Population Health & Chronic Disease Management
**Recommended Annual Cancer Screenings**

Each patient is unique so discuss with your provider the screening and treatment that is best for you.

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<th>Women</th>
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**Cervical Cancer**
- Ages 21-30, Pap every 3 years
- Ages 30-65, Pap every 5 years plus HPV
- Stop at age 65 if the patient has had 20 years of normal Paps

**Breast Cancer**
- Yearly mammogram
- Consult with your provider; he or she will help you determine a screening schedule that is best for you

**Prostate Cancer**
Discuss need for screening with provider. For men who decide to proceed:
- PSA screening with or without digital rectal exam

**Lung Cancer**
Certain patients are candidates for low-dose CT screening of the chest, which can find lung cancer in its earliest stages.
- If you are age 55-74 years old and have smoked for 15 years or more, check with your provider

**Colorectal Cancer**
- Colonoscopy recommended every 10 years. Beyond age 75, discuss the risks and benefits of testing with your provider

The above guidelines for breast, cervical and prostate cancer are recommended by Avera Medical Group. The guidelines for colorectal and lung cancer are from American Cancer Society recommendations.

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Population Health & Chronic Disease Management

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Dear reader,

This special edition of South Dakota Medicine is devoted to population health and chronic disease management. Before going on, I would like to pause for a moment to clarify between the two – population and public health. Traditionally, public health is defined as the critical functions of federal, state and local health entities who are involved in disease prevention/epidemics, the containment of environmental hazards, and the promotion of health behaviors. Organizations like the Centers for Disease Control and Prevention and the South Dakota Department of Health immediately come to mind. Population health is defined as the health outcomes of a group of individuals, including the distribution of such outcomes within the group. It is an approach that aims to improve the health of an entire population – which for us physicians, means our patients.

One method to improve the health of our patient population is the utilization of population health management (PMH) – which is different from disease management as it incorporates more than one chronic condition and often requires intensive care management for individuals of high risk. PMH requires the incorporation and utilization of a variety of individual, organizational, and societal interventions to improve health and reduce morbidity. It also requires the acknowledgment and acceptance of the fact that we as physicians cannot do it all. We must develop a health care team, incorporate and utilize ancillary providers to assist in the care and management of our patients, and refer and draw upon community resources to support our patients in between the times that we see them. To be successful, we also must acquire and utilize external data, educate and engage patients, establish and adhere to complex clinical practice guidelines, learn to coordinate effectively between the patient and care team, and track specific outcomes.

Health care reform has and will continue to drive change to the reimbursement models we currently know, and pay-for-performance and value-based reimbursement will forever change the way we practice medicine. Good thing we are up for the challenge.

I would like to give recognition to the South Dakota Department of Health for its support and contributions to this special issue. I would also like to thank our authors for all of their hard work, which made this project possible. May you find this issue informative and a resource for your practice.

Tom Hermann, MD
SDSMA President

South Dakota physicians,

As the number of South Dakotans suffering from chronic conditions like type 2 diabetes continues to grow and the health care landscape moves from fee-for-service reimbursement to a model based on pay-for-performance, population health management continues to gain momentum. This model of care brings providers together to coordinate and integrate all elements of patient care across the health care system – subspecialty care, hospitals, home health agencies, nursing homes – with the patient’s family, and public and private community-based services to achieve optimal health outcomes.

This special issue of South Dakota Medicine takes a closer look at the many components to consider when implementing population health management. Topics include who to involve in a multidisciplinary patient-centered team, roles within that patient-centered team, clinical preventive services available, incorporating health promotion strategies, utilizing community-based resources and increasing patient engagement.

The growing interest in population health management mirrors our department’s own strategic plan, which focuses objectives on promoting the right care at the right time in the right setting along with preventing and reducing the burden of chronic disease. We are pleased to be a part of this special issue and we hope it will be a valuable resource for you. As the state’s public health agency we value our continued partnership with South Dakota’s medical community and we thank you for what you do every day to promote, protect and improve the health of every South Dakotan.

Kim Malsam-Rysdon
Secretary, South Dakota Department of Health
It has been nearly 100 years since “public health” came into existence – arriving formally as a separate discipline during one of the most devastating infectious disease epidemics ever known – the great influenza scourge of 1918. Dr. William Henry Welch’s vision for the first fully designated school of public health at Johns Hopkins University followed his transformational work along with colleague Abraham Flexner in establishing a new paradigm for medical school education. A brief history of its origin and his leadership is worth recounting as we address population health in our time.

“Welch had turned the Hopkins model into a force. He and colleagues at Michigan, at Penn, at Harvard, and at a handful of other schools had in effect first formed an elite group of senior officers of an army; then, in an amazingly brief time, they had revolutionized American medicine, created and expanded the officer corps, and begun training their army, an army of scientists and scientifically grounded physicians.

On the eve of America’s entry in World War I, Welch had one more goal. In 1884, when the Hopkins first offered Welch his position, he had urged the establishment of a separate school to study public health in a scientific manner. Public health was and is where the largest numbers of lives are saved, usually by understanding the epidemiology of a disease–its patterns, where and how it emerges and spreads–and attacking it at its weak points. This usually means prevention. Science had first contained smallpox, then cholera, then typhoid, then plague, then yellow fever, all through large-scale public health measures, everything from filtering water to testing and killing rats to vaccination. Public health measures lack the drama of pulling someone back from the edge of death, but they save lives by the millions.

Welch had put that goal aside while he focused on transforming American medicine, on making it science-based. Now he began to pursue that goal again, suggesting to the Rockefeller Foundation that it fund a school of public health.

There was competition to get this institution, and others tried to convince the foundation that though creating a school of public health made good sense, putting it in Baltimore did not. In 1916, Harvard president Charles Eliot wrote bluntly to the foundation-and simultaneously paid Welch a supreme compliment—when he dismissed the entire Hopkins medical school as ‘one man’s work in a new and small university…. The more I consider the project of placing the Institute of Hygiene at Baltimore, the less suitably expedient I find it…. In comparison with either Boston or New York, it conspicuously lacks public spirit and beneficial community action. The personality and career of Dr. Welch are the sole argument for putting it in Baltimore—and he is almost 66 years old and will have no similar successor.’

Nonetheless, that ‘sole argument’ sufficed. The Johns Hopkins School of Hygiene and Public Health was scheduled to open October 1, 1918. Welch had resigned as a professor at the medical school to be its first dean…Welch was sick the day of the scheduled opening, and getting sicker. He had recently returned from a trip to investigate a strange and deadly epidemic. His symptoms were identical to those of the victims of that epidemic, and he believed he too had the disease.

The army Welch had created was designed to attack, to seek out particular targets, if only targets of opportunity, and kill them. On October 1, 1918, the abilities of that army were about to be tested by the deadliest epidemic in human history."

In 1919 Welch, identified as perhaps “the single most powerful individual in the history of American medicine,” hired Wade Hampton Frost as the first professor of epidemiology in the U.S. Frost, a 1903 MD graduate from the University of Virginia, had served as assistant surgeon in the Public Health and Marine Hospital Service (now the Public Health Service) and in the Hygienic Laboratory (forerunner to the National Institutes of Health). These posts brought him into contact with a number of infectious diseases including yellow fever and his emerging skill set led to studies of public health related to stream pollution, poliomyelitis and influenza. He also worked with Edgar Sydenstricker, the nation’s first national public health statistician, a collaboration that led...
to a deeper understanding of morbidity surveys and family studies. Their conclusions became foundational for Frost’s later work with tuberculosis (TB).}

Frost’s first decade at Hopkins was dedicated to defining the field of epidemiology, including basic course preparation and investigations into a number of acute infectious diseases such as diphtheria and the common cold. In fact, his original definition of epidemiology was “the natural history of the infectious diseases, with special reference to the circumstances and conditions which determine their occurrence in nature.” Frost’s epidemiologic discoveries earned him the title “pioneer epidemiologist.” He was to that end “the first to understand the importance of transmission in poliomyelitis – knowledge that prepared the ground for the worldwide campaign against that disease; the first to understand the cyclical nature of influenza…Further, he was the first to theorize that, as an infection spreads and increases in a population, its progress is slowed not only by the resulting decrease in susceptible persons due to immunizations but also by deaths in the host population.”

During the last decade of Frost’s life (1928-1938) he turned his attention to the study of chronic diseases through the lens of TB. TB was front and center as a major cause of disability and death, being the sixth leading cause of death in the U.S. accounting for 6.3 percent of deaths in 1930. There was likely a personal driver as well because Frost himself had been diagnosed with TB in 1917 leading to several months in a sanatorium. He also lost two of his siblings to TB. One of Frost’s seminal contributions to the study of TB transmission occurred in 1933, when he coined the concept of the “index case.” Frost’s work in the area of TB provided the framework for fundamental concepts in epidemiology and he was “the first to develop the historical cohort approach and undertake longitudinal cohort analyses…and the first to design life tables for expressing data in person-years.” Frost and his contemporary Major Greenwood at the London School of Hygiene and Tropical Medicine proposed that epidemiology define itself as the science of the “mass phenomena” of disease. This was an early foreshadowing to the concept of the “population” – to be further defined some decades later.

Now a century following “The Great Influenza,” the increasing prioritization of population health since the turn of the century has led to the era of quality improvement. Two reports and a law have heralded our time. The Institute of Medicine (IOM) reports in 1999 and 2001 established the case for improvement which would require fundamental redesign of the nation’s health care system. To Err is Human and Crossing the Quality Chasm shocked the establishment by showing how it was possible to have progress (medical advancement) without improvement (regularly harming patients from this advancement). In response to these calls, health care professions of all stripes (medical, nursing, pharmacy, etc.) began sweeping changes in curriculum – to address the constituents of improvement – culture of safety, human factors, teamwork/communication, reliable design, just culture, transparency, mindfulness, incremental care, professionalism and ethics. Many schools of public health have likewise shifted to offer tracks in quality improvement – giving “public health” a whole new meaning. This “Flexner Moment” belies a new reality of not just individual care but also population care – and to identify that which threatens both, including the system of health care itself. Several years after the IOM reports, an enforcer emerged in the form of the Affordable Care Act (ACA), aka Obamacare, which began requiring systematic change via the purse through things like Hospital Value Based Purchasing, Hospital Acquired Conditions Reduction, Hospital Readmission Reduction and Physician Quality Reporting System/Value Based Modifier programs. These follow the federal mantra of “pay for performance.” In this regard, a new idea is being fleshed out through the concept of the accountable care organization (ACO), which are “groups of doctors, hospitals, and other health care providers, who come together…to give coordinated high quality care to their Medicare patients.” While voluntary at present, there is no reason not to believe that the ACO will be central to population health going forward.

Despite awareness via the IOM reports – and reform attempts via the ACA, American medicine is still facing a serious public health dilemma. The nation’s quandary is defined by a trio of “viruses” known as Overuse, Underuse and Misuse – infecting every population. This triad threat was recently addressed by a blue ribbon panel commissioned by the National Academy of Medicine called the Vital Directions Steering Committee. The group identified 19 “issue areas” and included more than 150 leading health and policy experts. Herein is the sobering summary of the biggest population of them all:

“The U.S. health and health care system is at a critical juncture…..Unparalleled health costs, structural inefficiencies, fragmented care delivery, payment hardships, and proliferating administrative requirements impose burdens on individuals, clinicians, employers, and entire communities. The consequences are especially severe for those who are ill, lack needed medical and social services, and have lower incomes, as indicated by
the association of lower incomes with substantially lower life expectancy. But inadequate and inappropriate treatment, overdiagnosis and underdiagnosis, medical errors, and excessive costs are also experienced by many other individuals in the U.S. These serious systemwide challenges are complicated by increases in illness and disability from an aging population, emerging infectious diseases, and physical, behavioral, and mental health disorders such as opioid abuse, tobacco use, obesity, depression, and their related chronic diseases. Although U.S. residents with higher incomes have never been healthier, conditions such as these are life-altering threats for many individuals. The most recent data on U.S. life expectancy indicate not only sustained health disparities by income level and by race/ethnicity, but also a decline in overall life expectancy for the first time in nearly two decades.”

To solve a Rubik’s Cube of redesigning and paying for this monolith, opinions are legion reflecting deep divides and conflicting agendas both nationally and locally. Given the current hyper-complex, hyper-partisan, hyper-competitive and hyper-regulatory atmosphere, it is not too dramatic to question whether or not we now face a (hyper) crisis of authority. The default solution with something this consequential is to turn to the biggest player in the room – to Washington for the ground to stand on. Recently, for instance, the question of whether health care is a right or a privilege has resurfaced. Here are four potential responses to this reflexive binary choice. First, the only time “privilege” should ever enter the debate is as it applies to us as health care providers rather than to patients, for it is our privilege to care for any human being. Second, the notion of rights has a strong lineage and basis with within our republic – and the language of rights is being repeatedly cited by prominent health care leaders as a principal rationale for health care reform. However, as obvious to some as it sounds and while obliquely true, the notion of a “right-to-health care” may not be a particularly unifying theme, nor is it likely to be the ultimate motivation to preserve that we are so proud of in medical advancement and fix that which is so embarrassing to our tradition. The debate over rights in our society in fact is a divisive minefield, more often divorced from an original notion of rights as something bestowed and not entitled – as including gratitude, personal responsibility, intrinsic worth, respect for the other and a protection of the weak against the mighty. Third, if the language of rights as the reason for change is taken to its literal/logical end, then we would have to establish health care as an “inalienable right,” given to us by providence, as yet another basic part of the human condition, which the government may not infringe upon. Such a “constitutional amendment” (literally or metaphorically) would seem implausible in a context where even already established rights are endlessly debated. Fourth and most important, the great tradition of medicine did not emerge nor will it become transformational from a right-to-receive premise (neither “my privilege” nor “my right”) but rather from an obligation-to-give. Medicine’s authority has never come from the consumer or the state – and is neither conservative nor progressive, Democrat or Republican, capitalist or socialist. We answer to a higher obligation over all principalities and powers, to the truly biggest player in the room and the only authority with the gravitas to command our allegiance.

This obligation which I am calling the Knowledge of Improvement, is like a law transcending that posited by mankind, a law written on our collective humanity as though coming from the same author and a law which we can’t not know – arising from an ancient radical-ethical challenge (“Do unto others”) rather than a modern radical-egalitarian demand (“All differences must be eradicated”). It is intrinsic knowledge with a presence not unlike gravity – an ought pulling from within every civilization and every system of thought. It is to this law, which I have described previously as the “The Tao of Medicine,” “The Art of Medicine,” and “Healthcare in its Right Mind,” that we now turn. The venerable C.S. Lewis most famously described it as, “The Tao, which others may call Natural Law or Traditional Morality or the First Principles of Practical Reason or the First Platitudes, is not one among a series of possible systems of value. It is the sole source of all value judgments. If it is rejected, all value is rejected. If any value is retained, it is retained. The effort to refute it and raise a new system of value in its place is self-contradictory. There has never been, and never will be, a radically new judgment of value in the history of the world. What purport to be new systems or...ideologies...all consist of fragments from the Tao itself, arbitrarily wrenched from their context in the whole and then swollen to madness in their isolation, yet still owing to the Tao and to it alone such validity as they possess.”

Lewis identified eight universal laws within the Tao, including the “Law of General Beneficence” from which “Do no harm” arises. The Knowledge of Improvement is a manifestation of this broader historical Knowing, rooted in the wellbeing of “the other” and driven by the demands of selfless tradition, but is always under challenge by current sovereign forces. For instance, because of the dominion of numbers in the greater culture, it may be unwittingly treated as peripheral by health care leadership (including physicians), as compared to the central focus of
To list the advances in “modern medicine” over the past 100 years would fill hundreds of special editions in hundreds of journals – impossible to summarize and breathtaking in scope. In my own discipline, any measurement affecting population health would have to include the unveiling of the human microbiome, the elucidation of the human immunodeficiency virus (HIV) and the sub-cellular world of immunodeficiency, the curative approaches now available for hepatitis C, the development of several hundred antimicrobials – initially termed “miracle drugs,” the control/elimination of deadly epidemics through dozens of immunizations and the new world of molecular based diagnostics – all of which have contributed immeasurably to mankind. And this is just infectious disease, a tip of an iceberg. Medicine’s impact is a product of the modern age and the proudest example of modernity’s prime synonym – progress. But why having carried humanity so far does progress increasingly feel like thin ice?

The cultural critic Richard John Neuhaus in a provocative essay, The Idea of Moral Progress, stated, “Thinkers arguing from the most diverse perspectives have agreed that no one thing is so characteristic, indeed constitutive, of modernity as the idea of progress. To be modern is to believe that history is ‘getting somewhere’ in overcoming the problems and limitations of the human condition.”

Per Neuhaus, “The idea of progress…began with classical Greece and its fascination with knowledge…and (led to) a confidence that ever-expanding knowledge held the promise of something like a golden age.” However, as the 20th century began to wane, a serious question arose which asked if we had possibly reached the end of progress. Neuhaus again, “How can one seriously believe in progress at the end of what is undeniably the bloodiest century in history – the century of the Battle of the Somme, of Auschwitz, of the Gulag Archipelago, of Maoism, of obliteration bombing, and of mass starvation as government policy? In this century, so many people have been deliberately killed by other people that the estimates of historians vary by the tens of millions, and they end up by agreeing to split the difference or to round off the victim count at the nearest ten million. One might conclude that it has not been a good century for the idea of progress in general and of moral progress in particular.” Neuhaus concludes, “The question at hand is the idea of progress, and how that idea is now challenged not only by events in politics, society, and culture, but also by science, which, following its own rigorous methodology, discovers that there are many things we do not know and can never know. One may object that these limits are at the margins, that there are still vast fields of discovery open to future generations. But that is the way it is with limits; they are, by definition, always at the margin. They define the margins. The crucial point is that the link between knowledge and progress that was forged in classical Greece and that, in the form we call scientific, has been both the motor and the guarantor of the modernity project has now been broken. Or so we are told by some of the more impressive thinkers of our time.”

It is ironic that the Neuhaus essay appeared in August 1999 and only three months before the release of To Err is Human, American medicine’s most pessimistic assessment of its own progress. This report claimed that, “At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented…” It appears that medicine, too, like the broader modern context from which it arose, is facing its own questions of progress. While there is certainly no moral equivalency between the heinous events of the 20th century and health care’s current challenges, Neuhaus’ broader backdrop of unbridled progress within human history is instructive. To this point, with little “progress” since To Err is Human and per continued calls such as from the Vital Directions Steering Committee, health care’s “idea of progress” has reached a tipping point of sorts. But from where do we gain direction for the journey ahead, when the scientific method paradigm proves deficient and the corporate growth paradigm proves incomplete? Fortunately, two of the greatest among us are challenging the current debate with a pre-modern paradigm surrounding an embarrassingly simple idea – the patient is the reason for our existence.

In February 2010, I had the honor of visiting Johns Hopkins with two colleagues. We had been sent by our organization to a two-day conference on how to improve hand hygiene compliance. At the time there was an emerging awareness of just how significant health-care associated infections were becoming – involving more than 2 million patients per year in the U.S. and with an
 alarming rise in bacterial resistance. Despite the established fact going back 160 years to Ignaz Semmelweis, that hand hygiene is fundamental to reducing infections of all types, compliance with this basic measure was noted to be poor in multiple reports – typically in the 20-40 percent range. The Hopkins group had developed a rigorous approach whereby health care givers would be monitored on both the inpatient (secret shopper auditing) and outpatient (patient auditing) side with data being fed back to the individual units and clinics for improvement efforts. The program was named “WIPES,” a comprehensive infection prevention and control initiative. This population based approach has been very successful and we were excited to bring our learnings back to South Dakota. Our organization implemented the WIPES program in 2011 and as seen at Hopkins, we saw dramatic hand hygiene improvements from 16 percent compliance pre-WIPES to above 90 percent ever since. The success of this quality improvement strategy was made possible by implementing a classical improvement model, including human factors, reliable design, data transparency, local champions, tracking progress, and ensuring ongoing accountability.

As impactful as the Hopkins population oriented approach had become, what really caught our attention was the why, behind not just this effort to improve but in fact what had become the culture of Hopkins. A mindfulness surrounding a very important person was in the air on the first day of the WIPES conference. Feb. 22, 2010 was the ninth anniversary of the death of Josie King, an 18-month-old girl who lost her life in a Hopkins pediatric intensive care unit, as a result of medical errors. The story is partially recounted in the Hopkins Medicine Magazine article, “A Remedy of Errors.”

“After Josie had been moved from intensive to intermediate care, it was her mother who’d noticed the child’s thirst but was told not to let her daughter drink. Later, when (the child’s mother) Sorrel saw Josie’s eyes rolling back, she asked the nurse to summon a doctor. The nurse reassured Sorrel that Josie’s vital signs were fine. Sorrel asked that another nurse be called in; again, she was told not to worry. The following morning, Sorrel took one look at Josie and demanded a doctor. The medical team arrived, administered a pain reliever and at Sorrel’s request, okayed liquids by mouth. Josie guzzled nearly a liter of juice and gradually perked up. Early that afternoon, despite an order for no more narcotics, Josie was given an injection of methadone authorized by a different physician. Her heart stopped as Sorrel was rubbing her feet. A horde of physicians and nurses rushed in; Josie was whisked back to intensive care. But this time, the hospital that had come so close to healing her could not reverse the brain damage she sustained. She died on Feb. 22, 2001.”

The house that Welch founded; the top academic medical center in the world and by far the most heavily awarded research institution by the National Institutes of Health had just been brought to its knees by one little girl. I have previously written about this event and it is worth repeating:

“Josie’s death occurred because of communication failures and the mishandling of medications. While devastating to all involved, the response to this tragedy from both the King family and Johns Hopkins is instructive to all who would dare tread in health care delivery. Rather than running from the implications of Josie’s death for their organization, the Hopkins embraced transparency, making visible that which they (admittedly) knew very little about. In the process, Johns Hopkins has been transformed and is now leading change worldwide through their newly announced Armstrong Institute for Patient Safety and Quality. C. Michael Armstrong has been the chairman of the Johns Hopkins board of trustees since July 1, 2005, and has demonstrated that great results do begin with great leadership. Armstrong recently said, ‘I believe that everything we do at Johns Hopkins Medicine – research, education, clinical practice, hospital care – is driven by our priority and focus on patients.’ The beginning of the Hopkins journey, however, was led by the patient’s family. In this case, it was Sorrel King herself who spoke to their top leadership. Their story continues, ‘By September 2002, Sorrel King had mustered the strength to tell her story – not to the media, but to a standing-room-only throng of Hopkins Medicine leaders and staff who’d gathered in the hospital’s oldest auditorium. She and (husband) Tony had decided to donate a portion of their settlement back to Hopkins to fund the Josie King Patient Safety Program. ‘Josie’s death,’ Sorrel told the crowd in Hurd Hall, ‘was the result of a combination of many errors, all of which were avoidable. You are the only ones who can solve this problem. The medical community must be open to the possibility that shortcomings do exist, and you must be prepared to make the necessary changes. There’s little question that the Kings’ resolve to become partners with Hopkins gave a new sense of urgency to ideas for safety improvement that were already in the works. ‘That was one of the most important catalysts to move us forward,’ said Beryl Rosenstein, Hopkins Hospital vice president for medical affairs.”

The lesson from Johns Hopkins is that the patient exposes
the system, especially when they are harmed. Harm events provoke the why including why medicine exists in the first place. Hopkins answered that why in that they were “prepared to make the necessary change” and transformation followed. As every healthcare system likely has its own “Josie King,” transformation should be happening everywhere – but the commitment to transparency to get there is not comfortable. From Hopkins, we therefore learn that the Knowledge of Improvement is the conscience of the Knowledge of Progress for not all progress is improvement but all improvement is progress.

While the story of patient harm can be transformative, so can an idea from the very beginning. Such has been the case with the Mayo Clinic, which has built an entire enterprise from the outset on the Knowledge of Improvement, incarnating this older basis of Knowing. As a major contemporary of Welch, Dr. William J. Mayo in an address to the Rush Medical College graduating class of 1910 succinctly summarized the Knowledge of Improvement with the following, “The best interest of the patient is the only interest to be considered, and in order that the sick may have the benefit of advancing knowledge, a union of forces is necessary.”20 In the book Management Lessons From Mayo Clinic the authors articulate that the Knowledge of Improvement is in fact the governing principle of the organization.

“The needs of the patient come first” is woven into the fabric – the culture – of Mayo Clinic, and the clinic might not exist today were this not the case. The secret is not a course, a training program, a strategic goal, or a report card score... Strategic plans and all the significant operational strategies as well as the clinic’s operation tactics revolve around ‘the needs of the patient come first.’ This primary core value directs the organization by defining its ‘reason for being.’

This definition of the Knowledge of Improvement provides a leadership cornerstone for all health care organizations – because it defines the end (the best interest of the patient) and the means (union of forces) toward which the Knowledge of Progress (advancing knowledge) can be applied. The lesson from Mayo is that the Knowledge of Improvement precedes and governs the Knowledge of Progress for the personal is prior to the impersonal. This irressible knowledge of the “person” and prescient long ago from Mayo, has found its way into the very definition of “population” – away from the “statistical” and toward “populations as relational beings.”

In the case of Hopkins and Mayo we see more clearly the inter-connectedness of these two hemispheres of knowledge – both of which make up a “whole new mind” in solving health care’s current quandary.22,23 To this point while the Knowledge of Progress is science, the Knowledge of Improvement is social science or the study of the system of humans caring for the human. Improvement has everything to do with the system into which the patient enters, as in the case of Hopkins where both healing and harm arise. This understanding cannot be captured by the scientific method in its attempts to “prove.” Harm needs no proof, as the Hopkins did not need to design an RCT to determine if not putting the patient first would be harmful as compared to putting the patient first. Also as the banner of modernity, progress is always driven ahead to the “next thing.” Improvement as in the case of Mayo, however, is always driven back to the original thing, which is why it has never grappled with “mission” and “vision.” Likewise, medicine’s next thing must be the original thing to avoid the lesser thing. Neuhaus put it this way, “There can be no progress beyond but only within the civilizational circle of the moral truths into which we were born, by which we are tested, and to which we are duty bound…”

I close with a South Dakota example. Forty years ago this summer I began my third year of medical school with a three-month rotation in internal medicine. This brought me before a most gentle but intimidating man – Dr. Robert Talley. Later, and right up until his passing last fall, I never could call him “Bob” out of respect, which he found humorous. Talley, a cardiologist, was the chair of the Department of Internal Medicine at the University of South Dakota. He was a classically trained academic schooled in the scientific method and a student himself of the legendary J. Willis Hurst, of Emory University. Dr Talley was old school in the best sense, teaching us that everything begins at the bedside. He also introduced me to the RCT and how to read clinical studies. Talley’s story is now a legend of its own, with his rise to dean and then dean emeritus. It was in that Emeritus phase that he may have summarized his greatest legacy – one which has improved the health of hundreds of populations through the hundreds of physicians our medical school trained during his tenure. At a faculty meeting in November 2010, where a new medical school curriculum was emerging, he uttered words that will live on. Leaning back, he said the following: “If you think about it, the physician is primarily a social scientist and not a scientist. We work with others to help yet others.”24 Like Dr. William J. Mayo 100 years before, Dr. Robert C. Talley had defined the unchanging role we must all aspire to, one dedicated to the patient as the reason for our existence and the first person of every population. We ignore the Knowledge of Improvement to our patient’s peril, a Knowing without which progress is just change.
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Abstract
The increase in obesity rates in the U.S. and other less developed industrial countries have led to a worldwide epidemic of chronic disease states. Increased obesity rates are implicated in the treatment failures for illnesses such as coronary artery disease, diabetes, heart failure, hypertension and cancer. Effective prevention of obesity through diet and exercise contributes to the successful medical management of multiple chronic disease states.

Objective: Review the last 10 years of literature (2006-2016) on the effects of diet and exercise as they relate to the prevention of chronic disease.

Method/Data Reviewed: Cochrane Database of Systematic Reviews and other original articles using the National Center for Biotechnical Information database

Conclusion: The success in management of chronic disease lies in a physician’s ability to educate patients and effective utilization of the resources available to that provider. Patient accountability for their individual chronic disease states is a problem related to patient education, patient participation, access to care, and payment resources. Financial, racial, and socioeconomic barriers must be addressed in the creation of an effective plan.

Teaching on the importance of diet and exercise needs to occur early in life and be continually reinforced for successful outcomes. In the last 10 years, there has not been a significant study suggesting a single successful
Introduction

Chronic disease management has become “the” focus in modern medicine today as medical costs continue to rise as our population ages. The benefits of prevention, and its potential to reduce costs and improve outcomes, have gotten the attention of insurance companies, health care plans, and the U.S. Congress. The enactment of the Affordable Care Act on March 23, 2010 by President Barack Obama set in motion financial incentives for population-based health management and forced insurance companies and the medical community to look for the most cost effective means for the prevention of chronic disease. This change in incentives has led to a revisit of the value of a healthy diet and exercise in the management of chronic disease. Health care systems are now incentivized to reduce readmissions and physicians are encouraged to meet evidence-based quality measures to provide the best outcomes for patients with chronic disease states.

As physicians know, the process of disease prevention is not always simple. Prevention of chronic disease begins when patients are very young and evolves as they age. It is more successful with continuity of care. It is influenced by many different factors from genetics, personal choice and behavior, financial and socioeconomic position, education, and access to care. The complexity of this care has fallen generally on pediatric, family medicine, and internal medicine specialists, along with their nurses and advanced practice providers who assist in the coordination of the myriad of prevention issues in the ever shortening clinic visit.

Providers have been given electronic medical records with electronic alerts to assist in ensuring that vaccinations are reviewed, screening guidelines are met, and that annual health maintenance visits are done. A new focus has been placed on high impact patients with multiple chronic diseases. Teams of coordinators are now created to assist providers in the management of the increasingly complex patient. These teams assist in the collection and review of the massive amounts of detailed electronic records, attempt to ensure immediate access to care to prevent readmissions, review discharge instructions to prevent medication errors, and ensure that patients fill the prescriptions they are sent home with. The modern care team has evolved to now also include coordinated care staff nurses, dietitians, diabetic educators, schedulers, embedded social workers and psychiatric services. The days of individual physician care are long over.

The creation of healthy dietary habits and the education of patients on the benefits of routine exercise have the potential to have the biggest impact on chronic disease management in this era of the obesity epidemic. The barriers to success lie in changing behaviors rooted in years of misinformation, in creating a dialogue between employers and patients in the prioritization of “work-life balance,” and in changing society’s view that fast food and good healthy food can’t be the same.

The culture of food has changed over time and this has impacted health dramatically. In the past, it was common for families to cook together and sit down and eat together. Recipes were shared and the art of cooking was passed down from one generation to the next. More time was spent in the planning of a meal, going to the store to get the produce and items, and finally, time spent in the preparation of the meal. Today the pace of living has contributed to the developing health crisis. Time spent in the kitchen preparing food has become a barrier to living a healthy lifestyle for the busy parent. Children fly out of the house to run to activities and grab a meal on the way home or they will warm up a frozen dinner when they get home because it is quick. It is easier to go to a fast food restaurant and get a large caloric processed meal with poor nutritional value than to take the time to prepare a meal ahead of time or right away when people get home.
The Healthy Diet

There is no specific definition of the modern healthy diet. Consumers will spend millions of dollars looking for the perfect diet. Books will be read, infomercials will be quoted, and classes will be attended. It is the most commonly asked diet question in the physician’s office today: What is the best diet for me? Each diet will have a “value” to each individual patient and no one diet is best for all patients. The most success comes from the ability of the patient to balance their diet with exercise and the routine of their lives.

The most successful healthy diets today, such as the Mediterranean diet, suggest a high percentage of vegetables, fruits, fish, whole grains, healthy nuts and oils, limited unhealthy fats, low to moderate wine consumption and limited red meat intake (Figure 1). The health benefits of these diets can be seen by their impact on chronic disease states. The benefits of these diets are starting to be a focus of chronic care management.

According to Sofi et al., “greater adherence to a Mediterranean diet is associated with a significant improvement in health status, as seen by a significant reduction in overall mortality (9 percent), mortality from cardiovascular diseases (9 percent), incidence of or mortality from cancer (6 percent), and incidence of Parkinson’s disease and Alzheimer’s disease (13 percent). These results seem to be clinically relevant for public health, in particular for encouraging a Mediterranean-like dietary pattern for primary prevention of major chronic diseases.”

“High adherence to a [Mediterranean diet] is associated with a significant reduction in the risk of overall cancer mortality (10 percent), colorectal cancer (14 percent), prostate cancer (4 percent) and aerodigestive cancer (56 percent),” according to Schwingshackl et al.

There has been increased public interest in breaking down the science of what makes up a healthy diet. Macronutrients (carbohydrates, protein, fat, and fiber), micro nutrients (sodium, calcium, vitamin D, folate, other vitamins), and superfoods which contain polyphenols (resveratrol from grapes, wine, peanuts and curcumin from turmucir), antioxidants, phytochemicals, anthocynines (blueberries), and catechins (tea), each have individual evidence for impact on chronic disease. The specific combinations of these nutrients that would make up the perfect diet remains a mystery and the frequency and recommendation on individual superfood use continues to evade the general practitioner (Figure 2).

Dietary supplement companies have created confusion in what is recommended as part of a healthy diet and these advertisements and websites should not be relied upon for the general public’s source of information. The cooking, cutting, and processing of fresh fruits and vegetables also has some impact on the nutritional value of the foods. The specific loss of nutrient value is hard to define but it seems to be that the least done in the processing of foods, the more retained health value that will persist.

Unfortunately, today, when individuals choose to eat healthy, they end up paying more for that benefit. In a 2010 BMJ Open article by Mayuree Rao et al., a meta-analysis of 27 studies from 10 countries showed the variation in the cost of healthy foods versus non-healthy foods. Six major food groups were evaluated. The cost of healthy options varied the most among meats and protein options ($0.29 per serving) and was smallest among grains ($0.03 per serving), but overall the cost of a 2,000 kcal healthy diet was $1.56 per day more expensive than a non-healthy diet.
Cancer screenings save lives. This we know. But, it’s time to take it a step further. It’s time to do something. **MAKE A PROMISE.** Talk to your patients about lifesaving screenings for colorectal cancer. Because when it’s caught early, that’s when cancer is most treatable. Make the promise for yourself, your loved ones and your patients.

Learn more at [getscreenedsd.org](http://getscreenedsd.org)
(approximately $550 per year). If success can be reached by physicians and health care teams in convincing patients that the upfront cost for quality food will prevent chronic disease, the potential exists for more definitive reductions in patient morbidity and mortality.

The cost of eating healthy food can be even more of a barrier for certain socioeconomic groups at risk, those same groups that carry the highest risk for chronic disease states. The elderly and rural consumers are at high risk in South Dakota. The Native American population carries a disproportionate risk for diabetes and obesity, and combined with limitations to access to fresh food, educational resources, and access to health care, this group is at further risk for poor outcomes in chronic disease management.

Convenience stores and large supermarket chains can have significant variation in the cost of foods and the quality of food available. Local grocery stores may have limited stock options due to consumer buying patterns. The distance to drive to obtain food can be limited by an individual’s transportation availability and this impacts the quality of food based on access to fresh fruits and vegetables. Older patients may not have adequate assistance for transportation and rely on meals provided by home services instead of having access to healthy fresh foods. “Food deserts” are prominent in both rural and urban centers and further accentuate discrepancies in the health of the general population. Congress mandated the Institute of Medicine and the National Research Council to hold a two-day workshop in 2009 that most recently summarized this topic and Franco et al. in 2008 graphically described this process as well.

Community-based resources to provide access to fresh fruits and vegetables need to be expanded. Programs like “Bountiful Baskets” and community gardens are unique approaches to assist in expanding access to fresh food and the dietary education of the patient with chronic disease.

### Table 1. Healthy Food Availability Index, Comparing Two Supermarkets

<table>
<thead>
<tr>
<th>Location</th>
<th>Baltimore City</th>
<th>Baltimore County</th>
</tr>
</thead>
<tbody>
<tr>
<td>Racial Composition</td>
<td>97% African American</td>
<td>93% Caucasian</td>
</tr>
<tr>
<td>Median Household income</td>
<td>$20,833</td>
<td>$57,391</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Foods</th>
<th>Availability</th>
<th>Points</th>
<th>Availability</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skim milk</td>
<td>Yes</td>
<td>2</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>Fruits</td>
<td>17</td>
<td>2</td>
<td>59</td>
<td>4</td>
</tr>
<tr>
<td>Vegetables</td>
<td>38</td>
<td>3</td>
<td>74</td>
<td>4</td>
</tr>
<tr>
<td>Lean meat</td>
<td>No</td>
<td>2</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>Frozen foods</td>
<td>No</td>
<td>0</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>Low-sodium foods</td>
<td>No</td>
<td>0</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>100% whole wheat bread</td>
<td>Yes</td>
<td>2</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>Low-sugar cereals</td>
<td>Yes</td>
<td>2</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Modified NEMS-S (0-27)</td>
<td>18</td>
<td></td>
<td>25</td>
<td></td>
</tr>
</tbody>
</table>


Scoring system for healthy food availability, adapted to Baltimore from the Nutrition Environment Measures Survey in Stores

### Food Groups Availability Scores

- **Nonfat/low-fat milk** – 1 point if available; 1 point if greater than 33 percent shelf space; 2 points if greater than 50 percent shelf space
- **Fresh fruits and vegetables** – 0 points if not available; 1-4 points based on increasing number of varieties available (frozen or canned fruits and vegetables are not included)
- **Ground beef** – 90 percent lean: 1 point if available; 1 point if two or more varieties
- **Chicken** – boneless, skinless breast: 1 point if available; 1 point if two or more varieties
- **Frozen foods** – 1 point if low-fat TV dinners; 1 point if greater than 33 percent shelf space; 1 point if ratio of vegetables/ice cream shelf space greater than 15 percent
- **Low-sodium** – 1 point if low-sodium tuna; 1 point if low-sodium canned soups
- **100 percent whole wheat bread** – 2 points if available; 2 points if two or more varieties
- **Low-sugar cereals** – less than 7 g per serving: 1 point if available; 1 point if two or more varieties

Franco et al., 2008.

### Diet and Chronic Disease Management

It is clear that success in management of chronic disease states is impacted by diet and exercise. Diabetes, cardiovascular disease, hypertension, heart failure, and cancer are just a few examples in which a healthy diet and weight control are directly related to improved health outcomes. Dietary measures have long been recommended by specialty societies to impact specific disease management.
in conditions such as diabetes, heart failure and cardiovascular disease. Carb controlled diets, low salt intake, and low cholesterol diets are just a few examples.

South Dakota specific data on obesity and diabetes statistics, most recently collected in 2014, show rates of diabetes at 9.1 percent (13th lowest in the country) and obesity at 29.8 percent (28th in the nation). For Native Americans living in South Dakota, obesity rates reach 40 percent on the state’s reservations and 13 percent for diabetes, 4 percentage points above the Caucasian population average. Living in rural communities in South Dakota has also been shown to increase the risk of both obesity and diabetes.

Until recently, individual physicians were limited in their resources to manage large populations with chronic disease. An individual approach to each patient was tailored by a community and its resources. Small communities were at a disadvantage compared to referral centers with resources such as dietitians, diabetic educators, social workers and office staff to arrange follow-up and coordination of care. South Dakota has changed in the last 20 years due to the impact of large health care systems. Health care systems and insurance companies are now incentivized to participate in accountable care organizations (ACOs) to manage large populations of patients in the prevention and management of chronic illness and this has shifted resources to needy populations.

Despite new resources available for physicians and a push by managed care organizations and ACOs, there is no recent significant study to date to suggest that dietary and exercise programs are successful in controlling chronic disease states. In 2010 the U.S. Preventative Services Task Force (USPSTF) reviewed the effect of diet and exercise on cardiovascular disease and concluded that “medium to high intensity dietary behavioral counseling resulted in a small but statistically significant changes in adiposity, blood pressure, and cholesterol, as well as medium to large changes in self-reported dietary and physical activity behaviors. Evidence for changes in physiologic outcomes was strongest for high-intensity counseling interventions. Medium- to high-intensity physical activity counseling resulted in increases in self-reported physical activity. However, there was limited evidence for maintenance of behavioral or physiologic effects beyond 12 months. Most trials of high-intensity interventions that had follow-up beyond 12 months showed persistent beneficial changes in adiposity and lipids, as well as improvements in self-reported behavioral outcomes.”

With the knowledge that no “one” template exists for a successful model using diet and exercise to affect chronic disease, multiple organizations are beginning to create new models. High school curriculums are being altered to teach students the impact of healthy dietary choices, the benefits of exercise, and the dangers of obesity as early as possible. Educational grants from forward thinking foundations and think tanks are promoting healthy living behaviors. Communities are seeing chronic disease affect their populations and the costs associated with this unhealthy population. Universities are pursuing healthier cafeteria options and better choices in vending machines and partnerships with corporations that share their values. Medical schools and residency programs are beginning to emphasize community based health projects directed at healthy living and health systems and accountable care organizations are putting millions of dollars into the idea that prevention and education will reduce chronic illness and bring about cost savings.

Teaching kitchens may have the biggest potential impact on slowing down and controlling the rate of chronic diseases. These community-based or health system-based programs educate the patient on healthy choices and expose the patient to new ideas, new quality foods, and attempt to remove the barriers of misinformation. The model teaching kitchen involves a multidisciplinary approach to chronic disease management and prevention with a dietician, grocer, chef, and physician all involved in the teaching process. Whether this type of “re-education” will be successful is yet to be determined, but it offers a unique approach to chronic disease management.

**Exercise and Chronic Disease Management**

Individuals develop interest in exercise from childhood exposure to activities that they participate in. It is also a function of parental exposure. Parents who exercise pass down the value of exercise to their children and behaviors are subconsciously learned in the home environment. Sedentary children become sedentary adults. The amount of activity performed in childhood relates to the amount of exercise that most adults are willing to participate in as adults. In the healthy patient, lifelong attention to moderate to high intensity exercise provides continued health benefits.

The challenge for most physicians is feeling comfortable recommending a return to exercise and writing an exercise prescription in those patients who are adding exercise back to their health plan. Chronic health problems, such
as cardiac disease, diabetes, obesity, cancer and osteoarthritis, all limit exercise, but these barriers can be overcome with variations in the type of exercise available. Morbidly obese individuals with arthritis can exercise in a pool or on an exercise bike. Cardiac patients can monitor heart rate and workloads in controlled cardiac rehabilitation settings. Diabetic patients can adjust the duration and intensity of their workouts based on calorie intake and medicine delivery.

Wearable biotechnology may become the newest ally for physicians and individuals in the monitoring of the exercise prescription. Data points can be collected and shared over social media to help motivate patients and document progress through exercise routines. Smart scales can collect data and measure the percentage of body fat with transmission to computer databases. Phone and computer applications can provide streaming exercise videos to patients 24 hours a day without the need to go to a gym.

The USPSTF gives a Grade B recommendation for pursuing a healthful diet and physical activity in the prevention of cardiovascular disease in adults. Grade B evidence means that the USPSTF recommends the service and there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

Cardiovascular rehabilitation programs have proven benefits for cardiac patients. Anderson et al. performed a Cochrane Review in 2016 reviewing 16 trials and 14,486 people with coronary heart disease and found that “compared with no exercise control, exercise based [cardiac rehab] reduces the risk of cardiovascular mortality but not total mortality. We saw a significant reduction in the risk of [hospitalization] with [cardiac rehab] but not in the risk of MI or revascularisation. We identified further evidence supporting improved [health related quality of life] with exercise based [cardiac rehab].”

The evidence for prevention of diabetes mellitus by diet alone is not as strong as the data for a combined program of diet and exercise. Orozoco et al. in 2008 reviewed extended published trials ranging from one to six years in duration. These studies used calorie restriction, average physical exercise of 150 minutes a week and counseling from an exercise physiologist and a dietician to show a relative risk reduction in the incidence of diabetes by 37 percent with diet and exercise.

Improvement in diabetic control with the addition of exercise to the chronic disease management plan is much better documented. A Cochrane Review by Elliott et al. in 2006 showed a 0.6 percent decrease in hemoglobin A1C levels that proved to be both clinically and statistically significant in the management of the diabetic patient. In the clinical setting, exercise performed nearly as well as the addition of a new medication. Body mass was unchanged, visceral adipose tissue decreased, and a significant increase in insulin response was noted in one study.

Cancer patients can benefit in regards to quality of life measures related to exercise during and after their treatments. Mishra et al. in 2012 reviewed 56 trials with 4,826 participants randomized to exercise versus a comparison group. Exercise varied from walking, cycling, strength and resistance training, yoga or Qigong. Improvement in health related quality of life was seen after moderate or vigorous intensity versus mild intensity exercise programs.

Who is Accountable For Care?
One would hope that the individual patient would be accountable for their own care, but this is not always the case. Currently, patients are not penalized for their continued detrimental behaviors in regards to their chronic disease or their lack of active management in their own health care. Patients can continue to smoke despite having smoking-related health diseases. Noncompliance to medical advice and missed appointments does not carry personal accountability or financial responsibility.

Health care systems are rapidly developing mechanisms to override these barriers of care in an effort to reach improved patient outcomes with returned financial gain. Reducing readmissions has become a necessity for hospitals to maintain a margin of financial security. Outpatient coordinated care teams are created to manage chronic disease panels and electronic medical record registries are the weapon of physicians aligned with social workers to arrange compliance with physician recommendations and ensure that appointments are kept and quality measures are documented.

Physicians and health care systems are beginning to use disease specific preoperative mandates to motivate patients prior to clearance for high cost health care procedures. Bariatric medicine is beginning to put control mandates on conditions such as diabetes before surgery is being offered. Insurance companies are requiring educational programs to be completed before expensive surgeries are approved. Even national health systems such as those in...
England are beginning to pressure patients to “buy in” to their health before committing to the payment of surgeries related to diseases associated with lifestyle choices and personal health decisions. The National Health Service of England has been recently exploring a 12-month delay in elective surgeries in patients that don’t meet a weight loss goal and have a BMI greater than 30. This has raised concerns about the ethics of health care rationing.

As health insurance premiums rise, insurance companies and health care organizations are moving to reduce costs to improve profits. Both organizations see the drive for prevention of chronic illness as an answer to improved patient outcomes and increased profits. The U.S. Congress is incentivizing the management of large numbers of patients at risk, with increased compensation to the best providers and penalties for those who lag behind. Changes in the Affordable Care Act have benefited patients with pre-existing conditions but as of yet has not changed accountability. Patients are seeing huge increases in premiums as costs are shifted to the consumer.

The obesity epidemic has been seen to affect chronic disease states in other countries around the world besides the U.S. Before 1980, global obesity rates were generally less than 10 percent. Mexico, China, India, Russia, Brazil and many African nations have seen a doubling in the overweight status and a tripling of obesity rates. This led the Organization for Economic Co-operation and Development and the World Health Organization to create a “microsimulation [chronic disease prevention] model that implemented a so-called causal web of lifestyle risk factors for selected chronic diseases” and this information was reported in a 2010 Lancet article by Cecchini et al. (Figure 3). Chronic diseases (lung, colorectal and breast cancers, stroke, and ischemic heart disease) were found to be impacted by the more distal factors of diet and exercise. The breakdown of these two core health pillars led to a worsening of the major intermediate risk factor obesity. This led to further advance deterioration of proximal risk factors (hypertension, loss of glycemic control, and hyperlipidemia) and progressive chronic disease.

Various interventions were created to address the distal risk factors of lack of a proper diet and adequate exercise. School based health promotion campaigns, worksite health promotion interventions, mass media campaigns, primary care physician counseling, fiscal measures to address the cost of fruits and vegetables and food labeling were all used. Each of these interventions showed a delay in the onset of chronic disease rather than direct prevention of chronic disease states. The 2010 Lancet data showed “240,000-740,000 life-years can be gained every year in the seven countries through different interventions,

**Figure 3. Casual Web for Risk Factors and Disease Events Implement in the Chronic Disease Prevention Model**

![Casual Web for Risk Factors and Disease Events Implement in the Chronic Disease Prevention Model](image-url)
relative to a situation in which no prevention policies were in place and no standard care was offered in the relevant settings to a proportion of people developing chronic diseases who have access to medical care.”

Benefits gained were seen first in the high risk adult population (age 40 through 80) with targeted diseases that were counseled by primary care services. The benefits in children were not as immediately impactful in school based programs, but the overall benefit for patients 40 to 50 years down the road was thought to be comparative. Multiple interventions performed simultaneously were more successful than single interventions.

It is not a new argument that without the development of successful programs for low to moderate income countries it is estimated that the obesity epidemic will continue to have a significant effect on global mortality and the cost of health care. Even in 2007 Abegunde et al. estimated that inadequate programs would cost $250 million lives and $84 billion in lost national revenue from 2006 through 2015.

The Solution

Diet and exercise clearly have an impact on chronic disease. Physicians play a key role in the success of chronic disease management as they are involved in both the prevention and treatment of these problems. Primary care medical teams can be the most cost effective measure with the biggest impact on health care for the current and next generation of patients. Education on diets such as the Mediterranean diet, rich in fruits and vegetables, nuts, whole grains, healthy oils and an emphasis on more fish and less red meat have proven to be one of the best options for diet management. Mindfulness about eating and cooking should be emphasized and teaching kitchens integrated into behavioral and educational programs. Routine exercise needs to be brought back into the management plan for all chronic disease states as the reduction of obesity has a direct effect on the progression and treatment of chronic disease.

Individuals must become accountable for their behaviors. Health systems and government agencies are beginning to find innovative ways to reduce health care costs. Without changes in patient behaviors, the costs of obesity related illness will be shifted to the individual. Programs that change behaviors, with both a combination of behavioral and educational management resources, may prove to be the most cost effective way to reduce the ever expanding costs of medical care.

REFERENCES

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Healthcare providers play a huge role in helping tobacco users quit.

We know your recommendations and referrals make a difference. That’s why we have created some new tools to help keep you up to date.

Check out our new website at SDQuitLine.com for:

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- Training Opportunities
- Webinars
- Cessation Medication Information
- Special Provider FAQ

We’ve also expanded our services to help make it easier for you to connect your patients to our services. Tobacco users can always call the QuitLine to enroll or request a call from us and now they can also:

- Receive a free 2-week Nicotine Replacement Therapy (NRT) Kickstart Kit
- Receive a free Quit Guide in the mail
- Check out our new Do It Yourself Self Help section

Together we can give South Dakotans the support and tools they need to quit using tobacco.
Patient-Centered Home Model of Care and the Role of Patient Care Teams in the Treatment and Management of Chronic Disease

By Maryam Rahim Sheik, MBBS; Muhammad Shahjahan Khan, MBBS; and Jean M. Lageson, MD

Abstract
Patient-centered medical home (PCMH) is a concept of a team of providers caring for a panel of patients with the goals to improve the quality of care while simultaneously decreasing the cost of that care. The clinical evidence that the PCMH approach achieves either goal is mixed. More studies are in progress that will provide more data.

Patient Centered Medical Home Model of Care
The concept of the “patient-centered medical home” model of care (PCMH) was first proposed by the American Academy of Pediatrics in 1967. It is a comprehensive care model that is now supported by major primary care organizations including the American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, and American Osteopathic Association.1 The PCMH model focuses on a team of providers caring for a panel of patients rather than individual providers caring for individual patients. There are several different models of the team concept. Typically the group is physician-led with team members from nursing, case management, pharmacy and support staff. In adult medicine, the model was essentially established with an emphasis on chronic disease management and integration of care from multiple sites.2

The goal of PCMH is to make medical care easy and comfortable to access. Patients are assisted with all care needed, including services outside of the primary clinic such as physical therapy, counseling, home care and durable medical goods. There is often a need for proactive efforts to follow and manage issues, such as a weekly phone call from a nurse to check on daily weights for a patient with congestive heart failure, or detailed education about medications and help setting up medications with the pharmacist team member. This team approach to care has also been proposed as a way to extend physicians in recognition of an aging population and physician shortages.

There has been increased interest in the concept of the PCMH model in the past few years along with significant expansion of medical home initiatives in the past decade. PCMH adoption is felt to be “central to many efforts to reform the U.S. health care delivery system....” Hence, the PCMH approach will likely continue to expand, resulting in a significant increase in the literature on this subject.4

A very relevant editorial was published in the *Annals of Internal Medicine* in February 2016 that highlighted the need to categorize studies regarding the medical home concept to more accurately compare this literature. The article states that there is frequent conflicting literature on the topic, which makes evaluation of merit difficult. Rather, the article suggests stratifying the studies based on their objectives. The suggested stratifications are: 1) those studies that evaluate interventions applied to the medical home and that measure the effect of that intervention; 2) studies that compare practice characteristics to determine the degree of “medical homesness” of a practice (e.g., comparing whether one practice has more characteristics specific for a medical home than another), and; 3) patterns of care studies that mainly use patient surveys to compare health outcomes, and noting that these types of studies are often driven by differences in patients rather than in practices. The article suggests that it is clear that the first type of studies (intervention-based) are the most
useful to evaluate the effectiveness of a PCMH. Accordingly, the intervention studies would be the most relevant in the formation of future policies.\textsuperscript{5}

Unfortunately, there is no agreed-upon definition of what constitutes a PCMH – so there is variation in definitions and nomenclature in the literature. In this regard, it is useful to review the National Committee for Quality Assurance's (NCQA) recognition criteria for PCMH. It is the most widely available model used to integrate medical home concepts into primary care practices. Based on these criteria a somewhat standardized understanding of the characteristics that define a PCMH can be extrapolated. Namely, patient-centered access, team-based care, population health management, care management and support, care coordination, performance management and quality improvement.\textsuperscript{3}

Although a few systematic reviews have been published on the impact of PCMH, it is challenging to assess the full impact of the PCMH given that it is so multifaceted. However, improvement in quality, patient experience and lowering costs are common variables used in assessments of the PCMH.\textsuperscript{4,4} To understand the results of these studies it is important to evaluate how they are conducted. Often a definition of PCMH interventions is created as an inclusion criteria, see, for example, Jackson et al. In their 2013 review, the authors adopted an operational definition from the Agency of Healthcare Research and Quality (AHRQ) to enable more subjective comparison between studies. In order to be a PCMH “intervention” in this review, a study intervention required: “1) team-based care, 2) having at least two of four elements focused on how to improve the entire organization of care (enhanced access, coordinated care, comprehensiveness, systems-based approach to improving quality and safety), 3) a sustained partnership, and 4) having an intervention that involves structural changes to the traditional practice.”\textsuperscript{5,11}

This review revealed a small positive effect on patient and staff experience with the PMCH, and reduction in emergency department visits but not in hospital admissions. There was no evidence of cost saving. Overall, based on the systematic reviews by Jackson et al., the evidence for health care quality improvement with PCMH is modest at best and there is very limited improvement in cost of care. Indeed, several systematic reviews that were reviewed found that data was insufficient to determine effectiveness.

Despite such underwhelming results, there remains great interest in this model and several longer-term studies are underway that are evaluating the effects of the PCMH. One of these studies, titled, “The Patient-Centered Medical Home and Associations With Health Care Quality and Utilization: A 5-Year Cohort Study,” assesses 12 medical homes (all achieving the highest level of NCQA recognition) that were compared with primary care practices. After five years the medical homes had an increase in primary care visits, decrease in specialty visits, and decreases in both laboratory testing and hospitalizations. Additionally, there was improvement in half of the tested quality measures. In his editorial, Friedberg astutely points out that most of these changes appeared in the final year of the study when shared saving incentives had been introduced.\textsuperscript{5,9} This highlights the important element of financial incentives and their role in the PCMH construct.

As highlighted in the systematic reviews, the improvement in patient care and reduction in health care cost was not as robust as hoped. In the majority of these studies, the incentives given to primary care practices to become medical homes involved primary resources such as technical assistance and fees to aid in changes that needed to be made to the practices. New payment incentives, such as shared savings, have more recently been introduced. The effect of these interventions on quality and utilization of care was demonstrated in an observational study published in JAMA in 2015.\textsuperscript{12} The 27 medical homes in this study were eligible to receive shared saving bonuses if their total spending on patient care was less than expected for a year. There was no penalty if spending was more than expected. By the third and final year of the study the medical homes had significantly better performance on diabetes care, breast cancer screening, lower rates on hospitalization, emergency department visits and outpatient visits to specialists. These positive results suggest that more extensive use of financial incentives could significantly improve care in PCMH.

An important facet of this discussion involves electronic health records (EHRs). EHRs are a component of a majority of models of PCMH. Hence, a legitimate query arises about the possibility of EHRs being a confounder, i.e., whether the EHRs improve quality measures or the EHR effectively is the complete PCMH model. Kern et al. conducted a prospective cohort that compared quality of care provided by physicians in PCMHs who used EHRs compared with those who use paper records, and also with physicians who use EHRs but are not part of a medical home model. Based on this study, “the odds of quality improvement in the PCMH group were 7 percent higher
than in the paper group and 6 percent higher than in the EHR group (adjusted \( P < 0.01 \) for each).\textsuperscript{9} This suggests that the PCMH measures independently influenced outcomes.

**Management of Chronic Illness**

The management of chronic illness is the cornerstone of many primary care practices. The PCMH model has been studied with regard to chronic illness in multiple settings. The outcomes vary but include moderately positive results in terms of quality improvement, patient satisfaction, patient compliance and cost reduction, as discussed above.\textsuperscript{11-17} This is likely because of the many challenges that primary care providers face when treating patients with multiple chronic illnesses in the PCMH model. Perhaps the best way to illustrate these challenges is with a hypothetical patient with multiple chronic medical issues commonly seen in primary care practice.

The patient in this example is a 78-year-old Caucasian man with history of chronically reduced ejection fraction heart failure (ejection fraction per his last transthoracic echocardiogram was 30 percent), history of coronary artery disease (had coronary artery bypass surgery performed 20 years ago), history of insulin-dependent diabetes mellitus type 2, mild to moderate dementia, controlled essential hypertension and chronic stage 3 kidney disease secondary to his diabetes and hypertension. This patient lives in an assisted living facility and has family who live out of state. Based on the patient's multiple co-morbidities it is clear that he needs medical, social, and mental health support from a variety of providers and caregivers.

The primary care physician (PCP) caring for this patient is likely in charge of periodic follow-up and management of prescriptions. If the patient is seen by specialists, the PCP must coordinate care between specialists. Given the patient's dementia, the PCP needs to periodically assess his decision-making capacity. The PCP must also communicate with the patient's family and his living facility on a periodic basis to update them on the patient's general condition and possible additional needs. This is all when the patient's chronic conditions are stable. If he has exacerbation of his heart failure, the patient or his living facility will likely contact the PCP's office for instructions. In this situation, the provider must decide if the exacerbation warrants inpatient admission or whether outpatient diuresis would be sufficient. Frankly, the list of the PCP's responsibilities can appear endless and daunting at times. In addition to this, under most current payment plans, PCPs would not be compensated for additional time spent coordinating and addressing the multiple needs of such a complex patient.

In contrast, the PCMH model aims to assist the primary care practice in streamlining some of these processes to provide patient-centered, comprehensive and coordinated care. It is important to understand that though this concept has been around for 50 years it is still a very actively developing model and a variety of interventions could significantly improve its efficacy. A very relevant white paper was prepared for the AHRQ, U.S. Department of Health and Human Services, in 2012 titled, “Patient-Centered Medical Home: Challenges and Solutions.”\textsuperscript{18} This extensive document highlights the challenges that primary care practices, especially small ones, face when taking care of complex patients. The authors explored five health systems that had utilized several innovative strategies to improve the PCMH model. Several key recommendations are based on this assessment. First, the importance of case managers working with PCPs to coordinate patient care was highlighted. The authors recommend flexibility in the number of case managers based on the practice size and characteristics. Second, need for additional support such as EHRs, 24/7 call lines for after-hours coverage and referral tracking systems for the PCPs was highlighted. Third, increased compensation for PCPs for care coordination was explored. Several models for increased compensation for physicians taking care of patient with complex needs have been utilized. These include pay per member per month, shared savings, one time per patient fees, and others.

A 2009 AARP survey showed that a significant population of elderly patients (i.e., the population who suffer from the majority of chronic illness) experience challenges with their medical care. The survey states these challenges include “medical error (23 percent), poor communication (20 percent), readmission (15 percent) and lack of follow up (6 percent).” Clearly, there is a need for reform in the care of patients with chronic illness and complex needs. Based on this review we believe that the PCMH is a step in the right direction. However, more work is required to make this model practical and sustainable.\textsuperscript{18,19}
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Foundations, Core Principles, Values, and Necessary Competencies of Interprofessional Team-Based Health Care

By H. Bruce Vogt, MD, FAAFP; and Jeremy J. Vogt, PhD

Abstract

Health care reform has focused on improving health care delivery, quality, and patient safety. An interprofessional, team-based approach to health care is considered by many experts to be essential to meeting these goals. The evidence for this is growing. Core principles for team-based care and the interprofessional competencies necessary for a team to function effectively have been identified and can be taught. Resources for interprofessional education, which must begin at the health professions student level, are available to academic institutions, healthcare systems, and professional organizations to prepare students and current health care professionals for this cultural change. Models of successful collaborative practices exist in many forms and will continue to evolve as our expertise in best practices for interprofessional education and practice advance.

Introduction

A team-based approach to the provision of health care is increasingly prevalent as evidence mounts as to its impact on quality, safety, and efficiency. There are a number of initiatives responsible for the emphasis on team-based care as a key element of healthcare reform, all with the ultimate goal of improving health care delivery and patient outcomes. The concept is not new, is referred to by many names, is comprised of many models, and continues to evolve. The purpose of this paper is to review the roots of team-based health care and delineate its core principles and the necessary competencies of interprofessional
practice required for a health care team to function effectively.

Lexicon and Foundations of Team-Based Health Care

A team-based approach to the delivery of health care has been promoted for more than two decades and characterized by such terms as: collaborative, team-based, interdisciplinary, multidisciplinary, multiprofessional, and interprofessional. Its evolution is linked to health care reform with the goal of improving health care quality and patient safety. A definition of team-based health care modified from that of Naylor et al. is the following: the provision of health care to individuals, families, and/or their communities by at least two health professionals who work collaboratively with patients, family caregivers, and community service providers to accomplish shared goals and achieve coordinated, high-quality care. Team-based care is congruent with the concept of collaborative practice as articulated by the World Health Organization (WHO) and encompasses the “six aims” for improved health care elucidated by the National Academy of Medicine (NAM), formerly Institute of Medicine, that it must be: safe, effective, patient-centered, timely, efficient, and equitable. Interprofessional, interdisciplinary, and multidisciplinary all signify a collaborative, team-based approach to patient care. Interprofessional or multiprofessional, the former becoming the preferential term, connotes a team comprised of professionals exclusively, whereas inter- or multidisciplinary, implies inclusion of non-professional staff as a part of the team. Integrated health care is another term becoming prevalent in the nomenclature of collaborative practice. It too indicates an interprofessional approach to the provision of health care characterized by a high degree of collaboration and communication among a diverse group of health care professionals. By definition all integrated models are collaborative, but not all collaborative care is integrated. A specific model of integrated care – integrating behavioral health into primary care – is described in the article, “Collaboration in Primary Care Through the Integration of Behavioral Health Professionals” in this special issue of South Dakota Medicine.

Leading Influences and Resources in Health Care Improvement and Interprofessional/Team-Based Practice

As noted above, interprofessional team-based care is linked to health care reform and the NAM has been a guiding force. Its landmark 1999 report, “To Err is Human,” highlighted attention on quality care and patient safety. A follow-up report, “Crossing the Quality Chasm: A New Healthcare System for the 21st Century,” describes the “six aims” of improved health care. Another influential leader in reform is the Institute for Healthcare Improvement (IHI), which emphasizes a team-based approach to health care and developed the “Triple Aim” framework to optimize health system performance. The Triple Aim was proposed in a paper published in 2008 and has become the foundation of health care reform. It includes three dimensions: improving the patient experience of care, improving the health of populations, and reducing the per capita cost of health care. To help achieve the Triple Aim, the IHI created the “Open School” to provide professional development for health professions students and health care professionals through various venues (e.g., conferences, online courses, international network of chapters) and works with a variety of entities worldwide to improve quality and safety.

Another major initiative is TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety), an evidence-based teamwork system for health care professionals focusing on improved communication and teamwork skills. Developed by the Department of Defense’s Patient Safety Program and the Agency for Healthcare Research and Quality (AHRQ), the program focuses on collaborative teamwork and emphasizes the team’s knowledge, skills, and performance rather than that of an individual provider. It is designed to improve the quality, safety, and efficiency of health care by integrating teamwork into practice. There are multimedia versions of the curriculum designed for specific learners in specific settings.

In addition to the organizations and initiatives discussed above, the National Center for Interprofessional Practice and Education (IPE) is a major resource for the development and study of IPE. With a central focus on achieving the outcomes of the Triple Aim, the center seeks to strengthen the evidence base for the effectiveness of IPE and to develop and assess new models of IPE. Its Nexus Learning Center is a collection of interactive educational and practice resources to assist in the training for and implementation of IPE.

Core Principles of Team-Based Health Care and Personal Values of Team Members

Mitchell et al. ascribe five principles critical to effective team-based health care: shared goals of the team, clear roles for team members, mutual trust, effective communication, and measurable processes and outcomes. Well-defined agreed upon goals for the patient’s care, including a shared commitment to the patient or family’s involvement in
setting goals, and of the team’s work in providing patient care, are at the foundation of effective team-based care. Team leadership must be clear and the role, function, responsibilities, and accountabilities of all team members understood with each member working to his or her highest level of practice and ability. Mutual trust is critical to effective team-based care but may take time as members gain an understanding of each other’s knowledge, skills, and reliability. Communication among team members is paramount and in order to be effective, information transmitted must be timely, accurate, unambiguous, and honest. A final principle of team-based health care is continuous evaluation. This includes an agreement by team members to participate in the ongoing assessment of the successes and failures of their performance as a team as well as achievement of team goals. Certainly, achieving positive patient outcomes is the primary goal with the specific outcome measures variable depending upon the patient population served. Patient satisfaction with their health care experiences and team member job satisfaction are other important measures.

Along with these core principles of team-based care, certain personal values are imperative for an individual to be an effective team member. Honesty is crucial to maintaining mutual trust. Discipline is required to carry out responsibilities, follow prescribed protocols, and meet standards. Enthusiasm for seeking creative opportunities to learn and improve, and a dedication to reflect on lessons learned, allows for continuous improvement of team functioning. Finally, humility to recognize and respect the differences in training, and to acknowledge that as humans we all make errors and can rely on each other to help prevent or limit failures is essential. These personal values of an individual team member are clearly in concert with the core principles for an effective team.

**Team-Based Competencies**

The range of competencies for interprofessional practice extend beyond those specific to a given health care discipline. They can be taught and learned. But, meaningful, interprofessional education devoted to team-based practice must begin at the health professions student level in order to prepare graduates for the cultural change of interprofessional practice – to be “collaborative practice-ready health workers,” as coined by WHO. Students need to learn with and from each other to gain an understanding of and respect for a profession’s skills and scope of practice and to work effectively and efficiently with each other in the “real world.” A consequential step in team-based education was the release of the 2011 expert panel report of the U.S. Interprofessional Practice and Education Collaborative (IPEC), which elucidates four domains and 38 competences describing essential behaviors across the domains of IPE. The four domains of core competencies described are: values/ethics for interprofessional practice; roles/responsibilities; interprofessional communication; and teams and teamwork. An updated document released by the IPEC in 2016 designates “interprofessional collaboration” as a singular competence with the four originally described domains defined as competencies with associated sub-competencies. This contributes to a more universal taxonomy of competencies across the health professions.

The first competence defined by the IPEC, values and ethics, comprises sub-competencies, which pertain to putting the interest of patients (patient-centered) and populations first; recognizing and accepting individual differences and cultural values of patients and team members, promoting a climate of mutual respect for other health professions; developing a trusting, honest relationship with patients, family, and other team members; and maintaining one’s own professional competence. Clear communication of team members with patients and family, recognition of one’s own limitations and engaging professionals with complementary expertise, and an ongoing commitment to enhancing team performance and collaboration address the competence of roles/responsibilities. Sub-competencies in interprofessional communication incorporate utilizing effective communication techniques, including technology; respectfully expressing one’s opinions and encouraging those of team members; providing sensitive, instructive appraisal of others’ performance while accepting that of others graciously; and employing considerate language in difficult conversations such as professional conflicts. The team and teamwork competence embodies ethical practice; shared patient-centered and population-focused problem solving and accountability for outcomes; integrating knowledge and experience of others; performing in a variety of roles as needed by the team; and reflecting on individual and team performance to improve continuously.

**Adopting Team-Based Models**

A team-based approach to patient care, which incorporates the core principles and applies the competencies described above, may take many forms. It may be discipline or specialty-specific (e.g., psychiatry, oncology); disease-specific (e.g., diabetes mellitus, breast cancer); narrow in
focus (e.g., ambulatory program in diabetic foot care); an extensive inpatient program (e.g., rehabilitation for brain-injured patients); or, a comprehensive integrated primary care practice.

Team composition and functioning – two key basic constructs of team-based health care – can vary widely. Typically, when a group or system decides to change their practice to a team-based model of health care, the team composition is pre-determined by virtue of the personnel (e.g., clinicians, nurses, etc.) already comprising the practice. The group then endeavors to meet the needs of the patient population based upon the range of their skills and the services they currently provide. Unlike this usual approach, ideally, the needs of the patient population and the services to be provided by the practice should be determined first prior to constituting the team. The degree of team integration and the process by which the team functions dictates the extent of shared leadership, decision-making, and responsibility for development and execution of the care plan (including how the work is divided). It is also important that a team is adaptable to adjusting strategies, when the need arises, and for team members to be willing and able to shift responsibilities with or provide back-up for their colleagues. Differing opinions with regard to team leadership can be a barrier and is often framed within the context of professional scope of practice. In the “medical home” or “patient-centered medical home” team-based model of care, the physician is designated as leading “a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.” Though it is often appropriate for the physician to be in the role of “team leader,” this is not necessarily consistent with the fully embraced concept of team-based care. Team leadership may be best served depending upon the task at hand and the needs of the team.

Interprofessional team-based health care is considered by many experts to be essential to health care reform and its broad goals of improving the quality and reducing the cost of health care. There is increasing documentation that this collaborative approach is well-suited to ensuring care is patient-centered, safe, efficient, and effective. Educational resources are available for healthcare systems and academic institutions to prepare current and future health care professionals for the cultural change of interprofessional, team-based practice. Many models are in existence, will continue to evolve, and new ones developed as our expertise in best practices for interprofessional education and practice models advances.

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According to the American Cancer Society, there are nearly 14.5 million cancer survivors in the U.S., many of whom face physical, psychological, practical, informational, and spiritual challenges after the completion of cancer treatment (Cancer Treatment & Survivorship Facts & Figures, 2014-2015). Primary care providers play a critical role in providing much-needed follow-up care for cancer survivors. You can learn about caring for survivors of adult-onset cancers through the free cancer survivorship E-Learning Series. Continuing education credits are available at no cost.

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Collaboration in Primary Care Through the Integration of Behavioral Health Professionals

By Jeremy J. Vogt, PhD; and H. Bruce Vogt, MD, FAAFP

Abstract
Rising costs, poorer outcomes, and dissatisfied patients have challenged medical systems to rethink their approach to health care delivery. Although up to 70 percent of primary care visits stem from psychosocial issues, behavioral health services have traditionally occurred in separate buildings and systems. In order to decrease barriers and meet patients’ and providers’ needs, primary care practices have begun integrating behavioral health professionals into their clinics. Various levels of integration exist, but the best models fully integrate behavioral health clinicians into primary care teams, allowing for seamless collaboration. Behavioral health professionals are able to support the treatment of a number of mental and physical health conditions, and can provide such services as part of regular primary care visits. Although a number of obstacles exist to developing and optimizing integrated behavioral health services, efforts are underway nationally to decrease barriers and support further training and implementation.

Introduction
The problem of escalating mental and physical health problems, combined with increasing health care costs in the U.S., has been referred to as “the perfect storm of primary care.” Health care delivery has traditionally occurred in silos, separating the treatment of physical, mental, and substance use related conditions into different facilities and systems as a whole. Frustrated patients, poor health outcomes, and declining job satisfaction among providers have driven the effort to reduce fragmented health care and increase collaboration between medical and behavioral health professionals.

Although health care reform has amplified the conversation around the need for integration, the imbedding of behavioral health providers into primary care has been around since the 1970s. Family medicine residency programs were one of the first primary care settings to integrate, with the inclusion of a psychologist as part of the core faculty beginning around that time. Additionally, around the same period of time, a health maintenance organization (HMO) in New Haven, Connecticut, began experimenting with integrating a mental health service into its practice. However, it wasn’t until 1994 that the term “integrated primary care” was first referred to in a scholarly article by Blount and Bayona. Coincidentally, that same year, the National Academy of Medicine (formerly Institute of Medicine) defined primary care as “the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.”

The task of “addressing a large majority of personal health care needs” gets to the heart of the rationale for the integration of behavioral health into primary care. The ability of medical providers to meet all patient needs, including mental health, in a 15 to 20 minute visit has been demonstrated to be unachievable. Up to 70 percent of primary care medical appointments stem from psychosocial issues and primary care manages either directly or indirectly 80 percent of patients with psychological disorders. Furthermore, approximately 20 percent of patients consume 80 percent of available resources and...
often present with symptoms without discoverable organic causes that could potentially be more effectively addressed through an integrated primary care model.9,10

The Case for Behavioral Health Integration

Behavioral health integration has been identified as a key element in the “Triple Aim” effort to improve patient experience and outcomes, while decreasing costs.11,12 A number of barriers exist that impact patients’ ability to follow through with behavioral health treatment. Physicians and patients can often experience frustration in accessing behavioral health services due to shortages of mental health providers (leading to long waits), limited health coverage or referral options, and distance barriers for those in rural settings.13 Further, stigma toward seeing a mental health professional remains a common societal issue. Patients may be resistant to seek out mental health treatment due to negative beliefs about the mental health field or individuals with mental health problems. As a consequence of the above issues, 67 percent of patients with a behavioral health disorder will not get treatment and approximately 30 to 50 percent of individuals referred from primary care to a specialty mental health provider don’t make their first appointment.14,15 The presence of on-site behavioral health services mitigates a number of these barriers. Patients are able to gain initial exposure to a behavioral health provider (BHP) often the same day of the referral and receive on-going support in the comfort of their primary care home.

Research also suggests that integrated behavioral health care improves health outcomes, particularly in the treatment and management of depression,16 anxiety,17 and chronic illness.18 BHPs can improve detection of mental health conditions through the use of screening and diagnostic evaluations, which not only influences, but also expedites treatment. In a study of individuals with major depression, Katon and colleagues19 were able to show that 74 percent of individuals who received integrated behavioral health treatment experienced a significant reduction in symptoms compared to only 44 percent of those that received physician treatment plus referral to an external mental health center. Similar studies have shown patients are better able to manage their diabetes mellitus following treatment with behavioral health for comorbid depression.20

Investigations into the fiscal benefits of integrating care have also been promising. Most research has shown evidence of cost-offset, such that the additional expense of providing behavioral health services in primary care is offset by the subsequent reduction in associated health care costs.21 Such cost-offset has been shown to be as high as 40 percent among patients. Additionally, the impact of integrated behavioral health on high utilizing patients, particularly those with comorbid chronic physical health and mental health conditions, has resulted in significant cost-savings through a decrease in the number of primary care visits, emergency department visits, and hospitalizations.22,23

Models and Levels of Behavioral Health Integration

From system to system, models of collaboration and level of integration can vary depending on a number of factors including practice needs and feasibility. Although models are best viewed as falling along a continuum, they are generally placed into three categories: coordinated; co-located; and integrated.24 Coordinated models tend to involve the least amount of collaboration with behavioral health. Most often, this type of model involves the development of a referral and communication process with an outside specialty mental health service. However, primary care and behavioral health professionals operate in separate facilities and in some cases, health systems. In co-located models, BHPs share physical space with primary care professionals, and referrals are internal. In some cases though, behavioral health professionals may provide traditional mental health services and even be employed by an outside mental health agency. As a result, documentation and billing often occurs separately from the primary care clinic. Lastly, there are integrated models of care. In such models, BHPs are not only embedded within the clinic, but are full members of the primary care team and share the same health record and billing system as their medical colleagues. Such systems provide the most rigorous form of collaboration, and will be explored further below.

Behavioral Health Consultation in Primary Care

One of the most unique and beneficial aspects of integrated models is the ability for BHPs to be able to meet with patients as part of their routine primary care visit. Such same-day visits are often referred to as warm handoffs or exam-room consultations. Whether visits are integrated or scheduled, behavioral health professionals are able to provide a variety of services as part of their standard work. Such services include but are not limited to: mental health screening; diagnostic evaluation and clarification; intervention for both mental and physical health conditions; risk assessment/crisis counseling; medication consultation; and, care coordination. Services are also

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much more brief, typically 15 to 30 minute visits, compared to the more traditional 45 to 50 minute sessions observed in specialty mental health. This allows BHPs time not only to communicate and provide recommendations to their primary care colleagues in the course of a visit, but also see a larger number of patients per clinic day. It is not uncommon for a BHP to see up to 14 patients in a day. In some models, BHPs may limit the number of visits per year to individual patients to avoid their schedules becoming too full; potentially leading to longer waits for scheduled visits. It should be noted that BHPs are not expected to replace traditional mental health services, as certain patients may require higher-level treatment and/or case management. However, BHPs can help bridge care until patients are able to connect with specialty mental health.1,25

**Barriers to Integration**

Although evidence continues to emerge around the benefits of integrating behavioral health into primary care, a number of barriers exist that slow or hold up such practice transformation. To begin, the merging of historically siloed systems presents new challenges at a bureaucratic and interpersonal level. Although medical and behavioral health professionals both strive to improve the lives of their patients, differences in training, ethics, and work flows can create culture clash.24 Inevitably, the addition of a new team member is going to impact team dynamics. However, in this case, medical providers who are used to being the solo “primary” caregiver are being asked to collaborate and share treatment planning and intervention duties to work towards a common goal.

Another challenge exists in terms of finding well-trained BHPs that are able to adapt to primary care settings and meet the demands described above. One dilemma is that a large portion of the existing behavioral health workforce has never trained nor worked in a primary care setting. Professionals accustomed to working in outpatient mental health centers or private practice may have a difficult time adjusting to the pace of primary care. As noted above, BHPs are asked to provide diagnostic evaluations and therapeutic interventions in half the time of a traditional mental health visit. Additionally, BHPs must be flexible, able to easily shift tasks, and amenable to being interrupted in the middle of a patient visit to consult with a medical provider or, in some cases, meet with another patient in crisis. And, much like their primary care colleagues, behavioral health professionals are required to be generalists, both in terms of treating all ages but also capable of providing interventions to support patients around a variety of mental and physical health conditions.1

Lastly, there exist a number of health care systems that strongly believe in the value of behavioral health integration, but struggle to overcome certain operational issues. For one, space can be a limiting factor. In most clinics, exam rooms and desk space are at a premium and a behavioral health professional may require both depending on the clinic layout. Additionally, due to differences in privacy laws, clinics or systems may need to redesign or optimize their electronic health record to accommodate for behavioral health information, which can be a time consuming and costly endeavor. And perhaps most significant, many primary care clinics are funded through traditional financial frameworks that may not adhere well to behavioral health services. Health systems may be required to move away from fee-for-service based reimbursement and toward more global or capitated payments to neutralize costs.27,28

**Future Directions and Conclusion**

Despite the notable obstacles, the influx of behavioral health into primary care settings remains on the rise and experts predict it will become the new standard of care. There are a number of signs that point to this. To begin, efforts are currently underway in several states to support the development of integrated practices. For example, Colorado is currently engaged in a $65 million state innovation model grant with a goal of increasing access to integrated behavioral health to 80 percent of Coloradans by 2019.29 In order to meet this need, and adequately prepare the workforce, there has been an expansion in training programs geared toward preparing future and current behavioral health professionals for working in primary care, including co-locating training within medical residency programs.30 Further, there has been recent development of core competencies for integrated BHPs to aid in the training, hiring, and evaluation of such professionals.31 But beyond hiring competent providers, clinics are also recognizing the need and value of bringing in behavioral health specialists, such as addiction counselors, to increase their scope of practice. Substance use treatment, similar to specialty mental health, has long been performed as a separate, siloed form of care. Addiction counselors can not only help address various substance use problems, such as alcohol and tobacco use disorders commonly seen in primary care, but also assist medical providers in treating the increasing number of patients with opiate addiction.
Ultimately, practice leaders and administrators motivated to meet the challenges presented by the “Triple Aim” should look to their behavioral health colleagues to create lasting, collaborative partnerships that can be mutually beneficial and rewarding. However, due to the complexities and obstacles outlined above, it is important they approach development of integrated behavioral health programs by seeking out the necessary consultation and coaching, as well as, conducting careful analysis of readiness for integration including understanding their patients’ needs, clinic capabilities, and financial environment.

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Addressing the Challenges of Prescribing Controlled Drugs
Where Personalized Medicine, Patient Engagement, and Primary Care Collide

By Megan Bell, ScM, CGC

Abstract

Personalized medicine and patient engagement have become common buzzwords in the context of health care reform. Independently both concepts have showed some promise in impacting health outcomes, but when synergistically applied, they have more power, as both are critical pieces of personalized health care (PHC). PHC is a health care model that embraces the need for patient engagement along with personalized medicine technologies to make the health care process more personalized, patient-driven, and proactive. Primary care presents an ideal setting for the application of PHC through the use of patient engagement techniques such as patient portals, patient-generated health data, and self-management programs, with the goal of supporting a preventative proactive health care approach.

Introduction

There is increasing awareness in the field of health care for the need to shift away from a reactive disease-oriented model to an approach that is personalized, predictive, preventative, and patient-centered. The personalized and genomic medicine movement gained attention as a solution to this current challenge in health care beginning in the early 2000s with the sequencing of the human genome and subsequent rapid development of genomic technologies. Powerful predictive tools and tailored treatments became the expectation of personalized medicine.

Despite the increasing knowledge of genomics and introduction of personalized medicine tools, health care delivery models remain relatively unchanged. Additionally, rates of preventable chronic diseases have continued to increase over the last decade with about 50 percent of the U.S. population reporting at least one chronic condition. This is partially due to the fact that personalized care requires not only scientific tools but also strategies to make these tools personally relevant and applicable to the patient.

The truth is that people spend only a few hours each year with a health care provider. They spend the other 5,000 waking hours making independent decisions that profoundly impact their health. Therefore, the biggest question is: how do clinicians make a dent in prevention if they only have a few hours of direct patient contact each year?

Patient Engagement

Increased patient engagement offers an approach for answering this age-old question. Patient engagement has been seen as a “holy grail” of advancing and reforming health care and is often used interchangeably with concepts such as patient activation, patient-centered care, and empowerment. It has been defined as a concept that combines both a patient's willingness and ability to manage his or her own health with interventions designed to increase activation and promote behavior change. Due to the difficulty of operationalizing the broad concept of patient engagement, Hibbard et al. developed the Patient Activation Measure as a means to assess this variable.

Patient activation has been linked to increased participation in preventative behavior, healthy behavior change, and better health outcomes, such as lower hemoglobin A1c, cholesterol, and blood pressure. Additionally, several studies have shown that increased patient activation is associated with a better health care experience. Federal and state policymakers have embraced patient engagement as a strategy to tackle growing health care costs and
improve quality and, while more longitudinal data is needed, there is evidence of lower health care costs for highly activated patients.\textsuperscript{6,11} Although the concept of patient engagement does show promise, independently it lacks a model, defined interventions, and a plan for attainment.

**Personalized Health Care**

Personalized health care (PHC) has been proposed as a new health care delivery model, combining pieces of precision medicine, patient engagement, and behavior change methods to promote shared decision making and patient participation in health care, ultimately leading to better patient outcomes.\textsuperscript{1,12,13} PHC can be defined as a “coordinated strategic approach to patient care that broadly applies the concepts of systems biology and personalized, predictive, preventive, and participatory care.”\textsuperscript{14}

The three main characteristics of PHC are that it is personalized, patient-driven, and proactive. First, PHC embraces the use of emerging genomic and other precision medicine technologies to provide risk assessments and prediction models for directing preventive care.\textsuperscript{1} However, PHC is not just personalized because it incorporates genomic technologies; it is personalized because it incorporates factors from the holistic individual.\textsuperscript{1,11} Although genotyping and genetic risk information are important to the development of a personalized health plan, this information does not explain how a patient perceives his or her health, what motivates a patient, and what barriers exist in maintaining health and well-being.\textsuperscript{15} Therefore, perhaps the most critical piece of PHC is that is it patient-driven; it must be rooted in what matters to the patient and align with his or her future goals.\textsuperscript{13} In addition to being personalized and patient-driven, PHC must also be proactive and help bolster a person's capacity for enhancing health prior to signs of disease. These pieces all fit together because a personalized and proactive approach that is not driven by an engaged individual will likely not be successful at all.\textsuperscript{13}

**PHC in Practice**

Primary care is a unique and ideal setting for implementing the PHC model. Since the goal of this field is to embrace the full continuum of health care for patients across a lifetime, primary care also has the greatest opportunity to impact both personalized individual and population health. Although evidence of the benefits of integrating PHC into the clinical setting is still growing, several techniques and programs have demonstrated success. The adoption of patient portals and digital communication platforms within electronic medical record systems has recently become one of the most obvious and common ways to increase patient engagement and apply PHC. Providing patients both access to their personal health information and an easy communication path with their provider supports patient ownership in health care. Although patient portals have received criticism due to the difficulty with patient buy-in and lack of personalization, when combined with educational and engagement materials, patient portals have been shown to improve chronic disease management.\textsuperscript{16} Kaiser Permanente recently added the Online Personal Action Plan tool to aid its members in access to information about prevention, health promotion, and care gaps. Use of this portal was associated with care gap closure including colon, cervical, and breast cancer screening and hemoglobin A1c testing.\textsuperscript{16} Although patient portals do show hope in increasing patient engagement and facilitating chronic disease management, continued optimization, customization, and interactivity will likely support further engagement.\textsuperscript{17}

Gathering patient-generated health data presents another method of integrating PHC, and as described by its name, requires the engagement and participation of the patient. Through health apps and monitoring systems, patients collect and submit their own health data to be included in their chart. This has the potential to not only improve the completeness and accuracy of the patient’s symptom experience, but also gives providers opportunities to interact with the patient between visits, helps direct real time changes in treatment plans, and makes the patient an important contributor to his or her health care.\textsuperscript{18} Bringing the patient’s voice into the electronic medical record can therefore enhance engagement and partnership with the patient while supporting steps in chronic disease management.\textsuperscript{18}

Additionally, self-management programs have shown promise in boosting patient engagement and helping individuals manage their chronic health conditions more effectively.\textsuperscript{19} For example, the Better Choices, Better Health program, originally created by Stanford University, specifically focuses on fostering the self-efficacy of patients to manage their own chronic conditions. It does so by facilitating a workshop where participants meet for two-and-a-half hours, once a week for six weeks, in community settings.\textsuperscript{20} Subjects covered include exercise recommendations for maintaining and improving strength, flexibility, and endurance, strategies for communicating with health care providers, and tools for managing and tracking health issues.
fulfilling lives. The most effective self-management programs are those that are well-integrated into the health system with principles reinforced by health care providers during follow-up care.20

Conclusion
In summary, PHC combines several growing movements including personalized medicine and patient engagement. PHC is not just personalized because it incorporates genomic technologies; it is personalized because it embraces the patient’s goals and perspectives in designing and driving the whole health care process from prevention to treatment. Although there are many existing programs and techniques to help implement PHC, more efficacy data is needed and countless research questions must be answered. For example, what factors exert the greatest influence on patient engagement? How do interventions at the policy-making level affect engagement efforts and outcomes? With the support of validated interventions, PHC does have the potential to make meaningful impacts on both individual and population health, because ultimately what patients really want is health rather than health care.

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Population Health Management and Cancer Screening

By Bradley Kamstra, DO; and Mark K. Huntington, MD, PhD

Abstract
Population health management (PHM) is a new health care model being implemented. It has been defined as “the health outcomes of a group of individuals, including the distribution of such outcomes within the group.” This includes health outcomes and patterns of health determinants, and policies and interventions that link these two. Moving from a fee-for-service payment system to a quality- or value-based system, this model places on the clinician more responsibility for the costs of health care and its reimbursements. Screening for disease is an area that could benefit from PHM. Electronic health records (EHRs) employ algorithms to capture PHM-related data such as diagnostic codes, clinical quality indicators, and other parameters useful in identifying those for whom screening is appropriate and in monitoring the efficacy at implementing the screening in the clinic’s population. Registries of patients at risk for a variety of diseases are created in the EHR, and these patients can be notified to visit with their clinician for a shared decision-making conversation about the screening. PHM requires a team approach to input, analyze, and implement this data. The physicians must be the driving force behind population health, but advanced practice clinicians, nurses, case managers, quality coordinators, information technology support, and many others collaborate to make this successful.

Introduction
Cancer screening has become an important part of patient visits. Cancer prevention is important not only to improve patient outcomes, but also to reduce costs and maintain the resources required for high-quality cancer care. Optimizing cancer prevention, detection, and treatment fit well within population health management (PHM).1 PHM is a practice model being implemented in today’s health care systems. PHM has been defined as “the health outcomes of a group of individuals, including the distribution of such outcomes within the group.”2 The practical meaning of health outcomes varies depending on who is...
defining it: health care administration, physicians, or patients. While it may be difficult to reach a full consensus on what population health means, and which components of it are most important (Figure 1), it is apparent that we have to think differently about health, populations, and health care delivery. In our ever-evolving health care environment, perhaps the traditional way may not be the best answer.

There will be a paradigm shift in the practice of medicine. The patient encounter will require work-flow changes to ensure PHM-relevant data, beyond the clinical data required for the encounter, is recorded. This data can then be used to categorize the patient into appropriate subpopulation group(s) which can be employed for both clinical treatment and public health study purposes. This management of populations will include many different people to help retrieve, analyze, process, and act upon the information.

**Population Health**

Our contemporary health care system is founded upon payer-based management. Presently a fee-for-service model, reimbursement is moving toward a new model of payment that is based on quality measures. While ideally patient-oriented outcomes would define quality, at present process measures predominate.

This new model is less individualized (by patient or by physician), and takes a population-focused approach. Patients are stratified into well-defined groups based on the similar risks to their health. Strategies will be created for the care of the specific needs of this group. The overall concept is to decrease cost by preventing illness in those who are healthy, and improve quality of life, as well as improving outcomes, in patients with one or more chronic diseases. The population groups may be defined by a variety of characteristics, or combinations thereof, including age, gender, income, ethnicity, geography, health status, employment, disability, etc. “Such populations are of relevance to policymakers. In addition, many other determinants of health, such as medical care systems, the social environment, and the physical environment, have their biological impact on individuals in part at a population level.”

Caring for a population of identified patients is not a new idea. An early model was community-oriented primary care, in which the community – not merely the individual – is viewed as the “patient.” The joining of public health principles with clinical care was much more successful at improving overall health than clinical practice alone in its initial implementation, and was expanded successfully in many nations. The vocabulary of population health was introduced in 2003 by David Kindig and Greg Stoddart: “We propose that the definition be “the health outcomes of a group of individuals, including the distribution of such outcomes within the group, and we argue that the field of population health includes health outcomes, patterns of health determinants, and policies and interventions that link these two.”

A challenge with this approach is that it requires the collection of a large amount of data. In the past, collection of patient data was time consuming and required an extensive labor force. With the implementation of the electronic health record (EHR), information on patients can be collected more quickly and analyzed much more efficiently. Health care systems can apply this information to manage the health of their patients.

The transition to PHM will impact all aspects of health care delivery. Preventative medicine has much to gain from a PHM model. Focusing on individuals, communities, and defined populations, many disciplines collaborate toward this purpose, including the medical, social, economic, and behavioral sciences. Preventive medicine includes biostatistics, epidemiology, environmental and occupational medicine, planning and evaluation of health services, management of health care organizations, research into causes of disease and injury in population groups, and the practice of prevention in clinical medicine. While there is a board-certified specialty of
preventative medicine, the majority of clinical preventative medicine is implemented in the context of primary care. The goal is to protect, promote, and maintain health and well-being, in addition to preventing disease, disability, and death. Preventative care can be more cost-effective than curative care, so offers substantial economic advantages.

**Cancer Screening**

An important goal in primary care is the prevention or early detection of disease through screening. “Screening can be defined as the application of diagnostic tests in asymptomatic patients for the purpose of dividing them into two groups: those who have a condition that would benefit from early intervention and those who do not.”

A screening test is effective when it can diagnose the condition before it is symptomatic and when treatment initiated at this point is more effective than after symptoms develop. In other words, early diagnosis should lead to measurable improvements in morbidity and mortality compared with clinical detection of symptomatic disease.

Ideal screening programs consider several things. First, what is the effect of the disease process on the quality and quantity of life? Is treatment clinically- and cost-effective? Does early detection and treatment reduce morbidity and mortality? The performance of the screening test also matters. What is its sensitivity and specificity? Because of the consequences and costs of both false positives and false negatives, this must be discussed with the patient to ensure informed consent and shared decision-making. Finally, the characteristics of the population being screened matters. Is the disease sufficiently prevalent? How accessible is follow-up medical care? Are the patients willing to comply with subsequent diagnostic tests and necessary therapy.

Evidence-based and consensus guidelines have been released by various government and specialty organizations regarding cancer screening. Screening for various types of cancer has shown to be an effective preventative measure that providers can implement into practice. A summary of these, along with the strength of evidence, is presented in Table 1.

**Integration of Screening Into Population Health Management**

Besides being a good clinical practice, appropriate screening will be a significant part of the basis on which primary care physicians are reimbursed under the PMH model. As data reporting requirements continue to rise with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the quality/process improvement (QI) schemes of various other payer programs, one may begin to wonder how to navigate through each day and not feel weighed down by all the administrative burdens. Practically, how is screening implemented into daily clinical practice in the PHM model?

**An Example**

Consider the U.S. Preventative Services Task Force (USPSTF) recommendation for lung cancer screening.

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Recommendations</th>
<th>SORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>Teaching breast self-examination does not reduce mortality and is not recommended.</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Annual or biennial screening mammography should be offered to average-risk women 50 to 74 years of age.</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>For average-risk women 40 to 49 years of age, the risks and benefits of mammography are closely balanced. The decision to perform screening mammography should take into consideration the individual patient risk, values, and comfort level of the patient and physician.</td>
<td>B</td>
</tr>
<tr>
<td>Cervical</td>
<td>Cytology without HPV testing should be performed every three years starting at 21 years of age to screen for cervical cancer.</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Cytology with HPV testing may be performed starting at 30 years of age to increase screening intervals to every five years.</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Screening should stop after 65 years of age in the setting of three consecutive negative cytology results or two consecutive negative cytology plus HPV cotesting results, with the most recent test performed within the previous five years.</td>
<td>A</td>
</tr>
<tr>
<td>Colorectal</td>
<td>Patients 50 to 75 years of age using colonoscopy every 10 years, fecal occult blood testing every year, or flexible sigmoidoscopy every five years plus fecal occult blood testing every three years.</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Computed tomography colonoscopy is not recommended for routine screening.</td>
<td>A</td>
</tr>
<tr>
<td>Lung</td>
<td>Annual low-dose computed tomography to screen for lung cancer in persons 55 to 80 years of age with at least a 30-pack-year smoking history who are otherwise healthy smokers or who have quit smoking within the past 15 years.</td>
<td>B</td>
</tr>
</tbody>
</table>
The recommendation is to annually screen, using low dose computed tomography, adults between the ages of 50 and 80 who have a 30 pack-year history of smoking and currently smoke or have quit smoking in the last 15 years. There is strong, patient-oriented outcomes data to support this screening recommendation.10

An outpatient clinic within a specific community, such as a rural town in South Dakota, could define the parameters for screening in its EHR system and generate a report of all its patients who meet the criteria. These patients could be proactively contacted by clinic staff to schedule a discussion of their risks and recommended screening with their clinician, rather than waiting to identify these people when they come for health maintenance exam – or an acute clinic visit – as has been the most common approach in the past. Unlike the fee-for-service model, revenue is not generated solely by the clinician-patient interaction: the activities of other clinic staff in initiating contact with patients for the purposes of screening and other preventative interventions are reimbursed as QI measures are met, making these staff positions revenue positive. In addition, significant portions of this process are amenable to automation in many EHR systems.

Applying the principles of population-based health allows those at-risk to be identified and contacted via a more deliberate approach. Although this approach is population-based, individual care is not lost. Clinicians can offer patient-specific care plans and interventions based on the individual patient’s risks, needs, preferences, values, and capabilities. Patients participate in developing their customized care plan through shared decision making.

Similar strategies can be applied to other cancer screening recommendations (Table 1). The parameters of the specific screening would be used to develop the data base of patients to be proactively engaged in the implementation of the screening strategy. Several tools PHM (Table 2) are alluded to in this example, and warrant further discussion. These include registries, QI coordinators, and case managers.

**Registries**

With the advancing technology in EHRs, data can be captured related to a specific set of patient information. Many EHRs are designed to create clinical dashboards and population health data.11 These features serve to generate databases, also called registries, of patients who meet defined criteria. In this way, the population of the clinic, specifically subpopulations for whom screening is indicated, can be clearly defined. Specific diagnoses, elements of the history, laboratory disease markers, or specifically defined QI thresholds or MACRA measures can be identified and tracked. In the preceding example of lung cancer, a registry can be created using a Boolean operator of patients who are 50 to 80 years of age AND have a 30 year pack history of smoking. A registry can be maintained for this and other population health parameters, querying the clinic population on a regular basis to identify those who meet the criteria and allowing a proactive approach to screening (and other activities such as chronic disease management), and evaluation of the processes implemented to ensure patients are contacted for appropriate screening. Registries created within an individual clinic setting have the potential to be applied across entire health systems.

**QI Coordinator**

Population health requires a coordinated effort involving many different departments in the health care system. A QI specialist is someone who works to improve the overall quality of care that a health care facility provides to patients. This position includes collecting and analyzing data, formulating the data into meaningful information, and reporting it to the health care team. QI is implemented via a plan-do-study-act (PDSA) cycle in which processes are identified as in need of improvement and an intervention is planned (P). Once implemented (D), the effects of the intervention are tracked (S), and based on the results,

<table>
<thead>
<tr>
<th>PHM Component</th>
<th>EHR Component</th>
<th>Clinical Staff Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define the population</td>
<td>Registry construction (based on FMSH*, ICD-10†, demographics, etc.)</td>
<td>QI coordinator</td>
</tr>
<tr>
<td>Health assessment</td>
<td>Encounter data</td>
<td>Clinician Case manager</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>Registry</td>
<td>QI coordinator</td>
</tr>
<tr>
<td>Patient engagement</td>
<td>Registry-generated contacts</td>
<td>Clinician Case manager</td>
</tr>
<tr>
<td>Patient-centered intervention</td>
<td>Encounter order entry (based on shared-decision making on evidence-based screening)</td>
<td>Clinician Case manager</td>
</tr>
<tr>
<td>Impact evaluation</td>
<td>Registry (change in proportion of population screened).</td>
<td>QI coordinator</td>
</tr>
</tbody>
</table>

* FMSH = Family, medical, and social history  
† International Classification of Disease, 10th ed.
the intervention is fine-tuned or replaced with a different intervention (A) and the cycle begins again. The QI coordinator interfaces with clinicians, the business office, and information technologist, to identify patients within the clinic population for whom interventions such as screening are appropriate, and to evaluate the effectiveness of the processes put in place to get the patients the necessary care. While currently QI coordinators focus on ensuring that the clinic meets or exceeds the QI process measures defined by payers, ideally their role will expand to identifying and tracking other, internally-developed markers – especially patient-oriented outcome measures.

**Case Manager**

Another key player would be a case manager. This person is involved in the assessment, planning, care coordination, and advocacy for services to meet individuals and family’s needs. This position is key in developing patient engagement. In contrast to the QI coordinator, this position interfaces more closely with the patients than with the system, and is focused primarily on the D component of the PDSA process. The case manager is intimately involved in chronic disease management as well as the QI process improvement. Communication between the patient and the care team is critical for efficient, clinically- and cost-effective care. Case managers facilitate this and lead efforts as part of multidisciplinary teams in new models of care, such as the patient-centered medical home and accountable care organizations, to better integrate care for targeted populations. In the example of lung cancer, the case manager would be involved in contacting patients in the registry for screening, and even more so in facilitating additional diagnostic and therapeutic interventions indicated for those screening positive. Screening for cancer is only the first step in quality care – without a mechanism in place for management of the results of the screening, it should not be undertaken.13

**Conclusion**

Health care will continue to change in its administrative and the clinical aspects. The method by which evaluating and implementing patient care is approached will be one of those changes. Improving patient outcomes within a defined group of people, while trying to contain costs in their care, is foundational to a PHM model. One of the main strategies to achieve these goals is through aggressive implementation of preventative measures. Cancer screening can detect disease at its earliest stages to optimize treatments and decrease morbidity and mortality. Implementing screening with tools available through the EHR will facilitate this process. A team of qualified health care professionals to assist with data collection, analysis, and integration is essential to improve outcomes for our patients. As the health care system continues to change, clinicians need to adopt the new tools for improving patient’s health.

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- As a trusted medical professional, you should start the patient conversation that will save lives and arm women with the power to make good health decisions about breast cancer risk and prevention.
- Talk about family and medical history, lifestyle and health care options.

Patients need to understand that screening is not about a single age, but rather a lifetime of reassessing risk and health from year to year.
- Inform women about risk factors such as weight, alcohol intake, breast density and lack of physical activity.
- Include a discussion about the benefits and limitations of mammography. All women are at risk for breast cancer, but studies have shown most over or underestimate their risk.

Breast cancer assessment is never a one-time conversation.
- Because patient factors and risks change, it is extremely important to adjust your approach accordingly.
- Keep the conversation going with your patients. Adjust screening recommendations based upon any new health changes, family developments or age milestones.
- The conversation with women must start in their 20s and continue through the span of their lives with professional recommendations and adjustments tailored to their history.

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Comprehensive Cancer Control South Dakota

GI Health
Practice Guidelines for Hypertension

By David Zeigler, MD, PhD, FACP; Anish Patel, MD; and Candace Zeigler, MD, FACP

Abstract
Hypertension is very prevalent in South Dakota affecting approximately one-third of the adult population. Management and treatment of the disease has recently been the subject of considerable debate centered on what should be the blood pressure goal depending on the patient’s age and co-morbid conditions. Recently, a randomized trial of intensive versus standard blood pressure control indicated that a systolic blood pressure of less than 120 mmHg in patients at high risk for cardiovascular events but without diabetes, resulted in significantly lower rates of non-fatal major cardiovascular events and death from any cause. Several studies have also looked at goals for hypertensive patients with diabetes. This article will review some of these recent studies and controversies associated with them. Medication and non-medication recommendations for control of blood pressure will also be discussed.

Introduction
Hypertension poses a significant health risk for many individuals. Approximately 30 percent of all American adults are diagnosed with hypertension according to The National Health and Nutrition Examination Survey.1 Hypertension is the leading contributor to global mortality and disability and is increasing in prevalence in the U.S. due to the obesity epidemic and aging of the population. The long term sequelae of hypertension will impact the quality of life of many patients. There is room for significant improvement of our ability to appropriately diagnose and control hypertension.

The prevalence of hypertension in the South Dakota population mirrors the national trend and has increased over the last 20 years. Based on a 2013 South Dakota Department of Health survey, 31 percent of all South Dakota respondents have been told that they have high blood pressure. The national median for that year was 31 percent.2 The significant number of individuals with hypertension makes it imperative that we diagnose and treat hypertension effectively.

Clinical Presentation
In general, hypertension is symptom free with no forewarning of disease progression. Occasionally, patients have symptoms of headache or bounding pulse associated with severe hypertension or hypertensive emergency.

Hypertension is usually found during routine health visits. The U.S. Preventive Services Task Force recommends screening for elevated blood pressures at every medical visit and at least every two years for systolic blood pressures less than 120 mmHg and diastolic blood pressure less than 80 mmHg. Screening should be completed yearly if systolic blood pressure is between 120-139 mmHg and diastolic blood pressure between 80-89 mmHg.

Important risk factors for developing hypertension are age, race (hypertension is more common in the black population), family history of hypertension (either paternal or maternal), excessive salt intake, low potassium diet, excessive alcohol ingestion, obesity, dyslipidemia, vitamin D deficiency and stress.3,4,5

Hypertension is a major risk factor for developing premature cardiovascular disease in addition to ischemic stroke, hemorrhagic stroke and chronic kidney disease.6 Long-standing complications of these co-morbid conditions have been shown to increase the likelihood of arrhythmias, heart failure, myocardial infarction and other end-organ damage.7,8

Diagnosis
The general rule for diagnosis of hypertension requires at least two office visits with elevated blood pressure. It is important to trend these pressures to obtain a baseline, as
blood pressure readings are not a static value and are affected by many factors. Blood pressure readings should be taken in both arms and the readings should be roughly equivalent. A discrepancy of greater than 15 mmHg suggests the need for evaluation of other arterial disease. Additional orthostatic blood pressures may be checked if there is concern for postural/orthostatic hypotension which would affect further management if positive.

White coat hypertension has been shown to exist in up to 20 percent of patients with stage one hypertension based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) hypertension criteria. This is also known as isolated clinic hypertension in which ambulatory or office-visit blood pressures are consistently elevated while blood-pressure checks at home or other locations remain normotensive. To overcome this, an automated blood-pressure reading device can obtain one to five minute sequential blood pressure readings after the patient is left unobserved and in a quiet room for approximately five minutes. Another option is to provide ambulatory blood pressure monitoring which takes blood pressures throughout the day in regularly scheduled intervals. The patient then can return the device to be evaluated by the provider.

The opposite phenomenon, masked hypertension, is having consistently normotensive clinic readings while having elevated ambulatory findings and is found to carry increased risk compared to normotensive counterparts. A 24-hour ambulatory reading is required in these situations to uncover the underlying hypertension.

**Laboratory and Testing**

Routine evaluation of complete blood count (CBC), urine analysis (UA), basic metabolic panel (BMP), lipid panel and electrocardiogram should be performed. Microalbuminuria and echocardiography are also options for evaluation of end organ damage if needed. Renovascular testing may be completed in patients with clinical features warranting further testing.

**Treatment**

The treatment of hypertension can be confusing especially with the number of studies that have been recently published. The 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults (JNC 8) simplified the recommendations for hypertension with specific goals. The JNC 8 guideline differed from JNC 7 by only including major studies between 1966 and 2009 and added studies from December 2009 through August 2013 using the same criteria to ensure no major studies were missed. However, as a departure from JNC 7, these recommendations were less aggressive, especially in the elderly. For patients who were 60 and older, they recommended that systolic blood pressure should be lowered to less than 150 mmHg and diastolic blood pressure should be lowered to less than 90 mmHg. In patients under 60 years, they recommended treatment for elevated diastolic pressure with a goal of less than 90 mmHg. This recommendation was based on the Hypertension Detection and Follow-up Program, the Hypertension-Stroke Cooperative, the Medical Research Council Trial of Treatment of Hypertension in Older Adults, the Australian National Blood Pressure Study, and the VA Cooperative Studies. All these studies showed statistical benefits to reducing blood pressure with reduced cerebrovascular events, less heart failure, and reduced overall mortality. It is important to note that no studies that evaluated systolic blood pressures met the strict guidelines criteria. Despite this, the expert opinion of the committee was to maintain a systolic blood pressure less than 140 mmHg for those patients under the age of 60.

The target for patients with chronic kidney disease and diabetes mellitus also changed to a goal of less than 140/90 mmHg to provide improved safety for renal function in these individuals.

JNC 8 also expanded the recommendations of which antihypertensive medication to start when treating patients with hypertension. Their recommendation for first line agents included thiazide diuretics, calcium channel blockers (CCB), angiotensin converting enzyme inhibitors (ACEI), and angiotensin receptor blockers (ARB). There was strong evidence to support the use of thiazide diuretics for blood pressure control. In the case of patients with chronic kidney disease, the preferred first line agent is an ACEI or ARB. In the black population thiazides or calcium channel blockers should be considered as first line therapy. These recommendations are made with Grade B or moderate recommendation. To achieve optimal control, initially one drug should be started at a time. If goals cannot be achieved, consider titrating up the dose of the drug or adding a second drug. If three or more medications cannot achieve recommended goals, consider other classes of medications or consider referral to a specialist in hypertension. The committee did not recommend the combination of ACEI and ARB medications which can cause increased renal failure.

There was a fair amount of controversy surrounding the report of the JNC 8 report. Many experts felt that the recommendations were not aggressive enough. However, the committee only used data that was available from major multi-centered studies that included at least 2,000 participants. The limited number of studies that had quality data and good recommendations on blood pressure goals was surprising.
In 2015, the Systolic Blood Pressure Intervention Trial (SPRINT) was published to address this issue.\textsuperscript{15} SPRINT was a randomized trial of intensive versus standard blood pressure control. The study included 9,361 patients. It was stopped early after 3.2 years because of the significant decrease in heart attacks, non-myocardial infarction acute coronary syndrome, heart failure, cardiovascular death and stroke by 30% percent. It also lowered the risk of death by almost 25 percent. This study only included individuals age 50 or older with systolic blood pressure of 130 mmHg or higher and at least one additional cardiovascular risk factor. It also excluded individuals with diabetes or a prior history of stroke. The two arms of the study included the intensive arm with a systolic blood pressure target of less than 120 mmHg and a control group where there was a target of systolic blood pressure of less than 140 mmHg. The target group required an average of three medications to maintain their blood pressure control.

This does sound significant but it is important to note that study did not meet their goals of blood pressure control. The average systolic blood pressure in the intensive treatment group was 121.5 mmHg and was 143.6 mmHg in the standard treatment group. It is also important to point out that this was a relative risk reduction and that the decrease in event rates was from 6.8 to 5.2 percent over a 3.2 year period. This is an absolute risk reduction of 1.6 percent. During the same time there was a significant increase in serious adverse drug events in the aggressively treated group with a relative risk increase of 88 percent, or from 2.5 to 4.7 percent with an absolute risk increase of 2.2 percent. The serious adverse events included hypotension and acute kidney injury or kidney failure associated with the aggressive blood pressure treatment. Ortiz and James stated, “Some patients and their physicians may believe that the benefit (of going to 120 mmHg) is worth the additional effort, risks and cost of taking more medications, whereas others may not”.\textsuperscript{16}

It should also be noted that the blood pressures were taken with an automated cuff over an eight-minute period with quiet rest. This is different from normal clinic blood pressure recordings that use manual readings or blood pressures taken without adequate time for blood pressure to stabilize. This would mean that the blood pressure readings in the study would be 8-10 mmHg lower because of their method of measurement. This does not mean that blood pressure monitoring was incorrect but it makes it harder to correlate to a usual clinical practice. This is especially important in the elderly who become anxious or worried about going to see their physician.

The SPRINT study also excluded diabetics. The effect of antihypertensive treatment on mortality and cardiovascular morbidity in diabetic patients was examined in a meta-analysis by Brunstrom and Carlberg that included 49 trials involving 73,738 patients with diabetes.\textsuperscript{17} Their analysis showed that antihypertensive therapy lowered the risk of mortality and cardiovascular morbidity as long as the systolic pressure remained higher than 140 mmHg. Reducing the blood pressure below 140 mmHg increased the risk of cardiovascular death in diabetics. The adverse effect of excessive blood pressure lowering, in the meta-analysis by Brunstrom and Carlberg, is most likely related to decreased blood flow to target organs particularly during diastole. The recommendation for diabetics with hypertension should be a blood pressure of less than 150/90 mmHg. Messerli and Bangalore state, “Diabetic patients are at higher risk than nondiabetic ones but this risk cannot simply be abolished by excessive blood pressure lowering”\textsuperscript{18}.

Based on the HOPE 3 (Heart Outcomes Prevention Evaluation 3) trial,\textsuperscript{19} there was no evidence to support the initiation of antihypertensive treatment in patients with systolic blood pressure of less than 143 mmHg if other cardiovascular risk factors are not present. Treating patients without other cardiovascular risks who are at low to intermediate risk in the normal to high blood pressure range with antihypertensive drugs had no benefit in reducing morbidity and mortality.\textsuperscript{20}

The interpretation of the SPRINT trial may also be based on the relative decrease in blood pressure compared to the control (18 versus 5 mmHg). The beneficial effects of the treated group may be caused by the greater drop in blood pressure. This may be true for higher blood pressures as well. It may not be advisable to lower a significantly elevated systolic blood pressure to 120 mmHg but a 20 mmHg decrease would likely be beneficial. A more conservative approach is felt to be reasonable.

Clinicians are always trying to improve the lives of their patients and there is a strong desire to add more medications to lower the blood pressure to meet a goal and decrease a patient’s cardiovascular risk. However, it is important to think about the age of the patient. The Hypertension in the Very Elderly Trial (HYVET)\textsuperscript{21} looked at healthy individuals over the age of 80 with systolic blood pressures greater than 160 mmHg. They found that control of the blood pressure to less than 150/90 mmHg with thiazide diuretic with or without an ACEI lead to a significant reduction in the risk of cardiovascular death and all-cause mortality compared to placebo. They excluded ill and frail individuals and patients with orthostatic hypotension. It is important to assess the frailty of the elderly patient and account for polypharmacy and the cost of medication, which is common in the elderly population, when directing therapy.\textsuperscript{22,23} The principle to remember is to “first do no harm” and look at alternative ways to improve overall health.
Studies do provide some guidance on non-pharmacologic strategies to lower blood pressure. Patients should be encouraged to work on diet, exercise and weight reduction. A decrease of 10 percent of body weight in overweight and obese patients can significantly decrease blood pressure. While medications are still the mainstay of managing elevated blood pressure, lifestyle modification can provide patients with benefits while minimizing risks.

**Summary/Conclusions**

Treatment for hypertension has become increasingly confusing with the number of studies recently published. In general, medications are the mainstay of treatment of hypertension. Thiazide diuretics are still recommended for first-line treatment of hypertension but are not for everyone. They should be used with caution in the elderly and electrolytes need to be monitored. Additional first-line medications include ACEI, ARB, and/or CCB. In the case of patients with chronic kidney disease, the preferred first line agent is an ACEI or ARB. The combination of ACEI and ARB medications is not recommended because it can cause increased renal failure. As far as age specific guidance, in patients over 80 years of age the recommendation is for blood pressures to be less than 150/90 mmHg based on the HYVET. In patients between the ages of 60 and 80 without comorbid conditions, the goal for blood pressure should be less than 140/90 mmHg. In younger hypertensive patients (less than 65) who do not have diabetes mellitus, the goal should be less than 120/80 mmHg based on the SPRINT data. In patients with CAD and heart failure the recommendation is to be less than 140/90 mmHg. In patients with diabetes the recommendation is less clear. The meta-analysis by Brunstom and Carlberg would tend to indicate that the goal should be less than 150/90 mmHg. Another important aspect of treatment is lifestyle modification. Patients should be encouraged to work on diet, exercise and weight reduction as it provides a low-cost option with minimal risk compared to medications.

While new studies make treatment goals less clear, they serve to underscore the need for individualized treatment based on patient context. Going forward, hypertension will remain a continued challenge that will need more studies to clarify appropriate treatment plans. Until then, it is reasonable to use the available data as a guide when coming up with treatment approaches with the ultimate goal of avoiding the complications and costs associated with hypertension.

**REFERENCES**


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Prevention, Detection, and Management of Diabetes in South Dakota

By Amy L. Hogue, MD; and Mark K. Huntington, MD, PhD

Abstract
Diabetes mellitus (DM) is increasing in prevalence nationwide and in South Dakota, with an especially high prevalence in its American Indian population. Screening is not recommended for type 1 DM, but is for type 2 DM and pre-diabetes in certain populations. Fasting glucose, two-hour glucose tolerance test, or hemoglobin A1c are appropriate screening options. Treatment can include diabetic self-management education programs and medications. In addition to glycemic control, other cardiovascular risk factors must be reduced in these patients and specific testing and consultations should be performed to detect complications such as nephropathy or retinopathy. Along with routine age-appropriate immunizations, most diabetic patients should receive the pneumococcal polysaccharide vaccine (PPSV-23), influenza, and the hepatitis B series. Progression from pre-diabetes to type 2 DM can be prevented or delayed in some patients through lifestyle interventions and/or metformin. The South Dakota Diabetes Coalition (www.sddiabetescoalition.org) is an excellent resource for clinicians and patients.

Introduction
Diabetes mellitus (DM) continues to be a growing challenge in the U.S. In South Dakota, 8.2 percent of our adult population has been diagnosed with diabetes. Compared to the rest of the country, South Dakota’s overall prevalence is slightly lower than average (Figure 1). However, certain counties – specifically Oglala Lakota, Todd, Ziebach, Dewey, and Buffalo – have diabetes rates much higher than the national average, likely reflecting the increased prevalence of diabetes in American Indian populations. In addition, American Indians in the Great Plains region are over three times more likely to die from diabetes than Caucasians living in the same geographic areas. This disparity is actually greatest in South Dakota compared to the other states in the Great Plains region, with American Indians from South Dakota having a death
rate from diabetes 5.47 times than of Caucasians. There remains much to do to reduce the burden of diabetes in our state.

Screening and Diagnosis
Proper treatment of diabetes begins with detection. It is estimated that there are another 21,000 South Dakota adults who have diabetes, but have not been diagnosed yet. Additionally, another 35 percent of adults in South Dakota are suspected of having pre-diabetes.

Who should be screened for diabetes? There are no recommendations to screen for type 1 DM given this condition rarely presents asymptptomatically. The U.S. Preventive Services Task Force (USPSTF) does recommend screening all overweight or obese adults ages 40 to 70 for type 2 DM, based on solid patient-oriented evidence (grade B). Earlier screening can be considered for those with other risk factors including family history of diabetes, personal history of gestational diabetes or polycystic ovarian syndrome, or members of certain ethnic or racial groups including American Indians, African Americans, Asians, Hispanics or Latinos, Native Hawaiians and Pacific Islanders. These patients could be screened at a younger age or lower body mass index, though no specific recommendations were made. Additionally, the USPSTF did not make recommendations on screening frequency. The consensus-based American Diabetes Association (ADA) recommendations are more aggressive, screening all adults ages 45 every three years, regardless of risk factors; those with risk factors being screened at a younger age.

What are acceptable screening methods? Options include fasting plasma glucose, hemoglobin A1C (A1C), or a 75 g two-hour oral glucose tolerance test (OGTT). Additionally, a random plasma glucose 200 mg/dL or greater is diagnostic for DM if associated with classic hyperglycemic symptoms. If fasting glucose is performed, 100 to 125 mg/dL is considered pre-diabetic and 126 or greater is considered overt diabetes. A value of 140 to 199 mg/dL from the OGTT is considered pre-diabetic and 200 mg/dL or greater is diagnostic for diabetes. If choosing to screen with an A1C, it is important that the lab uses a method certified by the National Glycohemoglobin Standardization Program. Finger stick A1Cs are not recommended for use in diagnosis.

A1C values, bear in mind the patient’s other medical conditions that may influence the test result. For example, acute blood loss, chronic liver or kidney disease, hemolytic anemia, and pregnancy can falsely lower A1Cs. Hypertriglyceridemia, chronic iron deficiency anemias, acute renal failure, and splenectomy status can falsely elevate A1Cs. A1Cs between 5.7 and 6.4 percent are considered pre-diabetic and 6.5 percent or greater is considered diabetes. For all of the above tests, repeat testing is preferred to rule out a lab error prior to making this important diagnosis.

Treatment
Once patients are diagnosed, it is important to initiate treatment in order to improve outcomes and reduce microvascular complications. A frequent question asked is how does one know that patients are “controlled”? What does “controlled” mean? The ACCORD trial revealed that lower A1Cs are not universally better for all patients. There is evidence that diabetes management needs to be individualized and patient-centered, keeping in mind patients’ other co-morbidities, life expectancies, cultural practices, and risks of hypoglycemia. This can be challenging in a health care environment increasingly focused on universal quality measures, pay for performance, and population management. At this time, the ADA recommends treating to an A1C less than 7 percent for typical type 2 DM patients (SORT = C). For patients with
low life expectancy, multiple co-morbidities, older adults, and individuals with a history of severe hypoglycemia, less rigid goals are suggested such as treating to an AIC of less than 8 percent.6 Participation in diabetic self-management education programs (DSME) have been recommended for patients to learn more about their disease and the skills and behaviors needed for ongoing self-management (SORT = B). A recent meta-analysis published in *Endocrine* found that all-cause mortality was mildly decreased for those patients with type 2 DM completing a DSME program.3 DSME programs focus on education about the disease and potential complications, diet, exercise, and in some cases, blood glucose monitoring. Further studies do need to be done to assess efficacy of these programs, particularly looking at standardization and longer term follow-up.

There are currently 26 DSME programs in South Dakota that are certified by either the South Dakota Department of Health or the American Academy of Diabetic Educators (Table 1). In 2010, 64 percent of South Dakotans took a course in diabetic self-care.4 Unfortunately, only one of the five counties in South Dakota with the highest diabetic prevalence has a DSME program. Access to these programs can be geographically limited in our rural state. South Dakota ranks 41st in the nation for physician to population ratios and almost two-thirds of the state are health professions shortage areas (HPSAs).4

There is a little published data regarding the most effective way to administer DSME programs for American Indian populations. As mentioned at the start of this article, American Indians in South Dakota have very high death rates from diabetes compared to non-Hispanic Caucasians with diabetes. There are many reasons proposed for this including increased poverty, lower levels of education, more obesity, increased tobacco use, barriers to food access, and cultural differences in how diabetes is understood and treated.3 An interesting study was conducted in 2005 on the Cheyenne River Indian Reservation by researchers from South Dakota State University. One hundred and fourteen tribal members ages 18 to 65 were randomized to receive either monthly dietary education using the Medicine Wheel Model for Nutrition compared to regular dietary education from their clinician. The Medicine Wheel Model is a diet based on traditional consumption of macronutrients for Northern Plains Indians. There were no differences seen in Hgb A1C levels; however, there were small but statistically significant improvements in weight in the intervention group.10 Overall, there is a paucity of data on how to best provide diabetic education to our American Indian population.

Experts agree that all patients with newly diagnosed diabetes should undergo robust risk reduction for cardiovascular disease. This includes smoking cessation, blood pressure management, lipid control, aerobic exercise and healthy diet. Pharmacologic treatment of hypertension should be initiated for blood pressures greater than 140/90, regardless of the patient’s age.17 A lipid panel should be checked if not done in the last year and statin therapy should be initiated based on age and arteriosclerotic cardiovascular disease risk. For patients that are overweight, weight loss should be encouraged to reach a goal body mass index (BMI) of less than 25.6 Unfortunately, this is a daunting task for many patients. An exercise goal of at least 150 minutes per week of moderate intensity aerobic activity provides benefit for glycemic control beyond weight loss and cardiovascular benefits.5

Lifestyle interventions alone can be an option for some newly diagnosed patients whose A1Cs are close to the target range and are highly motivated to make changes. For other patients with A1Cs between 7.5 to 9 metformin is recommended as the first line pharmacologic therapy. Contraindications to metformin include patients with active alcohol abuse, progressive liver disease, and increased risk for lactic acidosis. Historically, metformin was contraindicated with creatinine greater than or equal to 1.4 mg/dL in women and 1.5 mg/dL in men. However, in April of 2016 the Food and Drug Administration updated its warnings regarding renal function with metformin-containing products. The new recommendations state that metformin should not be used with an eGFR less than 30 mL/minute and should not be initiated in patients with an eGFR between 30 and 45 mL/minute.12 Nausea and diarrhea are some of the most common side effects. For patients with contraindications to metformin, those unable to tolerate it, or those who are inadequately controlled on monotherapy, second line options can include sulfonylureas, thiazolidinediones, glucagon-like peptide-1 (GLP-1) agonists, alpha-glucosidase inhibitors, sodium-glucose cotransporter-2 (SGLT2) inhibitors, or dipeptidyl peptidase 4 (DPP-4) inhibitors. Each of these options has potential benefits, but also potential disadvantages and the choice should be patient-centered taking into account patient preferences, medical co-morbidities, and drug affordability (Table 2).
<table>
<thead>
<tr>
<th>Location</th>
<th>Diabetes Education Center</th>
<th>Address</th>
<th>Contact</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aberdeen</td>
<td>Avera St. Luke’s Hospital</td>
<td>305 S. State Street, Aberdeen, SD 57401</td>
<td>Carolyn Klinkhammer, 525 N. Foster, Mitchell, SD 57301</td>
<td>(605) 622-5588, (605) 995-2260</td>
</tr>
<tr>
<td>Mitchell</td>
<td>Avera Queen of Peace Hospital</td>
<td>1401 10th Ave West, Mobridge, SD 57601</td>
<td>(605) 845-8228</td>
<td></td>
</tr>
<tr>
<td>Redfield</td>
<td>Community Memorial Hospital</td>
<td>111 West 10th Ave, Redfield, SD 57469</td>
<td>(605) 472-1110 ext. 125</td>
<td></td>
</tr>
<tr>
<td>Brookings</td>
<td>Brookings Health System</td>
<td>300 22nd Ave, Brookings, SD 57006</td>
<td>Luann Thompson, 701 3rd Ave S, Clear Lake, SD 57226</td>
<td>(605) 696-9000, (605) 874-2141</td>
</tr>
<tr>
<td>Clear Lake</td>
<td>Sanford Clear Lake Medical Center</td>
<td>1401 10th Ave West, Mobridge, SD 57601</td>
<td>(605) 776-1109</td>
<td></td>
</tr>
<tr>
<td>Custer</td>
<td>Custer Regional Hospital Diabetes Education Program</td>
<td>1041 Montgomery Street, Custer, SD 57730</td>
<td>Lacy Burrell, 525 N. Foster, Mitchell, SD 57301</td>
<td>(605) 673-4150</td>
</tr>
<tr>
<td>Deadwood</td>
<td>Lead-Deadwood Regional Hospital</td>
<td>61 Charles Street, Deadwood, SD 57732</td>
<td>(605) 721-8939, ext 234</td>
<td></td>
</tr>
<tr>
<td>Madison</td>
<td>Madison Community Hospital</td>
<td>323 SW 10th St, Madison, SD 57042</td>
<td>(605) 256-6551</td>
<td></td>
</tr>
<tr>
<td>Rapid City</td>
<td>Community Health Center of the Black Hills</td>
<td>640 Florman Street, Rapid City, SD 57701</td>
<td>(605) 755-3300</td>
<td></td>
</tr>
<tr>
<td>Rosebud</td>
<td>Rosebud Diabetes Management</td>
<td>227 BIA 9, Rosebud, SD 57570</td>
<td>(605) 668-8279</td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Diabetes Self-management Education Centers in South Dakota

From www.sddiabetescoalition.org/Resources/Class-Locations.aspx
Insulin is the first line treatment for type 1 DM, and recommended for type 2 diabetics with weight loss or ketonuria, and those with significant hyperglycemia at time of diagnosis (such as A1C greater than 9.5 percent). Most type 2 diabetics can be started with a once daily long-acting insulin at 0.1 to 0.3 units/kg that can be titrated to goal based on fasting blood sugars. Some diabetics will need meal time insulin at time of initiation as well. There are established protocols for insulin initiation and titration that are helpful for physicians (Table 3). There are some reports of treating symptomatic type 2 diabetics with high dose sulfonylureas. This may be an option, particularly in patients that are absolutely refusing to take insulin.

In 2014, 90 percent of South Dakotans with diabetes reported seeing a health professional and 76 percent had two or more A1Cs checked. Both of these measures are significantly higher than many states. In addition to glycemic control, however, patients need to be monitored for the development of diabetic complications. Dilated eye exams are recommended yearly starting at the time of diagnosis for type 2 diabetics and five years after diagnosis for type 1 diabetics. Patients should have a comprehensive foot evaluation at least yearly, including assessment for symptoms of diabetic neuropathy and peripheral artery disease. Most experts recommend yearly microalbumin and creatinine to assess for diabetic nephropathy. Yearly dental exams are recommended.

Patients should have all age-appropriate immunizations if
they are not up to date. A new diagnosis of diabetes is an indication for pneumococcal polysaccharide vaccine (PPSV-23) if they have not already received this. The Centers for Disease Control and Prevention reports that only 37 percent of diabetics in South Dakota had received appropriate pneumococcal vaccination in 2014.1 Additionally, only 49 percent of diabetic South Dakotans were reported to have received influenza vaccines.1 A commonly overlooked recommendation is for administration of the hepatitis B vaccination series in unvaccinated adults with diabetes who are aged 19 to 59. This can be considered for those over 60 as well.14

Prevention

Most of the research regarding prevention of type 1 DM focuses on patients who are deemed to be high risk based on genetics, such as the siblings of type 1 diabetics. There have been a variety of medications tried for prevention, including use of oral, nasal, and parenteral insulins, none of which clearly show a benefit.15 There are several studies looking at interventions in infants’ diets including DHA supplementation, vitamin D supplementation, gluten restriction, and delayed cow’s milk introduction. Delaying cow’s milk to after one year (which is already the standard of care for other reasons) seems to have the strongest evidence at this time.15

Maintaining a normal BMI is one of the most modifiable factors to prevent prediabetes and progression to type 2 DM. Much of the research on type 2 DM prevention focuses on interventions for individuals who have already been diagnosed with prediabetes. A large multicenter trial randomized patients with prediabetes to intensive lifestyle intervention with a goal of weight loss of 7 percent or more, metformin, or placebo. Both the intensive lifestyle intervention group and the metformin group had decreased progression to type 2 DM compared to placebo,
with a greater effect seen from the lifestyle intervention group. A more recent study from the Department of Veterans Affairs found nutrition education alone could decrease progression to type DM, even independently of weight loss. Despite having effective interventions for prediabetes, in one study only 23 percent of patients that met laboratory criteria for prediabetes had a documented intervention recommended by their clinician in their ambulatory medical record.

### Conclusion

The need remains great. The South Dakota Diabetes Coalition (www.sddiabetescoalition.org) offers excellent resources for clinicians and patients and is providing continued advocacy for improved diabetic care in our state. We need to continue to bridge the gaps in health disparities in our state, particularly for our American Indian population that is disproportionately affected by this challenging disease.

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**References**


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**Special Issue 2017**

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Tobacco Cessation Strategies: It Takes a Village

By Debbie Anne Chiu Qua, MD

Abstract
Smoking is the leading cause of preventable death and chronic diseases in the U.S. Identifying smokers and providing appropriate intervention is therefore an integral part of each clinic visit. A combination of pharmacotherapy as well as behavioral counseling provides the best results. Pharmacotherapy includes nicotine replacement (patch, gum, lozenges), bupropion and varenicline. More recently, electronic nicotinic delivery systems (such as e-cigarettes, vaporizers/vape pens, and hookah pens) have become popular. Behavioral counseling includes identifying barriers to quitting or risk factors for relapse, and developing effective strategies to deal with these issues. A successful program requires a team-based approach, enlisting the help of adjuvant staff to reinforce cessation counseling and provide support services. The South Dakota Quitline is one of many good resources that the clinician can utilize to help with cessation and has one of the best quit rates in the nation.

Introduction
As of 2012, 22 percent of South Dakotan adults are smokers, which translates to an estimated 138,000 adults smoking cigarettes.1,2 Ill effects of tobacco use are well known as several studies have already elucidated this. For instance, smokers were found to be 11 times more likely than nonsmokers to develop lung cancer (RR, 10.92; 95 percent CI, 8.28-14.40). Smokers were four times more likely to develop chronic obstructive pulmonary disease (COPD) (RR, 4.01; 95 percent CI 3.18-5.05). Even passive smokers have increased risk of developing lung cancer by 1.41-fold (41 percent) and COPD by 1.72-fold (72 percent).3

Given the health burden smoking brings, the U.S. Preventive Services Task Force (USPSTF) guidelines recommend that clinicians ask all the patients about their tobacco use and provide tobacco cessation interventions for those who do.4 Moreover, we should also identify at-risk populations who once used tobacco to help prevent relapse.

Review of the Literature
There is evidence that brief clinician intervention advice at each encounter can increase smoking abstinence rates by 1 to 3 percent. The probability of quitting was 19 percent within one year and 45 percent within five years from first outpatient contact. Interestingly, even if smokers are not ready to quit, those asked about their tobacco use (or advised to quit) report being more satisfied with their care than those patients who did not have such a discussion.5

In the hospital setting, a 2012 meta-analysis found that intensive counseling (at least one session during hospital stay with continued support after discharge for at least a month) increased the likelihood of smoking cessation (RR 1.37, 95 percent CI 1.27-1.48).6 For those who are willing to quit, Fiore et al. proposed a five-step algorithm clinicians can follow: Ask, Advise, Assess, Assist, Arrange.7

1. Ask – about tobacco use and document.
2. Advise – to quit
3. Assess – willingness to quit smoking in the next 30 days
   • Pre-contemplation: not ready to quit
   • Contemplation: considering to quit
   • Preparation: actively planning to quit
   • Action: actively involved in a quit attempt
   • Maintenance: achieved smoking cessation
4. Assist – the patient to come up with a plan on how to quit
   • Assess prior experiences with attempts to quit
• Assess possible barriers to quitting
• Arrange – for follow-up

For those unwilling to quit, Fiore et al. suggest discussing the 5 R’s: 8

1. Relevance – of quitting (encouraging the patient to see why quitting will be important)
2. Risks – ask the patient to identify possible negative consequences of tobacco use (acute, long-term and risks for spouses)
3. Rewards – ask the patient to identify potential benefits of tobacco cessation and highlight those that seem to be most relevant to the patient.
4. Roadblocks – ask the patient to identify barriers to quitting and address elements of treatment that can help with these
5. Repetition – motivational intervention should be repeated every time the patient visits the clinic setting

Team-based Approach

Office members can help by asking each patient’s smoking status and reminding the clinician to address such when identified. One way to go about this is by adding smoking status to the vital signs. 9 In clinical settings where tobacco use has been universally documented, the rate at which physicians asked their patients about smoking and provided specific advice on quitting approximately doubled. 10

Certainly, physicians are not able to do all these alone. As doctors often have limited time during each clinic visit, the rest of the staff should be utilized to maximize the impact of treatment. Adjuvant staff (e.g., physician assistants, nurses, and medical assistants) can effectively implement these brief strategies by helping to reinforce cessation counseling and provide follow-up and support services to patients attempting to quit. 9 Collaboration is the key to increase success in tobacco control and effective collaboration always potentiates the reach of available program funds and resources.

Table 1. Summary of Pharmacotherapy (Adapted from Fiore et al) 8

<table>
<thead>
<tr>
<th></th>
<th>Dosage</th>
<th>Treatment period</th>
<th>Pros</th>
<th>Cons</th>
<th>Caution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine patch</td>
<td>One patch/day; 21 mg x 4 weeks then 14 mg x 2 weeks then 7 mg x 2 weeks; no need to taper if using 14 mg x 8 weeks</td>
<td>6-8 weeks</td>
<td>Easy to use, steady dose of nicotine</td>
<td>May cause skin irritation, insomnia; difficult to adjust nicotine dose in response to urges</td>
<td>Do not use if with uncontrolled eczema or psoriasis</td>
</tr>
<tr>
<td>Nicotine gum</td>
<td>4 mg (heavy smokers) every 1 hour (10-15 pieces/day)</td>
<td>Up to 12 weeks or longer if needed</td>
<td>Can control dose and helps with predictable urges (e.g., post prandial)</td>
<td>May stick to dentures</td>
<td>Do not take with acidic beverages</td>
</tr>
<tr>
<td>Nicotine inhaler</td>
<td>6-16 cartridges/day; need to inhaler 80x to use up cartridge</td>
<td>3-6 months</td>
<td>Easy to use; reduces urge to smoke</td>
<td>May cause dry mouth/throat; expensive</td>
<td></td>
</tr>
<tr>
<td>Bupropion SR</td>
<td>Days 1-2: 150 mg tab in morning Days 4 – onward: 150 mg tab BID</td>
<td>7-12 weeks (start 1-2 weeks before stop date); may use for up to 6 months</td>
<td>Easy to use; reduces urge to smoke</td>
<td>May cause dry mouth, headaches, nausea, abnormal dreams</td>
<td>Do not use if with seizure disorder or currently using MAOI</td>
</tr>
<tr>
<td>Chantix</td>
<td>Days 1-3: 0.5 mg daily; Days 4-7: 0.5 mg BID; Day 8-week 11: 1 mg BID</td>
<td>Initial treatment: 12 weeks, may continue additional 12 weeks. Start 1 week before quit date; stop smoking 8-35 days after starting drug</td>
<td>Good success rate, easy to use</td>
<td>May cause depression, suicidality, vivid dreams, sleep disorders, dry mouth, nausea</td>
<td>Need to renally dose if CrCl &lt; 30. Caution if with psychiatric disorder and seizure history.</td>
</tr>
</tbody>
</table>
Pharmacotherapy

Continued pharmacotherapy (up to 18 months) can help prevent relapse. However, note that optimal duration has not been established. Some of the commonly used pharmacologic aides include the following (this is also summarized in Table 1).

Nicotine Replacement Therapy (NRT)

**Mechanism:** binds to central nervous system and peripheral nicotinic-cholinergic receptors.

**Dose:**
- **Patch**: (7, 14, 21 mg per 24 hour patch); decrease dose after six weeks followed by the lower dose (or stop) every two weeks.
  - Gum – 4 mg dose recommended for those who smoke 25 or more cigarettes per day; 2 mg for lighter smokers. This can be chewed every one to two hours for six weeks with gradual reduction over a second six weeks for a total duration of three months.
  - **Lozenge**: 4 mg for those who smoke within 30 minutes of awakening; otherwise, 2 mg dose can be given every one to two hours for six weeks with gradual reduction over a second six weeks (maximum dose 20 lozenges /day).

**Common adverse reactions:** local erythema / rash (for patches), headache, palpitations, hypertension, tachycardia, gastrointestinal (GI) intolerance, insomnia, chest discomfort, abnormal dreams.

This is perhaps the most commonly used cessation aide that increases quit rate twofold compared to placebo. A randomized study found that 24 weeks of patch therapy was associated with higher abstinence rates compared to eight weeks of therapy (OR, 1.81; 95 percent CI, 1.23-2.66).12

A double-blind, multicenter, placebo-controlled smoking cessation trial studying 370 COPD patients who smoked a mean of 19.6 cigarettes per day who were given nicotine sublingual tablets for 12 weeks. They were all provided nurse-conducted support (office visits and telephone calls). This showed long-term efficacy of NRT for cessation, regardless of daily cigarette consumption. Abstinence improved St. George’s Respiratory Questionnaire (SGRQ) scores with a mean change of -10.9 (versus -2.9 for nonabstainers) and symptom score of -28.6 (versus -2.3 for nonabstainers).13

In a 2013 meta-analysis of nine randomized controlled trials (RCTs), the combination of nicotine patch with a short-acting NRT (gum, spray or inhaler) was more effective that a single type of NRT (RR, 1.34; 95 percent CI, 1.18-1.51).12 Another RCT compared 12 weeks of varenicline versus nicotine patch versus nicotine patch plus lozenge and did not find any difference in the confirmed quit rates.14

**Bupropion**

**Mechanism:** unclear exact mechanism; inhibits neuronal uptake of norepinephrine and dopamine.

**Dose:** 150 mg PO daily for three days then BID for seven to 12 weeks.

**Common adverse reactions:** headache, agitation, tachycardia, chest pain, weight loss, tremor, GI intolerance, abnormal dreams, insomnia, blurred vision.

Varenicline

**Mechanism:** blocks alpha-4-beta-2 nicotinic acetylcholine receptors.

**Dose:**
- 0.5 mg PO daily for three days, then 0.5 mg PO BID for four days then 1 mg PO BID for 11 weeks; may continue an additional 12 weeks if initial treatment is successful.

**Common adverse reactions:** GI intolerance, headache, vivid dreams, insomnia, fatigue, upper respiratory tract infections.

A RCT involving 507 patients with mild to moderate COPD were randomized to receive varenicline versus placebo for 12 weeks, with a 40-week nontreatment followup. It was found to be more efficacious than placebo for smoking cessation (42.3 versus 8.8 percent) and remained significantly higher through weeks nine to 52 (18.6 versus 5.6 percent, OR 4.04, CI 2.13-7.67). Serious adverse events were infrequent.15

Electronic Nicotinic Delivery System (ENDS)

These include e-cigarettes, vaporizers, vape pens, hookah pens that use liquid nicotine heated into an aerosol, which the user then inhales. According to Centers for Disease Control and Prevention (CDC), more than 3 million middle and high school students were current users of e-cigarettes in 2015.16 In surveys, a majority of e-cigarette users perceive these as a tool to quit conventional cigarettes or reduce their risk to tobacco-related disease.17

Common nicotine concentrations of e-cigarette liquids are 6 mg/mL, 12 mg/mL, 18 mg/mL or 24 mg/mL. Propylene glycol or glycerol are main components of most e-cigarette liquids. Testing of some e-cigarette products found the vapor to contain known carcinogens and toxic chemicals (such as formaldehyde and acetaldehyde), as well as potentially toxic metal nanoparticles from the
vaporizing mechanism.\textsuperscript{18}

While ENDS can be helpful adjuncts to tobacco cessation, all the potential harmful effects are not yet known. A single session of e-cigarette use (30 puffs 30 seconds apart), approximating nicotine exposure of one tobacco cigarette, induces significant inhibition of cough reflex sensitivity 15 minutes after its use.\textsuperscript{19} There is also limited evidence on the health effects of passive vapor exposure.

Nonetheless, most experts believe that inhaling e-cigarette vapor is likely to be less harmful than inhaling cigarette smoke.

**Alternative Aids**

A meta-analysis suggested potential benefit with acupuncture and hypnosis.\textsuperscript{20,21} Regardless of the method chosen, it is important for the patient to realize that their efforts to quit smoking will continue to receive the clinician's strongest support and assistance.

**Behavioral Counseling**

Meta-analysis found that behavioral counseling and pharmacotherapy each have strong evidence of efficacy but combination of the two produces the best results.\textsuperscript{22} Both individual and group counseling are effective. The latter would allow patients to learn coping techniques while supporting others attempting to quit at the same time. Clinician counseling would include giving information about nicotine dependence and withdrawal, identifying triggers and helping provide coping skills to deal with such situations.

Nicotine withdrawal – these include mood changes (depression, anxiety, irritability), increased appetite, weight gain, insomnia, difficulty concentrating and restlessness. Symptoms peak in the first three days of smoking cessation and abate over the next three to four weeks.

Association with environmental triggers – some smokers have difficulty quitting as they usually smoke while doing some pleasurable activities (e.g., while drinking their morning coffee, socializing with friends, after meals, drinking alcohol).

Stress – stress and anxiety are perhaps the more common barriers to quitting that I hear from my patients. Discussing relaxation and stress management strategies may be therefore helpful (e.g., meditation, muscle relaxation, stretching, deep breathing).

One of the best resources for patients in the U.S. is a free quitline support and counseling service (1-800-QUIT-NOW). This automatically links patients to the resources available in their state. The South Dakota QuitLine (1-866-SD-QUITS) has one of the best quit rates in the nation, with a standard quit rate of 42 percent, according to its published success rate (for users registered between Jan. 1 and Dec. 31, 2014 and surveyed between June 15 and July 15, 2015). It offers multi-session counseling and free medications (nicotine patch/lozenge/gum, bupropion, varenicline). More information can be found at http://sdquitline.com.

Other websites – there is also a website available for teens and young adults that provides a toolkit for tobacco prevention and cessation at www.RethinkTobacco.com. The American Lung Association has an online guide for smoking cessation at www.lung.org/stop-smoking. The South Dakota Department of Health Tobacco Control State Plan lists other local resources at https://doh.sd.gov/prevention/assets/TobaccoControlStatePlan.

Mobile text messaging can help suggest behavioral changes, provide positive feedback and allow patients to request additional assistance if needed. The National Cancer Institute has developed such a service, which adolescents and young adults can subscribe to at SmokeFreeTXT program.

**Relapse Prevention**

Hughes et al. estimated that 22 percent of smokers relapsed in the first three months.\textsuperscript{23} Some studies have estimated that 35 to 40 percent relapse between years one and five after quitting.\textsuperscript{24} Nearly two-thirds of smokers who relapse report desire to quit again within 30 days.\textsuperscript{25} I always tell my patients who have relapsed that most smokers would require several attempts before permanently quitting so they should not feel discouraged.

**Conclusion**

USPSTF recommends clinicians to provide tobacco cessation interventions for patients. To successfully provide this care, physicians cannot do it alone. The rest of the office ancillary staff should be utilized to help with cessation counseling and providing support services. For those who are willing to quit, one can utilize the 5 A’s: Ask about tobacco, Advise to quit, Assess willingness to quit, Assist with coming up with a plan and Arrange for follow-up. Pharmacotherapy works best when combined with behavioral counseling. In addition, there are several resources that are available such as the South Dakota QuitLine.


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Utilization of Community Resources

By Stephan D. Schroeder, MD, CMQ, CMD

Abstract
This article will highlight and provide selected examples of existing community services. It will attempt to serve as a reminder and reference for providers to help them improve efforts at utilizing available resources and perhaps institute new services. Coordinating care across all aspects of delivery can help achieve improved control of population health and chronic disease. Community resources can assist the efforts of providers in delivering more complete and continuous care. Those in health care are aided when a collaborative effort is used to help improve care. It is generally accepted that addressing chronic disease at a population level will help diminish cost and improve patient well-being. Social, economic and environmental factors account for a significant influence on health care outcomes.

The focus of health care delivery is generally centered around providers and facilities engaged in direct patient care and delivering continuous services. It is often aligned with a specific geographic site and tends to focus on emergent care and disease or condition management. More basic, and perhaps of significant importance to overall health care improvement, are community organizations that provide beneficial and supporting services and resources. This helps our population maintain health and prevent, or at least taper, the progress to chronic disease.

Chronic disease management has not received the “hot-button” front page status other health conditions receive. Infectious outbreaks such as Ebola or Zika gain immediate attention and media coverage. Trauma and acute MI or stroke are topics that are frequently given major focus from health care systems as they strive to coordinate efforts in addressing them. While chronic disease may not involve major legislative efforts or public awareness focus, it does involve significant cost, morbidity and mortality. Providers are generally trained to triage and treat from an acute face-to-face encounter with less regard for what transpires once the patient leaves the office or the hospital. Awareness of community services can be a crucial tool in managing chronic disease.

Individuals who engage in community efforts may vary in their availability, skills and services depending on where they are based and with whom they are employed. Health care providers can benefit from communicating with these service organizations regardless of whether it involves primary care issues or treatment following procedures or hospitalization. The concept of care coordination as well as services such as health homes depends on a culture of sharing available resources and avoiding the “silo mentality” which neglects community services that can provide timely, efficient patient care.

Creating sustainable, effective linkages between clinical and community services will help to improve patient understanding of disease prevention and chronic care. These services are a partnership between organizations that share the common goal of improving the health of people and the communities in which they live. This linkage can help connect providers with community organizations and public health agencies. The goal of these relationships is to promote healthy behavior by creating coordination between health care providers and public health agencies and community-based services. These connections help fill gaps in needed areas of care in many communities. Finally, there is a need to strategically plan and promote chronic care management improvement.
activities with the ultimate goal to assist, not replace or undermine, the work of providers.

There are a variety of options for community linkages including coordinating services at a single location, providing services at different locations and developing systems to refer patients to needed resources. Strategies that improve access to clinical preventive services such as screening or counseling will help reduce and prevent disease in communities. Having clinical, community and public health organizations work together provides a win-win scenario for those organizations, clinicians and patients. These patients often need assistance in changing unhealthy behaviors. Clinicians can help align those connections to community services. The Agency for Health Research & Quality (AHRQ) features examples of successful clinical and community collaborations and resources for linking clinical practices and community resources.

There is clearly a benefit in focusing on patient interests and embracing patient involvement in this community care. The importance of nonmedical determinants of health need significant consideration. Community size, history and culture are huge factors in how selected communities approach health issues. Overcoming these barriers can be a daunting task that will need a sustained effort by all those involved in providing care. Assessing and managing disease in patients with decreased health literacy is an ongoing challenge. Historically, disease has been approached as patients with a single disease, i.e., diabetes, coronary artery disease, arthritis, depression. Especially in older patients, chronic disease involves multiple conditions all of which can affect treatment and compliance. Condition specific guidelines fail to address comorbidities when the patient has many complex diseases. This emphasizes the need for patient and family understanding of how to manage and stabilize these conditions and further suggests the benefit of community resources. Nearly 67 percent of Medicare beneficiaries have two or more chronic conditions and over 93 percent of Medicare spending involves patients with two or more chronic conditions.

The common goal of better care depends on these relationships. All three elements of the Centers for Medicare & Medicaid Services (CMS) Triple Aim, which are improving quality, decreasing cost and promoting health, are needed to stabilize the future of health care delivery. The growth of bundled payment initiatives and other forms of reimbursement changes contain new models in health care delivery that will result in a shift in payment from volume to value. It will require a population health approach that expands beyond episodic care. Community services will be needed to support and meet the needs of patients across the care continuum. Developing linkages will only be successful if fragmentation can be overcome and information exchanged.

Many providers, including those new to care delivery may feel overwhelmed navigating and making sense out of multiple resources, especially as it involves the patients’ social settings. From the wider spectrum of federal support programs, such as the previously mentioned AHRQ, there are multiple organizations to assist those associated with larger communities and health systems. These include the Comprehensive Unit-based Safety Program (CUSP) and the TeamSTEPPS which are tools that allow providers to work together to increase teamwork, care coordination and patient safety. In addition, the Health Resources and Service Administration is the primary federal agency for improving access and helping with data collection of health care services for those who care for the uninsured, isolated or medically vulnerable patients.

Factors contributing to health in South Dakota communities, especially those in inner city areas or frontier rural regions, can be quite complex. Providing resources to the residents of these areas requires organizations with diversity and portability. Supporting providers in these settings will require resources, knowledge and expertise in caring for patients with limited resources and challenging travel distances.

State agencies including the Department of Health and Department of Social Services offer numerous programs to work with those with chronic disease. Tribal, county and local governments provide support with a large number of programs that address public health, patient well-being and population health. Educational institutions and community organizations are also stakeholders that can promote health and community services. Examples may range from social gatherings, business organizations, faith-based alliances, service clubs and age-related groups from youth to the elderly. All have the potential to collaborate and partner in providing the network needed to deliver community services. This may range from providing and delivering meals, helping with transportation or providing day-care type services. Local insight and feedback are crucial if progress is to be made. It truly takes a “village”
effort to care for one another.

Community health workers (CHWs) can be involved in integrating community-based efforts to prevent chronic disease. CHWs may be known by a variety of names including health advisor, outreach worker, navigator or promoter. They serve as a link or intermediary between health services and the community. This may include helping promote access, improving cultural competence and advocating for the patient. The CHWs can strengthen networks as they have some understanding of the social status and literacy of the patient, especially those in vulnerable situations. Evidence supporting their involvement continues to grow for conditions such as diabetes, hypertension, colorectal cancer screening and asthma. Two Institute of Medicine reports, 1) Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care and 2) A Population Based Approach to Prevent and Control Hypertension, emphasize the work of CHWs especially in high-risk communities in helping support healthy living strategies.

The South Dakota Department of Health Office of Chronic Disease and Health Promotion through the program Good & Healthy South Dakota encourages activity to prevent chronic disease. Likewise, programs such as Better Choices, Better Health provide an opportunity to implement and support disease management from a patient perspective in multiple chronic diseases. There are also disease-specific options such as Everyone with Diabetes Counts, which is a diabetes self-management education program offering evidence-based diabetic training. The South Dakota Diabetes Coalition is an example of an ongoing collaborative effort to improve the quality of life for South Dakotans at risk for or affected by diabetes. This group, like a number of similar organizations, is an effort of multiple entities coming together in a statewide or local effort to improve chronic disease care. These members include providers, dieticians, diabetes educators, health organizations, assorted product vendors and patients.

One of the aims of the Great Plains Quality Innovation Network is promoting efforts to increase patient and family engagement to improve community health care. This is a reflection on the CMS Triple Aim of better health, better care and lower cost. Clearly, managing chronic disease from a patient and community perspective will help achieve these goals.

Examples of Community Health Resources

- https://www.cdc.gov/chronicdisease
- http://goodandhealthysd.org
- http://healthysd.gov
- https://doh.sd.gov
- https://dss.sd.gov
- http://sddiabetescoalition.org
- http://champonline.org
- http://sdpublichealth.org
- http://communityhealthcare.net
- http://ruralhealthinfo.org
- http://thecommunityguide.org
- http://helplinecenter.org

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Genomic Medicine in Primary Care

By Catherine Hajek, MD

Abstract
Genomic medicine is a powerful tool with great potential to improve outcomes in the primary care setting. From a broad perspective, genomic medicine can be applied to rare disease, common disease and pharmacogenetics. There are applications in which it can be used to better identify rare disease, improve screening for common disease, reduce adverse drug effects and help to identify the right medication more quickly. This article provides specific examples of clinical applications for genomic medicine in the realm of cardiovascular disease to provide a better understanding of its potential use in primary care.

Introduction
The role for genomic medicine in the clinical setting has been rapidly evolving over the last several years. According to the National Human Genome Research Institute, genomic medicine is “an emerging medical discipline that involves using genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making).” The rapid evolution of this field is in large part due to the successful sequencing of the human genome, development of analytical tools needed to understand this information and the mechanisms to be able to store the massive amounts of data generated from these types of analytics. Additionally, the cost of genetic testing has been declining, which has increased patient access. We have the tools in place to be able to generate genomic information for a given patient, but how can we use this in a clinically meaningful manner?

The potential to impact patient care and ultimately patient outcomes using genomic information is immense and, from a primary care standpoint, can be classified into two broad categories: genes and disease risk and genes that predict treatment response. Genes and disease risk includes both rare disease and common disease. This article serves to provide examples of existing and potential applications of genomic medicine in the primary care setting with respect to these broad categories.

Genes and Disease Risk
Genetics with respect to disease risk can be viewed on a spectrum. On one end of the spectrum are rare alleles causing Mendelian conditions and on the other end of the
spectrum are common variants contributing to common disease risk. Rare alleles causing Mendelian conditions have very large effects and, when present, significantly affect an individual’s phenotype. Common alleles contributing to common disease have very small effects and may have very little effect on an individual’s phenotype. To better define the extremes and their application in a clinical setting, it is helpful to apply a specific phenotype. Coronary heart disease is a common condition presenting in the primary care clinic and is an area in which extensive work has been done to understand its genomic risk as well as the risk associated with rare variants, thus it serves as a good example phenotype.

**Genes and Risk for Rare Disease**

Approximately 30 million Americans are living with a rare disease. The overwhelming majority of these individuals are affected by a genetic condition and half of these individuals are adults. Often, these patients have a condition frequently seen in the primary care setting. These conditions may go undiagnosed due to their seemingly “common” presentation. The use of family history and genetic testing can help to identify these individuals and guide screening and treatment of the individuals and their families.

Familial hypercholesterolemia (FH) is a good example of a rare disease presenting with hyperlipidemia and coronary heart disease and, in some cases, early onset myocardial infarction. This condition is the result of pathogenic mutations in three genes: PCSK9, LDLRs, and APOB. Individuals with this condition have a significantly increased risk for premature coronary heart disease due to long-standing elevation of their low-density lipoprotein (LDL) cholesterol levels. FH is an autosomal dominant condition with two forms: homozygous and heterozygous. Homozygous FH is very rare, however heterozygous FH has been estimated to have a prevalence as high as one per 250 individuals, to one per 200 individuals. It is estimated that less than 20 percent of those affected are diagnosed, leaving a large portion of affected individuals without appropriate screening and treatment.

Historically, this condition has been identified clinically by evaluation of a patient’s LDL level and family history of early onset heart disease. This is a reasonable approach, but it doesn’t give a confirmatory diagnosis. There is also a chance that a diagnosis may be missed. Individuals in the same family with the same pathogenic mutation may have different LDL levels. One person may have levels that meet criteria for treatment, and the other may not. However, due to the lifelong exposure to elevated LDL levels, treatment would be appropriate for both patients in order to improve outcomes. Thus, screening family members of an affected individual using only LDL levels, may not be sufficient to identify affected individuals. Targeted testing of family members of the proband for the identified causative mutation can more efficiently and accurately identify affected family members to allow for better treatment and screening of affected individuals.

Debate continues as to whether genetic testing for FH is the best diagnostic, however, as the costs of genetic testing continues to decline, there is opportunity for its implementation in the clinical setting. Studies have shown that genetic screening for family members at risk for FH when there is a known causative mutation is the most effective screening strategy. There are limitations and complexities associated with genetic testing, but when a causative mutation is identified, family screening becomes quicker and more cost effective. Hyperlipidemia is a common phenotype presenting in the primary care setting, thus primary care providers have the unique opportunity to be the first to identify these patients and genomic tools can help in this process.

**Genes and Risk for Common Disease**

It is well accepted that there is a genetic component to common disease. For example, twin and family studies have established that 40 to 60 percent of susceptibility to coronary heart disease is heritable. Additionally, common diseases such as heart disease and hypertension often cluster in families; thus, we know there is a genetic influence. Many of these conditions are significantly influenced by an individual’s environment and lifestyle choices, which makes their genetic component difficult to quantify. Since 2007, genome-wide association studies (GWAS) have been used to help quantify the heritable component of common disease. GWAS use a case-control design in which study participants are genotyped for single nucleotide polymorphisms (SNPs) across the genome. Using these studies, associations can be made between a SNP and the trait, such as heart disease. Approximately 31,000 unique SNP-trait associations at GWAS level of significance ($5 \times 10^{-8}$) have been identified for many different common disease traits. Variants discovered are common in the population with minor allele frequencies typically greater than 5 percent and have a very small effect on disease risk with odds ratios generally less than 1.3. There has been a significant amount of effort placed on determining the significance of these variants and their role in the clinical setting. Genomic risk prediction in cardiovascular disease has been one of the areas of focus.

There is clinical utility for improved risk prediction in cardiovascular disease. Between 15 and 20 percent of patients who suffer a myocardial infarction are considered to be at “low risk” based on traditional risk factors; better risk prediction could help to identify these patients earlier. Genomic risk prediction has the potential to
improve this. GWAS have identified approximately 60 risk variants for coronary heart disease. There have been several studies evaluating the use of genetic risk scores using these risk variants for clinical risk prediction and medication stratification for coronary artery disease. A genetic risk score quantifies the risk conferred for a particular trait based on the number of risk variants that an individual carries. In the realm of cardiovascular disease, several studies have demonstrated that high genetic risk scores are associated with increased risk for cardiovascular events.\textsuperscript{10-13} Mega et al.\textsuperscript{14} found that individuals in the highest coronary heart disease genetic risk score category derived greatest benefit from statin therapy based on a number needed to treat that is significantly less than individuals in the lowest genetic risk category. Evidence for using genomic risk in coronary heart disease is certainly growing.

Despite the very promising nature of these results, there are still limitations to their widespread application in the clinical setting. First, the vast majority of GWAS have studied Scandinavian and Western European populations. Thus, the current set of identified risk variants are most applicable in those populations and have limited utility in other ethnicities. Second, risk prediction using genomic risk predictors has not outperformed the current clinical risk predictors such as the Framingham risk score. This is likely due to the fact that the only about 10 percent\textsuperscript{15} of the heritability of the coronary heart disease has been quantified by the current set of risk variants. Much of this missing “heritability” is thought to be related to rare variants not identified by GWAS, but also the very strict level of significance GWAS set as a criteria to identify SNP-trait associations.

Although the clinical utility of genomic risk appears promising in cardiovascular disease and other common diseases with the potential for improved screening in the primary care setting, further studies are required before its implementation in widespread use.

**Genes That Predict Treatment Response**

Pharmacogenetics concerns the relationship of an individual’s genetic composition with their ability to metabolize medications. Genetic factors can influence the efficacy of a drug as well as the potential for adverse effects. Nearly every pathway of drug metabolism, transport and action is influenced by genetic variation. The Clinical Pharmacogenetics Implementation Consortium publishes gene-based dosing guidelines for drug-gene relationships known to be clinically actionable. At present, Clinical Pharmacogenetics Implementation Consortium guidelines are available for more than 20 medications. Additionally, the Food and Drug Administration requires genetic information on package inserts for approximately 160 medications. These lists continue to expand annually.

In the realm of cardiovascular disease, great strides have been made in the use of CYP2C19 genotyping and clopidogrel use. Clopidogrel, a platelet inhibitor commonly used in patients undergoing percutaneous coronary interventions (pci) with stenting, is bioactivated by the cytochrome P450 2C19. The gene CYP2C19 encodes this cytochrome. Variation in this gene can affect how well the enzyme works and ultimately how effective clopidogrel is in platelet inhibition. In 2009, Mega et al. established that individuals who carry an abnormal CYP2C19 gene are at three-fold greater risk of coronary artery stent thrombosis.\textsuperscript{16}

The question remained of how to use this information in the clinical setting. Recently, however, the IGNITE network demonstrated that CYP2C19 genotype-guided antiplatelet therapy post-PCI improved outcomes. In a prospective multi-center trial, this study found that individuals who carry an abnormal CYP2C19 gene have two-fold fewer major adverse cardiovascular events post-pci if switched to an alternative to clopidogrel.\textsuperscript{17} This is the first study which clearly demonstrates improved outcomes with the use of CYP2C19 genotyping and opens the door to its widespread clinical use.

As with other pharmacogenetics variants, CYP2C19 influences the metabolism of many other drugs including proton pump inhibitors, antidepressants and anti-seizure medications. As the field continues to evolve and outcomes data grow, primary providers will have ample opportunity to use this type of information in the context of many other medications.

**Future Outlook**

The evidence for the use of genomic medicine in the clinical setting particularly in primary care continues to mount. Its applications include the ability to more efficiently identify those with rare disease, screen those with common disease and identify the right medication at the right dose for patients. This article focused on three specific examples of clinical application of genomic medicine to illustrate its potential, but there are many other rare diseases that present similar to common disease. GWAS have identified risk variants for many different common diseases which offer the potential for improved screening of common chronic disease as well as offering a better understanding of their underlying mechanism. And many other drug-gene relationships have been established involving commonly used medications which are relevant in the primary care setting. The outlook for clinical applications of genomic medicine is bright, but we must proceed with caution when implementing these new tools to ensure that evidence is sufficient to justify their use in patient care.
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WHEN IT COMES TO CHRONIC DISEASE, YOU ARE OUR FIRST LINE OF DEFENSE.

Healthcare providers play a vital role in preventing and controlling chronic diseases. In South Dakota, that includes referring tobacco-using patients to the SD QuitLine, ensuring screening for various chronic diseases takes place, using health information technology to ensure overall quality of care, and linking patients to other community health and education resources. For practice guidelines and other professional resources, visit www.goodandhealthysd.org/healthcare.
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When should one worry that he or she might be having a heart problem?

Unfortunately, heart symptoms can be all over the board, and sometimes there are no indications for trouble until very late in the game. On top of this, classic heart symptoms can be due to just esophageal spasm or musculo-skeletal strain, and not heart disease at all. That said, there are clues for heart trouble that signal us to seek help.

Taking into consideration the age, gender, size, life-style and situation of the individual in question can be helpful. In general there is a higher incidence of heart problems in people with a smoking history, positive family history, increasing age, and male gender. But heart problems can occur in anyone; so never cover-up or ignore symptoms especially knowing that heart disease in some people, especially diabetics and women, can present with unusual or very minimal symptoms.

Hypertensive and over-weight snorers should have an inexpensive night-time oxygen test to see if a full sleep study is needed. Sleep apnea is a dangerous and important cardiac risk-factor, and I believe way more worthy of attention than cholesterol. If suspicious, talk to your doctor, since discovering sleep apnea could add years to your life.

A middle aged or older person having a heavy sensation in the chest, neck, jaw, shoulder or arm that comes with exertion and is relieved with rest, could be a sign for blockage of coronary arteries. Called angina pectoris, this alone may not be dangerous unless coming on with a decrease in exercise. Still, angina means see your doctor. If these symptoms come on suddenly and do not go away with rest, then you have a very urgent problem, so call 911.

Heart weakness, also called congestive heart failure, or CHF, can be caused by heart-valve disease, long standing high blood pressure, chronic alcohol use, certain viral infections, and more. The most common symptom from CHF is shortness of breath, but almost every illness, especially lung disease can cause this too.

Heart rhythm problems are sneaky and many of us, including me, have a benign sporadic fluttering feeling in the chest that is not dangerous and means nothing, but is worth discussing with your care provider. Runs of heart rate in the 150 range, or rates so fast or slow as to cause weakness or passing out. If this happens to you, go the emergency room.

As complex as all these warning signs may seem, the most important way to diagnose heart disease starts with paying attention to symptoms.
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