sors were reprimanded by another country. "If the regulator in the other country said, 'Wait a minute, we've got a problem; we're going to suspend your licence', I can tell you that would terminate a clinical trial here pretty quickly."

According to Health Canada's Paul Spendlove, the department "has not changed its processes in any way," since the period referred to by Mithani and Peterson. But the department issued only one "Not Satisfactory" letter to clinical trial applicants between 2004 and 2007, as compared with 5 in 1999, 2 in 2000, 7 in 2001, 4 in 2002 and 4 in 2003.

Klein says Health Canada's inspection processes "parallel" those of the UK and US but the Canadian inspectorate is smaller than its counterparts; its inspections are fewer and it severely lags in issuing reports (sidebar, page 636). Dr. Stuart Macleod, a drug safety expert at the University of British Columbia, is concerned that Health Canada doesn't have sufficient personnel "to do what they're trying to do."

> "It could have happened here just as easily. There was nothing specifically about the UK that was lax." — Dalhousie University oncologist Dr. Michael Goodyear

Peterson, who left Health Canada in 2005, says the trials inspectorate was "resourced adequately" at that time but he worries that staff levels have not since kept pace with need.

The department also lacks what many would call basic data. Although it is working on a process for registration of clinical trials, this effort has lagged and there is now no trial registry, or even a registry of research ethics boards in Canada.

The latter is a real shame, says Goodyear, former chair of Dalhousie's research ethics board. "We have no way of finding out how many REBs there are in Canada and who they are and where they are," he says, adding that the problem is particularly acute in British Columbia, Quebec and Ontario, where private ethics boards often oversee clinical trials.

Canada also lags in any form of oversight of trials conducted outside its borders on products whose manufacturers are expected to seek regulatory approval from Health Canada. Departmental spokesperson Alistair Sinclair stated in an e-mail that for trials with sites in "India, China or other countries," the department relies on "international guidelines for the conduct of clinical trials" and monitoring by "sponsors and other regulatory agencies."

The migration of clinical trials to Eastern Europe, Latin America, India and China has been inexorable in recent years as the pharmaceutical and biotechnology industry move to take advantage of lower costs, larger populations of potential research subjects and less restrictive regulations. But it's come at the cost of spate of drug trial horror stories, prompting the World Medical Association to move to update its cornerstone guidelines on ethical trial conduct (*CMAJ* 2008;178 [2]:138).

The FDA, meanwhile, has moved to expand its capacity to conduct inspections in the developing world, promising to establish satellite offices in China, India and South America (*CMAJ* 2008;179[2]:131). Inspectors based overseas will mostly oversee manufacturing facilities, but they may also be in a position to monitor clinical trials.

For its part, the federal government seems focused on promoting Canada as a trials site and stemming the flow of trials to the developing world. At the Biotechnology Industry Organization's international meeting in San Diego in June, Industry Canada distributed literature promoting the nation as a competitive candidate for commercial clinical trials due to its low institutional overhead costs, thriving contract research industry and streamlined regulatory process. "Canadian trial sites," states one of those brochures, "are regularly monitored by Health Canada, the US FDA and industry sponsors." — Dr. Miriam Shuchman, Toronto, Ont.

DOI:10.1503/cmaj.081271

Moratorium urged for foreign visa trainees

At a time when Canada has a shortage of doctors, and qualified Canadian and international medical graduates are waiting in the wings to be certified, concerns are being raised about the number of foreign visa trainees in Canadian residency programs.

The Association of International Physicians and Surgeons of Ontario President Dr. Joshua Thambiraj, for example, estimates that only 20% of qualified international medical graduates in the province are getting residencies each year.

Meanwhile, Canada is providing residency spots and "training hundreds of foreign visa trainees who go back to their own countries, so they're not able to solve the doctor shortage in the province, or contribute in any way to Canada."

Thambiraj says that a logical solution to the backlog of international medical graduates waiting for residencies would be to place a moratorium on foreign visa trainees for 2 or 3 years.

Foreign visa trainees can be students in Canadian medical schools, residents, or postgraduate fellows. Many of them come from the Middle East, but they also come from Europe and the United States. Their governments typically pay their tuition and living expenses on the proviso that they return home to practise.

The Canadian Resident Matching Service pairs Canadian-trained medical school graduates with residency positions. No more than 1 or 2 visa trainees from any Canadian medical school can enter the match, which is generally restricted to Canadian citizens and permanent residents, says Danielle Cameron, an agent for the service. Sponsoring governments make arrangements directly with faculties of medicine.

According to the Canadian Post-M.D. Education Registry, Canadian medical graduates account for 69% of the total 11 961 residents and postgraduate fellows in Canada. International medical graduates — Canadian citizens or permanent residents educated outside of Canada — comprise about 12%. Visa trainees make up the remaining 19%.

That some are questioning their presence has not been lost on the visa trainees themselves.

Dr. Khalid Aba-Alkhai, who's doing a residency in cardiac surgery, understands why some people might want to refrain from accepting more visa trainees until the backlog of international medical graduates has been addressed.

But that doesn't absolve instructors of their obligations to the ones who are already here, he says. "If you accept someone, you have to treat him well until he graduates."

The chief executive officer of the Royal College of Physicians and Surgeons of Canada argues there is no need for a moratorium, because foreign visa trainees don't take up positions that could otherwise be filled by Canadian citizens or permanent residents.

"I think that the misunderstanding is in this expectation that if they disappeared, then the ministry would fund additional positions, and that hasn't been shown to be the case," says Dr. Andrew Padmos.

Meanwhile, visa trainees are "providing frontline, specialized health care services 24/7."

"Their governments are paying to provide Canadians with some pretty impressive medical services while the trainees are in this program, so I think we gain tremendous value from these individuals," he says.

Padmos says the solution is for governments to fund more residency positions for Canadian and landed-immigrant trainees. Postgraduate deans could then take fewer visa trainees as the funding for other trainees increased.

Dr. Nick Busing, the executive director of the Association of Faculties of Medicine of Canada, echoes that sentiment. "I would not want to reduce the number of visa residents without backfilling their positions with appropriately funded positions of Canadians and international medical graduates."

Reuters / Enrique de la Osa

International medical graduates say a temporary moratorium on internships for foreign visa trainees should be introduced so as to help train more doctors who plan to stay in Canada. Pictured here is the graduating class of the Latin American School of Medicine in Havana, Cuba.

Dr. Brian Day, past-president of the Canadian Medical Association, calls for balance.

"We don't want to deprive Canadian-trained graduates of opportunities to give positions away to foreign graduates. But, on the other hand, it is an economic reality that some of those coming from abroad help to subsidize programs that help Canadians in their training."

That may be the case for residencies, since foreign governments pay the salaries of foreign visa trainees. But according to Busing, the subsidy doesn't extend to medical undergraduates.

Tuition fees for foreign visa trainees vary widely, but they average about $25 000 per year, a fee that does not cover the costs of training that individual, he says. Canadian medical undergraduates pay much less, between $2000 and $17 000 per year, with the balance of the cost subsidized through tax dollars.

Like Busing and Padmos, Day says the best solution would be to expand the overall number of postgraduate positions.

Jonathan DellaVedova, president-elect of the Canadian Federation of Medical Students, says that "where there are space limitations in the system, we think that Canadian medical graduates are the best suited for and the most deserving of postgraduate positions." — Amanda Truscott, Toronto, Ont.

DOI:10.1503/cmaj.081128