

College acts on inquest's recommendations for MMT

In 2005, a coroner's jury made a series of recommendations aimed at preventing methadone-related deaths in Ontario. While the jury had a number of positive comments to make about the College's methadone program, it also drew up recommendations targeted at improving the program.

The 23 recommendations directed at the College ranged from tightening the criteria that qualify patients for take-home doses (carries) to reassessing prescribers every three years.

The coroner's jury made the recommendations after investigating four methadone-related deaths that had occurred in Oshawa in 2002 and 2003.

Dr. William Lucas, the coroner who presided over the inquest, said that the merit of methadone maintenance was never at issue, but rather the inquest set out to do a "bit of tweaking" in the system so as to prevent further methadone-related deaths.

The value of methadone maintenance treatment – not only to individual patients, but to society in general – was apparent throughout the inquest, said Dr. Lucas. He cited such positive spinoffs as a decrease in criminal activity, greater employability, and less costs to the health-care system.

"The jury made it clear that methadone patients deserve to be congratulated for attempting to

improve their lives. There is no doubt that these five people on the jury – who began this inquest with very little, if any, knowledge about addiction – came away seeing this as a positive program that needed to be encouraged," he said.

But it was apparent, said Dr. Lucas, that the program needed "some

However, the clinical judgments that they displayed were often so far outside the boundaries of the College guidelines that one would have to question how good these judgments really were," said Dr. Lucas.

"There is a huge difference between someone who is an acknowledged

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tightening up." For example, he expressed dismay with how liberally some of the prescribers chose to interpret the guidelines the CPSO provided for methadone maintenance treatment.

"These guidelines, developed by a group of experts, are put forward as best practices," he said. Thus, the College's expectation would be that the vast majority of methadone prescribers in the vast majority of patient situations would be following the guidelines as closely as possible, he said.

"Whereas, the physicians – at least, the ones that we saw during the inquest – seemed to believe the guidelines were simply suggestions, ones that allowed a fair amount of elasticity and clinical judgment.

expert in addiction medicine bending the rules and someone who is a more casual prescriber. You'd obviously allow the expert more leeway," said Dr. Lucas.

Shortly after the inquest, the College published a revised set of methadone maintenance guidelines, which incorporated many of the recommendations of the coroner's jury.

In the preface of its new document, the College does allow that in specific instances, where a patient's individual circumstances provide clinical justification for deviating from the guidelines, a physician may do so. "However, it is expected that he or she will document any deviation from the guidelines in the patient's medical record indicating

the clinical reason(s) for doing so," stated the preface.

Wade Hillier, manager of the College's methadone program, said he would expect such deviations to be rare. "This is a complex area of medicine," he said. "In adhering to these guidelines, physicians can be assured that they are providing care to their patients in the safest possible manner."

Below are the cases that Dr. Lucas chose to put before the coroner's jury. He said that these cases were selected because they epitomized some of the issues that needed to be addressed.

Excessive carries

SP, 48, was enrolled in the program for three years but continued to use a variety of other medications. An autopsy revealed "markedly elevated" levels of methadone as well as oxycodone and diphenhydramine in his blood.

SP, even though he was not clini-

cally stable, was permitted carries. In fact, he was permitted carries of 14-17 days. Even clinically stable patients, according to the guidelines, should not have more than six carries at a time.

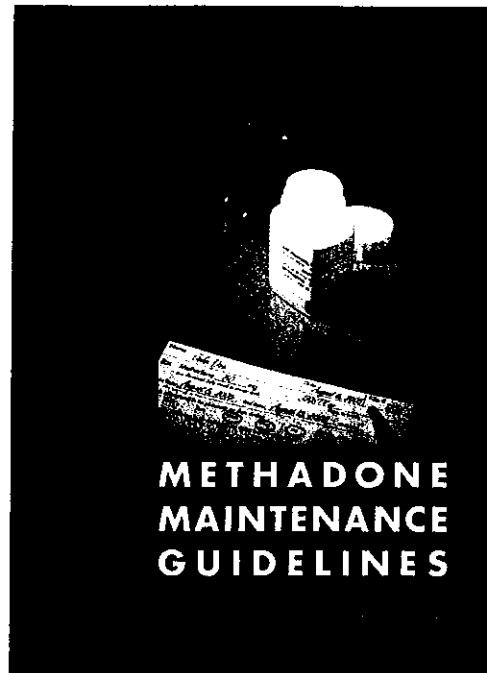
INQUEST RECOMMENDATION: The jury recommended that the privilege of carries be limited to those patients who have demonstrated clinical stability, defined in part by being opiate-free, benzodiazepine-free and illicit substances-free in the drug screening.

COLLEGE ACTION: This recommendation was addressed in the new Methadone Maintenance Treatment (MMT) Guidelines by expanding the definition of clinical stability. Specifically, it states that clinical stability is shown when the patient is emotionally stable, the methadone dose is stable, the patient no longer engages in sustained problematic drug or alcohol use and provides mostly negative urine drug screens, the patient's housing and employ-

The coroner's jury also directed a number of recommendations to the Ministry of Health and Long-Term Care. In fact, the Ontario government has announced a task force that builds on the recommendation from the Coroner's Office that the government establish an ongoing working group of stakeholders to review the broad issues of methadone maintenance treatment in the province. Specifically, the task force, which will have CPSO representation, will provide advice on:

- Who should receive methadone and how it should be used
- How to better train health care professionals in the use of methadone
- How to involve the community in establishing or relocating methadone clinics
- Quality assurance and assessment
- Payment models

The task force's target is to report to the government by the end of the year.



ment situation are stable, and the patient has adhered to the methadone treatment agreement and program requirements.

INQUEST RECOMMENDATION: The jury recommended random urine screening throughout all phases of treatment, rather than just the earlier stages. This recommendation is intended to prevent patients from orchestrating their drug use to minimize detection.

COLLEGE ACTION: The new guidelines recommend that physicians collect and assess a patient's urine continually on a fixed or random schedule, biweekly to monthly.

INQUEST RECOMMENDATION: The jury recommended that all methadone prescribers be reassessed every three years, as triggered by the three-year renewal of a physician's methadone exemption.

COLLEGE ACTION: A pilot study has been funded by the Ministry of

Health and Long-Term Care, and will be implemented in 2006/2007.

Initiation risks

DS, 28, had recently returned to the program when he died of an overdose in the fall of 2002. He received as a starting dose, the amount that he had previously been taking as a methadone patient a year earlier.

It has been reported that the most common reason for methadone overdose is overly aggressive prescribing during the first two weeks of treatment. The combination of overestimated tolerance and underestimated accumulation is the main cause.

There was also a prescribing error, which resulted in him receiving an even higher amount.

INQUEST RECOMMENDATION: The jury recommended more stringent and precise guidelines during the initiation phase of MMT, with expectations clearly communicated to patients.

COLLEGE ACTION: The College's

new guidelines include a section that sets out how physicians can reduce risk in the early stabilization phase. (See sidebar on page 17).

INQUEST RECOMMENDATION: The jury recommended that **returning** patients be treated the same as patients new to the program. The jury stated that a patient's condition may have materially changed and may necessitate different treatment of the patient.

COLLEGE ACTION: The new guidelines recommend that patients who have missed four or more days of methadone be put on a lowered dose when they return to the program.

INQUEST RECOMMENDATION: The jury recommended that the College remind physicians to write legibly.

COLLEGE ACTION: This is an ongoing requirement and the College communicates this expectation regularly.

Lack of integration

JJ, 42, had been in treatment for 10 months when she died in the fall of

2003 of "combined drug toxicity." JJ was also seeing a psychiatrist who was unaware that she was taking methadone and prescribed other drugs, including diazepam, quetiapine and olanzepine.

Her doses were increased within a short period. The family told her methadone prescriber that their mother was experiencing increased confusion, sleepiness and that she was "not with it." The doctor did not change the prescribed dose.

A third party – who did not live with her – was given responsibility for her carries and for monitoring doses and signs of sedation. The patient's drowsiness persisted and the patient was found dead soon after.

INQUEST RECOMMENDATION: The jury recommended that third party carries be strongly discouraged when the patient is not clinically stable to qualify for carries on their own.

COLLEGE ACTION: In the College's updated guidelines, it states that if a person is not eligible for carries as defined by the guidelines, carries

INQUEST SAYS MORE MMT PRESCRIBERS NEEDED

The jury charged with making recommendations in the methadone inquest directed the College to take further measures to encourage physicians to work in the field of methadone treatment.

The jury based its recommendation on the objective evidence of the effectiveness of the methadone program in saving lives. From 1996 when the College became involved in administering the methadone program in Ontario, methadone-related deaths dropped from 4.2 per 1,000 patients in treatment in 1996 to 1.7 per 1,000 patients in treatment in 2000.

The chief coroner for Ontario attributed the decline in deaths directly to the work of the College in developing methadone maintenance guidelines, and the peer assessment of physicians who provide methadone treatment for opioid dependence. Furthermore, studies have shown that patients are more likely to die if not receiving MMT than if they were maintained on treatment. Since the College began administering the methadone program, several thousand more Ontarians have been able to benefit from MMT.

Dr. Kumar Gupta, a Toronto family physician and member of the College's Methadone Committee said he hoped that the media attention surrounding the inquest did not have a chilling effect on potential methadone prescribers. "I would hope that physicians don't believe that bad outcomes from methadone are a common scenario. In fact, the opposite is true. Bad outcomes are common when opiate-addicted people are not treated, and methadone is a proven safe effective treatment when done correctly," he said.

must not be given to a third party unless the patient is under the care and supervision of a responsible health-care worker, and appropriate safety measures are in place.

INQUEST RECOMMENDATION: The jury recommended that a study be done to assess the feasibility of setting up a centralized computer monitoring system for all prescribed/dispensed drugs in Ontario, which can be accessed by all regulated health-care professionals involved in a patient's care. The study should take into account a possible pilot with the methadone treatment community.

Dr. Lucas told *Dialogue* that the stigma of being on methadone prevents many patients from disclosing this pertinent fact to their other health-care providers. "Currently, if they choose not to share the fact that they are addicted to drugs and are in a methadone maintenance program, then that information won't be shared. But we believe that the right hand should know what the left hand is doing, given that the potential for mixing drugs could be lethal," said Dr. Lucas.

Diverted carries

CB, 17, was not in a methadone maintenance program, but he died in the summer of 2003 after overdosing on methadone that he received from a third party.

This is another case, said Dr. Lucas, that underlines the importance of ensuring that carries are more closely controlled. "The jury understood that this was a drug that not only had the potential to be wonderful, but had the potential to be lethal," said Dr. Lucas.

"If the criteria for carries was tightened up so that the only people who were getting it were people who

Overly aggressive prescribing

It has been reported that the most common reason for methadone overdose is overly aggressive prescribing during the first two weeks of treatment. The combination of overestimated tolerance and underestimated accumulation is the main cause.

THE EARLY STABILIZATION PHASE (0-2 WEEKS)

Methadone has a significant risk of morbidity and mortality during the early stabilization phase. Due to its prolonged half-life, serum levels increase for up to five days at the same dose. Thus, a dose that is barely adequate on day one can be toxic by day three to five.

Methadone overdose can have an insidious onset. The patient may appear relatively alert during the day, succumbing to an overdose during a nap or at night. Early signs of toxicity include ataxia, slurred speech and euphoria. Careful prescribing, patient education, and intervention at the first sign of toxicity can reduce the risk of overdose.

Based on this, the following dosing protocol is recommended:

- The initial dose should be 10-30 mg of methadone per day for the first three days. Patients at high-risk for methadone toxicity should be started on no more than 10-20 mg.
- During the early stabilization phase, doses should not be increased by more than 5-15 mg every three to four days. Caution is advised when titrating patients at high-risk for methadone toxicity.

OTHER STRATEGIES FOR REDUCING RISK IN THE EARLY STABILIZATION PHASE

Avoid prescribing any sedating drugs during the early stabilization phase.

This includes benzodiazepines, non-benzodiazepine hypnotics, antipsychotics, antidepressants, and sedating antihistamines. Even moderate, therapeutic doses of these drugs may increase the risk of overdose if they are initiated at the same time as methadone and the patient is not fully tolerant to their sedating effects. Patients should also be advised to avoid alcohol and over-the-counter sedating drugs.

High-dose benzodiazepine users should be tapered before initiating MMT.

Benzodiazepine abuse and dependence are common in this population. As with opioids, it is difficult to accurately judge a patient's benzodiazepine use and tolerance. Benzodiazepine tapering, while difficult on its own, can be very complicated and potentially unsafe when attempted with methadone initiation.

General advice to the patient and family. Explain to the patient that it takes several weeks to reach the optimal dose of methadone, and it is dangerous to try to relieve withdrawal symptoms with benzodiazepines, opioids, illicit methadone or other drugs. Advise the patient to limit his or her driving or use of machinery after a dose increase, particularly in the first few hours after dosing. Advise the patient to take the methadone dose in the morning, since the risk of overdose is increased at night.

During the early stabilization phase, patients and their families (if the patient consents) should be educated about methadone toxicity. Patients should be assessed twice per week and not be granted any carries.

Explain the risks of diverted methadone. Even a single dose of methadone can be fatal to both children and adults. Patients are responsible for the safe storage of their methadone. Physicians must advise patients that it is dangerous to sell or give methadone to anyone, even in small doses, or done with 'good intentions.'

Educate the patient and family members about signs of impending overdose. Whenever feasible (with the patient's consent), a family member or significant other should be educated about the symptoms of overdose with clear instructions to go to the emergency department immediately at the first sign of toxicity. A patient information guide may be used for this purpose.

Intoxication at the pharmacy. At any stage of methadone treatment, the pharmacist should be instructed to alert the physician if the patient appears sedated or intoxicated. Intoxicated patients should not be medicated until assessed by their physician. If signs of intoxication are observed after ingestion of methadone, the patient should be sent to the hospital by ambulance for assessment.

Frequency of visits. Twice-weekly visits during the first two weeks of treatment are recommended, particularly if the patient is at increased risk for methadone toxicity or cannot be stabilized at a low dose. If possible, the visits should be scheduled for two to six hours after the methadone dose. The physician should inquire about sedation and other side effects.

Carries during initial titration. No carries should be granted during the first two months of treatment (including Sunday carries).

Missed doses. During the early stabilization phase, patients should be on the same dose for three to four consecutive days with no missed dose before a dose increase. If a patient misses two or more doses consecutively, he or she should be restarted at the initial dose (10-30 mg) for at least three consecutive days.

Negative initial urine drug screen and recent abstinence. In patients who report no recent opioid use or have a negative initial urine drug screen, methadone should not be initiated unless recently abstinent in a supervised setting (incarceration, inpatient program, etc.). These patients should have a long history of opioid dependence, strong urges to use and/or a good response to MMT in the past. The initial dose should be 5-10 mg, titrated upwards every five or more days in increments of 5 mg or less, with careful assessment of withdrawal symptoms and sedation.

demonstrated that they were reliable, honest and stable in their lives," said Dr. Lucas, "and if it was clear to them that this was a privilege that could be lost to them in an instant if they were caught not holding up their end of the bargain, then that would have a significant impact [on the amount of

carries that is diverted]."

Dr. Lucas said that he is pleased that the new guidelines also encourage physicians to explain the risks of diverted methadone to patients.

"Physicians must advise patients that it is dangerous to sell or give methadone to anyone, even in small

doses, or done with 'good intention,' states the guidelines. "Even a single dose of methadone can be fatal to both children and adults."

Making the situation more problematic, added Dr. Lucas, is that when a methadone-related death occurs, it is not always clear whether the methadone came from a methadone program or was obtained illegally. The *Regulated Health Professions Act (RHPA)*, because of privacy considerations, does not allow the College to currently share information about specific individuals with other organizations.

INQUEST RECOMMENDATION: The jury recommended that Health Canada study all aspects of methadone diversion. The rationale is, that in determining areas of diversion, safeguards can be put in place to minimize diversion for public safety.

INQUEST RECOMMENDATION: The jury recommended the Ontario government amend the *RHPA* to allow the College to share information with the Coroner's Office, while protecting the traditional privacy rights of the doctor-patient relationship. Pending this legislative change, the College and the Coroner's Office should seek a ruling from a judge allowing this sharing of information.

COLLEGE ACTION: The College is working with the Coroner's Office to obtain a ruling in an appropriate test case on what information can be shared. This may, in part, address some of the limitations imposed by the *RHPA*. ☐