Don't tamper with oxycodone

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Supplying patients with generic versions of oxycodone may be less expensive, but it is not a good idea. Oxycodone is a widely prescribed and strong opiate that, when used as directed, has an important role in controlling moderate to severe pain. However, it is also a popular drug of abuse.

Online drug forums are full of comments extolling the highs that can be achieved and advice about how to prepare tablets for intravenous injection. Many of the people posting comments appear to be patients seeking to inject their prescribed medication, although some report purchasing the tablets illicitly. Oxycodone has become so popular as an opiate of misuse that many pharmacies no longer keep it in stock and advertise that fact to deter thieves.

More concerning than the potential for misuse is the association between oxycodone and drug-related deaths. As prescriptions for oxycodone have increased, mostly in its sustained-release formulation, so have drug-related deaths. Between 1999 and 2004, deaths related to oxycodone rose 5-fold in Ontario; sustained-release oxycodone was introduced in 2000.[1] During this period, opioid-related suicides did not show an increase, and more than one-half of opioid-related deaths were deemed unintentional by the coroner.[1] It is unclear whether these deaths resulted from proper use of the drug, but some form of misuse to circumvent the slow release of the drug seems likely. The sustained-release formulation typically contains 3 times the dose of plain tablets; when crushed, injected or taken with alcohol, this high dose could lead to respiratory depression and death.

Mindful of these harms, and after considerable pressure from health authorities, the manufacturer of sustained-release oxycodone, Purdue Pharma Canada, introduced a tamper-resistant form of the drug and dropped the old formulation in March 2012. The new formulation is harder to crush and forms a gel when water is added, making injection difficult. However, the patent on oxycodone expired on November 25, 2012, and the first generic manufacturers have already applied for authorization to produce the drug. Although the generic forms will probably be just as good as the proprietary drug when used as intended, and likely somewhat less expensive, they will reopen a chapter of abuse that has been widely agreed should be closed and remain closed.

Legal restrictions on producing generic formulations are difficult to enact. Approval is usually granted if the manufacturer can show relative pharmacokinetic equivalence; exceptions to this rule are not straightforward. Health Canada is required to approve a product that has been shown to be bioequivalent to an already approved drug. The health minister or Parliament both have authority to act, but federal Minister of Health Leona Aglukkaq has refused to regulate generic oxycodone. Provincial health ministers may be more willing to tackle the issue; however, drug regulation falls under federal jurisdiction. The federal government could reclassify oxycodone as an addictive drug, like morphine, allowing more strict control of its use, consequently reducing access to an effective painkiller for patients who need it.

Physicians and pharmacists can take positive action. By always prescribing controlled-release oxycodone by brand name (with the caveat "do not substitute"), physicians could take a lead in protecting the public and their patients, who may be misusing their medications or selling them. Similarly, pharmacists could dispense tamper-resistant forms of the drug and avoid generic substitution. There is precedence for this course of action in the example of controlled-release antiepileptic agents and some other drugs, which are better prescribed by brand name to avoid variations in bioavailability. Alone, these steps are not enough. Protecting patients one consultation at a time will result in patchy adoption and is a far cry from the consistent public health policy that is essential on such an urgent issue of patient and public safety.

Fortunately, there is a simple way to effectively tackle this pharmacological foul-up, and it lies with the provincial formulary committees. Before a new drug is eligible for funding by a provincial health insurance plan, it must be approved for inclusion in the provincial drug formulary by the local formulary committee. It would be a responsible use of their powers for these committees to decide that only tamper-resistant formulations of oxycodone will be reimbursed by provincial plans. Already, one province has announced that it will not include generic oxycodone in its formulary unless it is tamper-resistant.[2] By physicians, pharmacists and provincial formulary committees acting together, we might be able to reduce the harms associated with this highly misused and potentially lethal drug.

References

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