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inside

BOGOTA’S NEXT STEP

The Colombian city is positioning itself as one of the main hubs to do business in Latin America and biotechnology is a main focus.

PRIMARY PREVENTION

With diseases like the measles still popping up in Canada, companies are working to make new vaccines, improve existing ones and develop new delivery technology.

MOMENTS IN TIME

Twenty years ago the ICCPE declared the wild poliovirus was eliminated from the Americas, the first WHO region to meet the goal of polio eradication.

feature

LIGHT AT THE END OF THE TUNNEL

More than 30 years after the HIV/AIDS epidemic began, researchers are making slow and steady progress toward an HIV/AIDS vaccine and cure.

standard

EDITOR’S NOTE
NEWS
Global leadership in a changing world

Come to Saskatoon, Saskatchewan October 5-8, 2014 for the Agricultural Biotechnology International Conference.

Saskatoon is the heart of agricultural biotechnology in Canada, the birthplace of canola, and home to a vibrant bioscience research cluster at the University of Saskatchewan and Innovation Place science park.

This year's conference will feature world-renowned bioscience experts, including:

Roger Beachy served as founding CEO for the Global Institute for Food Security in Saskatchewan (GIFS) and is founding director of the World Food Center at the University of California, Davis. He is a world renowned scientist with expertise in the field of plant sciences, molecular biology and biotechnology.

Nina Fedoroff is currently Director, Desert Agriculture Research Initiative (DARI) at King Abdullah University of Science and Technology. Fedoroff pioneered in DNA sequencing, determining the nucleotide sequence of the first complete gene.

Derek Byerlee has published extensively on intensification and land use and foreign investment in farmland. An Australian, he is currently a Visiting Scholar at Stanford University and a Fellow of the Agricultural and Applied Economics Association.

Ingo Potrykus is Professor Emeritus at the Swiss Federal Institute of Technology. His focus on food security led to the development of Golden Rice with high levels of beta-carotene, with the goal of reducing Vitamin A malnutrition in developing countries.

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Travel back in time with me.

If I told our ancestors from as recently as 60 years ago that we have shots that will prevent people from getting sick and dying from nasty killers like polio, measles, whooping cough, amongst other diseases, what would they say? I’m pretty sure they’d rip my arm off for that needle.

Now rejoin me in the present day. We have vaccines that prevent all of these previously eliminated diseases yet outbreaks still occur. Have we become so spoiled with medical advances that people are now shunning them?

The science cannot be any clearer. Vaccines work. Why wouldn’t you take them? Yet parents are not vaccinating their children. There have been at least 375 cases in the ongoing measles outbreak in British Columbia’s Fraser Valley alone. Other areas of western Canada and Ontario have also seen occurrences of the measles. These are not isolated incidents. An outbreak three years ago in Quebec racked up a whopping 725 confirmed cases, following a 2007 outbreak of 94 cases in La Belle Province. The Vancouver Olympics touched off an outbreak of approximately 80 cases in B.C. in early 2010.

The crazy part is we’ve conquered measles. The Pan American Health Organization, the WHO regional body for this region, said the Americas achieved elimination status in 2002, but the process of formally certifying that accomplishment hasn’t yet been completed.

Now this is the point where people will point to Jenny McCarthy. It is completely beyond my comprehension why fully functioning adult human beings are taking the advice of a former Playboy model and celebrity hookup over scientists with PhDs.

She is absurd, of that there is no doubt, but the blame needs to be spread around. The media deserves to shoulder its fair share of the responsibility for giving her the platform to spout her ignorance. But pharma and biotech companies are equally as culpable, if not more so. These companies have vaccines that work; the science is irrefutable. How far has our belief in pharma fallen when people will listen to the advice of a former Playboy model and celebrity hookup over scientists who have spent decades studying the safety and efficacy of these vaccines? And why?

The only way to get the right information in people’s hands is through education. A lot of people see pharma as the big corporate bogeyman that only sees dollar signs when it looks at patients. Perhaps it’s time for some harsh truths: show people what life would be like without vaccines. Prove to them their children will not get diseases around. The media deserves to shoulder its fair share of the responsibility for taking the advice of a former Playboy model and celebrity hookup over scientists with PhDs.

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The only way to get the right information in people’s hands is through education. A lot of people see pharma as the big corporate bogeyman that only sees dollar signs when it looks at patients. Perhaps it’s time for some harsh truths: show people what life would be like without vaccines. Prove to them their children will not get autism. Find a way to relate to them so they understand the importance, efficacy and safety of vaccines.

The next great vaccine hope is for HIV/AIDS (page 12). In talking to researchers and companies around Canada I discovered we might be closer than we think to a breakthrough. What’s the use though if it’s shunned?

Vaccines are perhaps the single greatest medical advancement humanity has made. Somewhere along the line people have forgotten that. It’s pharma’s duty to help them remember.
Mark Lievonen, President of Sanofi Pasteur Limited, the Canadian vaccine division of the Sanofi Group, has been awarded the Lifetime Achievement Award from Life Sciences Ontario (LSO).

"As the life sciences industry in Ontario continues to evolve, it's important to celebrate people who have made meaningful contributions to the growth and prosperity of the sector," said Paul Lucas, President and Chair of LSO. "Mark’s career is marked by outstanding achievements, unwavering dedication and commitment to the life sciences community, as evidenced by his leadership at Sanofi Pasteur, volunteer activities and supporting the advancement of the next generation of scientists.”

Lievonen joins prestigious past recipients including Dr. Calvin Stiller, a public policy champion instrumental in founding the Robarts Research Institute in London, the Ontario Institute for Cancer Research and MaRS, and Dr. Henry Friesen, a distinguished Canadian scientist, past president of the Medical Research Council of Canada, past president of the National Cancer Institute of Canada and founding chair of Genome Canada.

"As Sanofi Pasteur approaches its 100th anniversary in Canada, I am proud to represent an organization that has contributed to the growth and sustainability of Ontario’s thriving biotechnology sector,” said Mr. Lievonen. “Throughout my career, I have aspired to create a meaningful impact by stimulating innovation and enhancing Canadian competitiveness and productivity. I am humbled to be joining the ranks of esteemed leaders.”

Mark Lievonen, President and CEO of Sanofi Pasteur; Hon. Reza Moridi, Minister of Research and Innovation; Jason Field, Executive Director of Life Sciences Ontario. Photo credit: www.sanofipasteur.ca
CPhI Worldwide’s Pharma Insights report shows the R&D market is diversifying innovation, with increased out/in licensing of technology, partnerships, and mergers. Improvements in evaluation have also been credited with helping the sector grow at an impressive 8%, with long-term objectives now being considered at earlier stages within the development process.

Furthermore, the industry is evolving its model, maintaining innovative output whilst also standardising approaches to measuring effectiveness, and crucially, returns on investment – with 40% using QbD for analytical and tech, 18% using 6 Sigma, 15% stage gate and 12% lean techniques to evaluate effectiveness.

Unsurprisingly, with the milestone nature of moving between clinical stages, balancing long and short-term goals was seen as a major challenge (53%) and improving efficiency (38%) also highlighted the growing efforts to improve ROI between stages. However, a clear trend has emerged from this with more and more companies involving commercial side at an earlier and earlier stage with 30% beginning in pre-clinical and a further 30% prior to phase iii.

Almost a quarter of respondents sighted cancer as a major focus area for 2014, with antibiotics (13%), cardiovascular (12%) and CNS (12%) targets also featuring notably. Additional evidence for the cancer-focus also emerged from the novel areas companies are working on, with 37% researching combination drugs and 20% personalised medicines. Outside of cancer, it appears that improved drug delivery mechanisms are targeted as 17% were investing in nanotechnology and 12% directly in drug devices.

However, the source of innovation is increasingly diverse with growing partnerships (75%), mergers 20%, and out/in-licensing of technology (55% and 60% respectively). Clearly, a major factor in competitiveness both now and in the future is access to technology, and we are seeing a more collaborative approach. This is an important trend and one that should enable the industry to continually innovate, where even the smallest biotech can access crucial technology that enables them to move projects forward.

Clearly, a major factor in competitiveness both now and in the future is access to technology.}

WORLD'S FIRST BIOCIDE INJECTION SYSTEM BANISHES THE DIESEL BUG
Changes in the biodiesel and sulphur levels in modern bunker fuels are increasing the likelihood of microbiological fuel contamination for yachts, otherwise known as ‘the diesel bug’. Fuelcare, a specialist in improving fuel quality, has announced the world’s first biocide injection system to banish these fuel quality issues. The ‘Fuelcare Marine Bunker Injection System’ injects an additive when fuel is bunkered, with fuel pressure driving a turbine to inject a precise, consistent stream of a leading biocide. When used as a preventative measure the product can be injected into fuel by an automated injection system. By dosing automatically, this preserves fuel quality irrespective of re-inoculation of the diesel bug from bunkering fuel.

PARTNERS IN THE FIGHT AGAINST CANCERS
Curie-Cancer, the body responsible for developing Institut Curie’s industry partnership activities, and DNA Therapeutics, a biopharmaceutical company that is developing a new class of cancer drugs, are renewing their partnership. Their clinical and translational research program has developed Dbait molecules now in Phase I clinical trial in patients with advanced melanoma. The ongoing collaboration will aim to provide a new class of therapeutic cancer products to patients, including those who are resistant to conventional therapies.

EIGHTEEN MILLION FARMERS IN 27 COUNTRIES CHOSE BIOTECH CROPS IN 2013
The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) today released a report which indicates more than 18 million farmers in 27 countries planted biotech crops in 2013, reflecting a five million, or three per cent, increase in global biotech crop hectarage. According to the report, more than 90 per cent of farmers planting biotech crops are small and resource-poor. Of the countries planting biotech crops, eight are industrial countries and 19 are developing countries. For the second year, developing countries planted more hectares of biotech crops than industrialized countries.
BETTER THAN MIDDLE OF THE ROAD

Colombia is trying to overcome stereotypes by using biotech as a way to get past being a middle income country

BY NICOLAS HEFFERNAN
Colombia and innovation: in a game of word association, these words make an unlikely pair. Yet the South American country is beginning to make inroads as it pushes itself into the global consciousness as a place to do business and biotechnology is one of the key industries it’s targeting.

In the eyes of many, Colombia suffers from the perceptions of the past rather than the realities of the present. The past 10 years have brought huge economic development thanks to improvements in security, strong political stability and a growing middle class. These changes have led to GDP growth of 5.5 per cent in 2011 and 4 per cent in 2012 and foreign direct investment of $15.8 billion in 2012, a record for the country. Colombia is now the fourth largest economy in Latin America, after Brazil, Mexico, and Argentina.

One organization that can take some credit for developing the business climate in Colombia is Innpulsa, a two-year-old government program aimed at fostering business growth based on innovation and entrepreneurship. To achieve that aim Innpulsa has been trying to sell Colombia to the world.

“Every time people come to Colombia we get very good feedback,” says Catalina Ortiz Lalinde, Executive Director of Innpulsa. “In the last two years [visitor’s] expectations weren’t very high and we have over delivered. People are coming and thinking, ‘Really, Colombia and innovation?’ and they see the projects and they see what’s going on and they say, ‘Yeah, it might be at an early stage but the potential is there.’”

Yet a damaged reputation can be hard to overcome. While people wouldn’t put Colombia and innovation together in a word association game, Colombia and drugs and violence generates instant recognition. It’s impossible to ignore the conflicts that characterized Colombia from the 60s and seemed to climax in the 80s and 90s. Yet Ortiz Lalinde doesn’t shy away from the country’s past and argues it’s a sign of the potential for Colombia’s business community.

“We can’t run away from our past but it is our past,” she says. “I think the world has changed dramatically. Yes, some people still think of Colombia in the 80s and all the hardships but those hardships made us resilient and able to compete in very adverse conditions because Colombia, although it had those problems, our economy never did poorly, even in the worst narco and guerilla conflicts.”

Bogota

While Innpulsa is pushing Colombia as a whole, biotech is finding fertile ground in Bogota and the surrounding Cundinamarca area. The area is home to 127 companies and six multinationals working in pharmaceuticals and health services as well as 171 businesses and
18 multinationals in the chemicals and agrochemicals sector. It’s also attracted 323 food and beverage corporations and 350 energy firms.

Bogota boasts five of the top 100 universities in Latin America, with Universidad de los Andes ranked sixth overall. In total there are 12 universities, eight technology development centers and 11 research centres supporting 421 research groups with research directly related to biotechnology. With the largest number of active researchers, the Bogota region produces 47% of knowledge generation in Colombia and is the largest provider of skilled human resources: approximately 30,000 of its yearly 100,400 tertiary graduates are postgraduates and Bogota produces 44 per cent of the total PhDs in Colombia. In 2011 Bogota was categorized as the fifth most attractive city for innovation in Latin America.

The country’s potential in the life sciences is further enhanced by the fact Colombia is the most biodiverse country per square metre in the world, representing 10–14 per cent of the planet’s entire biodiversity, not counting microbial or marine components.

**Keraderm**

One of the ways to change perceptions about Colombia is to have a stream of successful Colombian companies to showcase to the world and Keraderm, a Bogota-based company, is one of the region’s success stories.

Started in 2008 by Rodrigo Soto, the company’s major focus is treating wounds with skin grafts. With more than 9 million burns each year and the chronic wound market valued at $132 million globally there is a lot of potential. The conventional way to treat a burn is to take healthy skin and cover the wounded areas, but that method requires an operating room and leaves scarring and pain. Keraderm takes a one centimetre squared section of skin from behind the ear and also draws blood from the patient. “In five days we produce 10-by-10 cm sheets covered with skin cells, we can make three sheets and if we need more we’ll take more skin samples and more blood. We can make as many as the patient needs,” says Soto. “We don’t leave any pain and it can be done in a doctor’s office or in the patient’s bed and we don’t leave any additional scars.”

The sheets are formed by separating the skin cells from the samples and putting them on a collagen mesh from a pig. “The blood is like the food for the cells,” says Soto. “They’re beautiful, you give them the right environment and they grow.” What sets Keraderm apart is it doesn’t use any donor tissue and it’s 25 per cent cheaper than their competitors, with each sheet costing $528.

However for all the strides Colombia has made, the country still isn’t at the necessary level to fully support a biotech company. When Keraderm first came to the authorities with their idea regulators didn’t know what to make of it. “We actually went to the regulatory people here and they told us that they have no idea about this,” says Soto. “Now we’ve managed to be able to get approved... as a skin tissue bank. We’re not that happy about being a bank tissue company, but it’s a way to get regulation.”

The company has been making sure they are GMP-compliant to ensure they can enter foreign markets but the whole process has cost the company time and money. Adding an extra layer of difficulty is the state of Colombia’s health care system. “We have a really difficult health system right now and it’s under a lot of financial problems,” says Soto. “Most of the public hospitals right now are struggling financially and that’s been really hard for us because it makes it more difficult to reach the hospitals.”

Soto is optimistic about expanding the company in Colombia before trying to expand in Latin America, Europe, China, India and lastly the United States.

Despite the difficulties that still exist for companies in the biotech sector Colombians are confident the country can reach the next level. “If we don’t play this game, if we don’t use technology there’s no way we... We’re very proud to have come to where we are, to be a middle income country,” Ortiz Lalinde says. “We don’t want to stay there, we’re ambitious and middle income ain’t good enough!”
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In 1982, the Centers for Disease Control used the word AIDS (acquired immune deficiency syndrome) for the first time to describe a cluster of 270 reported cases of severe immune deficiency in gay men in the United States – 121 people died. Within three years, at least one case of HIV had been reported from each region of the world. A decade after the first reported cases, AIDS was the number one cause of death for American men aged 25 to 44.

Fast forward three decades and the demographics of the disease may have changed but the epidemic shows no sign of abating. Every day nearly 6,300 people contract HIV globally—nearly 262 every hour. More than 35 million people now live with HIV/AIDS. The perception might be that Canada has a good control on infection rates yet the estimated 70,000 people currently living with HIV/AIDS is an 11.4 per cent increase from 2008. While the prevalence of the disease in Canada and the United States has fallen since the 80s, the numbers are staggering around the world, especially in Africa, which accounts for more than two-thirds of all people living with HIV/AIDS.

“In the early 80s there was an epidemic; frankly the epidemic is still there,” says Dr. Marc Ouellette, Scientific Director of the Canadian Institutes of Health Research (CIHR) Institute of Infection and Immunity. “It’s maybe less in Canada but there are 3,000 new cases every year and there’s about 70,000 Canadians that do live with HIV/AIDS. But in some regions of Africa, especially the sub-Saharan areas, the numbers are just incredibly high.”

In Africa, an estimated 1.2 million adults and children died of AIDS, accounting for 75 per cent of the world’s AIDS deaths in 2012. While death rates are high in underdeveloped countries, the disease has become controllable in places with greater access to medicine. There has been a lot of progress since the FDA approved zidovudine, the first anti-retroviral drug.

“When it was first discovered in the early 80s it was a deadly disease in Canada and now in Canada we can consider it a chronic disease,” says Ouellette. “When you had the first drugs in the mid-80s, the problem was the virus was acquiring resistance. Now, using multiple drugs, it’s much more difficult for the virus to become resistant and it has led to the control of the virus, especially in Western countries where they can afford and have good monitoring of the virus and the disease.” Current therapies keep the virus dormant but
it still lies in sanctuaries in the body. “When you’re on three therapies you don’t have sign of the virus but you know that it’s hiding somewhere, so one of the strategies now is to have drugs that will make the virus go out and then kill it.”

The goal posts are being moved when it comes to treatment thanks to success stories like the Berlin Patient and the Mississippi Baby who were cured through aggressive drug therapy programs. In the past, drugs were used to control HIV. “The new research agenda, and it is very exciting, is curing HIV.” Timothy Brown, also known as “The Berlin Patient,” is thought to be the only individual functionally cured of HIV.

The twin pillar in the search for a cure is the investigation for a vaccine. There has been a lot of impetus in the search for vaccines thanks to some recent success from around the world, including the Kang Lab at the University of Western Ontario, which, with the support of Sumagen Canada, became the first and only preventative HIV vaccine based on a genetically modified killed whole virus that has received FDA approval to start human clinical trials. “[Successes] shows it is possible but on the other hand there is also the realization that we need to better understand the interactions between the virus and the portion of the immune system that is at the level of the mucosa,” says Ouellette. “The vagina or the rectal mucosa is where we believe it’s going to be important to find the vaccine that will eventually prevent things.” Researchers are realizing there are some differences between the mucosa in animal models and humans which makes the challenge even harder. “It’s a better understanding of the virus and the host that will lead to a vaccine,” says Ouellette.

The resistance the virus acquired wreaked havoc with early drug therapies and that variability also makes creating a vaccine difficult. “There is a lot of mutation in the virus and that means the surface antigens change a lot,” says Ouellette. “Generating a vaccine of something that changes a lot is much more complex than against something that is quite stable.” HIV attacks the immune system so what usually generates the antibodies is weakened by the virus. “But now I think we have a good realization of this and generating vaccine is not a simple business also and in the three-year timeframe it’s certainly not unreasonable... we’ll have a vaccine.”

Although Ouellette is optimistic about a vaccine and a cure he is quick to stress nothing is imminent. “Neither for cures nor vaccines are we close yet but certainly there are a lot of efforts in that direction and I’m quite optimistic in the not so distant future we will have clinical trials with those approaches.”

In Africa, an estimated 1.2 million adults and children died of AIDS, accounting for 75 per cent of the world’s AIDS deaths in 2012.

The Mississippi Baby was born with HIV more than two years ago and appears to be the first documented case of a child being cured of the virus. “These are examples of strategies that were used to cure people from the virus that has made people very optimistic that at some point we will be able to cure,” says Ouellette. “There’s a scientific base now to think that indeed it is possible to get rid of the virus.”

The traditional way to tackle vaccines...
HIV/AIDS

Drug resistance made HIV/AIDS difficult to treat until drug cocktails were used. The adaptability of the virus also makes developing a vaccine more difficult.

Vaxing ain’t easy
Developing a vaccine for HIV is more difficult than most as the virus targets the immune system. The immune system looks at proteins coming through and checks whether the same infected antigen is already in the system. The virus makes the immune system ignore or tolerate the infecting agents and their antigens and the infection continues to progress until it creates more trouble for the host. “So in order to treat a chronic situation we have to re-educate the immune system so that our cells do not ignore or tolerate infectious agents.

HIV/AIDS IN CANADA*

71,300 people living with HIV infection
an 11.4% increase from 2008
2,250-4,100 newly infected people

NEW HIV INFECTIONS:
46.6% were men who have sex with men
37.2% were heterosexuals
13.7% were injection drug users

WOMEN living with HIV accounted for 23.3% of national total

ABORIGINALS account for 8.9% living with HIV and 12.2% newly infected

*as of 2011
Source: Government of Canada
In other words, you have to switch the recognition by the immune system from ‘self’ to ‘foreign,’” says George.

Akshaya does this by taking antigens and fusing them with foreign antibody fragments (Fc fragment), making disease-specific vaccines which look for the antigen presenting cells and the receptors on them. “When that happens, the system will look at it and the first impression will be ‘yes this is different because there’s a new protein,’” says George. At this point the immune system looks at the carbohydrates, the sugar molecules, which are changed by creating the vaccine in insect cells. If they are the same ones that are originally circulating, the system will say, ‘Yeah, forget it, we’ll be OK.’ Akshaya switches the recognition for the sugars by producing the vaccines in insect cells which put new carbohydrates on the vaccine, which are quite different from what human cells do. “That tells the system this is totally new, let’s take care of it. Do something,” says George. “Then the immune system picks up new T-cell and B-cell epitopes, and we have evidence to show that. Then it’s a whole new immune ballgame.”

The beauty of Akshaya’s vaccine is it can be used as both a prophylactic vaccine and also as an early-intervention therapeutic. George would prefer to focus on the preventative properties of the HIV vaccine as that is the world’s greatest need, but during a three- to nine-month window after infection the vaccine can be combined with antivirals to reactivate the immune system to ward off the virus. “There is more and more evidence that the immune system is not totally wiped out – there are some cells still hanging around,” says George. “You can still induce immune responses. You can expand them by post exposure vaccination.”

Progress to be made
Despite optimism, a cure and a vaccine can’t come quickly enough. Since the beginning of the epidemic, more than 75 million people have contracted HIV and nearly 36 million have died of HIV-related causes. The virus is spreading rapidly in Eastern Europe and Asia, where its incidence could outstrip that in Africa within a decade. Facing those startling numbers Ouellette also stresses the importance of the research the CIHR is doing on the social factors to lower the transmission of the disease. “To win the fight against HIV/AIDS it will have to be not one specific approach but a multiplicity of approaches that will all work together in synergy to be able to control it,” says Ouellette. “The disease is complex because it does have biological cause, which is the virus, but it’s also all the social and cultural determinants that also contribute to the HIV epidemic.”

That being said, HIV/AIDS will be truly conquered by biomedical advancements. Similarly to the advancements made with the social stigma toward the disease, vaccine and therapeutic research has come a long way. “I think there’s been a lot of progress,” says Ouellette. “But there’s still a lot of progress to be made.”
For Walter Hiebert, who was diagnosed with HIV in 1988 and given just six months to live, advances in HIV treatment literally saved his life. “I didn’t have any hope at all,” says the 56-year-old, who had to go on disability from his job as a registered nurse in a Vancouver hospital intensive care unit. As a patient of BC-based Dr. Julio Montaner, he was successfully treated with the HIV drug “cocktail” – a combination of three anti-retroviral drugs – which the renowned physician and researcher helped to develop. “The HIV drug cocktail saved my life and gave me hope,” says Hiebert, who went on to earn a graduate degree and now works full-time for a large telehealth organization.

In the past two decades, AIDS has been transformed from a fatal disease to a manageable condition by the drug cocktail. Dr. Montaner, director of the BC Centre of Excellence in HIV/AIDS (BC-CfE), director of AIDS Research and head of the Division of AIDS in the UBC Faculty of Medicine, and his team, also pioneered the wide international use of HIV Treatment as Prevention. This landmark approach cuts the chances of HIV transmission by over 95 per cent and was named by *Science* magazine as its 2011 “Breakthrough of the Year.” Its goal is to virtually eliminate AIDS and HIV transmission.

Unfortunately, HIV can become resistant to these drugs, leading to the development of full-blown AIDS and increasing the chances of a patient transmitting the virus to others.

Montaner and Dr. Richard Harrigan are leading a new $5 million research project, funded in part by Genome BC, to develop a single, improved drug resistance test based on the unique DNA of the patient’s HIV strain. “The new resistance test will make the therapy more effective in reducing the amount of HIV in the blood, which benefits patients and lessens the chance of spreading the virus,” says Harrigan, director of the Laboratory Program and head of genomics research at BC-CfE in St. Paul’s Hospital in Vancouver.

The researchers will develop new personalized tests, based on a patient’s DNA, to guide therapy and avoid serious side effects. The two types of tests – viral and human genomic – will help doctors prescribe the best drug cocktail for each patient, one that works well and minimizes side effects that may cause patients to stop treatment. “We plan to expand the number of human genomic markers tested so we can predict side effects for all classes of HIV drugs. Side effects drive whether or not patients take these drugs and stick with them,” says Harrigan.

Based on the latest DNA sequencing technology, this cutting-edge test will detect drug-resistant HIV strains that existing tests can’t. “This test will be a better, more sensitive tool that takes less time and is less expensive,” explains Harrigan.

It will also give patients like Hiebert – whose drug cocktail had to be changed after he developed resistance – an even better chance of staying healthy. “The new resistance test will be great for newly diagnosed people and people who have been HIV-positive for a long time. With better resistance testing, I know there’s a safety net. If I become resistant to a particular drug, I’m not worried because there are many others I could be given,” he says.

All HIV patients in Canada and their doctors will have access to the new test through the BC-CfE labs. The technology will be shared freely with labs globally, so it can be adopted quickly and widely. Montaner, Harrigan and their team are also creating a new early warning system to monitor and map drug resistance. It will pinpoint geographic or population “hotspots” where resistance rates are highest and the risk of transmission greatest. “We’ll be able to monitor the emergence of drug resistance in real time and identify patients with newly acquired drug-resistant strains faster. We can then intervene proactively and preemptively so the resistance doesn’t become widespread,” says Montaner.

Over 35 million people worldwide are infected with HIV and 70,000 in Canada and nearly $1 billion is spent on HIV drug cocktail therapies each year. Annual drug savings alone from the new resistance test will amount to $15,000 per year for each case of HIV avoided. Preventing 50 new HIV infections each year in Canada over five years would produce direct drug savings of $11.25 million – and that doesn’t include other medical costs for HIV patients, or lost productivity.

Additional funders for this project include Genome Canada, Genome Quebec, the Canadian Institutes of Health Research, ViiV Healthcare and the St. Paul’s Hospital Foundation.
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Every year, two to three million lives around the world are saved thanks to vaccines. That’s about the population of Toronto, Chicago or Houston.

“It’s the best primary prevention strategy against infectious disease and it’s probably the greatest medicinal product of all time,” says Dr. Dion Neame, a pediatrician and head of scientific and medical affairs at Sanofi-Pasteur, a global vaccine producer.

From product improvement strategies to vaccine-enhancing technologies, Canadian biotech and pharma companies are developing optimized vaccines to fight infectious diseases.

Developing & Improving Vaccines

Vaccines are a risky business. From conception to final product, it takes about 15 years and $1 billion dollars for a company to create a new one and when it comes to determining what disease to tackle next, Sanofi-Pasteur researchers start by looking for unmet medical needs.

“What is the epidemiology of a disease, how much disease are we getting, and what’s the significance of the disease in terms of morbidity and mortality. Those questions start the thought of a prevention strategy.”

The company is in the midst of creating a new vaccine for Clostridium difficile, an infection that causes symptoms ranging from diarrhea to inflammation of the colon that can be life threatening. C. diff, as it is often called, has been a persistent problem in hospitals and has a high death rate, particularly with the elderly.

Sanofi-Pasteur developed a scientific package on C. diff that was presented to Health Canada for approval, a review process that Neame says typically takes 12 months. The package included facts such as burden of illness, direct and indirect health care costs, vaccine efficacy and quality of life indicators. Neame says that Sanofi-Pasteur’s C. diff vaccine is expected to become available in the next few years.

Pharma companies like Sanofi-Pasteur are not only developing new vaccines, they are also working to improve on past products.

“In Canada, our numbers are in the area of 20,000 people getting admitted to hospital because of influenza each year,” says Neame. “And you have an average of 4,000 people dying, and close to 90% of the people who are dying are 65 and older.”

For years, researchers have been trying to figure out how to create a vaccine with a larger immunological response in people that are 65 years and older. Sanofi-Pasteur investigators reviewed the current standard of care, Fluzone, and determined that if they increase the number of antigens by four times the amount in a typical dosage a greater efficacy could be achieved.

The efficacy of the new influenza vaccine, Fluzone High-Dose (HD), was tested in a 30,000-person study in which half the subjects received the current standard of care and half received Fluzone HD. “The study results showed that there was a 24.2 per cent greater efficacy in the Fluzone High Dose versus the standard of care Fluzone,” says Neame.

This new influenza vaccine has already been licensed in the United States and is working its way through the licensing process in Canada.

Vaccine Enabling Technology

While many companies work on improving or developing vaccines, Halifax-based Immunovaccine is focused on advancing cancer immunotherapies and infectious disease vaccines with an innovative vaccine delivery system called DepoVax.

“A vaccine target needs to be exposed to the immune system to teach the immune system to recognize and fight it,” says Marc Mansour, the COO of Immunovaccine. “So the way you present the target to the immune system is really important.”

DepoVax creates a depot at the site of injection which forces the immune system to process the vaccine over a longer period of time than current vaccines. The platform uses liposomes to enclose targeted antigens and an adjuvant that are then placed in oil, which essentially increases the body’s immune response to the vaccine.

“The DepoVax formulation is oil-based and when it’s injected it stays there for weeks rather than hours,” says Mansour. “It forces the immune system to process the vaccine over that time.”
DepoVax technology produces a stronger, faster and longer-lasting immune response and has the capacity to be administered with a single dose. As a result, the vaccine enhancing technology has caught the attention of vaccine developers from across the globe.

The single-dose strategy was of particular interest to the National Institutes of Health (NIH), an agency of the US Department of Health and Human Services.

“There is a licensed anthrax vaccine that the US military uses, but it requires at least three initial immunizations and then repeated immunizations every year. If there’s a bioterrorism attack in the US, there will be no time to vaccinate the masses,” says Mansour.

The National Institute of Allergy and Infectious Diseases’ (NIAID) in the US have performed studies to assess Pfenex Inc.’s anthrax antigen or mutant recombinant Protective Antigen (mrPA) that has been formulated with Immunovaccine’s DepoVax delivery system. In these preclinical studies, all animals that were vaccinated with a single dose of mrPA – DepoVax were protected from anthrax infection. A dose response was observed in the first 28 days following the vaccination which suggests that animals may be protected within one month of a single immunization.

“The positive data from this latest study highlights the potential for the DepoVax platform to enable rapid response vaccines to combat bioterrorism,” says Mansour.

Mansour says the NIH has shown commitment to the formulation by offering funding and support for preclinical studies.

“Ultimately, the U.S. government is the only buyer for an anthrax vaccine so we want them invested in the program. We see it as a two-pronged opportunity: it validates our technology, but it also presents a commercial opportunity at very low development costs,” Mansour explains.

Company Collaboration

“We are driving the development of our own products but we also rely on other companies and their vaccines,” says Mansour. “We’re naturally open to collaboration, but now we’re seeing the industry more open to this approach as well.”

For Immunovaccine, partnerships are

HOW TO MAKE A MEASLES VACCINE

There are many ways to make a vaccine. Inactivated vaccines are produced by killing the disease-causing microbe with chemicals, heat or radiation, which prohibits the dead microbe from mutating back into its original disease-causing state. There’s also toxoid vaccines which can be used on bacteria that secretes toxins. Scientists inactivate toxins with formalin and these new “detoxified” toxoids help the immune system learn to fight off the natural toxin.

The measles vaccines contains a version of the living microbe and is called a live, attenuated virus. It was developed by Dr. John Franklin Enders, also known as the Father of Modern Vaccines, and was followed by a live attenuated vaccine which treats measles, mumps and rubella in a single shot that was developed by Dr. Maurice Hilleman of Merck & Co. The MMR vaccine is in use in Canada today along with the MMRV which adds varicella to the vaccine.

“This type of vaccine is made by taking the wild virus – the actual virus that harms people – and putting it through passages,” says Neame. “The virus is put into a medium where it grows very poorly. Most of the virus dies, but a fringe of that virus actually survives and is different from the majority of the wild virus.”

Researchers repeat this process using the fringe virus until eventually the virus is changed to a point that when it’s injected into humans, it creates an immunological response but does not create the disease.

“You’re creating a virus that’s different, so when you have a virus, the immunological response will protect you from the natural virus that causes the disease,” he explains.

By the early 1970s, a one-dose measles immunization program was in full effect and by the next decade approximately 95 to 100 per cent of the population was said to be immunized. Even with high immunization rates, outbreaks continued to occur across Canada and in 1992 a new two-dose program was recommended as part of a measles elimination strategy. But it wasn’t until 1997 that these new two-dose schedules and catch-up programs were adopted across the country – approximately two years behind the rest of the countries in North and South American.

Since there was slow uptake with the new vaccine schedule, a portion of the population is susceptible to measles and may not even know it. People born after 1970 and into the 90s who only received one vaccine have a 10 to 15 per cent chance of susceptibility. Although some of these people received the second shot during the catch-up schedule, not everyone was reached.

“Measles is very stable with regards to its generic material. Influenza alters and changes itself, but measles will generally always been the same,” says Neame. “If a child is immunized at one year of age, they’re only about 85 to 95 per cent protected and that’s why you need to get a second dose, at which point they’re almost completely protected.”

According to World Health Organization (WHO), the measles vaccine produced a 78 per cent drop in deaths between 2000 and 2012. Nevertheless measles is still one of the leading causes of vaccine-preventable deaths for kids around the globe particularly in countries with low incomes and weak health infrastructures. In 2012, the disease caused about 14 deaths per hour or approximately 122,000 total deaths.
a necessity rather than a choice, but over the last few years, Mansour says that an increasing number of pharma companies have started actively engaging in collaborative ventures.

“We’re seeing big pharma collaborate together on products that are not approved yet and doing interesting combination trials with their compounds,” he says. “That’s a huge shift in the industry. Now, both companies might win rather than both getting nothing if they work independently.”

With big pharma open to collaboration, companies like Immunovaccine are thriving. The company has a commercial licensing agreement with Zoetis (formerly Pfizer Animal Health) for a livestock vaccine and has several collaborations for infectious disease and cancer vaccines. It’s also collaborating with the Dana-Farber Cancer Institute on a cancer vaccine for cervical cancer. Simultaneously, the company is developing its own immunotherapeutic cancer vaccine called DPX-Survivac, which is designed to train the immune system’s CD8 T-cells to recognize and attack cancer cells containing survivin, a protein found in many cancers and many solid tumors, but not found in normal cells.

After a meeting with Merck KGaA at BIO Europe, Immunovaccine licensed the Survivac vaccine from the German company and quickly reformulated it with DepoVax. The drug moved into clinical trials in ovarian cancer patients and showed strong immune activation and potential for a clinical benefit in the Phase One trial. Immunovaccine is currently planning a large, randomized Phase Two clinical trial for DPX-Survivac in ovarian cancer which will be sponsored by the National Cancer Institute of Canada, and another in glioblastoma which will be funded by an Italian government grant.

Mansour says that Immunovaccine is becoming more selective about its collaborations in order to ensure their efforts translate into clinical programs. However, the company strongly believes in the power of partnership for the betterment of health care across the globe.

“We’re trying to be as efficient as we can and get the engagement from others to help us,” says Mansour. “The reality is that the industry needs to collaborate and learn how to work together. Then we can really make a difference in the lives of patients.”

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For many Canadians, media coverage of recent measles outbreaks in B.C., Alberta and Quebec might well stir up memories of the panic polio struck in the hearts of parents and children alike back in the 1950s, when it was one of the most feared diseases in industrialized countries.

Polio paralyzed thousands of children each year. In the largest medical experiment in history, American researcher Jonas Salk developed a vaccine that was tested on 1.8 million children throughout the US – generating 144 million data points, all of which was captured on punch cards. Thankfully, Salk’s vaccine proved effective and within two years of its development, annual polio cases in the US had shrunk from 35,000 in 1953, to 5,600 in 1957.

Today, punch cards are a thing of the past, but through advances such as predictive modeling, public health information exchange and cognitive computing systems that “learn,” technology continues to help governments, researchers and public health organizations around the world prepare for, predict and respond to disease outbreaks.

Measles. H1N1. Dengue fever. Malaria. The rise of global transportation, trade and climate change has made it easy for diseases such as these, once thought to be limited geographically, to now cross borders. Dengue fever, for example, has spread to over 100 countries, and malaria is responsible for over one million deaths each year.

In response epidemiologists have come to rely on disease and vaccine simulations to determine the spread of global infection. Until recently, these models were hosted on closed systems and took years to produce due to inefficient data collection and lack of computing power – too slow for effective response.

But as biology increasingly becomes an information science, the promise of better vaccine development and disease management is closer to reality, with the help of more open access to data-driven analytical methods.

Consider STEM, or the Spatiotemporal Epidemiological Modeler, which is an open source tool that can forecast and analyze the possible spread of infectious disease. It allows researchers and public health officials to simulate the spread of disease across both time and space, and test the likely impact of preventative measures.

Using data about the geography, transportation systems and population for 244 countries STEM can, for example, estimate how soon after the first case of a new influenza appears in San Francisco, California, it will peak in Mexico City, as well as data points such as the total number of potential disease outbreak cases.

STEM is free and open to any scientist or researcher who chooses to build on and contribute to its library of models, computer code or data. This openness helps create not only more advanced mathematical models, but also more flexible models involving multiple species, interactions between diseases, and a better understanding of epidemiology. This allows for the study of disease dynamics in humans and intervention strategies such as vaccine distribution.

In the case of malaria, using both the model and data from the World Health Organization, we worked with Johns Hopkins University to analyze the sensitivity of malaria to changes in temperature and precipitation. Knowing this makes it possible to predict where malaria incidence is most likely to increase or decrease, based on predicted environmental changes in a specific region.

Another tool in the battle for control over infectious disease is PHIAD, or Public Health Information Affinity Domain, which is a scalable network that uses Health Information Exchange (HIE) technology and standards to enable users at clinics and labs to share information, statistics and anecdotes electronically and analyze data collaboratively and in real time.

In 2009 and 2010, when swine flu cases in Mexico City reached pandemic proportions, Mexico’s Ministry of Health used STEM and PHIAD to develop new models of H1N1’s spread. Mexican health officials and our researchers were able to determine the “reproductive rate” of the flu – the number of secondary cases each single infected case will cause in a population with no immunity – and the likely effect of health policy decisions. For example, STEM showed the city’s decision to close restaurants and schools at the height of the outbreak cut the flu’s reproductive rate by 22 per cent.

Technology continues to aid governments, researchers and public health organizations around the world prepare for – and respond to – disease outbreaks. But to do this, pharmaceutical companies often need to screen millions of compounds to discover a handful of promising candidates. The main drawbacks of this process, known as wet lab screening, are that it is expensive, time-consuming, and produces widespread experimental errors.

One strategy to reduce or eliminate these challenges is to replace wet lab experiments with computer software that can essentially do the same thing. The problem with this approach is creating software that is accurate enough to be a reliable alternative. Today, new computer systems may hold the key to unprecedented accuracy.

Here in Canada, we’re working with a start-up called Chematria, Inc. to develop a new generation of drug discovery tools. By using the fastest supercomputer in Canada, researchers can predict the interactions between drugs and diseases. Advanced simulations such as these, promise to make the discovery of new vaccines and medicines faster, cheaper, and more efficient.

Progress has also been made in Canada with Panorama, a communicable disease surveillance and management process. It was designed to help epidemiologists and other public health professionals manage infectious disease outbreaks, and includes a tool for vaccine inventory management. It is currently implemented in three provinces.

Identifying the best therapies, and understanding how and why diseases spread means we can identify those regions most susceptible to emerging disease, inform public health, and allow them to focus on specific interventions where they can have the greatest impact.
Twenty years ago, the International Commission for the Certification of Poliomyelitis Eradication in the Americas (ICCPE) declared that the wild poliovirus was eliminated from the Americas, making it the first World Health Organization Region to meet the goal of polio elimination. On August 20, 1994, the Pan American Health Organizations reported that it had been three years since the last case of the wild poliovirus in the Americas where three-year-old Luis Fermin had the last registered case. It had been hoped that shortly after this milestone polio would be eliminated completely from the world but that has yet to happen.
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