Alberta MDs irate over prescribing privacy issue

Much to the chagrin of the Alberta Medical Association, a major collector of health data has "flip-flopped" on its previous policy and no longer allows doctors to refuse to share their drug-prescribing information with the company.

Until Sept. 9, IMS Health (Canada) allowed physicians, through its voluntary privacy code, to request that their information not be sold. IMS collects prescribing data from pharmacies, then sells it to pharmaceutical companies that in turn target high prescribers. Since IMS voluntarily initiated this opt-out policy in 1996, the company has received only a handful of requests. But that changed Aug. 28, when the AMA sent a letter urging all its member physicians to opt out.

IMS won't disclose how many requests it received, but it was enough for them to cancel the policy. "The letter-writing campaign was unbalanced and done to damage the integrity of the database," says company President Roger Korman. He feared it could lead to "consent bias."

The AMA is not amused. "IMS flip-flopped 180 degrees and said it would no longer honour its commitment," says President Brendan Bunting.

The AMA advised members to opt out after IMS appealed a March ruling by the provincial privacy commissioner that prescription information is private and it is a violation of the Alberta Health Information Act for pharmacies to sell the information without a doctor's expressed consent. The appeal could take years to resolve.

"We have no problem with them using the information for research purposes," says Bunting. "We do have a problem with them giving out the doctor's name."

The AMA is to consider strategies for dealing with the issue at its next board meeting. IMS, meanwhile, says it has done nothing wrong by eliminating the opt-out policy.

Federally, the privacy commissioner has concluded that this type of information is a work product and not protected private information, but another data-collecting company has appealed that decision. The CMA has received intervener status in that case (*CMAJ* 2003;168[3]: 325). — *Barbara Sibbald*, CMAJ

Helsinki Declaration revisited over concerns about human subjects

For the past 3 years, the World Medical Association (WMA) has been debating how human subjects, particularly in the developing world, should be treated by researchers. Since 1964, the main guidance in this field has come from the WMA's own Declaration of Helsinki, but almost 40 years later the debate about it continues.

During the WMA's World Medical Assembly in September, yet another working group was struck to re-examine paragraph 30 of the declaration, which was added in 2000. It states that after a study, every research subject should be "assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."

John Williams, the CMA's former director of ethics who now holds the same post with the WMA, says critics "claim this is impractical and unjustified and, if implemented to the letter, would prevent much research in developing countries from taking place." The critics including researchers, drug companies and the US Department of Health and Human Services.

Paragraph 30, along with paragraphs 19 and 29, were created because of controversy surrounding maternal–fetal HIV transmission trials in developing countries in the mid-1990s. A placebo was employed in the trials because it was considered that the research subjects would never have access to the expensive treatments then available. Many critics were outraged at what they considered exploitation of vulnerable research populations. "They agitated very vigorously for a revised declaration," says Williams.

At September's meeting, both the working group's revised wording proposed for paragraph 30 and its note of clarification were challenged. The Argentina Medical Association said the amendment "strongly weakens the spirit of the declaration," while the Brazilian Medical Association was concerned that the change "might weaken the intent and provisions of paragraph 19." That paragraph states: "Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results."

The clarification qualifies paragraph 30 by specifying that patients should continue to receive benefits emerging from the study "wherever possible."

Other WMA members, including the British, Croatian and Mexican medical associations, agreed with the proposed amendment, but most members wanted more time to consider it.

The CMA did not speak out at the meeting, but its representative, Past President Henry Haddad, said the association supports paragraph 30 because our "responsibility is primarily to the patient, not to science or industry." He added that "there will be problems implementing this in the developing world."

These include the availability and quality of health care, and the ability of countries to pay. "It will be important for Canada and others to lobby hard for this quality of care," Haddad said. "As part of the global community of physicians, we have an ethical obligation to help others."

WMA rules require at least 75% approval for documents dealing with ethics, says Williams, "so there will have to be a lot of consensus-building before the divergent views displayed so far can be reconciled enough for any change to take place." The working group recommendations will be presented at the WMA's May meeting.

"We are all agreed that the world's most vulnerable patients must be protected in research trials," said WMA Chair Yoram Blachar.

"The only question is, how best we can achieve that? That is what we shall continue to discuss." — *Barbara Sibbald*, CMAJ