### MEDICAL SCHOOL AND RESIDENCY PROGRAM CURRICULUM RESOURCES ON DRUG ABUSE AND ADDICTION

# A Problem-Based Learning Case on Prescription Drug Abuse—Patient S.K.

Tufts University School of Medicine (Massachusetts Consortium)

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November 8, 2009





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### Contents

| Introduction                                | 3  |
|---------------------------------------------|----|
| Educational Objectives                      | 4  |
| Problem-Based Learning Case of Patient S.K. | 5  |
| Facilitator Guide                           | 22 |
| Evaluation Tool                             | 42 |
| References                                  | 43 |
| Suggested Readings                          | 45 |
| Additional Resources                        | 47 |
| Pilot Information                           | 48 |

#### Introduction

The problem-based learning (PBL) case of Patient S.K. is a curriculum resource module designed to address the need to cover prescription drug abuse-related issues in the preclinical medical school curriculum. It is based on the true story and case report of a patient; however, considerable material has been added that was not present in the original case report. This additional material was created to satisfy the pedagogic needs and objectives of the PBL and the addiction medicine courses for preclinical medical students. This module is taught during one academic semester, and it includes up to four 2-hour PBL discussion group sessions and optional research questions for home study.

**Key words:** drug abuse; drug addiction; motivational interviewing; prescription drug abuse; substance abuse

#### **Educational Objectives**

The general learning objectives of PBL are that:

- Students will develop learning and communication skills, including problembased and self-directed learning, critical reasoning, teaching, and group skills.
- Students will integrate and explore learning opportunities that may not be available in the rest of the curriculum.
- Students will establish the attitudes and practice the skills that will create a strong foundation for lifelong learning.

The specific educational objectives of the PBL case of Patient S.K. are to:

- Describe the different types of pain and their mechanisms.
- Understand the role of opioids in the treatment of chronic non-cancer pain.
- Review the decisionmaking process used to determine whether patients with chronic pain should be treated in the hospital or as outpatients.
- Know available screening tools and diagnostic tests for alcohol and/or drug abuse.

#### **Problem-Based Learning Case of Patient S.K.**

This case consists of several parts:

- Situation
- History
- Physical exam
- Tests and procedures
- Consultants
- Management
- Closures

#### Situation

Patient S.K. is a 49-year-old man who comes to you, his family physician, because of persistent radicular low back pain that is interfering with his work.

#### **History**

#### Childhood and Family

#### Birth (place, perinatal difficulties)

No problems that I was ever told about.

#### **Childhood Illnesses (including immunizations)**

I had all immunizations and just routine childhood illnesses. Nothing special.

#### **Family History**

My father died of prostate cancer in his late 70s. My mother is 85 and has arthritis and difficulty walking. She uses a walker. I have one older sister. She is in good health.

#### **School History**

I graduated from Salem State College with a degree in economics. I have an M.B.A. from Northeastern University.

#### General

#### **Chief Complaint**

My low back pain is out of control, and I have to miss too much work.

#### **How and When Did Problem Start**

I started getting radiating low back pain about 15 years ago.

#### **Changes Since Problem Began**

My pain has gotten steadily worse and sometimes is so bad I cannot go to work. Often I need my wife to drive me to my office because the discomfort is too distracting for me to manage the car.

#### **Precipitating or Aggravating Factors to Problem**

I think I have been getting worse since my laminectomy 10 years ago. I feel like that's what precipitated my problem. I used to jog regularly and walk my two dogs, but those activities really made my pain worse. I guess I'd have to say that is why I gave up those physical activities about 2 years ago—they made me too uncomfortable. Jogging and even driving make the pain worse. The only thing that helps at all is when I take an oxycodone.

#### Similar Problem(s) Occurred in the Past and What Was Done About It (Them)

No, just the ones I've told you about.

#### **Hospitalizations, Operations, or Injuries**

I underwent a laminectomy 10 years ago. I was hospitalized 2 years ago for a necrotic foot ulcer and had to have the toes on my left foot amputated.

#### **Medical History (organ system specific)**

I have insulin-dependent, adult-onset diabetes. For the past 8 years I have had diabetic neuropathy.

#### Habits, Medications, Environment

#### Alcohol Use

I have not had a drink of alcohol in over 20 years. I am an alcoholic but I'm proud to say I have been in recovery for a long time.

Responses if CAGE questions are asked by the family physician (CAGE questions, Copyright 1974, American Psychiatric Association): Back when I was an active drunk, no doctor ever asked me these questions.

- Did I feel I should cut down? Yeah, plenty of times.
- Did people annoy me by criticizing my drinking? Some people did, so I just avoided them and hung out with my drinking buddies!
- Did I ever feel guilty about my drinking? Well, not at first, but later on, yeah, I felt like hell most of the time.
- Did I ever have a drink first thing in the morning? Oh, not often. But I guess sometimes, yeah, every now and then.

#### **Allergies**

None

#### Cathartics/Laxatives, Use of

I never used to, but I have noticed that I get constipated more often than when I was young.

#### **Daily Life, How Does Problem Affect**

My back pain interferes with my ability to work, and sometimes I need to have my wife drive me to work. I tend to be quite sedentary when I am home. Of course, at work I sit in my office using a computer or speaking on the phone. We have a lot of meetings, and I get uncomfortable if I have to walk much.

#### Diet

I am careful with what I eat and stick to the diets recommended by the diabetes association. The last few years I notice that I feel kind of full, even after small meals.

#### **Drug Use (recreational)**

I used to have a serious problem with oral amphetamines and also nasally inhaled cocaine when I was young, like in my 20s. I never got into any legal problems, like with the cops or jail or anything. Man, I was really lucky considering what an idiot I was when I was using. But like I said before, I am proud to be in recovery for 20 years. I attend Narcotics Anonymous.

#### **Exposures: Occupational, Environmental, Infectious, Other**

Nothing that I know of. Just the usual stuff, you know, people in the office who have colds.

#### **Medications**

I take 20 mg of long-acting (sustained release) oxycodone twice daily but it's not working any more. My pain just won't go away. I take Metformin 500 mg twice a day and Glyburide 5 mg once a day. I also take 30 units of Lantus every night.

#### Occupation

I am an advertising executive. I have been promoted steadily in the industry since I started. I make good money. However, I have been missing work lately due to this back pain.

#### **Reduced Capabilities**

I don't walk as much as I used to. I stopped jogging and walking my dogs about 2 years ago, because of my pain. I am really embarrassed to say I have been having problems getting or keeping erections. Did you want to know that?

#### **Residences and Travel History**

I've always lived in Massachusetts. I've traveled to Canada and to Europe several times on business, and my wife and I have taken a few cruises.

#### **Sexual History**

Heterosexual. No same-sex sexual contacts. No contacts with prostitutes. Monogamous with wife, but not very interested in sexual activity for the last few years. I am embarrassed to say that I have been having problems getting and keeping erections.

#### Sleep

I am sleeping more when I am in pain but my sleep is not restful. I guess I don't sleep as well as I used to. Yes, I do frequently wake up early, and then I can't get back to sleep, probably because I lie awake worrying about things.

#### **Tobacco/Smoking**

I don't smoke.

#### **Psychosocial**

#### **Attitudes and Feelings About Problem and Situation**

I am worried about my pain and my absenteeism. I am worried about losing my job if I have to keep missing work because I just can't stand the pain.

#### **Mentation, Changes in (confusion, memory loss)**

My thinking is normal and clear, which means I am vividly aware of my problems.

#### **Personality Changes**

I feel like I have progressively isolated myself from family and friends over the past 2 years. I just haven't felt like being away from home except when I have to for work.

#### **Psychiatric History**

None. I have been very active with Alcoholics Anonymous and Narcotics Anonymous for 20 years, but that is more like group therapy, isn't it? I've never seen a shrink.

#### Social History (including jobs, work situation, present family situation)

I have been married for 24 years. I have had a very successful career, so far, in advertising and have been promoted frequently. I work full-time. Over the past 2 years I have been feeling less interested in social activities. I stopped attending church. I don't like to go out anymore, unless I have to go to work. Even my relationship with my wife has suffered. She doesn't understand that my back pain is so bad that I need to use medication daily for it.

#### **Symptoms**

#### **Balance or Locomotion Difficulties**

My balance is good. I have trouble walking when the back pain gets so bad. Every movement hurts. It is hard to get comfortable.

#### **Bleeding or Bruising Tendency**

None

#### **Bone, Joint, or Muscle Abnormalities**

None

#### **Chest Pain**

None

#### Cough up Blood

None

#### Cough, Wheezing, or Shortness of Breath

None

#### Ears, Ringing in

None

#### **Eyes/Eyelids, Problems With**

A few months ago I had an episode of double vision. It lasted for a few hours. I don't know what caused it.

#### **Fatigue or Malaise**

I feel tired a lot, but I think it is because I don't sleep very well.

#### **Febrile Convulsions**

None

#### Fever

None

#### **Hair Abnormalities**

None

#### Headaches

No problem

#### **Hearing Loss**

None

#### Hoarseness

None

#### Leg Pain, Soreness, or Cramps

I get shooting pains in my right leg. Sometimes it is so bad I cannot walk.

#### **Memory Loss, Confusion, Difficulties in Mentation**

My memory is pretty good, and I have to think a lot in my work.

#### **Muscle Soreness or Stiffness**

None

#### **Muscle Twitching**

None

#### **Muscle Weakness or Wasting**

Frequently the episodes of pain in the thighs, hips, or buttocks are followed later by weakness in the legs.

#### **Night Sweats**

None

#### Pain(s)

I get shooting pains in my right leg and low back pain that comes and goes without warning. Often I feel it in my thighs, in my hips (which makes it painful to walk), and in my buttocks. It definitely gets a lot worse if I have been doing too much, like moving around or walking. I have to rest for a while before it will get better.

#### **Seizures or Change in Consciousness**

None

### Sensory Phenomena (sensory loss, spontaneous or altered sensation, cold/heat intolerance)

I get weird sensations in both of my lower legs and feet, like tingling. Sometimes it feels like burning. The bottoms of my feet are numb. I have to be really, really careful about tiny rocks or stones in my shoes. I got a really bad foot ulcer 2 years ago.

#### Skin Color (pallor, cyanosis, pigmentation of mucous membranes, etc.)

None

#### **Skin Lesions or Rashes**

None

#### **Speech or Communication Difficulties**

None

#### Sputum, Production and Characteristics of

None

#### Syncope

None

#### **Thirst**

None

#### **Urination or Bowel Habits, Change in**

I urinate more if my blood sugar is high. Sometimes I have difficulty emptying my bladder completely. Sometimes I leak a little. Over the past few years I seem to be having more and more problems with constipation. Sometimes I get a lot of bloating and nausea after I eat.

#### **Vertigo/Dizziness**

I get dizzy if I stand up quickly. When that happens I notice that my heart is usually racing. This never happened to me when I was young. Seems like it has been worse over the last few years.

#### **Visual Phenomena**

A few months ago I had an episode of double vision. It lasted for a few hours. I don't know what caused it.

#### **Voice Change**

None

#### **Weight Gain or Loss**

None

#### **Physical Exam**

#### Abdomen

Unremarkable

#### **Bones, Joints, and Muscles**

Unremarkable

#### **Breast**

Unremarkable

#### Chest

Unremarkable

#### **Extremities**

Surgical removal of toes evident on left foot, well healed

#### **Gait and Station**

He has normal gait.

#### **General Appearance**

A well-dressed, well-groomed obese man. He appears uncomfortable sitting.

#### Genital

Unremarkable

#### Hair

Unremarkable

#### Head, Eyes, Ears, Nose, and Throat

Normal cephalic, atraumatic. Pupils are small, equal, round, and sluggishly reactive to light. Conjugate gaze noted. Fundi are grossly normal on nondilated exam. Ears unremarkable. Nasal septum intact but appears ischemic with several small areas of mucosal erosion. Throat exam unremarkable.

#### Heart

Unremarkable

#### Lungs

Unremarkable

#### **Lymph Nodes**

Unremarkable

#### **Mental Status**

He is awake, alert, and oriented to person, place, and time. He has no difficulties with recent and remote memory. He has normal attention span and concentration. His language is normal.

#### Neck

Supple

#### Neurological

Strength in the upper and lower extremities is normal. Sensation is normal throughout except in the lower extremities, where loss of pain, touch, and proprioception are notable in both feet. His cerebellar function is normal. Deep tendon reflexes are normal. Plantar responses are flexor bilaterally.

#### **Pelvic**

Not applicable

#### **Peripheral Pulses**

Unremarkable

#### Rectal

Unremarkable

#### Skin

Unremarkable

#### Spine

Well-healed laminectomy scars. Diffusely tender to palpation over lumbar, sacral, and lower thoracic spine areas. Range of motion limited due to pain.

#### **Vital Signs**

Afebrile, BP 145/78, P 88, RR 12

Weight: 88 Kg Height: 168 cm

Orthostatics not done

#### **Tests and Procedures**

#### **Arterial Blood Gas**

Not done

#### **Blood Cultures**

Not needed

#### **Chest X Rays**

Not needed

#### **Complete Blood Count (CBC)**

Not done

#### **CT of Spine**

Postlaminectomy changes. No focal abnormalities. No bony lesions. Disc spaces slightly narrowed.

#### **Drug Screening**

Qualitative testing only, by standard immunoassay screen: negative.

#### Electrocardiogram

Not done

#### **Electrolytes**

Normal Na, K, Cl, CO2, Ca, Phos.

#### Glucose and Hemoglobin A<sub>1C</sub>.

Serum glucose (random): 280 mg/dl. Hemoglobin A<sub>1c</sub>: 9.8 percent.

#### **Liver Chemistries**

All are within normal limits

#### **Lumbar Puncture**

Not done

#### **Open Biopsy and Pathology**

Not done

#### **Pulse Oximetry**

Not done

#### **Renal Function Studies**

Normal BUN and creatinine

#### Renal Ultrasound

Not done

#### **Serum Total Protein and Albumin**

Not done

#### Skin Test—PPD

Not needed

#### Spine X Ray

Not done

#### **Sputum Smear, Culture, and Sensitivities**

Not needed

#### **Stool for Occult Blood**

Not needed

#### **STD Testing**

Not done

#### T-Cell

Not done

#### **Thyroid Function**

Not needed

**Urinalysis**Positive for glucose; negative for albumin

#### Viral Load

Not done

#### Consultants

#### Anesthesiologist

Recommends gradually increasing (titrating) dose of long-acting oxycodone from 20 mg twice daily to 80 mg three times daily. Recommends referral to pain management specialist while patient is admitted and pain management clinic for long-term pain management plan.

#### Cardiologist

Not requested

#### Cardiovascular Surgeon

Not requested

#### Chaplain

Not requested

#### **Dermatologist**

Not requested

#### **Endocrinologist**

Has been consulted by family physician intermittently for more than 15 years for advice regarding changes in diabetes management, which has been well followed. Patient compliance usually has been adequate. Endocrinologist agrees that history is consistent with the evolution of diabetic neuropathy and recommends consultation with a neurologist.

#### **Ethics**

Medical ethics review requested by nursing staff who questioned whether the choice to use opioid treatment in a patient with long prior history of a serious multiple substance use disorder was ethical.

#### Gastroenterologist

Not requested

#### **General Surgeon**

Not requested

#### **Hematologist**

Not requested

#### **Immunologist**

Not requested

#### Infectious Disease

Not requested

#### Internist

Not requested

#### **Nephrologist**

Patient should be screened for the presence of diabetic nephropathy. What do you want me to look for?

#### **Neurologist**

Agrees that history and previous physical exam findings are consistent with evolving diabetic neuropathy and specifically demonstrate evidence for peripheral neuropathy as well as autonomic neuropathy. Tone, muscle mass, and strength appear symmetrical. Extraocular movements and visual fields appear within normal limits. Recommends referral to an ophthalmologist to screen for retinopathy. Recommends referral to urologist to evaluate erectile dysfunction. Recommends referral to nephrologist to screen for nephropathy. Recommends against laminectomy for pain control, but instead recommends consultation with the pain management team.

#### Neurosurgeon

Not requested

#### **Nutritionist**

Agrees that BMI is in the range indicating obesity. What medical benefits can realistically be expected from an aggressive plan for weight reduction? What measures can be undertaken to accomplish significant weight reduction in this patient?

#### **Obstetrician-Gynecologist**

Not applicable

#### **Occupational Therapist**

Not requested

#### **Ophthalmologist**

Patient should be screened for the presence of diabetic retinopathy. A meticulous exam should be done after dilating both eyes. What do you want me to look for?

#### Orthopedist

Not requested.

#### Pain Management

Recommends gradually increasing (titrating) dose of long-acting oxycodone from 20 mg twice daily to 80 mg three times daily, using as an endpoint stabilization of pain and improvement in some of the functional losses. At that point would recommend 5 mg short-acting oxycodone, to be used up to 4 tablets per day

maximum for breakthrough pain, but limit the monthly maximum to 60 short-acting tablets.

#### **Physiotherapist**

Not requested

#### **Psychiatrist**

Observes that some of the patient's symptoms overlap with major depression, including sleep difficulty, decreased activities, social isolation, and change in sexual functioning. Recommends consultation with pain management team before treatment for depression because uncontrolled pain may lead to depression in some patients. How do I know whether the symptoms are due to the pain or whether the patient has major depression as well?

#### **Psychologist**

Patient has some symptoms of depression including loss of energy and interest in activities he once enjoyed. He also has changes in sleep. What other symptoms are associated with depression? How can other factors such as chronic pain and substance abuse affect a diagnosis of depression? How would you treat major depression?

#### **Radiologist**

If no spinal x rays were done, radiologist recommends CT scan of spine instead.

#### Rheumatologist

Not requested

#### **Social Worker**

Meets with wife to discuss more fully her concern about husband's chronic pain problems and past substance abuse history. The history section of the case reflects the wife's concerns.

#### **Thoracic Surgeon**

Not requested

#### **Transplant Team**

Not requested

#### **Urologist**

Recommends pharmacologic treatment for erectile dysfunction. Performs digital exam of prostate and obtains serum PSA, in view of family history of prostate cancer. Digital exam reveals mildly but symmetrically enlarged prostate. Serum PSA 1.9 ng/ml.

#### Management

#### Administration of Blood and Blood Products

None given

#### **Admit to Hospital**

Yes

Choose investigations. Choose procedures. Choose consultants. Choose diet.

Discuss discharge planning: what is the endpoint for determining when to transition the patient from in-hospital management to outpatient management for a problem that will require many weeks to stabilize?

#### **Analgesics**

Given for pain according to the protocol determined by the anesthesiologist.

#### Antibiotics/Antiviral

Not used

#### **Consent Forms**

Needed prior to all procedures

#### **Discuss Patient's Behavior With Patient and Family**

Explain that patient has a complex chronic pain disorder that will require inpatient initiation and outpatient continuation of management.

#### **Elastic Stockings**

Are these helpful in neuropathy?

#### **Heart Rhythm Monitoring**

Routine if there is concern regarding autonomic neuropathy and potential adverse response to pharmacologic management of pain.

#### **Hospital Medical Orders, Routine**

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Out of bed with assistance

#### Insulin

Continue chronic regimen established by patient, respecting importance of frequency and content of dietary intake.

#### **Intravenous Fluid and Electrolytes**

IV line in place for medication management and IV fluids for nutrition if patient is unable to eat.

#### **Measure Fluid Intake and Output**

Yes

#### **Monitor Temperature**

Yes

Routinely done in hospital

#### **Monitor Vital Signs**

Yes

Routinely done every shift

#### **Mood Elevators**

None given

#### **Nutrition**

What is the regular diet appropriate for diabetic patient? Snacks as indicated. Coordinate with patient's insulin regimen.

#### **Patient Education**

Patient is told the purpose and results of all tests performed and the cause of his symptoms. Patient is counseled on treatment options and prognosis. All of patient's questions are to be addressed.

#### **Psychotropic Drugs**

None given

#### **Sleeping Medication**

None given

#### **Weight Measurement**

Not needed

#### Closure 1—Outcomes

The patient appeared to stabilize in terms of pain and functional losses when the dose of long-acting oxycodone reached 80 mg three times daily. He began to regain some function as corroborated by his wife. Over a period of 7 months he was more willing to socialize, was sleeping better, was walking the smaller of their two dogs on weekends, and was able to tolerate occasional drives to visit friends or extended family. His work absences decreased, and he resumed driving to work independently. Side effects of treatment were limited to moderate constipation and intermittent sweating.

#### Closure 2—Follow Up

Patient S.K. was referred for treatment again in the Pain Management Program because he was caught stealing prescription pads from his family physician's office during visits over the previous 6 weeks and forging additional prescriptions for himself of long-acting and short-acting oxycodone. Patient S.K. is tearful during his evaluation and acknowledges the deceitfulness and criminality of his behavior. Patient S.K.'s wife

appears outwardly angry and tells S.K., "The same old lies and secrets are starting all over again. Just like with the cocaine and the rest of it!"

S.K. offers as explanation, "I did not want to get high, I just needed more medicine, and I thought Dr. Blank would get angry with me if I asked for more. I did a stupid thing."

#### **Closure 3—Discussion Points and Research Questions**

What are the mechanisms and types of pain? What is the significance of persistent pain? How is pain (subjective) able to be quantified (objective)?

The subject of pain provides a good basis for reviewing neuroanatomy, pathophysiology, pharmacology, and so forth.

The physical findings provide for a discussion of the anatomical basis of the abnormalities in this case.

Neurosurgery: criteria for performing laminectomy. How effective is surgery compared with pharmacologic treatment? Are other alternative therapies available? What about acupuncture? What about hypnosis? Who decides whether to treat: what is the role of the physician? the patient? the family? Are there ethical issues?

#### **Facilitator Guide**

This guide is a reference tool that will help you enrich your group's PBL experience. Each group that uses this case will take it in a different direction, discussing some aspects of the case in greater detail than others, each according to its current level of knowledge. PBL is a unique learning method because it helps students find the edge of their knowledge and develop research questions that are individually appropriate.

Typically, PBL sessions are offered to preclinical first- and second-year medical students to help them focus their self-learning experience as they interact with their peers and the facilitator. PBL is optimally offered in small discussion groups of up to 15 students to accomplish its objective of active student participation. However, a PBL case can be offered as a requirement for an entire class provided the class is broken into several small groups that discuss the same PBL case separately. Each working group normally takes between two and six 2-hour weekly sessions to cover a PBL case. Handouts with the history of the patient are distributed at the first session in the form of reading cards covering the bulleted parts of the case history outlined above. Symptoms, consultations, and test results are revealed gradually to students as they discuss which symptoms to look for and which specialists to consult. The objective is for the students to inquire on their own about symptoms, consultations, and tests to conduct for the patient and make decisions based on the gradual influx of information by the facilitator as the discussion of the case proceeds.

The general learning objectives of PBL are that:

- Students will develop learning and communication skills, including problembased and self-directed learning, critical reasoning, teaching, and group skills.
- Students will integrate and explore learning opportunities that may not be available in the rest of the curriculum.
- Students will establish the attitudes and practice the skills that will create a strong foundation for lifelong learning.

The specific learning objectives of the PBL case of Patient S.K. are to:

- Describe the different types of pain and their mechanisms.
- Understand the role of opioids in the treatment of chronic non-cancer pain.
- Review the decisionmaking process used to determine whether patients with chronic pain should be treated in the hospital or outpatient.
- Know available screening tools and diagnostic tests for alcohol and/or drug abuse.

Each of these objectives is addressed in the case of Patient S.K. While working on this case, students will further develop learning and communication skills through discussing aspects of addiction medicine and developing relevant research questions. They will have plenty of opportunities to explore areas not otherwise covered in the curriculum,

such as risk factors and treatment options for addiction. Also, by discussing the comorbidities associated with addiction, the students will be integrating their new knowledge with areas of medicine they may already be familiar with. The case of S.K. will encourage students to research the diagnoses, mechanism of action, and treatment of addiction. Furthermore, as students work through this case, they will learn that much of the information needed to address and treat patients with addictions is not found in traditional medical textbooks. This is especially true with respect to working with social workers, pain management clinics, and addiction treatment facilities. By finding methods of researching these topics, the students will be discovering tools that will further aid them in developing the skills necessary for lifelong learning.

This Facilitator Guide includes information on many topics your group may decide to focus on. You are not expected to be an expert on each of these topics. The students should be encouraged to research these areas and teach one another the information they have discovered. Students are provided with additional information if the need arises. They can use this information to help encourage discussion or to add some important points to a discussion already underway. Also, if a group has exhausted a particular topic but something pertinent was not discussed, you are encouraged to share this knowledge with your group.

Along with information on topics likely to be discussed, a section addresses the closures presented at the end of the case. This material is to be used in the same way as the rest of the Facilitator Guide. Students should always be encouraged to direct their own learning and discussions when possible. The facilitator can use small amounts of information to redirect a discussion if it seems that the student-directed discussion has drifted too far from the basic learning objectives of the case. Once a topic has been discussed in full, the facilitator is welcome to share all the information in this guide if he or she chooses to.

Although each time the case is used it will develop in a slightly different way, the subsequent outline is basically how the case of S.K. is envisioned to flow.

After reading the introduction of Patient S.K., the students will begin asking questions as if taking a complete history and physical. One method that works well is to have one student assigned as the record keeper. This student should record information under the topics of "what we know," "what we want to know," "hypotheses," and "learning questions." Students are given a list of the bold headings in each section described above—History, Physical Exam, Tests and Procedures, Consultants, Management, and Closures—to choose which questions to ask. The responses to the questions that the students receive are directly below each heading. The exact information that each group acquires varies as members determine as a group which questions are most important to know. Along the way, they will develop hypotheses and learning questions and will discuss what they would like to know in addition about their patient.

Note: The facilitator should use this guide to answer the student inquiries.

Patient S.K.'s responses to their questions will likely bring up some of the following topics:

- Low back pain
- Laminectomy
- Neuropathy
- Diabetes mellitus and medical treatment
- Alcohol, oral amphetamines, cocaine, oxycodone
- Alcoholics Anonymous and Narcotics Anonymous
- Erectile dysfunction
- Depression
- Double vision
- Chronic pain

Keep in mind this list is not exhaustive. What your group decides to focus on may surprise you! Students will choose some of their topics to focus on and research. Between sessions, the students will individually research the learning questions assigned to them. At the next group meeting, each student presents what he or she has researched to aid in the self-direction of the group in the discussion of the case. How many days the group spends on each of these steps depends on the individual group.

At the end of each session, the students can summarize the case up to that point; then each chooses a topic to be researched and presented. At the beginning of the next session, each student can give a brief presentation and include handouts so that the whole group can learn from his or her efforts. Students should be encouraged to conduct their research by using not only online and text sources, but also expert opinions, which they can find at their own institution. Once a complete history and physical have been exhausted, the students will be offered the opportunity to order tests and ask for consults. Some topics that might be brought up at this time include:

- Drug testing
- Hemoglobin A<sub>1c</sub>
- Pain management clinics
- Risk factors for prescription drug abuse
- Ethics review board
- Diabetic nephropathy
- Diabetic neuropathy retinopathy
- Erectile dysfunction
- Obesity
- Role of social workers
- Prostate cancer and PSA

Finally, the management of this patient and each closure will be discussed. The topics focused on here will be:

- Chronic oxycodone use
- Drug-seeking behaviors
- Pain
- Treatment of back pain/chronic pain

#### **Discussion of Closures**

You may find that by the time the students arrive at the closures, much of the content has already been discussed. The closures are meant to provide further direction to the case so that each group will cover these important learning objectives.

 Effectiveness of long-term pain management on oxycodone Side effects of oxycodone How chronic oxycodone use could affect our patient's work ability Discussion of driving while on oxycodone

### Penalty for prescription forging Screening for drug abuse, particularly in patients with chronic pain How to address potential drug-seeking patients

#### 3. Mechanisms and types of pain

Significance of persistent pain

How pain (subjective) can be quantified (objective)

Neuroanatomy

Pathophysiology

Pharmacology

Anatomical basis of the abnormalities in this case

Criteria for performing laminectomy

Effectiveness of surgery compared with pharmacologic treatment

Acupuncture

Hypnosis

Decisionmakers, the physician, patient, and family. Are there ethical issues?

#### **Background Material To Assist Facilitator in Answering Student Inquiries**

The following information provides background material about opioid addiction in a patient with chronic pain, diabetic neuropathy, and a history of substance abuse disorders.

1. Chronic pain: The physical findings in chronic pain can be quite limited and nonspecific. This should provide for a discussion of the anatomical basis of pain (peripheral nervous system as well as central nervous system) and the abnormalities in this case.

The International Association for the Study of Pain (IASP) (see <a href="http://www.iasp-pain.org">http://www.iasp-pain.org</a>) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." Pain is generally categorized as acute or chronic. In contrast to chronic pain, acute pain is potentially severe, usually comes on quickly, and lasts for a short period. In general, the cause of acute pain is easily discernible by the physician (e.g., burn, infection) and is most commonly treated by correcting the underlying problem.

About 50 million Americans suffer chronic pain each year. Chronic pain is defined as pain that persists beyond the expected time of healing, or more than 3 to 6 months, and does not respond well to standard treatments. It is associated with specific and nonspecific medical conditions such as cancer, AIDS, rheumatoid arthritis, osteoarthritis, low back pain, spinal stenosis, and failed back surgery. 11 Although a number of disorders may cause chronic pain, generally speaking there are two types of conditions that underlie its pathogenesis: nociceptive and neuropathic. The nervous system is responsible for the perception of pain. Nociceptive pain is associated with tissue damage and a normal nervous system (e.g., pain associated with osteoarthritis), whereas neuropathic pain is associated with physiological nervous system dysfunction (e.g., diabetic neuropathy, postherpetic neuralgia). Not infrequently, these two types of pain coexist. The most common chronic nonmalignant pain disorders are myofascial pain, osteoarthritis, chronic low back pain, fibromyalgia syndrome, and peripheral neuropathy. 14 Repeated stimulus of the pain neurons in chronic pain can lead to sensitization (or increased responsiveness) over time. This sensitization can in turn cause increased pain sensation, perception of nonpainful stimuli as painful, or referred pain across other spinal segments.<sup>10</sup>

Neuropathic pain is defined as pain initiated or caused by a primary lesion or dysfunction in the nervous system. The most common causes in older adults are diabetes mellitus and reactivation of herpes zoster (e.g., postherpetic neuralgia). Axial arthritis (e.g., cervical and lumbar spondylosis) associated with radiculopathy is also considered by many experts to be a form of neuropathic pain. Other causes of peripheral neuropathy in older adults include alcoholic polyneuropathy, chemotherapy-induced polyneuropathy, entrapment neuropathies, postmastectomy pain, postthoracotomy pain, nerve compression or infiltration by tumor, phantom limb pain, postradiation plexopathy, and trigeminal neuralgia. Central poststroke pain may also present with symptoms that mimic peripheral neuropathy.<sup>14</sup>

**Diagnosis:** The first step in evaluating low back pain is the identification of "red flags" (e.g., fever, unintentional weight loss, sudden change in pain quality) indicative of a serious underlying disorder such as malignancy or spinal infection. These possible diagnoses should be evaluated with a targeted history and physical examination. If a serious condition is suspected, diagnostic imaging should be pursued promptly. Conversely, in the absence of red flags, imaging is rarely indicated. More frequently in elderly patients, imaging, when used as a screening tool, should be thought of as a way to demonstrate the absence of disease (e.g., compression fractures, metastatic bone disease, disc space infection) rather than as a way to diagnose the cause of pain.<sup>4</sup>

**Treatment Options:** The treatment of chronic pain often requires a multidisciplinary approach. In addition to physicians (including anesthesiologists, neurologists, and orthopedists, among others) and nurses, teams may include physical therapists, psychologists, pharmacists, occupational therapists, recreational therapists, social workers, case managers, nutritionists, chiropractors, and family and caregivers.<sup>10</sup>

Although many healthcare professionals who treat pain have successfully changed their perceptions and practices, many barriers, limitations, and controversies remain, particularly in the treatment of chronic pain. The use of opioids to relieve pain in patients with chronic non-cancer pain remains quite controversial. This controversy is based on concerns that opioids may be ineffective and unsafe and may lead to addiction or abuse. According to the American Pain Society, opioids alone are rarely effective in the treatment of chronic pain. The results of clinical surveys and retrospective case series involving patients with non-cancer chronic pain have been inconsistent in regard to resolving these controversial issues. The results of clinical surveys and retrospective case series involving patients with non-cancer chronic pain have been inconsistent in regard to resolving these controversial issues.

Review and meta-analysis of clinical evidence have revealed that opioids are commonly prescribed but may be efficacious for only short-term treatment for chronic back pain (<16 weeks). Long-term trials of opioid efficacy for chronic back pain are lacking, and other evidence indicates that the long-term efficacy of opioids for chronic pain may be limited.<sup>9</sup>

Opioid analgesics or tramadol is an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled (or is unlikely to be controlled) with acetaminophen and nonsteroidal anti-inflammatory drugs (NSAID)s. Non-opioid pain relievers, which do not have addiction potential, include aspirin, acetaminophen, ibuprofen, naproxen, and other NSAIDs. Other first-line treatments of chronic pain include anticonvulsants (e.g., gabapentin or pregabalin), tricyclic antidepressants (e.g., nortriptylline, desipramine), or topical anesthetics (e.g., capsaicin, lidocaine patch). A combination of different types of analgesic medications at lower doses is often more effective than a single high-dose medication. However, care must be used when combining these treatments because the potential for drug–drug interactions exist between opioids and both the anticonvulsants and antidepressants. <sup>10</sup>

The oral route of drug administration is most appropriate for patients receiving opioids, although rectal, transdermal, and parenteral routes of administration are used in specific

situations. For continuous chronic pain, opioids should be administered around-the-clock, and several long-acting formulations are available that require administration only once or twice daily. Opioid doses should be titrated according to agent-specific schedules to maximize pain relief and maintain tolerability. A patient's failure to respond to a time-limited course of opioids should lead to reassessment and consideration of alternative therapies or referral for further evaluation. Evidence is insufficient to recommend one opioid over another.<sup>10</sup>

Adverse effects include constipation, nausea and vomiting, sedation, cognitive impairment, and respiratory depression. Constipation is the most common side effect and should be closely monitored because it is a major reason for noncompliance. Treatment options for opioid-induced constipation include laxatives, opioid receptor antagonists, in particular drugs that do not cross the blood-brain barrier like methylnatrexone or prokinetic agents like metoclopramide or misoprostol that cause the propulsion of intestinal contents. Tolerance to the analgesic and adverse effects as well as physical dependence, which causes withdrawal symptoms on discontinuance, may occur with opioid use. 10

Successful pain treatment (as defined on an individual basis) and symptom management are attainable goals for the majority of patients with chronic pain. Treatment for chronic pain is about much more than medication. It can also involve stress relief and relaxation, physical therapy, massage, acupuncture, yoga, cognitive behavioral therapy, improved sleep and nutrition habits, and exercise. Through a multidisciplinary approach to pain management, a patient can learn to pace activities so that the patient's expectations are realistic about how much he or she can do in a certain period. Other treatment options using advanced technology also exist. For example, transcutaneous electrical nerve stimulation (TENS) is available in situations that are closely monitored by a physician or physical therapist. However, this technology is extremely expensive, so it may not be the most cost-effective way to manage chronic pain.

2. Identify and discuss considerations influencing whether a patient with chronic pain should be hospitalized or managed entirely as an outpatient (e.g., advantages and disadvantages of each approach; cost-effectiveness of each approach; short-term versus long-term cost considerations).

Professional societies and governmental and regulatory agencies have developed standards and guidelines for the management of acute and chronic pain in the hospital or in outpatient care. These organizations, which include the World Health Organization (WHO), IASP, the U.S. Agency for Healthcare Research and Quality (AHRQ), and the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), continue to work toward the humane goals of relieving unnecessary pain and improving patient quality of life.

The undertreatment of pain has become a public health crisis. Historically, many hospital pain management programs have been ad hoc in nature, with informal

programs run by one or more clinicians with a special interest in the subject. Many hospitals provide pain care but not pain management. Because of these challenges, it is critical to get support from the medical staff (i.e., physicians, nurses) and administration up front. Physicians and nurses must know general principles of opioid treatment: whom to treat; how to match analgesic therapy to pain severity; available routes of administration; appropriate dose administration regimens; dosage levels for treatment initiation and titration; risk factors for prescription drug abuse; common adverse events; and effects of opioid therapy, such as tolerance to most adverse effects and physical dependence.

Individuals with chronic pain referred to specialist chronic pain management programs frequently wait months to years for assessment and care. The best outcomes are achieved in patients treated in group-based pain management programs using cognitive-behavioral therapy to improve physical function, change unhelpful thinking, and improve patients' understanding of their situation.

Cost-effectiveness depends mostly on successful pain management for the patient through the combination of opioid-based and non-opioid therapies on a case-by-case basis. In many cases, chronic pain cannot be eliminated. Instead, treatment is centered on helping patients cope with the pain and be as productive as possible.

Finally, when addressing whether a patient should be hospitalized for pain management, the patient's insurer may play a role in the decisionmaking process because some insurers may not justify inpatient care if the planned treatment is not IV opioids, which could not be administered at home.

#### 3. Pain management programs and factors contributing to prognosis.

IASP, an affiliate of WHO, has a set of guidelines for desirable characteristics of pain treatment and management facilities. The goal of pain treatment is threefold, according to the American Pain Foundation: to lessen the pain, to improve functioning, and to enhance quality of life.

The following types of facilities have been identified and officially classified or certified:

- Multidisciplinary Pain Centers—Organizations of health professionals and scientists who conduct research, teaching, and patient care related to acute and chronic pain.
- Multidisciplinary Pain Clinics—These facilities are staffed by physicians of different specialties and other healthcare providers who specialize in the diagnosis and management of patients with pain. They do not offer research or teaching activities. These clinics may provide diagnostic and treatment facilities that are outpatient, inpatient, or both.
- Pain Clinics—Pain clinics are healthcare delivery facilities that focus on the diagnosis and management of pain. Some clinics may specialize in a specific

diagnosis or in pain related to a specific region of the body. Pain clinics may be large or small but should have more than one practitioner.

Pretreatment to posttreatment changes in pain severity and pain interference are associated with treatment satisfaction and effectiveness, improvement in pain condition, and quality of life. Pretreatment to posttreatment change in disability is significantly related to ratings of treatment effectiveness, improvement in pain condition, and quality of life. Pain intensity, pain interference, and disability are important outcome dimensions of pain management programs.

# 4. Determining eligibility of patients for opioid therapy. Physician-prescribed opioids leading to opioid addiction. Legal and ethical aspects to be considered. Other choices in pharmacological therapy.

It has been estimated that 3.2 to 18.9 percent of patients with chronic non-cancer pain become addicted to their medications. Because of substantial risks with long-term opioid use, potential benefits and harms should be carefully weighed before starting therapy. In particular, physicians should be aware of potential risk factors for prescription drug abuse such as heavy tobacco use, lifetime or family history of substance abuse, lifetime or family history of mental illness, history of legal problems, and so forth. The presence of these risk factors should not preclude the use of opioid therapy for pain management but should raise the awareness of the physician and perhaps increase the level of monitoring.

One example of physician guidance and oversight of their patients in the treatment of chronic pain using opioids is through the use of "universal precautions" as outlined by Gourlay and colleagues.<sup>8</sup> Their article proposes 10 precautions that may be taken to protect a patient against becoming addicted to prescription opioids. These precautions include the following:

- Make diagnosis with appropriate differential.
- Complete psychological assessment including risk of addictive disorders.
- Obtain informed consent from the patient.
- Create a treatment agreement between patient and physician.
- Make pretreatment and postintervention assessments of pain level and function.
- Complete appropriate trial of opioid therapy with or without adjunctive medicine.
- Reassess pain score and level of function regularly.
- Regularly assess the "Four A's" of pain management (analgesia, activity, adverse effects, and aberrant behavior).
- Periodically review pain diagnosis and comorbid conditions (including addictive disorders).
- Carefully document treatment.

#### 5. Screening for illicit drugs and alcohol abuse.

Screening for most high-risk behaviors and addictions can be performed by at least three methods: questioning, testing, and physical examination. This approach points to

central questions, such as what is detected, how long drugs of abuse remain detectable in urine, and what physical exam findings suggest illicit drug abuse and possible comorbid conditions (e.g., sleep disturbance, loss of appetite, loss of interest in sex).

#### Screening tools and diagnostic tests for alcohol abuse include:

- CDT (carbohydrate-deficient transferrin): most sensitive test (but rarely used in the United States)
- GGTP (or GGT) (gamma glutamyl transpeptidase): more than 30 units per liter is induced in liver with 4 or more drinks/day/for 2 weeks
- MCV (mean corpuscular volume): more than 95 microns/cubic ml in males and more than 100 microns/cubic ml in females
- LFTs: AST, ALT, and alkaline phosphatase
- CAMP (cyclic adenosine monophosphate): WBC of alcoholics is 3x normal
- EtG (ethyl glucuronide): alcohol metabolite present in urine for 5 days postdrinking
- CAGE (Cage Questions, Copyright 1974, American Psychiatric Association). A
  positive response on two or more of the four questions is generally considered
  the cutoff value, indicating a potential alcohol problem.
  - Have you ever felt you should CUT down on your drinking?
  - Have people ANNOYED you by criticizing your drinking?
  - Have you ever felt GUILTY about your drinking?
  - Have you ever taken a drink first thing in the morning (EYE-OPENER) to steady your nerves or get rid of a hangover?
- (SASQ) Single Alcohol Screening Question: "When was the last time you had more than five drinks in one day?" (four drinks for women). Any positive response within the last 3 months is positive and requires evaluation.<sup>3</sup>

Screening for other drugs of abuse: The NMASSIST—NIDA-Modified Alcohol, Smoking, and Substance Involvement Screening Test (see <a href="http://ww1.drugabuse.gov/nmassist/">http://ww1.drugabuse.gov/nmassist/</a>) provides a short questionnaire for physicians to ask to determine whether a patient is abusing a variety of substances including cannabis, cocaine, prescription stimulants, methamphetamines, inhalants, sedatives, hallucinogens, street opioids, and prescription opioids. (Modified from the WHO ASSIST questionnaire). Urine drug testing may be used to confirm the presence of a drug or the use of multiple drugs as well as to augment screening (i.e., biological testing should not preclude screening). For more information on biological specimen screening for other drugs, see

http://www.nida.nih.gov/nidamed/resguide/specimentesting.html.

**Signs of opioid abuse on PE:** Signs of opioid abuse include evidence of intravenous use, sedation, and signs of withdrawal such as dysphoria, anxiety/restlessness, yawning, diaphoresis, muscle and joint aches, lacrimation, piloerection, rhinorrhea, insomnia, mydriasis, N/V/D, tachycardia, cramps, and fever.

# 6. Confidentiality laws affecting husband and wife in the case of substance abuse. How interviewing in the presence of family may lead to either misreporting or underreporting of substance abuse history.

Although substance abuse is a behavior that threatens the abuser's health and life, State and Federal laws vary regarding the rights of adults and minors to confidential evaluation and treatment. In general, ethical concerns demand that patients provide informed consent before the interview with or without next-of-kin present. Consent forms routinely describe assessment procedures, confidentiality safeguards, potential risks and benefits of participation in a given treatment, and alternative as well as investigational treatments. Evidence indicates that many participants still fail to understand fully or retain the information presented, and it has been suggested that clinical trials using patient interviews include a systematic evaluation of the quality of the informed consent process. In

#### 7. Diabetic neuropathy: mechanism, diagnosis, treatment.

Diabetic neuropathy (DN) is a serious and debilitating complication of both type 1 and type 2 diabetes. DN is also the most common complication of diabetes, reaching a 45-to 50-percent prevalence compared with 25 to 30 percent of retinopathy and 20 percent of nephropathy.<sup>3, 13</sup> It imposes a considerable burden on a patient's quality of life and the healthcare system. Despite the prevalence and severity of DN, there are no effective treatments, except the maintenance of euglycemia.

DNs can be focal or diffuse, proximal or distal, affecting both peripheral and central nervous system, causing morbidity with significant impact on the quality of life of the person with diabetes, and can result in early death. The pathology of DN is characterized by progressive nerve fiber loss that gives rise to positive and negative clinical signs and symptoms, such as pain, paresthesia, and loss of sensation. Distal symmetric sensory or sensorimotor polyneuropathy (DSP) usually involves small and large nerve fibers. Large-nerve-fiber neuropathies produce numbness, ataxia, and uncoordination, impairing daily activities.<sup>5</sup>

DSP represents the most relevant clinical manifestation affecting approximately 30 percent of the hospital-based population and 25 percent of the community-based samples of diabetic patients.<sup>3</sup> The incidence of DSP is approximately 2 percent per year. The most important etiological factors that have been associated with DSP are age, poor glycemic control, diabetes duration, and height, with possible roles for hypertension, smoking, hypoinsulinemia, and visceral obesity. Accumulating evidence suggests that not only surrogate markers of microangiopathy, such as albuminuria, but also those used for polyneuropathy, such as nerve conduction velocity (NCV) and vibration perception threshold (VPT), may predict mortality in diabetic patients. Elevated VPT also predicts the development of neuropathic foot ulceration, one of the most common causes for hospital admission and lower limb amputations among diabetic patients.

Persistent or episodic pain is localized predominantly in the feet. The pain is often described as a deep-seated aching or it may have a burning, thermal quality. Evoked pain, such as allodynia (pain due to a stimulus that does not normally cause pain [e.g., stroking]) and hyperalgesia (severe pain due to a stimulus that normally causes slight pain [e.g., pinprick]), may be present. The symptoms may be accompanied by sensory loss, but patients with severe pain may have few clinical signs. Pain may persist over several years causing considerable disability and impaired quality of life in some patients, whereas it remits partially or completely in others, despite further deterioration in small fiber function. Pain remission tends to be associated with sudden metabolic change, short duration of pain or diabetes, preceding weight loss, and less severe sensory loss.

Compared with the sensory deficits, motor involvement is usually less prominent and restricted to the distal lower limbs resulting in muscle atrophy and weakness at the toes and foot. Ankle reflexes are frequently reduced or absent. At the foot level, the loss of the protective sensation (painless feet), motor dysfunction, and reduced sweat production resulting in dry and chapped skin due to autonomic involvement increase the risk of callus and foot ulcers. Thus, the neuropathic patient is at high risk of developing severe and potentially life-threatening foot complications, such as ulceration, osteoarthropathy (Charcot foot), and osteomyelitis, as well as medial arterial calcification and neuropathic edema. DSP is a major contributory factor for diabetic foot ulcers, and the lower limb amputation rates in diabetic subjects are 15 times higher than in the nondiabetic population. Therefore, an early detection of DSP by screening is very important. This becomes even more imperative because many patients with DSP are asymptomatic or have only mild symptoms. Most amputations can be potentially prevented if appropriate screening and preventive measures are adopted.

**Diagnosis:** A careful history and detailed physical examination are essential for the diagnosis. Small-nerve-fiber neuropathy often presents with pain but without objective signs or electrophysiological evidence of nerve damage and is recognized as a component of the impaired glucose tolerance and metabolic syndromes. The greatest risk resulting from small-fiber neuropathy is foot ulceration often leading to gangrene and amputation. The symptoms should be divided into positive symptoms (e.g., patients feel awful and complain) and into negative symptoms (e.g., patients may not complain). The latter is particularly important for the necessity of foot care.

**Pathogenesis:** Pathogenetic mechanisms underlying the progressive nerve fiber loss seem to be multifactorial, including glycation, reactive oxygen species, and altered protein kinase C activity. When fibers undergo active nerve fiber degeneration or impaired regeneration, those fibers exert exciting impulses, thus inducing subjective symptoms such as pain or paresthesia (positive symptoms). Once nerve fibers are lost, the loss of sensation will take place. With increasing loss of fibers, the area of sensory loss or its severity will be augmented (negative symptoms). In this stage, every effort should be made to prevent the foot from requiring amputation.

**Prevention:** Preventive strategies and patient education still remain key factors in reducing complication rates and mortality. Symptomatic therapy has become available; and newer and better treatment modalities, based on etiologic factors, are being explored with potential for significant impact on morbidity and mortality.

**Treatment:** Etiological therapy is aimed at modifying the pathophysiological mechanisms underlying the neuropathy, some of which are common in different neuropathic conditions. Diabetic painful neuropathy (DPN) is one of the most prevalent causes of neuropathic pain. DPN management consists of excluding other causes of painful peripheral neuropathy, maximizing diabetic control, and using medications to alleviate pain. Whether glycemic control is linked to the development and severity of DPN remains controversial. Drugs such as aldose reductase inhibitors, ACE inhibitors, lipid-lowering agents, and alpha-lipoic acid (thioctic acid) may have a useful role to play. Placebo-controlled studies have shown that opioids, and antiepileptic and antidepressant drugs together with capsaicin, are effective for alleviating DPN. Tramadol and oxycodone have been shown to be effective in studies of limited duration; but adverse side effects, such as constipation and physical dependency, may limit their usefulness. Of the antidepressant drugs, the tricyclic antidepressants have been shown to be effective for alleviating DPN. These medications are widely used, but their anticholinergic and sedative properties may not be well tolerated by patients. There is also good evidence that the serotonin-norepinephrine reuptake inhibitor antidepressant drugs venlafaxine and duloxetine are effective for treating DPN. The gabapentinoid group of drugs, gabapentin and pregabalin, appear to be the most evidence based of the antiepileptic drugs for treating DPN. Of the newer antiepileptic drugs, lacosamide appears to be the most promising for alleviating DPN. Capsaicin has the best evidence base of all the topical agents, but local anesthetic patches may also have a useful therapeutic role. It is not possible to nominate a single drug as the first-line treatment for DPN, and there is evidence that a low-dose combination of two or more drugs rather than a single agent may provide better symptomatic relief with fewer adverse effects.

#### 8. Management of Type II diabetes including insulin and routine labs.

The goal of all diabetic therapy is to keep serum glucose in the range of 100 to 120 mg/dl. The best routine laboratory assessment of glycemic control over time is the measure of HbA<sub>1</sub>C, which is a determination of the fraction of total hemoglobin that has been nonenzymatically glycosylated by glucose on the [beta] chain. The normal level is 4 to 6 percent and the American Diabetes Association recommends that diabetic patients should not have HbA<sub>1</sub>C levels in excess of 8.5 percent of total hemoglobin. The goal of all diabetes therapy is to maintain the serum glucose and HbA<sub>1</sub>C at these levels to minimize serious long-term adverse effects of hyperglycemia.<sup>1, 6</sup>

The main shortcoming of conventional insulin therapy is that the pharmacokinetic profile does not match the physiologic insulin secretion present in healthy individuals. The need for optimal glucose control is accompanied by the risk of significant hypoglycemic events. The Diabetes Control and Complications Trial demonstrated that a 10-percent improvement in HbA<sub>1</sub>C resulted in an 18-percent increase in hypoglycemic events. The availability of long-acting analogs augments the capabilities of the new short-acting agents so that when they are used concurrently, more precise serum glucose control can be achieved with minimal risk of hypoglycemia. The introduction of both new short-and long-acting analogs with increased stability and less variability has helped achieve further improvements in glycemic control. New technologic developments have been focused on these goals by either production of agents that more closely mimic normal physiologic release of insulin or delivery devices that respond to insulin secretion in a more physiologic manner.<sup>6</sup>

#### **Insulin administration:** Methods of insulin administration include the following:

- Buccal/oral-administered insulin is being developed in an effort to find a painless, safe, and effective alternative to injected insulin.<sup>6</sup>
  - Oral insulin preparations require resistance to enzymatic degradation to be effective. Nobex Corporation (Durham, North Carolina) has developed a hexylinsulin monoconjugate 2, which has alterations in the insulin physiochemical structures that resist gastric enzymatic degradation. Small studies have demonstrated that a single oral dose of 0.5 to 1.0 mg/kg is as effective in lowering postprandial serum glucose as a subcutaneous dose of regular insulin.<sup>6</sup>
- Inhaled insulin is approved for preprandial use in the United States in adult patients with diabetes. This formulation of insulin has a more rapid onset of action than subcutaneous-administered regular insulin. Therefore, the use of oral/buccal-administration of insulin can be preferable to needle injection regardless of the drug abuse history of the patient. However, the duration of action is similar to that of injected regular insulin (inhaled is oral in the case of insulin); therefore, there is no significant pharmacokinetic advantage to this mode of delivery. The efficacy of oral/buccal insulin has been demonstrated in proof-of-concept studies, but long-term safety data are not yet available.<sup>6</sup>

Other novel agents may either provide an alternative therapeutic strategy or offer useful adjuncts to existing therapies.<sup>5</sup>

- Glucagon-like peptide 1 (GLP-1) is produced in the small intestine. GLP-1, also released in a postprandial manner, promotes insulin production and secretion, reduces glucagon secretion, delays gastric emptying, and induces satiety. However, GLP-1 is rapidly degraded by dipeptidylpeptidase IV (DPPIV), which reduces its usefulness in vivo.<sup>5</sup>
- Amylin is a hormone secreted after a meal complementing insulin, produced by pancreatic beta cells, which have glucose-lowering effects.<sup>5</sup>

# 9. Meaning of transient "double vision" and differential diagnosis; transient ischemic attacks (TIAs) and optic neuropathy.

The patient is at increased risk for strokes due to his history of uncontrolled diabetes. Nonarteritic anterior ischemic optic neuropathy might also be a rare side effect of treatment for erectile dysfunction (ED). MRI and angiogram are the most common diagnostic approaches, after the clinical evaluation. In this patient, MRI will help exclude potential causes (other than his microvascular disease) of double vision (diplopia).

Diplopia typically results from acquired ocular misalignment. Monocular diplopia (10 percent of cases), which persists when the fellow eye is covered, is usually the result of refractive error, lens opacities, or migraine. Cranial nerve paralysis is the most common cause of binocular diplopia, resulting from hypertension, diabetes, head injury, neoplastic or inflammatory intracranial disease (herpes zoster), myasthenia gravis, or congenital malformations.<sup>10</sup>

#### 10. Causes and treatments for erectile dysfunction.

**Erectile dysfunction:** ED is defined as the consistent or recurrent inability of a man to obtain and/or maintain a penile erection that is satisfactory for sexual performance.<sup>2</sup>

ED is a common condition of aging men. Indeed as many as 50 percent of men older than age 40 will suffer some degree of ED. It has substantial impact on interaction with their partners, families, and employment. ED may be a harbinger of more serious vascular events and is commonly associated with depression.<sup>2</sup>

ED is generally a multifactorial condition that mirrors the diseases of aging, most commonly those with associated psychological, neurological, and most importantly vascular abnormalities.

Common risks factors for ED include aging, chronic renal failure, substance abuse including alcohol abuse, obesity and the metabolic syndrome, sedentary lifestyle, and significant depression. The majority of risk factors for ED, however, are vascular diseases including hypertension, dyslipidemia, ischemic heart disease, peripheral vascular disease, and the sequelae of diabetes mellitus. Many of the medications used to treat these conditions are also associated with ED. Indeed, the antihypertensives are often related to ED. The most significant of these are the thiazide diuretics that, through

their impact on the sodium pump mechanism in the corpus cavernosum, decrease the ability for erectile function. Similarly, thiazide diuretics have been associated with lowered androgen levels. Antihypertensive medications that are most erection friendly include A2R blockers, calcium channel blockers, alpha blockers, and angiotensin-converting enzyme inhibitors. Medications used for the treatment of depression are likewise associated with decreased erectile function. Indeed, the selective serotonin reuptake inhibitors (SSRIs) are significant causes of ED.<sup>2</sup>

**Evaluation of ED:** Diagnosis of ED begins with a careful history and asking the patient about his sexual function during clinical visits. Once identified, ED must be carefully considered with full history, careful physical examination, and laboratory studies to include markers of vascular risk factors, diabetes, and hypogonadism. This evaluation should include a sexual and psychosocial history with information on ED onset. duration, progression, associated medications, and risk factors. Because many patients and partners are uncomfortable in discussing sexual function, it is important that patients be placed at ease and each portion of the history and physical examination be carefully explained. Initial history can be facilitated through the use of self-administered questionnaires. The most clinically useful of these is the Sexual Health Inventory for Men. Once the history has been completed, targeted physical examination should evaluate secondary sex characteristics, genitalia for testicular size, and an examination of the prostate gland for possible prostatic malignancy or prostatitis. Laboratory testing should include studies for diabetes, hypercholesterolemia, and hypogonadism. Because the first symptom of diabetes, hypercholesterolemia, and hypogonadism can be ED, a high index of suspicion for these associated conditions should accompany all examinations of patients with ED.<sup>2</sup>

**Treatment of ED:** A stepwise care approach to the management of ED permits adequate and effective treatment of ED in the most conservative and noninvasive fashion possible. Because oral medications are the principal method for the treatment of most men with ED, these can be considered first-line therapy. Other elements of first-line therapy that should precede the prescription of oral medications include lifestyle modification, modification of drug therapy (especially antihypertensive medication), psychosocial counseling, smoking cessation, and androgen replacement therapy if indicated. Oral phosphodiesterase type 5 (PDE5) inhibitors can be administered once underlying healthcare and lifestyle considerations have been optimized.<sup>2</sup>

The treatment of ED was revolutionized by the introduction of PDE5 inhibitors in 1998. Sildenafil citrate is the first orally active inhibitor of PDE5 to be approved and widely used for the treatment of ED.<sup>2</sup>

Men with documented deficiencies in androgen levels should have normalized androgen levels in association with oral medication treatment. It has been demonstrated that eugonadal men respond better to sildenafil than men who are hypogonadal.<sup>2</sup>

**Oral agents for the treatment of ED**: A number of therapeutic agents were used for ED before phosphodiesterase-inhibiting medications. These agents, such as alpha

blockers, apomorphine, trazodone hydrochloride, yohimbine, and other herbal medications, demonstrated poor responses in comparison with placebo in double-blind studies.<sup>2</sup>

#### 11. Prostate Cancer and PSA.

Approximately 1 in 6 men in the United States will eventually receive a diagnosis of prostate cancer, and 1 in 34 will die from it. The median age at diagnosis is 68 years; this is the highest age-specific incidence of any cancer. The average age at the time of death among men with metastatic disease is 80 years. Compared with White men, Black men have a 40-percent higher risk of the disease and twice the rate of death. The mortality due to prostate cancer has steadily declined for a decade, and it decreased by 4 percent per year between 1999 and 2003. This decrease may be attributable to several factors, including earlier detection of cancer and improved local and possibly systemic treatment. Because PSA testing has advanced the diagnosis (e.g., the lead time) by 5 to 10 years and because a 65-year-old White man could be expected to live an average of 16.3 more years and a Black man 14.5 more years, the estimation of life expectancy is a key determinant in the selection of therapy. 12

No forms of imaging accurately estimate the extent of tumor and its location within the prostate or in the area surrounding it. The National Comprehensive Cancer Network (NCCN) guidelines recommend imaging studies in only a selected group of patients.<sup>12</sup>

PSA level is prostate specific but not cancer specific. To correct for elevations arising from benign disease, PSA density, free PSA, and PSA velocity can be measured. PSA measurements actually reflect cancer risk, with the risks of cancer and of aggressive cancer increasing with the level of PSA. The recently developed risk calculator from the Prostate Cancer Prevention Trial, which integrates family history of prostate cancer, digital rectal examination findings, PSA test result, age, ethnicity, and history of a prior prostate biopsy with a negative result, allows clinicians to assess a patient's individual risk of cancer. This risk should be examined in the context of a patient's life expectancy and comorbidity as well as his concern about the possibility of prostate cancer. The terms "normal" and "elevated" as descriptors of PSA results should be abandoned.<sup>12</sup>

In addition to PSA and digital rectal examination findings, there are other risk factors of importance, such as age, family history of prostate cancer, ethnicity, other hereditary and environmental factors and attributes (e.g., diet, body mass index, supplement use), and a prior biopsy with negative results for cancer.<sup>12</sup>

#### 12. Addiction, pain, and psychiatric disorders.

Depressive disorders and substance dependence are highly prevalent in the general population and co-occur frequently, both in clinical samples and the general population. Common explanations for the higher rates of mood symptoms among addicted individuals are the presence of a "stand-alone" mood disorder with concomitant substance use, secondary mood symptoms induced by protracted intoxication,

withdrawal or chronic pain, or a combination of independent and substance-induced mood symptoms. The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV-TR) stipulates that a mood disorder can be considered independent if the signs and symptoms of the disorder predate the onset of substance use, exceed that attributable to substance use alone, or persist for more than 4 weeks beyond the period of acute substance intoxication or withdrawal. 16 Although patients with mood symptoms and substance abuse should be interviewed carefully to establish the chronology of signs and symptoms of the two disorders, it is often difficult to obtain this information reliably, particularly at the earliest ages of onset, because of frequent periods of intoxication and possible cognitive impairment from protracted substance abuse. The use of temporal markers (e.g., major life events) and the availability of knowledgeable individuals may help establish a valid psychiatric history in patients who abuse substances. However, studies that have analyzed systematically the sociodemographic, psychiatric, and substance-related features of independent or substance-induced depressive episodes have yielded conflicting results concerning the extent of psychopathology in patients with independent or substance-induced depression. The consultation with a psychiatrist and a psychologist for a patient who suffers from chronic pain, mood symptoms, and prescription drug abuse is, therefore, all the more necessary in the absence of vigorous diagnostic criteria.

#### 13. Ethics review board.

In cases in which healthcare providers or nursing or medical staff raise an ethical issue for prescribing opioids to a patient with a prior history of drug abuse, an ethics review board (ERB) of the hospital will minimally provide a consultation of the ethical consequences of the clinical decision to treat with opioids, and in some hospitals the ERB will provide a resolution to the issue. Ethics committees can be valuable resources, because they can provide recommendations of how to proceed in individual cases. Administration and clinical staff are members of the board and patient representatives can provide input.

#### **Acknowledgments**

The case of Patient S.K. is based on the true story and case report of a patient; however, considerable material has been added that was not present in the original case report. This additional material was created to satisfy the pedagogic needs and objectives of the PBL and addiction medicine courses. These supplemental components were integrated into the core elements presented in the published article, and then the aggregate case was adapted for the 'P4' method of presentation. The case of Patient S.K. and the accompanying Facilitator Guide have been developed by Ralph Aarons, M.D., Ph.D., and Emmanuel N. Pothos, Ph.D. Helpful advice and suggestions were provided by Scott Epstein, M.D. Funding for the development of this case was provided by the National Institute on Drug Abuse Centers of Excellence for Physician Information—Massachusetts Consortium and the Tufts University School of Medicine.

The original case report of Patient S.K. is included in a scholarly article dealing with the ethical perspectives involved in medical decisionmaking around addiction and the treatment of chronic pain and is included in the citations below.

## **Evaluation Tool**

| Case Evaluation: Patient S.K.                 |                                                                             |  |  |  |
|-----------------------------------------------|-----------------------------------------------------------------------------|--|--|--|
| Facilitator Name:                             |                                                                             |  |  |  |
| Comment on the Str<br>improve this curriculum | engths and Weaknesses of This Case: (please let us know how to m resource): |  |  |  |

(Optional)

| Issues Raised During Discussions | Discussed<br>Briefly | Discussed<br>In-Depth | Researched | You<br>Consider<br>Key Issue |
|----------------------------------|----------------------|-----------------------|------------|------------------------------|
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## **Suggested Readings**

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## **Additional Resources**

## American Academy of Pain Management

13947 Mono Way #A Sonora, CA 95370 (209) 533-9744

## American Chronic Pain Association

P.O. Box 850 Rocklin, CA 95677 (800) 533-3231

## **American Pain Foundation**

201 North Charles Street, Suite 710 Baltimore, MD 21201 (888) 615-7246

## **American Pain Society**

4700 West Lake Avenue Glenview, IL 60025 (847) 375-4715

### National Chronic Pain Society

P.O. Box 903 Tomball, TX 77377 (281) 357-4673

#### **Pilot Information**

The pilot curriculum PBL case Patient S.K. was offered to our entire second-year class (171 students) following their participation in the Principles of Addiction Medicine course. The total number of PBL discussion groups was 31. Sixteen groups consisted of 6 students each and 15 groups consisted of 5 students each. Each group had a facilitator, who had received training in PBL. The total number of faculty facilitators involved in the pilot curriculum was 22. Nine facilitators were 4th-year medical students.

Each discussion group covered the PBL case in up to four 2-hour sessions. Contact time varied from group to group because different issues or research questions for home study were raised by different groups.

We are currently evaluating the data collected and anticipate having results in 2010.