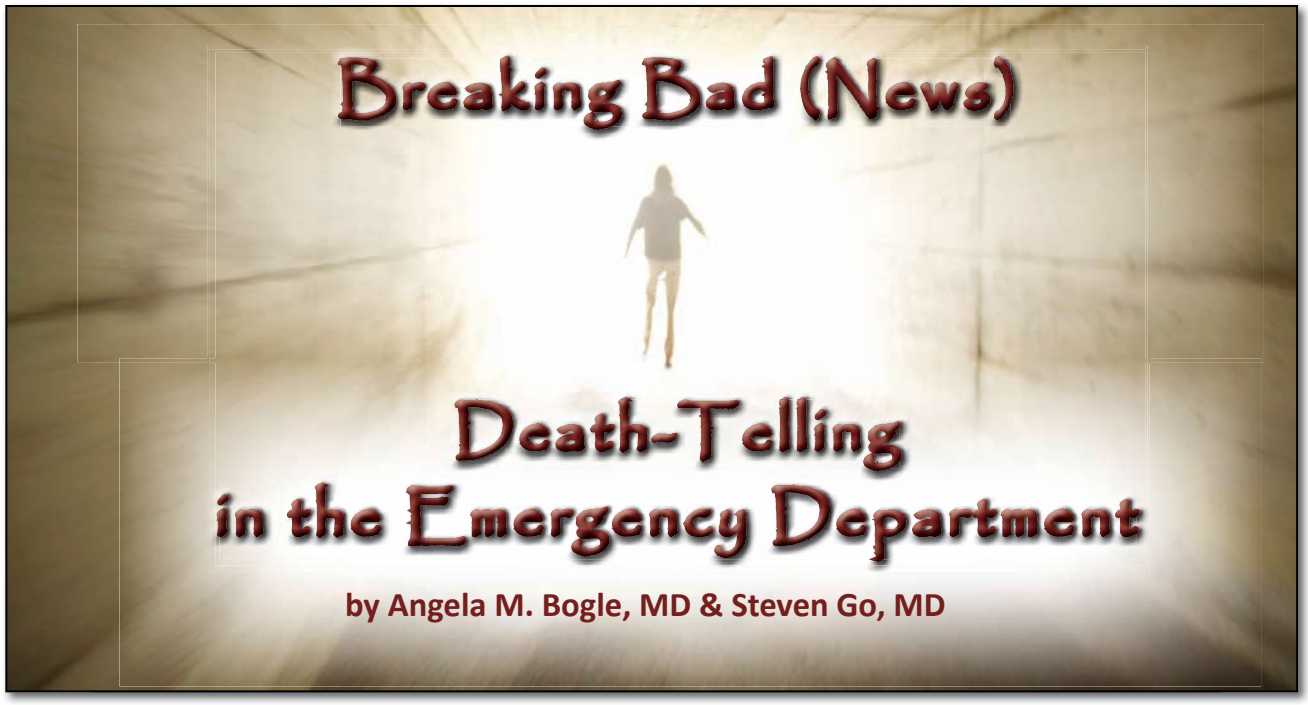
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Breaking bad news is one of a physician's most difficult responsibilities and is highly stressful for all involved parties, especially in the setting of sudden death.

Abstract

Many physicians struggle with death-telling in sudden death. Families can be negatively impacted by suboptimal death-telling. Appropriate preparation and education can make death notification less stressful for the physician and may help decrease the development of pathologic grief in the surviving family members that can occur when death is unexpected. Although still controversial, there is a growing body of evidence that family witnessed resuscitation may be beneficial to the grieving process and desired by the public.





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A previously healthy 21-year-old male comes to your community emergency department (ED) for a cough that started 4 days ago. He denies fever, shortness of breath, and chest pain. He does admit to a remote history of drug abuse. He states he is feeling "OK" and is only here because his family insisted he come because they were worried he might have pneumonia. His vital signs are normal and he appears well; therefore, he is triaged to the waiting room. About 30 minutes later, the patient complains of shortness of breath and he is brought back to an exam room. The patient is now hypotensive, tachycardic, and pulse oximetry is noted to be 87% on room air. A chest x-ray reveals severe pulmonary edema and an EKG shows ST segment elevation in multiple leads. The patient is taken to the cardiac catheterization lab by the interventional cardiologist, who makes the diagnosis of a ruptured aortic valve due to damage from endocarditis. The patient is returned to the ED to await emergent transfer to a tertiary facility; however, the patient rapidly decompensates and a Code Blue is called. Despite the absence of return of spontaneous circulation, resuscitation efforts are prolonged while the ED social worker attempts to contact the patient's family to come to the ED. Finally, the resuscitation is terminated and the patient is pronounced dead. Several hours later, the patient's elderly mother arrives and asks you: "What's going on with Mikey?"

"I'm sorry. Your loved one is dead."

These are the words no one wants to hear. Unfortunately, these are also the words almost all doctors have had to say at one time or another. Breaking bad news is one of a physician's most difficult responsibilities and is highly stressful for all involved parties, especially in the setting of sudden death.[1-3] The surviving family will never forget this moment, and will often recall the exact events of that day years later, including the manner in which the news was delivered.[2] Therefore, a suboptimal death-telling experience can have a negative impact on the grieving process.[4]

In addition, it has been well established in the literature that medical education is lacking in the area of death notification.[2,3,5] Lack of education and experience in breaking bad news contributes to the stress and discomfort of physicians, particularly in sudden and unexpected deaths.[6] Just as other procedural skills can be learned, so can death notification. Fears, including the fear of being blamed, of not knowing what to say, of not knowing how to cope with survivors' reactions or how to express their own emotions, can also be overcome with better education.[6,7] Therefore, this article will discuss various issues surrounding death-telling in the emergency department to help equip the reader with the skills necessary to deal more effectively with these difficult situations.

Grief Reactions in the ED

Death in the hospital usually occurs under one of two circumstances. The first is expected death, where family and friends are aware that the patient is in the dying process and have had time to prepare for the loss.[3] The other is sudden and unexpected death, which is the type most commonly encountered in the ED.

Grieving is a natural process that should be expected when a person loses someone important to them.[8] It also involves many different emotions and is different for everyone. Most people experiencing normal grief go through periods of sorrow, numbness, guilt and even anger.[9] These feelings gradually ease, and with time, acceptance and understanding of the loss is achieved.[8,9] The length and intensity of the grieving process varies from person to person, but for some people, the feelings of loss don't improve with time and can become debilitating. This is known as complicated or pathologic grief. Signs and symptoms of complicated grief can include intense sorrow, depression, suicidal thoughts, post-traumatic stress disorder and increased risk for conditions such as heart disease, cancer and high blood pressure.[2,9] The exact cause of complicated grief is not known and is likely multifactorial.[9] Factors that may increase the risk of developing complicated grief are the loss of a loved one due to an unexpected or violent death, including car accidents, murder or suicide,[9] as well as a lack of a support system for the surviving family members.[2,9] Additionally, lack of compassion or kindness from the health care team when delivering bad news may trigger a violent grief reaction.[2,3] These factors, compounded by intrinsic features of the ED (e.g., impersonal setting, time constraints due to needs of other patients, clergy or other support staff not readily available, lack of established physician-patient relationship) make death notification in the ED especially stressful and can also increase the risk of developing complicated grief.[2,5]

Death-Telling in Person

The medical literature consistently indicates that families of the deceased patient would like to hear the news from a caring and empathetic member of the patient care team.[3,5,6] This important responsibility generally falls to the physician taking care of the patient. Regardless of the clinical experience of the physician, the uncertainty and discomfort associated with breaking bad news can cause some physicians

Table 1
Suggested Guidelines for Death-Telling in Sudden Death

- Verify the patient's name and medical data
- Have support staff present if available
- Place family in comfortable, private room
- Look like a professional
- Introduce yourself and your role in the patient's care
- Sit or stand at eye level with the family
- Listen to what the family already knows
- Recap what has happened during your care
- Break the bad news directly but compassionately
- Allow time for the family to react
- Express sympathy
- Answer questions

Physicians should learn to view survivors as their patients too, and take necessary steps to reduce the potential complications of this life-altering event.

to disengage emotionally.[1] Perceptive family members of the deceased can often tell when a notifier is just "going through the motions", and this can have deleterious impact on the bereavement process.[6]

To help avoid these types of suboptimal interactions, physicians can take certain measures to improve the death-telling experience of the family. (See Table 1).[1,3,5,6] The following guidelines should be viewed as suggestions rather than absolute dogma, since individual situations, personalities, and family dynamics vary. Nevertheless, there are general literature-based principles which have been shown to foster better communication that should be considered.

First, enlist the help of support staff (preferably a chaplain or social worker) and ask them to place the family in a private, clean, comfortable room.[3,5] Support staff can provide very useful information such as who is present and what the general mood of the room is. If there is a concern for possible violence in reaction to bad news, a security officer may be invited to be nearby. Confirm the dead patient's name and review relevant medical facts and clinical data BEFORE entering the room.[1,5] Take the time to make sure your appearance and manner is as professional as possible. Some family members may find a sloppy or soiled appearance, a harried demeanor, or behaviors such as gum chewing rather off-putting.

Enter the room with the chaplain and/or social worker and introduce yourself and the role you played in the care of the patient to each person in the room. Confirm their relationship to the deceased. For example: "Hello, my name is Dr. Heisenberg. I'm the doctor taking care of Mr. White. May I know who you are please and how you know Mr. White?" Maintain an open posture and match the eye level of the family members. In other words, if the family members are standing, remain standing. If they are sitting, sit, but also maintain a clear pathway to the door for safety reasons. Ask the family to tell you what they know already about the circumstances of the patient's care. Listen carefully for details about their perception of the events leading up to the patient being brought to the ED, as this can yield important details about the family's mood, social situation, and level of medical sophistication. Professional translators should be used liberally if there is any question of English competency. Families sometimes report guilt and feel they did not react appropriately during the deceased's medical emergency.[3] If appropriate, take this opportunity to alleviate unreasonable guilt.[5] For example: "You did the right thing in calling 911." Avoid criticizing prehospital personnel or the care provided. Provide a brief synopsis of what has occurred during your care in the ED. Avoid using medical jargon such as "MI" or "intubated". Instead say "heart attack", or "breathing tube".[3,5,6]

At this point, break the bad news compassionately, using direct and clear language. Avoid using euphemisms, such as "passed on", or "no longer with us". Instead say "he has died", or "she is dead".[3,5,6] This will help avoid confusion and misinterpretation of the information just received by the family

Allow a moment of silence while the information is processed and be prepared for the grief response. Cultural, ethnic and social backgrounds can contribute to how people respond to bad news.[5] Some may react with silence, some may cry softly, some may wail or sob loudly, and some may flail their body around. Physical support, such as a hand on the shoulder or knee may be comforting to some, however, be mindful of cues that this is either acceptable or not from the family.[5] Avoid a judgmental attitude towards individual reactions, but be watchful for harmful behaviors, such as physical violence or angry confrontations. After the initial grief response has subsided, offer to answer questions. You may need to repeat or clarify some facts, however, avoid providing excessive information as that may only increase confusion for families.[5] An expression of empathy, without implying wrong doing, such as "I'm sorry for your loss" is appropriate and recommended.[5] It is common that although the family may not have questions at the time of the death-telling, they may have questions later. Therefore, the physician who cared for the patient should remain available to answer any questions. If appropriate, the physician may also provide a business card or contact information in case the family has a question after they have left the ED.

Most families will want to view the dead patient, and usually this is appropriate. Avoid using the term "the body," as the deceased is still considered a person by the family. Be sure the patient has been cleaned as well as possible and warn the family about what they might see, such as skin color and temperature changes, disfiguring injuries, and rescue devices (e.g., IVs, central lines, endotracheal tubes). While rescue devices are sometimes disturbing to see, the family should be informed that they may not be removed from the patient.[5] In the case of violent deaths, such as murder, suicide or other suspicious deaths, the case may be going to the medical examiner. In these instances, the family may not be allowed to view or touch the patient. Be sure to have this information on hand before allowing the family to see the patient. Support staff should be present with the family at all times during the viewing process. In addition, since this may be the family's first encounter with the death of a loved one, staff should be prepared to answer questions regarding next steps such as funeral home information, autopsy requests, and support group resources. Typically, a social worker or clergy staff member can provide the necessary paperwork and informative pamphlets to the family; however, having a previously prepared "death packet" containing this information may be helpful. Staff should provide a constant presence for any further grief response, and also to let the family know when it is alright to leave the ED.[5]

Deathtelling by Telephone

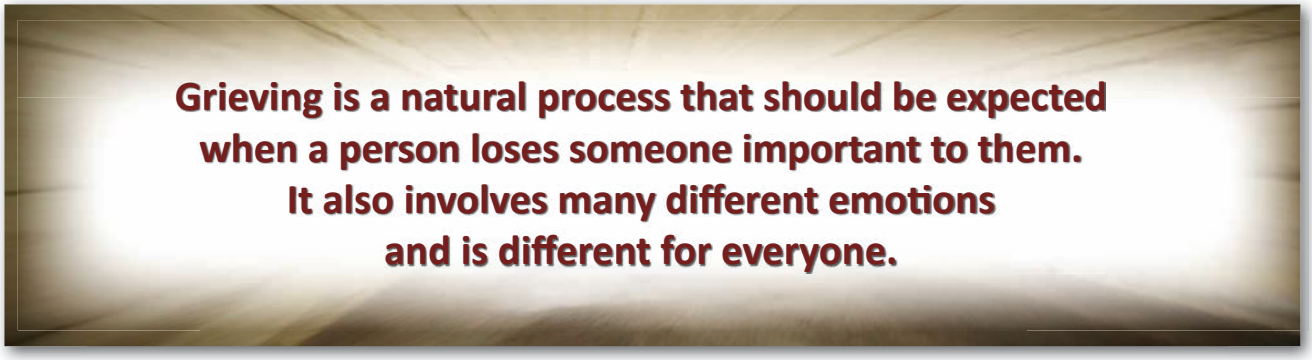
In some cases of sudden or unexpected death, the family may not be present at the time of death and will need to be contacted by telephone. This initial contact is generally made by the social worker or chaplain who can inform the family that their loved one is very sick and they should come to the hospital. In general, it is not recommended to break bad news over the phone.[3,10] However, if the family is not able to be physically present at the hospital, or if they are demanding to know what is going on immediately, it may be necessary.[5,10] When having such telephone conversations, ensure the person who will be receiving the bad news is in a safe place, sitting down, not driving a car, and preferably not alone.[3,10] There is a paucity of literature regarding the best way to deliver bad news telephonically. We recommend the use of simple language, the avoidance of medical jargon and above all, a thoughtful, compassionate approach. Be sure to allow adequate time to answer questions and have a social worker or chaplain on the phone to help facilitate the death-telling. Needless to say, death-telling should not be done by text messaging or email.

Family Presence During Resuscitation

When resuscitative efforts have failed, the next step traditionally is to terminate the code, and then inform the family. However, there is a growing body of literature addressing family presence in the resuscitation room. Since its proposal in the late 1980s, the idea of family presence during resuscitation has been debated in the literature.[11,12] Some physicians believe that family members who are present during resuscitation efforts are at increased risk for emotional burdens, particularly if those efforts involve highly invasive procedures.[11,12] Additionally, some fear that family members may interfere with resuscitation efforts, physically get in the way, cause prolongation of futile resuscitations, and be more likely to sue.[12,13] Finally, the privacy and right to confidential medical treatment for the patient being resuscitated must be considered.[12]

On the other hand, being present during resuscitation efforts may help the family members by providing a sense of closure, allowing them one last goodbye, and the opportunity to see for themselves that everything possible was done to save their loved one.[11-13] A 2013 French study[11] investigated the effect of family presence during resuscitation on the family members as well as the health care team. The health care team was well-trained and followed a scripted protocol in dealing with the family.[13] The primary end point was the proportion of surviving relatives with post-traumatic stress disorder (PTSD)-related symptoms on day 90 following the cardiac arrest of a loved one. Secondary endpoints of the study included the presence of other psychological variables, the effect on the health care team and the frequency of medico-legal claims. The investigators found that family presence during resuscitation was associated with less anxiety, depression and PTSD-related symptoms at 90 days and did not interfere with medical efforts, increase the stress of the health care team or result in medico-legal issues. Two notable limitations of this study were that the resuscitations took place in people's homes and not all patients included in the study died.[11]

A 2006 study[14] involved a random telephone survey designed to determine the public's perception on witnessed cardiopulmonary resuscitation (CPR). A total of 408 people participated and were asked a variety of questions regarding demographic information as well as opinions on witnessed resuscitations. They were asked to rate several questions on the following scale: strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree. A large number of people answered positively (201) to the statement "I would want to be in the room with a loved one during CPR", compared to 151 who answered negatively. Of the remaining 55 people, 50 answered "neither agree nor disagree" and 5



answered "don't know". Interestingly, those that desired CPR on themselves were more likely to believe that family and friends should be allowed to witness CPR and in general were more positive about the concept of witnessed resuscitation. Variables such as level of income, education, or religion did not appear to influence people's opinions. It should be noted that the study was conducted in rural Pennsylvania, and more studies in urban, diverse populations are needed.

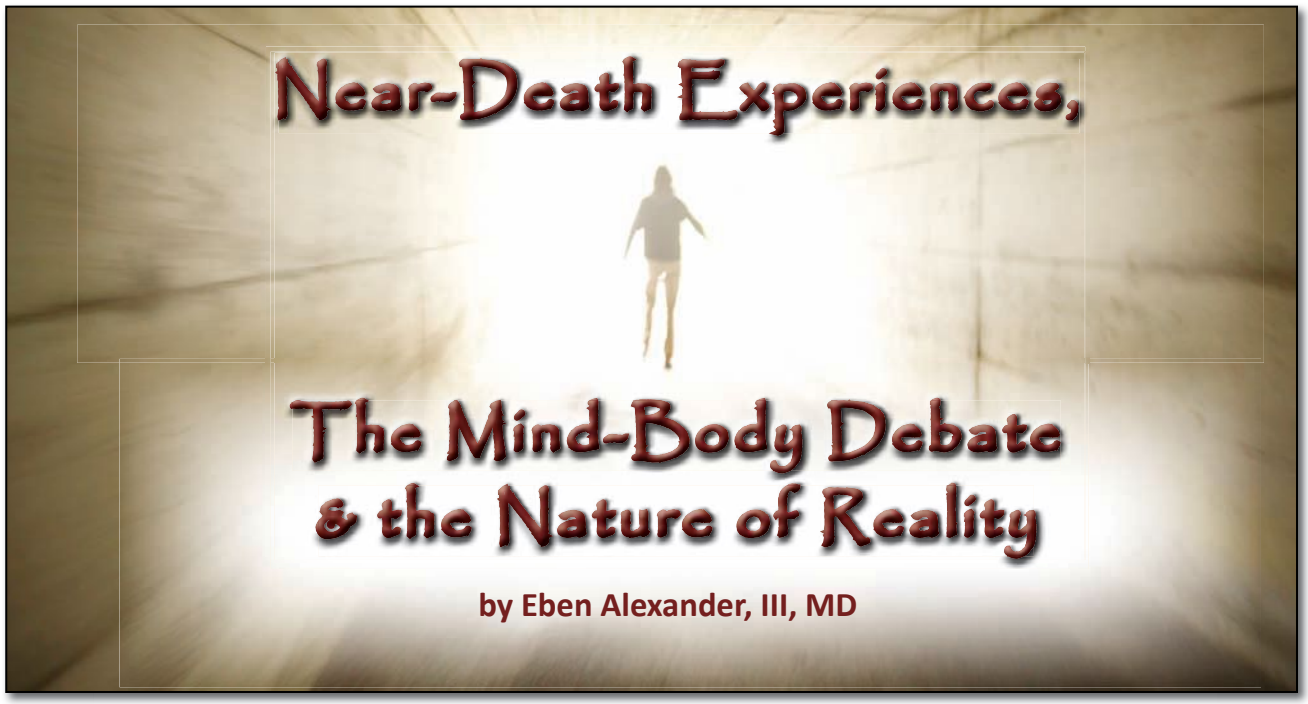
In summary, while still controversial, the current trend of the literature seems to indicate that witnessed resuscitation may actually decrease prolonged or complicated grief and may be generally accepted by the public. Accordingly, the 2010 American Heart Association's guidelines on cardiopulmonary resuscitation and emergency cardiovascular care state: "Offering select family members the opportunity to be present during the resuscitation and designating staff within the team to respond to their questions and offer comfort may enhance the emotional support provided to the family during cardiac arrest and after termination of a resuscitation attempt."[15] Although more research is needed to fully understand the impact of family presence during resuscitation, it should be strongly considered as an option when appropriate. If this is not already usual practice in an individual ED, it would be most optimal to have a well-reasoned, evidence-based protocol in place prior to implementation of such an option to reduce the chances of an untoward outcome.

Conclusion

Notifying family of the death of a loved one is never easy. In many ways, the surviving family members of the deceased become victims themselves in the immediate period following the notification.[2] Physicians should learn to view survivors as their patients too, and take necessary steps to reduce the potential complications of this life-altering event. These steps should include better education in death notification, familiarization with the grief and bereavement process, the development of a personal strategy for death-telling, and the consideration of family presence during the resuscitation.

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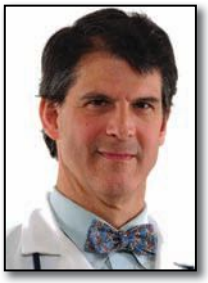
In essence, the longstanding presumption that the sheer complexity of the brain somehow leads to the creation of consciousness fails – no one has been able to offer even the most basic explanation about how that might unfold.

My Near-Death Experience

As a neurosurgeon with over twenty years' experience in academic neurosurgery, I thought I had a pretty good idea of how the brain and mind worked. I then awoke early in the morning on November 10, 2008, with severe back pain, followed by the worst headache of my life, and a rapid descent into a week-long coma that began with status epilepticus. I recall nothing that happened in my hospital room over the next seven days, but later came to learn many of the medical details of my illness through discussions with physicians who cared for me and by reviewing my medical records and imaging studies.

For reasons that remain obscure, I had contracted a rapidly progressive case of E. coli meningo-encephalitis. My neurological exams revealed extensive cortical damage, with some brainstem signs (extraocular motor dysfunction) evident that first day. My CT scans revealed global neocortical involvement (none of the eight lobes of my brain was spared) – cerebral edema, profuse sulcal enhancement and blurring of the gray-white junction. On the third day, my cerebrospinal fluid (CSF) protein was 1,340 mg/dl, my CSF white blood cell count was 4,300 per mm^3, and my CSF glucose level was down to 1.0 mg/dl. I was extremely ill, with diminishing chances for survival and virtually no chance for recovery. My physicians never found a cause for my mysterious malady. [1,2]

The last evidence of any "normal" neocortical function was in the first hours in the ER when witnesses heard me cry out "God help me" after hours of nonsensical gibberish and moans (I have no personal memory of this).



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Such a rapid descent into coma, combined with the diagnosis of gram-negative bacterial meningitis, signaled at best a 10% probability of survival at the time I presented to the ER.

My meningitis was initially unresponsive to triple intravenous antibiotics, and relentlessly progressed until the seventh day, at which point my physicians estimated my chance of survival had slimmed to 2% and recommended termination of antibiotics due to the hopeless prognosis. My meningitis finally began to subside on that seventh day, as I began the long and arduous process of awakening back to this world.

Initially, I was completely amnesic for my life before coma. I remembered no words, no personal memories of my life, no religious or scientific concepts, and nothing about being human or existing in this universe. I did not recognize dear family members standing around my bedside. All I remembered was where I had just been, in an extraordinary odyssey that seemed to last for months or years – although it had all occurred within the seven days I lay unconscious in the hospital.

Words and language returned over the following hours and days, and childhood and major life memories were restored to me over a week or two. The rest of my prior knowledge, including over twenty years' experience in neurosurgery and all other scientific and intellectual knowledge, returned in layered fashion, quite complete by eight weeks or so after my coma. My physicians continue to be astonished by my miraculous recovery.

Given the extraordinary memories I had of my time deep in coma, the emerging picture of the entire experience proved impossible to explain as a simple brain-based phenomenon (i.e., as a hallucination, dream state, drug effect, or confabulation). Our modern understanding of the role of the neocortex—the outer surface, or human part, of our brains—holds that it is necessary for the detailed construction of consciousness, but the extreme severity of my meningo-encephalitis rules out the participation of my neocortex in generating memories during those seven days. Thanks to its preferential destruction of the neocortex, severe meningo-encephalitis is, essentially, a perfect model for human death. That fact would nominate the disease for widespread study in brain and consciousness research, save for one problem: it almost always results in death. Almost no one returns to tell the tale.

As my doctors told me soon after my return, my neocortex was too damaged for me to have experienced anything, much less the extraordinary, ultra-real spiritual realms I visited repeatedly deep in my coma. But I knew I had experienced something remarkable, and I wanted to record and analyze that experience as best as possible – I knew that details of my experience might help refine our understanding of the brain, especially the neocortex, and its relationship to the mechanism and phenomenon of consciousness.

As described in detail in my book *Proof of Heaven: A Neurosurgeon's Journey into the Afterlife*,[1] my memories from deep in coma began in a coarse, murky, unresponsive realm, which I labeled the Earthworm's Eye View. In retrospect, I believe this extremely foreboding, subterranean existence was the best consciousness my physical brain could muster while my neocortex was being destroyed by aggressive gram-negative bacteria.

If one had asked me before my coma, "What would be the next step beyond that Earthworm's Eye View in the progression of your severe meningo-encephalitis?" I would have assured you the next phase would be one of no awareness at all. I would have been absolutely wrong.

In fact, the next phase was introduced to me by a slowly spinning white light of great clarity, associated with a perfect musical melody. The approaching light opened like a rip in the fabric of that ugly subterranean realm, leading up into an ultra-real valley (the Gateway Valley) filled with light and colors beyond the normal visual spectrum. It seemed so much more real than this earthly realm – fertile and filled with eternally growing plants, blossoms and buds on trees opening in ripe bloom, sparkling waterfalls and mists, dancing souls and swooping angelic choirs above. One does not see with the eyes, nor hear with the ears, in that realm – at times, the observer becomes entire swaths of that realm as a way of learning lessons about it all, even to the point of becoming other beings and groups of beings to feel and know their own knowing – to empathize with them and know them completely. Communication there goes light years beyond our simplistic linear thinking, beyond the bottleneck of linguistically constrained awareness we experience in these physical bodies in the earthly realm.

I had no body image during any part of this journey, but was moving up through that brilliant valley as a speck of awareness on a butterfly wing, accompanied by millions of other swooping and soaring butterflies of indescribable beauty. There was a lovely young woman accompanying me on the butterfly wing, one who never spoke a word, but whose thoughts of unconditional love and assurance came straight into my awareness. She promised me I would be taken care of, that I had nothing to fear, and that I was completely loved by the awe-inspiring Creator of all that is (as are we all). I came to see that unconditional love has the potential to bring infinite healing.

Causal relationships in that realm, even the temporal flow of events there, all occur in what I call "Deep Time," which is much more robust and related to Divine purpose than the events of our lives in the relatively loose temporal causality to which we are accustomed.

I then realized that the chants and hymns emanating from the swooping angelic choirs above were providing yet another portal into higher realms. The lowest (earthly and spiritual) dimensions collapsed down as my awareness entered increasingly refined spiritual realms, finally arriving at what I called the Core – infinite inky blackness, filled to overflowing with the Divine unconditional love of the Creator, and with brilliant light emerging from an orb brighter than a million stars. I was aware of a strong sense of the three of us – a Divine Being beyond all description, the brilliant orb (a translator or interpreter, perhaps?) and my conscious awareness, which by now was joined with all of consciousness throughout the multiverse, transcending a limited personal consciousness. Through wordless conceptual flow, I was informed I was not there to stay. They would teach me many things, but I would be going "back." Since I had lost all my memories of life on earth, I had no idea what that meant.

The Divine Being and the orb proceeded to demonstrate so much about all of reality – the fundamental role of love and of consciousness or soul in that realm and in all of existence; the constructs of space-time-mass-energy used to build up this physical world; the role of this physical realm as a kind of "soul school" where we learn and exchange lessons of unconditional love, compassion, forgiveness and mercy; the connectedness of all sentient beings, indeed of all consciousness, to all others and to the Divine. As is typical for such extraordinary journeys, the deeper aspects of these teachings far exceed the capacity of human language – which was created to describe earthly scenarios – to do them justice.

When I initially tried to share my stories with my physicians, they firmly reminded me that my neocortex had been too badly damaged to allow for anything more than the most rudimentary of experiences. Certainly my brain could not have generated or received the ultra-real odyssey I was describing. Given how little I remembered about the brain and mind, and of my own illness, I simply believed my doctors' statements that it must have been a "trick of the dying brain."

As I told my older son, Eben IV, who was majoring in neuroscience in college at the time: "It was all way too real to be real." Within days of waking from the coma, he could tell I had been fundamentally transformed. The scientist in me was eager to research what had happened to me, but Eben advised me to write down everything I could remember about the coma journey before reading anything about near-death experiences, physics or cosmology. I followed his advice and over the next six weeks wrote around 20,000 words describing my experience before allowing myself to delve deeply into the literature on near-death experiences (NDE), which I had never previously perused.

A Monumental Challenge to Understand

I sought to explain everything I remembered from coma as a brain-based mechanism. I was prepared to accept my doctors' assertion that it was a "trick of the dying brain," but I was driven to discover what that trick was. The nine best hypotheses, none of which ultimately held up under scrutiny, are outlined in Appendix B in Proof of Heaven. My conclusion, after months of analysis with my doctors and other interested colleagues, was that what I'd witnessed really happened – just not in the physical universe, or in my brain.

That conclusion followed an astonishing revelation about the identity of the beautiful companion on the butterfly wing, whose appearance I could remember so well. I knew I had never seen her before my illness, yet the NDE literature consistently shows that such a "guardian angel" should be one who had been crucially important to me in my lifetime.[3-8] Four months after coma, I discovered that she was in fact the birth sister I had never known, who had died two years before I even knew of her existence. That revelation was the catalyst that launched me into a more complete understanding of the reality of my journey.

Concluding that my experience actually happened, but outside of my brain and the physical universe, demanded an extraordinary shift in my worldview. Such a shift was mandatory if I were to move toward any comprehensive understanding of the world that could incorporate my strange experience and begin to explain the vast spectrum of similar experiences reported over the last several thousand years. At the core of it all was the need to more fully refine our understanding of the nature and mechanism of consciousness itself.

The Enigma of Consciousness

As a neurosurgeon, I was taught that the brain creates consciousness. Consciousness, based on that conventional view, is an illusion manifested by the subatomic particles, atoms and molecules of the brain all simply following natural laws. The same line of conventional thinking necessarily concludes that we are all acting at the whim of the natural laws governing all of those subatomic particles and their more complex arrangements in molecules and cells of the brain. In other words, none of us actually has free will at all.

To put this challenge in perspective, it is important to point out that the only thing any one of us truly knows to

exist is our own consciousness. What we call "the external world" is actually a model constructed in our minds. Conventional neuroscience would remind us that every experience and memory we've ever had is nothing more than the patterns of electrochemical flickering of 100 billion neurons encased in a three-pound gelatinous mass floating in a warm dark bath. Nothing more. A model of reality, and perhaps a mechanism for processing reality, but not reality itself.

Thus the many physicists and cosmologists who claim to be close to defining a "theory of everything" seem woefully premature, given that a far more robust understanding of the phenomenon of consciousness is necessary for any alleged theory about the nature of reality. Only a few recent physicists have actually risen to this challenge, including Roger Penrose, Henry Stapp, Brian Josephson, and Amit Goswami. But the mystery of the measurement problem in quantum mechanics – which says the observer's mind is intricately involved with the physical reality being observed, i.e. that consciousness is fundamental, not an illusion created by the physical brain – drove many of the brilliant founding fathers of quantum mechanics, including Max Planck, Erwin Schrödinger, Louis Debroglie, Sir James Jeans, Werner Heisenberg, Wolfgang Pauli, and Albert Einstein, into mysticism as they sought deeper understanding.

The Hard Problem of Consciousness

My quest also illuminated for me the Hard Problem of Consciousness (HPC), arguably the most profound conundrum known to all of human thought. Although the background challenges of the HPC had existed for millennia in the form of the 2,600-year-old Mind-Body Debate, neuroscientists were running headlong into the HPC in the latter decades of the 20th century. It was finally labeled the Hard Problem of Consciousness by David Chalmers in his brilliant book "The Conscious Mind," published in 1996.[9]

In essence, the longstanding presumption that the sheer complexity of the brain somehow leads to the creation of consciousness fails – no one has been able to offer even the most basic explanation about how that might unfold. One might expect such a fundamental assumption would be well established after the profusion of neuroscience research in recent decades.

The truth is that the more we come to understand the physical workings of the brain, the more we realize it does not create consciousness at all.[10-15] We are conscious in spite of our brain! The brain serves more as a reducing valve or filter, limiting pre-existing consciousness down to the trickle of the illusory "here-now" in which we find ourselves in this physical realm. This idea is revolutionary, but not new; nineteenth-century luminaries including William James and Frederic W.H. Myers advocated for more serious consideration of the filter theory.

The near-death experience community, as well as related spiritually-transformative experiences of all stripes, provides compelling evidence that consciousness is fundamental in the Universe.

To those who recoil at the suggestion that the brain does not create consciousness, I would mention two common clinical observations that support this idea:

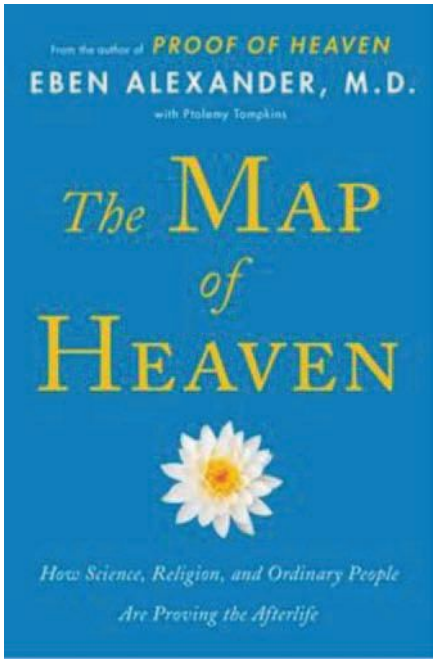
1) terminal lucidity (in which elderly demented patients often have oases of great clarity and insight about their lives, often peaking when they are aware of the souls of departed loved ones there to escort them to the other side), and

2) acquired savant syndromes (in which damage to the brain, be it head trauma, stroke, autism, or what have you, reveals a lacune of super-human mental function, such as fantastic capabilities for memory of lists, graphic, artistic or musical abilities, calculational abilities, etc.).

This thinking is not new in our modern neuroscientific era. Dr. Wilder Penfield of Montreal, one of the most prominent neurosurgeons of the 20th century –who probably still holds the record for number of electrical stimulations of the brain in awake patients during his decades-long career treating epilepsy – wrote a book in 1975 summarizing evidence that the mind (and free will) is not created by the brain.[16]

Synthesis of Science and Spirituality

Thus, the ongoing interpretation of my deep coma experience, and of tens of thousands of similar spiritually transformative experiences over millennia and across the



The Map of Heaven: How Science, Religion, and Ordinary People Are Proving the Afterlife

BOOK REVIEW

by Eben Alexander, MD

"Eben Alexander proves to us once again that experience is the greatest source of knowledge. Relying on his own near death experience and those of others who have written to him, Eben takes us from the wisdom of the Greek philosophers through to modern medical researchers to give us an overview of that mysterious place known as the afterlife. . . . A courageous book that tackles the question of life after life with science, philosophy and the heart rending experiences of many who have gone to the other side."
-Raymond A. Moody, Jr., M.D., Ph.D., author of Life After Life

Source: Amazon / Paperback: 208 pages
Publisher: Simon & Schuster; Reprint edition (October 7, 2014)
ISBN-10: 1476766401 / ISBN-13: 978-1476766409

globe, opens the door to a far richer understanding of the nature of reality. The non-locality of consciousness, i.e., that we can know things beyond the ken of our physical senses, is fundamental in the evolving science. Many top-tier scientists are already pursuing this version of truth,[3,4,11,13,14] one far grander than anything offered by the simplistic materialistic science that fails to answer the most basic questions about consciousness or approach the enigma around the phenomena addressed through quantum physics (specifically the measurement problem).[10-12,17-20]

The near-death experience community, as well as related spiritually-transformative experiences of all stripes, provides compelling evidence that consciousness is fundamental in the Universe. Spirituality and science strengthen each other greatly. Global awakening to this grand concept, not just among scientists but among all of us, is beginning even now.

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MM

The Spirit of Compassion: Has It Grown Weak?

by Robert Bondurant, RN, LCSW

The MPHP has provided very comprehensive services because of the financial support we are given by medical staffs, hospital administrators and individual donations.



Robert Bondurant, RN, LCSW, is the Executive Director of Missouri Physicians Health Program.
Contact: www.themphp.org

Recently the Missouri Physicians Health Program (MPHP) initiated a new campaign called the Spirit of Compassion in which we sent a mailing to the entire MSMA membership. Our request for financial support of your program to help troubled physicians has of this writing generated a mere 10 responses from 4,000 members.

I am very aware of the difficult state of our economy. Many of the medical students, residents, and senior physicians struggle to pay for the help they need. The MPHP helps by providing scholarships to at least lessen the burden for the costs of our services. The financial future is not looking better but even more ominous.

To me what happened in the early 1970s was nothing short of a miracle. A profession actually stepped forward to help their colleagues. The AMA and the Federation of State Medical Boards collaborated to provide a response to the concern for the high rate of suicide and substance abuse among physicians. It was physicians who blazed a new trail and showed other professions what could be done. Today, airline pilots, lawyers, nurses, social workers and psychologists have followed your example.

The MPHP was started in the late 1970s and was managed by Dr. Donald McIntosh from his home in Kansas City. In the mid 1980s, the MSMA stepped forward to support Dr. McIntosh in his compassionate work for his professional colleagues. The MSMA has provided the foundation for the program. They have supported our advocacy work before regulatory agencies, interventions, referral for treatment, intensive monitoring and our being available for any type of trouble a physician may have.

Recently I gave a lecture for a hospital-based residency program. Afterwards, I received a phone call from a senior physician who attended the lecture. He had an adult child with an alcohol problem and the physician/father needed some guidance and asked for help. The MPHP could not monitor the child but we could recommend resources and provide suggestions that could ease this father's burden and was most appreciative of our assistance.

We know and are experienced with more than just substance abuse. We provide a very broad range of services. We have professional staff located throughout Missouri. The MSMA has encouraged our wide range of

services and statewide capability to serve physicians.

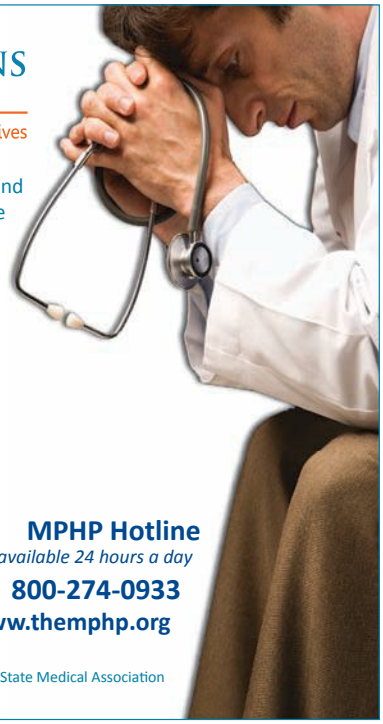
Many of our sister programs do not assist students or residents and assist only with alcohol and drug problems and have a limited geographical reach. The MPHP has provided very comprehensive services because of the financial support we are given by medical staffs, hospital administrators and individual donations. The MPHP is independent of the Missouri Board of Healing Arts, and thus we do not benefit from licensing fees or tax dollars like some programs. By avoiding these sources of income, your program is able to remain independent and focus on advocacy alone.

The MPHP is not a new concept. We are over 30 years old (or 40 years from the time that Dr. McIntosh started his work). With age comes experience and wisdom. However, too often as a program or people get older, they can be neglected or even forgotten. Please don't let that happen to your MPHP. We are only as strong as our support. Recapture that Spirit of Compassion by responding to the opportunity to provide financial support and advocate for the program in your hospital, group practice, or organization. If you are a financial supporter, please renew your support by providing the resources we need to be there for you and your colleagues.

If you haven't received a request letter, please contact us. We want you to be a part of the Spirit of Compassion that began this program. Join us now! Get the spirit! **MM**

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The Missouri Physicians Health Program is proud to recognize the following organizations and individuals who contributed to our annual fund drive. We are truly grateful for their generosity which helps provide crucial support as we strive to provide high quality physician health care services and meet the demand for our services statewide.
We encourage you to contribute to this effort as we reach toward our goal for 2015.

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157th Missouri State Medical Association Annual Convention

April 17 - April 19, 2015 ◆ Westin Crown Center ◆ Kansas City

PRELIMINARY PROGRAM

Pre-Convention Meetings

Thursday, April 16

2:15 pm	MSMA Insurance Agency Board Meeting
3:30 pm	MSMA Executive Committee
3:30-6:30 pm	Convention Registration
3:30-6:30 pm	Exhibitor Setup & Registration
5:00 pm	**MSMA Council Meeting**
6:30 pm	Alliance Dutch Treat Dinner [Offsite]
6:30 pm	University of Missouri Awards Reception & Dinner [Offsite]
7:00 pm	**MSMA Council Reception & Dinner**

Convention Meetings

Friday, April 17

6:30 am-4:00 pm	Convention Registration
6:30 am	University of Missouri Breakfast
6:45 am	Moneta Breakfast
7:00 am	**Exhibit Hall Opens/Continental Breakfast for all Conferees**
8:00 am	**Opening Session MSMA House of Delegates**
8:30 am	Alliance Board Meeting
10:00 am	Alliance General Assembly - Session I
10:00 am	**Reference Committee A**
10:30 am	**Reference Committee B**
11:00 am	Physicians Health Committee Meeting & Luncheon
Noon	SLMMS Caucus & Luncheon
Noon	KCMS Caucus & Luncheon
Noon	"Spirit of the Alliance" Awards Luncheon
1:30 pm	**MSMA General Session**
1:30 pm	Medical Student Section Meeting
3:30 pm	**MSMA General Session**
2:30 pm	Alliance Past President's Reception
5:00 pm	OMSS Business Meeting
5:30 pm	Medical School Alumni Receptions
7:00 pm	Alliance Foundation Fundraiser/Dinner Casino Night

Saturday, April 18

6:30 am-4:00 pm	Convention Registration
7:00 am	**Exhibit Hall Opens/Continental Breakfast for all Conferees**
All Day	CME Programs, Lectures & Meal Functions
8:00 am	**MSMA General Session**
8:30 am	Alliance General Assembly - Session II
9:00 am	International Medical Graduate Section Meeting
10:00 am	**MSMA General Session**
10:00 am	MMPAC Meeting
10:30 am	Exhibit Hall Closes
Noon	Alliance Installation Luncheon
1:00 pm	AMA Issues
1:00 pm	Resident Fellow Section Meeting
1:00 pm	Young Physicians Section Meeting
1:30 pm	**MSMA General Session**
2:00 pm	Missouri State Medical Foundation Meeting
2:30 pm	Alliance Board Meeting
3:15 pm	OMSS Educational Session
3:00 pm	Component/Specialty Society Leaders Meeting
5:15 pm	Reception: 50-Year Pin Recipients & MSMA Past Presidents
6:30 pm	**MSMA Presidential Inauguration**
7:30 pm	**MSMA Presidential Reception** *Entertainment, Hearty Hors d'oeuvres & Cash Bar*

Sunday, April 19

7:00 am	District Breakfasts & Caucuses
8:15 am	**Second MSMA House of Delegates**
Immediately Following Closure of the HOD	MSMA Council Meeting

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2015 ANNUAL CONVENTION GENERAL SESSION TOPICS & SPECIAL EVENTS



American Medical Association Presentation

Carl A. Sirio, MD
Friday, April 17 ◆ 8:00 am



The Positive Aspects of Medicine

Col. Jim Coy, DO
Saturday, April 18 ◆ 8:00 am



Current USPSTF Screening Recommendations

Michael L. LeFevre, MD
Friday, April 17 ◆ 1:30 pm



Challenging Ethical Issues in Medicine Through Clinical Vignettes

David Fleming, MD
Saturday, April 18 ◆ 10:00 am



How Emotions Affect the Practice of Medicine

Danielle Ofri, MD
Friday, April 17 ◆ 3:30 pm



Population Health Management

Peter A. Brawer, PhD
Saturday, April 18 ◆ 1:30 pm

PLUS

- Multiple Medical Specialties Programming
- Two-Day Exhibit Showcase
- House of Delegates
- Foundation Fundraiser Casino Night/Dinner
- Presidential Inauguration & Reception



To Sign or Not to Sign? Hospital Employment Contracts for Physicians

Elizabeth A. "Libby" Snelson
Saturday, April 18 ◆ 3:15 pm

Food and Health Challenges

Thank you for including in your Journal scientific articles that so clearly illustrate the inherent linkage between food and health challenges. National leaders need to see that public policy must be informed by scholarship in order to effectively serve their constituents. The Ebola epidemic is another critical problem that deserves similar scholarly attention, and the University of Missouri is poised to contribute to that problem in new ways.

The Ebola epidemic now centered in three West African countries, Guinea, Liberia, and Sierra Leone, is not only a life threatening disease, but it also significantly threatens the food security of the region. The U.S. Agency for International Development is leading our government's response, aligned with the CDC and the Department of Defense and many UN Agencies such as the World Health Organization, and Non-Governmental Organizations that have large presence on the ground in those countries. These workers deserve our praise for the risks they face daily as they undertake essential service to the global society. The current strategy is to eliminate Ebola in humans and enable economy recovery as quickly as possible. The latter cannot be achieved, however, unless the former is successful. Ebola must be contained in order for public policy to effectively support production and marketing systems.

This is where the University comes in, because so much new knowledge is required on all fronts. The Deaton Institute became deeply involved in the discussion last October at the World Food Conference where dire predictions of 30-40 percent losses of food availability raised concern across the food and health communities. Reports of land abandonment, loss of trust and disruptions of labor in key processing and transportation facilities, in the financial and economic support systems of those already fragile societies, and genuine human empathy for the many victims of the epidemic, all contributed to an unease among observors here and abroad. Members of the university community felt a deep need to contribute.

It was recognized that emergency food aid will address short term food availability, but guiding the transition to a sustainable system of food security and strength in the agricultural economy is quite another challenge. The Institute was asked to take leadership in formulating a recovery strategy in coordination with the Global Health Response and Resilience Alliance, and a multidisciplinary team of faculty, students and staff stepped forward to contribute. The team incorporates faculty from medicine, public health, plant and animal science, biology, nutrition, agricultural economics, anthropology, sociology , and behavioral sciences from across the diverse programs of the University of Missouri. We recognize the vast strengths of our University community that is exceptional among America's higher education landscape. Even more exceptional is the creativity and dedication they bring.

In many ways, responding to Ebola takes us into new territory, but being a "frontier university", the first public university west of the Mississippi, inspires both dedication and creativity. The efforts of such esteemed colleagues, with no guarantees of success, also deserve commendation. I am honored to be involved with my colleagues in this process and look forward to providing you with a progress report in the future.

Brady Deaton, PhD
Chancellor Emeritus, University of Missouri

Genetically Modified Organisms Crops In Agriculture? Food For Thought

I would like to comment on the article, "Why We Need GMO Crops in Agriculture," by Melvin J. Oliver, PhD (November/December 2014). My contention is that not only do we not need GMOs in agriculture, but we should eliminate GMOs from our food supply (including indirectly in our animals) because of the abundance of evidence that they are likely dangerous. In a 1998 lawsuit by public interest attorney Steven M. Drucker, 44,000 pages of the FDA's internal documents proved that the consensus of their own scientists was that GMOs could not be presumed safe; that they were different and dangerous; could lead to diseases and needed long-term safety studies. ("How the U.S. Food and Drug Administration Approved Genetically Engineered Foods Despite the Deaths They Had Caused and the Warnings of its Own Scientists About Their Unique Risks" executive summary, by Steven M. Drucker). Their warnings were ignored and GMOs got "fast-tracked." It may help to know that our current "Food Czar," Michael Taylor, was previously a Monsanto attorney. In the first nine years since introduction of GM crops in 1996, the incidence of people with three or more chronic diseases nearly doubled from 7% to 13%. (Kathryn Anne Paez, et al, "Rising Out-Of-Pocket Spending For Chronic Conditions: A Ten Year Trend," Health Affairs 2009;28(1):15-25). Causation? Maybe, we don't know because the GMOs haven't been tested sufficiently. Over 93 scientists have signed a statement that there is no consensus on the safety of GMOs. ("No scientific consensus on GMO safety" ENSSER October 21,

2013) For a good summary of the concerns get "Genetic Roulette: The Gamble of Our Lives" by Jeffery M. Smith (DVD, 2012 available on Amizon.com).

Robert R. Jones, MD
Pediatrician, Nevada, Missouri
MSMA Member since 1978

GMO Author Reponds to Food For Thought

Thank you for taking the time to read and comment on my article. As I discussed in the article, from all of the studies conducted to look at the safety of GM crops, there is no evidence that they are any different, in terms of public or animal health, from crops developed by conventional breeding practices. I refer you to Nicolia et al. (reference 24) and the reports of the NRC and European Commission that address these claims directly for both livestock and humans. As a scientist, and as I am sure you are aware, one has to be very careful in how you interpret or act upon simple correlations and until one applies scientific rigor and methods to obtain reliable data to gain objective insight they remain hypothetical. There has been an equally strong increase in organic food sales since 1996 that tracks the increase in the production of GM crops. The independent variables that lay between any of these comparisons are numerous and would require specific studies to address any cause and effect relationships. Many such studies have been conducted by numerous agencies and researchers, as I document in my article, and there is no substantiated link between adverse health issues and GM crops. As for scientific consensus, I think I have documented that extensively in the article (for more information, see reports on GMOs by the American Medical Association, the National Academy of Science, The Royal Society of London, European Plant Science Organization, and the American Society of Plant Biologists among others). From a scientific perspective, it is difficult to comment on the 1998 lawsuit without having scientific data and information that might have factored into any deliberations that led to its dismissal.

Melvin J. Oliver, PhD
Supervisory Research Geneticist, USDA
Agricultural Research Service
University of Missouri

The Courts Should Not Apply the Seriously Flawed Learned Intermediary Doctrine

In the article titled "Product Liability Suits Involving Drug or Device Manufacturers and Physicians: The Learned Intermediary Doctrine and the Physician's Duty to Warn" (Missouri Medicine November/December 2014) attorney Jason Husgen cites a case of toxic epidermal necrolysis (TEN) in a patient who received Zithromax, an antibiotic and Daypro, a non steroidal anti-inflammatory drug. According to the Learned Intermediary Doctrine the drug company is not responsible for this untoward reaction. It is the physician whose failure to warn who is liable under this doctrine. This doctrine, especially as described in the example given in the article, is completely impractical.

I have been in practice fifty years and have treated tens of thousands of patients and have never seen one case of TEN or its related condition Stevens Johnson Syndrome. I think most doctors in clinical practice have had similar experiences. Am I supposed to tell every patient about every risk, no matter how rare, that is present in the warning section of the package insert? NSAIDS can be obtained over the counter. Who is liable and who pays when a serious drug reaction occurs in that situation?

A far better solution to this problem can be found in the National Vaccine Injury Compensation Program. When a vaccine related injury or occurs death occurs compensation is paid out of a fund which is government funded by a small excise tax. The trial lawyers, of course, do not like this arrangement because they are out of the loop. They are constantly challenging the program in every ingenious way that they can think of.

For rare serious reactions that occur with drugs either a set aside should be made by the drug companies to compensate injured patients or an excise tax as in the vaccine injury program should be applied. Physicians can and do tell patients about the serious side effects and possible allergic reactions of drugs used to treat patients with life threatening diseases but cannot warn patients about every rare untoward reaction.

The Learned Intermediary Doctrine shifts liability from the drug and device manufacturers where it rightfully belongs to the physician. The other beneficiaries of the doctrine are the trial lawyers both plaintiff and defense. Doctors are much more vulnerable to law suits than are wealthy drug companies and device manufacturers. The author describes the reasoning the courts used to arrive at the Learned Intermediary Doctrine, which I find unconvincing and a violation of common sense. The Courts should not apply this seriously flawed doctrine.

Arthur Gale, MD
Internal Medicine, St. Louis
MSMA Member since 1976

MM

New *Missouri Medicine* Editorial Board Member

Missouri Medicine announces a new addition to its Editorial Board. Members are selected on the basis of exceptional professional accomplishments and expertise in their specialty.



Pradeep Sahota, MD, MSMA member since 2003, is the new Neurology Editorial Board member, replacing Marilyn Rymer, MD. Dr. Sahota is Professor and Chair of Neurology at the University of Missouri School of Medicine. He is also the Director of the Sleep Disorders Center and Sleep Medicine Fellowship Program there. *Missouri Medicine* thanks Dr. Rymer for her service.

MU Medical School Has New Dean



The University of Missouri School of Medicine's new dean is Patrice Delafontaine, MD, who came to Columbia from Tulane University in New Orleans, where he has served as the chief of cardiology, director of the Tulane University Heart and Vascular Institute at Tulane University School of Medicine, and medical director of cardiovascular services at Tulane University Hospital and Clinic.

Delafontaine has extensive research experience in biomedical research, including cardiovascular disease. He earned his MD from the University of Geneva in Switzerland, then completed his fellowship at Harvard Medical School and Brigham and Women's Hospital.



Richard Baumann, MD, MSMA member since 2002 of Hannibal, recently attended the American Orthopaedic Foot and Ankle Society Complete Foot Care Course in Charlotte, NC.

Robert Curtin, MD, MSMA member since 2010 of St. Louis, recently joined Esse Health's Southroads Internal Medicine.

Family practice physician **D.L. David, MD,** MSMA member since 2005, of Poplar Bluff, is now seeing patients at Southeast Medical Plaza in Dexter two days a week.

Saint Francis Medical Center has announced the addition of **Thomas S. Diemer, MD,** MSMA member since 2008 of Cape Girardeau, to its executive team. Diemer has accepted the newly-created role of vice president of quality.





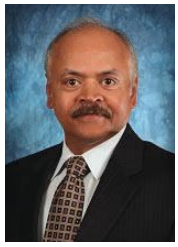
Golden Valley Memorial Healthcare recently welcomed **Amie Etters, MD,** of Clinton, to its team. She has been a member of MSMA since 2000.



MSMA is proud to have as a new, young-physician member, **Keith Gildehaus, MD,** a surgeon with Mercy Clinic Surgical Specialists and recently-inducted Fellow of the American College of Surgeons.



Fitzgibbon Hospital is bringing urology services to its outpatient clinic with the addition of **Winston Harrison, MD,** MSMA member since 1977 from Columbia.



St. Anthony's Medical Center added **Surajit Majumdar, MD,** to its St. Anthony's Physician Organization as a primary care physician. He is a new member to MSMA from Rolla.



Tatyana I. Metelitsina, MD, joined the physicians at Eye Care Specialists, LLC, in Cape Girardeau in 2014 to help fill the growing need for an additional vitreoretinal surgeon. She also joined MSMA in 2014.

Cross Trails Medical Center added **Patrick O'Hara, MD,** MSMA member since 2000, to its Perryville office.

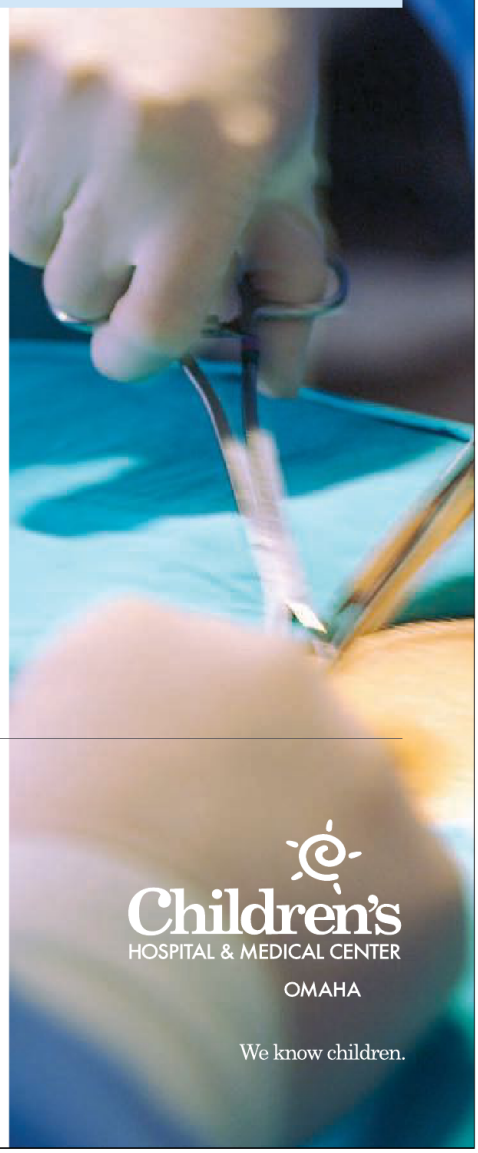


A celebration was held in November at Mercy Hospital in Cassville to honor **Jaime Zengotita, MD,** MSMA member since 2012, for providing a decade of service with Mercy.

MSMA member names in bold

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Why 'Metrics' Overload Is Bad Medicine

by Victoria R. McEvoy, MD

Doctors must focus on lists and box-checking rather than patients.



Victoria R. McEvoy, MD, is an assistant professor of pediatrics at Harvard Medical School.

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'Quality" has been the buzzword in health care for a decade, but the worthy goal is driving health-care providers to distraction. All stakeholders—insurers, patients, hospital administrators and government watchdogs—are demanding metrics to ensure that money is spent wisely. Metrics do matter: Pre-operation checklists, hand-washing mandates, length-of-stay goals for inpatient stays, and infection rates for patients with catheters have improved health care in a perceptible way. But holding physicians accountable for specific outcomes or measures of patient compliance ignores the complexity of managing a patient's care. Metrics are chosen because they are measurable, not because they are proxies for excellence.

Primary-care providers like me are bearing the brunt of these often misguided efforts. As front-line providers responsible for a patient's health, we have had every aspect of our professional lives invaded by the quality police. Each day we are provided with lists of patients whose metrics fall short of targeted goals. For example, pediatricians have been charged with addressing the rising obesity rate in children. Pediatricians want to fight obesity but are skeptical of the tools used to do so. Obesity is a complex issue that includes nutrition, exercise habits, home dynamics, community resources, school compliance, parental modeling, screen time, metabolism and genes. And changing human behavior presents enormous challenges.

Nevertheless, the quality police demand that for any child who comes in for a physical whose body-mass index is above the 85th percentile, I must comply with certain measures—what we call box checking. I first need to check a box stating that the child is overweight. Then I must acknowledge that I entered "overweight" in his problem list. Next, I need to check a box stating that diet and exercise counseling were provided. Finally, I need to be sure that the counseling is documented in the patient note. If this patient has asthma, I need to check more boxes for an asthma action plan, use of a asthma-controller medication, and flu-shot compliance.

When a healthy child visits, I must complete these tasks while reviewing more than 300

other preventative care measures such as safe storage of a gun, domestic violence, child-proofing the home, nutrition, exercise, school performance, safe sex, bullying, smoking, drinking, drugs, behavior problems, family health issues, sleep, development and whatever else is on a patient's or parent's mind. While primary-care providers are good at prioritizing and staying on time—patient satisfaction scores are another quality metric—the endless box checking and scoring takes precious time away from doctor-patient communication. Not one of my patients has lost a pound from my box checking.

Since it's so difficult to measure things that are worth measuring, questionable measures are used to satisfy demands for accountability. For example, one of the pediatric goals is get all children a 3-year-old well-child visit. Why is that the doctor's responsibility when it's a parent's job to make the appointment? Primary-care providers are forced to monitor innumerable other metrics, including hemoglobin A1Cs for diabetes, LDLs for high cholesterol, colonoscopy rates for patients over 50, emergency-room visits for all patients, eye exams for diabetics, flu shots and many others. Primary-care providers are swamped with lists, report cards and warnings about their performance.

Countless other personnel have been recruited in primary-care practices and hospitals to manage the metrics. While controlling health-care dollars is paramount, the financial toll for pursuing these measures is significant. Medicine is becoming a nanny state in which doctors must chase down patients because one metric is off. Then there's transparency. Many of these quality measures are part of large contracts between hospital systems and insurers. Large financial payouts depend on meeting certain targets. If a hospital decreases readmission rates by 10%, for example, money gets returned. Individual providers are rewarded with payouts for certain behavior such as printing out "visit summaries" to give to patients, no matter if the information is helpful. Extra work should perhaps be rewarded with extra money, but patients should be aware of what's driving doctor behavior. The reason a physician called after a hospitalization may not be purely out of concern for the patient's welfare; there could be a metric involved.

There are certainly good metrics. "Med reconciliation," reviewing and updating medication lists when a patient meets with a physician, is well-accepted as a good metric. But many other measures have little bearing on improving patient health. Would you rather your doctor won the "quality" contest by doing good list management and robust box checking or spent that time listening to you? **MM**



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P MPM I A

How to Improve Data Security in 2015

by Deborah Juhnke, IGP, CRM

We must first understand where our data is and who has access, an aspect of every good risk analysis of data security.



Deborah H. Juhnke, IGP, CRM, is Director of Information Governance Consulting for Husch Blackwell, LLP in Kansas City. The Firm acts as outside general counsel to the Missouri State Medical Association.
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The information contained in this article should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and readers are encouraged to consult their own attorney regarding specific legal questions.

The Issue

"End-users, sysadmins, and developers lead the pack when it comes to mucking things up, though pretty much all of us are guilty." These are simple, yet telling, words from Verizon's 2014 Data Breach Investigations Report.[1] The report statistics indicate:

- Forty-six percent of all data security incidents in health care come from theft or simply losing a laptop or other device containing confidential information—triple that of almost all other industry sectors
- Physical loss is 15 times more common than theft
- Most thefts occur in the work area, followed by homes and vehicles.

The 10th annual Verizon report is compiled from actual data security incidents reported by global law enforcement agencies, information security agencies, forensics organizations, and the Information Sharing and Analysis Center (ISAC), including the National Health ISAC. It finds, "Nine out of ten of all breaches can be described by nine basic patterns." Almost 75 percent of all health care incidents may be attributed to three of these patterns: physical theft and loss (46 percent), insider misuse (15 percent), and miscellaneous error, such as misdelivery, publication, and disposal (12 percent).

Criminal attacks on health care are increasing, however, rising 100 percent in four years according to the Ponemon Institute's Fourth Annual Benchmark Study on Patient Privacy & Data Security, now affecting 40% of organizations surveyed. Indeed, the recent Anthem data breach may prove to be the largest to date, affecting some 80 million people. And as of February 9, insurance regulators plan to launch a national investigation into the breach. As we have learned from last year's Target and Home Depot breaches, the greatest risk for breach may in fact begin with business associates or other third party contractors, as they are often less likely to have sophisticated controls in place. The health care field shares other characteristics with retail's visible victims, including a high volume of incidents and slow response times.[2]

Biggest Worries?

Although employee negligence is considered the biggest security risk by Ponemon (75%), almost the same percentage of respondents (73%) is not confident or only somewhat so that their business associates would be able "to detect,

perform an incident risk assessment and notify their organization in the event of a data breach incident…."

And as if these better-known cyber-risks were not enough, there is growing concern that the "Internet of Things"—uniquely identifiable connected devices, such as conferencing systems, medical devices, web servers, and cameras—is increasingly leveraged to expand the attack surface and carry out denial of service attacks, malware infections, cyber espionage, and data theft.[3]

These vulnerabilities were made visible by the Norse threat intelligence infrastructure during a sample evaluation of the health care sector, collected between September 2012 and October 2013. The analysis showed that 375 U.S.-based health care-related organizations had been compromised (likely unknowingly), ranging from small providers to well-known teaching hospitals. Some examples: 7 percent of malicious traffic came from radiology imaging software, 3 percent from video conferencing systems most likely used for consults and remote procedures, and another 7 percent from video conferencing systems. These types of devices are typically not thought of as being vulnerable to outside attack.

What Should We Do?

Understanding that data security threats are a persistent challenge is a good first step. There is no such thing as a one-time project to ensure security, and assuming that the IT department has it covered is shortsighted. There are certainly things that IT must do to harden systems against intrusion, such as changing factory default configurations and passwords, and including other network-attached devices such as surveillance cameras and fax machines in their device list for security controls. (For an example of how simple it is to find and exploit defaults, just do a Google search for "default password.") True data security, however, relies upon more than just IT controls.

The best way to uncover your own particular vulnerabilities is to conduct a risk assessment. Required by the HIPAA Security Rule for both covered entities and business associates, a well-done risk assessment will help you:

- Identify *all* the storage locations of protected health information (PHI) in your organization;
- Determine the particular threats and vulnerabilities you face—some of which may not be technical at all; and
- Identify compliance gaps and suggest remediation.

Keep in mind that, though necessary and eminently helpful, the risk assessment is not a panacea. We've probably all at one time or another taken a test just to get by, only to forget the content or fail to comply with its guidance in the future. A risk assessment, like a driver's test, is not simply an exercise to get through, but is intended to lead to improvements in performance. Some may also think a risk assessment is simply IT penetration testing—can the "bad guys" get in?—but it is much more than that. Consideration must be given to things as diverse as physical security of both facilities and devices, access authorizations, and termination procedures for employees.

At minimum, HIPAA requires an understanding of where your protected or sensitive data is before you can manage or protect it. That means not only the obvious EHR or billing systems, but also e-mail, mobile devices, laptops, wherever PHI may live.

But I'm OK if I Out-Source My IT, Right?

No. In fact, the Ponemon survey found that health care organizations surveyed did not trust their third parties or business associates with sensitive patient information. Ironically, among the top three types of business associates they worry most about are *IT service providers*. It is understandable that most small organizations must outsource their IT, but be sure not to take the vendor's compliance for granted.

Due diligence in selecting your business associates, particularly those supplying information technology services, will go a long way toward identifying security weaknesses. Ask about any past incidents, what technology tools they use, and what their encryption practices are. Look at employee turnover, their experience dealing with protected information, and whether they have been subject of an independent audit. These are just a few of the many metrics that support a good due diligence process when selecting vendors. For agreements already in place, there is no time like the present to review them for deficiencies and opportunities for improvement upon renewal. The exercise of simply locating all pertinent agreements may be enlightening!



Need Information about Anthem's Data Breach?

- www.msma.org/AnthemDataBreach
- www.AnthemFacts.com

As of the time of this printing, Anthem, the health insurance behemoth, announced in early February 2015 that it was the victim of a very large and sophisticated data theft attack. Personal information on some 80 million current and former Anthem customers was breached, including names, addresses, birthdates, and Social Security numbers; all the information necessary for identity theft. At the time of this writing it appears that no medical data or credit card information was stolen, but the scope of the breach is still under investigation.

Anthem says it will inform affected customers by mail before the end of February, and will offer free identity fraud protection. A series of FAQs can be found at www.msma.org/AnthemDataBreach, and Anthem asks all current and former customers to keep a regular eye on a special website it has created to provide updates and guidance. Visit www.AnthemFacts.com

Please feel free to share this information with any of your office staff who currently have or at one time had Anthem coverage.

Getting Started

The message for health care providers—from the largest hospitals, to small practices, to continuing care retirement communities—is that the path to improved data security begins with controls to protect us from ourselves. We must first understand where our data is and who has access, an aspect of every good risk analysis of data security. Audit processes, including periodic review of user accounts and logs, can help thwart both intentional and inadvertent breaches. Protecting the data itself, through encryption and data loss prevention software (DLP), will help minimize the damage when the inevitable happens and someone loses a device.

Above all, however, we must renew our efforts to inform and train our personnel, from the highest executive to the clerical staff. Indeed, the Verizon report notes: "The data seems to suggest that highly repetitive and mundane business processes involving sensitive info are particularly error prone…[and] this pattern contains more incidents caused by business partners than any other." Training and awareness are both undervalued and underutilized.

- Understand yourself: Perform a risk assessment
- Understand your business associates/contractors: Use good due diligence & contract review practices
- Understand your employees:Provide continual training & security awareness reminders.

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Health Information Technology Advances Health Care Delivery and Enhances Research

by Eduardo Simoes, MD

Information technology-based health care data systems have been shown to increase the efficiency not only of health care delivery but also of health research studies.



Eduardo Simoes, MD, MSC, MPH, is the Chair and Health Management and Informatics Alumni Distinguished Professor at the University of Missouri School of Medicine.
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The fields of health management and health information technology (HIT), health informatics inclusive, are intertwined; one cannot distinguish where one field begins and the other ends. There are no areas in health care management currently being carried out without informatics support, especially those areas requiring the most advanced information technology and informatics innovations, such as electronic health records, clinical decision support systems, and health care data analytics.

Both HIT and health informatics hold promises of efficiency, cost reduction, and improved health care. A recent evaluation reported a median revenue increase of $49,916 per full-time physician after operating costs were attributed to EMR-associated efficiency gains from the elimination of paper charts, as well as transcription savings, better charge capturing, and reduced billing errors.[1] Numerous reports by the National Academy of Sciences have identified the transformative potential of information technology to control costs and improve outcomes in health care.[2,3,4,5]

For all these reasons, the field of health informatics has grown steadily over the past fifteen years.[6] Much of this growth can be attributed to the U.S. government. The first major incentive for health informatics development dates from 1996 with HIPAA, when the health care community was asked to embrace Health Information Technology (HIT) and required health plans, health care clearinghouses, and certain health care providers, including pharmacists, to create electronic data interchanges for electronic transactions (see Table 1). Another critical line of investment in IT was the passage of the Health Information Technology for Economic and Clinical Health (HITECH) provisions of the American Recovery and Reinvestment Act of 2009, which was to promote the widespread adoption and use of health IT, and ultimately improve the quality, safety, and efficiency of the U.S. health care system. HITECH included incentive payment programs and technical assistance for eligible health professionals and hospitals to adopt, implement, or upgrade certified electronic health records (EHRs) and to achieve the Meaningful Use (MU) of HIT.[7,8] Also, the massive investments required by HITECH and the Accountable Health Care Act (ACA) since 2009 further contributed to HIT growth. In 2009, the U.S. Department of Health and Human Services received congressional authorization to spend $27 billion to support implementation of HITECH, and in 2010, ACA budgeted nearly $20

Table 1 - UNITED STATES GOVERNMENT INCENTIVES ELECTRONIC HEALTH RECORDS		
Act or Law (Year)	Strategy	Strategy / Electronic Transaction
HIPAA (1996)	• asked health-care community to embrace Health Information technology (HIT) in 1996 • created an electronic data interchange that health plans, health-care clearinghouses, and certain health-care providers, including pharmacists, are required to use for electronic transactions	• claims and encounter information • payment and remittance advice • claims status • eligibility • enrollment and disenrollment • referrals and authorizations • coordination of benefits • premium payment
Tax Relief and Health Care Act of 2006 (TRHCA), CMS Physician Quality Reporting Initiative (now called Physician Quality Reporting System (PQRS)) (2006)	• a voluntary physician electronic reporting program.	• voluntary physician electronic reporting
Electronic Prescribing (eRx) Incentive Program, created under the Medicare Improvements for Patients and Providers Act (2008)	• provides incentives for eligible physicians who e-prescribe Medicare Part D medications through a qualified system. • this program converted to a penalty program last year for physicians who don't use eRx.	• e-prescribe Medicare Part D medications
HITECH Act (2009)	• higher Medicare and Medicaid payments to physicians who adopt and "meaningfully use" EHRs – up to $44,000 under Medicare and $63,750 under Medicaid • $30 billion in new Medicare and Medicaid incentive payments • $500 million for states to develop health information exchanges (HIE) • AHRQ has awarded $300 million in federal grant money to more than 200 projects in 48 states to promote access to and encourage HIT adoption. • Over $150 million in Medicaid transformation grants awarded to three states and territories for HIT in the Medicaid program under the 2005 Deficit Reduction Act.	• "Meaningfully use" EHRs • HIEs
ACA (2010)	established uniform standards that HIT systems must meet	• automatic reconciliation of electronic fund transfers and HIPAA payment and remittance • improved claims payment process • consistent methods of health plan enrollment and claim edits • simplified and improved routing of health-care transactions • electronic claims attachments.
ACA (2010)	voluntary PQRS electronic reporting program has become a mandate. Starting in 2015, Medicare payments will be reduced for nonparticipating physicians	

billion over five years to support the widespread adoption of health information technology.[9,10]

DHSS has provided clear guidance to providers as to the expectations of the development in the adoption and implementation of EMR.[11] Meaningful use of certified electronic health record technology is expected to improve the quality, safety, and efficiency, as well as reduce health disparities. Other expected outcomes of meaningful use are the engagement of patients and family, greater level of care coordination, and population and public health.

Currently, it is estimated that at least 78.4% of medical practices, 59.4% of non-federal acute care hospitals, and 89% of critical-access hospitals in the United States have adopted some form of EMR.[12,13,14]

The speed and magnitude of the EMR adoption has, however, been minimized by the slow pace at which services have been able to migrate from a basic level to a comprehensive system, as was expected in HITECH. A likely reason for this status quo is the time and cost of implementing changes in medical practice to accommodate EMR and related functions. It has been estimated that an average five-physician primary care clinic needs to invest about $162,000, with an additional $85,500 in maintenance expenses during the first year, to implement an EMR.[15] Also, an average of 134 hours per physician is needed to prepare to use EMRs during patient visits. Another study of primary care practices found the cost to be "$32,409 per physician through the first 60 days after the EMR system was launched, with one-time costs for hardware of $25,000 per practice and an additional $7,000 per physician for personal computers, printers, and scanners. The annual cost of software and maintenance was approximately $17,100 per physician."[16]

Furthermore, despite the large investments by the federal government and the continued growth of information technology (IT) and health informatics, many studies failed to demonstrate evidence for recommending the use of health informatics to improve quality of health care and reduce health care costs.[17,18,19,20] Moreover, others have identified that increased use of government mandated technology, IT inclusive, was associated with both increased costs of running medical practices and decreasing number of private practices, since many new physicians preferred to be employed versus owning an expensive practice.[21,22] Two recent surveys (2013 and 2014) have actually indicated diminished support for EMR use among physicians.[23,24] One of the surveys (2014) reported about 50% of respondents said "implementation of EMR systems has made the quality of patient care worse" while 69% said "coordination of care with hospitals has not improved".[24]

Nevertheless, all in all, there appears to be a positive balance of evidence in favor of adopting information technology for health care, and health care actors continue to invest in this sector. A 2012 report estimated that providers, payers, and physician groups will be spending over $69 billion on health care-related IT and telecommunications services over the next six years. This represents a compounded growth rate of 9.7% over the forecast period, increasing from $9.1 billion in 2012 to $14.4 billion in 2017.[25]

Six manuscripts in this issue of *Missouri Medicine* address different aspects of health care management and informatics that should interest physicians who have a stake in managing the best health care possible to their patients.

Khatri's is original research which describes IT capabilities essential for health care delivery and their relationship with the population-based mortality rate from heart attack.[26] In its background review, the article illustrates business organization and processes with examples ranging from specialties to hospitals to comprehensive academic medical centers. Its main finding underscores the interactive effects of IT capabilities, workers' efforts, and flexibility on health outcomes.

Information technology-based health care data systems have been shown to increase the efficiency not only of health care delivery but also of health research studies. The article by Mosa et. al focuses on an academic medical center's experience in creating online data capture and a research data repository for the purpose of translational research.[27]

The ethical controversies about proper use of informatics in health care management are explored by Phillips' article.[28] The principles of health care ethics are systematically reviewed for health informatics practices. In this essay, the difficulties in keeping a balance between ethics and the implementation of HIT faced by planners and practitioners in the field are discussed in four topics and eight sub-topics, ranging from confidentiality and privacy to patients' portals.

Two articles cover distinct health evaluation

and research methodologies highly dependent on IT capabilities. Boren's and Moxley's article provides a basis for and step-by-step processes of systematic review of the health literature.[29] Systematic reviews are the basis for evidence-based medicine and provide critical information for decision making at the management level. Therefore, it should be used as a tool not only by academic researchers but also by health care managers and practitioners. Alafaireet et. al describes the application of concept mapping (CM) for building clinical research strategies necessary to study mental health.[30] The study is useful for both health researchers and practitioners because it describes how concept mapping use can increase critical thinking and clinical preparedness of medical staff and patients to address recidivism of mental health patients.

Finally, the larger issue of change in the management and practice of health care is framed by Hicks and Bouras through the optics of past (early managed care) and new (health care reform) organizational and policy models.[31] The authors' conclusions and recommendations center on the physician-management relationship.

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Disclosure

None reported.

MM

Health Management and Informatics

Effective Implementation of Electronic Medical Records and Health Information Technologies

by Naresh Khatri, PhD

Health information technologies, such as electronic medical records, have a great potential to improve patient safety and reduce cost of care. Their benefits in health care organizations have remained far from realized at least partly due to lack of proper implementation.



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Abstract

Information Technology (IT) capabilities are necessary for realizing the full promise of health information technologies in improving health care delivery process. In this study, three key IT capabilities for health care organizations are identified and their relationship with 30-day mortality rate from heart attack examined in a national sample of U.S. hospitals. The findings indicate that the negative relationship of IT capabilities with mortality rate from heart attack is mediated by effort/flexibility put forth by health care workers.

Introduction

Health care providers are implementing health information technologies (HITs), such as electronic medical records (EMRs) and computerized physician order entry (CPOE), rapidly in response to the American Recovery and Reinvestment Act of 2009. The number of certified HIT vendors in the United States has increased from 60 to more than 1,000 since mid-2008.[1] Many scholars/experts, however, express major concerns about the substantial and often unexpected risks resulting from the use of HITs, which are compounded by the extraordinary pace of HIT development and implementation.[2,3,4] According to these experts, the provision of "meaningful use" in the Health Information Technology for Economic and Clinical Health (HITECH) may merely prop up the HIT market without improving quality.[3] Even worse, this may end up saddling health care providers with dysfunctional HITs that would be hard to change or replace later.[4]

Undoubtedly, information technology is a powerful tool and has a great potential to transform health care.[5] The pertinent question is how to get it right without wasting a lot of time and resources.[6,7] For example, by leveraging IT investments during the 1990s, banks saw a 25% reduction in branches and a 20% reduction in full-time employees.[8] McAfee and Brynjolfsson, the leading scholars on information technologies, studied all publicly traded U.S. companies in all industries from the 1960 to 2005 and found that the performance spread across organizations had grown continuously as the most successful IT deploying organizations pulled away from the pack.[7] These scholars underscore the importance of proper deployment and exploitation of information technologies rather than merely acquiring them.

The capacity of HITs to realize the transformational vision envisaged in health care reform depends largely upon whether the systems installed are designed to produce the information

required to make possible the quality and cost reforms that are sought.[5] Today's HITs are not configured properly and do not sufficiently support aspects of care delivery that are vital to improving care and controlling costs.[9]

When the federal government began providing billions of dollars to push hospitals and physicians to use electronic medical and billing records, the goal was not only to improve efficiency and patient safety, but also to reduce health care costs. In reality, the move to electronic health records may be contributing to billions of dollars in higher cost for Medicare, private insurers, and patients by making it easier for hospitals and physicians to bill more for their services, whether or not they provide additional care.[10, 11]

The complexity of health care delivery coupled with the extent to which HITs permeate the entire health care delivery process makes implementation of HITs one of the most formidable tasks. The effective implementation of HITs is influenced by various organizational factors – especially the availability of IT expertise, among others.[12] It comes as no surprise that most health care providers are struggling in implementing HITs effectively. The outsourced HIT systems have a tendency to "airdrop" information technologies without concomitant changes in organizational cultures and management systems.[13] However, computerization is not simply buying computer hardware; instead it involves a broader collection of complementary investments and innovations, some of which take years to implement.[9, 14]

Several studies in information systems management research show that IT investments produce operational improvements only when they are accompanied by the development of effective IT capabilities.[15, 16, 17] IT capabilities of an organization enable it to acquire, deploy, and adapt IT-based resources to improve organizational processes and performance.[17, 18] Lu and Ramamurthy found that, when IT spending is not properly channeled into IT capability, greater IT spending has a negative effect on organizational performance, suggesting that IT capability is critical in realizing greater organizational performance.[15] This finding also underscores the fact that huge, impudent IT investment is not necessarily beneficial to organizational performance. This may be a result of the wrong infrastructure or incompatible systems, delayed and rushed implementations, or islands of automation meeting local needs without integration across the enterprise. For example, Smith, Buller, and Piland studied over 300 multi-specialty and 600 single-specialty groups and concluded: "Simply throwing resources at staffing or at major equipment support, such as computer hardware and software, probably does not necessarily lead to financial success…more is not always better. Thus, procuring the right IT design with appropriate capabilities for tasks and goals could produce high returns rather than simply ensuring that IT is in place".[19]

IT should be organized around business processes rather than the other way around.[7] In health care, the IT initiatives seems to be more concerned with technical aspects, in the process ignoring the vital contextual factors that make or mar IT projects.[13, 18] This happens because typical health care organizations lack sufficient IT expertise/capability and as a result they approach IT projects rather simplistically; treating them like typical health technologies such as a new medical device or a new medical procedure.[20, 21] For example, a comprehensive academic medical center appointed a registered nurse as its chief information officer with no prior background or training in IT and the people in-charge of the implementation of the outsourced HIT system were physicians who themselves acknowledged that they did not have any knowledge or expertise in IT.[13] It is hard to fathom if such managers can comprehend the IT needs of the organization, what IT systems and technologies can meet those needs, and what changes in organizational processes can be made to enhance health care delivery. A result is that the private vendor has been charging exorbitant price for a poor product that is hampering the quality of care.

Previous research has failed to find a robust and consistent relationship between IT investments and firm performance, which has led to IT experts to coin the term 'IT Paradox'. There are two plausible explanations for the apparent IT paradox (lack of relationship between IT investments and organizational performance). First, given the complexity of IT implementation, organizations without IT capabilities even if they pour a lot of resources into computer hardware are not likely to succeed in deriving the benefits of their investments. On the other hand, organizations with greater IT capabilities may get more out of their IT investments because they can identify more appropriate, potent, and cost effective HITs and deploy them more effectively. Second, HITs, instead of a direct connection with clinical outcomes, may have an indirect connection mediated by other organizational variables. In health care, the relationship between IT investments/capabilities and quality of patient care may be mediated by how ITs may enable health care workers put forth more effort and make them more flexible in meeting patients' needs.

Methods

Design, Sampling, & Data Collection

Using a stratified sampling approach, 400 acute care hospitals were selected, with 100 hospitals each from the four geographical regions of the United States: Northeast, Southeast, Midwest, and West. In addition, to gather information on hospitals serving the rural population, a stratified sample of 200 critical access hospitals, with 50 hospitals from each of the four geographical regions was used. Thus, a total of 600 hospitals formed the sample of the study.

The data were gathered from multiple informants using a survey questionnaire. The names and exact titles of the senior managers of the 600 hospitals were collected from the directory of the American Hospital Association, which is available both in printed and online formats. The directory listed names of 2,205 senior managers of 600 hospitals to whom the survey questionnaire with a personalized cover letter was sent through the regular mail. A total of 458 completed questionnaires were received, with an overall survey response rate of 20.8%. In all, 286 respondents represented the management/business side of hospitals (91 chief executive officers, 27 chief operating officers, 33 chief financial officers, 86 chief human resource officers, and 49 chief information officers) and 172 respondents represented the clinical side of hospitals (39 chief medical officers, 34 chief nursing officers, 32 directors of radiology, 33 directors of laboratories, and 34 directors of rehabilitation).

The survey was administered using the total design methodology by Dillman et. al over a period of several months in 2012.[22] The questionnaires were coded to match respondents with their organizations. Since the pre-notification letter has been found to increase the response rate, a pre-notification letter was sent to all the informants indicating that they would receive a questionnaire in about a week's time. This letter was followed by the first-wave of the survey. The first-wave of the survey was followed by a thank-you-cum-reminder card after about ten days. A second-wave of the survey was mailed to all participants after another four weeks.

TABLE 1

Means, Standard Deviations, and Correlations of Study Variables

	Variable Name	Mean	S.D.	1	2	3	4	5
1.	Status, Vision & Competence of CIO[1]	4.56	.97					
2.	IT Infrastructure[1]	4.47	1.05	.56**				
3.	Technical & Business Skills of IT Staff[1]	4.66	.94	.63**	.59**			
4.	Employee Effort & Flexibility[1]	4.80	.78	.36**	.39**	.46**		
5.	30-Day Mortality from Heart Attack[3]	15.71	1.62	-.08	-.01	-.06	-.14*	-

[1] N = 458, scales range from 1, strongly disagree, to 6, strongly agree; data gathered via uestionnaire
[2] N = 220; data gathered from *Hospital Compare* database
* p < .05
**p < .01

Measures

This study consisted of relationship among three variables; IT capabilities, employee effort and flexibility, and the 30-day mortality rate from heart attack. The data on IT capabilities and employee effort/flexibility were gathered through the survey. The data on the 30-day mortality rate from heart attack were gathered from the Hospital Compare website.

IT Capabilities

The scales of IT capabilities used in the study are available from the author upon request. A pilot study involving 102 senior managers of hospitals in Missouri was conducted to test the reliabilities and validities of three dimensions of IT capabilities. The first dimension with eight items was labeled as the vision and competence of the chief information officer (CIO) (Cronbach's $\alpha = .93$). A sample item in the scale includes 'The CIO of my hospital has a compelling vision of how to use IT to enhance hospital performance'. The second dimension of IT capabilities with four items was termed as IT infrastructure (Cronbach's $\alpha = .93$). One of the items in the scale is 'IT infrastructure greatly helps my hospital in identifying and developing key applications of IT for improving business processes rapidly'. The third dimension of IT capabilities was named as professionalism of IT staff and it included five items (Cronbach's $\alpha = .91$). A sample item in the scale is 'IT people in my hospital possess excellent IT skills'.

TABLE 2
Multiple Regression Analysis of the Relationship between IT Capabilities and Employee Effort/Flexibility

	Variable Name	Unstandardized Coefficients		Standardized Coefficient Beta	Significance Level
		B	Std. Error		
1.	Constant	2.809	.175		.000
2.	Status, Vision & Competence of CIO	.053	.045	.066	.236
3.	IT Infrastructure	.116	.040	.156	.004
4.	Technical & Business Skills of IT Staff	.274	.048	.329	.000
5.	Adjusted R Square	.233			

Employee Effort/Flexibility

Employee effort and flexibility was premised to be the mediating variable in the study. The scale has five items that were adapted from previous studies.[23, 24] A sample item in the scale includes 'Our employees are very willing to take increasing load during challenging times'. The scale showed good reliability (Cronbach's $\alpha = .92$).

30-Day Mortality Rate from Heart Attack

The data on the 30-day mortality rate from heart attack were collected from the Hospital Compare website and were available for 220 cases. Thus, the sample size of 220 cases was used for analyzing the relationship of the mortality rate from heart attack with IT capabilities.

Results

The descriptive information (means, standard deviations, and correlations) among the study variables is presented in Table 1. The correlations of the three IT capabilities with employee effort and flexibility are positive and significant, but are insignificant with the 30-day mortality rate from heart attack. The correlation between employee effort/flexibility and the 30-day mortality from heart attack is significant and negative ($r = -.14$, $p<.05$).

To test whether the relationship of IT capabilities with the 30-day mortality rate from heart attack is mediated by employee effort/flexibility, a best fitting path model was developed (see Figure 1). The model shows that the competence and vision of the CIO is the main driver of two other IT capabilities, IT infrastructure, and professionalism of IT staff. Whereas the vision and competence of the CIO had a significant positive correlation with employee effort and flexibility, it showed insignificant relationship when regressed along with IT infrastructure and professionalism of IT staff (see Table 2), indicating that IT infrastructure and professionalism of IT staff mediate the relationship of the vision and competence of the CIO with employee effort and flexibility. Employee effort and flexibility, in turn, fully mediates the negative relationship of IT infrastructure and professionalism of IT staff with the 30-day mortality rate from heart attack. Thus, the study finding lends support to the idea that the relationship of IT capabilities with the mortality rate from heart attack in U.S. hospitals is mediated by employee effort and flexibility

Dicussion

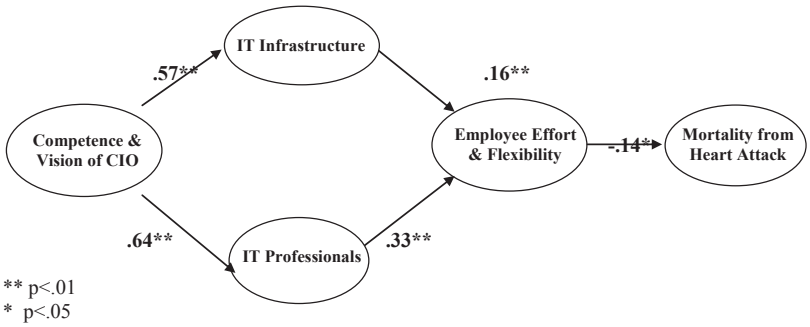
This study finds evidence that IT capabilities are negatively associated with 30-day mortality rate from heart attack in a national sample of U.S. hospitals. The relationship is not direct but mediated by employee effort and flexibility. In other words, IT capabilities may reduce mortality rate from heart attack by boosting greater effort and flexibility of health work workers.

Health information technologies, such as electronic medical records and computer physician order entry, have a great potential to improve patient safety and reduce cost of care. However, their benefits in health care organizations have remained far from realized at least partly due to lack of proper implementation. Health care providers seem to approach the implementation of HITs in a rather simplistic manner, treating them just like other medical technologies. Unfortunately, the implementation of HITs is far more complex as they constantly evolve and permeate the entire health care delivery process.

To implement HITs effectively, health care organizations need to develop in-house expertise and capabilities in information technologies. There are three critical IT capabilities. First, IT savviness of the CIO is pivotal to the realization of IT value in health care organizations. Thus, CIO being an important member of the top management team, he or she having a solid technical expertise and a compelling IT vision for the organization, he or she developing great rapport with heads of other units and departments, and he or she understanding the fundamentals of health care delivery

FIGURE 1

The Best Fitting Path Model[1] of the Relationships between IT Capabilities, Employee Effort, and 30-Day Mortality Rate from Heart Attack



** p<.01
* p<.05
N = 220

[1] Path Coefficients are standardized beta weights from multiple regression analysis.

process (e.g., hospital operations and needs/concerns of patients) are crucial. Second, in addition to CIO, health care providers also need to have a cadre of other IT professionals who have necessary technical, behavioral, and business skills. For implementing IT initiatives effectively, IT people must possess technical and interpersonal skills, communicate and interact effectively with employees and managers in other units, be conversant with change management, and have requisite expertise in conceiving and developing cost effective applications of IT to support clinical and business needs of the organization. The third IT capability is the underlying IT infrastructure. Proper IT infrastructure helps health care organizations identify and develop key applications of IT for improving care and business processes rapidly, share information across services, locations, and specialties.

Conclusion

The study findings suggest that HITs should be geared to facilitate effort and flexibility of health care workers. Health care organizations operate in a highly service-oriented context. Thus, to deliver exemplary care, health care workers need technologies that can support them in their interactions with patients. Health care organizations need to move away from a clinician-centric model to a patient-centric model and HITs with associated capabilities can go a long way in doing so.

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Disclosure

None reported.

MM

Health Management and Informatics

Online Electronic Data Capture and Research Data Repository System for Clinical and Translational Research

by Abu Saleh Mohammad Mosa, Illhoi Yoo & Jerry C. Parker

The Electronic Data Capture system allows the researchers to collect, store, and manage data electronically in a secure and HIPAA-compliant central research data repository; this can significantly reduce research-related time, effort, and costs.



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Abstract

Data is at the core of any clinical and translational research (CTR). In many studies, the electronic data capture (EDC) method has been found to be more efficient than standard paper-based data collection methods in many aspects, including accuracy, integrity, timeliness, and cost-effectiveness. The objective of this article is to present a secure, web-based EDC system for CTR that has been implemented by the Institute for Clinical and Translational Science (iCATS) at the University of Missouri School of Medicine.

Introduction

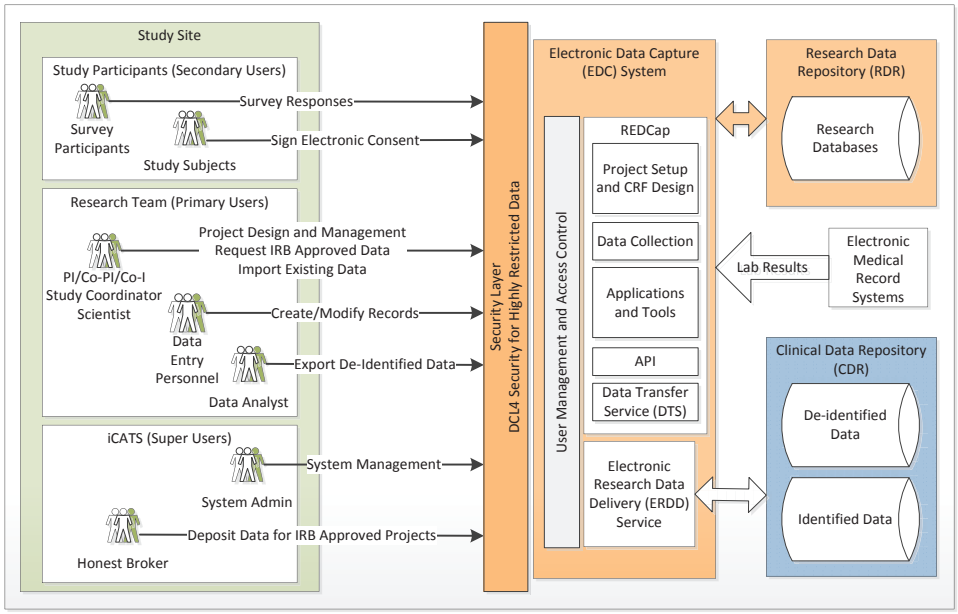
In clinical and translational research (CTR),[1] questions are answered by analyzing relevant data. Data is at the core of CTR. Almost all CTR projects have a data management component that increases cost and decreases efficiency. The data capture strategy must ensure the quality of data in order to produce effective research outcomes.[2] In addition, the regulatory authorities for CTR, such as the Institutional Review Broad (IRB), require a secure, HIPAA-compliant data management plan.[3] The objective of this article is to describe a secure, web-based application for CTR data management that has been implemented by the Institute for Clinical and Translational Science (iCATS)[4] at the University of Missouri School of Medicine.

Traditionally, the standard method of data capture in CTR projects includes two steps. In the first step, data is collected using paper-based case report forms (CRFs). In the second step, data is manually entered into electronic databases from paper-based CRFs for the purpose of data analysis. This standard paper-based data capture method is inefficient in terms of data accuracy and timeliness. The alternative to the standard data capture method is the electronic data capture (EDC) method in which data is directly entered into electronic databases using electronic CRFs. In recent years, the adoption of EDC systems for CTR has greatly increased. For example, Emam et. al. (2009)[5] estimated that about 41% of clinical trials used some form of EDC system during 2006-2007. The use of EDC systems increases data accuracy[6–9], decreases research-related costs[6,7,10], decreases overall data capture time[6,7,9–13], and ensures data integrity, security and compliance with HIPAA.[14] In this article, we describe an online EDC and research data repository (RDR) system for CTR.

System Implementation

Figure 1 presents the system architecture and user interactions

Figure 1
EDC and RDR System Architecture and User Interactions



used at the iCATS. The system consists of three main components: an electronic data capture (EDC) system, a research data repository (RDR), and a security layer. The system interacts with the clinical data repository system for retrieving clinical data for IRB-approved research projects. The EDC system has three subcomponents: user management and access control, REDCap, and electronic research data delivery (ERDD) service. The main features and subcomponents of the system are discussed in the following sections.

Electronic Data Capture System

User Management and Access Control

In the Electronic Data Capture (EDC) system, there are three user groups: super users, primary users, and secondary users. The super and primary users are required to create user accounts to access the system, whereas the secondary users are not. The system utilizes the university-wide federated access control service (known as the Shibboleth single sign-on authentication service) for authenticating the super and primary users. Accordingly, those users do not need to maintain separate accounts for the EDC system.

The super users are the employees of iCATS. They have two roles: system administrator and honest broker. The system administrator manages the EDC and RDR system, and the honest broker handles the data requests from various research teams. The honest broker is an individual who collects and provides PHI data to research investigators in an IRB-approved manner[15]. The primary users include the members of a research team such as project owners (e.g., principal investigators (PIs), co-principal investigators (co-PIs), co-investigators (co-Is), study coordinators, and scientists), data entry personnel, and data analysts. The project owners have access to the project management tools such as the project setup and CRF design module as well as all the applications within REDCap. The data entry personnel have the user rights to create or modify records, and the data analysts have the user rights to export de-identified data for data analysis purpose.

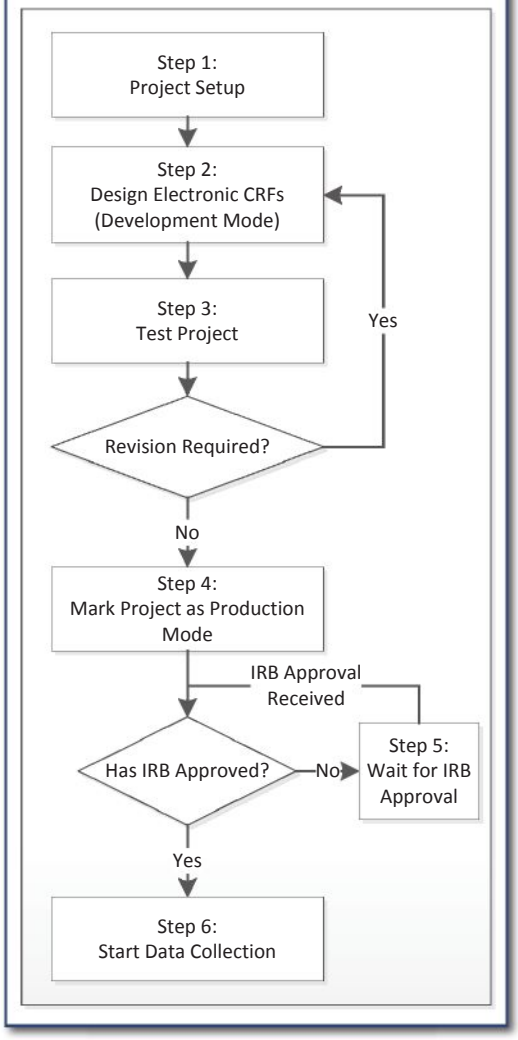
The secondary users are study participants including study subjects and survey participants. Study subjects can use the system to sign electronic consents. Any data collected from the study subjects are entered into the research database by the data entry personnel. Laboratory results can be either entered into the research database by data entry personnel or imported electronically from the Electronic Medical Record (EMR) system. If a project includes survey instruments, participants can record their responses through personalized URLs or a public URL.

Research Electronic Data Capture

Research Electronic Data Capture (REDCap)[16] is the core component of the EDC system. REDCap, developed at Vanderbilt University (VU), is a secure, web-based informatics application for developing and managing online surveys and research databases for CTR. As of April 2014, the developer team at VU has collaborative support from 1,017 active institutional partners in 79 countries (known as the REDCap Consortium). REDCap has already been implemented in all of the NIH Clinical

and Translational Science Award institutions.[17] Figure 2 presents a typical workflow for the EDC process in REDCap.

Figure 2
A Typical Workflow in REDCap



Project Setup

The first step of the EDC process is project setup (see Figure 2). In CTR, data is captured from study participants. REDCap allows two types of data collection instruments: data entry forms and surveys. Data entry forms are intended for storing data that are collected by clinicians, researchers, or any designated data entry personnel at the study site. Survey instruments are intended for collecting survey responses from study participants. There are two data collection modes: classic and longitudinal. In the classic mode, data collection is carried out only once per study subject. In the longitudinal mode, data collection is performed multiple times per study subject.

Electronic Case Report Form Design

The second step of the EDC process is designing electronic Case Report Forms (CRFs) (see Figure 2). REDCap provides a simplified methodology for building research databases quickly and easily through the online designer module. The online designer provides functionality for CRF design through an intuitive user interface. The CRFs can be designed from "scratch" or downloaded from the shared library[18]. REDCap also allows downloading the data dictionary that can be edited by experienced REDCap users and uploaded to REDCap to reflect the changes in the CRF design.

To further facilitate CRF design, there are 12 types of fields in REDCap that allow many types of data capture for CTR. Section separators with header text can be used to organize the fields into sections. Table 1 presents the field types and their properties in REDCap. The design of a field is defined by various field properties: "Field Label" defines the question or label for a field in CRF; "Variable Name" is used for data export and data analysis; "Validation", "Minimum" and "Maximum" field properties are used for performing validation on text inputs and ensuring data integrity; "Required" indicates that the field is a required field; "Identifier" indicates that the field contains personally identified information or Protected Health Information (PHI); "Alignment" defines the position of the field in the CRF; "Field Note" allows the display of short instruction on a field; "Choices" defines the pre-defined input for a field; and "Equation" defines the equation for the calculated field.

REDCap allows two types of text input: Text Box and Notes Box. The Text Box field allows single–line, short text input, while the Notes Box field allows for a large amount of text input up to 65,535 characters. The Text Box field can be validated for predefined text patterns such as data, time, email, integer, number, phone, and zip code; it also allows setting the minimum and the maximum values for validated text input. In addition, the Text Box field provides a date and time picker for date and time validation. The validation on text input improves data integrity by preventing invalid input. Thus, use of validation on text input is strongly recommended.

There are three types of multiple choice input: the Radio Buttons and Drop-down List fields allow single answer only; the Checkboxes field allows multiple answers. The choices in the multiple choice fields can be coded with numeric values for the purpose of data analysis. The Yes/No and True/False fields allow binary choice inputs; Yes and True values are coded as 1; No and False values are coded as 0. REDCap also has developed a Slider Bar or Visual Analog Scale in which the selection is between 0 and 100. The File Upload field allows end users to upload any files type. The Descriptive Text

Table 1 Field Types and Field Properties

Field Types \ Field Properties	Label	Variable Name	Required	Identifier	Alignment	Field Note	Validation	Minimum	Maximum	Choices	Equation
Text Box (Short Text)	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Notes Box (Paragraph Text)	✓	✓	✓	✓	✓	✓					
Calculated Field	✓	✓	✓	✓	✓	✓					✓
Multiple Choice Radio Buttons Drop-down List Checkboxes	✓	✓	✓	✓	✓	✓				✓	
Binary Choice Yes – No True - False	✓	✓	✓	✓	✓	✓					
Slider / Visual Analog Scale	✓	✓	✓	✓	✓	✓					
File Upload (for users to upload file)	✓	✓	✓	✓	✓	✓					
Descriptive Text (with optional image/file attachment)	✓	✓									
Dynamic Query (SQL)	✓	✓	✓	✓	✓	✓					

field allows displaying text with an inline image. The Dynamic Query field, available to super users or system administrators only, allows creation of SQL Select statements to populate drop-down lists.

Calculated fields allow users to define an equation to calculate a value based on data in other fields. Variable names of other fields are enclosed within square brackets to define the equations. An equation can be defined using 4 mathematical operations (add, subtract, multiple, and divide) and 12 functions (round, round-up, round-down, square root, exponents, absolute value, minimum, maximum, mean, median, sum, and standard deviation).

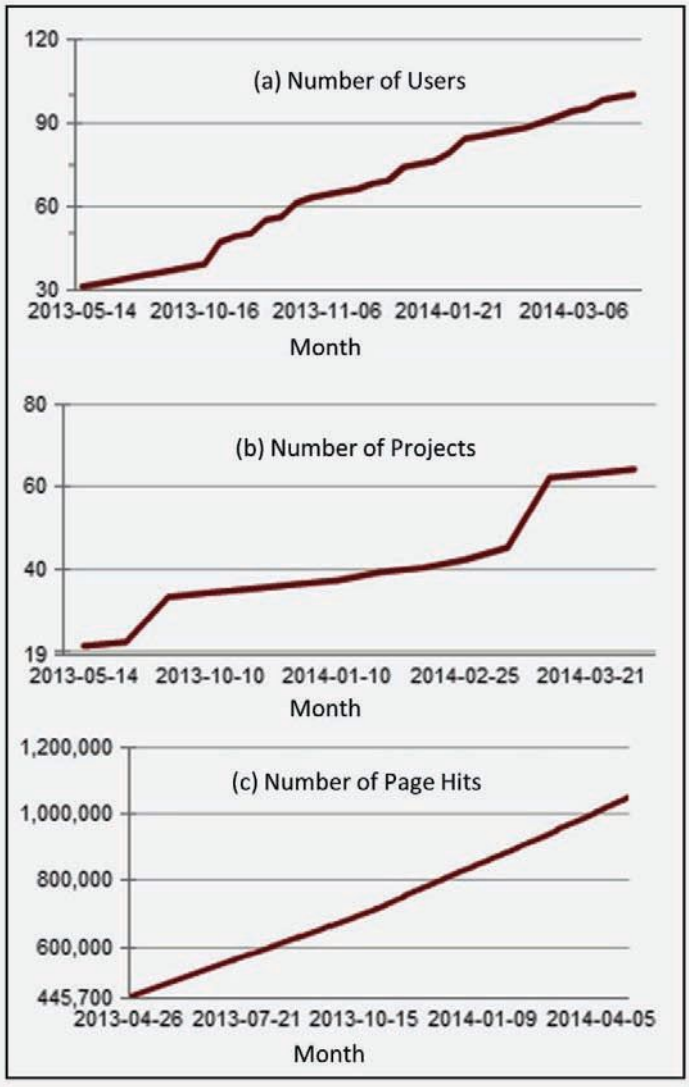
There are two other widely-used features for CRF design: matrix of fields and branching logic. In CRFs, a group of similar multiple-choice fields (either single-answer through radio buttons or multiple answers through checkboxes) can be displayed in a very compact manner by using the matrix of fields. This is a widely used feature in designing survey instruments. The branching logic is used for hiding/showing certain fields within a form based on the values in other fields. The attribute-value pairs are combined with logical operators (AND and OR) to define a branching logic.

Data Collection

While the project is in development mode, a strong recommendation is that CRFs be thoroughly tested and revised as desired before starting real data collection (Step 3 in Figure 2). Once the CRFs are tested and found satisfactory, the project should be marked as "production mode" before starting real data collection (Step 4 in Figure 2). Although modification of CRFs is allowable in "production mode", the recommendation is not to do so once data collection has started. In production mode, changes in CRF design should be reviewed very carefully to avoid potential data loss.

The project needs to be approved by the IRB before data collection can be started (Step 5 in Figure 2). The final step of the EDC process is data collection (Step 6 in Figure 2). To create new records or to modify existing records, primary users will need to have access to the CRFs with "create/modify records" user rights. The data is entered using the electronic CRFs through a web-based application and stored in the research database which resides in the RDR. Survey participants receive either a generic public URL or personalized unique URLs correlating each participant to record their survey responses. If a project contains both data entry forms and survey instruments, the

Figure 3
System Usage Charts from May 2013 to April 2014
(a) Number of Users
(b) Number of Projects
(c) Number of Page Hits



survey responses are stored with the corresponding records of each participant to ensure data integrity.

REDCap Applications and Tools

REDCap provides several applications and tools for project management. Access to the applications is controlled based on a user role within the project.

The Calendar application allows maintaining a project calendar that helps to organize project schedules, especially for scheduling the study subjects' visit for longitudinal data collection. In longitudinal projects, study subjects are seen multiple times (called events) for data collection. The Scheduling Generator module can be used to generate the schedules based on the predefined events and stored in the project calendar. The study coordinator and the data entry personnel can greatly benefit from this application by ensuring on-time data collection.

The Data Export Tool allows users with appropriate access permission to export data from a project. The data export functionalities include exporting data in Microsoft Excel, SAS, Stata, R, or SPSS format for all or selected fields; data export also allows HIPAA-complaint de-identification; this tool is useful for the data analyst role. The Data Import Tool application is useful for project owners (e.g. PIs, co-Is, co-Is, or scientists) in order to import data from existing sources. The File Repository application enables the users to store, retrieve, or upload files and documents in a project. The previously exported data files also can be retrieved from this application. The Data Comparison tool can be used to compare two records in a project.

REDCap keeps track of all activities including data exports, changes in project design, and the creation, modification or deletion of users and data. The Logging tool is used for auditing all changes within a project. The Field Comment Log application allows the display, search, or download of comments associated with the fields. Records can be locked with or without E-signature, and the locked records can be managed using the E-signature and Locking application. The record locking options can be customized for individual CRFs using the Record Locking Customization application.

The Graphical Data View and Stats application displays descriptive statistics and aggregate results in graph form that can be used for data cleaning and evaluation. The Data Quality application has two functions: defining data-quality rules and executing those rules to check for discrepancies. There are some pre-defined data-quality rules available to every project such as missing values, missing values within required fields only, field validations for incorrect data types and out of range values, outliers for numeric fields, and multiple choice fields with invalid values. The Report Builder application creates and exports customized reports.

REDCap API: REDCap provides an Application

Programming Interface (API) for exporting project metadata (e.g., data dictionary), records, files, events, and users; it also allows importing records and files in a secured and automated manner from external applications remotely. For example, connection is possible to REDCap from R software for retrieving the data and performing analysis.

Data Transfer Service

Data from external sources can be directly entered into REDCap projects through the Data Transfer Service (DTS). The process requires a user to map data fields from external sources to REDCap project fields. DTS loads data from external sources into REDCap in a periodic manner and makes the data available to the project owners for adjudication before saving into their projects.

Electronic Research Data Delivery Service

The Electronic Research Data Delivery (ERDD) service is available to researchers through the honest broker. The function of the honest broker is to deliver data from the identified database to researchers who have IRB approved projects[15]. The ERDD service enables CTR researchers to get clinical data, including protected health information (PHI) from the clinical data repository (CDR) system. The CDR system was implemented using an open source system called Informatics for Integrating Biology and the Bedside (i2b2)[19] with the goal of secondary reuse of existing clinical data for CTR. The researchers can utilize the system for cohort identification, retrospective data analysis, and hypothesis generation. The CDR system has two databases: de-identified and identified databases. CTR researchers have aggregate access to the de-identified database. The aggregate access allows a researcher to query the de-identified database to generate a patient count based on inclusion and exclusion criteria. Once the data subset is identified for a CTR project, the researcher can submit an IRB application to get approval for data download. The honest broker then retrieves the data from i2b2 in electronic format and deposits the data into the research database through the REDCap data import tool.

The honest broker performs the ERDD service in four steps. First, data is exported from the CDR system for the requested query. Second, a CRF is created in REDCap for all the columns in the dataset. Third, the dataset is converted into a REDCap-importable format. Fourth, the dataset is imported into REDCap.

Research Data Repository

Research databases are stored in the Research Data Repository (RDR), which is built upon the MySQL database management system. The databases are designed through the electronic CRF design module. All the fields in the CRFs have unique variable names within a project and these are used for storing the data into the database as attribute-value pairs.

System Security Layer

The University of Missouri classifies PHI data (subject to HIPAA regulations) as Data Classification Level 4 (DCL4 – Highly Restricted)[20]. The EDC system is secured with a DCL4 security layer that is maintained by the Division of IT at the University of Missouri.

System Usage and Discussion

Figure 3 presents the system utilization graphs for the past year (May, 2013 to April, 2014). The three charts show: (a) number of users, (b) number of projects, and (c) page hits. All of the graphs present a linear growth of system usage. Currently, the EDC system hosts 64 projects and involves 102 users. A total of 43 projects are currently active with 19 projects in production status and 24 projects in development status. Out of those 43 active projects, 35 projects contain survey instruments.

The web-based EDC system that has been implemented provides several benefits over traditional data collection strategies using paper-based CRFs. First, it facilitates the design of project-specific electronic CRFs with data validation and audit trail capabilities that reduces project-specific programming and improves the quality of data. Second, the EDC system allows federated authentication with role-based access control to facilitate collaborative access to data from anywhere at any time. Third, it can store data and project specific documents in a highly-secured central research data repository with scheduled backup service. Fourth, it allows importing bulk data from other systems and exporting data to common statistical packages for data analysis.

Currently, there are two semi-automated processes that could be fully automated. First, the data entry related to lab results requires manual data input into the REDCap project. The manual process is not user friendly for large projects, and it can be fully automated. In CTR, the study subjects are seen by clinicians at the study site who may collect some of their data through laboratory tests. Once the test is complete, the lab results are available in the EMR system. The DTS allows data from external sources (such as EMR) to be entered directly into REDCap projects. Currently, the process is underway to design the data mapping from EMR to REDCap to enable the DTS service. Second, the honest broker has to complete the four semi-automated steps for transferring the data electronically

from CDR to a REDCap project. The future goal is to develop a fully automated process in which those steps are combined into a software application using the REDCap API and i2b2 web services.

There are limitations to implementing an EDC system based on REDCap. First, REDCap can host only small to medium sized projects because of its data storage design. Data is stored using the Entity–Attribute–Value (EAV) model, instead of the relational model. The EAV model allows metadata-driven project development, so it is not suitable for storing a large amount of data. Second, REDCap projects are partially portable; projects cannot be exported from one REDCap system to another. The only way to port a project is by exporting the data dictionary from a REDCap system and importing the data dictionary into another REDCap system. However, the project settings are not exported with the data dictionary. Thus, the project settings have to be applied manually. In addition, the exported data cannot be imported directly; it requires some modification to the data file. For example, the calculated fields cannot be imported. Third, REDCap API does not allow importing a data dictionary. Thus, the project fields cannot be created programmatically. As a result, the ERDD application must create a data dictionary first, and the honest broker needs to upload the data dictionary into the REDCap project requiring one manual step. Alternately, the ERDD application can be developed as part of the REDCap system, instead of developing a standalone application.

Conclusion

We have implemented an online EDC system for the CTR researchers at the University of Missouri. Adoption of the system has been increasing gradually. The EDC system allows the CTR researchers to collect, store, and manage research data electronically in a secure and HIPAA-compliant central research data repository; this can significantly reduce research-related time, effort, and costs so that CTR researchers can focus on data analysis and their research activities.

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Disclosure

None reported.

MM

Health Management and Informatics

Ethical Controversies About Proper Health Informatics Practices

by Win Phillips, PhD

Despite the existence of the HIPAA regulations and institutional monitoring of records, snooping, hacking, public breaches, and health care identify thefts still occur.



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Health informatics studies health care information and communication, both of which have been greatly affected in recent years by the use of computers and the web by both clinicians and patients. Many practices now use electronic medical records (EMRs) and computerized provider order entry (CPOE). Patients often surf the web seeking health information. But some uses of computers in health care are controversial and raise ethical concerns, especially when patient safety and outcomes are at stake.

For guidance about ethics, health care often relies on the principles of respect for autonomy, nonmaleficence, beneficence, and justice.[1] Respecting autonomy means allowing individuals control over their lives. Nonmaleficence requires refraining from harming patients, while beneficence entails providing beneficial care. (Beneficence also includes preventing harm – as opposed to refraining from harm, which is nonmaleficence.) Justice seeks a fair distribution of resources and responsibilities.

These principles have relevance to health informatics practices. In the discussion over the ethics of such computer use in health care, we see a recurring theme of tensions among the principles of respect for autonomy, beneficence, and nonmaleficence.

For example, EMR systems can benefit patients by improving care access, quality, coordination, and cost.[2] If the ideal use of EMR and CPOE systems provides significant patient benefit, there would seem to be a moral obligation for clinicians to use them. But some clinicians find the inconvenience of such systems to be a burden, and patients can experience clinician use of such systems during medical encounters as intrusive. Furthermore, what if clinicians using such systems in actual practice engage in documentation techniques that may be dangerous to patients? Would that call into question that use of such systems is a moral obligation? Or only that if used, such systems must be used in a morally responsible fashion? Tension among the ethical principles also occurs in the area of patient use of the web and social media. How can we respect the autonomy of patients to use these technologies while at the same time preventing possible patient harm from inaccurate information and illicit prescription medication purchases?

Confidentiality and Privacy in a Wired World

Clinicians and institutions using EMR systems must ensure patient health information confidentiality and protect patient privacy. With computer systems this seems a

difficult task because records are easily shared with more people: physicians, nurses, other clinicians, clerks, coders, managers, information technology staff, insurance personnel, the government, patients, vendor staff, and even patients themselves. Health information exists not only in an institution's electronic medical records but is also made available through health information exchanges, personal health records, and patient portals.

Those working in health care have a moral (and legal) obligation to protect information confidentiality and patient privacy. Electronic records and associated systems are thus monitored and secured to prevent privacy breaches. The moral basis of such an obligation is in respecting patient autonomy (keeping patients in control of their health information), and refraining from harming and preventing harm to patients (nonmaleficence and beneficence), as might occur, for example, through disclosure of embarrassing information. Patients who feel their health information will be kept confidential will more likely share it willingly with providers, which is important for optimal care.

Yet despite the existence of the HIPAA (Health Insurance Portability and Accountability Act) regulations and institutional monitoring of records, snooping, hacking, public breaches, and health care identify thefts occur.[3, 4] Perhaps even greater security technologies and policies are warranted. But strict security measures are often in tension with clinician needs for convenient and timely access to such information. Clinicians already chafe at what they see as overly strict and burdensome security requirements such as having to constantly log in after a short auto-log out, change passwords at regular time intervals (and meet technical requirements for password acceptability, making them difficult to recall, and be unable to reuse previous passwords), remember multiple user names and passwords for different systems, be unable to store chart notes on computers that leave the facility, establish VPN (Virtual Private Network) connections to access hospital records from home, and authenticate/justify one's role before accessing particular patient records. Information technology staff need to work with clinicians and seek their input in security techniques, otherwise they risk clinicians trying to bypass security measures out of frustration.

Respecting patient autonomy may even entail allowing patients to weigh in on some policy decisions. Hospitals debate whether patient consent to Health Information Exchange (HIE) participation should be in the form of an opt-out or opt-in policy. Opt-out policies may increase patient participation. But allowing patients to opt-out of participation in a Health Information Exchange may not safeguard patient autonomy as much as would requiring patients to opt-in. How much information needs to be provided to patients about the HIE for an opt-out policy to constitute consent that is truly informed? From reading a technical paragraph in a consent form presented by a receptionist, do patients fully understand what information is being made available where? These questions will be even more relevant if a nationwide HIE (a National Health Information Network (NHIN) or Nationwide Health Information Network (NwHIN)) is realized because patients may object to having to opt-out to prevent their personal health information being made available practically anywhere to any provider at any institution. Some patients are so apprehensive about loss of control they worry about health information stored in an EMR quite apart from an HIE – some desire an opt-out policy for certain information in the EMR.[5]

Clinical Documentation Practices

Not only are confidentiality, privacy, and security requirements sometimes controversial, so too is the trade-off between documentation accuracy and convenience. Clinicians have a moral responsibility to make sure medical records are accurate, but accuracy is sometimes sacrificed to convenience through questionable EMR documentation practices.[6]

Copy and Paste

One area of concern is the use of what has been termed "content importing technology" (CIT).[7] EMR systems commonly allow copy and paste techniques from one note to another, even between different patients, and they allow copying from the notes of other providers. Many EMR systems allow the clinician to import almost all of the content of a previous note (a note documenting a past encounter) into a new note (a note for a different encounter). This particular functionality may be called "pull previous" or "copy forward." Identical sections appearing in completely different notes created using such techniques may be considered instances of "cloned documentation." EMR systems also often feature templates, or preconfigured note structures that may already be prepopulated with section contents for a specific type of procedure or even for a specific disease. Other common shortcuts are capabilities to automatically

include a complete and normal review of systems and to import lab results directly into a chart note. Providers insist on such techniques because they can be tremendous documentation time-savers.

But used carelessly such shortcuts can result in inaccurate notes and may create legal liability problems.[8] When copying, importing, or using templates, the provider is supposed to carefully review the note for faithfulness to what actually happened in the current encounter. Medical decisions made on the basis of inaccurate notes may compromise patient safety or outcomes. Copying and pasting another clinician's content without proper attribution might be considered plagiarism or fraud.

Such documentation problems may be the result of not just carelessness but unfamiliarity with the system. To be used optimally, EMR systems require user training.[9] It is often difficult for providers to fit training into a busy patient schedule, but institutions have a moral responsibility to provide clinicians with adequate training and providers have the responsibility to avail themselves of it.

Computer in the Exam Room

Another controversy is over the presence of the computer in the exam room, and this too can become an ethics matter if it affects what occurs during the clinician-patient encounter. Some providers interact with EMR and CPOE systems while at the same time trying to engage the patient. A computer being used for documentation in the exam room can function as a physical or psychological barrier between provider and patient. Patients who feel physicians interact more with the computer than with them may feel alienated and consequently decline to share important concerns.[10]

Structured Data

A final documentation issue concerns structured data. Increasingly, the federal government (meaningful use requirements) is requiring at least some of the information in a note be structured data. Structured data exists when such information is in a discrete form that can be optimally stored in the fields of a database. In such a form, and aggregated, patient information can be used for secondary data analysis. Data querying and data mining could yield important previously undetected patterns about patient symptoms, diseases, treatments, and complications. Such information could also be used for public health surveillance.[11] Structured data is also often needed to trigger decision-support features in the system.

Because computers cannot yet fully "understand" natural language sentences, the traditional narrative text of a chart note does not result in structured data in the database. Current natural language processing programs may be able to convert some of narrative text to structured data, but by and large to get structured data into a database the clinician must enter it that way. Hence the existence of drop-down menus, data entry boxes, and the like for entering vitals and creating problem lists and medication lists, for example.

Some providers find entering data by such techniques saves time, while others find it tedious. Unfortunately, though, it is the provider who bears the burden of having to enter data in a way the computer requires, not in a way that they might find more convenient (narrative dictation). Completeness may also suffer. Chart notes created by structured data entry techniques may resemble an outline more than a detailed story, which may make it difficult for other clinicians reading the note to get an adequate sense of the "patient's story." Can one tell the unique story of a particular patient by using drop down menus without something being left out? Will the provider then resort to using both structured data entry and accompanying narrative text, which would seem to take longer than narrative text alone?

Secondary data analysis made possible by structured data raises questions about privacy and consent and thus ultimately patient autonomy.[12] Some seek to justify use of patient information in secondary data analysis on the basic of serving the public good.[13] But a patient may object that their consent to use of personal health information for treatment, payment, or operations (TPO) does not automatically include consent to use for scientific research, no matter how noble; they never agreed to details of their clinical encounters being used for that, even in aggregated, de-identified form.

Decision Support

EMR and CPOE systems often include decision-support features, such as diagnosis aids, medication recommendations, customized information displays (such as graphs showing trends), clinical calculators (for example, for dosing), available guidelines and protocols, and warning messages and alerts (for example, about possible drug-drug interactions). As mentioned, these

functions sometimes key off of structured data. For example, dosing recommendation depend on the patient's weight being entered in a special data-entry box rather than being buried in a narrative paragraph. Drug-drug interaction problem detection depends on a medication list completed by drop-down menu choices rather than a narrative paragraph listing medications.

Ethical

Several ethical issues arise about the development and use of decision-support technologies. If such a technology is available, and might help prevent patient harm or improve patient outcomes, is the provider morally obligated to use it? Since the provider is the ultimate decision-maker, what if the provider relies on decision-support recommendations that prove incorrect? Is the provider morally (or legally) at fault? Does the vendor bear any moral responsibility for incorrect recommendations or faulty software? What if the problem is not faulty information in the system, but rather a poorly designed display that misleads or is easily misinterpreted by the provider?

Legal

On the other hand, there may be legal liability issues if the provider decides not to make use of available decision-support recommendations.[14] Government regulations and the courts would decide whether particular software programs could be held legally at fault under standards of ordinary negligence or strict product liability. Vendors commonly write "indemnify and hold harmless" clauses into contracts with purchasers to avoid such responsibility.[16] But one could argue that vendors nevertheless bear moral responsibility for using best practices to develop and test their software systems.

Functionality

In some cases, decision support functionality can become intrusive and counterproductive. For example, too many warnings can cause "alert fatigue."[16] Furthermore, if the provider cannot override an alert when legitimately needed, the system may hinder, rather than enhance, proper patient care.[17]

Social Media

Information and Advice

The explosion of social media during the last decade has created many opportunities in health care for using the web and mobile devices; some of these are characterized as "consumer informatics." Associated informatics-related fields or subfields are mHealth (mobile devices) and eHealth (electronic delivery, such as online eVisits). On the web patients can obtain health-related information, interact in blogs and support groups, purchase health-related products (such as exercise equipment, monitoring devices, and nutritional supplements), engage in eVisits, access medical records and pay hospital bills through patient portals, maintain personal health records, and even buy prescription medications.

Web sources have a moral obligation to ensure health information provided is accurate, since to do otherwise may harm patients. It is not easy for the patient to discern what is accurate, and much health information on the web is inaccurate.[18] Online blogs, forums, and support groups may spread incorrect information or imprudent health advice that may be physically or psychologically harmful.

Prescription Medication

Of questionable morality is the alleged practice of some pharmaceutical companies of operating support group sites whose real purpose is clandestine market research. Also controversial is pharmaceutical companies engaging in online direct-to-consumer (DTC) advertisement of drugs in an attempt to have patients "pressure" physicians to prescribe them and perhaps also to subtly advertise to physicians directly. Such advertisements may appear to patients searching for information about associated diseases or participating in related online forums. Patients may be unaware they are being targeted.

Patients use the web for more than information – they can buy prescription medications from online pharmacies. While some legitimate pharmacies have an online sales presence and require prescriptions for purchases, others are from unknown businesses and may provide prescription medications to patients without prescriptions. In such cases the patient has no way of knowing what he or she is really buying. It may be illegal for those in the United States to buy from online pharmacies located outside the country, but the fact that some consumers buy medications from such sources raises possible ethical concerns in itself. Patients may think they are getting a better price. Are American drug prices so high some patients cannot afford them? Or they may think their provider will not meet their medication needs. Do patients have trouble obtaining needed

medications from their local physician and pharmacy? In cases where cost or access is an issue the principle of justice, interpreted as fairness to all patients in provision of health care resources, may be relevant.

The ethical issue for health care professionals is about what guidance to give patients about use of sites dispensing information, advice, or medications. Steering patients away from all such sites seems unrealistic. Recommending specific reputable sites may be more helpful, but obviously self-diagnosis from web information is no substitute for seeing a provider. Some hospitals and practices themselves make health information available on the web in an attempt to provide a reliable source of information for patients. Cautioning patients about online prescription purchases from questionable sites would also seem important. Again, though, sometimes here we see a tension between following the obligation to respect patient autonomy and preventing harm to patients (beneficence).

Patient Portals

To further engage patients in responsibility for their health, patient portals are now available for viewing and paying on financial accounts, as well as accessing limited clinical data. Some facilities allow patients to access their own medical records or lab test results via a patient portal. Critics contend lab results could be easily misinterpreted by a patient. Some hospitals offer personal health records that download information from the hospital records. Obviously if data must be entered into PHRs by patients a concern is possible inaccurate or missing information. Other patient delivery modalities are eVisits, telehealth, and email communication. eVisits have found limited use to help with monitoring and management of chronic conditions for existing patients but it would be arguably irresponsible to attempt to provide extensive management of complex conditions or seeing new patient via eVisits. Telehealth, similar to eVisits but often for monitoring purposes only or making more extensive use of video interaction, also is better suited to some usages (emergency trauma transport) than others (more complicated initial diagnoses). Some physicians are willing to engage in email exchanges with patients but for only limited purposes. Confidentiality concerns, unrealistic patient expectations of service or for immediate replies, time constraints, and reimbursement issues make email of limited usefulness.

Clinician Use

Clinicians themselves need to exercise caution on the web. They should never post patient pictures or protected health information (PHI) on social media sites, such as Facebook, even if the patient is not easily identifiable. Griping about patients, other clinicians, or health care management should also be avoided. Some physicians feel the same should hold for patient behavior and so refuse to take patients who will not sign a pledge to refrain from negative reviews of the physician on websites. While the desire to avoid unfair damage to one's reputation is understandable, a coercive stipulation like this seems difficult to square with the moral obligation to always place the patient's interests above one's own.

The use of EMRs and CPOEs is seemingly becoming a standard of care.[19] The challenge will be to use this new standard of care in a morally responsible manner.

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MU HMI Health Management and Informatics

Systematically Reviewing the Literature: Building the Evidence for Health Care Quality

by Suzanne Austin Boren, PhD & David Moxley, MLIS

Undertaking a literature review includes identification of a topic of interest, searching and retrieving the appropriate literature, assessing quality, extracting data and information, analyzing and synthesizing the findings, and writing a report.



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Abstract

There are important research and non-research reasons to systematically review the literature. This article describes a step-by-step process to systematically review the literature along with links to key resources. An example of a graduate program using systematic literature reviews to link research and quality improvement practices is also provided.

Introduction

Systematic reviews that summarize the available information on a topic are an important part of evidence-based health care. There are both research and non-research reasons for undertaking a literature review. It is important to systematically review the literature when one would like to justify the need for a study, to update personal knowledge and practice, to evaluate current practices, to develop and update guidelines for practice, and to develop work related policies.[1] A systematic review draws upon the best health services research principles and methods to address: What is the state of the evidence on the selected topic? The systematic process enables others to reproduce the methods and to make a rational determination of whether to accept the results of the review. An abundance of articles on systematic reviews exist focusing on different aspects of systematic reviews.[2-9] The purpose of this article is to describe a step by step process of systematically reviewing the health care literature and provide links to key resources.

Systematic Review Process: Six Key Steps

Six key steps to systematically review the literature are outlined in Table 1 and discussed here.

1. Formulate the Question and Refine the Topic

When preparing a topic to conduct a systematic review, it is important to ask at the outset, "What exactly am I looking for?" Hopefully it seems like an obvious step, but explicitly writing a one or two sentence statement of the topic before you begin to search is often overlooked. It is important for several reasons; in particular because, although we usually think we know what we are searching for, in truth our mental image of a topic is often quite fuzzy. The act of writing something concise and intelligible to a reader, even if you are the only one who will read it, clarifies your thoughts and can inspire you to ask key questions. In addition, in subsequent steps of the review process, when you begin to develop a strategy for searching the

literature, your topic statement is the ready raw material from which you can extract the key concepts and terminology for your strategies. The medical and related health literature is massive, so the more precise and specific your understanding of your information need, the better your results will be when you search.

Table 1. Systematic Review Steps

Step	Action
1	Formulate the Question and Refine the Topic
2	Search, Retrieve, and Select Relevant Articles
3	Assess Quality
4	Extract Data and Information
5	Analyze and Synthesize Data and Information
6	Write the Systematic Review

2. Search, Retrieve, and Select Relevant Articles

The retrieval tools chosen to search the literature should be determined by the purpose of the search. Questions to ask include: For what and by whom will the information be used? A topical expert or a novice? Am I looking for a simple fact? A comprehensive overview on the topic? Exploration of a new topic? A systematic review? For the purpose of a systematic review of journal research in the area of health care, PubMed or Medline is the most appropriate retrieval tool to start with, however other databases may be useful (Table 2). In particular, Google Scholar allows one to search the same set of articles as PubMed/MEDLINE, in addition to some from other disciplines, but it lacks a number of key advanced search features that a skilled searcher can exploit in PubMed/MEDLINE.

An effective way to search the literature is to break the topic into different "building blocks." The building blocks approach is the most systematic and works the best in periodical databases such as PubMed/MEDLINE. The "blocks" in a "building blocks" strategy consist of the key concepts in the search topic. For example, let's say we are interested in researching about mobile phone-based interventions for monitoring of patient status or disease management. We could break the topic into the following concepts or blocks: 1. Mobile phones, 2. patient monitoring, and 3. Disease management. Gather synonyms and related terms to represent each concept and match to available subject headings in databases that offer them. Organize the resulting concepts into individual queries. Run the queries and examine your results to find relevant items and suggest query modifications to improve your results. Revise and re-run your strategy based on your observations. Repeat this process until you are satisfied or further modifications produce no improvements. For example in Medline, these terms would be used in this search and combined as follows: cellular phone AND (ambulatory monitoring OR disease management), where each of the key word phrases is an official subject heading in the MEDLINE vocabulary. Keep detailed notes on the literature search, as it will need to be reported in the methods section of the systematic review paper. Careful noting of search strategies also allows you to revisit a topic in the future and confidently replicate the same results, with the addition of those subsequently published on your topic.

3. Assess Quality

There is no consensus on the best way to assess study quality. Many quality assessment tools include issues such as: appropriateness of study design to the research objective, risk of bias, generalizability, statistical issues, quality of the intervention, and quality of reporting. Reporting guidelines for most literature types are available at the EQUATOR Network website (http://www.equator-network.org/). These guidelines are a useful starting point; however they should not be used for assessing study quality.

4. Extract Data and Information

Extract information from each eligible article into a standardized format to permit the findings to be summarized. This will involve building one or more tables. When making tables each row should represent an article and each column a variable. Not all of the information that is extracted into the tables will end up in the paper. All of the information that is extracted from the eligible articles will help you obtain an overview of the topic, however you will want to reserve the use of tables in the literature review paper for the more complex information. All tables should be introduced and discussed in the narrative of the literature review. An example of an evidence summary table is presented in Table 3.

5. Analyze and Synthesize Data and information

The findings from individual studies are analyzed and synthesized so that the overall effectiveness of the intervention can be determined. It should also be

Table 2. Examples of Electronic Bibliographic Databases Specific to Health Care

Bibliographic Databases	Topics	Website
Cumulative Index to Nursing and Allied Health (CINAHL)	nursing and allied health	http://www.ebscohost.com/biomedical-libraries/the-cinahl-database
EMBASE	international biomedical and pharmacological database	http://www.elsevier.com/online-tools/embase
Medline /Pubmed	biomedical literature, life science journals, and online books	http://www.ncbi.nlm.nih.gov/pubmed/
PsycINFO	behavioral sciences and mental health	http://www.apa.org/pubs/databases/psycinfo/index.aspx
Science Citation Index (SCI)	science, technology, and medicine	http://thomsonreuters.com/science-citation-index-expanded/
SCOPUS	scientific, technical, medical, social sciences, arts, and humanities published after 1995	http://www.scopus.com/
The Cochrane Library	evidence of effectiveness of interventions	http://www.thecochranelibrary.com/

Note: These databases may be available through university or hospital library systems.

observed at this time if the effect of an intervention is comparable in different studies, participants, and settings.

6. Write the Systematic Review

The PRISMA[12] and ENTREQ[13] checklists can be useful resources when writing a systematic review. These uniform reporting tools focus on how to write coherent and comprehensive reviews that facilitate readers and reviewers in evaluating the relative strengths and weaknesses. A systematic literature review has the same structure as an original research article:

TITLE: The systematic review title should indicate the content. The title should reflect the research question, however it should be a statement and not a question. The research question and the title should have similar key words.

STRUCTURED ABSTRACT: The structured abstract recaps the background, methods, results and conclusion in usually 250 words or less.

INTRODUCTION: The introduction summarizes the topic or problem and specifies the practical significance for the systematic review. The first paragraph or two of the paper should capture the attention of the reader. It might be dramatic, statistical, or descriptive, but above all, it should be interesting and very relevant to the research question. The topic or problem is linked with earlier research through previous attempts to solve the problem. Gaps in the literature regarding research and practice should also be noted. The final sentence of the introduction should clearly state the purpose of the systematic review.

METHODS: The methods provide a specification of the study protocol with enough information so that others can reproduce the results. It is important to include information on the:

- Eligibility criteria for studies: Who are the patients or subjects? What are the study characteristics, interventions, and outcomes? Were there language restrictions?
- Literature search: What databases were searched? Which key search terms were used? Which years were searched?
- Study selection: What was the study selection method? Was the title screened first, followed by the abstract, and finally the full text of the article?
- Data extraction: What data and information will be extracted from the articles?
- Data analysis: What are the statistical methods for handling any quantitative data?

RESULTS: The results should also be well-organized. One way to approach the results is to include information on the:

- Search results: What are the numbers of articles identified, excluded, and ultimately eligible?
- Study characteristics: What are the type and number of subjects? What are the methodological features of the studies?

Table 3. Example of an evidence summary table

Author/Yr	Sample Size	Technology	Duration	Delivery Frequency	Control	Intervention	Measures	Results
			Months					C vs. I
Benhamou 2007 [10]	30	SMS, V, PDA, I	12	Weekly	No weekly SMS support	Weekly SMS diabetes treatment advice from their health care providers based on weekly transfer of SMBG and QOL survey every three months	HbA1c	+0.12 vs -0.14%, P<0.10
							SMBG	+5 vs -6 mg/dl, P=0.06
							QOL score	0.0 vs +5.6, p< .05
							Satisfaction with Life	-0.01 vs + 8.1, P<.05
							Hypo episodes	79.1 vs 69.1/patient, NS
							No of BG tests/day	-.16 vs -.11/day, NS
Marquez Contreras 2004 [11]	104	SMS	4	Twice/Week	Standard treatment	SMS messages with recommendations to control Blood Pressure	% of compliers	51.5% vs. 64.7%, P=NS
							Rate of compliance	88.1%vs. 91.9%, p=NS
							% of patients with BP control	85.7% vs. 84.4%, P=NS

Notes: BP = blood pressure, HbA1c = Hemoglobin A1c, Hypo = hypoglycemic, I = Internet, NS = not significant, PDA = personal digital assistant, QOL = quality of life, SMBG = self-monitored blood glucose, SMS = short message service, V = voice

- Study quality score: What is the overall quality of included studies? Does the quality of the included studies affect the outcome of the results?
- Results of the study: What are the overall results and outcomes? Could the literature be divided into themes or categories?

DISCUSSION: The discussion begins with a non-numeric summary of the results. Next, gaps in the literature as well as limitations of the included articles are discussed with respect to the impact that they have on the reliability of the results. The final paragraph provides conclusions as well as implications for future research and current practice. For example, questions for future research on this topic are revealed, as well as whether or not practice should change as a result of the review.

REFERENCES: A complete bibliographical list of all journal articles, reports, books, and other media referred to in the systematic review should be included at the end of the paper. Referencing software can facilitate the compilation of citations and is useful in terms of ensuring the reference list is accurate and complete.

Resources

The following resources may be helpful when writing a systematic review:

CEBM: Centre for Evidence-based Medicine. Dedicated to the practice, teaching and dissemination of high quality evidence based medicine to improve health care Available at: http://www.cebm.net/.

CITING MEDICINE: The National Library of Medicine Style Guide for Authors, Editors, and Publishers. This resource provides guidance in compiling, revising, formatting, and setting reference standards. Available at http://www.ncbi.nlm.nih.gov/books/NBK7265/.

EQUATOR NETWORK: Enhancing the QUAlity and Transparency Of health Research. The EQUATOR Network promotes the transparent and accurate reporting of research studies. Available at: http://www.equator-network.org/.

ICMJE RECOMMENDATIONS: International Committee of Medical Journal Editors Recommendations

for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. The ICJME recommendations are followed by a large number of journals. Available at: http://www.icmje.org/about-icmje/faqs/icmje-recommendations/.

PRISMA STATEMENT: Preferred Reporting Items for Systematic Reviews and Meta-Analyses. Authors can utilize the PRISMA Statement checklist to improve the reporting of systematic reviews and meta-analyses. Available at: http://prisma-statement.org.

THE COCHRANE COLLABORATION: A reliable source for making evidence generated through research useful for informing decisions about health. Available at: http://www.cochrane.org/.

Examples of Systematic Reviews To Link Research and Quality Improvement

Over the past 17 years more than 300 learners, including physicians, nurses, and health administrators have completed a course as part of a Master of Health Administration or a Master of Science in Health Informatics degree at the University of Missouri. An objective of the course is to educate health informatics and health administration professionals about how to utilize a systematic, scientific, and evidence-based approach to literature searching, appraisal, and synthesis. Learners in the course conduct a systematic review of the literature on a health care topic of their choosing that could suggest quality improvement in their organization. Students select topics that make sense in terms of their core educational competencies and are related to their work. The categories of topics include public health, leadership, information management, health information technology, electronic medical records, telehealth, patient/clinician safety, treatment/screening evaluation cost/finance, human resources, planning and marketing, supply chain, education/training, policies and regulations, access, and satisfaction. Some learners have published their systematic literature reviews [14-15]. Qualitative comments from the students indicate that the course is well received and the skills learned in the course are applicable to a variety of health care settings.

Summary

Undertaking a literature review includes identification of a topic of interest, searching and retrieving the appropriate literature, assessing quality, extracting data and information, analyzing and synthesizing the findings, and writing a report. A structured step-by-step approach facilitates the development of a complete and informed literature review.

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Health Management and Informatics

Applying Concept Mapping to Solving In-Patient Mental Health Recidivism

by Patricia Alafaireet, PhD, Adam Bouras, MHA, Howard L. Houghton, MD, Beau J. Lavoie, PharmD, Jaie P. Lavoie, PharmD, Beth Cressman, MHA & Saumil Modi, MHA

Concept mapping is a tool for organizing and representing knowledge and concepts and the relationships that can exist between concepts.



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Abstract

Concept Mapping is a powerful research tool using visual representation to expose the complementary impact and synergy of factors affecting a specific process. This article outlines an example, in the domain of mental health, of concept mapping applied to the specific issue of readmissions or recidivism of mental health patients. Concept mapping is used to unify the diverse perspectives found across the existing literature and in mental health care delivery so that patient input and engagement in the care process can be maximally applied to improvement in the delivery of local inpatient mental health care and, penultimately, to transformation of an inefficacious care delivery model.

Introduction

The National Institute of Mental Health (NIMH) strategic plan addressed the need to tackle the irreversible cost and health implication of unsuccessful mental health interventions.[1] The strategic plan proposed in part to promote and disseminate the evidence based of successful mental health interventions, and in part the need to develop new and better interventions.[1] NIMH stressed that these interventions should take into consideration the diverse needs and circumstances of people with mental health.[1] In fact, NIMH, like other studies, highlighted the importance of developing clear and strong intervention designs.[1-3] The ideal design should identify and define the complementary impact of each mental health driver and the synergy between them that creates the undesired mental health outcome as well as defining those drivers whose co-action leads an appropriate care delivery cycle. This paper presents a case study abstracting the use of a concept mapping approach as a research methodology to remedy the gaps health providers' ability to achieve the patient driven intervention design needed to change patient and provider behavior.

Concept mapping (CM) is a tool for organizing and representing knowledge and concepts and the relationships that can exist between concepts.[4] CM provides a strong, multifaceted strategy to assess the basic building blocks of data that underpin successful intervention design. Beyond this, using a CM in a clinical setting allows for a wider view of etiological factors that more adequately consider the complexity of the patient's situation as a whole rather than a piecewise function of patient situational characteristics. The complexity inherent in mental health treatment continues to pose a major research challenge that is complicated by the need to evaluate success on

the basis of outcomes that are often complexly related to process changes. Paul, beginning in 1967, discusses the complexity of psychotherapy research and treatment evaluation.[3] He argues that measuring the outcome(s) cannot be accurately achieved without defining, beforehand, the outcome variables, and the many other latent variables that may indirectly confound measurement of the outcome variables.[3] Therefore, Paul suggests that, during the process of study design, researchers need to question the treatment, the person who is providing it, and whether the proposed treatment is most effective for a particular patient with a specific mental illness, and the other circumstances surrounding the patient that may impact treatment effectiveness. CM assists in delineating processes as multi-level sources of impact at the individual patient level, at the treatment or interventional viability level, and at the level at which care providing organizations can understand the efficacy of certain constellations of drivers that could or do interrupt the recidivist cycle. Ultimately, understanding and measuring the effects of changes to these levels of processes creates the potential to affect the underlying taxonomy of care delivery.

To begin this kind of measurement and expand on Paul's strategy, an exhaustive list of drivers associated with mental health related behaviors is required to depict the patient's situation accurately. These drivers form the basis for developing well-founded interventions and experimental procedures, and as well as suggesting outcomes for evaluation. From this perspective, several studies and scholarly articles embraced developing a CM prior implementing any treatment. van Manen et al. (2012) compiled a comprehensive list of patient characteristics that were found pertinent to treatment selection with personality disorders.[5] Later, the authors recruited 29 experts to rank those characteristics based on their level of influence on patient health outcomes. Similarly, Saha (2010) developed an educational CM to increase awareness of mental sickness and mental hygiene.[6] Corcoran (2005) developed a mental referral checklist to identify mental health needs of youth in the juvenile justice system.[7] To do so, the author used a CM to help identify and cluster those needs into meaningful sets. Considering these examples, this research team developed a strategy whereby concept mapping played an integral role in developing and guiding the clinical research strategies to be used, especially the complex multi-dimensional analyses which are required to study mental health.[8-10] The material reported in this article is part of an extensive pre-study. Going forward, extensive research is planned in which CM is a strong qualitative method through which relationships among drivers are defined and additional drivers are added to close any remaining gaps, thereby increasing understanding of the causality effect on patient outcomes. Furthermore, the research will utilize concept mapping to increase medical staff and patient critical thinking and to improve clinical preparedness.[11] The comprehensive and relational aspects of concept mapping allows patients to be seen more holistically because the entirety of a patient's situation and how this affects their clinical status can be

Table 1: Mental Health Drivers Domains and Subdomains

Domains	Subdomains	Number of Drivers
Demographic Domain (D1)	Gender, Age, Immigration, Relationships, Community Related Drivers, Education, and Health Related Drivers	16
Economic Domain(D2)	Health Insurance, Income Level, Employment Status, Treatment Payment Methods, and Other Economic Related Resources	47
Cultural Domain (D3)	Region, Religion, Customs, and Family, Individual, Organization Culture, and Community	52
Criminal Domain (D4)	Sexual Crime, Criminal History, And Participation In Criminal Prevention Program, Criminal Behavior, Number Of Criminal Offenses, and Type of Criminal Offenses	34
Diagnosis Domain(D5)	Type Of Mental Disease, Symptom Screening Tool Scores, Comorbid Conditions, Substance Abuse Disorders, and Uncategorized	177
Legal Domain (D6)	Court Related, Driving Related, Family Related Drivers, Criminal Arrests Related Drivers, Substance Abuse Related Drivers, and Legal Issues Related To Violence	53
Treatment Domain(D7)	Hospital Stay Characteristics, Pre-Hospitalization Characteristics, Post Care Post Outpatient Treatment, Counseling Behavioral, Pharmacotherapy Treatment, Readmission Drivers, Criminal Justice, Clinical Assessment Tools, and Other Treatment	135
Living Arrangement Domain(D8)	Family Related Issues Causing Housing Issues, Housing Type, Community Issues Related To Housing Access, Employment Problem Causing Restricted Access To Stable Housing, Relationships Issues Related To Housing Issues, and Location Related Housing Issues	36
Prescription Drug Domain (D9)	Antipsychotics, Antidepressants, Mood Stabilizers, and Other Uncategorized Prescription Drugs	36

Figure 1
High Level CM Summary of Mental Health Drivers

Note: the number in parenthesis shows the type of association and the effect size of the association that can exist between domains. The type of the association takes one in case of bi-directional relationship, and two for bi-directional relationship. The effects size or the expected size of the relationship ranges between one and five, where one refers to weak relationship and five refers to strong relation.

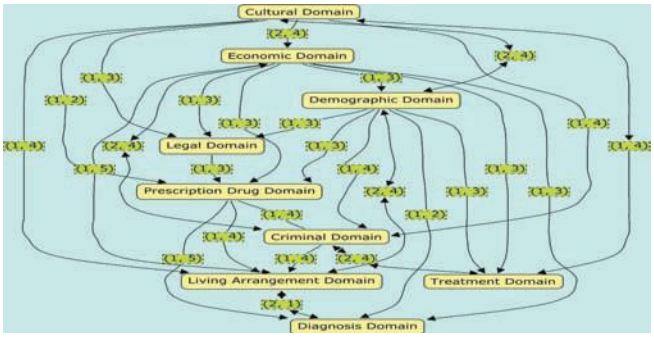
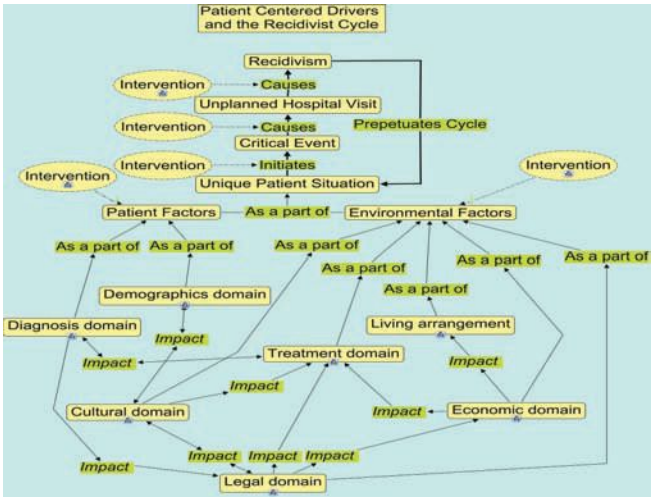


Figure 2

Concept map showing drivers that impact a mental health case and the level for an intervention to break the mental health recidivism cycle.



Concept Map Approach

As part of a pre-study done in support of a patient generated research project around recidivism, four research assistants conducted a content analysis on a list of systematically retrieved articles related to recidivism or contextually similar situations, from multiple domains, including health care, criminal justice and anthropology. The intent of this content analysis was to document the relationships among different drivers found in previous research to affect mental health status, length of stay, and recidivism to in-patient care by mentally ill patients. A CM was then developed to summarize these relationships. During the literature review process, 586 drivers where collected from 600+ articles. These drivers were partitioned into 55 subject derived sub domains, and these sub domains were grouped into 9 major domains (see Table 1). Most of the drivers reported in this literature review are related to diagnosis and treatment with 177 and 135 drivers respectively. The economic and legal domains are the second densest domain with 53 and 52 drivers respectively.

The complexity of predicting mental health status, and thus the possibility of recidivism, requires a detailed understanding of the magnitude of effect of each driver and the connections between them. The number of relationships or associations that exist among drivers can grow exponentially. For instance, this literature review developed 586 drivers from which 2^{586}-587 sets of driver associations can be developed. These associations are best understood when represented at the major domain level by allowing more naïve individuals to clearly visualize the type of relationships to expect between drivers (see Figure 2).

Concept mapping is also useful to help patients and providers understand the relationships between and among individual drivers. Figure 2 shows the two types of associations that exist between different drivers: a causal and a simple relationship. For instance, drivers from D1 can have a causal relationship with drivers from D3, and D8. Similarly, drivers from D7 have a causal relationship with drivers from D9, and D6. Furthermore, the CM shows the magnitude of the relationship that can be found between drivers. This magnitude ranges from one to five, where one is a weak relationship and five is a strong relationship. For example, D1 and D3 have a strong causal relationship. Therefore, cultural and demographics drivers can proxy each other.

visualized in one complete model rather than a segmented collage of risk factors spread across various clinical notes. Such visceral understanding is required if patients and care providers alike are to move beyond an intellectual understanding of the problem of recidivism to care to long term changes in behavior. The involvement of medical staff and patients in developing more refined concept maps increases the patient centeredness of research efforts and the interventions created and trialed. CM also allows both patient and care givers to look at factors in the patient/provider situation that are positive or protective in nature, rather than relying only those factors which are supporting a deficit.

This CM exercise identified five locations where an intervention could be implemented. These potential interventions target patient characteristics, environmental factors, and the overall patient situation (in which both patient and environmental factors are targeted simultaneously), as well a critical events that can cause unplanned hospital visit, and the scenario at the hospital visit level. From these targets an intervention designed to break the recidivism cycle can be developed. However, as implementation cost, effectiveness, and length of the intervention are major factors in the design of cost effective interventions, their effect on the likelihood of long-term behavior change must be considered. Interventions, in this case, that target environmental or patient factors may prove to be most cost and care effective, because they supersede the critical event state that involves an extensive value chain of care provision.

Application of Concept Mapping to Recidivism Preventing Interventions

CM can help target where an intervention is warranted. Figure 3 illustrates an application of CM to a recidivism case developed for this research from a real patient situation (see Box 1). To demonstrate how CM can be used to develop intervention points, this study trialed the possible implementation of an intervention by targeting the cause that led to patient readmission through the use of an in-depth case developed from an actual patient situation (see Box 1).

Learning Experience

The application of CM to the present research study as part of a successful recidivism prevention effort is broad if compared with the findings from van Manen et al. (2012), where the authors suggest that there are two major criteria (patient tolerance to emotional pressure and to support and expressive continuum) when empirically selecting treatment for personality disorder patient.[5] van Manen's work serves this project well as a foundation upon which the analysis of drivers allows the apportioning of drivers into comprehensive domains. It does so by narrowing the selection of drivers to specific domains. Supported by this domain allocation, concept mapping can improve understanding of the patients' situation, increase health providers knowledge about the causes of recidivism, and as well as aid in the development of patient accepted interventions that are cost effective and improve the delivery of care through long term behavior change.

Box 1

Excerpt Overview of Patient M's Current Situation

M is a 50-year-old white, English speaking male. He was recently incarcerated for domestic abuse and assault. M is currently receiving repeat assessment and treatment for depression, drug and alcohol abuse, agoraphobia, and self-inflicted wounds about the hands and arms. M has received in-patient care on 15 occasions in the last 12 months, each time accepting care when his wife or child brought him to the ER. His care has been received from 3 in-patient facilities. The primary diagnosis for each of these previous hospitalizations is drug and alcohol abuse, usually resulting in him being disorientated and verbally abusive. Each time, his visit was lasted 3-6 days, usually until he was fully detoxified and coherent. M also uses marijuana multiple times per week and when he has access to it, misuses both prescription oxycodone and Xanax. M has been married twice. M usually lives with his wife of 26 years in a home he built and owns. The home is located in a very rural area and 30 minutes travel is needed to reach a highway... (More details were available in the full case and will be provided upon request).

Conclusion

The results of this research pre-study aimed at developing a patient centered approach to recidivism interventions suggests that mental health professionals and patients alike can benefit from the results of the application of concept mapping to mental health drivers as part of the process of reducing recidivism to in-patient mental health care.

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Health Management and Informatics

Physician-Management Interactions in the Current 2015 Environment

by Lanis L. Hicks, PhD & Adam Bouras, MHA

Future business models should emphasize the physician-management interactions that increase changes in practice behaviors that both improve outcomes and reduce costs.



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Introduction

As anyone in the health care field can attest, the current environment is volatile and even chaotic at times. The only thing that appears constant is change. With all the pressures from new organizational structures, changing payment mechanism, government regulations, health care reform, economic downturn, etc., it is no wonder that the relationships between physicians and management are often strained. Not only does the current landscape change and reshape the physician-management relationships, but the physician-management relationships also change and reshape the health care landscape.

The historic role of physicians and other health care providers in the health care system is well documented.[1,2] In the past, physicians had a great deal of autonomy in how they practiced medicine, set prices, and used hospital resources to deliver patient care. Over time, this historic autonomy of physicians has eroded, with insurance companies creating review and preauthorization requirements for payment of services, government increasingly setting price and utilization requirements, and hospitals forced to focus on cost containment strategies and reduced resources available. These various pressures have created conflicts among physicians and between physicians and other sectors of the health care system.

In this article, physician-management interactions refer to the type of interactions that exist, or may develop, between physicians and other participants in the health care system. These interactions are result of, and in response to, environmental and structural changes in the health care system, especially the changes that involve the costs of and payments for health care. The shift in payment mechanisms and the changes in the structure of health care organizations have impacted the strategic alliances of physicians, and changed their perceptions and strategies for providing care in the current environment.

Early Managed Care

Historically, physicians were mainly paid on a fee-for-service (FFS) basis, creating the system that focused on providing identifiable and measurable procedures and services.[3] Although still a feature in the current health care system, the role of fee-for-service began to decline substantially with the promotion of managed care in the mid-1980s to mid-1990s, and current value-driven payment systems are expected to eclipse fee-for-service medicine by 2020.[4] Managed-care impacted the physician-management relationship with the introduction of more invasive utilization requirements and the use of capitation for payment. It introduced a combination of innovation, restructuring, and controls in the delivery of and payment for health care services.

Capitation, which typically pays physicians and other health care providers per enrolled member per month, significantly changed incentives and behaviors of providers. Under capitation, physicians were placed at financial risk for care provided and patients seen – physicians received a predetermined amount per enrolled member regardless of the amount or type of services provided. Physicians began to experience much more outside scrutiny and control over their practices.[5]

In addition to the use of capitation to pay providers, managed-care also encouraged many physicians and hospitals to form integrated delivery systems (IDSs) in an attempt to manage services provided, costs, and spread the risks associated with managed care. The formation of IDSs typically took one of two forms. One involved the creation of a single, legal entity through mergers and acquisitions, resulting in single ownership of the members of the organization. The second involved the formation of a separate corporation called a physician-hospital organization (PHO), which provided a vehicle for contracting with managed care organizations.[6] PHOs, however, allowed participating entities to retain their separate ownership and activities under this arrangement. While IDSs were viewed as a way to counter the power of managed care organizations (MCOS), they did not become major players in the system, partly because their loose organizational structure did not provide sufficient controls to change provider behavior or have payment systems that did not align with the goals of the PHO.[7] Without alignment of goals, tensions between physicians and management increased, as separate strategies for maximizing different goals evolved.

Health Care Reform

Following enactment of health care reform in 2010, new or modified types of organizational and payment mechanisms have emerged, and are increasing in number and influence. While the organizational structures and payment mechanisms vary, their commonality is a value-driven focus on patient-centered care and controlling rising costs. This increasing emphasis on value-driven health care is altering the delivery of health care and the relationships among participants in the system.

Coming out of health care reform is a new organizational structure impacting physician alliances – the accountable care organization (ACO). ACOs are groups of providers that have taken collective financial and service delivery responsibility for the cost and quality of health care services needed by a patient population. Through contracts with insurers, members of the ACO are expected to work collaboratively to improve the health outcomes of patients while reducing the growth in health care costs – do more with less.

To be successful, ACOs require coordinated clinical and managerial leadership across the continuum of care.[8] In the ACO, the management of patient care involves a team of professionals, as well as the patient and, when appropriate, the patient's family. Historically, the responsibility of caring for the patient was shared among a variety of professionals acting independently, with the physician, especially the primary care physician, having the dominant role in the team. In the ACO, while the physician, especially the primary care physician, has a key role, it may not be the dominant role. Depending upon the needs of the patient, a different health or social services professional may have key responsibility for determining the services needed by the patient.[9] In ACOs, primary care teams assume the cornerstone role in managing the care of patients. This primary care team needs to coordinate all primary and specialty care needed across the full continuum of care, including social support services, and the wishes and preferences of patients, needed to improve the health status of the patient.

As the primary care team takes on additional responsibilities, many are doing so under a new payment system that bundles all resources needed to treat an episode of care under a single payment.[10] While bundled payment has some of the same incentives as capitation in terms of not paying for each discrete service provided, it differs in focus. Capitation provides a set payment for all enrolled members regardless of services utilized; the ACO only receives payment when a patient presents with a cover diagnosis, and then all services required for that episode of care for that patient is under the bundled payment umbrella. A key to the success of ACOs, regardless of their organizational structure, is balancing the interests of payers, accreditation bodies, patients, and community groups with the interests of the health care providers. Since many of these entities are competing with physicians for limited resources, and reduce ability of physicians to work independently, tensions increase among them.

As the above discussion indicates, health care reform involves major changes in the lives of physicians – their incomes, degree of autonomy, transparency of care, work environment, and clinical routines.[11] These changes impact the relationships between physicians and management, and physician satisfaction, and result in a number of decisions by physicians regarding their practices.

Responses of Physicians

With all this turmoil and uncertainty occurring in health care, one response of physicians has been to sell their practices to a hospital, a large group practice, a physician management company, or to a commercial payer. In

addition to existing practices being sold, increasingly new physicians entering the market are electing employment over private practice.[12] These various types of organizations are acquiring physicians in order to maintain volume or to redirect referral patterns of patients. While hospitals were the dominant purchasers early in the movement, they have substantially reduced acquisitions recently, and group practices and physician management companies have become the leaders in acquiring physician practices.[13]

As physicians become employees rather than independent practice professionals, it is critical that their employers engage them effectively. With all the changes physicians and the health care system have been experiencing, it is unrealistic to expect physicians to automatically understand how to function in their new role and to implement necessary and desired changes in behavior without guidance and education. Since physicians are responsible for many of the frontline decisions made determining efficiency, cost, and quality of care, their understanding of the impact of their decisions on the health care system is critical.[14] While it is important for physicians to understand the types of changes that need to occur in clinical practice in order to reduce avoidable utilization, clinical variation, and costs, it is also important that they understand how to effect the necessary changes. Tensions increase between physicians and management when management expects physicians to change without providing adequate education and tools to enable the physicians to make the desired changes. To improve relationships, physicians need to be provided appropriate training to increase their ability to make needed changes, to receive effective communications about the desired changes and the need for those changes, and to have physician role models available for guidance to achieve the needed changes.[15]

As physicians are increasingly being asked to participate in risk-based payment models, it is very important that they have an understanding of how the models work and what the risks involved are. While physicians may be familiar with some of the terminology involved in risk sharing, they often do not understand how the models actually work.[16] For physicians to be engaged and effectively participating in the decisions required in these models, they need to understand how they work and what the impacts are of various decisions made. To minimize physician-management conflicts, training, communications, and physician leadership involvement are again critical.

As physicians join other health care organizations, it is important that they examine the culture of these organizations before joining to assess if the mission and values of the organization are substantially different from their own. To be successful, there needs to be shared missions and values, and that typically means provider inclusiveness within the business model where physicians play a critical role.[17] When cultural differences are large, they create increasing tension between physicians and management, as responsibilities and accountability diverge and different goals become the focus of acitons.

Conclusions

The health care system is currently undergoing some of the most disruptive changes in history. These changes are creating pressures on the relationships between physicians and management that require careful assessment and management. Both physicians and management need to re-evaluate their historical relationships and understand what types of compromises and mutually beneficial changes are needed to survive and prosper in the current environment. Future business models should emphasize the physician-management interactions that increase changes in practice behaviors that both improve outcomes and reduce costs.

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Disclsoure

None reported. **MM**



Health Protection for Nicotine Addicts: A Challenging Goal

by Jane McHowat, PhD

Despite recent awareness of the health risks of cigarette smoking, a significant number of the population remain smokers or nicotine users. Consequently, there is an urgent need to identify agents that can modify the adverse effects observed in affected patients.



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Cigarette smoking is generally accepted as the most preventable cause of death in the United States.[1, 2] Between 1997 and 2001, cigarette smoking and exposure to tobacco smoke resulted in approximately 438,000 premature deaths and $92 billion in productivity losses annually in the United States alone.[3] Although the incidence of adult smokers in the United States dropped between 2000 and 2005, the decline has leveled out, and it is estimated that 25.9 million men (23.9 percent) and 20.7 million women (18.1 percent) are smokers.[4, 5] More alarmingly, it is estimated that as many as 40% of non-smokers, including children, are exposed to second-hand smoke.[6] The incidence of smoking is inversely related to the level of education and is more common in adults who live below the poverty line.[3] Those individuals from low incomehomes have a higher prevalence of smoking (32.3 percent) than those living above the poverty level (23.5 percent).[7] In addition to disparities regarding the incidence of smoking, studies from the Multiethnic Cohort study have highlighted racial and ethnic differences in the effect of smoking on cancer risks that are also modified by the number of cigarettes smoked daily.[8]

Smokers have increased risk of cardiovascular disease, insulin resistance and hypercholesterolemia.[1, 2] Smoking is also a leading cause of cancer, including cancers of the lung, esophagus, larynx, mouth, throat, kidney, bladder, pancreas, stomach, and cervix, as well as acute myeloid leukemia.[9] Cigarette smoke has been estimated to contain over 7,000 chemical compounds. Components of cigarette smoke have been analyzed with respect to their greatest potential for toxic effects. Studies found that 1,3-butadiene presented the most significant cancer risk; acrolein and acetaldehyde had the greatest potential to be respiratory irritants; and cyanide, arsenic, and the cresols were the primary sources of cardiovascular risk. Other chemical classes of concern include other metals, N-nitrosamines, and polycyclic aromatic hydrocarbons.

It is estimated that over 10,000 Missourians die from tobacco-related disease each year,



It is estimated that over 10,000 Missourians die from tobacco-related disease each year, highlighting the need for identification of agents that can be identified to protect the health of patients who smoke.

highlighting the need for identification of agents that can be identified to protect the health of patients who smoke. In this issue of *Missouri Medicine*, McCarthy, O-Keefe and DiNicolantonio review the literature regarding administration of carvedilol and spirulina to manage the pathologenic impact in chronic tobacco users.

McCarty, O'Keefe and DiNicolantonio (See page 534-539) note that high bilirubin is associated with favorable health outcomes, possibly via NADPH oxidase activity. The antioxidant effect of bilirubin may alleviate the increased risk for smoking-related diseases. Since spirulina contains the biliverdin derivative, phycocyanorubin, the authors propose that oral spirulina could mitigate the adverse effects of semi-stable soluble compounds in cigarette smoke. This is a particularly attractive use for a nutraceutical, however, only one study has been published in which oral phycocyanin has been examined on lung health in rodents. Thus, as of yet, there is little evidence in the literature that the treatment would alleviate the progression of smoking-induced effect.

The authors also address the increased sympathetic activity induced by nicotine and propose that treatment with a beta-blocker such as carvedilol may be protective. However, the use of these agents is generally avoided in COPD patients. As with spirulina, there is only one study that has examined the effects of carvedilol on subsequent nicotine exposure.

Their review article discusses the potential for therapeutic strategies to manage nicotine addiction and highlights the difficulty in managing these patients. Clearly, smoking or nicotine use cessation is ideal, but in reality alternative measures need to be explored more fully. Tobacco research intensity has declined over the years, with emphasis placed on cessation or prevention strategies. Despite the thousands of publications on tobacco use, there is still much we do not know about the detrimental effects of the thousands of chemical compounds present in cigarette smoke. Which compounds contribute to which diseases and how can we manage the effects? Unfortunately, when it comes to tobacco smoking, there are still more questions than answers.

Future research is needed to clearly delineate the biochemical and pathological responses to cigarette smoking in order to identify therapeutic targets in the future.

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Carvedilol and Spirulina May Provide Important Health Protection to Smokers and Other Nicotine Addicts: A Call for Pertinent Research

by Mark F. McCarty, BA, James H. O'Keefe, MD & James J. DiNicolantonio, PharmD

Administration of spirulina may have potential for mitigating the pro-oxidant effects of cigarette smoking that contribute to smoking's adverse impact on vascular health, lung integrity, and cancer risk.



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Abstract

Nicotine and soluble semi-stable aldehydes and ketones in cigarette smoke are key mediators of the elevated risks for vascular disease, cancer, and chronic obstructive pulmonary disease observed in smokers. Nicotine, via sympathetic stimulation, increases risk for both vascular disease and cancer. Comprehensive suppression of sympathetic activity with the well-tolerated drug carvedilol, which inhibits beta1, beta2 and alpha1 adrenergic receptors, may be protective to smokers and other nicotine addicts. The soluble aldehydes and ketones in tobacco smoke appear to exert their adverse effects through activation of NADPH oxidase complexes in vascular tissues and in the lungs. The phytochemical phycocyanobilin (PhyCB), richly supplied by the edible cyanobacterium spirulina, in studies on rodents and in human cell cultures has shown the ability to safely mimic intracellular bilirubin's physiological role as an inhibitor of NADPH oxidase activity. It therefore may have potential for mitigating the pro-oxidative effects of tobacco smoke aldehydes and ketones. Joint administration of carvedilol and spirulina merits exploration as a strategy for moderating the pathogenic impact of smoking in chronic tobacco users who either fail to quit or refuse to try cessation of tobacco. Carvedilol may be appropriate for those who manage a nicotine addiction in other ways (smokeless tobacco, e-cigarettes, nicotine gum). Further clinical studies to evaluate the impact of carvedilol on cardiovascular risk factors in nicotine addicts, and rodent studies to assess markers of lung inflammation in smoke-exposed rodents fed PhyCB, are recommended.

Adverse Impact of Semi-Stable Organic Oxidants in Tobacco Smoke

The adverse effects of smoking tobacco on vascular health appear to be mediated primarily by nicotine and a range of soluble and relatively stable organic compounds in the smoke capable of undergoing spontaneous addition reactions with thiols and other nucleophiles within vascular cells.[1] Notably, these compounds include alpha, beta-unsaturated aldehydes or ketones such as acrolein and crotonaldehyde, and are the major constituents of cigarette smoke. The insoluble tars in tobacco smoke that contribute importantly to mutagenesis in the lung, upper respiratory tract and oral cavity have limited access to the systemic vasculature.

A number of studies have observed that exposure of endothelial or vascular smooth muscle cells, *in vitro* or *in vivo*, to cigarette smoke extract (CSE) rich in such soluble compounds leads to induction of oxidative stress generated primarily by NADPH oxidase complexes.[1-7] Concurrent inhibition of these complexes largely alleviates the adverse effects of CSE exposure on endothelial or smooth muscle function. CSE exposure has likewise been shown to boost NADPH oxidase activity in airway epithelia, tracheal smooth muscle, keratinocytes, and glioma cells.[8-16] Activation of various PKC isoforms, and/or c-Src, by the reactive compounds in CSE, appears to mediate NADPH oxidase activation; activation of protein kinase C (PKC) does not appear to be secondary to activation of phospholipase C and diacylglycerol generation, and so might reflect direct interaction with PKC protein.[15] These compounds are also likely to be key mediators of the inflammatory lung damage that markedly increases chronic obstructive pulmonary disease (COPD) risk in smokers, and may contribute to lung carcinogenesis. Highly active oxidants in cigarette smoke, too unstable to exert systemic effects directly, also contribute to this lung inflammation. (Summarized in Figure 1.)

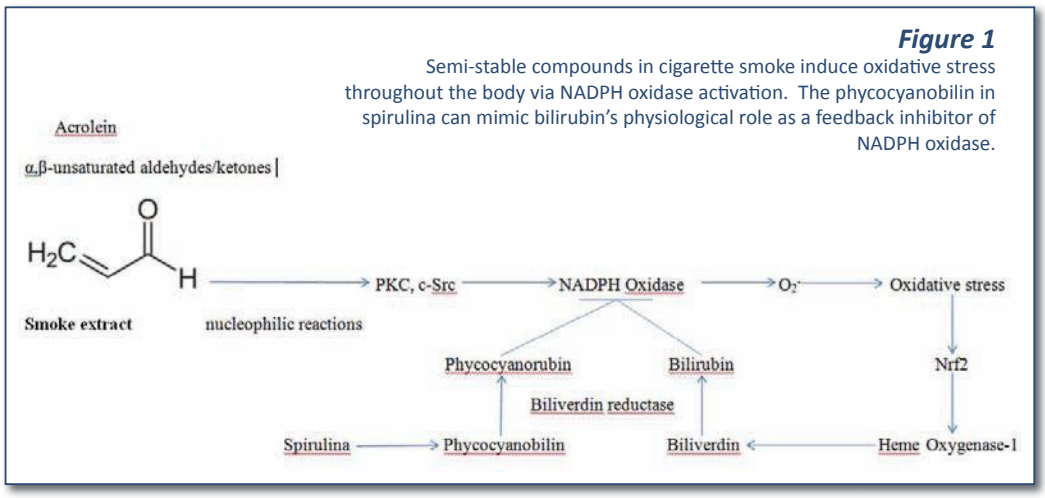


Figure 1

Semi-stable compounds in cigarette smoke induce oxidative stress throughout the body via NADPH oxidase activation. The phycocyanobilin in spirulina can mimic bilirubin's physiological role as a feedback inhibitor of NADPH oxidase.

Protective Potential of Spirulina

The intracellular antioxidant activity of bilirubin, generated by activation of the inducible heme oxygenase-1 (HO-1) in response to oxidative stress, has been traced to the capacity of low nanomolar concentrations of bilirubin to inhibit certain NADPH oxidase complexes.[17-20] The many prospective epidemiological studies correlating elevated serum bilirubin with favorable health outcomes may reflect either a direct impact of circulating bilirubin on NADPH oxidase activity in cells (possibly important when bilirubin levels are very high, as in Gilbert syndrome), or the ability of serum bilirubin to serve as a marker for more efficient activation of HO-1 in oxidant-stressed cells.[21-23]

In a twenty year follow-up of the health status of over 500,000 adults monitored by primary care physicians in the British Health Service, Horsfall and colleagues reported that incidence rate of lung cancer per 10,000 person years in men in the top decile of serum bilirubin at baseline was 1.5, as contrasted with 5.0 in those in the bottom decline.[24] The inverse association of bilirubin with lung cancer risk held up after adjustment for multiple relevant covariates, including smoking status. The findings in women were quite similar (0.8 vs. 3.0). With respect to risk for COPD in men, the incidence in the top decile of baseline bilirubin was 7.5, as compared to 19.5 in the bottom decile. These findings likewise were validated after appropriate statistical adjustments for covariates, and the findings in women were similar (7.5 vs. 14.8). The findings on lung cancer are confirmative of a previous Belgian prospective study, in which lung cancer mortality in men was 60% lower in the upper vs. lower category of baseline bilirubin, after multivariate adjustment.[25] Similarly, in a Taiwanese prospective cohort of over 400,000 individuals, incidence rate per 10,000 was 3.73 and 7.02 in the upper and lower bilirubin quartiles, respectively ($P=0.003$); mortality rates in those quartiles were 2.46 and 4.84, respectively ($P<0.001$).[26] These findings were significant for those that had ever-smoked, but not non-smokers. With respect to risk for cardiovascular disease, this also tends to correlate inversely with baseline bilirubin levels in a number of prospective studies.[27-29]

In aggregate, these considerations suggest that the antioxidant effects of bilirubin have considerable potential to alleviate the increased risk for lung cancer, COPD, and vascular disorders associated with smoking. Although there are no rich natural sources of bilirubin or its more soluble precursor biliverdin that could be employed for nutraceutical use (and these complex molecules are expensive to synthesize), cyanobacteria such as spirulina can contain about six parts per thousand dry weight of a biliverdin derivative, phycocyanobilin (PhyCB). This can be converted within cells to a bilirubin homolog, phycocyanorubin, which appears to share bilirubin's capacity to inhibit NADPH oxidase complexes.[30-32] This likely explains why, in a large number of rodent studies, oral administration of spirulina,

or of phycocyanin, the spirulina protein to which PhyCB is covalently attached, has exerted anti-inflammatory and cytoprotective effects, including marked inhibition of early atherogenesis in hamsters.[30, 33-35] Administration of free PhyCB has recently been shown to inhibit nephropathy in diabetic mice, and to exert marked anti-inflammatory and antioxidant effects on the brain after simulated stroke in rats.[32, 36] Hence, we propose that regular oral administration of adequate amounts of spirulina, phycocyanin, or of concentrated PhyCB may have potential for mitigating the adverse effects of the semi-stable soluble compounds in cigarette smoke on vascular health, lung integrity, and lung cancer induction. Surprisingly, there appears to be only one published study to have evaluated the impact of spirulina/phycocycanin on lung health in rodents; this found that oral phycocyanin suppressed induction of paraquat-induced alveolitis and fibrosis in rats.[37]

Nicotine Contributes to Vascular and Cancer Risk in Smokers

Nicotine, via its stimulatory effects on sympathetic activity, also seems likely to play a mediating role in the vascular risks, and perhaps even cancer risks, associated with smoking. Elevated resting heart rate, a rough correlate of systemic sympathetic activity, correlates with increased risk for cardiovascular mortality and cancer mortality in prospective epidemiology; these correlations persist after adjustment for established risk factors that can modulate heart rate, such as BMI, smoking, and exercise training.[38-44] While the impact of sympathetic activity and nicotine on cardiovascular risk evokes little surprise – the use of smokeless tobacco has been linked to increased risk for myocardial infarction and stroke, albeit less dramatic than the increase associated with smoking[45, 46] - the impact on cancer risk has been less understood. Recent studies establish that a high proportion of cancers express beta2-adrenergic receptors whose activation makes these cancers more aggressive and harder to kill.[47-49] This may explain why both psychological stress and cigarette smoking have been linked to poorer cancer prognosis in a number of studies, and why concurrent use of non-specific beta-blocker drugs has been associated with improved prognosis in some cancers, including lung cancer.[50-65] Hence, the propensity of nicotine to activate beta2 receptors in cancer-prone tissues may help to explain why smoking increases cancer risk in many organs not directly exposed to cigarette smoke. With respect to lung cancer, the American Cancer Society Prevention Study II found that, when comparing smokers who switched to chewing tobacco with those who quit nicotine altogether, the former were at higher risk not only for mortality from coronary disease and stroke, but also lung cancer (HR=1.46, 95% CI 1.24-1.73).[66]

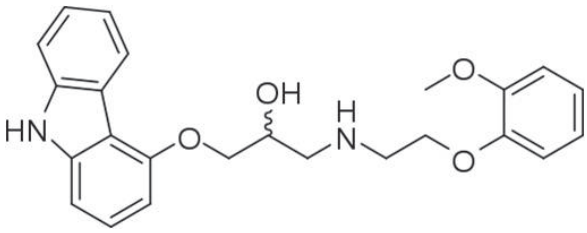
Protective Potential of Carvedilol

If a nicotine-mediated increase in sympathetic activity is responsible for much of the vascular risk and even some of the cancer risk associated with smoking, then comprehensive suppression of sympathetic activity in smokers may be protective. In particular, the drug carvedilol (see Figure 2), which inhibits beta1, beta2, and alpha1 receptors, and is generally well tolerated in recommended dose ranges, may have potential in this regard. Likely because of its ability to concurrently inhibit alpha1 receptors, thereby inducing arteriolar vasodilation, carvedilol does not appear to have the adverse impact on cardiac output, insulin sensitivity or diabetes risk seen with many other beta-blockers.[67, 68] To date, only one published study has examined the effects of carvedilol in abstinent smokers receiving a bolus dose (4 mg) of nicotine.[69] The subjects, who had not smoked since the previous evening, received placebo or one of two doses of carvedilol at 8:00 a.m. followed by a light breakfast. Two-and-a-half hours later, a 4 mg nicotine lozenge was administered. Both doses of carvedilol blunted the stimulatory impact of nicotine on heart rate and blood pressure. Importantly, carvedilol did not suppress the pleasurable sensations which the subjects reported after nicotine administration, whereas it did inhibit some of the perceived "bad effects" of the potent nicotine dose. Carvedilol did not influence ratings of tobacco withdrawal symptom severity. These findings suggest that carvedilol may have potential for alleviating much of the health risk associated with smoking or other types of nicotine usage (smokeless tobacco, e-cigarettes, nicotine gum), while not impeding nicotine's ability to provide positive psychic reward and prevent withdrawal symptoms. As these authors state their findings "may have treatment implications given the cardiovascular risks associated with smoking, some of which are thought to be mediated by the noradrenergic system." [69] Unfortunately, this insightful report appears to have received little attention and, to date, no follow up.

Smokers are of course at increased risk for COPD, and many practitioners are reluctant to use beta-blockers – especially non-selective beta-blockers such as carvedilol – in the context of COPD, owing to concerns regarding triggering of bronchoconstriction or blunting of response to beta2 agonist bronchodilators. This reluctance does not appear to be warranted based on a survey of current clinical evidence. While it is true that forced expiratory volume in 1 second (FEV1) tends to be slightly lower when patients with COPD are treated with carvedilol as opposed to bisoprolol,[70] this small difference appears to have little impact on hard endpoints. As Minor and colleagues summarize in a recent review, "In retrospective and observational analyses, both cardioselective and noncardioselective beta-blockers appear to

Figure 2

Carvedilol provides comprehensive inhibition of nicotine-triggered sympathetic activity by blocking beta1, beta2, and alpha1 receptors. (Failure to inhibit alpha2 receptors is not a drawback, as these act presynaptically to provide feedback suppression of sympathetic activity.)



decrease mortality in COPD patients with and without overt cardiovascular disease, including those with hypertension, heart failure, and atherosclerosis, as well as those undergoing major vascular surgery….Beta blocker use did not decrease the effectiveness of beta2 agonists….In general, these findings do not support current recommendations for the preferential use of cardioselective beta-blockers."[71] Hence, concerns regarding COPD should not discourage use of carvedilol in smokers, with or without COPD.

Suggestions for Clinical Research

It is therefore proposed that carvedilol treatment may be a rational strategy for addicted smokers who fail to quit or refuse to try smoking cessation, or for those who use smokeless tobacco, e-cigarettes, or nicotine gum to manage their nicotine addiction. Longer-term controlled studies evaluating carvedilol administration in nicotine users (smokers or non-smokers), focusing on endothelial function and a wide range of other cardiovascular risk factors, assessing risk for hypotensive complications in normotensive subjects, and determining whether carvedilol influences positively or negatively the subjective satisfaction provided by nicotine, appear worthwhile.

Administration of spirulina – or of phycocyanin or other concentrated sources of PhyCB – may have potential for mitigating the pro-oxidant effects of cigarette smoking that contribute to smoking's adverse impact on vascular health, lung integrity, and cancer risk. Evaluating this latter strategy in rodent models of smoke exposure would be an appropriate first step in assessing spirulina's potential for protecting smokers. Inasmuch as high intakes of spirulina might be required to achieve an optimal antioxidant effect in humans – an extrapolation from rodent studies suggests that 15-30 g daily may be needed in this regard[30] – and most people find the flavor and odor of spirulina disagreeable, development of spirulina extracts highly enriched in PhyCB may be required to enable the full protective potential of spirulina to be tested. Such extracts could also make it feasible to conduct the prospective double-blind studies required to most convincingly assess PhyCB's antioxidant/anti-inflammatory activity in humans. Alternatively, development of functional foods in which the flavor of spirulina is adequately masked can be contemplated. Ultimately, clinical trials could be designed to examine PhyCB's effects on lung markers of inflammation and on vascular risk factors in smokers.

Physicians should construe smoking as a medical condition – a nicotine addiction. The first priority should be to persuade people to discontinue smoking or nicotine use, as this will be more protective than any compensatory measures. But if such efforts fail, rational strategies for minimizing the associated risk should be employed.

Other nutraceutical/pharmaceutical strategies may be of benefit to smokers. There is reason to suspect that ample intakes of long-chain omega-3 fatty acids – most notably docosahexaenoic acid (DHA) – may provide important protection to the lungs and vascular system of smokers.[72-80] This will be the topic of a separate report. Tobacco smoke increases the body burden of cadmium, which may contribute significantly to the pathogenic impact of smoking;[81, 82] high-dose zinc supplementation may have potential for alleviating cadmium toxicity.[83]

Metabolic syndrome, like nicotine use, is associated with an up-regulation of sympathetic activity and heart rate, stemming from the impact of hyperinsulinemia on brain regulatory centers, that likely contributes to the increased vascular and cancer risks associated with this syndrome.[84] Hence, carvedilol therapy may likewise have important protective potential for patients with metabolic syndrome. Analogously, NADPH oxidase activation is a key reason for the oxidative stress associated with this syndrome, pointing to a potential for spirulina to provide protection in this regard.[85-91] Curiously, nicotine tends to promote metabolic syndrome and hyperinsulinemia, both by acute effects on insulin sensitivity mediated by increased lipolysis and a direct cholinergic action on muscle fibers, and in the longer term by a tendency to accumulate fat selectively in visceral stores.[92-94] Hence, both the peripheral effects of nicotine, and central effects mediated by hyperinsulinemia, contribute to sympathetic over-activity in smokers.

References

References exceeded space. Email lfleenor@msma.org for the listing. **MM**



Artificial Vision: Hope for the New Millennium

by Jonathan C. Tovey, MD & Dean P. Hainsworth, MD

The restoration of vision to some degree by retinal prostheses is a dream that is becoming a reality in patients blinded by various retinal degenerations such as Retinitis Pigmentosa.



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Introduction

The prospect of living life without vision is daunting, yet millions of people around the world face this challenge daily. Globally, the major causes of blindness include cataract, glaucoma, age-related macular degeneration (AMD), corneal scarring, diabetes mellitus, and others.[1] Sight restoration is a testament to the miracle of modern medicine which is visible in the form of cataract removal with subsequent synthetic intraocular lens implantation, full and partial thickness corneal transplantation, etc. Unfortunately, patients suffering from other causes of vision loss such as macular degeneration and other retinal dystrophies are not as lucky as the etiology of many ocular disorders is still not well delineated and treatments are all but non-existent. However, with the advent of artificial vision devices a cure may be on the horizon for patients with these types of currently incurable disorders. Recently the Food and Drug Administration (FDA) granted approval for the marketing of a retinal prosthetic system for use in patients with late-stage retinitis pigmentosa (RP), a retinal disorder of photoreceptor function. This review provides a brief historical background to artificial vision, current available retinal implants, and future directions in restoring vision.

Vision at a Glance

Vision is arguably the most important sense and has been the subject of study of countless researchers through the ages. The complexity of the visual cascade including the multiplicity of cells and neurotransmitters involved is not completely understood. In order for vision to occur, light traverses the tear film on the ocular surface, cornea, aqueous (fluid in the anterior chamber), pupil, lens, vitreous (fluid in the posterior chamber), and finally the inner retina to stimulate light-sensitive photoreceptors in the outer retina lining the back of the eye. [2]

The outer retina houses 150 million photoreceptors, known as rods and cones, highly metabolic and specialized cells that sense light in dark and brightly-lit environments respectively. The choroid, a dense network of blood vessels deep to the retina, supplies the photoreceptors (see Figure 1).[3]

The stimulated photoreceptors relay the visual "message" via a retinal network to the 1 million retinal ganglion cells (RGC) which make up the optic nerve and eventually synapse at the lateral geniculate nucleus (LGN) after a partial decussation of nasal fibers at the optic chiasm.[3] From the LGN, the message is relayed through the optic radiations to the primary visual cortex in the occipital lobe

where it is converted to meaningful vision. Vision may be affected by an anomaly at any one of these steps such as photoreceptor malfunctioning seen in RP or AMD or a damaged visual cortex due to an occipital lobe lesion/tumor.[2,4] Interventions to correct or bypass these abnormalities have been investigated including retinal implants. Such visual prostheses seek to mimic the step that is impaired in the creation of artificial vision and are sometimes referred to as "bionic eyes".[2]

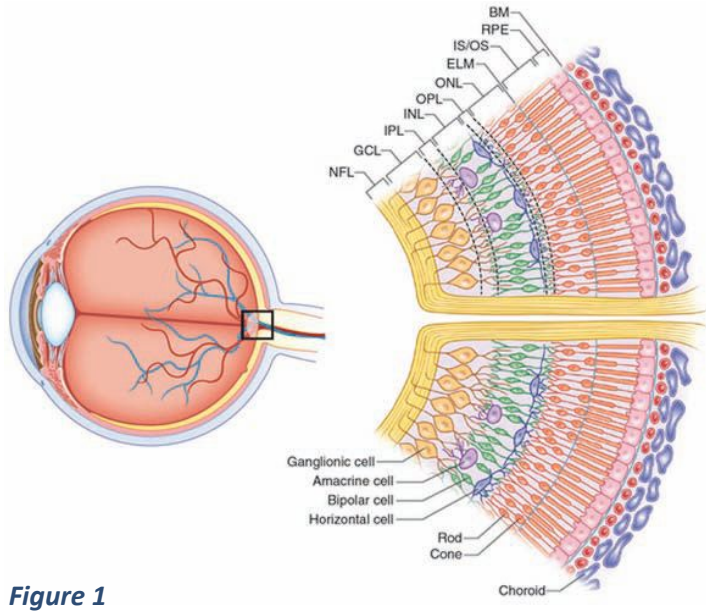


Figure 1
Layers of the Neurosensory Retina
From anterior to posterior the layers of the retina include the internal limiting membrane which lines the inner retina (ILM), nerve fiber layer (NFL), ganglion cell layer (GCL), inner plexiform layer (IPL), inner nuclear layer (INL), outer plexiform layer (OPL), outer nuclear layer (ONL), external limiting membrane (ELM), rod and cone inner and outer segments (IS/OS), and the retinal pigment epithelium (RPE). Deep to the RPE lies the choroid which supplies the RPE and outer retina including the photoreceptors.
Source: http://www.retinareference.com/anatomy/

History of Retinal Implants

The idea of a bionic eye is not new and dates back to the mid-1700s when electrical stimulation of human tissues was being tested. In 1755, Charles LeRoy applied an electric current to a metal coil wrapped around the head of a patient blind from cataract (the clouding of the natural lens of the eye) and elicited flashes of light (phosphenes) described by the patient.[5] In 1929 the renowned German neurosurgeon Otfrid Foerster showed that electrical stimulation of the occipital lobe of a subject could produce the perception of a phosphene.[6] This phenomenon was duplicated 2 years later in a patient with hemianopia due to a gunshot injury to the left optic radiation. This was revolutionary as it demonstrated evidence of visual perception years after a visual pathway insult and vision deprivation.[7] Since then, several attempts and different strategies have been undertaken to recreate vision via electrical stimulation. The pioneers in this regard were Brindley and colleagues who conducted the first clinical trial using the bionic eye in the 1960s. They implanted a device containing 80 electrodes over the visual cortex and were able to elicit reproducible phosphenes in their subjects.[8,9] It wasn't until the 1990s when interest in developing visual prostheses surged. This was in part due to newer, smaller biomaterials becoming available as well as improvements in electronics and retinal surgical techniques. At least a score of research groups are in the midst of developing visual prostheses with the bulk being retinal prostheses.[10] Presently, a handful of retinal prosthetic devices are in large-scale clinical trials with evidence of well-demonstrated functional vision.[11] Two disorders that may be treatable by retinal prostheses are RP and choroideremia.

Retinitis Pigmentosa

Among blindness-causing disorders, perhaps those with a genetic cause (i.e. retinitis pigmentosa) are the most devastating as they affect both eyes and frequently leave the patient totally blind.[12] Retinitis pigmentosa (RP) includes a variable group of disorders characterized by progressive degeneration of photoreceptors in the outer retina and the neighboring retinal pigment epithelium (RPE).[13] Thus the term retinitis pigmentosa (RP) is semantically incorrect as the entity is due to a degeneration of photoreceptors and not inflammation. RP may occur in a non-syndromic form where only ocular clinical manifestations are found (65% of RP cases in the USA) or as part of a syndrome, involving other organs, the most frequent being Usher syndrome (RP w/congenital sensorineural hearing loss).[14,15] In regards to ophthalmic irregularities, RP is frequently associated with cataract and cystoid macular edema (CME), the swelling of the central retina. With 100,000 people affected by RP in the USA, the global



Figure 2
Retinitis Pigmentosa (RP)
Color fundus photo right eye of patient with RP showing classic clinical findings of waxy pallor of the optic nerve, vascular attenuation of the retinal vessels, and diffuse bone spicule pigmentation of the retina.
Source: http://eyewiki.aao.org/images/1/d/d8/Retinitis_Pigmentosa_fundus.jpg

prevalence of RP is reportedly 1/4000.[16] RP may occur as an isolated sporadic disorder (30%), or may be inherited in an autosomal dominant (30%), autosomal recessive (20%), X-linked (15%), or mitochondrial (5%) fashion.[14,17] RP has been found to be associated with at least 50 different gene defects.[14] Over 100 gene loci have been reported to cause RP with the most common being due to mutations in rhodopsin, a key photoreceptor protein in the phototransduction cascade described previously. Presently 50% of cases have an unknown molecular genetic basis. What's more, patients with the same genetic defect may have variable severity of the disease.[17] Typical RP is characterized by retinal pigment deposits visible on funduscopic examination (bone spicules), waxy pallor of the optic disc, and attenuation of the retinal vessels (see Figure 2).

Patients generally experience nyctalopia (night blindness) due to the loss of rod function early on, progressive peripheral visual field loss leading to a ring shaped scotoma and tunnel vision, and ultimately blindness. Although not the major cause of vision loss in RP, CME and posterior subcapsular (PSC) cataracts are occasionally present. CME may be treated with topical or oral carbonic anhydrase inhibitors while cataractous lens extraction surgery may be undertaken to treat PSC cataracts.[18] Although low vision aids (i.e. magnifiers, etc.) are usually recommended, currently no effective therapeutic approach exists to halt progression of vision loss or restore vision in RP. Thus, visual prognosis in patients with RP is very poor. Instead, treatment is aimed at decelerating the degenerative process via ultraviolet light protection and vitaminotherapy (i.e. vitamin A) even though three randomized clinical trials showed no benefit, treating complications associated with RP (CME and PSC cataract), and assisting patients deal with the psychosocial impact of blindness including vocational and mobility training.[13,17,19]

Choroideremia

First described by Mauthner in 1872, choroideremia refers to the absence (-eremia) of the choroid.[20] Choroideremia has typical features of RP including pigmentary changes of the posterior pole (polus posterior bulbi oculi), nyctalopia, and visual field loss. However, the X-linked rod-cone dystrophy differs from typical RP in that funduscopic examination shows normal retinal vessels and optic nerve appearance, and diffuse atrophy of the RPE and choroid (see Figure 3).

Due to a mutation of the CHM gene that encodes geranylgeranyl transferase, a Rab escort protein, the disease affects primarily males and has a prevalence of 1:50,000.[20,21] It is characterized by progressive atrophy of the choroid, retinal pigment epithelium (RPE), and photoreceptors. As with RP, there is no treatment that is effective for choroideremia and low vision aids are generally prescribed during periodic ophthalmologic assessment.[20]

Current Developments & Approaches in Retinitis Pigmentosa Treatment Research

Many strategies are presently under investigation in an attempt to restore vision via electrical stimulation of different parts of the visual pathway. These can be categorized into retinal and non-retinal methods. The difference in these approaches lies in the functionality of the optic nerve. In conditions where at least part of the optic nerve is functional a retinal approach would be ideal. However, a non-retina approach is called for if the optic nerve is non-functional.[4] In regards to retinal strategies subretinal, epiretinal and suprachoroidal approaches are being studied by various research groups around the world while others are targeting

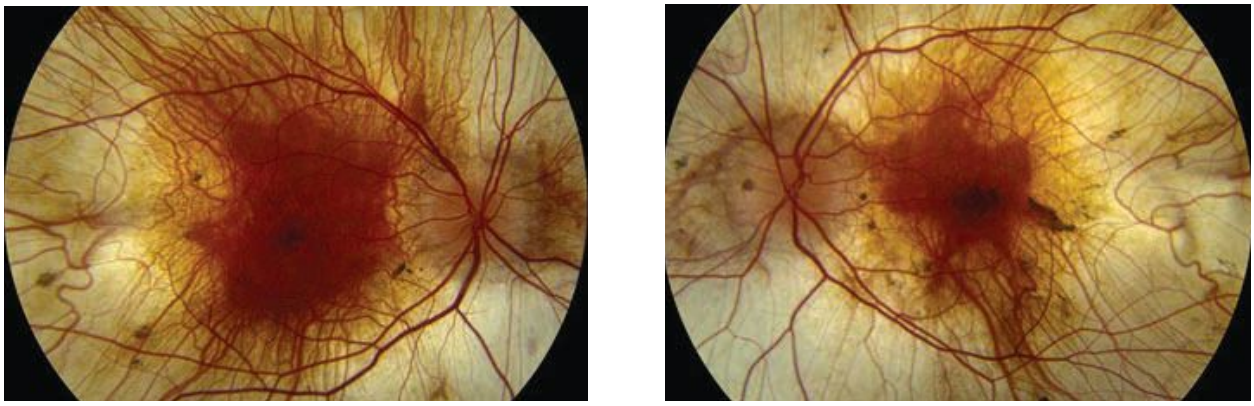


Figure 3
Choroideremia
Color fundus photos of 18-year-old male with choroideremia showing diffuse choroid and retinal pigment epithelium (RPE) loss in the periphery with central preservation in the macula. Although the patient had constricted visual fields, he had 20/20 visual acuity in both eyes.
Source: http://webeye.ophth.uiowa.edu/eyeforum/atlas/pages/Choroideremia.htm

the optic nerve and brain directly (i.e. LGN and visual cortex). Institutions in Japan (Osaka University) and South Korea (Seoul National University) are employing suprachoroidal strategies where devices are placed between the sclera and the choroid. Interestingly, an Australian group, Bionic Vision Australia, is approaching the matter in a completely extra-ocular fashion.[22] Each of these different approaches has advantages and disadvantages. An obstacle that is common to all approaches is that they are anticipated to be effective primarily in patients with acquired (as opposed to congenital) blindness. However, a cortically-based visual prosthesis may prove beneficial for most causes of blinding disease, regardless of the cause.[22] Safety is another concern as most approaches require intraocular or intracranial manipulation.

Retinal Prosthesis

In outer retinal dystrophies such as RP and choroideremia the photoreceptors and underlying RPE of the outer retina have degenerated while sparing the inner retina (i.e. RGCs, bipolar cells) and the remainder of the visual pathway.[23] Retinal implants are a novel approach to restore vision in these types of retinal degenerations. The key question remains how can one reproduce the function of such a delicate tissue as the outer retina? Retinal prosthetic systems attempt to mimic this function by:

1. efficiently capturing visual images from the outside world in real time;
2. converting the captured images into important neurological signals;
3. activating the RGCs and the downstream components of the visual cascade from the optic nerve to the visual cortex.[24]

These prosthetic systems consist of a photosensitive unit (i.e. camera), a processing unit, and an array of small electrodes in direct "contact with the targeted structure", in this case the retina.[22] Although several prosthetic systems have been developed and are under investigation, only two are commercially available for clinical use in human patients. The Argus II retinal prosthesis system (Second Sight Medical Product, Inc., Sylmar, CA), obtained Conformité Européenne (CE) marking in March 2011 for public use in Europe and approval from the Food and Drug Administration (FDA) in February 2013 for humanitarian use based on safety and probable benefit.[25] The alpha-IMS implant (Retinal Implant AG, Reutlingen, Germany), received CE marking in July 2013.[25] The Argus II is the only retinal prosthesis commercially available in the US and as such will receive most of our attention in this review.

Argus II Retinal Prosthesis System

Device Described

The Argus II is made up of several components including a surgically implantable device with intra- and extraocular components as well as an external portion that is worn by the user.[26] The external unit is comprised of a small camera and transmitter mounted on spectacles in addition to a video processing unit (VPU) with a rechargeable battery that may be worn on a belt or shoulder strap (see Figure 4).



Figure 4

Argus II External Unit

Image of Argus II external unit including camera and transmitter mounted on glasses, video processing unit (VPU), and rechargeable battery (©Second Sight Medical Products).

Figure 5

Argus II Internal Unit

Image of Argus II system internal unit (below) comprising implant coil, electrode case, electrode cable, and rectangular electrode array of 6 x 10 round electrodes (center) (©Second Sight Medical Products).



The part of the system that is implanted on and in the eye is made up of a coil (for receiving and transmitting information) and a case that houses vital electronics fixed to the external part of the eye or sclera (see Figure 5). The internal implantable component consists of a rectangular electrode array of 6 x 10 round platinum-coated electrodes (60 total), each 200 microns in diameter, with center-to-center spacing of 575 microns. The electrode array covers a visual angle of 11° x 19° (~22° diagonally) and is surgically attached to the inner retinal surface.[25,26] The microarray is linked to the cased electronics via a metallized polymer ribbon cable that traverses the sclera of the eye at a specific location, the pars plana. The camera captures video that is sent to the VPU which transduces the information to electronic signals that are then sent to the transmitter coil on the spectacles.[26] The data is delivered to the surgically implanted episcleral receiver coil and antenna in a wireless manner and is then sent to the electrode array (by way of the ribbon cable) where stimulus pulses are released.[26] The electrical stimulation of the residual surviving retinal cells triggers the visual pathway inducing cellular responses in the inner retina that are directed to the central visual system, resulting in perceptions of vision as previously outlined.

Surgical Procedure

The Argus II system utilizes an epiretinal approach to stimulate RGCs by way of a 60 electrode array on the retina itself.[27] The external electronics (i.e. electronic stimulator and antenna) are sutured to the scleral shell of the eye via an encircling silicone band, in a similar fashion to performing a scleral buckle for a retinal detachment. Then the microelectrode array and cable (that traverses the eye wall) is inserted through a scleral incision at the pars plana. The electrode array is then attached to the epiretinal surface using a microtack (see Figure 6).[26]

Safety and Efficacy

The Argus II clinical trial was conducted during a 26 month time period from June 2007 to August 2009 but was extended past its end-date for research purposes. This was a single-arm, prospective, unmasked (for safety purposes) multicenter (US and Europe) clinical trial where 30 patients with retinal degeneration underwent implantation of the Argus II device. The mean age of the patients was 58+10 years, with 97% (n=29) having bare light perception vision and 3% (n=1) with no light perception. Of the 30 patients, 28 had RP, 1 had choroideremia, and 1 had Leber congenital amaurosis.[26] All 30 patients perceived phosphenes during electrical stimulation. One device failed at 10 months post-implantation due to communication failure with the implant and was left in the eye. Another device was explanted at 14 months after implantation due to recurrent conjunctival erosion which can be seen with other ocular implants with internal and external components such as glaucoma

drainage devices.[26] Other adverse events noted in the trial were hypotony (low intraocular pressure) and infection including culture negative endophthalmitis in three patients. The rate of these events decreased however with subsequent implants.[26,28] Of the remaining 28 subjects, performance in various visual tasks such as localization of objects and detection of motion improved in 27/28 and 16/28 subjects with the system on versus off respectively. In addition, letter reading was tested in 22 subjects. Six patients identified letters of the alphabet at a rate of 63.5% with the system on vs 9.5% with the system off. All 22 patients were able to identify a group of 8 letters correctly at a rate of 72.5% with the system on vs 16.8% with the system off.[29]

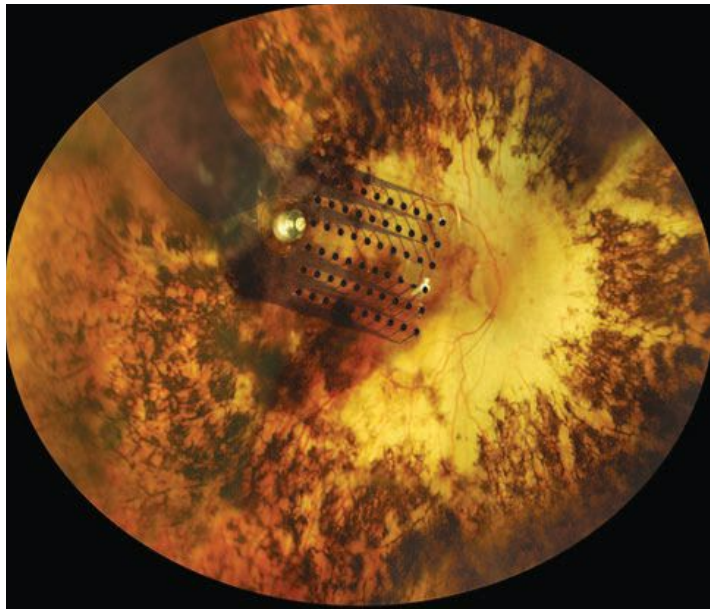


Figure 6
Argus II Microelectrode Array
Intraocular view of Argus II electrode cable and 6x10 electrode array with epiretinal attachment with retinal microtack.
Source: http://www.kellogg.umich.edu/argusii/images/Retinal_implant-hires.jpg

Patient Selection

According to the second sight website the Argus II has been approved for use in patients with "severe to profound" RP who meet strict criteria as follows:

- Age 25 years or older
- Visual acuity of bare light or no light perception (NLP) in both eyes (evidence of intact inner retina layer function must be confirmed if no residual light perception is present).
- History of useful form vision.
- Must be without the native intraocular lens (aphakic) or have a synthetic intraocular lens (pseudophakic). If the patient's natural lens is present, it will need to be removed during the implant procedure.
- Candidates must be both willing and able to undergo the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation as well as annual follow up examinations.
- The Argus II retinal prosthesis is intended to be implanted in a single eye (the worse-seeing eye).[30]

The Argus II prosthetic system is expensive costing about $145,000 in the US.[31] However, a recent study reported that the device is a cost-effective way to treat patients with RP as the incremental cost effectiveness ratio (ICER) for the Argus II was found to be below the societal willingness to pay in most EU countries.[32] Fortunately, in August 2013, the Centers for Medicare and Medicaid Services (CMS) approved the Argus II implant as a new technology, agreeing to provide payment in both inpatient and outpatient settings.[33] It should also be noted that the patient selection process is extremely important as patient compliance is paramount in the rigorous follow-up testing schedule (every 3 months and yearly after the first year).[34] As such, patients and medical staff alike must be prepared for an arduous and lengthy course of visual rehabilitation.[34] Physicians wishing to refer potential candidates for implantation of the Argus II retinal prosthesis may refer to the Second sight website http://www.2-sight.eu/en/healthcare-professionals-en.

The Argus II system is only available at select locations in the US, Mexico, UK, France, and Switzerland. In the US, Centers of excellence located in 12 cities offer the implant: Ann Arbor, MI; Atlanta, GA; Baltimore, MD; Chicago, IL; Cleveland, OH; Dallas, TX; Durham, NC; Los Angeles, CA; Miami, FL; Nashville, TN; Philadelphia, PA; San Francisco, CA.[35]

Three government organizations reportedly provided support for the realization of the Argus II: The Department of Energy, National Eye Institute at the National Institutes of Health, and the National Science Foundation. Grant funding totaled more than $100 million.[36]

Future Direction for Argus II

SSMP is working to improve the performance of the Argus II. Currently vision processing algorithms include edge detection and contrast enhancement. Other features such as obstacle identification and face detection may be added as well as a digital zoom for visual acuity improvement for specific tasks.[25] The attachment of the electrode array to the retina may be modified by improving the retinal tacking surgical technique or making alterations to the implant itself. Over the next couple of years SSMP hopes to study color coding (the current version is black-white-gray scale) and explore the possibility of adding an eye tracker to the prosthetic system to permit more natural eye scanning techniques.[25] As of late2013/early 2014, 35 Argus II prosthetic systems have been implanted commercially with the goal of surpassing 2000 implants in the next 5 years.[25] A clinical trial of the Argus II as a potential treatment for AMD is scheduled to commence in Europe within the next year. This is extremely exciting as presently the Argus II is only indicated as a treatment for retinal degenerative diseases such as RP. The next few years will see the introduction of the next-generation, higher-acuity implant with increasing number of electrodes (240 as opposed to the current 60) for testing in preparation for clinical trial. The addition of electrodes in the periphery to increase the visual field may also be investigated. Of note, in the next 5 years, SSMP plans to conduct a clinical trial utilizing a cortical prosthesis based on the Argus II design to evaluate the clinical risks and benefits of this approach.[25]

Alpha-IMS Implant

Although not currently approved for use in the United States, the alpha-IMS device has been tested in two clinical trials in Europe including 47 patients and is approved for public use in Europe. One of these clinical trials, a multicenter international trial, is still ongoing.[37] The alpha-IMS device differs from the Argus II in that it uses the patient's own eye to capture images thus negating the need for an external video camera. The implant consists of an internal and an external component.[37] The internal part is made up of:

1. a subretinal photovoltaic silicon micro-photodiode array (MPDA);
2. an internal induction coil buried subdermally behind the ear (retro-auricular);
3. a silicone cable connecting the internal coil to the MPDA.[24]

The MPDA consists of 38 x 40 (1500 total) square electrodes (50 x 50 microns), and measures 3 x 3 mm, covering 10° x 10° in the visual field (15° diagonally).[25] The microchip implant is intended to be placed sub-foveally or in close proximity to the fovea so as to optimize stimulation of the MPDA by incoming light. The silicone cable from the MPDA exits the eye through the choroid passing the lateral orbital rim before diving beneath the temporalis muscle in the sub-periosteal space to gain access to the retro-auricular area where it terminates in the internal coil.[24] Due to its subretinal location, it is thought that bipolar cells are stimulated directly. As the alpha-IMS device utilizes intraocular light sensing, it does not rely on head scanning but rather on normal eye movements. A disadvantage of the alpha-IMS implant however is that it has limited control over stimulation parameters. For example, the offset and gain cannot be adjusted for individual electrodes (it can be done jointly for all electrodes), whereas the Argus II device allows for the adjustment of various stimulation variables for individual electrodes.[25] Due to the extensive extraocular path of the connecting silicone cable (from the intraocular environment to the retro-auricular position), a multi-disciplinary surgical approach is needed for alpha-IMS device implantation with participation of vitreoretinal, oculoplastics and ENT/maxillofacial surgeons. The surgical procedure is relatively lengthy taking 6-7 hours compared to the Argus II device which has a surgical time of 2-3 hours. Both devices may be surgically removed without serious complications.[24]

A monocenter study of 9 enrolled patients with retinal degeneration (8 subjects with RP, 1 patient with cone–rod dystrophy) implanted with the alpha-IMS showed promising results after a 3-9 month follow up period. However, two adverse events were reported. One subject developed post-operative subretinal bleed with secondary intra-ocular pressure increase (46 mmHg), which resolved with medical treatment. Another patient unfortunately suffered intra-operative damage to the optic nerve when the implant tip touched the optic nerve. This led to a visual acuity of no perception of light.[37] The remaining 8 patients tested could perceive light and could detect and identify objects used in a table setting. Half of these patients (n = 4) were able to read letters from a reduced set.[37]

With 25 times more electrodes than the Argus II

(1500 vs 60 electrodes respectively), the alpha-IMS retinal prosthesis system also demonstrated best visual acuity of 20/546. This allowed patients to be able to detect and localize light and motion, identify, localize and discriminate high contrast objects, and read large font letters.[3,37] While this was a single center study, a follow up multicenter testing of the IMS is underway in Oxford, London, Hong Kong, and Budapest among other centers. Long-term stability, safety, and visual recognition ability will be investigated in depth in the future.[37] The Alpha IMS implant recently received NUB innovation status and is now eligible for reimbursement in Germany where the microchip was invented.[38]

Other Approaches

Retinal prostheses offer a potential cure for patients with retinal degenerations such as RP bypassing the damaged photoreceptor cells of the outer retina in the visual pathway. The past decade has seen a surge in interest in biological approaches to sight restoration (or sight prolongation) as an increasing number of researchers have focused their efforts towards this goal. Novel treatment modalities emerging from the research pipeline include optogenetics, stem cell therapy, and gene therapy among others. We briefly summarize a few of these areas below.

Optogenetics

While most retinal prosthetic systems elicit action potentials via electrical charges other alternative methods are in development. Optogenetics seeks to replace degenerated, nonfunctional photoreceptors by conferring photosensitive properties on the remaining inner retinal cells (i.e. bipolar cells). This is achieved by incorporating photosensitive cation channels such as channelrhodpsin-2 or halorhodopsin into the remaining bipolar cells/retinal ganglion cells using virus vectors.[39,40] Optogenetics provides a biochemical toolbox that has great clinical potential as new opsin variants with different functionality are introduced.[41,42]

Stem Cell Treatment

The target of stem cell research is to replace nonfunctional photoreceptors by generating a new population from various sources of mesenchymal stem cells (MSCs).[43] Relatively safe, stem cell treatment has been known to cause few adverse effects with some patients experiencing fever, rash, and self-limiting bacterial infection.[43] MSCs can be acquired from several accessible human adult tissues including bone marrow, blood, and adipose and dental tissue.[43] In regards to the eye, conjunctiva and trabecular meshwork MSCs have been shown to produce photoreceptor-like cells in vitro.[44,45] In an in vivo rat model of retinal degeneration, subretinal injection of MSCs led to the differentiation of photoreceptor cells of the outer retina.[46] In addition to the production of new photoreceptors, MSCs are thought to release neurotrophic factors that may have neuro-protective properties. The paracrine effects of MSCs have been investigated in an effort to prevent or retard photoreceptor degeneration. This was demonstrated in a handful of studies where bone marrow-derived MSCs rescued dystrophic retinal photoreceptor cells in a rhodopsin knockout mouse model and the Royal College of Surgeons rat model.[43,47] The replacement of defective RPE cells with embryonic stem cell (ESC)-derived RPE cells in an attempt to salvage and reestablish photoreceptor cell function has also been studied along with subretinal insertion of photoreceptor precursors from ESCs.[24] The use of ESCs is controversial and holds ethical concern. Currently there are three stem cell treatment clinical trials using MSCs underway internationally targeting retinal diseases including RP with one study being conducted in the United States.[48]

Neurotrophic Factor Treatment

While MSCs release neurotrophic factors that may rescue or protect photoreceptor cells, the delivery of the neurotrophic factor itself to the photoreceptors is another strategy to treat RP and other retinal degenerations. Ciliary neurotrophic factor (CNTF) delivery via intravitreal injection has been reported to preserve cone photoreceptor cells and their light-sensing function in a rat model of rhodopsin mutation.[49] Another study involving CNTF showed that although the neurotrophic factor led to marked improvement in photoreceptor morphology and survival in a mouse model of RP, this did not translate to an improvement in visual function as measured by electroretinogram.[50] Many neurotrophic factors have short half-lives and sustained delivery requires multiple intravitreal injections limiting the clinical potential.

One option is to combine gene therapy technology to deliver genes encoding for neurotrophic factors via virus vectors. Dalkara et al. reported that adeno-associated virus (AAV) delivery of the gene for glial-derived neurotrophic factor (GDNF) led to increased expression of GDNF resulting in sustained functional rescue of photoreceptors for more than 5 months.[51] Another avenue that has been explored in a clinical trial is an encapsulated form of RPE cells that produces CNTF (Neurotech Pharmaceuticals, Inc.). This form of encapsulated cell technology was not only found to be safe in the Phase 1 clinical trial but also showed an improvement in visual acuity in a few of the 10 patients with advanced RP with the implant (three of seven eyes).[52] Phase 2 trial has demonstrated a dose-dependent increase in retinal thickness, including the photoreceptor layer as seen on time domain optical coherence tomography (OCT) imaging without change in visual acuity.[53]

Gene Therapy

As a number of pathological causes of blindness such as RP have a genetic origin, other researchers are pursuing genetic approaches including replacement and suppression gene therapy to treat RP. Gene therapy is largely dependent on the type of mutation present. For example, in dominantly inherited forms of RP, mutations characteristically alter the amino acid sequence that is transcribed leading to harmful variants of the encoded protein (gain-of-function mutations). One method to remedy these alterations is to knock down the mutant gene (gene silencing) in hopes that the remnant normal copy of the gene will supply adequate amounts of normal functional protein or that another introduced normal copy of the gene will step in.[16] Recently a group from the University of Utah illustrated the efficacy of RNA interference (RNAi) knockdown for silencing genes involved in dominant retinal dystrophies. In their retinal degeneration mouse model expression of short hairpin RNA (shRNA) produced in photoreceptors was evident 1 week after subretinal injection of AAV carrying shRNA expression cassettes and gene silencing activity persisted for 1 year. Delayed onset of retinal degeneration, significant improvement in both photoreceptor survival and visual function were seen.[54]

In contrast to dominantly inherited diseases, recessively inherited diseases are generally due to genetic modifications that remove the encoded protein (loss-of-function mutations). In order to replace the absent protein one may introduce a normal copy of the specific gene into the diseased tissue.[16] In regards to RP one study reported that wild type rod-specific phosphodiesterase PDE6 delivery via lentivirus vector in a mouse model of RP partially rescued photoreceptors.[55] Subretinal injection of AAV vectors containing the RPE65 gene successfully restored vision in mice and dogs with RPE65 mutations.[16] Interestingly, PDE6 mutation is known to be a cause of Leber congenital amaurosis (LCA) a severe form of RP. In human trials of wild type RPE65 gene delivery with AAV vector, gene therapy was deemed safe with no evidence of immune response, inflammation or viral spread. Although patients with LCA exhibited improved light sensitivity, nystagmus frequency (involuntary rhythmic eye shaking/wobbling), and navigation around an obstacle, significant improvement in visual acuity was seen only in a limited number of patients.[56] Recently gene therapy was tested by the MacLaren group as a potential treatment modality for choroideremia in six male patients and showed improved photoreceptor function.[57]

Conclusion

The restoration of vision to some degree by retinal prostheses is a dream that is becoming a reality in patients blinded by various retinal degenerations such as RP. In early clinical studies, some patients have already exhibited extraordinary visual outcomes with the Argus II system and especially the alpha-IMS implant. However, many obstacles remain in improving current retinal prosthetic systems. Much like the refining process of cochlear implants which evolved over two decades, retinal prostheses will continue to improve in the future as better, smaller biomaterials become available, and safety profiles improve. This will also pave the way for other types of prostheses designed to replace a defective step or cell type in the visual pathway in patients suffering from other causes of blindness.

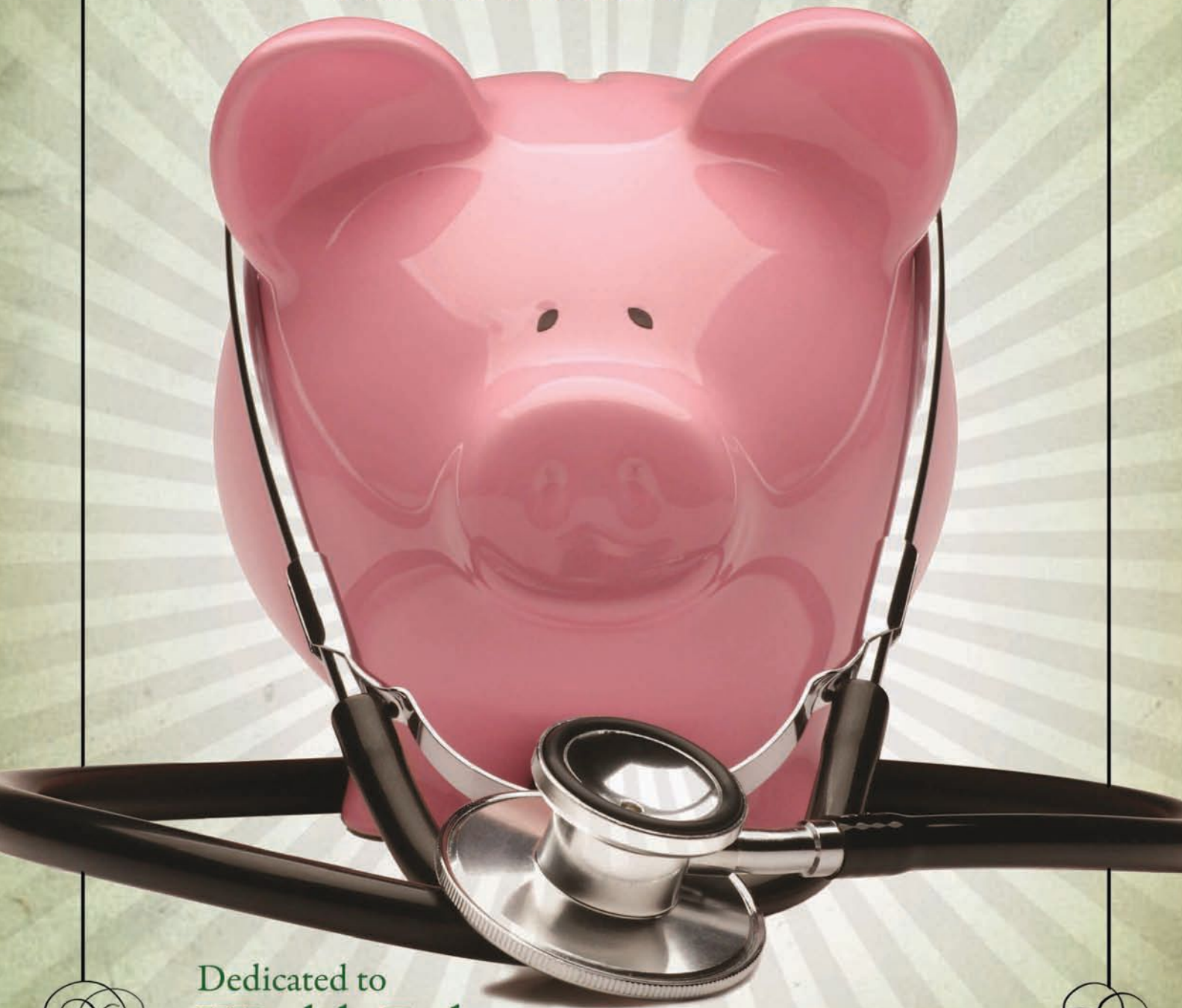
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Disclosure

None reported. **MM**

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