A SURPRISE TREND IN SUICIDES: WERE THEY ACCIDENTAL?

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After two patients overdosed on the same drug, this medical center's patient safety team took a closer look at their suicide records and what they found led to the removal of this drug from their formulary. Here's their retrospective case review.

ithin the VHA, the root cause analysis (RCA) process is used to investigate and review findings from all actual and potential sentinel events—defined, respectively, by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as any unexpected occurrence of death or serious physical or psychological injury and any unexpected risk of such occurrence. This process was implemented throughout the VHA in 1999 (after the creation of the National Center for Patient Safety and its Patient Safety Program) with the goal of reducing, and ultimately preventing, iatrogenic adverse events within the system.¹

When a patient enrolled in the VHA attempts or commits suicide,

a multidisciplinary RCA team is assembled. This team is comprised of a facilitator (usually, the facility's

patient safety manager) and the frontline staff (physicians, nurses, mental health care practitioners, social workers, and pharmacists) who were involved in the patient's

The VHA uses this process to review all suicides of enrolled veterans, even those that occur in the community.² (The term community, or outpatient, suicide is used to differentiate such an event from an inpatient completed suicide.) Most medical facilities never experience an inpatient sentinel event; community suicides are less rare.

In September and October 2001, staff at the Bay Pines VA Medical Center (BPVAMC) in Bay Pines, FL received two back-to-back reports of outpatient suicide by propoxyphene overdose. I was prompted by this apparent trend to perform—with the help of a staff pharmacist and psychiatrist—an aggregate, retrospective analysis of all community suicides recorded for our facility during fiscal years 2000 and 2001. Our RCA teams had reviewed 15 such cases, which represented 47% of the total RCAs completed at our facility during that two-year period. Through our retrospective review, we sought to determine whether any of these apparent suicides had been, in fact, inadvertent overdoses. Our findings caused us to reevaluate the possibility of accidental death among these 15 patients and brought to light an issue that hadn't previously been a focus of our suicide RCA teams: the potential lethality of certain drugs.

In this article, I'll discuss the RCA review process as it was implemented initially at our facility and how we modified this approach after completing our retrospective analysis. I'll also describe the findings of our analysis and the facility formulary changes that have been driven by them.

ANALYZING COMMUNITY SUICIDES

The RCA process for investigating outpatient suicide is more difficult than that for inpatient events because so many of the variables contributing to the patient's death

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appear to be out of the health care providers' control. The mere fact that an incident occurred in the community, rather than while the patient was on the grounds receiving care from the facility, can give RCA team members the false impression that a systems issue, such as poor patient education or inadequate follow-up, couldn't have been a contributing factor.

After leaving the supervised care of the medical facility, patients often fail to follow recommended treatment plans, abandon drug regimens, or make decisions that go against medical advice. These high risk behaviors—written about frequently in medical literature—are common but not easily managed.^{3,4} Initially, therefore, our community suicide RCA reviews focused primarily on our availability to the patient and our screening and intervention procedures for patients at high risk for suicide.

During the course of these reviews, the RCA teams identified some instances in which access to care was suboptimal—the patient's next appointment had been scheduled too far into the future, for example, or it had been canceled by the provider and not promptly rescheduled. The teams also investigated whether the patient had undergone a suicide risk assessment or had been screened for posttraumatic stress disorder or a major depressive disorder. If these assessments had been performed, the team then checked for accuracy and follow-up as possible areas for improvement. In some cases, the patient hadn't had an encounter with the facility staff for three or more months prior to death—whether due to inadequate follow-up or missed appointments. The varying circumstances made it difficult to gauge the actual contribution of specific systems issues to the outcome.

A SHIFT IN FOCUS

When the two propoxyphene overdoses came to light, it signaled a shift in focus for our RCA teams—from psychiatric assessment and access to care to the potential lethality of certain medications. Since neither of the two patients had been considered at high risk for suicide, our teams wondered if the overdoses might have been accidental, rather than intentional.

The proximity and similarity of the two cases also initiated widespread discussion of the potential risk of patients receiving prescriptions from multiple providers. Our retrospective review revealed that multiple RCA teams had noted as a contributing factor the patient's ability to obtain medication from multiple providers—including emergency department (ED) staff, psychiatrists, primary care providers, and community health care providers. We recognized the need to strengthen the checks and balances in place in our system of coordinated care, especially during nights and weekends and when the prescription involved such potentially lethal drugs as benzodiazepines and opioid analgesics, including propoxyphene (see "Propoxyphene: Report by the VA's Medical Advisory Panel" on the next page).

The ED staff thus began limiting the amount of medication they prescribe to patients to just enough to get through the weekend or night, after which the patient would need to be assessed by the primary care provider before continuing with the drug.

IDENTIFYING A TREND

Of the 15 reported outpatient suicides that occurred during the twoyear period we studied, nine (60%) involved drug overdoses. In five (56%) of these cases, propoxyphene was the major substance identified in the autopsy toxicology report (Table). In four (44%) of the nine cases, the primary medication identified in the toxicology report was a prescription received from somewhere other than a VA facility. Those four included one case each of propoxyphene, benzodiazepine, hydromorphone, and a tricyclic antidepressant. It was reported that these four patients either stole medication from another family member or obtained a prescription from a non-VA provider. Patients who had received prescriptions from BPVAMC staff most often were obtaining drugs from multiple providers within our medical center. For example, they might have received an antidepressant or benzodiazapine from the psychiatry service and pain medication from the ED or primary care staff.

In 13 of the 15 cases (87%), the patient had a history of a mental health or substance abuse problem. Propoxyphene had been prescribed for acute or chronic pain or for an exacerbation of chronic pain in four of the five cases categorized as propoxyphene overdose. The conditions were mostly musculoskeletal in nature (for example, chronic back pain or a new injury related to a fall or strain), but we identified no trend in medical diagnosis.

The eight men and one woman who died of drug overdose ranged in age from 39 to 49 years. Six (67%) of the nine had been evaluated at least once within the past year by a mental health care professional or were seeing one regu-

Propoxyphene: Report by the VA's Medical Advisory Panel

The centrally acting opioid analgesic propoxyphene is related structurally to methadone and is indicated for the treatment of mild to moderate pain. There's an associated risk of psychological and physical dependence at greater than recommended doses. ^{1,2} Overlapping levels of therapeutic and toxic blood concentrations (0.1 to 1 µg/mL) have been identified. ^{1,3} There's also an associated tolerance with extended use, and overdose can result in respiratory depression, cardiac toxicity, or both. ^{1,3,4} The opioid antagonist naloxone is effective in reversing the respiratory depression associated with propoxyphene overdose, but because of propoxyphene's quick gastric absorption, medical intervention needs to be immediate. ^{1,4}

In 2001, the Pharmacy Benefits Management Strategic Healthcare Group and the VA's Medical Advisory Panel completed a review of the efficacy and safety of propoxyphene. The report stated that propoxyphene is associated with serious toxicity, including coma, respiratory depression, pulmonary edema, seizures, cardiac arrhythmias, and death. These effects occur primarily in patients who have characteristics associated with intentional or unintentional overdose—such as history of prescription drug misuse or psychiatric or emotional problems—and in those who combine moderate (six to 20 capsules or tablets) or suicidal (20 or more capsules or tablets) overdoses of propoxyphene with alcohol or other central nervous system (CNS) depressants or with acetaminophen.

The report added that the danger of the additive or potentiating effects on the toxicity of the combination of CNS depressants and propoxyphene can't be overemphasized, citing an isolated case in which coingestion of a sublethal quantity of alcohol with just two capsules of propoxyphene resulted in death. In a few cases, postmortem drug concentrations lower than 1 µg/mL suggested that death could have occurred after the patient ingested therapeutic doses of propoxyphene alone, without coingestion of alcohol or other CNS depressants. 5

In patients deemed at high risk for overdose, the report concluded that the potential for propoxyphene toxicity probably outweighs its potential analgesic effects—and recommended that the drug not be prescribed for such patients.⁵

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larly for such conditions as anxiety, substance abuse, or depression. This is consistent with past research, which supports the idea that middle-aged men with mental health problems are at a greater risk for suicide and accidental death by means of drug overdose.³⁻⁷

In most of the original RCA reviews, the question of intent wasn't addressed. The classification of the deaths as suicide by the medical examiner, therefore, may have biased these reviews. The teams did not look for the root cause of death; they accepted, without question, the report of the medical examiner and worked from that point forward. The medical record reviews had focused on assessment of suicide risk, documentation of related behavioral changes, intervention, and follow-up.

A medical literature search cross-referencing propoxyphene and suicide yielded several articles identifying both the associated risk of accidental overdose and the possibility of accidental deaths being mistaken for suicides.^{5–10}

Only after the two consecutive overdoses by propoxyphene did my patient safety team and I consider accidental overdose as a possible trend. Having taken into account the possibility of bias in the original RCA reviews, our retrospective analysis of the RCA reports revealed that while teams may have wondered initially about the patient's actual intent, they did not question or challenge the lack of such evidence as suicide notes or threats to friends or family. The teams accepted, perhaps erroneously, the manner of death as suicide and completed the RCA process under this assumption.

The goal of the original suicide case analyses had been to identify

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Table. Suicide among veterans enrolled at the Bay Pines VA Medical Center, Bay Pines, FL, FY* 2000 through 2003

	No. of suicides				
Method of suicide†	FY 2000	FY 2001	FY 2002	FY 2003	Total
Gunshot	2	3	3	2	8
Propoxyphene OD‡	1	3	1	0	5
Benzodiazapine OD	0	2	0	0	2
Hydromorphone OD	1	0	0	0	1
Tricyclic OD	0	1	0	0	1
Hanging	1	0	0	0	1
Jumping	1	0	0	0	1
Multidrug	0	0	3	0	3
CO§ poisoning	0	0	2	1	2

*FY = fiscal year. †These categories were assigned according to autopsy findings, even though some patients' postmortem toxicology reports identified additional medications or alcohol at lesser levels. ‡OD = overdose. §CO = carbon monoxide.

possible contributing factors from a "systems perspective" and to establish action plans to improve future outcomes. While the RCA teams noted cases in which the patient had overdosed on propoxyphene in an attempt to get pain relief, they failed to question the manner of death as intentional suicide, focusing instead on the possible inadequacy of pain assessment strategies and treatment by the primary care team. The RCA teams also discovered that some patients had received propoxyphene from departments other than primary care—probably because the patients knew their primary care provider would have prescribed the drug in a limited fashion or not at all. But here too, instead of investigating the potential danger of propoxyphene in such cases, the teams focused on improving communication between services and limiting the capacity of certain providers to order opioid analgesics for patients documented as being at high risk for suicide. The teams identified a need for warnings in the computerized medical records of patients who are at high risk for suicide but neglected to emphasize the high risk accompanying the medications themselves.

Our retrospective review uncovered only two suicide notes reported in the nine cases of drug overdoses. To evaluate intent in the other seven cases, we searched the patients' records for triggering situations or events or comments from family members or practitioners that supported the possibility of suicidal intent. In one case, we concluded that the anniversary of a significant traumatic experience could have been construed as reason for intent. The other six cases had such documented risk factors

as diagnosis of cancer or relationship problems, but it seemed that the medical examiner had made a speculative leap when classifying these cases as suicides. They involved no significant anniversaries, new financial strains, statements to family or friends of intent, or suicide notes. A count of the number of pills missing from the medication bottles indicated that the patients may have been taking the actual maximum recommended dosage or just slightly more than prescribed. In the cases in which intent was questionable, there weren't newly filled prescriptions with large numbers of pills missing. We concluded that the classification of these patients' deaths as suicides may have been influenced by the fact that they had histories of mental health problems or substance abuse and by their ages.9

LESSONS LEARNED AND CHANGES MADE

Medical literature warns practitioners against administering propoxyphene to patients prone to suicidal behavior because of the lethality associated with overdose. Not all of the patients whose cases we reviewed were receiving mental health services, and of those who were, not all were considered at risk for suicide. Nevertheless, when prescribing such a potentially dangerous drug, health care providers should keep in mind that patients with any history of selfmedication or nonadherence to a medication regimen are at risk for accidental overdose. In addition, those patients who are unable or unwilling to abstain from alcohol consumption risk accidental overdose from the combined effect of the propoxyphene and alcohol.²⁻⁷ Such patients should be

prescribed an alternative pain reliever or directed to substance abuse counseling before therapy is initiated.

Identification of this possible trend substantially increased our awareness of the risks associated with propoxyphene in certain patient populations. Prompted by our review, the BPVAMC's chief of primary care and I coordinated a roundtable discussion between primary care practitioners to identify certain misperceptions that might have contributed to propoxyphene's frequent prescription. Since, in terms of efficacy, propoxyphene is considered comparable to codeine, extra strength acetaminophen, or acetylsalicylic acid, many assumed it to be as safe.^{8,11}

In addition, the growing regulatory emphasis (by both the VHA and JCAHO) on using numeric pain assessment scales to ensure the adequate treatment of pain had some providers feeling "boxed in to treating a number." The pressure from patients, accrediting organizations, patient advocacy organizations, and legal cases may have played a role in the use of propoxyphene as an "opioid placebo." A placebo, of course, is not an acceptable form of pain treatment, and this practice illustrates some of the communication problems between providers and patients that can interfere with treatment planning. When faced with a patient verbalizing the need for considerable analgesia, a provider who is reluctant to prescribe stronger opioids, such as oxycodone, might prescribe propoxyphene, believing it to be safer than oxycodone and as effective as necessary. This scenario suggests the need for further provider education regarding pain assessment and management.

The complex challenge of treating acute and chronic pain in patients at high risk for suicide or nonadherence is an ongoing concern, especially given patients' access to multiple VA and private providers. The original RCA reviews spotlighted this vulnerability and pinpointed several potential systems changes (including potential drug misuse warnings in patients' computerized medical records and improved communication between internal providers concerning all potentially lethal medications) that might help us avoid accidental and intentional overdoses in the future.

Our retrospective, aggregate review highlighted the need for a comprehensive analysis of the risks and benefits of the various opioid analgesics and pointed to the importance of patient education in preventing accidental adverse outcomes. Furthermore, in July 2003, propoxyphene was removed from the formulary at the BPVAMC.

While our control over suicidal intent is arguably more limited, our role in the prevention of accidental overdoses can be great. We can, for example, limit the number of providers who can write prescriptions for high risk patients and use computerized alerts and controlled substance contracts. As one of our RCA teams proposed, our facility may benefit from a specialized interdisciplinary "pain team" who would oversee the treatment of patients with complex, chronic pain needs who are also at high risk for suicide. We're in the midst of recruiting a pain specialist to round out such a team, which currently includes a nurse practitioner, pharmacist, psychologist, and psychiatrist.

The RCA process and our review of its use over two years have

proven to be great tools for enabling us to identify system issues that played a role in a variety of sentinel events. Our retrospective review, though limited by size, taught us several important lessons. When investigating cases deemed suicides by the medical examiner, we have learned not to start with the assumption of suicide and proceed from there in searching for system failures, but rather to start with the known death and come to our own conclusions. It also has provided us with valuable information regarding communication between multiple services and has prompted us to make substantial changes regarding prescription medications.

Since propoxyphene was removed from the BPVAMC formulary, there has been no increase in suicides from other opioids prescribed in its place. The overall community suicide rate has declined as well—from six, nine, and nine in 2000, 2001, and 2002, respectively, to three in 2003, of which none were overdoses. As aggregate reviews aren't used routinely to analvze community suicides, further discussion and investigation into the benefits of using the RCA process on an individual versus aggregate basis may be warranted. This fiscal year, the VHA will analyze aggregate community suicide data on a quarterly basis, which may help us identify more trends. •

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