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# RHODE ISLAND MEDICAL JOURNAL

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# The Meaning of 'Integrity' in the Health Professions

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This issue of *The Rhode Island Medical Journal* calls out a conflict in our concept of the integrity of health professions. The typical construction of integrity of health professionals – *Primum non nocere* (first, do no harm – an expression of the ethical precept of non-maleficance) – dates from the pre-scientific age, before the as-

sociation of science, health and public health was understood. *Primum non nocere* was likely the mid-nineteenth century Latinization of the Greek promise, ἐπι δηλήσει δὲ καὶ ἀδικίῃ εἶρξεν (to abstain from doing harm). Set in the context of the Hippocratic Oath, that promise helped professionals and the public understand that there were activities that were carried on for the profit of the professional but which might pose risk to patients, and created the first professional obligation to put the good of patients and public health above self interest. In the pre-scientific age, before well-designed double-blinded clinical trials (that incorporate appropriate endpoints and statistical power), much of what professionals did was as likely to be harmful as it was beneficial, and only the ethical professional, who had years of experience, could tell the difference. The location of the principal of non-maleficance in an oath, overseen, at least theoretically, by a higher power, created a sacred space around health professionalism, and made it clear that health professionalism stood apart from the activities of the marketplace. The marketplace exists for the profit of individuals. Health professionalism, the Oath seemed to say, exists for the common good, even though the Oath was created when there was no way to establish what that good represented.

But since the beginning of *scientific* medicine and *scientific* public health, *beneficence*, another ethical principle, has been understood to be important to the notion of integrity in health professionalism, and to be part of the meaning of medicine as a profession itself. Beneficence, or un-self-interested advocacy, suggests that health professionals have an ethical obligation to effect affirmative good, instead of just refraining from doing measurable harm, and



This image of the Hippocratic Oath was used by the 3rd General Assembly of the World Medical Association in 1949 in London, when it adopted the international code of medical ethics.

is a construct that has become meaningful only during the scientific age of medicine and public health, an age in which we have tools for measuring the personal and public health impact of what we do. In order for the health professions to be beneficent, we need to be able to show how our activities create measurable benefits to individuals and the society itself. The principle of beneficence, then, requires a science

that is evidence-based, that chooses meaningful endpoints, that include a population-based analysis and measures and reports the cost benefit of our activities, since society has a responsibility to weigh the benefits of the service we provide against the cost of other services and activities that it might consider in the public interest. Thus, accountability and transparency, as well as fidelity (truth telling about risks and data) and advocacy, have become part and parcel of the integrity of health professionalism, as the power of scientific medicine has evolved. Beneficence also means that over-treatment, the self-interested misuse of data, and the use of advertising to purvey false or misleading data, has become unethical on its face. In addition, the affirmative obligation for advocacy, for health professionals to come into the public arena and explain our science and to advocate for its widespread use in making public choices and changing behaviors, has become part of the ethical obligation of health professionals (again, as the evolution of scientific medicine has changed our ethical obligations, and changed the meaning of medicine as a profession itself).

In this special edition of *The Rhode Island Medical Journal*, six important contributions help us understand the difference between non-maleficence and beneficence in the practice of today's health professionals. **LORI KEOUGH, PhD, MEd, FNP-BC**, lays out the ethical responsibility of health professionals to be immunized against common infectious diseases, and sketches the logic behind the influenza vaccination mandate for health professionals who practice in health care institutions. **JEFFERY BORKAN, MD, PhD**, addresses the affirmative need for primary care health professionals to

practice in teams, in order to achieve best patient and population health outcomes. **ROSA BAIER, MPH; LORI KEOUGH, PhD, MEd, FNP-BC**; and **JAMES McDONALD, MD, MPH**, look at transitions of care as an area of professional responsibility, but one which sometimes has been abandoned by the health professional community, leaving the US to become a place where 20 percent of our frail elderly are readmitted to the hospital with 30 days of hospitalization, surely an example of a glaring health professional failure. James McDonald, MD, MPH correctly construes appropriate prescribing of opiates as an affirmative professional responsibility, where the lack of health professionals' understanding of the full import of the need both to do good and to do no harm has led to an epidemic of prescription drug overdose deaths in the US and in Rhode Island. **CATHERINE CORDY, RPh**, and **PATRICK KELLY, RPh**, explain the functioning of the Rhode Island Prescription Monitoring Program, a new tool that helps health professionals to do good (as they do no harm) when it comes to opiate prescribing, a tool whose use is imperative before opiates are prescribed. And finally, **JAMES McDONALD, MD**, explicates best practices around opiate prescribing, so that health professionals can use this powerful class of medication in the interest of patients, without incurring huge public health risk.

We hope this issue of *The Rhode Island Medical Journal* will help all health professionals understand how the meaning of integrity in the health professions has changed, and how science allows us to go beyond "do no harm" and move into the realm of helping patients, and all Rhode Islanders, live better lives. ❖

## Failure to Become Immunized When Caring for Patients: An Ethical and Professional Obligation

LORI KEOUGH, PhD, MEd, FNP-BC

In late September 2012, changes to the Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW) were proposed to reflect the most current (2011) recommendations of the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP). One of the proposed changes drew many people to a public hearing: the requirement that all Health Care Workers (HCW) either receive seasonal influenza vaccine or wear a mask when providing face-to-face patient care during "period(s) in which flu is widespread." A brief review of the rationale for mandating seasonal influenza vaccination among HCWs follows, along with ethical implications. The risks and benefits of seasonal influenza vaccination are reviewed as well.

### Who Must Be Vaccinated And Why?

HCWs make valuable contributions to our health care system and are essential in meeting patients' health care needs. HCWs, broadly defined, are those individuals who are employed or volunteer in a health care facility and have direct contact with patients, including, but not limited to, physicians, physician assistants, nurses, nursing assistants, pharmacists, clinicians and therapists from all disciplines (for a complete definition see RI Regulations: R23-17-HCW, 2012). When individuals become licensed HCWs, they accept the responsibility to uphold professional standards of care and practice, defined by a specific code of ethics. Regardless of professional discipline, all HCWs are obligated to adhere to the general ethical principles of *non-maleficence*, the duty "to do no harm," and *beneficence*, to behave in way that promotes patients' best interests. These principles imply an obligation not to expose patients to vaccine-preventable illnesses which HCWs may themselves contract and transmit to patients, in short, to make provisions (e.g., vaccination of HCWs) to avoid doing harm to patients and to enable HCWs to continue giving care to patients (by themselves avoiding illness).

The notion that HCWs may spread pathogens dates back to Ignaz Semmelweis' 19th-century data on the infection of patients whose providers had not washed their hands. Since that time, HCWs have been enjoined to minimize the risk of disease transmission to patients (and vice versa) by washing



hands before and after patient encounters, by allowing themselves to be screened for communicable diseases such as tuberculosis, and by allowing themselves to be vaccinated against vaccine-preventable communicable diseases such as rubella. (See, for example, relevant Rhode Island regulations: <http://www.health.ri.gov/immunization/for/healthcareworkers/index.php>).

### Why Vaccinate?

Seasonal influenza is a significant public health issue. In the United States alone, it causes more than 200,000 hospitalizations and 36,000 deaths annually.<sup>1</sup>

Fortunately, seasonal influenza vaccines have proven to be effective in preventing illness onset in a majority of exposed-but-vaccinated people, with the exception of those who are immune-compromised or immune-suppressed. Several random control trials have demonstrated significant reductions in influenza-related mortality – as high as 44% among nursing home residents and hospital inpatients – when HCWs are vaccinated.<sup>2-9</sup> Similarly, mathematical models of seasonal influenza vaccination of HCWs in nursing homes suggest a 60% prevention of influenza virus infections among vulnerable patients.<sup>10</sup>

Reasons to vaccinate *both* patients *and* HCWs against influenza are well documented. HCW vaccination *indirectly* protects high-risk patient populations for which *direct* immunization does not suffice to reduce risk, e.g., infants, elders, and patients who are immune-compromised or immune-suppressed.<sup>6</sup> As well, vaccination reduces the risk that HCWs will become infected, thus contributing to societal immunity ("herd immunity"), and reducing workforce attrition during influenza outbreaks.<sup>10,11</sup>

In fact, many scientific and government organizations have recognized the importance of HCW seasonal influenza vaccination, and have supported efforts to increase the proportion of HCWs thus vaccinated. Since July 2007, for example, the Joint Commission has required some hospitals and long-term care centers to establish onsite influenza vaccination programs, including education and the evaluation of coverage. In this vein, the Centers for Medicaid and Medicare Services is likely to require hospitals (beginning in 2013) to report influenza vaccination coverage as part of inpatient quality reporting. Furthermore, many professional

societies have endorsed influenza vaccination requirements for HCWs: the Infectious Diseases Society of America, the National Foundation for Infectious Diseases, the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control, and the American College of Physicians. (See: <http://www.immunize.org/honor-roll/>)

**Table 1.** Benefits and risks associated with administration of influenza vaccine

Costs	Benefits
Vaccine Side Effects: Soreness at the injection site, low-grade fever, aches, Guillian Barre Syndrome, allergic reaction	Patient Safety and Public Health: <ul style="list-style-type: none"> <li>• Decreased morbidity and mortality</li> <li>• Increased safety and quality of care</li> </ul>
Economics: Upfront costs for employers offering vaccines at no cost to employees	Economics: Savings in influenza related health care expenditures and time missed from work due to illness

### The Historical and Scientific Aspects of Vaccine Controversy

The controversy surrounding mandatory vaccination, in general, dates back almost a century (Stern, 1927), and perhaps even further. The controversy incorporates issues of individual rights *as well as* ethical obligations to do no harm and to promote the best interests of patients, and the costs and benefits of seasonal influenza vaccination for various groups (Table 1).

### Safety Issues

Safety concerns (vaccine side effects) likely represent the most commonly cited reason to not be vaccinated. Although seasonal influenza vaccine is both safe and effective *most* of the time, adverse reactions can and do occur. These events are closely monitored and researched by the CDC’s Vaccine Adverse Events Reporting System (VAERS). In 1990, VAERS was established as a national passive reporting system, accepting reports from the public on adverse events associated with vaccines licensed in the United States. According to VAERS (<http://www.cdc.gov/flu/professionals/acip/adverse-tiv.htm>), serious adverse events are rare, often 1 or 2 per million, and in clinical trials, serious adverse events associated with the use of seasonal influenza vaccine were reported to occur in less than 1% of all vaccinations.<sup>12,13</sup> Similarly, although it is true that an individual can be vaccinated and still contract the flu, being vaccinated significantly decreases the chance of disease transmission.<sup>2-9</sup>

### Why Mandate?

Significant precedents for mandatory vaccination are well established in the United States.<sup>14</sup> In the early 20th century, for example, the country was ravaged by communicable diseases that have been virtually eliminated since that time because of mandatory vaccination (Table 2).<sup>14</sup>

Specific to seasonal influenza vaccines, the CDC has *recommended* that health care workers get yearly influenza vaccine

since 1981, with a national goal of 90% of HCWs vaccinated (CDC, 2012). As noted, some health care organizations *offer* no cost vaccines to their workforce and others *assure* high vaccination rates by *mandating* vaccination. Nonetheless, during the 2009-2010 influenza season, an estimated 61.9% of HCWs were vaccinated, and during the 2010-2011 influenza season – the season *after* the 2009 H1N1 pandemic – an estimated 63.5% of HCWs were vaccinated. In comparison, 98.1% of HCWs whose employers *assured* vaccination were vaccinated in the 2010-2011 influenza season.<sup>15-17</sup>

Given the history of vaccine uptake percentages in HCWs whose employers offer optional influenza vaccination, it is unlikely that voluntary programs will achieve vaccination rates sufficient to protect the health and safety of patients. Therefore, in line with licensed health professionals’ obligation “to do no harm” (non-maleficence), on the one hand, and to promote health (beneficence), on the other, mandating seasonal influenza vaccination is essential.

We should note that In the United States, HCWs are not the only group required to be vaccinated against communicable diseases. Children, for example, are required to be vaccinated prior to enrollment in school, camp or child care settings – a requirement that dates back to the 1850s in Massachusetts for smallpox vaccination.<sup>15-17</sup>

### Why Regulate?

In the past, seasonal influenza vaccination has been left in the hands of individual health care organizations, under the aegis of quality and safety standards. Some *offered* vaccination; others *required* it. Some *offered vaccine at no cost* to HCWs, while others *passed on the cost* to HCWs. In a situation such as this, rules and regulations, under the aegis of strong laws, are a good way to achieve uniformity.

Newly promulgated (December 2012) regulations in Rhode Island do not require HCWs to obtain annual vaccinations for seasonal influenza, but rather, require HCWs to protect their patients against influenza transmission one way or another: *either* by being vaccinated, *or* by wearing a mask for direct patient contact during periods in which flu is widespread. This approach places responsibility on the individual HCW, who, not withstanding possible medical exemptions, is accountable for his/her choice to obtain, or not obtain, the influenza vaccine.

Ever since society began understanding the mechanisms of communicable disease transmission, HCWs have had an

**Table 2.** Early 20th Century Reports of Communicable Disease Cases and Deaths in the United States<sup>14</sup>

Year of Reporting	Communicable Disease	Number of Cases	Number of Deaths
1900	Smallpox	21,064	894
1920	Measles	469,924	7,575
1920	Diphtheria	147,991	13,170
1922	Pertussis	107,473	5,099

ethical obligation to protect themselves and their patients from exposure. Now, the obligation to protect patients from seasonal influenza has been enshrined in Rhode Island law and its accompanying rules and regulations. This development will work to protect patients, enhance the public's trust, and protect a much-needed healthcare workforce.

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## Training the Primary Healthcare Team for Transformed Practices

*Healthcare in America is being transformed, but is the healthcare workforce prepared?*

JEFFREY BORKAN, MD, PhD

### ABSTRACT

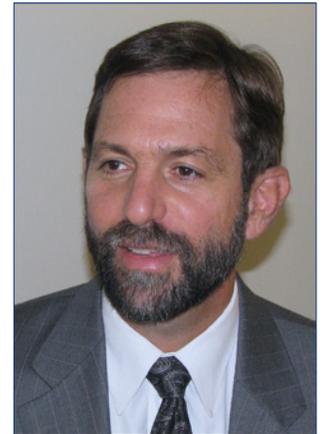
Sweeping changes are taking place in American healthcare, with new practice models rapidly emerging such as Patient Centered Medical Homes and Accountable Care Organizations. Payment mechanisms, so long based on fee for service, are being augmented and in some cases supplanted by “per member per month” and “pay for performance” approaches, as risk contracts become more common – and normative. Is the health workforce ready for these changes? What professional skills and competencies are needed for “transformed practices?” This paper addresses these questions, examining the current state of training for the health professions today, exploring the development of skills, attitudes, and knowledge across the educational continuum, and suggesting future directions for professional development.

**KEYWORDS:** Patient Centered Medical Homes (PCMHs), Accountable Care Organizations (ACOs), healthcare transformation

### INTRODUCTION

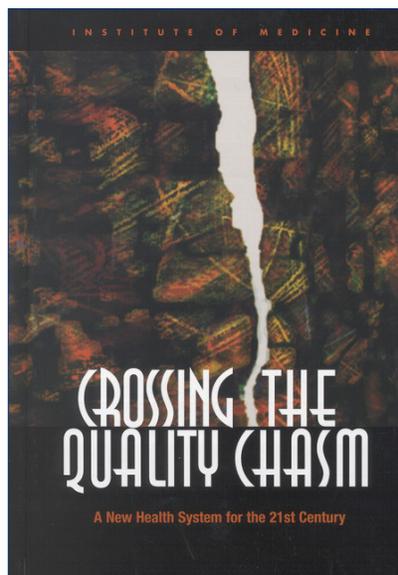
Sweeping changes are occurring in American healthcare, accelerated by the implementation of the Accountable Care Act. These range from new practice models such as Patient Centered Medical Homes (PCMHs) and Accountable Care Organizations (ACOs), to innovative payment mechanisms. New norms are being created as fee for service is being augmented and in some cases supplanted by “per member per month” and “pay for performance” approaches and as risk contracts become prevalent. The further implementation of the Affordable Care Act will ensure that more patients and families have health insurance coverage. This likely will bring a greater focus on primary care and prevention, as well as a vastly increased demand for comprehensive, whole-person, first-contact care, provided by generalists such as family physicians, primary care internists, and pediatricians.

However, achieving optimal health and well-being for patients, their families, and communities may demand more than what an individual physician can provide. Institute of Medicine reports, including *To Err is Human—Building a Safer Health Care System*,<sup>1</sup> *Crossing the Quality Chasm*,<sup>2</sup> and *Integrating Primary Care and Public Health*,<sup>3</sup> have underscored the critical need for developing new approaches to patient care that focus on patient safety, primary care, and population health in order to deliver high-quality care. New emerging models, which promise to transform practice with improved quality, outcomes, and patient experience at lower cost, such as PCMH and ACO, will require that primary care doctors act in teams with a range of other providers in caring for individuals, communities and populations. To be successful, these teams – composed of physicians, nurses, behavioral health specialists, pharmacists, medical assistants, and others – will need to know how to work together in an integrated, coordinated, seamless fashion. In addition, tomorrow’s healthcare teams must be as facile in matters such as population health,



information technology, and care coordination as they are in measuring blood pressure, diagnosing ailments, or writing prescriptions.

The goal of this article is to examine the current state of healthcare workforce training for “transformed practices” in the new healthcare environment, to suggest key skills and competencies that are required for success, and to stimulate both discussion and action. The focus of analysis is the preparation of members of healthcare *teams* for work primarily in *Patient Centered Medical Homes* and secondarily in *Accountable Care Organizations*, but the skills thus examined are generalizable to other integrated, coordinated settings. (Table 1)



**Table 1.** Characteristics of Patient Centered Medical Homes and Accountable Care Organizations

Patient Centered Medical Homes <sup>1</sup>	Accountable Care Organizations <sup>2</sup>
<ul style="list-style-type: none"> <li>• Personal physician</li> <li>• Physician directed medical practice</li> <li>• Whole person orientation</li> <li>• Care is coordinated and/or integrated</li> <li>• Quality and Safety</li> <li>• Enhanced access</li> <li>• Payment reform</li> </ul>	<ul style="list-style-type: none"> <li>• Group of physicians, other healthcare professionals, hospitals and other healthcare providers that accept a shared responsibility to deliver a broad set of medical services to a defined set of patients across the age spectrum and who are held accountable for the quality and cost of care provided through alignment of incentives.</li> <li>• Primary care should be the foundation of any ACO</li> <li>• The goals of an ACO structure are to improve the quality and efficiency of care provided and to demonstrate increased value from health care expenditures.</li> </ul>

**Table 2** lists important domains of essential skills and competencies.<sup>1,2</sup> Though many of these elements are present in the curriculum of a broad range of medical schools, students often have limited exposure to them. For example, though inter-professional teamwork is often critical in the professional lives of physicians, irrespective of discipline, Alpert Medical School of Brown University devotes only two half-days to the topic through a recently established program. Furthermore, systematic review of training in these skills and competencies is lacking in the main.

**Where in the educational continuum can skills, attitudes, and knowledge be obtained?**

**Table 2.** Domains of Skills and Competencies Required for Transformed Practices such as PCMH and ACOs<sup>5,6</sup>

Essential Skills
<ul style="list-style-type: none"> <li>• Patient Centered / Whole Person Care</li> <li>• System-Based Care</li> <li>• Practice-Based Learning</li> <li>• Communication &amp; Professionalism</li> <li>• Teamwork &amp; Interprofessional Training</li> <li>• Chronic Disease, Practice &amp; Population Management</li> <li>• Coordination &amp; Transitions of Care</li> <li>• Quality, Performance, &amp; Practice Improvement</li> <li>• Information Technology</li> <li>• Integrated Behavioral Health</li> </ul>
Additional Skills
<ul style="list-style-type: none"> <li>• Facilitative Leadership vs. Authoritarian Leadership</li> <li>• Aligned Vision for Clinical Care, Operations, and Financial Function</li> <li>• Healthy Relationships Characterized by Rich Communication, Shared Trust, and Regular, Protected Time to Reflect and Learn</li> </ul>

One of the key questions in preparing the healthcare workforce for transformed practices is how to reach them for training. No one has as yet designed a single, unified system that can improve skills and competencies efficiently, effectively, and generally, i.e., across *all* types of healthcare professionals, irrespective of level. As transformed practices become more widespread, new skills and competencies will be required, not only of students in the various health professional schools, but also of persons in the vast professional workforce currently deployed. Ideally, the knowledge, skills and attitudes required for such work would be included at multiple points in “educational spirals” – with greater depth and complexity at each level of training. Professional schools would offer theoretical and experiential learning in key skills and competencies right at the start of training, and continue the formation process through graduate and post-graduate training, residencies, and fellowships. Lifelong learning would be encouraged with further opportunities for continuing education/professional development, incentivized with regulatory certification and recertification. As well, healthcare professionals would learn about transformed practices *through their own experiences as patients* in such settings.

**What are the skills and competencies needed for transformed practices?**

Multiple new essential skills and competencies will be needed for members of the healthcare team to function effectively in transformed practices. *Essential skills and competencies* are defined as skills and competencies which enable people to perform tasks required by their jobs, as well as to adapt to changing job requirements.

**What is the current state of training for specific professions?**

*Physician Assistants (PAs) and Nurse Practitioners (NPs)* Many essential skills and competencies required for transformed practices are intrinsic to PAs’ and NPs’ training and roles, including a focus on team-based care, care coordination, and integration of the various elements of care. Currently, major differences exist in the variously defined roles of PAs and NPs in the PCMH, varying from being considered a part of the healthcare team (PCPCC definitions)

to capacity for independent practice in states where this is allowed (NCQA standards). Nonetheless, "The American Academy of Physicians Assistants (AAPA) supports the medical home concept as a means to expand access and improve the quality of patient care." [Adopted 2008 and amended 2010], and as a result, continuing education sessions are offered at PA educational conferences regarding the PCMH, and recently, an online community of PAs involved with PCMHs has been initiated.

### Nursing

As with PAs and NPs, many essential skills required for transformed practices are intrinsic to training and role – from team nurse to nurse care manager. Traditional nursing skills have been put to the test by the demands of the new roles in transformed practices, for example, the role of the "nurse care manager." Although the majority of nurses in such new roles have little or no additional training, they have expanded access to continuing education through collaborations and online courses. One of first of these opportunities was offered by John Hopkins and is composed of online learning modules. The Hopkins' "Guided Care" program is designed to produce a "specially educated registered nurse" who "plays a critical and central role in ensuring that patients receive high-quality and coordinated care."<sup>3</sup> Another interesting development has been the establishment of new national standards for master's level programs in nursing that incorporate criteria for Quality Improvement and Safety, Translating and Integrating Scholarship into Practice, Informatics and Healthcare Technologies, Health Policy and Advocacy, Interprofessional Collaboration for Improving Outcomes, and Clinical Prevention and Population Health.

### Medical Assistants, Medical Office Assistants, Coaches, and Patient Navigators

Few training programs provide medical assistants, medical office assistants, coaches, or patient navigators with the skills and competencies needed for transformed practices. Individuals in these roles who work in transformed practices such as PCMHs must get upgraded mostly through on-the-job training. However, some collaborative and working groups help to facilitate training for these crucial workers, and a few programs, such as one offered by the University of Utah, are designed specifically for new models of practice.

### Pharmacists

Pharmacists, perhaps more than any other professional group, have engaged in training in the skills and competencies needed to serve transformed practices through innovative educational programs at select schools of pharmacy in Ohio, New Jersey, Minnesota, Washington State, and Connecticut, among others. Interdisciplinary team training in schools of pharmacy is common. In addition, advanced continuing education is frequently offered by professional groups with efforts to encourage expanded roles to include

provider/medical service functions. A concerted effort has been made to enhance the patient-pharmacist-physician collaborative relationship with the pharmacist as a physician extender, using evidence-based practice in areas such as chronic disease management.

### Behavioral Health

Behavioral health professionals, whether psychologists, psychiatrists, social workers, or other therapists, have had particularly good access to training for collaborative practice and interprofessional teams. Given the high incidence of psychosocial complaints and the connection of health and behavior, integrated behavioral health services is considered to be one of the essential requirements of any meaningful primary care initiative. The American Psychological Association provides multiple opportunities to train the psychological services workforce. Other groups, such as Collaborative Family Healthcare and the Society of Teachers in Family Medicine, provide relevant annual conferences and training opportunities, as well. Although formal specialty in primary care psychology has yet to emerge, increasing numbers of formal training experiences, including postdoctoral fellowships, rotations on internships, and practicum experiences at the doctoral level have appeared. Psychology residency training in "primary care psychology" is available at a few locations (including the Department of Family Medicine at Brown University).

The field of social work has given much thought to the role of social workers in the patient centered medical home. There are natural parallels in traditional social work skills and competencies, such as comprehensive case management for the whole person – medically, socially, psychologically, functionally and economically – within the context of his/her support system. Social workers are trained to assess, intervene, and consult at multiple levels – individual, family, community – and to provide care coordination and patient navigation. Social workers not only provide essential support to patients and patients' families, but also tend to know *what* services are available in a given community and *how* to access them – capabilities that are critical to transformed practices.<sup>4,5</sup>

### Medical and Osteopathic Students

Medical and osteopathic students around the US are beginning to get exposed to PCMH clinical sites and curricular modules at a number of schools, including the Alpert Medical School of Brown University. A growing number of PCMH-relevant clerkship programs are in place and scores in the planning phase. One medical school, the University of Oklahoma at Tulsa, may represent a "best practice." In 2009, the OU President announced, "...new models of care such as patient centered medical home... must be taught to physicians in training if we are to create a high quality and more efficient health care system in the US." OU has proceeded to provide such training in their medical schools, with others

planning to follow. The proposed *Primary Care-Population Health Program* at the Alpert Medical School will expand the OU model even further. Twenty-four students per year will receive a unique education that integrates basic science with medical science and population health.

### Residency Education & the PCMH

Individual and networked pediatrics, family medicine, and internal medicine residency programs around the country have converted their training sites to patient centered medical homes, with improvements in the curriculum to provide necessary skills. A 2012 survey of Departments of Family Medicine reveals that nearly 90% are actively involved in transforming the care model in at least one of their residency program teaching clinics to a PCMH model.<sup>6</sup> Their approaches vary widely, however, from focusing on special populations for the PCMH, such as the homeless (e.g., Jefferson Medical), to creating a PCMH with single third party incentives (e.g., Michigan Blue Cross Blue Shield), to creating a PCMH with multiple third party incentives (Brown-CSI-RI), to whole-system reform with incentives (Cleveland Clinic, Kaiser, and Group Health). A few areas have organized regional collaboratives to transform primary care residencies into medical homes. The best known of these initiatives are Washington State's Medical Home Collaborative (11 residencies), the "I3 Collaborative" in South Carolina, North Carolina, and Virginia (23 programs: Family Medicine, Internal Medicine, Pediatrics), and a Colorado initiative (7 Family Medicine programs).

### Fellowship Programs

At the present few fellowship programs prepare recent residency grads for PCMH and other transformed practice and leadership. Four exceptions include:

- "Transforming Primary Care" Fellowship in PCMH at UCLA-Harbor
- Individual fellowship with Dr. Perry Dickinson at U of Colorado, Denver
- Einstein School of Medicine Fellowship (includes PCMH team building)
- Healthcare Hot-Spotting and Super-Utilizer Fellowship, Crozer Keystone Health System, Department of Family Medicine, Camden Coalition of Healthcare Providers, Cooper University Hospital

### Suggestions for the Future

We will have to do more if we expect to prepare the health-care workforce to meet the needs of emerging transformed practice models. Healthcare professional training programs in all fields need to be involved and need to work together. Although we appear to be in a rapid-expansion phase in education, training, and consultation, we need additional demonstration and full-scale projects at the local, state, and national levels. In addition, we will likely need new educational models that reach learners and veteran staff where they live and work. These will have to be tailored to specific professional roles and settings. New efforts to collect, disseminate, and evaluate curricula, teaching methods, and educational mediums should be encouraged.

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## Transitions of Care: Professional Expectations

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### ABSTRACT

Successful cross-setting care transitions require timely, accurate and sufficient communication of clinical information between healthcare providers, so that downstream providers can immediately assume responsibility for patient care. However, despite our desire to provide the highest quality care to our patients, much variability exists in the frequency and effectiveness of communication during transitions. This article describes care transitions using case studies and a review of current policy, and then proposes professional standards. To define professional standards for care transitions, the authors draw upon their combined experience with licensure, regulation and quality improvement. They also present information about the Department of Health's Continuity of Care Form and Healthcentric Advisors' Best Practice Measures for Safe Transitions. Both tools establish core expectations for communication that can improve patients' experiences and health outcomes, as well as facilitate cross-setting collaboration, relationship building, and referral patterns.

**KEYWORDS:** Care transitions, communication, professional standards, patient safety, cross-setting

### TRANSITIONS IN CARE

A care transition occurs when a patient moves from one healthcare provider or setting to another.<sup>1,2</sup> Successful transitions require timely, accurate and sufficient communication of clinical information between healthcare providers, so that downstream providers can immediately assume responsibility for patient care.<sup>3,4</sup> Well-executed transitions can improve outcomes and patient satisfaction, decrease costs and ensure that patients understand how, when and where to seek help.<sup>4,5,6</sup> But how do providers know what is their responsibility regarding care transitions? And how can we build a healthcare system in Rhode Island that ensures that providers have the knowledge and means to implement such expectations? Although both the American Nurses Association (ANA) and national medical associations<sup>7</sup> have endorsed a care transitions consensus policy statement that calls for clear communication, timely information transfer and professional accountability (see Table 1),<sup>8</sup> a great deal of

variability exists among providers (by role and setting) in the frequency and effectiveness of communication during transitions – despite our desire to provide the highest quality care to our patients.

### Case Studies

**Case 1:** A 39-year-old woman presents to an outpatient clinic complaining of headache, fever and neck pain. The provider conducts an exam and assessment. The nurse takes vitals, administers medications and obtains labs. The provider tells the patient to go to the nearest emergency department (ED). He offers directions to the emergency department; the patient knows how to get there and travels there by personal vehicle. In the ED after triage, registration and sitting in the waiting room for two hours, the patient has a generalized tonic-clonic seizure. The patient is evaluated by ED staff immediately and, after appropriate diagnostic evaluation, determined to have meningitis.

**Case 2:** An 82-year-old male had cardiac bypass surgery last year and now admitted for an aorta-femoral bypass. The surgery is complicated and unexpected complications, pneumonia, wound infection and atrial fibrillation lead to a prolonged hospital stay. Upon discharge late Friday night, he is given a list of his medications. Although mentally quite sharp, he is confused regarding the dosage of the beta blocker: the cardiologist in the hospital told him to take two tablets twice a day and the prescription says one tablet once a day. He is confused about the dose of the antibiotic as well that was written by the hospital physician. He leaves messages for the cardiologist, the hospital physician and his primary care provider seeking clarity. Not knowing what to do, he does not take any medication. Three days later, he is readmitted for shortness of breath.

### State of the Science:

#### Evidence to Support the Need for Transitions in Care

In our increasingly fragmented healthcare system, providers often do not have the information we need to ensure seamless care delivery within or between settings. For patients discharged from the hospital, for example, this can result in medication errors,<sup>9</sup> incomplete transfer of discharge information to downstream providers (including community

Table 1. Transitions of Care Consensus Policy Statement

National Recommendation <sup>1</sup>	Current Status Rhode Island	Future State
1. Accountability	Based on individual organizations' policies and procedures.	Well established professional standards for relevant disciplines
2. Communication: clear and direct communication of treatment plans and follow-up expectations	Communication standards (content and timing) are set forth in Healthcentric Advisors' Safe Transitions project's setting-specific care transitions best practices (available upon request).	Communication occurs in real time, is multidirectional and is interoperable with various interfaces.
3. Timely feedback and feed forward of information		
4. Involvement of the patient and family member, unless inappropriate, in all steps	Based on individual organizations' policies and procedures	Patients have up to date personal health record and achieved optimal level of health literacy.
5. Respecting the hub of coordination of care	Fragmentation across settings of care Pockets of successful coordination of care	Patients are routinely part of a PCMH where care is transparently coordinated. Infrastructure is supported by up to date technology.
6. All patients and their family/caregivers should have and be able to identify who is their medical home or coordinating clinician (i.e., practice or practitioner).	Recent legislation requires patients to self-identify their primary care physician, although requirements to print the PCP's name on insurance card were eliminated.	PCMH is fully integrated into a health care system.
7. At every point along the transition the patient and/or their family/caregivers need to know who is responsible for their care at that point and who to contact and how.	Healthcentric Advisors' care transitions best practices incorporate the four patient activation concepts pioneered by Dr. Eric Coleman, <sup>2</sup> including ensuring that patients understand their conditions, the "red flags" that should prompt outreach and whom they should call for help.	Patients/Caregivers optimize secure media for multidirectional relevant communication.
8. National standards should be established for transitions in care and should be adopted and implemented at the national and community level through public health institutions, national accreditation bodies, medical societies, medical institutions etc., in order to improve patient outcomes and patient safety.	National standards do not yet exist, but Healthcentric Advisors' care transitions best practices establish local standards. The Office of the Health Insurance Commissioner has directed local health plans to incorporate the hospital best practices into contracting.	Well established and accepted national standards which incorporate professional expectations, appropriate reimbursement and technology
9. For monitoring and improving transitions, standardized metrics related to these standards should be used in order to lead to continuous quality improvement and accountability.	Healthcentric Advisors' care transitions best practices include metrics that are driving the quality improvement activities underway by the Safe Transitions project's five community coalitions. The hospital and physician best practices are also incorporated into some providers' contracts with local health plans.	Quality metrics are used continuously and tied to health outcomes.

1 Snow V, Beck D, Budnitz T, et al. Transitions of Care Consensus Policy Statement American College of Physicians-Society of General Internal Medicine-Society of Hospital Medicine-American Geriatrics Society-American College of Emergency Physicians-Society of Academic Emergency Medicine. Gen Intern Med 2009 August;24(8):971-976.

2 Coleman EA, Parry C, Chalmers S, et al. The care transitions intervention: results of a randomized controlled trial. Arch Intern Med 2006 Sept 25;166(17):1822-8.

physicians)<sup>10,11</sup> and increased healthcare utilization,<sup>12</sup> all of which reduces the likelihood of optimal patient outcomes. In 2009, the Commonwealth Fund's State Scorecard on Health System Performance ranked Rhode Island 49<sup>th</sup> out of 51 for ambulatory care-sensitive hospital admission among Medicare beneficiaries<sup>13</sup> and Rhode Island Department of Health data demonstrate approximately one in five hospitalized adults are readmitted to the same hospital within 30 days of discharge.<sup>14</sup> Both measures are considered somewhat preventable with high-quality care, and are often used as proxy measures for care transition outcomes.

Numerous efforts are underway in Rhode Island to improve care transitions, including the Rhode Island Department of Health's long-standing Continuity of Care Form,<sup>15</sup> required for facility-to-facility transitions, and Healthcentric Advisors' Medicare-funded Safe Transitions project,<sup>16</sup> which includes multi-stakeholder collaboration to implement systems change that improves care coordination and reduces unplanned care and costs.<sup>17</sup> Since the project began in 2008, readmissions have decreased from 31.7 to 25.1 per 1,000 Medicare beneficiaries.<sup>18</sup> This translates to 802 fewer Medicare patients readmitted to the hospital between June and December 2011 and \$8.4 million in cost avoidance to Medicare during just that six-month period. These successes illustrate Rhode Island's leadership to date and the potential for collaboration to further improve the quality of care we provide.

To define professional standards for care transitions, the authors drew on their combined experience with licensure, regulation and quality improvement. Our methods included reviewing the care transitions literature and consensus statements, case studies from disciplinary issues, and qualitative input collected throughout the Safe Transitions project and during a November 2012 group discussion with the project's community advisory board. The board includes inpatient and outpatient physicians and representatives from commercial health plans, Medicaid, and the home health, hospice, hospital, nursing home and physician office settings. We also drew from Healthcentric Advisors' setting-specific care transitions best practices, developed via stakeholder consensus between 2009 and 2012.\* The best practices (available upon request) are based on Rhode Island providers' preferences and the medical evidence, where it exists, and establish expectations and metrics for clinician-to-clinician communication and patient activation.

The appropriate transition of care of a patient is not an obscure vexing patient safety issue. Although at times complex and involving multiple entities, this patient safety issue can be solved with purposeful coordination and appropriate infrastructure. Facilities and institutions can create, maintain and refine the infrastructure needed to facilitate appropriate transitions. Ultimately, it is the professionals involved, whether nurses or practitioners who are accountable for the coordination and safe transition of the patient.

### ***Minimum Expectations and Roles of Clinicians***

Clinicians practice in different settings; e.g., acute, home health, nursing homes and urgent care settings. Further, patients come into care under a variety of circumstances planned or unplanned. Navigating the health care system for most patients has challenges and is not intuitive.<sup>19</sup> At times, patients expect and need the provider's expertise regarding the next setting of care. Initiating a transition of care is usually a medical decision and at times, urgent or emergent (unplanned).

Successful transition toward a different setting of care is affected by several predictable variables. Practitioner consideration of the acuity and complexity of the patient, as well as nature of setting (scheduled or unplanned) are just some of the essential questions that need to be addressed. The transition should be viewed as a complex act and requires thoughtful action and direction for its success.

### ***Common Transitions of care include:***

- Outpatient to higher level of care (emergency department visit, observation stay or inpatient visit)
- Inpatient to higher level of care (ICU)
- Inpatient to residential type setting (assisted living, skilled nursing or long-term care)
- Inpatient to outpatient (return to specialist or primary care office, with or without home health services)

Although the actual transition might look different for each setting, minimum expectations are common to all transitions. This minimum expectations includes:

- The medical diagnosis
- Updated medication list
- Results of tests
- Pending tests
- Name of the treating clinician
- Phone number to call if more information is needed
- Follow up or Discharge instructions
- Professional to professional communication at time of transition

### **The Role of Health Professionals**

These minimum expectations lend themselves to essential content that can be incorporated into the care delivery process. Who communicates the essential components to ensure a seamless transition is not as important as that the essential components take place effectively. It is imperative that practitioners, organizations and related entities integrate this practice into their normal everyday practice.

The Table below illustrates one way of looking at this issue regarding roles and settings of care. Note that in some cases, redundancy is warranted (seeking a higher level of care) and in other cases redundancy is not needed (lower level of care).

**Table 2.** Professional Standards to Ensure Timely and Adequate Information Transfer

Best Practice	Provider referring a patient for unplanned care	Provider receiving a patient	Provider discharging a patient <sup>1</sup>	Regular provider, <sup>2</sup> if aware of recent unplanned care <sup>3</sup>	Professional Standards
Send summary clinical information when referring patients.	X		X		<ul style="list-style-type: none"> <li>Should include the reason for referral, results of tests, pending tests, and the name and contact information of the referring clinician.</li> </ul>
Respond to time-sensitive questions from next provider, as needed.	X		X		<ul style="list-style-type: none"> <li>Should include immediate contact with staff (a clinician or clerical staff who can address the specific question) or a return call within one hour.</li> </ul>
Notify primary care physician (PCP) about unplanned care, if not referred.		X			<ul style="list-style-type: none"> <li>PCP: Any clinician identified by the patient as their regular doctor.</li> <li>For hospital visits, should occur at the beginning of the hospitalization. For ED and urgent care visits, can occur with the summary clinical information sent at discharge.</li> <li>Should include contact information for a clinician (physician, nurse practitioner or physician assistant) who cared for the patient or has access to the patient's medical record.</li> </ul>
Perform medication reconciliation.		X	X	X	<ul style="list-style-type: none"> <li>Excludes ED patients admitted to the hospital.</li> <li>Includes, at a minimum, identifying which medications the patient should stop, start or adjust after discharge.</li> <li>Should occur in every provider encounter.</li> </ul>
For hospitalized patients, schedule outpatient follow-up appointment prior to discharge.			X		<ul style="list-style-type: none"> <li>Should include the date, time, location and contact information for questions or to reschedule.</li> <li>Should incorporate patient feedback, e.g., when the patient can obtain transportation.</li> <li>If the patient has no known PCP, should assign the patient to a PCP and schedule a new patient appointment.</li> </ul>
Provide patient with effective education.			X	X	<ul style="list-style-type: none"> <li>Excludes ED patients admitted to the hospital.</li> <li>Should include the diagnosis, any medication changes and reason for change, condition-specific "red flags" that should prompt outreach (including a contact name), activity and other limitations, and needed follow up.</li> <li>"Effective" education: Should assess the patient's understanding of the information provided (e.g., teach back) and incorporate health literacy and cultural competence.</li> </ul>
Provide patient with written instructions.			X		<ul style="list-style-type: none"> <li>Excludes ED patients admitted to the hospital.</li> <li>Should include the information provided verbally as part of effective education (see above) as well as the name and phone number of the clinician (physician, nurse practitioner or physician assistant) who cared for the patient, if more information is needed after the visit.</li> </ul>
Send summary clinical information to next provider.	X		X		<ul style="list-style-type: none"> <li>Recipients should include the PCP and other home care or nursing home provider, if applicable.</li> <li>Should be sent within 24 hours.</li> <li>It should include the medical diagnosis, updated medication list, results of tests, pending tests, name of the treating clinician, phone number to call if more information is needed, discharge instructions, and recommended follow up.</li> </ul>
Outreach to high-risk patients via phone.				X	<ul style="list-style-type: none"> <li>High-risk patients: aged 80 years or older; with a diagnosis of cancer, chronic obstructive pulmonary disease, or congestive heart failure; with polypharmacy (≥8 medications); or with a hospitalization in the previous six months.</li> <li>Includes an outpatient clinician (physician, nurse practitioner, physician's assistant or nurse) phone call with the patient, family or caregiver to assess the patient's condition and adherence to recommended care and to reinforce follow-up.</li> </ul>
Conduct follow-up appointments with patients discharged from the ED or hospital to the community.				X	<ul style="list-style-type: none"> <li>For hospital visits, should be scheduled by the hospital prior to hospital discharge; if not, the physician office should outreach.</li> <li>Within 14 days of discharge from the ED or hospital, unless the timeframe is otherwise specified and documented in the medical record.</li> <li>Can be with a clinician (physician, nurse practitioner, physician's assistant or nurse) at the community physician's office or with a specialist, such as cardiologist, who cares for the patient in an outpatient setting.</li> </ul>

1 From any setting, including hospital, home health agency, nursing home or urgent care setting  
 2 Regular provider: The primary care physician or any other clinician identified by the patient as their regular provider  
 3 Unplanned care: Emergency department, hospital or urgent care center utilization

### **Minimum Standards of Professional Conduct vs. Aspirational Standards of Professional Conduct**

Arranging for a seamless transition of care may seem like a novel concept to some, unobtainable to others and long overdue to many. This important patient safety issue is essential to the responsible practice of medicine and nursing.

Currently the Boards are taking a proactive role and educating health professionals regarding transitions of care. It is anticipated that in time, challenges will be overcome and this will become a seamless part of the health care experience.

Ideally transitions of care will surpass the minimal data set and transitions will be multidisciplinary, multi-directional, concise and customized to the patient-transition experience.

There are existing tools for patients and practitioners regarding appropriate transitions<sup>20</sup> which include medication lists, checklists and validated evidence based risk assessment tools.

### **Challenges & Opportunities vs. Barriers and Facilitators?**

There are several challenges that face healthcare providers in facilitating best practices in transitions of care and, by virtue, are often the same challenges providers face in meeting professional standards of transitions of care. It is our argument that the resources expended in achieving and maintaining optimal transitional care for patients will ultimately save resources beyond what is expended implementing them. Here are some of the common barriers to safe and quality care transitions and some workable solutions to facilitate transitions.

All healthcare providers are challenged by time, especially in an increasingly complicated health care environment. There is little or no financial reimbursement for providers to send or receive patients in an optimal fashion. Currently, transition care is largely subsumed in current reimbursement schedules for routine evaluation and management of patient conditions or as part of the overall hospital cost. Moreover, in many settings, there is no longer a single practitioner responsible for communication and follow-up of transition and coordination of care, blurring the roles and responsibilities of the multiple healthcare providers typically involved in care. However, transitions are an essential part of patient care and healthcare providers have a legal, ethical and moral obligation to utilize every opportunity to ensure patient transitions meet, at the least, the minimal standards for quality and safe patient care. Although there are systems barriers that impede successful patient transitions, there are pragmatic solutions that an individual provider can employ to ensure they uphold professional standards of transitioning care for their patients. It is understood that communication, verbal, written and electronic, is an essential attribute of professional practice and care transitions across the continuum. These are skills are individual skills that can be enhanced. All healthcare providers are accountable for communication and ensuring that pertinent information is relayed

in a timely fashion when sending or receiving patients.

Collaboration and communication are essential attributes of transitions, but institution infrastructures often function in silos, making it problematic to delineate responsibilities between care providers and institutions. Even within affiliated institutions, vertical transitions are often not well executed.<sup>21</sup> For example, hospital care providers may not be available after discharge, even when the primary care provider is employed at the same organization. This is problematic when a community provider is trying to clarify or understand a patient's post-discharge plan of care. Similarly, acute-care institutions struggle with poor medical histories and lack understanding of the patient's community plan of care. Further, the professionals involved in patient care may not have practiced in the settings from which they have received or are sending patients, and, as such, may not understand the capacity or infrastructure of these settings. A viable solution is to ensure that the patient, care givers and the receiving provider have accurate up-to-date contact and a covering provider to answer questions for periods when not available.

### **Patients and families an important element**

Patients and their families are also important elements of transition care. While patients have rights to receive safe and quality transitional care, they also have responsibilities to assist and participate in the process. However, patients often do not understand their plan of care for many reasons. Primarily, the plan is often multi-faceted and complicated; patients may be impaired, both cognitively and/or physically, thus limiting their ability to participate at an optimal level. Family may or may not be involved and may also be limited in their understanding of the plan of care. There may be health literacy, cultural and language barriers. Healthcare providers can practice with a patient centered care model and should encourage patient and family/caregiver involvement, when appropriate, and reinforce patient responsibilities to help develop, understand and be able to communicate their plan of care and who their providers are in different settings. Care and consideration should be exercised when determining the plan of care for a patient. The plan of care should be simplified to the extent possible without decreasing quality or jeopardizing safety. Clear written and verbal communications are essential, and providers should use tools that already exist to facilitate transitions such as medication reconciliation and the continuity of care form.<sup>22</sup> Care instructions should be simple and clear, including a distinct plan for post transfer care, resources and who to direct questions to. Healthcare providers can be leaders in their institutions and in their fields to educate, and bring to the forefront, the standard of care for their profession as it relates to transitioning their patients. Checklists and follow-up protocols can be adapted for each setting to assist clinicians to understand their roles and accountability within settings. This will assist clinicians to understand their roles

and also to share responsibility for transition care among clinicians. In addition, it would help educational programs to implement discipline specific transition principles in their curriculum and training.

## CONCLUSIONS

Transitional care is an essential attribute of any patient plan of care. Although each profession is accountable for discipline specific elements of transitional care, prior to specific regulatory requirements being implemented, standards for discipline specific best practices need to be developed and implemented in the health care system. Both the RI DOH Continuity of Care Form<sup>15</sup> and best practices guidelines<sup>16</sup> are available to guide providers on how to best meet patient transition needs. Further, these tools assist to improve communication and patient activation by establishing core expectations based on clinicians' preferences and evidence, where it exists, and by creating measures that can be tracked over time. They also establish core expectations for communication that can improve patients' experiences and health outcomes, as well as facilitate cross-setting collaboration, relationship building and referral patterns. Implementing the best practices acknowledges the reciprocal nature of the healthcare system and the collective need for communication between healthcare providers to ensure delivery of high-quality care.

The time has come for interested stakeholders to further develop transitions of care to a more codified position. The logical next step might be a collaborative endeavor to modify and create regulatory changes that definitively address transitions of care.

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The authors thank the members of Healthcentric Advisors' Safe Transitions project's community advisory board, who met to discuss professional standards. The advisory board encompasses inpatient and outpatient physicians and representatives from commercial health plans, Medicaid, and the home health, hospice, hospital, nursing home and physician office settings. We also thank the providers and stakeholders who collaborated with the Safe Transitions project to develop the care transitions best practices.

Through collaboration with the Rhode Island Department of Health and other community stakeholders, Healthcentric Advisors' Medicare-funded Safe Transitions project aims to transform the Rhode Island healthcare system into one in which discharged patients and their caregivers understand their conditions and medications, know who to contact with questions, and are supported by healthcare professionals who have access to the right information, at the right time. This is our vision statement.

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## Footnote

\*After testing evidence-based care transitions interventions locally and systematically gathering input on providers' preferences and needs, Healthcentric Advisors collaborated with physicians, nurses, health plans and community leaders to develop care transitions best practices for six provider settings: community physicians, emergency department, home health agencies, hospitals, nursing homes and urgent care centers.

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# Appropriate Prescribing of Opiates as Professional Conduct

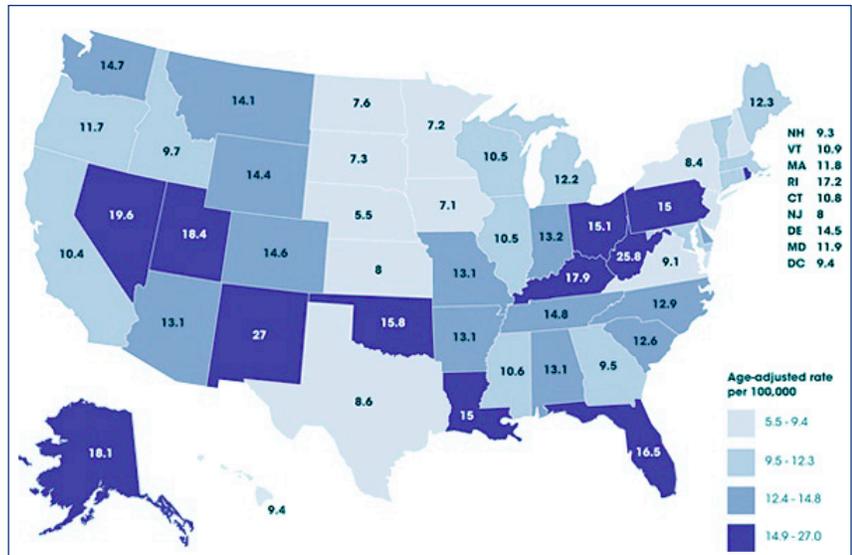
JAMES V. McDONALD, MD, MPH

## ABSTRACT

Prescription drug abuse/misuse in Rhode Island and the US is an epidemic. Chronic pain is often treated with prescription opiates which offer some relief, yet present risks to the patient of dependence, addiction and overdose. Physicians find themselves at times at odds with their patients regarding the management of pain and may feel bullied or pressured regarding prescribing. The Rhode Island Board of Medical Licensure and Discipline recognizes the value of established parameters for responsible and safe prescribing.

**KEYWORDS:** Prescription drug abuse, responsible prescribing, [www.health.ri.gov/saferx](http://www.health.ri.gov/saferx)

Drug Overdose Rates by State, 2008



## A PROBLEM OF PAIN

Relieving pain, healing the sick, caring for people, lending an ear and helping others are perhaps some of the reasons we chose to go to medical school in the first place. No one desires to have an adversarial relationship with a patient, yet the issue of long-term opiate use can create conflict in the exam room. Patients are in a difficult position as is the prescriber. All too often the problem of treating pain can lead to an unintended vicious cycle of pain, opiate use, addiction and all that comes with the disease of addiction.

Most physicians did not see the prescription drug abuse epidemic coming. A common teaching years ago was to “treat pain” and that patients will not become addicted. It is clear addiction to pain medication does occur, that addiction is a disease<sup>1</sup> and chronic pain is challenging to manage. Physicians can find themselves between the proverbial “rock and hard place” as they try to manage pain, yet protect their patients from a remedy known to be addictive and currently responsible for 4 deaths weekly in Rhode Island.<sup>2</sup>

In 2008, Rhode Island ranked 7th among states regarding deaths from overdose of prescription drug abuse.<sup>3</sup> Prescription drug abuse has been declared an epidemic by the CDC,<sup>4</sup> perhaps the most vexing epidemic of our generation. The purpose of this article is to highlight expected practices and standards when it comes to responsible opioid prescribing.

## STATUTORY AUTHORITY

The Board of Medical Licensure and Discipline derives its statutory authority from § RI 5-37<sup>5</sup> and is charged with its mission: “To protect the public through enforcement of standards for medical licensure and ongoing clinical competence.”<sup>6</sup> The Board has long advocated that pain be treated appropriately and responsibly.<sup>7</sup> There is no prohibition from using opiates; rather the expectation is that opioid medications be prescribed responsibly<sup>8</sup> and thoughtfully. It is the expectation that prescribers will meet minimum expectations regarding standards of care and understand that treatment goals are tailored to the patient. Elimination of pain may not be possible without undue risk to the patient and control of pain maybe the best achievable goal.

## EXPECTED PRACTICES AND STANDARDS

Minimum standards when prescribing opiates are appropriate to establish boundaries and clearly communicate expectations of the physician community.

### Medical Records

It is expected that the physician will maintain appropriate medical records<sup>9</sup> and more specifically, the medical record should contain the following elements:

1. appropriate medical history and physical examination
2. diagnostic, therapeutic and laboratory results
3. consultations
4. treatment objectives
5. coexisting disorders, alcohol, substance use history
6. informed consent
7. controlled substance log
8. medications (including date, type, dosage and quantity prescribed)
9. narcotic/pain management agreements
10. problem summary list

Medical records should be current, immediately available for review, and stored securely for at least 5 years.

### Physician Patient Relationship

An appropriate physician patient relationship should exist. Evidence of this should be readily apparent in the medical record. Prescribing opiates without physically seeing a patient is inappropriate unless for a brief (less than 5-day period) for an emergency.

### Prescribing to Self and Family

In accordance with the policy set forth by the AMA,<sup>10</sup> it is inappropriate to treat immediate family members or oneself with controlled substances of any type.

### Informed Consent

Informed consent is an interactive process and involves at a minimum a meaningful exchange of information regarding the proposed treatment or non-treatment. This is important before prescribing opiates, particularly if for longer than 5 days. Attention should be directed to indication for treatment, side effects, risk of addiction and the patient's responsibility in preventing diversion. Patients should be specifically directed that this medication has potential for dependence and is intended only for the patient and never to be shared with a family member. Sharing prescription drugs is a violation of state<sup>11</sup> and federal law.<sup>12</sup> Non-opiate options including no treatment for pain should be part of the dialogue. Documentation of this consent is expected in the medical record and should be periodically updated if opiates are used long-term.

### Pain Agreement

The use of a pain contract, pain agreement, provider patient agreements, controlled substance agreement or a similar agreement is expected when prescribing opiates for long term use.<sup>13</sup> These tools are available from multiple sources and often can be tailored to your practice.<sup>14</sup>

Pain specialists should consider a trilateral opioid contract<sup>15</sup> which includes the patient, pain specialist and primary care provider. This promotes transparency, reduces the risk of diversion and can effectively bridge the pain clinic and primary care provider.

Establishing clear boundaries help frame outcomes, expectations, as well as allow treatment to be started in a non-judgmental and objective manner. The agreement should be reviewed periodically and updated to reflect changes. Some may consider the practice of *Universal Precautions*,<sup>16</sup> having an agreement with every patient who is prescribed a controlled substance.

### When to Refer

Periodically patients will exceed the scope of your practice and appropriately need to be referred. Understanding your strengths and limitations is wise and should consider the patients' best interests. Some have advocated strong consideration of referral to pain medicine, addiction medicine or other appropriate entity when morphine equivalent dose is 120mg/day.<sup>17</sup> Referral can certainly occur before that dose and perhaps should occur sooner than later. Strong consideration should be considered to a multidisciplinary<sup>18</sup> approach to the treatment of chronic pain and refer to appropriate disciplines as clinical judgment dictates.

### Treatment Plan

The treatment plan should state objectives by which treatment can be evaluated. Performing a functional assessment prior to treatment and as treatment progresses tailors therapy to the individual needs of the patients. Additionally, addressing the functional impact of pain and translating it to objective relevant goals which are verifiable encourages prescribing decisions connected to outcomes demonstrated by the patient.<sup>19</sup> Complete analgesia may not be possible nor in the patient's best interest, yet efforts should be directed at optimizing functional outcomes.

### DIVERSION

Diversion occurs when a prescribed medication for one person is given to another person. Diversion is common; it occurs in many patients who may be diverting opiates to support their own addiction, for financial gain or for other reasons. Physicians need to be cognizant that opiates are frequently diverted, often by friends or family of the patient.<sup>20</sup> Periodically monitoring the patient with urine toxicology screens is expected as well as using existing tools to monitor patient's utilization. Patients who frequently refill medications early, lose medications, or have negative urine screens should raise suspicions.

### Prescription Monitoring Program

Rhode Island is one of 42 states that currently has an active prescription drug monitoring program (PDMP).<sup>21</sup> The PDMP allows prescribers to currently see what schedule II and III drugs their patients are taking. There are limitations to this tool – it does not show schedule IV and V medications routinely and the data may be up to 30 days old. Currently, prescribers can only see patient's activity in one state. There is

presently not a national PDMP. The PDMP has been shown to positively impact prescribers' habits and reduce in some states opioid misuse.<sup>22</sup> A best practice is to review the PDMP before prescribing any controlled substance to a patient. It is expected that every prescriber of controlled substances will use the PDMP often and incorporate it into daily practice.

## ADDICTION

Addiction is a disease, often chronic, relapsing and challenging to diagnose and treat. Physicians should periodically review their treatment and differentiate if they are treating chronic pain, dependence, addiction or a combination. Honest discussions are appropriate for the exam room and making a diagnosis of addiction may not be well received by a patient, yet that does not make it less true. Patients often need to hear this message multiple times from multiple sources before they seek help.

## CONCLUSIONS

The prescription drug abuse epidemic is perhaps our greatest public health challenge. Regulatory agencies such as the RI BMLD can establish guidelines, enforce law and continue to educate the professional community. No physician has ever been disciplined by the BMLD for responsible opioid prescribing. Physicians are highly encouraged to treat pain appropriately, yet to do it responsibly and transparently.

The vast majority of Rhode Island physicians are conscientious, caring and compassionate and trying to manage this issue as best they are able. There are consequences, however, for those who do not prescribe opiates responsibly. The BMLD takes very seriously those who prescribe irresponsibly or are complacent with this serious issue. Physicians are well advised to keep up to date on current practices regarding prescribing opiates and exhaust all other reasonable options before initiating therapy.

Physicians must practice responsible opioid prescribing, collaborate and refer as needed while using existing tools and resources. Perhaps most important is to remember the exam room represents a sacred space where trust, honesty and healing are the most valuable currency we have with our patients. The exam room should be a "safe place" for the patient and physician. Although physicians are under enormous pressure from external entities, respecting the patient and determining what is best for the individual in front of you should hearken back to why you entered this profession in the first place.

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# Patterns of Prescribing – The Rhode Island Prescription Monitoring Program

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## ABSTRACT

Drug overdose and abuse is a growing epidemic nationally and for Rhode Island. The Rhode Island Prescription Monitoring Program (PMP) is a web-based system that collects all schedule II and III prescription information for prescriptions dispensed in or into Rhode Island. The Rhode Island Board of Pharmacy at the Rhode Island Department of Health operates this program and uses the information for investigative purposes to curb drug overdose and professional misconduct. Two case studies are presented to illustrate the use of PMP in Rhode Island.

**KEYWORDS:** Inappropriate Prescribing (E02.3193490), Opioid-Related Disorders (F03.900.675), Public Health (N06.850), Pharmacy (H02.646)

## INTRODUCTION

The Rhode Island Prescription Monitoring program (PMP) of the Rhode Island Department of Health (HEALTH) is a perpetually updating database of all schedule II and III controlled substance prescriptions dispensed within and into the state. Rhode Island first enacted legislation authorizing HEALTH to collect and use this information in 1997, and with recent software upgrades in 2012, this information is now widely available for external use by prescribers, pharmacists, and law enforcement officials.

Matters involving narcotics or prescribing are under the jurisdiction of the Rhode Island Board of Pharmacy, the entity responsible for operating the PMP and enforcing the laws and regulations pertaining to prescription drugs. Pharmacy Board investigators have been active and engaged in the investigation of inappropriate prescribing, diversion of drugs, and misconduct involving narcotics, assisting other licensing Boards within HEALTH. Prior to the advent of PMP, Board of Pharmacy investigators were tasked with monitoring a growing prescription drug abuse epidemic with a paucity of timely prescription data. Investigators now have the capability to centralize and analyze data once scattered throughout 200 independently operating retail pharmacies into one condensed database.

Rhode Island suffers heavy costs from prescription drug abuse. About two percent of all deaths in the state (about one-fourth of all “accidental deaths”) are “drug-related,”

and of these, more than half involve opioids, either alone or in combination with other drugs.<sup>1</sup> In addition, prescription drug abuse not only harms patients, but also has a devastating effect on families, neighborhoods, and the health care system. In response, investigators from the Rhode Island Board of Pharmacy are utilizing the full potential of the PMP to curb this epidemic and protect the health, safety, and welfare of the public.

## Case Studies

Two recent cases illustrate the effectiveness of the PMP in an investigatory capacity.

**Case 1 (Excessive Prescribing):** This case began with several seemingly unrelated reports of multiple patients filling prescriptions for high dose opiates at local pharmacies. Although the patients in question initially appeared to be unrelated, based on age, address, and apparent diagnosis, investigators were able to determine that they had a common prescriber. The PMP can isolate a single prescriber and consolidate all prescriptions under that registration independent of pharmacy location, third party payer status, or drug type. Investigators subsequently developed a prescriber-specific report which revealed that the prescriber was authorizing prescriptions for 30 days of identical high dose opiates to the same patient in 10-15 day cycles. The patients frequented multiple pharmacies on a complex schedule, never visiting the same pharmacy prior to the expected due date of the prescription, and paying out of pocket for the cost of the medication. (Previous to development of the PMP, this behavior would go unnoticed, since patients and prescribers were able to circumvent the safeguards of third party payer reporting. Using the PMP, however, investigators can analyze prescribing patterns even when patients or prescribers are actively attempting to deceive the system.) Eventually, investigators were able to determine that some patients received close to 900 days worth of narcotics in a single calendar year through the issuance of identical prescriptions. Furthermore, investigators observed instances where the prescriber wrote identical prescriptions, up to 3 in a single day, resulting in hundreds of dosage units being diverted. Findings were transmitted to the prescriber’s licensing board and the prescriber’s license was suspended, dismantling an opiate ring, and drying up a source for illicit prescription narcotics.

**Case 2 (Excessive Dispensing):** Pharmacy Board investigators conducted a review of a pharmacy's dispensing history to analyze dispensing patterns over a period of time. Excessive dispensing of narcotics was found. One patient, for example, obtained refills of high dose narcotics earlier than scheduled, based on the prescription's quantity and directions, ultimately receiving over 500 days worth of narcotics in one calendar year. Problematic dispensing such as this led investigators to examine the behavior of pharmacy staff regarding drug utilization reviews and the questioning of early narcotics refills, and found them wanting, raising concerns about professional competency. As with other PMP investigations, this matter was referred to the appropriate licensing board, where responsible parties faced disciplinary sanctions and were forced to address system failures to prevent excessive narcotics dispensing in the future. Thus the PMP was used not only to prevent the diversion of narcotics, but also to enforce practice standards, leading to improved quality of care.

## CONCLUSION

The PMP is a critical tool in the effort to prevent drug abuse and diversion in order to ultimately promote better health outcomes for patients and to improve professional standards in the licensing community. PMP use will be able to close the net on the pharmacy world, increasing transparency, and curbing the inappropriate distribution of prescription opiates. In concert with the overarching mission of the Department of Health, investigators will continue to use the PMP to dry up the flood of inappropriate narcotics in our communities while concurrently promoting a higher standard of care among health care professionals.

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# Opioid Prescribing: Guidelines, Laws, Rules, Regulations, Policies, Best Practices

JAMES V. McDONALD, MD, MPH

*"Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."*<sup>1</sup>

## ABSTRACT

Prescription drug abuse, misuse and unintentional overdose deaths are major public health concerns and have captured the attention of regulators at every level. There is no shortage of guidelines, laws, rules, regulations, and policies regarding opioid prescribing. Physicians struggle with their duty to treat pain, and yet balance this against the risk to patients as well as the potential for diversion. There are gaps in policy and resources such as lack of interdisciplinary pain clinics, addiction treatment, and education for prescribers and patients.

**KEYWORDS:** Prescription drug abuse, accidental deaths, [www.health.ri.gov/saferx](http://www.health.ri.gov/saferx), [www.health.ri.gov/painmeds](http://www.health.ri.gov/painmeds)

## INTRODUCTION

Physicians struggle with the duty to treat pain, specifically non-cancer related pain and the growing problem of diversion of prescription drugs. The statistics on prescription drug abuse are sobering if not shocking. In 2009, there were over 15,500 deaths from prescription drugs and 30% of those involved methadone.<sup>2</sup> 2010 data from the Substance Abuse and Mental Health Administration (SAMSHA) reveals 13.7% of individuals over age 12 have used prescription pain killers for non-medical reasons in their lifetime.<sup>3</sup> The most common pharmaceuticals people use for non-medical purposes are: hydrocodone, oxycodone, and fentanyl.<sup>4</sup>

This has all occurred during a time when efforts have been increased from multiple entities to assess pain as a "5th vital sign,"<sup>5</sup> and to treat pain more aggressively, and when direct advertising to consumers for pain medication has increased.<sup>6</sup>

Regarding controlled substances, the World Health Organization "considers the public health outcome to be at its maximum (or balanced) when the optimum is reached between maximizing access for rational medical use and minimizing substance abuse."<sup>7</sup> This balance is elusive and underscore's the relationship between analgesic efficacy and its potential for abuse<sup>8</sup>. It is important to emphasize that the opiate drugs that are most effective in relieving pain are also the ones with the highest risk of abuse. It is no secret

this entire issue is a dilemma for clinicians and represents a significant challenge to the every day practice of medicine.

## What's out there?

The Rhode Island Board of Medical Licensure and Discipline is concerned about prescription drug misuse, dependence and related deaths. We should further explore what can be learned from existing efforts of policymakers, and what common ground and gaps in policy exist.

Federal Entities	State Governments	Professional Societies	Pharmaceutical/ NGO
DEA <sup>9</sup>	Washington <sup>10</sup>	American Pain Society <sup>11</sup> American Academy of Pain Management <sup>12</sup>	Federation of State Medical Boards <sup>13</sup>
CDC <sup>14</sup>	Ohio <sup>15</sup>	American Academy of Pain Management <sup>16</sup>	Cares Alliance <sup>17</sup>
FDA Blueprint <sup>18</sup>	Colorado <sup>19</sup>	American Society of Anesthesiologists <sup>20</sup>	Endo Pharmaceuticals <sup>21</sup>
White House <sup>22</sup>	Iowa <sup>23</sup>	American Academy of Family Physicians <sup>24</sup>	American Chronic Pain Association <sup>25</sup>
DOD/VA <sup>26</sup>	Arizona <sup>27</sup>	American College of Physicians <sup>28</sup>	Purdue Pharmaceuticals Pain education <sup>29</sup>

The extensive variety of guidelines, toolkits, regulations, etc., highlights the significance and pervasiveness of this issue. Clearly, from the perspective of prescribers, patients, regulators, payers and government this is one of the most important issues of our day. Each entity above has addressed this issue to some extent; the State of Washington took the unique step of creating very specific legislation focusing on prescribers.

## Washington Pain Rules

The Washington pain rules were enacted into law 7/1/2011 in response to the epidemic of prescription drug abuse in this state<sup>30</sup> yet recognizing the important role in the appropriate treatment of pain. These pain rules are specific to non-cancer treatment of pain and specifically address several aspects of chronic pain management. These include:

1. evaluation of the patient
2. detailed documentation requirements
3. treatment goals/plan
4. informed consent
5. highly detailed written agreement for treatment of pain and monitoring
6. periodic review of the patient
7. appropriate treatment for episodic care
8. recommendations for when to obtain consultation, including a mandatory threshold based on morphine equivalent dose
9. defines who can be considered a pain management specialist
10. strongly recommends use of prescription monitoring program

The Washington Pain Rules are specifically addressed to prescribers and attempt to balance the need for appropriate pain management while recognizing the public health threat from diversion, dependence and addiction.

The pain rules are not without their critics with some expressing that patients with legitimate pain needs are not having these needs addressed.<sup>31</sup> The American Academy of Pain Management has supported these rules, yet highlighted that confusion, misinterpretation and clarification is needed.<sup>32</sup>

Although the Washington pain rules were initially a practice guideline,<sup>33</sup> the main criticism of the pain rules is they were ultimately enacted as law. It has been suggested that physicians leery of the legal burden and expense of this law on their practice have chosen not to treat chronic pain in their patients, leaving the patient caught in the middle.<sup>34</sup> Some physicians have chosen to interpret these rules as so restrictive as to stop prescribing narcotics.<sup>35</sup> This may be an unintended consequence of this legislation, although the legislation clearly highlights as one of its goals that patients with chronic pain be appropriately treated.

The Washington Pain Rules have not been around long enough for a thorough evaluation, yet were constructed in a collaborative manner and with an evidenced-based<sup>36</sup> approach. Time will tell if such a legislative approach has effectively turned the tide in Washington.

### Common themes among many regulators

After a review of many of these guidelines and statements, there are several common themes which should be noted.

1. Recognition of balance and responsibility to appropriately treat pain while also recognizing that opioid medications are addictive and subject to diversion.
2. The morbidity and mortality from opioid medications is a national epidemic.
3. There are standard practices that reflect responsible opioid prescribing.

4. There are accepted tools that reflect responsible monitoring of patients who take opioid medications.
5. There is often a need for an interdisciplinary/multidisciplinary approach to pain management.

### Role of Regulatory Agencies

Regulatory agencies, like the Rhode Island Board of Medical Licensure and Discipline (BMLD), are charged with a specific mission: *"To protect the public through enforcement of standards for medical licensure and ongoing clinical competence."*<sup>37</sup> Establishing and enforcing regulations, promoting and conducting education and ensuring a competent workforce reflect the major activities of the BMLD.

Limitations on regulatory agencies and the problem of prescription drug abuse highlights one of our most significant limitations. Regulatory agencies do not get in the exam room with the prescriber, their reach is from a different level and their regulation or guidance is expected to be interpreted in the context of a legitimate prescriber-patient relationship. Regulatory agencies are counting on the prescriber to have exercised sound professional judgment and made the best effort to construct the most appropriate treatment decisions for the individual patient.

### Unique Challenges

Opioid addiction/dependence/abuse presents several challenges due to the addictive nature of the medication and the unpleasantness of pain. Additionally, accumulating evidence indicates that opiates may cause an additional problem, opioid induced hyperalgesia (OIH).<sup>38</sup> Paradoxically, this therapy which alleviates pain has the potential to make patients more sensitive to pain and may make matters much worse for the individual patient.<sup>39</sup> Patients with OIH typically experience this after escalating doses of opiates which are not controlling their pain and often report the pain to be different in character than previously reported pain.<sup>40</sup>

### What Can Rhode Island Learn From All of This?

#### Policy Gaps and Bridges

There are gaps that exist when it comes to the appropriate management of pain. Patients with chronic pain and prescribers perceive our health care marketplace lacks an alternative for pain control with opioid medications. Although there is debate on the business case for interdisciplinary pain clinics, they have been shown to be cost effective, yet uncertainty exists on the optimal combination of professionals in an interdisciplinary pain clinic.<sup>41</sup> It should be noted that an interdisciplinary clinic differs from a multidisciplinary clinic in that in the former, all professionals share the patient and collaborate with the patient on treatment goals and outcomes. There is a place in the health care system for an interdisciplinary non-pharmacologic approach to chronic pain.

Another gap is the relative shortage of resources for patients with addiction and reluctance of some in viewing addiction as a chronic disease. Effective treatment for

addiction does exist yet is not effective for all patients. Additionally, addiction is a chronic disease and relapse is part of the disease process. Addiction is a complex disease that requires time, collaboration and perseverance not just for the patient, but the treating team.

Although many resources exist for providers in managing chronic pain, what is missing is a simple tool kit specific to various common clinical settings. Providers need practical tools they can easily implement and incorporate into their work flow.

Additionally, prescribers would benefit from targeted training in conflict resolution, bullying and how to handle manipulative patients. Patients who are addicted or dependent often exhibit aberrant behavior and physicians are generally not prepared to handle this in the time- constrained, busy and complex clinical milieu.

Additionally, there is a profound lack of patient education regarding this public health epidemic. Patients are not typically informed of the risk of taking opioid medication and do not have an opportunity to do their own risk/benefit analysis. This suggests the need for more explicit regulation which defines the terms when informed consent shall be obtained when prescribing opiates. It is difficult to reliably assess which patients are at risk for addiction; therefore many have advocated an approach which incorporates "universal precautions."<sup>42</sup> This approach destigmatizes the issue of addiction and allows for a frank discussion of the risks and benefits of the proposed treatment for pain.

## CONCLUSIONS

The complex issue of pain, opioid dependence, addiction and abuse represents a multifaceted and difficult issue. There is no rapid solution forthcoming and the clinical landscape for this is uncertain and problematic. This issue reflects one of the largest barriers to patients with chronic pain achieving a state of optimal health. There are plenty of policy gaps and opportunities to address for the foreseeable future.

The prescription drug abuse epidemic cries out for collaboration from prescribers, policymakers, payers, law enforcement, behavioral health, complementary and alternative medicine providers, educational professionals and more. Each generation has its mountains to climb; this issue will not be solved with Herculean efforts by any single entity; rather a combined and coordinated approach that may redefine health care as we know it to accomplish a sustainable solution.

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