MACLEAN'S

SWINE FLU SCREW-UP: CAN CANADA'S VACCINATION PLAN BE FIXED BEFORE IT'S TOO LATE?

Maclean's
Mon Nov 23 2009
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Column: NATIONAL

Canada is barely a few weeks into the biggest mass immunization campaign in the nation's history, and by now everyone has heard -- or worse, lived -- a flu shot horror story. "It's been chaotic," admits Dr. David Scheifele, director of the Vaccine Evaluation Centre in Vancouver, which is associated with the B.C. Children's Hospital. His own experience is no exception. Recently, Scheifele ordered nurses at his hospital to administer the pandemic H1N1 vaccine to the highest priority health care workers, those in the emergency room, intensive care unit, and labour and delivery area. He knew there was a limited supply of shots, so nurses visited the targeted groups with a mobile cart. "We thought that was really smart. No advertising. This was a sensible way to interact with the people who needed the vaccines."

But pandemonium erupted. "Legions of people were basically crashing the party," he recalls, including non-priority clerical and medical staff. There was such a "clamour" and so many "irate people incensed that they were being turned away" that the nurses had to return the next day with a security guard. "It is preposterous, the notion that nurses delivering a vaccine would be mobbed and fear for their safety," he says. "Who could ever have imagined a scenario like that?"

It's a question public health officials at every level should be asking themselves, given the bewildering events that have unfolded since the pandemic flu shots started rolling out of the Quebec plant of GlaxoSmithKline (GSK) in mid-October. In Toronto, pregnant women and other vulnerable groups were forced to stand outside for up to seven hours, come rain or wind, to get immunized. In Calgary, a shuttered flu clinic that had run out of vaccines detonated a chorus of profanities among the jilted -- a manifestation of "flu rage," as psychologists have christened H1N1 anxiety. Some family physicians who tried to get their own vaccine rations for their most susceptible patients, including those with cancer, were denied. Yet NHL players, robust young men with strong immune systems, somehow managed to get their arms poked. As if all this weren't surreal enough, then came the political rhetoric by Liberal party president Alfred Apps, who wondered in a rousing email to colleagues whether this flu pandemic is Canada's hurricane Katrina.

Indeed, it's easy to feel like H1N1 has been wildly mishandled. "Botched" is the buzzword these days. Most of the provinces and territories have received only a fraction of the vaccine they were initially promised. British Columbia, for instance, expected its first shipment to be a million doses; it got a quarter of that amount, and so far the ensuing weekly shipments have also fallen short. On the other hand, many of the provinces and health units have been accused of sitting on vaccines because they don't have the manpower to administer all the needles at once.

Just making this flu shot has been more trouble than anyone anticipated. The virus has been difficult to grow in the lab (a necessary step in creating a vaccine), which experts say has slowed down GSK's production rate. Critics are also enraged that Canada, unlike the United States and other countries, only hired one pharmaceutical company to produce the shots. And just when the vaccine-making got underway, GSK had to interrupt that production to create a different version for pregnant women. This short supply of flu shots has forced governments to encourage "priority sequencing" so that the most at-risk populations get immunized first -- though many healthy people have jumped the queue. "I think we assumed we were indeed a civil society," says Scheifele. "That's not necessarily the case when people are scared."

The growing sense of panic matches the rising death toll. Across the country, 135 people have been killed by H1N1 since last spring, when it was first identified in Canada, including an alarming number of otherwise healthy, vibrant young people. Nearly three dozen deaths have occurred in the first 10 days of November alone, which corroborates Canada's chief public health officer's assertion that the "second wave" of the pandemic flu is ramping up. "We expect to hear of more illness and deaths in the coming weeks," says Dr. David Butler-Jones. "This is something we have to be prepared for, as much as it saddens us."

But for most people, accepting that someone in their community -- maybe their own family -- could die of H1N1 seems

incomprehensible, if not reprehensible. Amid all the deaths, dwindling vaccine supplies and talk of a potential third wave, most Canadians have reached the same conclusion: the country's public health authorities -- federal, provincial and local -- have failed us miserably. What if this was the big one? What if we weren't so lucky, and H1N1 turned out to be the virulent influenza strain that experts have been bracing for -- the one capable of killing thousands of people in a matter of weeks? How many people would have perished while waiting in line for a shot?

We were supposed to be ready for this. The federal government spent millions of dollars and many years crafting an official "Pandemic Influenza Plan," and at 550 pages, the latest draft tackles every imaginable what-if and what-to-do. The document is so detailed that it even includes a write-up about where to store flu-infected corpses if the morgues run out of space. (Try the local hockey rink first, the report says, and if that's full, a refrigerated grocery truck will suffice.) The provinces and territories seemed equally prepared -- on paper, at least. Each one boasts its own pandemic road map, and like the national version, they leave little to chance. The Ontario plan goes so far as to point out that at some vaccination clinics, "Mennonite populations might need hitching posts for horses."

So earlier this year, when a scary new strain of the influenza virus surfaced in Mexico and spread across the globe, health authorities in Canada were armed with a very thick playbook. Unfortunately, that same playbook points out what so many shot-seeking Canadians now know: "No plan is or will be perfect; in fact, it may only be in hindsight that areas of improvement can be identified."

Ask anyone who braved the long and winding lineups and the verdict is already in: our immunization rollout was horribly bungled. How, after all, can the same plan that contemplates the parking needs of Mennonites allow pregnant women to stand in the rain?

But to suggest that the entire effort has been a universal debacle isn't fair either. While it's clear that many mistakes -- and assumptions -- were made, pinpointing the culprit is not as easy as opposition politicians like to proclaim. "Pandemics occur three times a century," says Dr. Arlene King, Ontario's medical officer of health. "There are going to be bumps in the road." Some of those bumps should have been spotted well in advance. Others were unavoidable.

Any debate about what's happened over the past few weeks must be framed by one scientific fact: a pandemic influenza virus is not a seasonal flu virus. It is a never-before-seen strain that spreads rapidly from country to country, and no matter how swiftly the experts act, it takes time to create a vaccine. Unlike a typical flu shot, which can be produced months before the flu season actually arrives, a pandemic strain appears out of nowhere, just as H1N1 did in April. "Even if everything works perfectly, it takes about six months from the time you have a virus until the time you can produce a vaccine," says Dr. Tim Brewer, an infectious disease specialist at McGill University. "And there were some production problems with this virus. It didn't grow as well in the egg cultures as they had hoped. That was a real challenge."

Adding to that challenge was the fact that this year's seasonal vaccine was in the final stages of production when the H1N1 vaccine was ready to be made. Rather than cancel the seasonal version (the regular flu kills thousands of people, too), the World Health Organization (WHO) recommended that every country complete its production runs before pumping out the new H1N1 vaccine. Canada heeded that advice. "No one jettisoned their seasonal vaccine production lines," says Dr. Earl Brown, a virus expert at the University of Ottawa and adviser to the country's chief public health officer. "You really would have to say: 'Gee, there's not going to be any need for seasonal flu vaccine. Let's forget about it this year and tell the companies to throw the stuff in the garbage.' "

Looking back, some experts are now convinced that was a fatal error. "It was a terrible mistake," says Dr. Richard Schabas, Ontario's former medical officer of health. "We're not seeing any seasonal flu, which I think was predictable, and we are seeing an early flu season from H1N1, which I think was also predictable. Whether it was a reasonable decision or not at the time, it's turned out to be a very wrong decision."

Another controversial decision was Ottawa's sole-source contract with GSK. The rationale was sensible enough. In 2001, Jean Chrétien's Liberals believed that in the event of a global flu outbreak, it would be prudent to have a vaccine produced by a Canadian factory on Canadian soil. That way, if the borders were ever shut down, the shots would flow.

But last week, amid production interruptions at GSK's plant in Sainte-Foy, Que., federal officials confirmed that they will consider buying future vaccines from multiple suppliers in order to avoid potential shortfalls. The numbers speak for themselves. In the first three weeks of the rollout, from Oct. 12 to Nov. 1, the feds distributed an average of 1.95 million doses per week to the provinces. Last week, the provinces received only 711,000 shots -- barely one-third the usual amount. Some flu clinics had no choice but to shut their doors.

Common sense suggests that more suppliers would equal more supply, but Scheifele is not convinced. "It's the virus that's the villain here, not the logistics of vaccine purchasing," he says. "One would have to split the expected target numbers between the two companies, and the reality would have both of them struggling to meet their quotas." Even the U.S. is suffering through

shortages. "It's been an across-the-board struggle."

A few weeks ago, the struggle actually had nothing to do with supply. Public health officials across the country were not worried about running out of vaccine; they were worried that nobody would show up for the shot. Governments peppered the airwaves with TV and radio ads, urging Canadians to roll up their sleeves. "A few days before our clinics opened, I was being asked questions by the media about how we were going to persuade people to be immunized," says Dr. David McKeown, Toronto's medical officer of health. "Polls were telling us that many people did not want to be immunized, and we were planning for that." One survey conducted in late October found that only 49 per cent of Canadians planned to get the shot.

But despite the surveys, it is now clear that many health authorities in fact grossly underestimated the public's appetite for immunization. Yes, the feds ordered a whopping 50 million doses of the vaccine, but some local officials wrongly assumed there would be plenty of vials to go around as soon as their clinics opened -- even though they knew full well that the vaccine would be shipped in spurts. Some regions were downright irresponsible. The Public Health Agency of Canada asked that the early doses be reserved for high-risk populations -- health care workers, pregnant women, children between six months and five years old, and people under 65 with chronic medical conditions -- yet there was Alberta Premier Ed Stelmach, declaring that it was everyone's civic duty to receive the shot. "We're the province that is offering flu vaccines for every Albertan, not just to the high-risk groups," he boasted.

That same morning, newspapers across the country carried the smiling photos of a 13-year-old boy from Toronto named Evan Frustaglio. Infected with H1N1, the aspiring hockey star collapsed and died on his bathroom floor. "That image is just so powerful," says Dr. Natasha Crowcroft, director of surveillance and epidemiology of the Ontario Agency for Health Protection and Promotion. "As a parent, as soon as you realize this is a real thing that's happened to a real child and that it could have been your son, your views change completely."

Though tragic, Frustaglio's death did what the country's public health machine could not: convince the masses to be immunized against H1N1. Literally overnight, flu clinics that were expecting steady streams of traffic were suddenly bombarded by worried parents and other jittery citizens. Canadians who once had no intention of being pricked in the arm were now asking an obvious question: the government told me to get the shot, so why am I being turned away?

"I don't know if there were mixed messages, but there was not a clear message," says Dr. Ethan Rubenstein, an infectious diseases expert at the University of Manitoba. "The right message -- that the rest of the population stay home, and at-risk groups go first -- came a bit late."

Even when the message is perfect, vaccinating the entire country in the midst of a pandemic is a monumental undertaking, and when something goes wrong, the reasons are rarely cut and dried. The logistics alone are simply overwhelming. Ottawa's job is to order the vaccine and distribute it evenly to the provinces and territories, which then funnel the supply to local health units. It arrives from the plant in 500-dose boxes, which must be repackaged into smaller batches and then shipped, in refrigerated trucks, across the country. Delivery by plane is forbidden, because the "cold chain" requirement -- between two and eight degrees Celsius -- is not possible at high altitudes.

At the heart of Canada's pandemic plan is a premise that most Canadians would rather not hear: everyone cannot receive the shot on the same day. Or even the same month. If GSK meets its weekly target -- two million doses per week -- it could still take up to four months to vaccinate the population. (Butler-Jones has repeatedly promised that everyone will have access to the shot by Christmas.)

"I don't think the actual rollout of the vaccine -- in terms of needles going into arms in public health clinics -- is going all that badly," says Schabas, now the chief medical officer of health for Hastings and Prince Edward Counties in eastern Ontario. "The problem is the vaccine is always going to roll off the assembly in relatively small amounts, day to day and week to week. We're never going to start with enough vaccine to do everyone at once, so there was always the possibility that there would be more people who wanted the vaccine initially than were going to be able to get it."

Amid all the virtuous finger-pointing, that is a crucial point. During a pandemic, patience is as much a part of the plan as logistics. "I think people's expectations are very high for many things, and this is no different," says Dr. Eilish Cleary, New Brunswick's chief medical officer of health. "People are used to getting health care when they want it. I personally think it's extraordinary that we had a new virus appear on the scene in April, and already we've got a vaccine into a fair proportion of the country."

Five weeks into the process, Ottawa has delivered more than 8.5 million doses to the provinces, enough for one-quarter of the Canadian population. Whether that is a "fair proportion" is up for debate, but one thing isn't: when it comes to actually sticking those needles into people's arms, some regions are doing a much better job than others.

In Sault Ste. Marie, Ont., for example, the vaccine is administered by appointment only. Residents simply phone a hotline, book

a time slot, and show up for the needle. "People line up on the phones -- if you can call that a line," says Dr. Allan Northan, the region's medical officer of health. "You're not out in the cold. You might be told that because of your good health you may have to wait another two weeks, but you're not told that after waiting five hours in a line."

Contrast that with Toronto, where five-hour lines were standard operating procedure in the first few days. "The initial demand was unexpected," admits Toronto's McKeown. But he explains the backlog this way: when the vaccine first began to arrive in mid-October, the master plan was to deliver it to select hospitals and doctors' offices, and then open 10 walk-in clinics -- capable of injecting up to 120,000 people a week -- on Monday Nov. 2. After Frustaglio's death, however, McKeown decided to open a few clinics early. "We were opening them on very short notice, and we had high demand," he says. "That led to the initial long lines, but really only for the first two days. Once we kicked into full gear with our other clinics, the lineups were not there."

Visit one of the clinics today, and the lineups have vanished. In fact, the city's master plan has turned out to be more than sufficient, despite the early logjams. All told, only 50,000 people have actually shown up for the shot. Dr. David Fisman, an epidemiologist and professor of public health at the University of Toronto, describes the initial chaos this way: "It would be basically like going from traffic jam to traffic jam and saying: 'Oh, you know the world is bunged up today,' whereas in other places the roads may be flowing fine."

Of course, it's also entirely possible that many would-be visitors were simply scared away by those snaking lines they saw on the news. Hundreds of thousands of "healthy" people who don't fit in the high-risk categories have also received the message loud and clear: stay away until we tell you otherwise. When they finally get the green light, those clinics may be swamped all over again. "I think we're all hoping we won't have the lines we had before," says Butler-Jones, adding that local health authorities have taken a range of steps -- from expanding hours to distributing wristbands -- in an effort to limit wait times. "We're all anticipating that the continued rollout will be better."

In the meantime, the question lingers: why, in the middle of a pandemic, do so many public health units insist on holding those massive clinics? Would it not be more efficient to distribute the vaccine more widely to family doctors as well?

Surprisingly, most pandemic plans recommend the centralized approach as a way to ensure supplies are not wasted -- on the Toronto Maple Leafs, for instance, or the board of directors at Mount Sinai Hospital. The underlying fear, which has proven true in those cases, is that some doctors will promise to give the shots to high-risk patients, and then do what they please in the privacy of their own offices. "I suppose you're going to have that no matter what," says Dr. Stephen Wetmore, president of the Ontario College of Family Physicians. "But most doctors want to be involved in the vaccine program. Family doctors vaccinate patients. That's what we do. Why they thought, all of a sudden, that we are a bunch of bumbling idiots and wouldn't be able to do this is beyond me."

Dr. Elisa Venier, a family doctor in Toronto, is still waiting for her order to be filled, so she "begged and borrowed" a few doses from a colleague and organized a mini-clinic for her highest-risk patients. "I had one patient who started chemo that morning," she says. "He is 33 years old, hasn't been eating, is very, very unwell. Now, imagine him in a lineup for six, seven, eight hours."

So what does all this mean for the average Canadian who still hasn't received a flu shot -- and still isn't sure when that will happen? As with all things pandemic, there is no easy answer. Influenza waves, which are characterized by a bell shape of sickness in a given geographic area, tend to last between 10 and 12 weeks. In the case of H1N1, the earliest signs of a second wave showed up in September, and in many places it already seems to be nearing the peak. In other communities, such as Kingston, Ont., the pandemic has actually started to retreat.

That means despite the intense messaging about the importance of getting immunized, the worst of this second wave could be over before a good portion of Canadians even roll up their sleeves. As distressing as that sounds, Fisman says that "anyone who is straightforward with you would acknowledge that." So the question then becomes: is it worth carrying on with the flu shots?

The answer depends on whom you believe. A debate is brewing between experts over the likelihood of a third wave. In previous pandemics, a more serious winter wave followed the autumn one. If that happens again, the H1N1 vaccine would still offer protection during the next round of infection.

But Schabas insists that the notion of a third wave is nonsense, a convenient theory to alleviate our surprise at how few people have actually died. He is so convinced we won't see another round of pandemic H1N1 that he is considering telling healthy people in his area not to bother getting vaccinated. Fisman, who conducts mathematical modelling for **MITACS**, a Canadian research network, says his calculations also do not point to a third wave. But he is careful with his forecast because he says there may still be isolated pockets of H1N1 in the coming months.

Even if there is no third wave, experts argue that getting the pandemic shot is still important because there is a good chance

H1N1 will become part of future seasonal flus, including what may come next fall. Dr. Monika Naus, an epidemiologist and director at the B.C. Centre for Disease Control, also predicts that H1N1 will become part of "the fabric of circulating strains for quite a while to come." In fact, Naus says that there is "every expectation" that the World Health Organization will recommend that H1N1 be incorporated into the next seasonal vaccine.

Whatever comes next, everyone acknowledges this much: the H1N1 strain has provided a test run for public health authorities, an opportunity to learn a few hard lessons about what Canada can do better next time. Many health experts are calling for a complete rethink of how we deliver shots, even suggesting the creation of a national immunization program that would require all the provinces and local health units to roll out the pandemic flu vaccine in the same way. Crowcroft admits that it borders on blasphemy to propose that provincial and local authorities bow down to federal rules about their own well-being, but she's not a fan of differentiation for its sake alone. "It doesn't make a lot of sense to have different approaches. I know that goes against the Constitution of Canada, but it might have made some issues a lot easier." Adds Scheifele: "It confuses the daylights out of the public when one province is saying one thing and the adjacent province is saying something else. There are lots of points where you wish there was just a czar who said: 'We're doing it this way.' "

For now, the experts are just happy that H1N1 hasn't been the catastrophe that health authorities have been bracing for -- and had in mind when they wrote the frightening federal pandemic plan. "I'm grateful that it's not the 1918 pandemic, that the mortality rates aren't higher," says Naus. "If we had that kind of situation in this type of vaccine supply we'd be in a much harder place."

Much harder. What if a dozen Evan Frustaglios had died in the arms of their helpless parents? What if triple the number of fear-stricken people showed up at the country's understaffed, under-supplied flu clinics? What if their frustration at being turned away led to violence? And what if -- despite the best efforts of GSK -- something else went wrong at the production plant and vaccines suddenly stopped flowing?

The answer, unfortunately, is that we would be pumping out the flu shot at much the same pace as we are right now. Of course, if this was a deadlier pandemic, many other measures would be implemented immediately. Schools, social centres and places of employment would close down, quarantines would be ordered at the first sign of infection, and the national stockpile of antivirals would be deployed en masse. And squabbling over who deserves the flu shot first would soon be trumped by unthinkable choices over who gets the last life-saving ventilator -- the 65-year-old man with a bad heart, or the 21-year-old woman with a whole life to live?

Maybe the lineups aren't so bad.

Edition: All
Length: 4182 words
Idnumber: 200911230008

Tone: Strongly Negative
Ad Value: $41,241
Circulation: 369,486