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VITAMIN D:
An Evidence-based Review & Approach to Management

DRUG TAKEBACK PROGRAMS

Enabling QUALITY IMPROVEMENT in PRACTICE for *Controlled Prescribing* (EQUIP-4-CRx)

FALL 2012 · VOLUME 77

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STRONG MEDICINE FOR KENTUCKY

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message from the PRESIDENT

I want to begin by thanking Dr. Bill Bryant, from Owensboro, for representing us at the HB1 Oversight Committee Meeting in Frankfort. I have received nothing but positive comments about his presentation. I had Gerry put his testimony up on our website for all to read. So, please visit our website to read it. Our HB 1 webinar was a big success. We had 76 physicians to participate live and another 10 that reviewed it afterwards. The webinar generated a lot of questions that we were able to convert into a Q&A file. If you didn't participate – please contact our EVP Gerry Stover at gerry.stover@kafp.org to get the Q&A file and link to view the recorded video. Also, I want to thank Carole Christian and Roz Cordini with the Wyatt law firm for their excellent presentation on HB 1 and for working up the Q&A document. I expect more meetings on this issue and likely several bills to be introduced in the 2013 General Assembly. I encourage you to become familiar with the issue and provide your thoughts to me through Gerry.

IN LISTENING TO THE PRESENTATION ON THE PRESCRIPTION DRUG EPIDEMIC IT BECAME OBVIOUS **THERE IS NO 'SILVER BULLET'.**

In August I attended a regional meeting of family medicine leaders from the south. I learned that a lot of the issues that we face are common in our sister states. In listening to the presentation on the prescription drug epidemic it became obvious there is no 'silver bullet'. I did find that there were common themes of education and strengthening licensure boards' regulator authority. Another hot topic was Medicaid expansion. As you know it's the political 'hot potato' as politicians are trying to distance themselves from it in states where the voting majority is against it. Medicaid expansion will be a big budget item but I suspect that it will go through because of the decrease in payments to hospitals for uncompensated care. The last item that I want to share from this meeting is how the Patient Centered Medical Home movement is doing. Most states were like us in that payers are not compensating us for becoming certified as PCMH. Yet there is hope as I learned from a North Carolina colleague that their local Blue Cross and Blue Shield are increasing their overall payments by 30% for being NCQA PCMH certified. The other ray of hope for the spread of PCMH is the Medicare CPC initiative in the Cincinnati-Northern Kentucky market. Thanks to Dr. Glenn Loomis with St Elizabeth Physicians for getting over 73 providers qualified for this PCMH type initiative.

Finally, I am attending on Friday September 14th a rural workforce meeting called by Cabinet Secretary Haynes. Increasing the number of family physicians in the Commonwealth is our number one legislative priority and is in keeping with our vision for a 'family physician for all Kentuckians'. I promise to keep good notes from this meeting so as to have something for the President's 'blog'.

I want to close by saying thanks to all of you that are working hard in your communities to make a difference. Our greatest legacy as a specialty is that we are the front line physicians that are trained in the whole person with a community focus.

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message from the ASSOCIATE EDITOR

When I was interviewing for my current position as Medical Director of the Bluegrass Community Health Center, one of the first questions asked of me was, "Do you treat chronic pain?" I thought a moment before I answered, because even though I knew I was being asked if I prescribed narcotics or not, I had to think about why the answer to that question was so important and how I might better explain my philosophy. I think I responded…I hope I responded…as I always feel, "No, I do not treat chronic pain, I care for patients who sometimes suffer from pain." For me, as a Family Physician, I cannot seem to get away from the fact that my patients have all kinds of issues they want to talk with me about. Sometimes it is arthritis in their thumb. "Doc, my thumb hurts. Do you think it's arthritis?" "Yup, I think it's arthritis." "Thanks, I just wanted to know." Sometimes the arthritis is not just in the thumb, but in the hip, and it keeps my patient up at night and the ibuprofen she had been using helps but now her creatinine is 1.6 and her blood pressure won't come down or her stomach hurts too much with NSAIDs. What do I do? I discuss options with the patient: Physical Therapy, Yoga, Orthopedic referral, and maybe a Lortab now and again. I reassess the patient's progress subsequently, and if any of the treatments cause adverse effects, I need to be able to stop or adjust those options.

Sometimes things go wrong. Mrs. C's pills are taken by her grandson. Can I send more hydrocodone into that home? Perhaps not. Or I see JS after a three year absence. JS is 32 years old and he comes in today because he is addicted to opiates and wants me to help him withdraw. "So, how did this happen," I ask innocently. "Well, you remember that bad case of shingles I had 3 years ago. Well, it so happens I liked those pain pills you gave me and I got hooked. At first, I got them from family and a couple friends, but then I needed to buy them off the street, sometimes 20 Lortab 10's a day. I can't believe it has gone this far and I really need help to stop." So I pick my jaw up off the floor and spend some time talking about what had happened and what should happen next. Being the introvert and self-reflective person I am, I of course think about my role in JS's history. Refusing to prescribe adequate medication for pain control doesn't seem to be the answer.

Working at a Community Health Center, I see many patients who are medically underserved and frequently socially fragile. Their housing, food, and income sources may be tenuous at best. Though these individuals also suffer from pain and anxiety, using controlled substances to treat those ailments is extremely risky both for the patient and for society. If I had to choose between tolerating a painful back and feeding my children, I might sell some of my Lortab's, too. So in many cases, my decision to prescribe or not prescribe controlled substances for my patients is straight forward. "I will work with you and use different methods to treat your symptoms, but opiates and benzodiazepines cannot be part of the plan." Patients who see me as their primary care provider and our clinic as their medical home accept that. But there are some patients, after long discussions of options and risks, explanation of pain contracts, and KASPER assessments, who seem to do better with a controlled medication. I have a few patients I am certain are more functional with this treatment, despite the side effects and risks. I hope, in the future, those decisions seem right. I think about our treatment choices every time I see those patients. I make sure they are adhering to the

plan and remain functional. I would like to say in the past that I always checked their KASPERs. Now I do. And I certainly must take into consideration what it means to write a prescription for 60 methadones or Klonopins, both for the patient sitting in front of me and for society as a whole.

I am sure there are many stories out there, about how clinicians have personally addressed the prescription abuse problems in their communities, both before and after the passage of HB1. As Dr. Rutherford points out in her article on the Drug Take Back Programs, the mortality and morbidity associated with prescription drug abuse in Kentucky is growing and must be a public health priority. That is not to say this is purely a problem with Family Physicians prescribing too many pain pills, but the data showing the number of individuals who get illegal prescription drugs from family and friends speak volumes as to how these medications make it onto the streets. Health care providers, including Family Physicians, have not done enough to stem the progression of this disease. Berland and Rodgers in the August 1, 2012 edition of the American Family Physician, present an approach clinicians should use in prescribing narcotics for chronic, nonterminal pain.[1] This approach may be considered time intensive but mirrors what is asked of us by HB1. With HB1, and the mandatory use of KASPER when prescribing controlled substances, many practices are struggling to meet the legislated requirements. We, at the KAFP Journal, would like to hear the concerns and the successes that have occurred in trying to implement the new rules. As with any public health threat, it will take champions from many professions, medicine, law enforcement, education, and others to combat this problem. I hope we, as Family Physicians, lead the charge.

1. Berlan D and Rodgers P. Rational Use of Opioids for Management of Chronic Nonterminal Pain. *American Family Physician*. 2012;86(3):252-264.

The data showing the number of individuals who get illegal prescription drugs from family and friends speak volumes as to how these medications make it onto the streets. Health care providers...have not done enough to stem the progression of this disease.

KEISA BENNETT, MD, MPH

VITAMIN D:
An Evidence-based Review and Approach to Management

Case: A 55 y/o female here for general physical asks, "I know I should take calcium, but I heard on the Today Show that most people don't get enough vitamin D. I've been taking one Os-Cal a day when I remember. Is that enough?"

Inquiries like this are now common in many Family Physicians' office. Vitamin D has become both a trendy and controversial topic in recent years, leaving the conscientious physician in a quandary as to whether to spend precious time keeping up with the literature or to dismiss the vitamin D movement as just another fad. The pace of research and reviews on vitamin D is so rapid, that it is impossible to represent the literature in a brief and yet up-to-date manner. This article attempts to summarize the most relevant studies, present a reasonable approach for managing vitamin D and to provide the most helpful studies for practitioners and patients.

Physiology of Vitamin D

Vitamin D is a fat-soluble derivative of cholesterol that has endocrine, paracrine, and autocrine functions. Figure 1 shows the basic mechanism of how vitamin D is made into its active form of 1-25-OH-vitamin D (calcitriol). The presence of phosphate, calcium and parathyroid hormone in Figure 1 indicate the complex feedback involved in regulating vitamin D activity in that both affect the level of active calcitriol. These homeostatic mechanisms keep the level of calcitriol normal throughout a large range of vitamin D intake and skin production, making calcitriol levels an inaccurate source of information on adequacy of vitamin D stores. For that reason, the precursor 25-OH-vitamin D is the molecule that is measured to assess status.[2]

Epidemiology of Vitamin D deficiency

The definition of vitamin D deficiency is controversial inasmuch as researchers and clinicians disagree on whether vitamin D is protective against a number of conditions. The Institutes of Medicine, for example, recently released guidelines defining vitamin D deficiency as levels below 20 ng/mL* based on the association of lower levels with rickets and osteomalacia.[3] The Endocrine Society, on the other hand, finds enough evidence to support levels of 20-30 ng/mL as having likely benefits. They therefore define an insufficiency category of vitamin D in that range as well as a true deficiency below 20 ng/mL.[4]

Regardless of labeling as deficient or insufficient, studies show that a large number of people worldwide fall below both the 20 and 30 thresholds. In the US, the National

* Note that in the U.S., ng/ml units are most common. The more common international units are nmol/ml, which is approximately 2.5 times the ng/ml value.

Health and Nutrition Survey (NHANES) of 2005-2006 defined deficiency as under 20 ng/mL and found a prevalence of 41.6%, which among self-identified Hispanics was 69% (OR vs. whites 3.2) and blacks 82% (OR 9.6). Despite speculation that postmenopausal and elderly women are at increased risk, there were no significant differences by age group or gender.[5] This study and others confirm definite risk factors for lower vitamin D levels as race (although it is controversial whether differences are due to skin pigmentation or other factors,)[6] obesity, low sun exposure through latitude or culturally-based skin covering, conditions affecting absorption such as gastric bypass (bariatric or reflux surgery) and celiac disease, as well as metabolic factors such as liver or kidney disease or certain co-administered medications (anti-retrovirals, antifungals, glucocorticoids and some antiepileptic drugs).[4,7]

Vitamin D Sources

The primary source of vitamin D is conversion of the cholesterol-based precursor in the skin under the catalyst of UVB radiation. Although UVB exposure produces large amounts of vitamin D, it makes up less than 10% of solar ultraviolet radiation, and at higher latitudes is not present in enough intensity in the winter to produce any vitamin D.[6]

The only significant natural dietary source of vitamin D is fatty fish, such as cod. Although certainly not a staple in most American diets, cod liver oil and other natural fish oil supplements can provide adequate dietary vitamin D. The American diet is supplemented through addition of synthetic vitamin D to milk, which has been successful in reducing the incidence of Rickets, indicating at least some effectiveness of the synthetic version of the vitamin. Supplements come in the form of vitamin D2 (ergocalciferol – a form synthesized from yeast), which is available as a prescription of 50,000U, usually used 1-2x weekly in those with documented deficiency, as well as vitamin D3 (cholecalciferol – derived from fish oil and the same version made in the skin), commonly available over-the-counter as 200, 400, 1000, 2000, and 5000U dosages. All of the over-the-counter products are the D3 variety, so patients don't need counseling to distinguish the two if buying their own supplement.

Bone health, fracture prevention

In observational studies optimal vitamin D level to promote bone density has been widely variable[8] but reviews demonstrated no clear patient-oriented benefits over 20 ng/mL.[9] Most recently the USPSTF published an updated meta-analysis finding that combined vitamin D and calcium supplementation can reduce fracture risk among the elderly, with the caveat that benefit may be smaller among community-dwelling relative to institutionalized elders. Effective doses ranged from 300-1100U/day of vitamin D and 500-1200mg a day of calcium.[10]

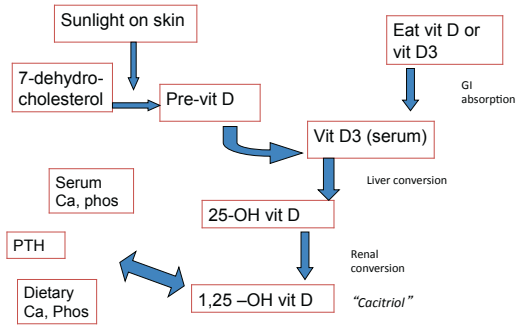
Fall prevention, functional improvement

Vitamin D related osteomalacia (implying vitamin D levels under 10 ng/mL) is associated with nonspecific myopathy that is reversible with supplementation, though resolution may take months to years in adults.[1] Observational studies have consistently shown associations with vitamin D levels and measures of frailty, including falls; however, the blood levels and/or intakes at which risk of falls becomes significant have not been consistent across studies As a note of caution, two recent RCT's employing more intermittent dosing of very high doses of vitamin D actually demonstrated increases in falls and fractures.[1] In the one that gained national attention, Sanders, et al. used 500,000U administered yearly and found moderately significant increased rate ratios of 1.15 for falls and 1.26 for fractures. The concerning results may be explained by relatively adequate baseline vitamin D levels of approximately 20 ng/mL with a rise to nearly 50 ng/mL, a level also associated with risks in other studies.[11-14]

Cardiovascular health

The largest segment of new vitamin D studies have occurred in the realm of cardiovascular health, although it is important to note that there are still no RCT's designed to have cardiovascular disease measures as primary outcomes.[15] The largest nationwide observational study (n = 15,363), performed on the NHANES III (National Health and Nutrition Examination Survey 1988-94) sample found an increased risk of cardiovascular death with a significant incidence risk ratio IRR of 1.40 in the lowest vs. other quartiles of vitamin D level (less than vs. greater than 13.5 ng/mL). The study suggested that vitamin D deficiency differences accounted for some of the increased CV risk in black as compared to white subjects.[16] The Framingham study produced a significant hazard ratio of 1.62 for cardiovascular events for hypertensive subjects at vitamin D levels < 15 ng/mL as opposed to > 15 ng/mL. At the same time, however, this study discovered a trend toward increased risk of CV events again as levels increased past 35 ng/mL, particularly at level at or above 50 ng/mL.[13] The study group responsible for the IOM report did not find enough evidence to confirm cardiovascular benefits of vitamin D but did acknowledge a possible benefit of raising the levels of those profoundly deficient into a more average range, with no additional benefit above 30 ng/mL.[3,9] Unfortunately, other studies have corroborated the association of calcium supplementation with an elevated CV risk,[17,18] leaving clinicians and patients in a quandary over the need to supplement calcium for vitamin D to be effective in improving bone and muscle health but risking a worsening of propensity to CV events with that supplementation.

Brief! Physiology Review



Leventis P. and Patel S. Clinical aspects of vitamin D in the management of rheumatoid arthritis. Rheumatology 2008; 47:1617-1621. [1]

continued on page 12 >>

Cancer prevention

The RECORD (Randomized Placebo-Controlled Trial of Vitamin D-3 and/or Calcium) trial found no differences in cancer mortality associated with vitamin D, calcium or combined supplementation,[19] while the USPSTF meta-analysis found the available data to be too limited and heterogenous to draw any conclusions.[10] In terms of individual cancers, the observational data is most robust for colorectal cancer and probably next for breast cancer; however, the few controlled trials of supplementation generally failed to demonstrate benefits,[20] though there are some exceptions.[21]

Mortality

In one large Italian observational trial, subjects in the lowest (< 10.5 ng/mL) relative to the highest (> 26 ng/mL) quartiles of vitamin D had a significant hazard ratio of 2.11 for mortality adjusted for multiple risk factors.[22] Similarly, NHANES III subjects in the lowest quartile of vitamin D level (< 17.8 ng/mL) were at higher risk of all-cause mortality relative to other quartiles with a relative risk of 26% and a mortality rate ratio of 1.26.[23] The RECORD Trial, however, found no difference in mortality.[19] The only meta-analysis focusing on mortality also found a nonlinear relationship, with mortality RR of 0.86 for increases of 5 ng/mL, 0.77 for increases of 10, and 0.69 for increases of 20. They determined an optimal vitamin D level of 30-35 for mortality outcomes.[24]

Harms and risks

Although a number of individual studies have suggested that intakes of up to 10,000U a day are safe in terms of failing to result in acute hypercalcemia in the vast majority of healthy adults,[4,25] many researchers have begun to focus on longer-term risk of mildly to moderately elevated calcium values. Although variations in vitamin D assays make it difficult to determine cut-off points for risk even at the population level, the preponderance of evidence seems to suggest a "deficiency" risk level below 15-17 ng/mL and an "over-supplementation" risk level above 50 ng/mL but possibly even as low as 35 ng/mL.[3,26,27] It is important to note that there is no known toxicity of vitamin D acquired through sun exposure, even in the case of heat stroke, as the feedback mechanisms in the skin seem to convert excess vitamin D into inert analogs.[6] (See Table 1.)

My approach

The constant flux of new studies makes responsible management and counseling extremely challenging. My own handling of vitamin D has evolved from lack of awareness to fairly overzealous testing and supplementation to a more conservative approach, all within the last 5 years, and I expect it to keep changing. Despite disappointing results in current studies of supplementation, the evidence that very low levels are clearly associated with health risks and the consistent association of moderately higher levels with reduced all-cause mortality are compelling reasons not to ignore vitamin D completely. No organizations recommend screening in the general population; however, given the difficulty in predicting deficiency, I maintain a low threshold to test, targeting patients with low sun exposure or dairy intake, those with most chronic illnesses, or those complaining of bone and muscle pain. I also test those with the risk factors of obesity, darker skin, frailty, or taking certain AED's, antifungal or anti-retroviral medications. If levels in tested adults are in the mid-20's or higher, I consider that result adequate and advise them to continue whatever they're doing. (A baseline level above 50 should prompt inquiry about high self-dosing, and/or a check for parathyroidism or related conditions.) If levels are in the high teens or low 20's, I recommend a higher dose over-the-counter supplement of 2000-5000U a day for 6 months followed by a reduction to 800-1000U with or without re-testing. For those with levels lower than 17-18 at baseline, I recommend the weekly prescription or 5000U daily until testing shows they are solidly into the 20's, at which point they can reduce to a maintenance dose of 800-1000U a day. There is no guideline

National guidelines (Table 1)

	Institutes of Medicine[3] (2011)	Endocrine Society[4] (2011)	American Assoc Pediatrics[28] (2008)
Intake age 0-1	400U*	400U	400U***
Intake age 1-18	600U	600U	400U***
Intake age 1-70	600U	600U	N/A
Intake > age 70	800U	800U	N/A
Goal level	20 ng/mL	20 ng/mL**	Not defined
Clinical goal	Prevention of rickets, osteomalacia, fracture	Bone health**	Prevention of rickets
Upper limit	4000U/day	Not defined	Not defined
Treatment of deficiency	Not defined	age <18: 2000U/d or 50K/week for 6 wks age 18+: 6000U/d or 50K/week for 8 wks	Not defined

*based on extrapolated rather than empiric data

**acknowledges that higher intakes are likely needed if vitamin D is indeed causative in prevention of chronic illness other than bone health. Also that adequate treatment doses may be up to 3x those listed above in obese and those on certain medications.

***from birth in all infants and children. Exclusively breast-fed children require supplementation regardless of mother's intake per current evidence (though there are studies in progress of adequate levels can be achieved through maternal supplementation). Children do not need supplementation if taking approximately 32oz of milk or formula a day.

for frequency of testing, but I find that at these baseline levels, it typically takes up to 6 months to achieve a goal level, even with the prescription version, and can be longer for the OTC version. I prefer doses slightly higher than the society recommended 600U due to what seems to me to be a good balance of potential for possible non-skeletal benefits and an amount that is almost certainly safe for the vast majority of patients. Of course it is appropriate now to consider responsible utilization of health care resources in testing considerations. For children I follow the AAP guidelines and recommend 400U a day at all ages unless the child is taking 30oz or more of milk or formula a day. Exclusively breastfed infants are a high priority. I don't test levels in this age group unless I'm especially concerned about risk factors or over-supplementation.

Patient understanding of vitamin D continues to range from complete unawareness to high-level self-supplementation after learning about vitamin D from media sources. It isn't uncommon now for patients to also be confused by different recommendations and prescriptions from all their various doctors. As a primary care provider, you can play a valuable role in patient education, though it is a challenging one to navigate under these circumstances. While considering individual patients and their circumstances, I counsel patients that the best way to get vitamin D is through responsible and reasonable sun exposure (not tanning beds) when possible, and that the best source of calcium is dietary. When those sources are inadequate for various reasons (and assuming no risk factors for hypercalcemia), supplementation of 800-1000U of vitamin D and 600-1200mg of calcium is reasonable.

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Enabling QUALITY IMPROVEMENT in PRACTICE for *Controlled Prescribing* (EQUIP-4-CRx)

Kentucky's primary care providers have heard the statistics depicting the prescription drug abuse epidemic in the US and especially in Kentucky. The statistics are widely distributed in the media and extensively discussed in legislative meetings. They probably know that one in fifteen Kentuckians have reported misusing prescription drugs and over 1,000 lives are lost each year in Kentucky to prescription drug overdoses. [1,2] They also know that a percentage of their patients have legitimate needs for prescription narcotics.

There is an estimated 116 Million chronic pain patients in the US and primary care providers serve as the main providers of pain care for chronically ill patients.[3,4] According to the Office of National Drug Control Policy, the top providers of extended-release, long-acting opioids are general practitioners and family medicine doctors (27 percent of opioid prescriptions).[5] The goal of adequately treating patients with legitimate needs for controlled prescription drugs, while not contributing to the problem of drug diversion and addiction is often a difficult, time consuming challenge. Furthermore, most primary care in the US and in Kentucky is delivered via small independent practices, especially in rural areas. Without the resources of large healthcare organizations, practices have little time to develop and implement measures that will efficiently utilize the 'checks and balances' needed to protect themselves and their patients.

A grant from the US Health Resources and Services Administration (HRSA) recently allowed researchers in the UK Department of Family and Community Medicine to examine possible solutions to this dilemma through a pilot project developed on a systems-based, facilitated quality improvement (QI) model. The project was to test the feasibility and uptake of QI interventions for the prevention and management of prescription drug abuse in primary care practices. A project steering committee consisting of UK faculty, community physicians, and representatives from the Kentucky Academy of Family Physicians and the Kentucky Cabinet for Health and Family Services developed the project objectives and content. The steering committee elected to modify and extend the recent experiences from the *Enabling Quality Improvement in Practice for Diabetes Management* (EQUIP-4-DM) project that was based on QI strategies for the management of diabetes in rural primary care practices. The EQUIP model is based on the formation of a QI collaborative and the facilitation of tailored systems-based practice improvements. Using the EQUIP framework, *Enabling Quality Improvement in Practice for Controlled Prescribing* (EQUIP-4-CRx) was formed (IRB Approval # 10-0236-P2H).

The pilot project was based on four main objectives: 1) form a collaborative of primary care providers and their staff members aimed at streamlining and improving practice processes for the prevention and management of prescription drug abuse, 2) deliver CME on topics of medical

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management of prescription drug abuse, chronic pain and anxiety, using evidence plus the insight and experiences of primary care providers, 3) implement tailored systems-oriented quality improvement interventions in participating practices, and 4) evaluate the uptake and short term impacts on the intervention.

Eleven practices throughout the state were invited to participate in the 16 month interventional pilot project. Each practice identified a physician champion and a staff member to serve as the in-house QI Manager. During the course of the project, participants (both the Physician Champion and QI Manager) and UK faculty gathered in Lexington for three half-day meetings for the delivery of CME and idea/best practice sharing. Uptake and utility of the QI interventions were measured by pre- and post-surveys of practice-level use of QI tools and strategies by the providers and staff as well as ease of adherence to guidelines for prescription of controlled drugs.

In order to carry out the statewide project, the researchers enlisted the help of the Office of Research Engagement for Advancing Community Health (REACH) field coordinators located at five UK Centers for Rural Health. The REACH field coordinators, trained in change facilitation, served as the liaisons between the UK team and the participating practices throughout the study. REACH Coordinators helped the practices identify and implement changes tailored to their specific practice and providers as well as deliver tools and overall project support. They met on-site at the practices and continued regular visits for 6 months, and then continued communication via phone and email over the course of the 16 months.

The delivery of CME (with 20 hours of credit for physicians) was central to the three collaborative meetings. Examples of topics included: distribution/discussion of regulatory compliance and guidelines working with the Kentucky Board of State Licensure, the Cabinet for Health and Family Services [mainly the Kentucky All Schedule Prescription Electronic Reporting (KASPER program)] and the DEA; evidence based management of chronic pain; handling upset/angry patients in the office setting; and recognition and management of prescription drug addiction. The project was also supported by a web site that had evidence-based literature and tools for participants' use provided by the project faculty and the collaborative participants.

The intervention aspect of the project centered around tailored change facilitation (via the REACH field coordinators) to set attainable QI goals, establish and implement plans, facilitate the use of evidence-based strategies for process improvement and clinical QI, assess progress and collect data. Examples of interventions included: using patient contracts for all patients being prescribed narcotics, increasing KASPER use, using urine drug screen protocols while understanding limitations, standardizing policies and distributing responsibilities to staff members, increasing patient education, increasing pharmacy communication, using tracking and reminder systems, and planning pain management visits.

To evaluate the feasibility and uptake of the project, data were gathered from a variety of sources including direct observation, pre- and post- surveys and structured interviews.

The EQUIP-4-CRx model proved to be feasible in the participating practices with positive changes observed and reported such as increased use of patient contracts and distributed staff responsibilities. The Physician Champion and the QI manager both reported that the collaborative workshops with CME and the tailored facilitation via the REACH field coordinators was the most valuable. QI interventions were implemented successfully and both managers and physicians reported a commitment to the new changes as well as looking for future QI measures to implement. The results of the small pilot study had clinical implications that need further investigation on a larger scale.

Ultimately the goal of this project was to test the feasibility and value of the EQUIP-4-CRx pilot project in community primary care practices. The pilot study and the team members assisted the providers and staff in looking at their current practices and incorporating QI measures aimed at improving patient care and regulatory compliance.

The recent passing of Kentucky House Bill 1(HB1) this past Spring requires clinicians to examine patients, take full medical histories, and check KASPER before writing prescriptions for opioids. These added measures, while intended to protect patients and providers, are often time consuming to implement into an already overscheduled, long day. When news of HB 1 passing spread through the medical community, we hope that the practices involved in EQUIP-4-CRx continued their day, business as usual.

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For more information on EQUIP-4-CRx and other EQUIP-based models, please visit: http://www.mc.uky.edu/equip-4-pcps/

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"THE GOAL OF ADEQUATELY TREATING PATIENTS WITH LEGITIMATE NEEDS FOR CONTROLLED SUBSTANCES, WHILE NOT CONTRIBUTING TO THE PROBLEM OF DRUG DIVERSION AND ADDICTION IS OFTEN A DIFFICULT, TIME CONSUMING CHALLENGE"

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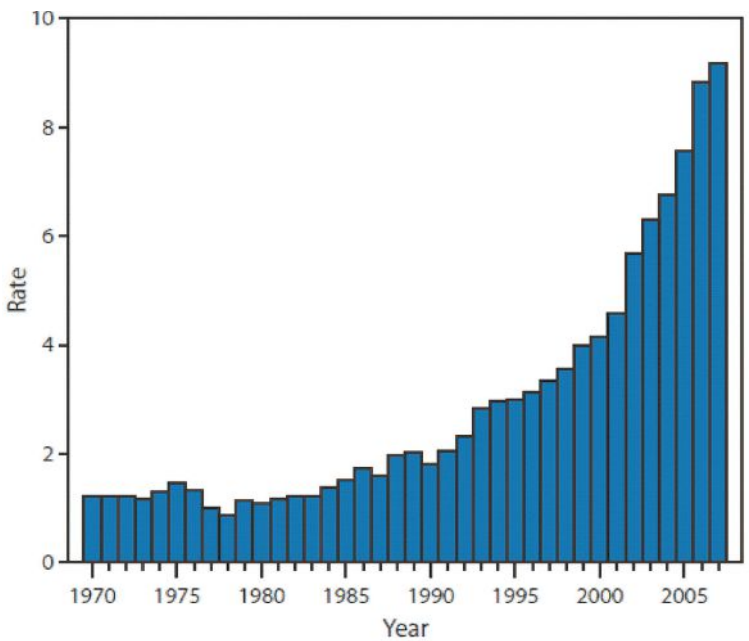
DRUG TAKEBACK PROGRAMS

Since 1997, prescriptions of opioids have increased exponentially in the United States. In 2007 alone, providers in the United States, including family physicians, prescribed enough opioids to allow every person in this country to take 5mg of Vicodin every 4 hours for 3 weeks.[2] Overdose deaths due to prescription opioids have also dramatically increased over the past decade (figure 1). From 2004-2008, emergency department encounters due to the non-medical use of opioids tripled.[2] Among people reporting non-medical use of prescription drugs, approximately 70 percent of them obtained the drugs from a friend or relative.[4] For every death due to prescription drug abuse, there are 10 people admitted to treatment programs, 32 emergency department visits, 130 people who abuse or are dependent on opioids, and 825 non-medical users of opioids.[5] (figure 3) While answering the call to treat pain more compassionately, health care providers have unfortunately helped fuel an epidemic that is killing 3 people daily in Kentucky.[8]

FIGURE 1. Rate* of unintentional drug overdose deaths — United States, 1970–2007



Source: National Vital Statistics System.
Available at http://www.cdc.gov/nchs/nvss.htm.
* Per 100,000 population.

As of December 2011, Kentucky ranked sixth in the nation, with approximately 1000 deaths per year due to prescription drug overdoses.[5] (figure 4) Overdose deaths now outnumber accidental deaths due to automobile accidents in Kentucky.[8] The prescription drug abuse epidemic not only affects people in the prime of their lives, but also greatly affects their families and friends, including children who are often separated from their addicted parents and placed in foster care.

Prior to 1990, physicians prescribed narcotic pain medications primarily for cancer related pain or for acute pain resulting from injury or surgery. During the 1990s, medical educators and pharmaceutical representatives encouraged health care providers to treat chronic non-cancer

FIGURE 3. **In 2008, there were 14,800 prescription painkiller deaths.**[5]

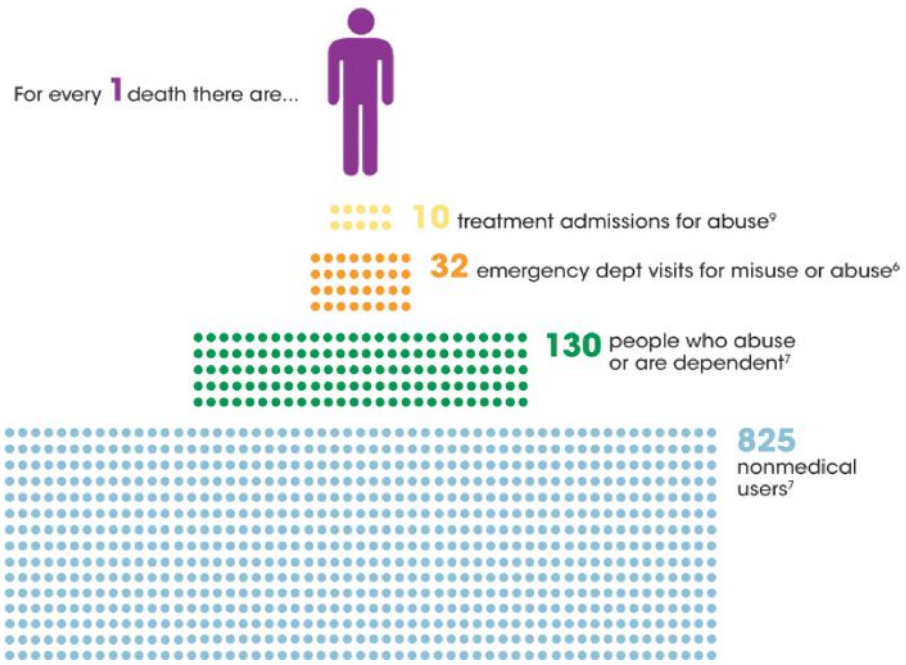
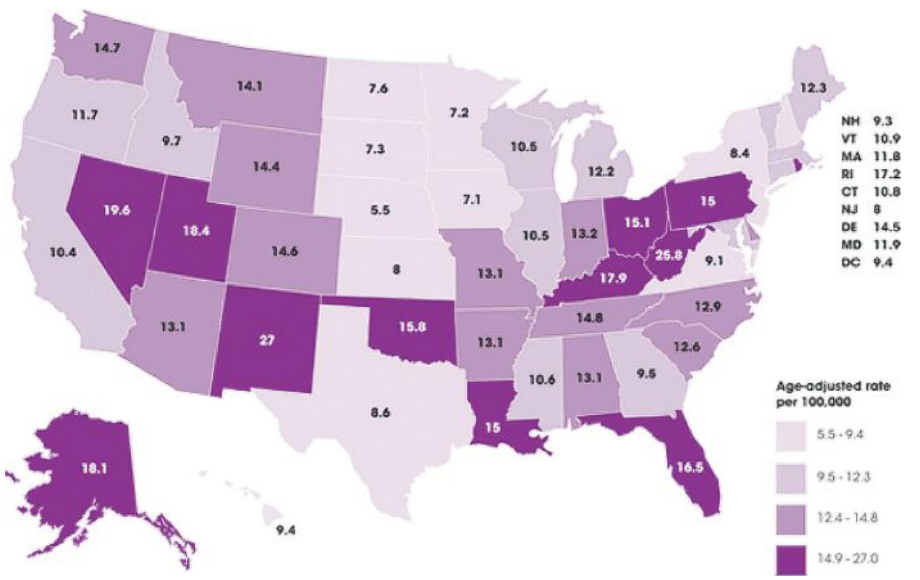


FIGURE 4. **Drug Overdose Rates by State, 2008** [5]



pain more aggressively, which ultimately led to greater prescribing of opioids for pain caused by chronic musculoskeletal conditions, such as arthritis and degenerative disc disease. Increased prescribing of opioids occurred despite insufficient evidence to support their use for chronic non-cancer pain.[8]

Although some patients with chronic pain complaints clearly benefit from narcotic pain medications, many others will not improve and will experience significant harm. Tolerance to opioids occurs in as few as 2 weeks in many patients, and other patients develop decreased pain thresholds and hyperalgesia due to opioid treatment.[1]

Primary care physicians are ideally positioned to address this epidemic, by more cautiously prescribing scheduled drugs, educating patients about the correct use and risks associated with the abuse of scheduled drugs, identifying and treating substance abuse and addiction, and educating patients on the proper disposal of unused medications.

Proper disposal of unused medications should help curtail the abuse and diversion of scheduled drugs. In addition, proper disposal of unused medications will help to minimize the environmental impact of unused prescriptions in landfills, which eventually make their way into the water supply.[6] While long term consequences of environmental contamination with pharmaceuticals are uncertain in people, studies in fish have demonstrated significant harm. Evidence from a study by Karen Kidd et al., in the 22 May 2007 issue of Proceedings of the National Academy of Sciences, reported the collapse of a population of fish in a lake containing high levels of a synthetic estrogen found in hormonal replacement therapy.[6]

Many patients taking prescription medications are unaware of how to dispose of unused medications. The Food and Drug Administration (FDA) and the White House Office of National Drug Control Policy have established guidance, including a list of 27 medications recommended for disposal by flushing, since risk of ingestion outweighs risk to the environment. Other medications, not on the list for flushing, should be combined with coffee grounds, cat litter, or another unpalatable substance and eliminated in the household trash.[4]

The Controlled Substance Act, which did not include regulations on

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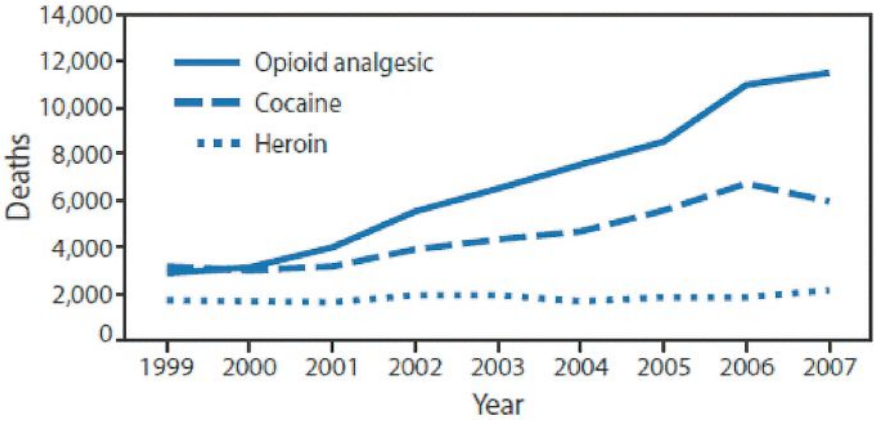
FIGURE 2. Number of unintentional drug overdose deaths involving opioid analgesics, cocaine, and heroin — United States, 1999–2007



Source: National Vital Statistics System. Multiple cause of death dataset. Available at http://www.cdc.gov/nchs/nvss.htm.

disposal of unused medications, was amended by the Responsible Drug Disposal Act of 2010 and the Safe Drug Disposal Act of 2010, which led to the development of DEA sponsored drug take-back programs. Since 2010, the DEA has organized four National Prescription Drug Take-Back Events, which collectively removed 774 tons of medication from circulation at more than 5000 sites around the country. Another event is planned for September 29, 2012. In addition, the DEA is currently drafting rules to provide easier access to drug disposal.[4]

In Broward County, Florida, the Sheriff's Office and the United Way Commission on Substance Abuse sponsored Operation Medicine Cabinet events approximately every two weeks. The program is ongoing and provides drug disposal sites at over 30 locations, including police stations, parks and community centers. Incentives, such as gift cards to local pharmacies are provided as extra encouragement to people to dispose of unused medications. At each disposal site, a police officer separates controlled substances from noncontrolled substances and counts all scheduled drugs. Pharmacists assist in identifying medications and counting the disposed medications. The collected medications are then sealed in boxes by law enforcement officers and later incinerated.

In Kentucky, many local law enforcement agencies voluntarily collect unused medications for incineration, which is the most environmentally conscientious method of disposal. However, many health care providers and pharmacists are unaware that local law enforcement provides this service. Physicians, pharmacists, and law enforcement officials in Kentucky need to collaborate to create programs like Operation Medicine Cabinet throughout the state. The Coalition for a Healthy Oldham County, for example, is currently working on initiatives to address the growing prescription drug abuse and overdose epidemic in our area. One of our goals will be to provide ongoing methods of disposal of unused and/or unwanted medications.

Primary care physicians can help address the current prescription drug abuse epidemic in several ways:

1. Provide information to patients on proper disposal of unused medications. The FDA provides information on their website www.fda.gov/consumer. National Prescription Drug Take Back Days information is available at www.deadiversion.usdoj.gov. The KAFP will soon launch an interactive map, detailing the locations of unused drug depositories throughout Kentucky.

2. Follow pain management guidelines closely and utilize tools such as urine drug screens and KASPER to identify potential abuse and diversion of scheduled drugs.

3. When changing a scheduled medication due to an adverse event or ineffectiveness, ask patients to bring the unused medication to the office before providing a new prescription.

4. Offer advice to patients identified with a possible substance abuse or addiction problem. Patients who are discharged for aberrant behaviors related to prescription drugs often continue to doctor shop or obtain drugs illegally, instead of getting the help they need. A letter stating that scheduled drugs will no longer be provided, but other medical problems, including possible addiction, will be addressed is an alternative to dismissal. Under these circumstances, a patient with a prescription drug problem will be more likely to return to his primary care physician for help when he is ready for it.

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"AMONG PEOPLE REPORTING NON-MEDICAL USE OF PRESCRIPTION DRUGS, APPROXIMATELY 70% OF THEM OBTAINED THE DRUGS FROM A FRIEND OR RELATIVE."

Dr. Rutherford graduated with a Masters in Public Health from Johns Hopkins in 1999 and received her M.D. in 2003 from Eastern Virginia Medical School. She completed a residency in family medicine in 2006 at Portsmouth Family Medicine Residency, and subsequently practiced in Carrolton, Kentucky for 5 years. Currently, she practices family medicine in La Grange, Kentucky, where she resides with her husband, a detective for the Louisville Metro Police Department, and their two young sons. With a particular interest in addiction, Dr. Rutherford also prescribes Buprenorphine to treat opioid addiction with SelfRefind in Frankfort and Carrollton. She plans to take the addiction medicine board examination in December. Dr. Rutherford is working with the Coalition for a Healthy Oldham County to address substance abuse issues in her community.

The M1 Perspective:

Administrative Experiences at Bluegrass Community Health Center

This summer, we participated in a month long experience in family medicine at the Bluegrass Community Health Center (BCHC) in Lexington. We each applied to work at BCHC as part of the Summer Research Program, supported by the University of Kentucky College of Medicine. The clinic primarily serves low income and refugee patients of Central Kentucky. Our experiences shadowing and working with the administrative staff gave us insight into the special challenges and associated health disparities of these patient groups. We both came into this experience with interests in public and community health and preventive medicine, fostered by our previous academic and research backgrounds. Neither of us had extensive exposure to the administrative side of health care, so working with both the clinical and administrative staff was not only a great learning opportunity, but also good preparation for our future as physicians.

We utilized the clinic's electronic medical records (EMR) to create rules within the system to improve patient care. These rules identified patients who fit certain criteria and alerted clinical staff to provide education or interventions as specified by the rule. Many of the rules we created specifically targeted Spanish speaking patients, including preventive care reminder letters about mammograms and pap smears. Areas of EMR rule development included well child checks, childhood vaccinations, KASPER monitoring, and annual flu shots. We also prepared Spanish health educational materials for the health care providers to disseminate to Hispanic patients. All of our work within the EMR was to enable the providers to make better clinical decisions and improve patient care, both of which are criteria of "meaningful use" for EMR adoption.

While endeavoring to create rules within the clinic's EMR system, we came across numerous obstacles that challenged our patience (pun intended!). While some rules were simple to create and pulled the appropriate patients, other rules seemed to have minds of their own, sometimes pulling the correct patients and the next day, not. Attempting to make sense of the many inconsistencies we came across in the system, we had to perform the dreaded task of calling IT. Lauren, our administrative supervisor, explained the task to us this way: "The reason I'm asking you to do this [call IT] is so you remember one day when you are doctors, to have patience with those back in administration when your electronic medical records aren't working." Unfortunately, we had more than one phone call with IT during the month, and those experiences taught us that even though a problem can be identified, the solution is not always simple or easily fixed.

During our time at Bluegrass Community Health Center, we also helped the clinic in their quest to achieve Patient Centered Medical Home (PCMH) status. This status is conferred upon primary care providers who organize their care around the patient, utilizing medical teams to coordinate and improve the quality of patient care. Since many of the patients have migratory lifestyles due to their economic status, it is especially important to have consistent medical care. As BCHC works towards their PCMH status, patients are forming personal relationships and gaining the benefits of continuity of care when seeing the same provider and staff each visit. Much of our work within the EMR as well as our collection of patient satisfaction surveys will aid the clinic to meet standards for PCMH recognition.

We saw the significance of PCMH throughout our time at BCHC, but it was especially apparent when working with refugee patients, many of whom have been separated from family and friends. Therefore, forming relationships with health care providers is not only beneficial for their physical health, but also for their mental wellbeing. The medical teams at BCHC include a counselor to address the psychological needs of all refugees, some of whom have experienced traumatic and violent events in their lives. The compassion exhibited by the medical teams at each clinic visit provides a stable support base for patients' overall wellbeing. Observing interactions between the medical teams and patients has demonstrated the value of the collective effort of all clinic staff in creating a patient centered medical home.

Working at Bluegrass Community Health Center this summer was a great experience for both of us. We were able to increase our knowledge of patient care and follow-up, as well as work with patient populations to which we previously had limited exposure. Working within the clinic's EMR was enlightening, as we were able to develop new skills and learn about the many benefits and challenges of the technology. Knowing that we have helped improve the quality of patient-centered interaction and care at the clinic is rewarding. Learning about administrative practices at BCHC has been influential in our view of primary care and has afforded us a distinct perspective from our peers who lack administrative experience, an outlook that will surely benefit us as future physicians.

Deborah Hickman is a first year medical student at University of Kentucky College of Medicine. In 2012, she earned a BA in Biochemistry at Transylvania University. Deborah is from Lexington, Kentucky.

Sarah Nester is a first year medical student at University of Kentucky College of Medicine. In 2012, she earned a BA in Kinesiology at Rice University. Sarah is from Florence, Kentucky.

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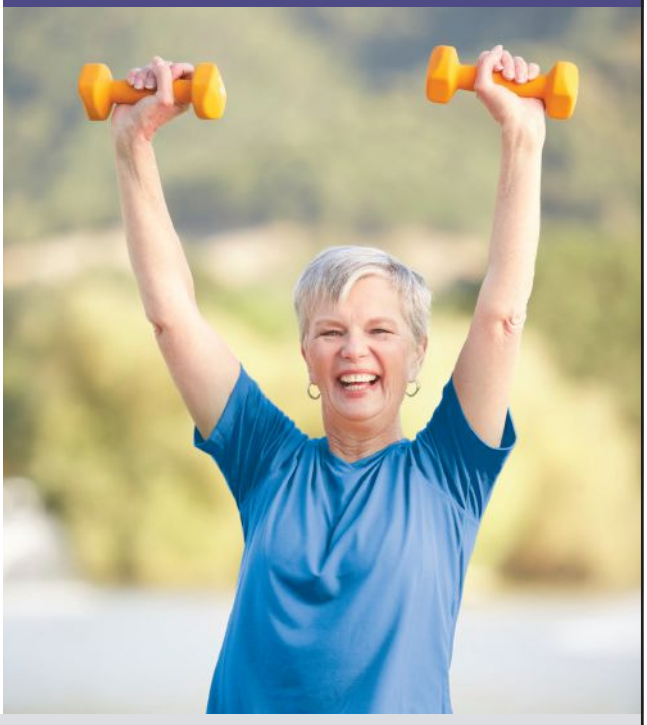

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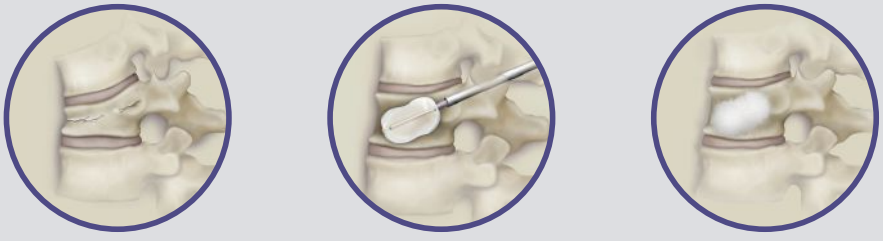

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