

ABSTRACT

Utilizing Protocols in the United States Healthcare System

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In the current United States healthcare system, there are no standardized methods of practicing medicine. There is also no consistent standard by which physicians are reimbursed for their services. Consequently, the cost of healthcare in the United States is much higher than other countries, while the quality of care is not proportionally higher. In order to combat this problem, utilizing evidence-based protocols can help to reduce the unnecessary costs involved in healthcare and simultaneously improve the quality of care through best practices. In order for the protocol driven system to function properly, there are a few obstacles to overcome such as gathering strong evidence for protocol creation, creating an unbiased and well represented committee, and physician compliance. Through proper planning and employment of modern technology, evidence-based protocols are an effective means of providing positive healthcare reform in the United States.

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Utilizing Protocols in the United States Healthcare System

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CHAPTER ONE

Introduction

In the United States healthcare system today, there are no required standardized methods of practicing medicine. Physicians who are self-employed or hospital employed practice medicine according to their professional training or their professional experience. Some physicians, however, are beginning to embrace the concept of systematic evidence-based medicine in making decisions regarding best practices. In fact, many hospitals and professional organizations are utilizing the evidence available to create protocols as a means to guide physician practices and standardize methods of treatment. One of the viable solutions that can improve overall quality of care and reduce the costs of care will be the implementation of evidence-based protocols to standardize physician treatment practices. These protocols can also serve as a basis to create a uniform and regulated method of reimbursing physicians. This thesis will seek to explore why protocols are effective and give suggestions for implementation of protocols within the current healthcare system.

In addition to the variation in practice, there are also variations in the ways that physicians are reimbursed for their services. The most traditional method, of course, is the fee-for-service model in which physicians are directly reimbursed for services rendered. One method that seeks to improve upon the fee-for-service model is the pay-for-performance model in which physicians are incentivized by giving them bonuses for

doing well in certain quality measures. Oftentimes, hospitals will also incentivize these programs with bonuses for their employed physicians that can prove better efficiency and quality of healthcare. (Werner, Kolstad, Stuart, & Polsky, 2011)

A pilot program has been adopted by the Centers for Medicare & Medicaid Services (CMS), which utilizes the practice of bundled payments in which the hospitals, post-acute care providers, primary providers, and all others involved in an individual patient's care are paid in one lump sum. CMS's argument is that research has shown that bundled payments can align incentives for providers to allow them to work more closely in relationship with one another since any recognized savings are divided amongst the team members. (CMS, 2014) When the team works together efficiently, it can reduce the cost of healthcare and provide more comprehensive healthcare to patients.

Fortunately, even with all the different types of practices and different means by which physicians are reimbursed, the ultimate aim and goal of many of those involved in deciding policies is to improve the quality and efficiency of healthcare while reducing extraneous costs. With the mindset of improvement and efficiency, it is much easier to discuss the relationship between "aligning incentives" and utilizing evidence-based medicine for the benefit of patients.

Physician Practices

Most people in the United States have visited a physician at some point in their lives and they likely have experienced the traditional method of patient management. The physician asks questions regarding medical history and performs a physical exam in order to create an assessment and plan of treatment. Typically, the variability amongst physicians comes when ordering diagnostic tests and determining treatment.

One of the disadvantages for this method of medicine is that most physicians will be inclined to practice medicine based on what they are taught from their mentors in residency programs or in their studies at medical school. Although required to take continuing medical education courses, physicians are not required to “update” their repertoire of knowledge regarding best practices and change patient management. It is quite likely that many physicians will become outdated in their practice despite their years of clinical experience. In a systematic review article written by a group of physicians from Harvard Medical School, researchers sought to explore the relationship between years of practice (physician’s age) and their performance in the categories of knowledge, diagnosis and screening, therapy, and outcomes measurements. Their results showed that “overall, 32 of the 62 (52%) evaluations reported decreasing performance with increasing years of practice for all outcomes assessed” (Choudhry, Fletcher, & Soumerai, 2005). Since physicians do not and cannot always learn the newest treatment options that may be more effective or have fewer side effects, they are limited by their inability to utilize these newer practices.

Another disadvantage to the current style of practice is that some physicians feel that they need to practice defensive medicine in order to protect themselves from litigation. According to a recent study, over 76% of physicians feel that the fear of malpractice litigation has hurt their ability to provide quality care to their patients. The study also determined that 79% of the physicians said that they had ordered more tests than they would based only on professional judgment of what is medically needed, and 91% have noticed other physicians ordering more tests. (Interactive, 2002) This method of practicing medicine not only decreases the quality of care but also increases the costs

of healthcare. A study in 2006 by Price Waterhouse Coopers, performed for America's Health Insurance Plans, estimated that costs associated with medical liability account for between 7 percent and 11 percent of health insurance premium dollars; direct costs of litigation and widespread practice of defensive medicine increase healthcare spending by 10 percent, with a disproportionate increase in outpatient and physician costs. (Coopers, 2006)

As a response to this problem, there are those who promote the concept of evidence-based medicine. The term was coined in the 1990s when it first started to gain popularity, but the idea of evidence-based medicine's philosophical origins extend back to mid-9th century Paris (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). Evidence-based medicine (EBM), as Sackett describes in his article, is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. In writing his article, Sackett also defends the use of evidence-based medicine in arguing that good physicians utilize both clinical experience and the use of external evidence and neither one is adequate alone. (Sackett et al., 1996) With more physicians now engaging in EBM and seeking to improve the quality of care, one of the aspects of quality of care includes the concept of patient-centered care.

Patient-centered care is a term that is widely used to describe the idea that medicine should be centered on a patient's individual needs. Many new initiatives agree on the need for patient-centered care, but the question that some physicians ask is how patient-centered care really affects patient outcomes. In a study conducted in Canada, researchers sought to answer that exact question. Drawing on data from 39 primary care physicians, the researchers concluded that "patient-centered communication influences

patients' health through perceptions that their visit was patient-centered, and especially through perceptions that common ground was achieved with the physician. Patient-centered practice improved health status and increased the efficiency of care by reducing diagnostic tests and referrals.” (Stewart et al., 2000) As the article suggests, patient-centered practice focuses on reducing diagnostic tests, referrals, and hospitalizations. It also seeks to provide higher quality of care by involving the patient in decision making. The practice differs from traditional methods in that the physician acts as an advisor to the patient, instead of a director that does not take a patient’s desires into account when prescribing treatment. Thus, patient-centered practices can ultimately improve patient outcomes by decreasing unnecessary procedures and tests and cultivating the physician-patient relationship.

In utilizing evidence-based medicine, one particular approach to implementation is the use of protocols to ensure that there is a standardized system of practice. By creating protocols for specific illnesses and conditions, there can be more control over the quality of care that each provider is giving. It can also address the problem of outmoded practices since protocols can continually be updated electronically and will allow physicians to be up to date with current methods of treatment. A more uniform method of practice allows for better quality control and can help eliminate extraneous procedures. One example of how standardization improves quality comes from examining the aviation industry. In the aviation industry, using complex systems correctly and efficiently to complete the job without problems is vital. One notable example of the failure of the aviation industry was a “crash between two jumbo jets that resulted in the deaths of 583 people in 1977. The post-crash investigation highlighted the lack of

effective communication among the crew, captain, and air traffic control.” (Dirk H. Alander, 2011) To combat the problem, the aviation industry utilized programs to improve communication among members in the cockpit and also began utilizing standardized check-lists and protocols. By utilizing safety protocols and pre-flight protocols properly, aviation safety is improved greatly. In a similar respect, healthcare can benefit from the utilization of protocols and standardized checklists for all of those involved in the healthcare industry. For example, a research study conducted in Atlanta emergency departments sought to compare emergency departments which utilize protocols in their type 1-observation units and emergency departments that did not utilize protocols in their observation units to see if there was an observable difference in efficiency and cost of care in those units. The results were that

“compared to patients receiving observation services elsewhere in the hospital, patients cared for in “type 1” observation units—dedicated units with defined protocols—have a 23–38 percent shorter length-of-stay, a 17–44 percent lower probability of subsequent inpatient admission, and \$950 million in potential national cost savings each year.” Researchers “estimate that 11.7 percent of short-stay inpatients nationwide could be treated in a type 1 unit, with possible savings of \$5.5–\$8.5 billion annually.” (Ross et al., 2013)

In support of the concept of a well-designed system, the authors of “To Err is Human” explore the concept that “preconditions (conditions that result in errors) are latent failures embedded in the system”. The authors continue to discuss that errors result in a decrease in patient outcomes as well as significant expenditures necessary to treat the new health problems. Some of the results of the studies the authors quote are as significant as \$348

million in costs due to adverse events in hospitals. Their suggestions are to combat these preconditions through designing systems that take “into account people’s psychological limits” and eliminating them through use of “operational procedures” and through use of technology which can “enhance human performance” through automation. (Kohn, Corrigan, & Donaldson, 2000) Protocols, therefore, seem to be a viable option to achieve the goal of improving quality of care by creating a system that reduces errors and inconsistencies while also reducing avoidable and unnecessary costs.

Physician Reimbursement

The current state of healthcare in the United States utilizes a variety of payment options to reimburse physicians. Yet while there are efforts to decrease the costs of healthcare, some of the models for reimbursement are not effective in influencing physician behavior. One of the original models for payment to physicians is services rendered or the fee-for-service method of paying physicians. This model of payment pays physicians for office visits in addition to any services that they render such as x-rays, MRIs, surgical procedures, and so on. While this model is currently the dominant means of payment, there is one major problem with the model. The fee-for-service model does not properly align the incentives for physicians to provide high quality of care to patients. In an article written by the United Health Group, they discuss some of these problems arguing that “fees are typically the same regardless of the quality of care provided, and thus do not provide incentives for high-quality care — and in some instances, such as avoidable readmissions to hospitals, total payments are greater for lower-quality care.” (Group, 2012) In a similar article, the Center for American Progress agrees with this argument stating that healthcare spending in the United States is going to be higher than

\$8,000 per person which is more than twice the average of other developed countries but it does not necessarily yield better results. Also as an interesting statistic, 78 percent of employee sponsored insurance was fee-for-service as of 2008. (Calsyn & Lee, 2012)

These articles point out the true problem that while physicians are paid through the fee-for-service program, they are not incentivized properly to continue to reduce the costs of healthcare. They are actually “rewarded” for doing tests and procedures that may not be necessary in order to ease patient anxiety or even for less “noble” reasons. This phenomenon is termed provider-induced demand in which a physician recommends procedures that may not be necessary, and patient dependence on physician expertise leads the patient to follow the physician’s referral.

There is also less incentive to provide the “best” quality healthcare the first time a patient is admitted to a hospital because repeated visits continue to provide reimbursement. This problem serves as a significant portion of the excess cost in healthcare. A study published in the New England Journal of Medicine corroborates this fact, in which the researchers concluded that re-hospitalization rates in large part contribute to the overspending on healthcare among Medicare patients in a fee-for-service program. Through their data analysis, the researchers predicted that up to \$17.4 billion was spent in 2004 alone for unplanned re-hospitalizations. (Jencks, Williams, & Coleman, 2009) There are clearly benefits to transitioning away from fee-for-service that will help with the disproportionately high United States healthcare spending. One possible solution for the problem would be to transition to a system that does not provide reimbursement for subsequent re-hospitalizations to remove the incentive for not providing proper and complete care on the first visit.

In an attempt to fix the problems with fee-for-service, Medicare and Medicaid revealed a new model of payment called the pay-for-performance model. In this model, physicians are incentivized to improve quality of care by providing bonuses for physicians that score higher on certain quality measures. Incentivizing physicians to take better care of their patients through financial bonuses seems to be a sound tactic, yet research articles show mixed results. Some research articles provided either weak evidence for pay-for-performance or the pay-for-performance efforts were only a single factor in a larger group of quality improvement efforts. Another problem with the pay-for-performance model is that it is difficult to determine adequate quality measures. Quality can be defined by both objective standards such as re-hospitalization rates, as well as more subjective standards such as patient-physician relationships. Furthermore, it is difficult to determine whether pay-for-performance incentivizes physicians to improve quality of care or incentivizes physicians for process measures. The concept is similar to how teachers in the public school system may not be teaching students in order to teach them the subject matter, but instead aim to teach them how to score high on achievement tests. In conclusion, studies done to assess physician incentives have not yielded adequate results to fully support the idea of utilizing the pay-for-performance model.

(Christianson, Leatherman, & Sutherland, 2008)

Yet another method of payment that has sought to better align incentives of all the healthcare providers is the concept of bundled payments. In bundled payment systems the hospital, acute-care physician, primary physicians, and every other team member involved in a patient's care are paid one lump sum. The purpose of bundling payments then is an attempt to encourage communication and cooperation and to minimize costs

among all those involved in taking care of patients. Therefore, the physicians work in conjunction with the hospital and post-acute care providers in hopes of reducing re-hospitalization and of providing the best and cheapest care possible specifically for inpatient and post-acute care. Research done in the Netherlands, however, shows that it is difficult to objectively measure effectiveness of such programs. As the researchers note,

“It is up to insurers to determine whether they get value for money based on a complex set of structure and outcome indicators. Many of these indicators are not yet readily available for new programs such as bundled payment. Thus, it is often difficult for insurers to check whether they are charged for care more than once and whether the care has been delivered as agreed.”(de Bakker et al., 2012)

So while it seems to be a sound idea, it is difficult to get providers to buy into the bundled care program much less measure improvements. The bundled payment system also does not properly incentivize physician practices. Theoretically the system serves to help align physician incentives with the team, but the hospital’s interests are sometimes in direct competition with those of the physician. The hospital seeks to reduce costs of healthcare by reducing use of resources on patients to generate increased income for hospitals. But by reducing physician reimbursement and limiting physician autonomy in choosing resources to use, physicians are discouraged from working harder for less reimbursement and less choice.

Another system that has recently been developed by the Medicare program under the Affordable Care Act is the system known as the Accountable Care Organization (ACO). The ACO system is aimed to collectively reduce costs by working as a team of healthcare providers. The theory behind this is that it will allow for reduction of

spending, improve preventative care, and give patients more satisfaction with the level of care that they are receiving. As Susan DeVore of the Premiere healthcare alliance writes: “ACOs could also provide incentives for clinical integration by offering financial rewards to caregivers who work cooperatively to provide a continuum of care and achieve agreed-upon measures of success.” (DeVore & Champion, 2011) The system also works among the providers in similar ways that bundled payment systems work by encouraging providers to work together in an ACO to ensure reduced costs and best care of individual patients. The ACA, however, gives flexibility to ACOs in terms of determining what payment system that they wish to adopt whether it is fee-for-service, bundled payments, etc... The mentality behind this is that ACA hopes that ACOs will mold the system to whatever best fits the individuals of their locale. One of the initial problems with the system as DeVore notes is in establishing a good value measurement for determining improvements. (DeVore & Champion, 2011) Thus determining the proper financial incentives for providers is still a problem with this system. Finally, while ACOs seek to align incentives through means of contracting and communication among providers it is still difficult to ensure that everyone on the team is truly working effectively. Also, by allowing the ACOs to choose what payment programs that “work best” it still does not necessarily address the fundamental problems with each system of payment.

The recurring problem in the current systems of payment is that physicians are not economically incentivized to continue to improve their practice methods. More specifically, physicians are not incentivized to practice evidence-based medicine. Protocols derived from evidence-based medicine could serve to standardize both physician behavior as well as physician reimbursement in order to moderate and reduce

unnecessary costs. They can also serve to align economic incentives for physicians by rewarding compliance or by significantly penalizing physicians for non-compliance.

CHAPTER TWO

Evidence-based Medicine

Evidence-based medicine (EBM), as described earlier, is the practice of medicine that utilizes conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patient. (Sackett et al., 1996) Much like any of the other sciences such as biology, chemistry, physics, and other STEM fields, evidence-based medicine is a philosophy of practice that seeks to continually improve methods and techniques to treat patients systematically. It constantly seeks to change in light of new research, new technology, new ideas, cost and the reevaluation of old practices or techniques. (Cluett, 2006) Thus, for the individual practitioner, EBM involves first utilizing knowledge about the patient. As Sackett describes in his article, it involves clinical expertise which is the use of individual patient's predicaments, rights, and preferences in making clinical decisions about their care. The second component of the diagnosis process, however, involves utilizing what he calls "external clinical evidence" which utilizes current diagnostic techniques and technology to try to gain accuracy and precision in diagnosis. (Sackett et al., 1996)

One of the benefits of utilizing evidence-based medicine is that there is an improvement in patient safety and outcomes. According to an IDC Health Insights article as many as 18% of medical errors can be attributed to inadequate, incomplete, or outdated patient information. (Dunbrack, 2013) Lack of information and having incomplete knowledge of a situation will not produce high quality care. That is why

evidence-based medicine emphasizes the importance of utilizing the correct and effective diagnostic tools to have a thorough understanding of an individual patient's situation. Physicians utilize decision analysis to be aware of the potential limitations to the techniques that are currently employed. For example, in a study done to evaluate mammography's effectiveness as a tool for breast cancer detection, researchers found that of 9747 screening mammograms, 6.5% of them were false positives. Furthermore, for the women that had repeated screenings, 23.8% of women had at least one false positive. (Christiansen et al., 2000) The article, while specifically focused on mammograms, shows that even some of the more routine diagnostic exams run the risk of giving faulty information. The physician is thus given misleading information and possibly a misdiagnosis.

Another commonly used diagnostic tool that is highly debated is the prostate-specific antigen (PSA) test. After PSA tests were first introduced, men ages 50-75 have been recommended to have yearly screenings as a diagnostic tool for prostate cancer detection. Unfortunately, the current data does not strongly support the use of the tests and in fact some studies show an adverse effect of overtreatment due to misdiagnosis from PSA tests. For example, one study concludes that over-diagnosis rates for prostate cancer due to the PSA tests are about 42% in the United States. The table on the following page shows their findings based on the three models.

Table 1: PSA screening and the diagnosis of prostate cancer in the SEER 9 population aged 50-84 years during 1985-2000, as predicted by the three models (Draisma et al., 2009)

Table 1. PSA screening and the diagnosis of prostate cancer in the SEER 9 population aged 50–84 years during 1985–2000, as predicted by the three models*

Group	Item	MISCAN	FHCRC	UMich
A	No. of screening tests	7919110	7769666	7433518
B	No. of men diagnosed with PC†	238720	243565	230449
C	No. of screen-detected cancers	106061	103058	86975
	Percentage of group A	1.3	1.3	1.2
	Percentage of group B	44.4	42.3	37.8
D	No. of overdiagnosed cancers	44499	28874	19872
	Percentage of group B	18.6	11.9	8.6
	Percentage of group C	42.0	28.0	22.9
E	Lead time, y			
	Non-overdiagnosed, mean	6.9	5.9	5.4
	Censored, mean	7.8	5.9	5.7
	Uncensored, mean	10.0 (median)	7.2	8.8

* PSA = prostate-specific antigen; PC = prostate cancer; SEER 9 = the nine core catchment areas in the Surveillance, Epidemiology, and End Results program of the National Cancer Institute; MISCAN = the microsimulation screening analysis model based on ERSPC Rotterdam, calibrated to SEER 9 incidence; FHCRC = the microsimulation model developed at the Fred Hutchinson Cancer Research Center, explicitly linking PSA levels and prostate cancer development; UMich = the analytic model developed by Dr Tsodikov (University of Michigan); ERSPC = European Randomized Study of Screening for Prostate Cancer.

† Observed number of men diagnosed with prostate cancer = 235112.

The implications of the table are that there are a significant number of over-diagnosed cancers due to the PSA screening. Cognizance of the fact that information can potentially be erroneous, therefore, leads the physician who practices EBM to utilize other information to have a more complete picture of the situation. In the case of false positives, physicians utilizing EBM would also be aware that none of the diagnostic exams are ever foolproof. Therefore, more information would be gathered before making a diagnosis and before potentially making any unnecessary treatment recommendations.

Yet another aspect of EBM is ensuring that there is strong evidence supporting the use of particular techniques. In the case of mammography and PSA screening, even though both of the exams are currently part of the standard of care, the evidence supporting their use is lacking. In fact the US Preventative Services Task Force now recommends that physicians discontinue use of PSA tests and reduce the use of mammography, yet there are physicians who continue to order them. For PSA screening tests alone, “the annual bill for P.S.A. screening (alone) is at least \$3 billion, with much

of it paid for by Medicare and the Veterans Administration.” Even the creator of the PSA test, Dr. Ablin states in his article that the PSA test is

“hardly more effective than a coin toss. As I’ve been trying to make clear for many years now, P.S.A. testing can’t detect prostate cancer and, more important, it can’t distinguish between the two types of prostate cancer — the one that will kill you and the one that won’t.” (Ablin, 2010)

Another research study examining the effects of PSA screening on mortality rates supports Dr. Ablin’s claim concluding that “after 7 to 10 years of follow-up, the rate of death from prostate cancer was very low and did not differ significantly between the two study groups: a PSA screening group with rectal exams and a control group receiving standard care of either PSA screening or rectal exams, but not annually.” (Andriole et al., 2009) Similar contradictory evidence has been offered for mammography exams which also constitute billions of dollars in testing with evidence that “annual mammography in women aged 40-59 does not reduce mortality from breast cancer beyond that of physical examination or usual care when adjuvant therapy for breast cancer is freely available”. (Miller et al., 2014) In a recent study, estimates were that the “average expenditures for each false-positive mammogram, invasive breast cancer, and ductal carcinoma in situ in the twelve months following diagnosis were \$852, \$51,837 and \$12,369, respectively. This translates to a national cost of \$4 billion each year.” (Ong & Mandl, 2015) Having strong and adequate evidence supporting the use of techniques is important to avoid unnecessary costs, ineffective care, and potentially harmful consequences to patients. Currently, the debate over PSA tests and mammography continues despite strong evidence against the use of the techniques. If the current system of healthcare were to

adopt evidence-based medicine practices, it would create an environment in which physicians would discuss practices in context of proper objective evidence as opposed to physicians' perceived measures of effectiveness.

In addition to improving patient safety, EBM is also beneficial because it allows the physicians to provide higher quality of care. Arguably, there are few if any treatment methods that are perfect; even the most established standards are not without their cons. That is why EBM's focus on improvement and open mindedness towards new techniques and methods is valuable for improving the quality of care provided to patients. For example, in the case of acute myocardial infarctions a study has shown that few hospitals are able to meet the standard 90-minutes or less interval between arrival at the hospital and intracoronary balloon inflation (door-to-balloon time). Even though this has been the established recommendation, the methods of making it a reality are not always well known or utilized. In the study, researchers found that there were six practices that were effective for making that standard interval. A few of the practices were as simple as the emergency physician activating the laboratory or having an attending cardiologist available to assist in emergency situations. Simple strategies such as these that were proven to be effective were not as widely adopted as one would expect. (Bradley et al., 2006) EBM seeks to eliminate these simple errors by utilizing data and studies such as this to adopt best practices for treating patients. Researchers often seek to improve established practices or to evaluate the efficacy of practices though they are not necessarily intentional. The practice of EBM seeks to bridge that gap between research and practical application in the healthcare field. Therefore, physicians that practice EBM

will help to establish better practices and continue to improve the quality of care for patients.

Another example of some of the problems of quality control in the current systems of practice and how evidence-based medicine improves quality of care is in the case of hypertension treatment. An investigation on the self-reported hypertension practices among primary care physicians conducted by Drs. Hyman and Pavlik revealed that there was a wide range of responses when it came to the first-line treatment choices.

Table 2: Most Common First-Line Drug for Monotherapy in Selected Patients (Hyman & Pavlik, 2000)

Table 2. Most Common First-Line Drug for Monotherapy in Selected Patients*						
Rank Order	Whites		African Americans		Hispanics	
	Drug	Using	Drug	Using	Drug	Using
1	ACE inhibitor	44	Diuretic	43	Ace inhibitor	31
2	β -Blocker	19	Ca ⁺ blocker	27	Diuretic	30
3	Diuretic	15	ACE inhibitor	17	Ca ⁺ blocker	21
4	Ca ⁺ blocker	14	β -blocker	12	β -blocker	16
5	Others	8	Others	1	Others	2

**The selected patients were all aged 40 to 60 years. ACE indicates angiotensin-converting enzyme; Ca⁺, calcium channel.*

The researchers also asked in the questionnaire about the physician's familiarity with the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC) hypertension guidelines (the guidelines below are the most updated guidelines).

Table 3: Guideline Comparisons of Goal BP and Initial Drug Therapy for Adults With Hypertension (James, Oparil, Carter, & et al., 2014)

Guideline	Population	Goal BP, mm Hg	Initial Drug Treatment Options
2014 Hypertension guideline	General ≥60 y	<150/90	Nonblack: thiazide-type diuretic, ACEI, ARB, or CCB; black: thiazide-type diuretic or CCB
	General <60 y	<140/90	
	Diabetes	<140/90	
	CKD	<140/90	ACEI or ARB
ESH/ESC 2013 ³⁷	General nonelderly	<140/90	Diuretic, β-blocker, CCB, ACEI, or ARB
	General elderly <80 y	<150/90	
	General ≥80 y	<150/90	
	Diabetes	<140/85	ACEI or ARB
	CKD no proteinuria	<140/90	ACEI or ARB
	CKD + proteinuria	<130/90	
CHEP 2013 ³⁸	General <80 y	<140/90	Thiazide, β-blocker (age <60y), ACEI (nonblack), or ARB
	General ≥80 y	<150/90	ACEI or ARB with additional CVD risk ACEI, ARB, thiazide, or DHPCCB without additional CVD risk
	Diabetes	<130/80	
	CKD	<140/90	ACEI or ARB
ADA 2013 ³⁹	Diabetes	<140/80	ACEI or ARB
KDIGO 2012 ⁴⁰	CKD no proteinuria	≤140/90	ACEI or ARB
	CKD + proteinuria	≤130/80	
NICE 2011 ⁴¹	General <80 y	<140/90	<55 y: ACEI or ARB
	General ≥80 y	<150/90	≥55 y or black: CCB
ISHIB 2010 ⁴²	Black, lower risk	<135/85	Diuretic or CCB
	Target organ damage or CVD risk	<130/80	

Abbreviations: ADA, American Diabetes Association; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CCB, calcium channel blocker; CHEP, Canadian Hypertension Education Program; CKD, chronic kidney disease; CVD, cardiovascular disease; DHPCCB, dihydropyridine calcium channel blocker; ESC, European Society of Cardiology; ESH, European Society of Hypertension; ISHIB, International Society for Hypertension in Blacks; JNC, Joint National Committee; KDIGO, Kidney Disease: Improving Global Outcome; NICE, National Institute for Health and Clinical Excellence.

Researchers found that 41% of the physicians had not heard of or were not familiar with JNC guidelines. This finding is evident in the first-line treatment choices made because JNC guidelines at the time recommend the use of diuretics or beta blockers as a first line agent. Therefore, researchers analyzed the data utilizing multiple logic regression models to show the disparity between those unfamiliar with the evidence-based guidelines and those familiar with the guidelines. Their results were that familiarity with JNC guidelines was associated with lower treatment thresholds, and familiarity with evidence-based research methods was associated with greater use of diuretics or beta blockers as first line agents. (Hyman & Pavlik, 2000) Thus, utilizing protocols can improve quality of care in patients by standardizing treatment consistent with established guidelines and evidence because more physicians would utilize more effective drugs. Yet the current system does

not provide adequate incentive for physicians to follow hypertension protocols. Thus, a combination of payment reform and practice reform would be necessary to properly implement protocols.

CHAPTER THREE

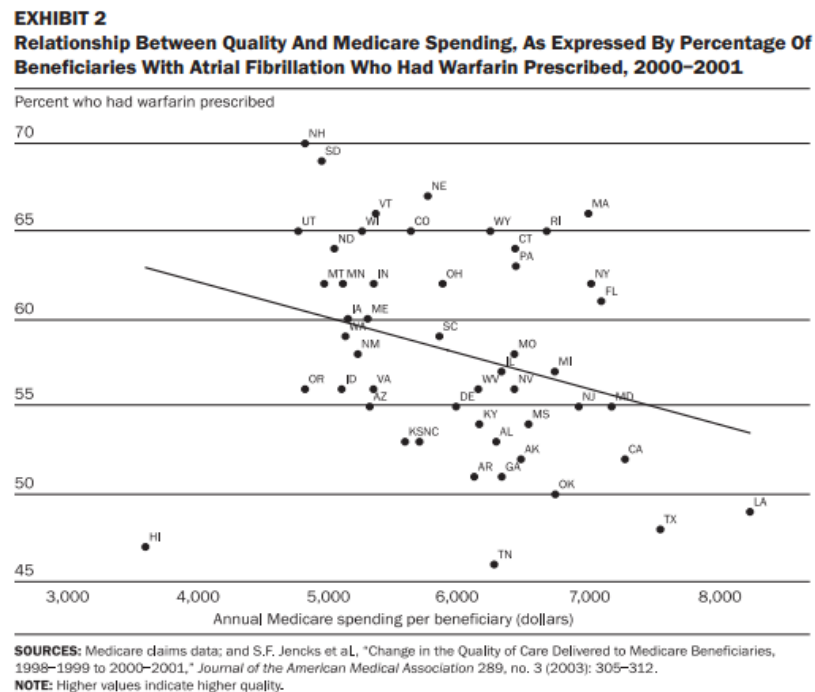
Utilization of Protocols in Medicine

The treatment choices and diagnostic tools for many illnesses are not consistent across various hospitals and physicians. Oftentimes what constitutes best practices for specific specialties is also highly debated among physicians. Some physicians are not aware of or not familiar with the newest treatment options that are available which could reduce significant side effects of previous treatments; while others mistakenly assume that the newest and most expensive treatment options equate to the most effective treatment. Both of these scenarios cause inconsistencies among hospitals and disrupt the standard of care throughout the nation.

One of the major misconceptions revolving around healthcare treatment is that the quality of care is inextricably linked with the cost of healthcare. Many patients assume that higher cost of treatment is the equivalent of higher quality of care. Current research, however, shows the exact opposite trend to be the case. One prominent example of this is the relatively high healthcare costs in McAllen, Texas. In 2006, Medicare spent \$14,946 per enrollee in McAllen, almost twice the national average. Although the hospitals in McAllen were equipped with the newest technology available, Medicare ranked the hospitals' quality of care lower on twenty three of the twenty five quality measures than the hospitals in El Paso which were less well equipped. Many of the patients between 2001 and 2005 were also fifty percent more likely to receive specialist care in McAllen than in El Paso, yet the patients in McAllen were doing worse. (Gawande, 2009)

Other research studies have been done to examine the quality of care in relation to the cost of healthcare, such as the study conducted by researchers at Dartmouth who were intrigued by how widely varying the utilization of high-quality care was between and within states. Thus, they conducted a study examining the relationship between quality of care and Medicare spending for individual states to see if the phenomena could be attributed to a direct correlation between quality and spending. The researchers utilized twenty-four quality measures developed by the Medicare Quality Improvement Organization (QIO) which revolve around six common medical conditions: acute myocardial infarction, breast cancer, diabetes mellitus, heart failure, pneumonia, and stroke. Ultimately, researchers found that states that spend more money per beneficiary are negatively correlated with overall quality of care. (Baicker & Chandra, 2004)

Figure 1: Relationship Between Quality and Medicare Spending, As Expressed By Percentage of Beneficiaries With Atrial Fibrillation Who Had Warfarin Prescribed, 2000-2001 (Baicker & Chandra, 2004)



As astounding as the data may be, the implication for healthcare treatment options is that increasing cost of treatment does not equate to improved quality outcomes. In fact, utilization of high-quality and effective care oftentimes results in decreased costs of treatment.

Dartmouth research also has compared “spending differences across both regions and hospitals and found that most of the spending was due to differences in use of the hospital as a site of care (versus, for example, hospice, nursing home, or the doctor’s office) and to discretionary specialist visits and tests.” (Atlas, 2010) Dartmouth researchers also sought to examine some of the commonly held beliefs regarding practice variation and cost variation such as the belief that the less economically affluent areas would result in higher Medicare spending. They stated that “in a recent *New England Journal of Medicine* paper, using a sample of 15,000 Medicare beneficiaries, (they) found that poverty explained little of the variation in health care spending across regions – at most 4%.” (Atlas, 2010) The reasons for practice variation across the United States thus cannot be fully attributed to some of the more commonly held beliefs of economic differences and availability of the most up to date resources. Therefore, employing best practice protocols is a viable means of reducing practice variation and thus reducing costs of unnecessary procedures across the United States.

In the case of hypertension, a study published in the *New England Journal of Medicine* concluded that full implementation of the 2014 guidelines for hypertension therapy could potentially prevent about 56,000 cardiovascular events and 13,000 deaths annually while saving costs. Utilizing the effective treatment options controlled hypertension better and reduced the risk for other complications in addition to saving

money through less costly prescriptions. These treatments can also provide savings by preventing the need for treatment of secondary problems, such as renal failure, particularly for patients with cardiovascular disease or patients with stage 2 hypertension. (Moran et al., 2015)

Table 4: Projected Average Annual Incremental Results of Providing Therapy for Patients with Untreated Hypertension between the Ages of 35 and 74 Years (2014-2024) (Moran et al., 2015)

Table 3. Projected Average Annual Incremental Results of Providing Therapy for Patients with Untreated Hypertension between the Ages of 35 and 74 Years (2014–2024).*					
Strategy	Newly Treated Patients, as Compared with Status Quo	Cardiovascular Events Averted, as Compared with Status Quo	Change in Cardiovascular Costs, as Compared with Status Quo	ICER, as Compared with Status Quo	ICER, as Compared with Previous Strategy†
	no.		\$		
Women					
Treat all patients with cardiovascular disease‡	161,000	6,000	–287,000	Cost-saving	Cost-saving
Treat patients with stage 2 hypertension who do not have cardiovascular disease	844,000	15,000	–552,000	Cost-saving	Cost-saving
Treat patients with stage 1 hypertension plus diabetes or chronic kidney disease	1,164,000	8,000	–246,000	Cost-saving	Cost-effective§
Treat patients with stage 1 hypertension who do not have diabetes or chronic kidney disease	2,487,000	8,000	–149,000	Cost-saving	Cost-effective§
Men					
Treat all patients with cardiovascular disease‡	705,000	9,000	–755,000	Cost-saving	Cost-saving
Treat patients with stage 2 hypertension who do not have cardiovascular disease	1,948,000	26,000	–1,640,000	Cost-saving	Cost-saving
Treat patients with stage 1 hypertension plus diabetes or chronic kidney disease	1,649,000	20,000	–904,000	Cost-saving	Cost-saving
Treat patients with stage 1 hypertension who do not have diabetes or chronic kidney disease	3,093,000	14,000	–122,000	Cost-saving	Cost-saving

* Data were calculated with the use of the Cardiovascular Disease Policy Model on the basis of a simulation of the 2014 guidelines of the Eighth Joint National Committee for hypertension treatment. A status quo simulation provided a projection of coronary heart disease and stroke events, costs, and quality-adjusted life-years (QALYs) for the U.S. adult population between the ages of 35 and 74 years during the period from 2014 through 2024, on the assumption that untreated patients would remain untreated. ICER denotes incremental cost-effectiveness ratio.

† In this comparison, each incremental strategy is compared with the step before it in the study model as follows: step 1, simulate status quo of no treatment in these patients; step 2, treat all patients with untreated hypertension and cardiovascular disease and compare with step 1; step 3, treat patients with stage 2 hypertension who do not have cardiovascular disease and compare with step 2; step 4, treat patients with stage 1 hypertension plus diabetes or chronic kidney disease and compare with steps 2 and 3 combined; and step 5, treat patients with stage 1 hypertension who do not have diabetes or chronic kidney disease and compare with steps 2, 3, and 4 combined.

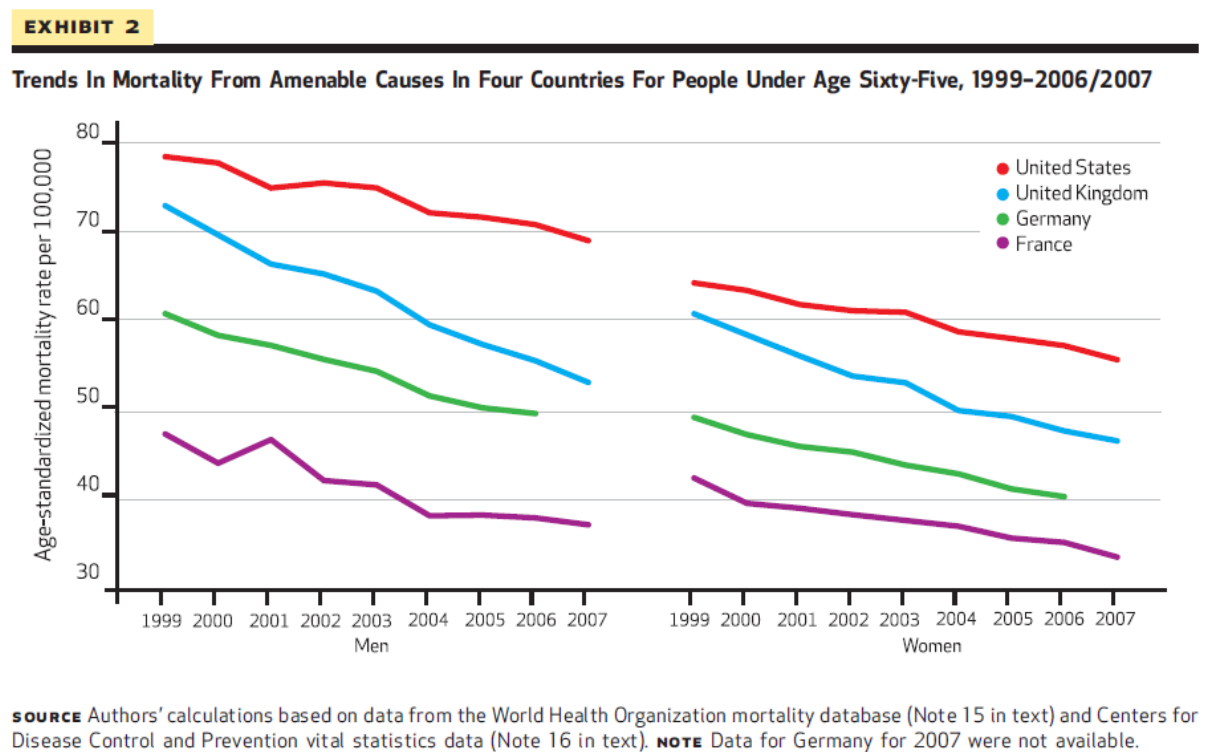
‡ Patients in this group were included in analyses of all the other listed strategies, except for the status quo of no treatment.

§ Treatment was considered to be cost-effective if the cost was less than \$50,000 per QALY. The ICER for women with stage 1 hypertension and cardiovascular disease was \$9,000 per QALY gained for those with diabetes or chronic kidney disease and \$22,000 per QALY gained for those without diabetes or chronic kidney disease.

Another major problem within the current healthcare system that protocols can address is management of easily treatable diseases. Due to the inconsistencies in patient management such as treatment timing and implementation of different therapies, not all easily treatable diseases are well taken care of in the United States. A comparative study conducted to examine the trends and patterns of amenable mortalities in the United States

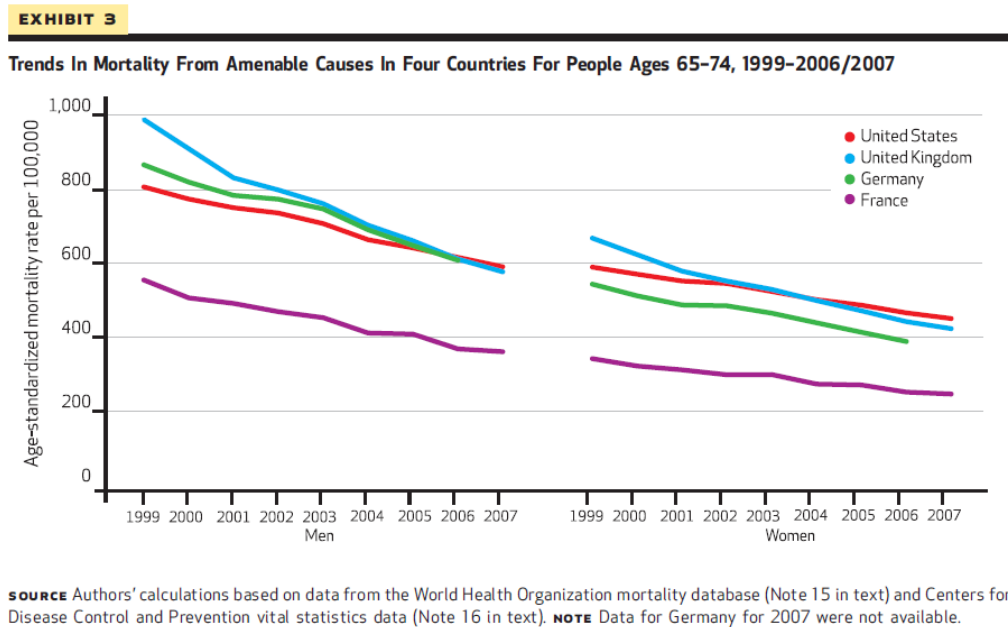
compared to France, Germany, and the United Kingdom reflects this problem within the US system. According to the study, the United States has a higher mortality rate from amenable causes than all of the other countries for people under the age of sixty-five (see figure 3). Amenable causes in the article was defined as diseases that if treated properly should rarely, if ever, cause death. (Nolte & McKee, 2012)

Figure 2: Trends in Mortality From Amenable Causes in Four Countries For People Under Age Sixty-Five 1999-2006/2007 (Nolte & McKee, 2012)



For people between the age of sixty-five and seventy-four the United States initially had a lower mortality rate, but the other countries soon greatly reduced their mortality rate as opposed to the slower downward trend of the United States.

Figure 3: Trends in Mortality From Amenable Causes in Four Countries For People Ages 65-74, 1999-2006/2007 (Nolte & McKee, 2012)



The researchers conclude that the difference in outcomes is not attributed to individuals but is a result of receiving care according to guidelines and adequate treatment by primary care providers to reduce unnecessary hospital admissions. Both of the researcher's conclusions are precisely what can be accomplished through utilizing protocols to ensure that patients are receiving treatment according to regularly updated guidelines.

Not only are protocols useful in reducing costs of healthcare and in preventing deaths, but protocols are also the most effective means of eliminating harmful and defunct practices. Conventionally, physicians who have acquired experience through years of practice in the field of healthcare are believed to provide higher quality of care. Yet, data suggests that there is an inverse relationship between the number of years that a physician has been in practice and the quality of care that a physician provides. In a

systematic review, researchers concluded that 52% of the evaluations they found reported decreasing performance with increasing years in practice for all outcomes assessed. They also found that 74% of the studies related to adherence to standards of appropriate therapy showed a partially or consistently negative association between physician age and adherence to standards of appropriate use of therapy. Older physicians may be gaining more experience, but they are paradoxically not able to provide technically appropriate care because they stray progressively from the newer protocols. (Choudhry et al., 2005) The utilization of protocols is an effective means of alleviating some of the problems produced by this negative correlation. In creating a more objective and standardized means of practicing medicine, it produces an environment which utilizes best practices to ultimately result in improvements in the quality of patient care regardless of the experience of the practitioner. In fact, the positive impact may be particularly significant in less economically stable environments since the most effective treatment options are often not the most expensive treatment options such as in the case of hypertension therapy.

This phenomenon has been recently discussed in a Health Affairs article in which the author describes it as a resistance to “de-innovation” or giving up of old practices. According to Dr. Ubel, “as hard as it is for people to adopt new practices, a pervasive asymmetry in human psychology makes it even harder to give up old technologies and old ways of doing things.” Dr. Ubel describes the challenge referencing physician resistance to the contrary evidence to PSA tests and mammography tests as discussed earlier. He attributes the resistance to physician biases that cause physicians to adamantly stand behind their previous experience and practices despite contrary evidence. Dr. Ubel

concludes by saying that with all the various psychological factors involved in resistance to de-innovation, awareness of these biases is important to overcoming these barriers. (Ubel & Asch, 2015) In regard to protocol creation, this article shows that physician compliance can only be achieved by being careful when creating protocols to utilize solid evidence to eliminate biases.

CHAPTER FOUR

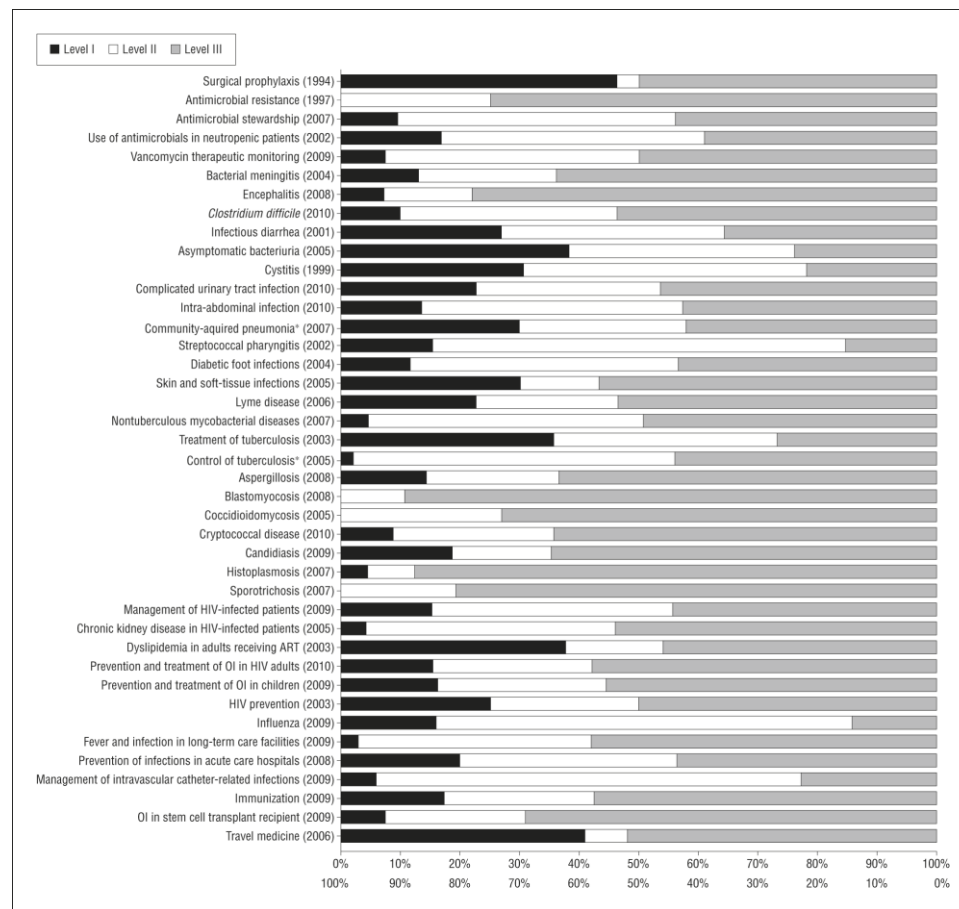
Potential Obstacles to Protocol Utilization

While the theory and rationale of protocol utilization and the reasons for utilizing protocols are relatively straightforward, the implementation of protocols requires prudence and deliberation. One of the first potential confounding problems with protocol utilization is the actual process of protocol creation. There are some guidelines set forth by current organizations such as the National Heart, Lung, and Blood Institute (NHLBI) that recommends that protocol creation should (1) use systematic reviews of existing evidence; (2) use explicit and transparent processes that minimize distortion, bias, and conflict of interests; and (3) provide clear explanations of the logical relationships between alternative care options and health outcomes. They also suggest that the ratings of both the quality of evidence and strength of the recommendation be included in the protocol for physicians to view themselves.(DeBaun, 2014)

Beginning with the first recommendation, the use of systematic reviews of existing evidence seems to be an important start to protocol creation. Unfortunately, current data revolving around many of the commonly treated diseases and health related complications is weak at best. For example, an analysis of the overall level of evidence behind Infectious Diseases Society of America practice guidelines reveals that surprisingly, over half (55%) of the recommendations were based on level III evidence (expert opinion only). Even for the class A recommendations (good evidence for support), 37% of the recommendations were based on level III evidence and only 23%

were level I (≥ 1 randomized control trial). The complete diagram of their analysis is shown below. (Lee & Vielemeyer, 2011)

Figure 4: Comparison of 41 guidelines using percentage distribution of quality of evidence underlying individual recommendations. ART indicates antiretroviral therapy; HIV, human immunodeficiency virus; and OI, opportunistic infection. *Used a grading system that constituted a modification of the standard Infectious Diseases Society of America evidence-grading system. (Lee & Vielemeyer, 2011)



With the lack of current data, success in any evidence-based medicine endeavor therefore requires an increase in comparative effectiveness research (CER), which aims to generate and analyze evidence to compare various treatments and find evidence for the most effective treatments for different populations and individuals.

In fact,

“Congress, in the American Recovery and Reinvestment Act (ARRA) of 2009, appropriated \$1.1 billion to jump-start the nation’s efforts to accelerate CER. In the ARRA, the Institute of Medicine (IOM) was asked to recommend national priorities for research questions to be addressed by CER and supported by ARRA funds. The IOM committee identified three report objectives: 1) establish a working definition of CER, 2) develop a priority list of research topics to be undertaken with ARRA funding using broad stakeholder input, and 3) identify the necessary requirements to support a robust and sustainable CER enterprise.” (Medicine, 2009)

In the report, the IOM gave a list of 100 initial top priorities for CER which includes many treatments that are performed daily, but have not been thoroughly researched. As an example of some of the recommended topics of research:

Figure 5: List of Priority Topics by Quartile Ratings (display within quartile does not indicate priority rank) (Medicine, 2009)

First Quartile

Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.

Compare the effectiveness of the different treatments (e.g., assistive listening devices, cochlear implants, electric-acoustic devices, habilitation and rehabilitation methods [auditory/oral, sign language, and total communication]) for hearing loss in children and adults, especially individuals with diverse cultural, language, medical, and developmental backgrounds.

Compare the effectiveness of primary prevention methods, such as exercise and balance training, versus clinical treatments in preventing falls in older adults at varying degrees of risk.

Compare the effectiveness of upper endoscopy utilization and frequency for patients with gastroesophageal reflux disease on morbidity, quality of life, and diagnosis of esophageal adenocarcinoma.

Compare the effectiveness of dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others.

Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

Compare the effectiveness of different strategies of introducing biologics into the treatment algorithm for inflammatory diseases, including Crohn’s disease, ulcerative colitis, rheumatoid arthritis, and psoriatic arthritis.

Compare the effectiveness of various screening, prophylaxis, and treatment interventions in eradicating methicillin resistant *Staphylococcus aureus* (MRSA) in communities, institutions, and hospitals.

Compare the effectiveness of strategies (e.g., bio-patches, reducing central line entry, chlorhexidine for all line entries, antibiotic impregnated catheters, treating all line entries via a sterile field) for reducing health care associated infections (HAI), including catheter-associated bloodstream infection, ventilator associated pneumonia, and surgical site infections in children and adults.

The second recommendation by the NHLBI involved utilization of a process that minimizes bias and conflict of interests. On first glance, creation of a committee composed of the top physicians in each specialty to create guidelines for the practice seems to be a simple method. In fact, since 1972 the Social Security Amendments established similar groups called professional standards review organizations (PSROs). The PSROs were tasked to monitor and control both cost and quality of care provided by physicians serving Medicare and Medicaid patients. While the PSROs were not effective, they eventually led to quality improvement organizations (QIOs) which now are “paid by the CMS under contract to review care and determine whether care is reasonable, necessary, and provided in the most appropriate setting”. (Shi & Singh, 2001)

Unfortunately practicing physicians are often compensated by pharmaceutical or device manufacturing companies and thus it is difficult for them to maintain objectivity if asked to create protocols. Furthermore, committee members must all be well versed in the current research in order to give proper recommendations. Yet this impediment is not insurmountable since there are existing organizations such as the NHLBI or the Joint National Committee which have been tasked with protocol creation. The requirements for the committee members would most likely include full disclosure of potential conflicts of interest and being well-versed in the current literature. It would also be prudent to utilize physicians in the specialty from various parts of the nation to encompass the various socio-economic situations. In order to diversify the committee, medical researchers as well as members with business experience in the medical insurance industry and hospital administration experience should also be included in the committee.

Finally, the third recommendation for protocol creation revolves around providing clear explanations of the protocol recommendations and health outcomes. Hypertension protocols such as the one provided by the JNC, for example, provide a justification for utilizing diuretics or beta-blockers as the most cost effective and efficient first-line treatment option. Furthermore, when providing protocols for groups of practitioners, it would be important to have brief explanations and data to present to physicians as supplemental knowledge.

Another potential obstacle to utilizing protocols is physician compliance with the protocols. According to a study done by Columbia University in conjunction with the CDC, adherence to various policies regarding prevention of central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), and catheter-associated urinary tract infections (CAUTI) is not high. Many hospital ICUs had low adherence according to the survey. Adherence to prevention policies ranged from 37 to 71 percent for CLABSI, 45 to 55 percent for VAP, and 6 to 27 percent for CAUTI. (Stone et al., 2014) When physician compliance with simplistic policies is not as high as expected, it would only be worse with protocols involving more intensive disease management. Therefore, the implications according to the authors is that physician compliance with protocols is not a given. An encouraging thought, however, is that current systems of implementation do not utilize many of the suggestions raised by various authors regarding implementation of a comprehensive protocol system. These suggestions include an audit and feedback process, in which:

“an individual’s professional practice or performance is measured and then compared to professional standards or targets. In other words, their professional

performance is ‘audited’. The results of this comparison are then fed back to the individual. The aim of this process is to encourage the individual to follow professional standards. Audit and feedback is often used in healthcare organizations to improve health professionals’ performance. It is often used together with other interventions, such as educational meetings or reminders.” (Jamtvedt, Young, Kristoffersen, Thomson O'Brien, & Oxman, 2003)

A third potential counter-argument to the utilization of protocols is that physicians may question what protocol use will do to innovation and the ability of physicians to practice the art of medicine effectively. Physicians may believe that the standardization of health care will remove a physician’s ability to treat complex patient situations or their ability to utilize new and experimental treatment options. Yet protocol creation and adherence is not synonymous with an absolute and uncompromising system of care for individual patients, which would be a misunderstanding of the purpose of a uniform standard of care. Protocols would be created with the overall state of healthcare in mind and will largely be effective for the majority of patients. For successful implementation of protocols in the current healthcare system, it would certainly have to allow for physician judgment to have its proper role in individual patient care. For example, one could imagine a situation in which a nurse follows a protocol in treating a patient, but the patient is not responding to the recommended treatment. In this situation, the physician would exercise his professional judgment and experience in altering the treatment method to fit the individual patient. There will always be exceptions to protocol recommendations when treating patients, thus physician judgment is still necessary in situations where there is clear evidence that the protocol treatment is not optimal for the

patient (i.e. allergies or incompatible medications). In a study studying a similar concept, researchers compared the clinical San Francisco Syncope Rule (SFSR) and physician decision making when predicting serious outcomes in patients with syncope. Researchers found that physician judgment when diagnosing patients with syncope was relatively accurate. Yet, “contrary to their judgment, physicians still admit a large number of low-risk patients. The SFSR performs better than current physician performance and has great potential to aid physician decision making.” (Quinn, Stiell, McDermott, Kohn, & Wells, 2003) In a similar manner, protocols are a good means of aiding physician decision making and allowing physicians to have current evidence of best practice. But it is not a replacement for physician knowledge and decision making ability.

Yet another impediment to comprehensive protocol use is the need to communicate new and updated protocols. Physicians when first transitioning to new protocols need to learn the updated practice standards and may have difficulty transitioning from their old ways of practice. In fact there have been a few articles written specifically to address the “tendency for physicians to become entrenched in a way of practicing medicine and skeptical of new evidence”. (Mitka, 2012) Physicians are trained to practice medicine in residency programs and from their mentors and often do not update their practices for many years. Thus, there is the problem of overcoming the resistance to change as well as the problem of information dissemination. The problem again is not insurmountable when looking at technological tools such as cellular devices or computer updates. There are certainly ways to update protocols and disseminate information relatively seamlessly.

Finally, another potential concern that physicians may raise about utilizing protocols is the availability of resources, particularly in a rural setting. Researchers are currently studying the effects of utilizing mobile technology and satellite technology, which has been collectively coined as telemedicine as an effective means of providing information to providers and to treating patients remotely. Thus far, it seems that it can be an effective means of distributing protocols and as a means of training the healthcare professionals that are available especially with the internet becoming more readily available. As discussed earlier, protocol creation does not preclude the use of inexpensive and readily available technologies. In fact, some of the more effective treatments such as the hypertension treatments are relatively cheap.

In the case of the lack of a trauma unit or lack of ability to deal with severe cases, there continues to be a need to develop better access to care. Organizations such as the National Health Service Corps (NHSC) or utilization of Migrant Health Centers (C/MHCs) under the Office of Rural Health have also currently been influential in improving medical access. (Shi & Singh, 2001) Yet even under circumstances in which a lack of resources is available, one research study shows that “Triage and stabilization of severely injured rural trauma victims at Level III EDs before Level I transfer provide outcomes similar to national results”. Therefore, for rural medicine, protocols can be utilized in situations to better stabilize patients for transfer to trauma units. (Veenema & Rodewald, 1995)

CHAPTER FIVE

Conclusions and Recommendations

Utilization of evidence-based medicine in protocol creation and implementation can be a powerful tool towards advancing the future of healthcare. By creating a more standardized best practice approach towards treating illnesses, the overall quality of healthcare can be improved. In addition, the reducing the cost of healthcare is vital for the advancement of the United States healthcare system by making healthcare more affordable. Yet, while the practice seems to be a sound theory, the difficulty comes with the implementation of the practice.

The first possible stumbling block for protocol creation is the lack of strong evidence concerning some of the most commonly treated illnesses and diseases. Yet the lack of evidence is not a result of an inability to collect the data especially with the modern electronic medical records systems that are in place. As mentioned previously, organizations such as the JNC or the NHLBI have dedicated time towards studying certain illnesses and treatment options and have already created functional protocols. For example, in the field of cardiology, many organizations have banded together to create appropriate use criteria for coronary revascularization in which they have created a simplistic model for physicians to follow regarding the topic. (Patel, Dehmer, Hirshfeld, Smith, & Spertus, 2012)

The lack of data is also a result of a lack of focused effort towards researching comparative effectiveness on a larger scale. Thus, with a combined national effort of both organizations and individual physicians who are willing to contribute to the different fields can help collect and analyze the data. Organizations such as PCORI (Patient-Centered Outcomes Research Institute), a not for profit institute, have recently helped to provide more than \$64 million to fund such efforts already. (Rubenfire, 2015) The inclusion of physicians in the efforts of protocol data collection can serve as a factor in solving the problem of compliance and the problem of disseminating the information by creating awareness of the protocol creation efforts. Even after more protocols are created, there is still the need for continual re-evaluation of information and the collection of new information as new treatment options are created. Therefore, while some physicians may argue against the utilization of protocols because they believe it will stifle creativity in the art of medicine, protocols still allow room for physicians to contribute to providing new and updated information.

Another potential problem is the selection of the committee members that will serve to ultimately help decipher and determine the proper treatment recommendations for protocol creation. It is especially pertinent since there are potentials for biases and for conflicts of interest. A notable example would be the case of Dr. Charles Denham, who had been involved in the Leapfrog Group, a national patient-safety organization which establishes guidelines. According to news reports, the U.S. Justice Department accused Dr. Denham and his private company, Health Care Concepts, of taking \$11.6 million in contracts from healthcare supplier CareFusion in 2008 which were deemed to be excessive payment for the services ordered. Unsurprisingly, in 2009 Dr. Denham co-chaired a

National Quality Forum committee recommending CareFusion products over other competitors such as 3M. (Carlson, 2014) With cases such as Dr. Denham's, it is important that all of the committee members are screened thoroughly for potential conflicts of interest and biases. Thus it should be mandatory that much of the protocol creation process involves transparency in the determination of protocols. Data and meeting records should be made publicly available and, the committee members should be selected according to their experience in the specialties. Furthermore, financial relationships with outside companies should not be allowed in order to help reduce the possibility of conflicts of interest. There should be, however, members of the committee that have experience in academic research fields as well as members that have had previous administrative experience in the hospital or insurance setting to bring a market perspective into the determination for cost of care.

Once protocols are created, the first problem that arises is the problem of mass dissemination of information. That problem is the most reasonably solved by the utilization of electronic medical records (EMR) in hospitals and practices. Currently, more practices are adopting electronic medical records from various companies. Yet while the EMR software from companies such as the Epic system are supposed to be able to "communicate" with other electronic medical records, there currently is no means to fully share information between different systems. Therefore, regardless of what program that practices and hospitals adopt, the software programs and companies need to share data seamlessly. By doing so, patients records will be accessible in any part of the country and will allow for more comprehensive care for the individual patient. Furthermore, using an EMR will be an effective way of ensuring that physicians can have up-to-date information

concerning the newest protocols for their patients. Whenever a diagnosis is typed into the system, it can automatically pull up the newest protocol so it is not necessary for physicians to remember all of the newest changes. This concept is similar to the concept of updating cellular devices or computers through the network systems. It can also be designed so that the system provides simple depictions of the treatment choices based on the level of evidence and the physician's diagnosis. An example can be found below:

Figure 6: Appropriate Use Criteria for Coronary Revascularization Focused Update (Patel, Dehmer, Hirshfeld, Smith, & Spertus, 2012)

870 Patel et al. JACC Vol. 59, No. 9, 2012
Appropriate Use Criteria for Coronary Revascularization Focused Update February 28, 2012:857-81

Low-Risk Findings on Noninvasive Study						Asymptomatic				
Symptoms Med. Rx						Stress Test Med. Rx				
Class III or IV Max Rx	U	A	A	A	A	High Risk Max Rx	U	A	A	A
Class I or II Max Rx	U	U	A	A	A	High Risk Normin Rx	U	U	A	A
Asymptomatic Max Rx	I	I	U	U	U	Int. Risk Max Rx	U	U	U	U
Class III or IV No/min Rx	I	U	A	A	A	Int. Risk No/min Rx	I	I	U	U
Class I or II No/min Rx	I	I	U	U	U	Low Risk Max Rx	I	I	U	U
Asymptomatic No/min Rx	I	I	U	U	U	Low Risk No/min Rx	I	I	U	U
Coronary Anatomy	CTO of 1-vz, no other disease	1-2-vz. disease, no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease, no left main	Coronary Anatomy	CTO of 1-vz, no other disease	1-2-vz. disease, no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD

Figure 2. Appropriate Use Ratings by Low-Risk Findings on Noninvasive Imaging Study and Asymptomatic (Patients Without Prior Bypass Surgery)

A = appropriate; CTO = chronic total occlusion; I = inappropriate; Int. = intermediate; Max = maximum; min = minimal; Med. = medical; prox. LAD = proximal left anterior descending artery; Rx = treatment; U = uncertain; vz. = vessel.

Simple tables such as these should help reduce the risk of misunderstanding of protocols and will also make it more efficient for physicians to gather the information that they need regarding the appropriate treatment options. If necessary, there can also be hyperlinks embedded in some of the protocols to provide complete explanations of the data and the recommendations for the protocol creation.

Electronic medical records are also useful in solving the problem of physician compliance. There are currently companies such as Crimson that help audit large

physician groups and practices by utilizing the data from each physician. Crimson has programs to help physicians analyze their patterns of practice by comparing them against other physicians in the same group or from across the nation. Crimson can therefore give feedback and data regarding best practices as well as data to help direct efforts to improve efficiency within individual practices ("Crimson," 2015) Pre-existing companies could help analyze the physician practices which can compile data regarding the prescriptions, tests ordered, and more. By utilizing established organizations that have the ability to handle "big data," it is possible to help monitor individual physicians relatively easily. There can be a system by which physicians are given monthly or yearly reports comparing their habits with the national practices and the best practices to give feedback to physicians. There can even be support staff available to help give advice to physicians on how to better utilize protocols within their practices. Other healthcare practitioners can also utilize the system for more basic diagnoses. As discussed in a research article regarding EMR and hypertension, the researchers concluded that the "EMR was associated with improved hypertension management for each of the individual physicians who used it. This also supports the idea that the EMR may potentially improve patient care for other providers who may use it." EMR use was also found to be positively correlated with increased prescriptions of the recommended treatments for hypertension. (Kinn, Marek, O'Toole, Rowley, & Bufalino, 2002) As seen in the figure on the following page.

Figure 7: Effects of the electronic medical record on different blood pressure medication use (Kinn, Marek, O'Toole, Rowley, & Bufalino, 2002)

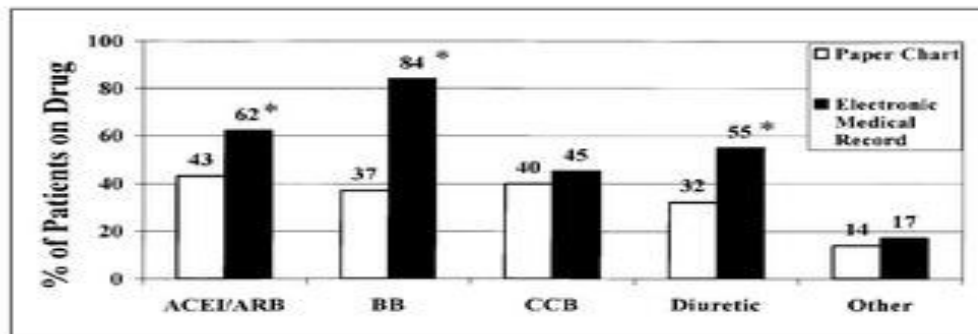


Figure 3. Effects of the electronic medical record on different blood pressure medication use. Open bars indicate the paper chart control group. Solid bars indicate patients followed in the electronic medical record. ACEI=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; BB= β blocker; CCB=calcium channel blocker; other=antihypertensives other than ACEI, ARB, BB, CCB, or diuretics. * $p < 0.001$

Another major deterrent to protocol utilization is the problem of physician compliance. Current methods of protocol use have limitations on physician compliance based on factors such as years of practice as well as other resistances to “de-innovation”. There are a few strategies to improve compliance, such as providing an auditing and feedback system to physicians comparing their compliance rates with the other physicians in the nation. (Jamtvedt et al., 2003) Appealing to them from a professional standpoint is a simple method of encouraging physicians to improve performance. On a related note, physicians can even have a direct feedback system built into the electronic medical records that notifies them when they prescribe treatment if it does not directly correlate to the pre-determined protocols.

For some physicians, simply appealing to professionalism may not be adequate so there should be penalties in place for physicians that refuse to comply. The protocol

system should be worked into the reimbursement system so that cost of care can become more standardized. Thus, treatments that are not included in protocols will not be reimbursed by insurance companies and in fact physicians should receive a significant penalty at the end of the year if their compliance rates fall below a certain percentage. There may be physicians who believe that this idea is unfair and they may argue that it removes a physician's ability to practice the art of medicine. To combat this problem, there will be opportunity for a physician to earn reimbursement for procedures not explicitly utilized in protocols. In the auditing reports, physicians will be allowed to explain why they prescribed certain forms of treatment and how it is beneficial to their patient(s). Since the protocols will give a range of treatment options, especially for those that do not have strong effectiveness data, it should provide physicians with ability to practice medicine according to their expertise. The other method of aligning incentives for physicians would be to give incentives for compliance with protocols so that they receive a bonus for achieving a certain percentage of compliance (i.e. 90%). This concept is similar to the current pay-for-performance model that grants bonuses for physicians that have higher quality outcome measures. One study in which 40% of compensation for physicians in the Fairview Health Services ACO was tied to quality measures showed that "providers whose baseline performance was in the lowest tertile improved three times more, on average, across the three quality metrics studied than those in the middle tertile, and almost six times more than those in the top tertile." (Greene, Hibbard, & Overton, 2015) The implications of the study are that with large performance incentives such as penalties or bonuses, the programs are effective particularly for the lowest performance groups. Thus in combining the auditing and feedback system with a

substantial financial rewards or penalty system would be able to encompass a larger spectrum of physicians.

As far as reimbursement is concerned, standardizing treatment will allow for a more standardized method of reimbursement for practices. Physicians will not be reimbursed for extraneous practices and practices that significantly stray from the established protocol. Therefore, there is neither incentive to perform extra procedures nor to order extra tests and there is also less reason to fear reprisal from medical law suits if the physicians comply with the protocols. Currently some organizations have suggested employing clinical practice guidelines (CPGs) to serve as the “standard of care” requirement, since physicians must prove they provided proper care according to current medical malpractice law. Advocates of creating CPGs state argue that “physicians would operate under less uncertainty, and consequently would practice medicine less defensively. Additionally, physicians would have an incentive to comply with CPGs, which represent our best estimate of what constitutes good quality care.” (Mello, 2001)

Ultimately, integrating protocols developed from following evidence-based medicine into the healthcare system is a viable method to achieve the goals of improving the overall quality of care and reducing the cost of healthcare in the United States. My recommendations on the subject are that the first priority to achieving the goal of utilizing protocols is to achieve a strong evidence base to create protocols. Proper data collection and evidence-based medicine is vital to creating valid and reliable protocols. Another part of protocol creation would be selecting a diverse committee to oversee protocol creation for various specialties. Each committee should consist of physicians well-versed in current research and practices, medical researchers, as well as members familiar with the

business aspects of healthcare such as hospital administrators. In addition, the protocol discussions should be publicly available and all of the conflicts of interest should be disclosed. Protocol design should be simplistic so that physicians can easily understand protocols through diagrams and charts as well as have the ability to read the current data the protocols are based on through use of hyperlinks.

As far as dissemination of protocols is concerned, utilizing electronic medical records (EMRs) that are accessible through the internet and between different software systems (i.e. Epic) is vital. The choice of which specific software system to utilize is a choice that can be left to different practices as long as they communicate with other software systems to provide a continuous network of records. Protocols should also be displayed when physicians enter a diagnosis into the electronic medical records system to ensure that physicians can view and utilize them properly. Their compliance with the protocols can thus be monitored and audited by data companies such as Crimson to provide feedback to individual physicians regarding their performance. In the case of exceptions to the protocol, physicians should also have the ability to provide a justification of why an alternative treatment is provided to avoid being penalized and to be reimbursed for services.

In order to improve physician compliance, it would be better to penalize physicians for lack of compliance rather than incentivize physicians to comply with protocols. This concept is derived from research regarding intrinsic motivation (personal interest) and extrinsic motivation (external rewards), in which “tangible rewards tend to have a substantially negative effect on intrinsic motivation (...) Even when tangible rewards are offered as indicators of good performance, they typically decrease intrinsic

motivation for interesting activities.” (Deci, Koestner, & Ryan, 1999) Therefore creating a penalty for physicians below a minimum compliance level, such as withheld reimbursement or financial penalties, would be a more effective means of improving compliance.

Finally, reimbursement for services will be based on the protocol recommendations. Physicians will only be reimbursed for the recommended services per the protocol and will not be reimbursed for extraneous tests and procedures without proper justification. Protocols should eventually be used in medical malpractice tort laws to help reduce physician fear of reprisal and to help possibly reduce the cost of medical malpractice insurance. There may be additional obstacles to creating a comprehensive protocol system, but the potential obstacles are outweighed by the benefits of a more standardized system of practice within the United States.

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