North Korea is playing dangerous games !

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Bio News

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John McAfee the Belize spymaster uncovers 'ricin, terrorist plots'

Source:http://www.channelregister.co.uk/2013/01/07/john_mcafee_spymaster/?goback=.gde_3711808_member_201920318

Infosec daredevil John McAfee claims he became a spymaster in Belize after giving laptops infected with espionage malware to police and government officials.

McAfee, who moved to the central American low-tax haven some years ago, further claimed he supervised a ring of 23 women and six men as operatives, and tasked them with striking up relationships with targets and extracting secrets.

The eccentric millionaire hatched the scheme after a crack Belizean cop squad raided one of his properties, shot one his dogs and seized hundreds of thousands of dollars in kit. The Gang Suppression Unit was searching for a supposed meth lab and guns but found nothing. No charges were brought but the incident put the founder of antivirus biz McAfee Inc at loggerheads with the authorities.

In a quest to exact revenge after receiving no apology for the bungled bust, McAfee set himself up as a spymaster, as explained in a lengthy article on his official WhoIsMcafee.com blog:

I purchased 75 cheap laptop computers and, with trusted help, installed invisible keystroke logging software on all of them – the kind that calls home (to me) and disgorges the text files. It also, on command, turns on and off the microphone and camera – and sends these files on command.

I had the computers re-packaged as if new. I began giving these away as presents to select people – government employees, police officers, cabinet minister's assistants, girlfriends of powerful men, boyfriends of powerful women.

I hired four trusted people full time to monitor the text files and provide myself with the subsequent passwords for everyone's email, Facebook, private message boards and other passworded accounts. The keystroke monitoring continued after password collection, in order to document text input that would later be deleted. So nothing was missed…

I next collected my human resources for the complex social engineering I would have to do. I arranged with 23 women and six men to be my operatives. Eight of the women were so accomplished that they ended up living with me. It was amazingly more efficient and they were easily convinced to check up on each other. One was so accomplished that she became a double agent and nearly got me killed.

The tech tycoon claimed he infiltrated two national telcos using his operatives in order to tap the phone lines of his enemies. He further claimed various social engineering tricks were put into play.

In all, McAfee reckons he set up an extensive spook network with tentacles into every aspect of life in Belize. By his own account, the malware maverick was looking for evidence of corruption to turn the tables on those who trashed his property.

But what he apparently found were details of extramarital affairs and far more disturbing information. He alleged data uncovered showed that officials were helping Hezbollah-aligned terrorists to get Belizean passports and identification cards.

Mostly this supposed intelligence came from electronic taps on immigration department computers but McAfee claims he had some human intelligence as well:

I had located an individual working in immigration who was trustworthy and willing to talk. I discovered that an average of eleven Lebanese males were given new identities each month. One month there were sixteen.

McAfee claims he sent one of his female operatives to befriend one of these Lebanese militants, who supposedly turned out to be sexually violent and intent on using Belizean papers to gain entry to the United States:

Belize is clearly the central player in a larger network whose goal is to infiltrate the US with individuals having links to terrorist organizations. What is different today from the wholesale

Belizean passport selling of ten years ago, is that the false citizenships that are created for these men are coupled with a network of handlers designed to move the individuals, and their cargo, into the US

'I'm not an idiot... the US government is letting the ricin plot happen'

McAfee goes on to accuse members of Hezbollah of establishing a training base in Nicaragua, south of Belize. The supposed terrorists formed links with the Zetas, the infamous Mexican drug cartel, and may be using deadly ricin from plants grown at the training camp, we're told. The Zetas, according to McAfee, smuggle the poisonous protein in return for advanced weaponry from Hezbollah:

I know all of this because I reassigned resources and for the past three months have had two people in Nicaragua that have made connections with the Hezbollah camp and I have three people in Mexico who have made connections with mid-level Zeta members. I will release no information at this point that will implicate these five people. Both the Hezbollah camp members and the Zeta organization, combined, have thousands of female connections. This small post will implicate no one.

The 67-year-old biz baron also accused a high-ranking Belizean security official of masterminding human trafficking and arranging the false passports for members of Hezbollah - and threw in an unsubstantiated allegation of another senior member of the government orchestrating a murder.

The elaborate tale of corruption and criminality reads like something from a John Le Carre spy novel, but *El Reg*'s security desk suggests it's more akin to *The Tailor of Panama* than *Tinker, Tailor, Soldier, Spy*. Either McAfee has stumbled upon one of the greatest conspiracies of recent times or it is possible his network of informants and agents are spinning an ever more elaborate story perhaps to keep the money from McAfee flowing.

The blog post, titled *A Clear And Present Danger*, suggests the British-American programmer is more of a fan of Tom Clancy's Jack Ryan potboilers.

McAfee famously became the centre of Central America's most high-profile manhunt in recent history late last year. The antivirus pioneer was named by police as a "person of interest", but not a suspect, after his neighbour Gregory Faull was found dead in a pool of blood on the island of Ambergris Caye, Belize, in November.

McAfee went on the run with his 20-year-old girlfriend for three weeks before crossing the border to Guatemala. He was detained by the authorities soon after entry after his location was revealed by coordinates embedded in the metadata of a photograph published online by a *Vice* magazine journalist. McAfee claimed he faked a heart attack in order to buy enough time to appeal against his deportation back to Belize, and subsequently jetted off to Miami, US.

His antics on the run included developing various desperate disguises - such as blacking up with boot polish and sticking a tampon up his nose to pretend to a Guatemalan trinket salesman - and sending a look-alike over the Mexican border with a North Korean passport as a diversionary tactic while he slipped into Guatemala.

What happens when two almighty conspiracy theorists meet on air?

McAfee appeared on relentless conspiracy theorist Alex Jones' *Infowars* show at the weekend to talk about what Jones described as the "latest chapter in bizarre-o-world". McAfee denied fabricating the Belize-Hezbollah yarn as a means to thwart possible attempts by Belize to obtain his extradition. He also denied the allegations were an elaborate prank*.

"This is not a joke," he said. "My practical jokes do not lean towards the dangerous."

The interview, which lasts about 35 minutes from the 48 minute mark, also features the most detailed account to date of McAfee's flight from Belize. Apparently he waited for rain so that the army's troops would be sitting in their cars rather than manning checkpoints on the route down from the Guatemalan border. The whole party stayed in a hotel overnight, in disguise, before making their way across the river to the border town of Livingstone in Guatemala.

McAfee said he planned to move to the American mid-West, a place where people work hard and "everyone is armed" and capable of defending themselves - and a place where "anyone from Hezbollah, for example, would stick out like a sore thumb".

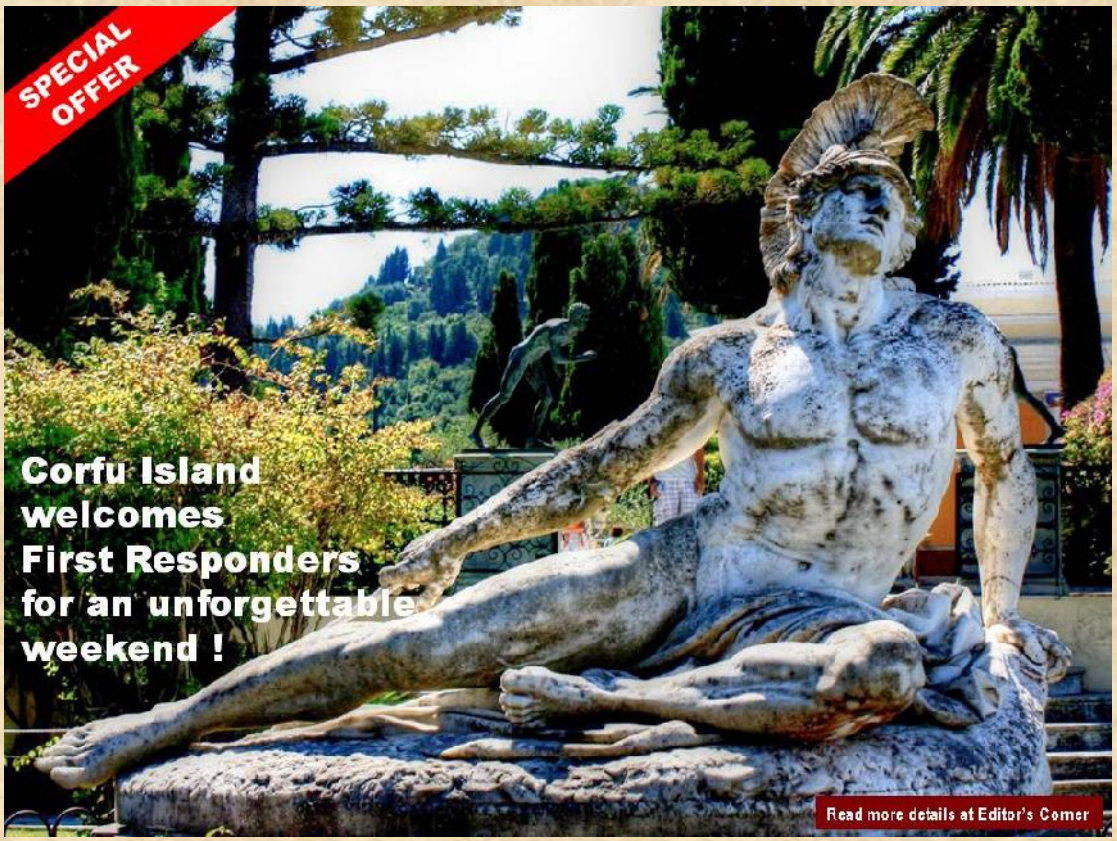
He added that he'd be "an idiot" to not consider the possibility that hit men would come after him.

"I've released routes and organisational links and names within the Belizean government that are protecting these people and handling these people. Of course I'd have to be concerned," McAfee said. He alleged that "US government is letting the [ricin plot] happen" either "purposefully" or in furtherance of "wider goals".

Jones, a talk-show host who said the 11 September 2001 attacks were an inside job, concluded that McAfee is either telling the truth, "is partially telling the truth and has become paranoid" or is "one of the best liars and storytellers".

Bootnote

* McAfee earlier claimed that his extensive postings on an underground internet forum about the powerful effects of MDPV - a psychoactive drug better known as bath salts and touted as a stimulant with sexual arousal effects whose side-effects include paranoia and psychotic delusions – were just an elaborate joke.



The hospital from where you don't return

Source:http://www.presseurop.eu/en/content/article/3223801-hospital-where-you-don-t-return?xtor=RSS-9

In the mountains of Bohemia, near the Polish border, lies a small hospital – the only one of its kind in Europe: The Biological Defence Centre in Těchonín is designed to treat the poor unfortunates who contract the world's most dangerous viruses or fall victim to a biological terrorist attack.

There once was a young Czech solder – let's call him Jiří – who spent a year in the Congo on a tour of duty. In the town where he was serving, there was an outbreak of Ebola. The likelihood that he would contract this almost invariably deadly disease, which causes a person to bleed to death from inside, was very high.

So when he got a nosebleed one day he was certainly scared. However, he knew that he must not endanger his family or anyone else. When he returned to the Czech Republic, the army's medical unit immediately sent him into quarantine at the Biological Defence Centre in Těchonín.

A researcher in a Nuclear, Biological and Chemical (NBC) protection suit collects samples for a biological laboratory probe in Těchonín

This is a hospital from where really sick patients almost never return. It's a military hospital, hidden away in the Orlické Mountains. It is the only facility of its kind in Europe. And it's the only hospital in the Czech Republic whose priority is less treating patients as much as protecting the population who live beyond the barbed wire.

As the number of BIOHAZARD! warning signs reveal, it's a hospital for isolating patients with highly contagious diseases and also serves as a kind of back-up hospital in the event of terrorist attacks using biological weapons such as anthrax or SARS.

Empty beds

There is something else exceptional about it: it has almost no patients. Jiří was its only patient, not counting soldiers returning from foreign missions who always have to spend 24 hours in quarantine here. Every year there are around 1,000 of them.

Why do almost all the civilians returning from areas where dengue fever is raging or Ebola not head here? Because no one in the Czech Republic has looked into this kind of protection for civilian employees. Neither does our own army know what to do with this exceptional hospital.

Jiří was lucky. Despite fears he had contracted Ebola, a two-week quarantine showed that there was no infection and he was allowed to go home. Jiří is one of the few people who know what it's like inside a state-of-the-art facility.

Almost everything here is made of stainless steel, and patients are examined by doctors wearing suits with their own air supply. Doors open with soft clicks, as all the rooms are at less than atmospheric pressure.

Even though patients are close by, behind triple-glazed glass, it takes a few minutes for any of the doctors to reach them. There are no doors directly connecting doctor with patient. That's intentional.

Security buffers

Even if the patient is choking, the staff must first change into the spacesuits and pass through the security zone. It takes about three minutes to reach a patient. Ward rounds are done here using microphones inside the spacesuits – what the doctor says is entered into a computer by his colleague standing on the other side of the triple-glazed windows. Almost all the devices are disposable, including the expensive monitors. To disinfect them after

contact with a patient that really did have Ebola would be unrealistic.

Anyone who arrives here as a patient lives in a kind of aquarium with its own air and water and a closed waste-handling system. Unlike other hospitals, this one is unlikely to operate on patients, even if it does have an operating hall. Provisions for autopsies, though, have certainly been made. The post-mortem room with its laboratory is right next to the patients' ward.

The spread of deadly infectious diseases is often swift and it's important to identify the type of contagion as soon as possible in order to protect others.

The hospital has its own petrol station, heliport, a mobile hospital for infectious diseases with its own laboratory, and sewage treatment including a fishpond into which the cleaned water is drained and where fish sensitive to contamination are monitored to ensure the water truly is safe.

One of the hospital's rooms is full of mice. Here, in collaboration with a team formed under the late Professor Antonín Holý, research is carried out on some viruses, such as the E. coli virus that sparked a diarrhoea epidemic across Europe last summer that left dozens of people dead.

Research is a tradition here, after all: it was in Těchonín that a unique bank of viruses was kept until 1992, and was later destroyed by order of the Minister of Defence. Today microbiologists have to buy these expensive microbes, such as the diarrhoeal E. coli, from abroad.

The Centre for Biological Control has three tasks: the first is isolation and quarantine, for just such cases like Jiří. The second is research, and the third is educational.

Crisis training

The hospital functions as a training site where doctors and lab workers carry out tests under biological hazard conditions. They learn what to watch out for and how, for example, to transport patients in body isolation units without endangering themselves or their surroundings.

"We work with the civilian system. Doctors from infectious disease clinics, emergency medicine specialists, and even medical students come here," says Petr Navrátil, the Czech Army's chief public health officer. And of course, soldiers themselves train here in what to do in the event of a biological threat to the population. It's called disaster medicine.

The danger of bioterrorism remains: biological weapons are cheap to develop, and they are effective. However, the future of the Centre for Biological Protection in Těchonín is unclear, and everything points to its closure. "The decision has not been made, but in view of the cuts to the Defence Ministry budget, how to keep it running is a very difficult question," says Defence Ministry spokesman Jan Pejšek. At a time when the Army is looking intently at every crown spent, to make sure there is enough for uniforms and petrol, it is hard to justify pouring money into the Centre.

In short, we have a unique facility, which cost an awful lot of money, but which can essentially only be used when some nightmarish infectious disease breaks out. Closing it would mean that we have thrown away 2bn crowns (€80m). If we keep it, it will cost a minimum of 100m crowns (4m) a year just to keep the hospital running.

Preserving the whole facility is impossible; which ultimately means it is doomed, as aging equipment will not be replaced – and certainly not in the middle of an emergency, just when we need it. What about selling it? There's no buyer. The army has approached the ministries of Foreign Affairs, Health and the Interior, and has highlighted the importance of Těchonín for the security system of the state to the State Office for Nuclear Safety and the Academy of Sciences and all the other institutions – but none want to contribute to the cost of running it. The search has also spread beyond the Czech Republic's borders.

"Negotiations have been held with the World Health Organisation, the EU Council, the European Commission, the European External Action Service, and bilateral talks have been held with several countries within NATO (e.g. the UK) and even outside it (Serbia). No agreement has been reached, though," shrugs the spokesman.

Revenue, or security?

Těchonín, though, might earn its own way, if just the upper echelons of the Czech Army would try harder. The courses that are held there, for example, could invite in paying participants from abroad – both NATO troops and civilian medical professionals. The local labs could be used commercially or could carry out research that pays for itself thanks to grants and patents.

And, finally, the centre could offer its locations, when they are not being heavily used, to filmmakers. The box-office hit *Outbreak*, with Dustin Hoffman, was filmed in a similar American bio-centre. Still, all the same, must the Centre really pay its own way?

Such a property always plays an important role in the strategic protection of the nation's population. The Army has distanced itself from the decision over what to do with Těchonín. The fate of the complex is to be decided by the National Security Council. Perhaps in February.

Biological Defence Centre at Techonin

The Centre at Techonin is a specialised medical institution of the Czech military ensuring complete biological defence primarily in favour of the Armed Forces of the Czech Republic´s personnel. It is one of two branches of the Central Military Health Institute based in Prague.

Primary mission:

- Isolation of bacilli carriers of dangerous deseases and prevention of spreading of contagious deisease to the rest of population;
- Identification of the kind of contamination, determination of diagnosis, suggestion and taking necessary measures - especially in issues of prevention;
- Treatment of affected persons;
- Biological defence research.

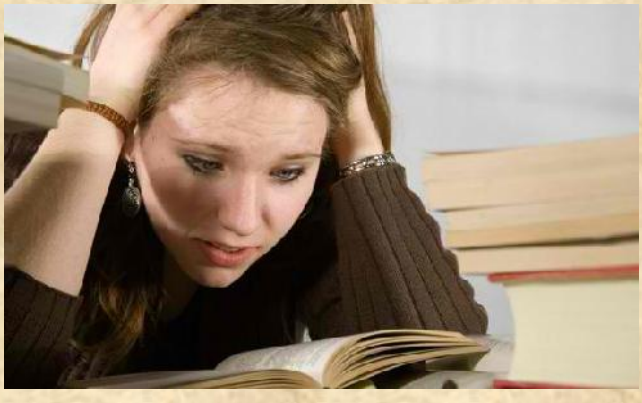
The Centre includes the Specialised Infection Hospital for persons affected with dangerous or exotic infections under biosafety level 3 & 4 conditions equipped with laboratories for diagnostics of selected biological agents. It offers isolation-quarantine capabilities for examination of troops following their foreign mission is over.
The Centre serves as a training and education facility both for military and civilian specialists from the Czech Republic and within NATO (Centre of Excellence).
The Centre is part of the Integrated Rescue System of the Czech Republic, and at the same time, it is involved in the NATO biological defence system.

Pandemics Porn

Delicious, smart reads about dangerous, nasty germs.

By David Dobbs

Source:http://www.slate.com/articles/health_and_science/pandemics/2012/12/pandemics_books_authors_and_tweets_the_best_stories_about_the_worst_diseases.single.html



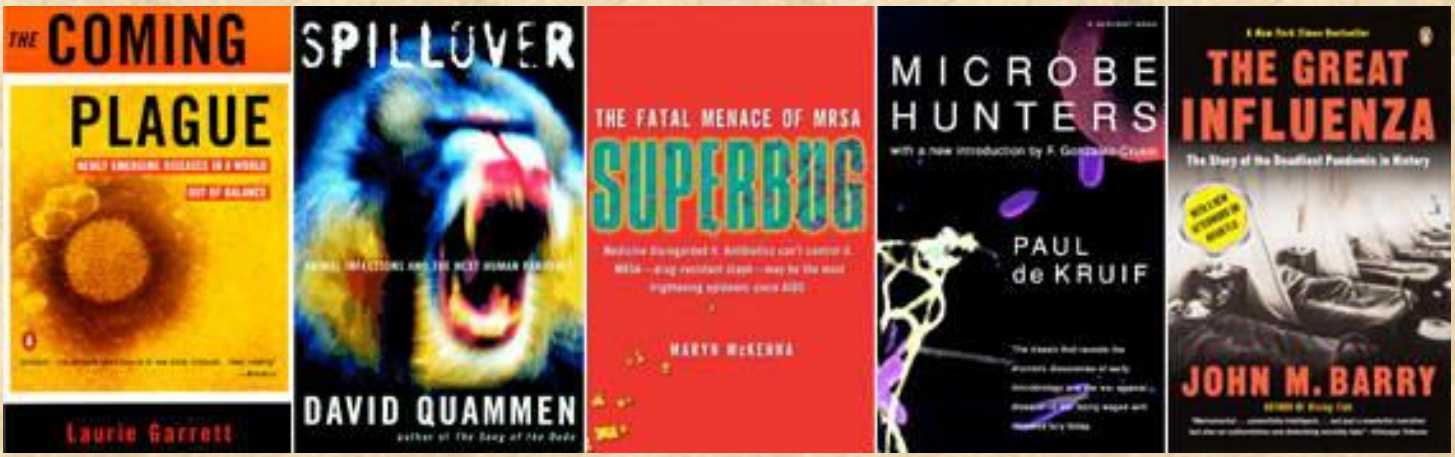
Germs are terrifying

The germs have been busy. In the United States this year alone, we've lost people both to old enemies such as whooping cough and to relatively new spillovers from other animals, such as hantavirus and West Nile virus, which killed more than 240 Americans this year, a record. Diseases we've come to think of as utterly foreign, such as dengue fever, are spreading through the United States. Meanwhile, further afield but far too near, we've seen two separate Ebola outbreaks; one of Marburg; alarming blips of Q fever; an unsettling and unsettled game of whack-a-mole in the Mideast with a new SARS-like coronavirus; and the news that because gonorrhea has now developed resistance to yet another antibiotic, we possess just *one* that still gives pause to this old

intimate. If that drug stops working before we develop a better one, expect a steady drip of ugly cases.
More bad-bug news pops up almost weekly, and it stands to get worse for a while, maybe for decades. More bacterial strains will develop antibiotic resistance, and our continuing disruption of virus-rich and fungus-rich ecosystems worldwide will invite yet more pathogens to make us part of their life cycles. We will live increasingly in a world where you might die because a bat happened to sleep in a certain tree in Tanzania or a particular robin landed in your backyard.
Pandemic diseases hold an irresistible allure for both writers and readers, as they involve threats both universal and personal, deep scientific mysteries from cellular to ecosystem levels, and urgent scientific sleuthing with high stakes. If the subject sometimes lends itself to oversimplified and sensationalistic journalism, it has also inspired a bounty of writing that is riveting while being thoughtful, nuanced, and deeply informed. And this work comes in every form and length, from 140-character tweets to 600-page global tours.
Here I offer a guide to the best of this work. I've drawn from my own reading and from the suggestions of top infectious-disease writers (more on them shortly). We'll start long, with books, and end, as we should, with tweeted expirations of germ-inflected wisdom.

Best Books

We face an embarrassment of riches here, and if it's hard to know where to start, it's easy to name a fivesome that will immerse you in the drama of pandemics both past and future while giving a fine



understanding of the science.
Leading the way almost 20 years ago, and still absolutely trenchant today, is Laurie Garrett's *The* Coming Plague: Newly Emerging Diseases in a World Out of Balance, which vividly and judiciously reports the global forces creating a new infectious age. It remains essential reading, with astounding prescience.
Warm from the presses, meanwhile, comes David Quammen's Spillover: Animal Infections and the Next Human Pandemic—one of the year's best books of any kind. This rich, engrossing work entrances as much with its darting literary elegance and deep humanity as with its exquisitely measured, layered reveal of the global strands binding us to a world of beauty and death.
Equally riveting is Maryn McKenna's way-too-close-to-home SuperBug: The Fatal Menace of MRSA. This bacterium (methicillin-resistant Staphylococcus aureus) is everywhere these days, including, perhaps, on your keyboard and almost certainly on your nose. As McKenna makes vivid, its spread and its increasing resistance to antibiotics can turn a routine cut or hospital visit into a deadly saga.
Finally, there are the classics Microbe Hunters, Paul de Kruif's 1934 account of how the bug-hunters got started, and John Barry's The Great Influenza: The Story of the Deadliest Pandemic in History, which makes scary reading anytime near flu season.

Longreads

"The First Alert," from Maryn McKenna's *SuperBug*, tells of a 13-year-old boy's battle with MRSA. "Where Will the Next Pandemic Come From? And How Can We Stop It?," in *Popular Science*, opens the puzzle box that David Quammen explores at more length in *Spillover*. In

"The Hunt for the Origin of AIDS," in the *Atlantic*, Jon Cohen sifts through AIDS-origin theories both well-founded and weird.
"The Flu Hunters," a classic piece by Gretchen Reynolds in the *New York Times Magazine*, follows the hunt, far from over, to figure out how to prevent future flu pandemics on the scale of the one that killed 20 million to 50 million people in 1918. "Undead: The Rabies Virus Remains a Medical Mystery," in *Wired*, an excerpt from the new book by Monica Murphy and Bill Wasik, *Rabid*, shows how bizarre this old affliction is; some of the comments are as unsettling as the story. Bruce Barcott's "Death at Yosemite," in *Outside*, shows how zoonotic diseases such as the much more obscure hantavirus can pop up, suddenly and fatally, even in the most sublime settings.
Finally, "The Rise of Drug-Resistant Gonorrhea," by Jerome Groopman at *The New Yorker*, has some unsettling news about the human pharynx. And his colleague Michael Specter, in "A Deadly Misdiagnosis," shows how misguided attempts to fight tuberculosis—possibly the disease that most threatens us—may actually strengthen its hand. Don't read this while you have a cough.

Breaking News and Analysis

Health and science sections of the *New York Times,* National Public Radio, and Reuters, as well as *Science* and *Nature*'s news departments, all cover infectious disease pretty well. If you read those, you'll catch most of the big news, though it requires sieving out from other stories. (The *Guardian*'s infectious-disease news tag does the sieving for you.)
To build your own filters, you can perform specific author/subject-tag searches at those and other publications, then bookmark the self-updating results. I've included such searches in the following links for the *New York Times*' Denise Grady; *Nature*'s Declan Butler and Brendan Maher; NBC's Maggie Fox; *Science*'s Jon Cohen and Martin Enserink; and the *Canadian Press*' Helen Branswell. All of these journalists do top-flight work. Branswell's reporting, alas, goes criminally overlooked in the United States (except by other health journalists). She focuses with particular intensity on swine, bird, and seasonal flu, navigating their changes, overlaps, and frightening uncertainties with particular grace and foresight; she is my go-to for flu.
Those folks will get you the main goods. Meanwhile, as with many deep but narrow topics in today's media environment, the infectious-disease beat benefits greatly from a handful of blogs, including some written by journalists, that track back stories, side stories, and follow-ups with a detail and steadiness that mainstream media doesn't allow. Two favorite blogs among bad-bug journalists are Humanosphere Health blog, kept by Tom Paulson, and the *Guardian* Health Blog, written by health editor Sarah Boseley.
Finally, freelance journalist and blogger Maryn McKenna is unmatched in reporting and contextualizing infectious-disease news with stories that'll scare the antibodies out of you. (She also possesses a disturbingly cool radio voice.) The easiest way to follow McKenna is at her blog, Superbug. (Disclosure: She and I both blog for *Wired*.) She repeatedly sees the *big* in the big stories, from new coronaviruses to the CIA's lethally destructive fake-polio-vaccine boondoggle in Pakistan, before almost anyone else does. For a sample, see her ***Slate*** piece on dengue fever.

Global Disease in 140

Finally, if you've dumped your RSS reader and newspaper home pages for Twitter, you're in luck, for many of the writers named above use Twitter to link to, curate, and discuss both their own and others' breaking coverage. Particularly sharp are Helen Branswell, Maryn McKenna, Laurie Garrett, Maggie Fox, David Quammen, Declan Butler, Brendan Maher, Jon Cohen, and Martin Enserink; and last but not least, Michael Coston, who blogs at Avian Flu Diary and tweets, indefatigably, as Fla_Medic.

David Dobbs writes frequently on science, psychiatry, sports, and other exotic cultures, and has tracked the DSM saga at his blog. He is working on The Orchid and the Dandelion, a book about how genes and culture shape us, and we them.

CBW Magazine
Journal on Chemical and Biological Weapons
Winter / July-December 2012
ISSN: 0974-0619

"Biological Warfare": Col (Retd) B.K. Sinha, Surendra Publications, Delhi, 2010.

Mr. Parveen Bharadwaj

The author is a Research Intern at the IDSA, New Delhi.

Summary

The book attempts to stress emphasis on establishing effective public health infrastructure. It also argues with respect to having more public debates and awareness on these issues to influence state policies. However the book also beautifully highlights the major hurdles in the implementation of Biological Weapons Convention (BWC) and it also expressed the concern that imminent advancements in biotechnology will further complicate biological warfare in the future.

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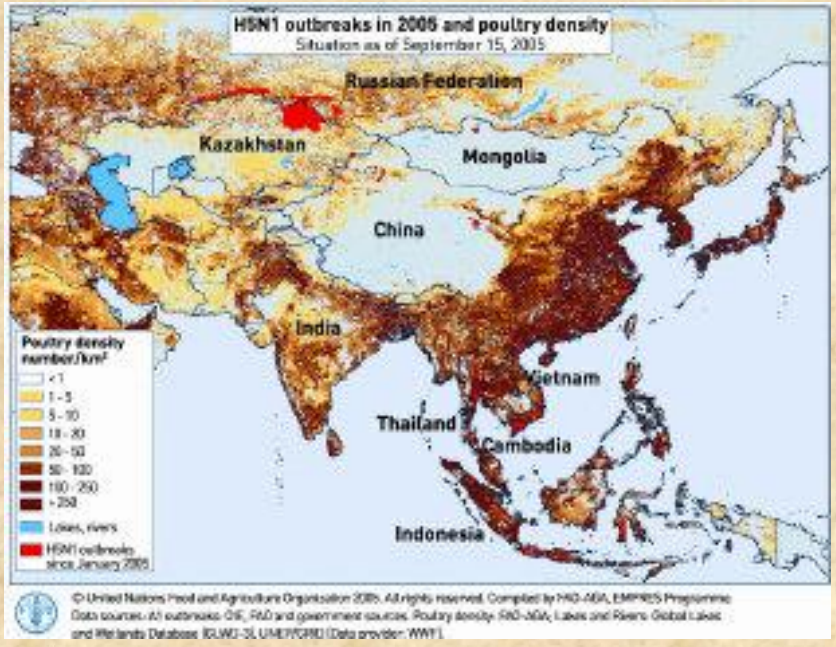
New bird flu strain may be bioterrorism

Source: http://www.thejakartapost.com/news/2013/01/10/new-bird-flu-strain-may-be-bioterrorism-says-bin.html

Indonesia's top intelligence agency has scrutinized the spread of a new strain of the avian flu virus that has killed thousands of ducks over the past few months, saying the disease **could be a form of biological weapon used by foreign countries**.



"My agency has been following this phenomenon since the beginning. We have to stay alert as the global development of biological weapons has been very fast. In the future, this kind of biological attack will be used in wars," National Intelligence Agency (BIN) chief Lt. Gen. Marciano Norman said at the State Palace on Thursday.

However, an intelligence investigation had yet to find any proof that the current bird flu outbreak in some places across Indonesia was a form of biological attack or a test of biological weapons by foreign countries, he added.

"We are closely monitoring developments. We cannot jump to conclusions without strong proof," he added. "We are asking relevant bodies with relevant competence to dig deeper into the new virus while we will back them up."

Coordinating Political, Legal, and Security Affairs Minister Djoko Suyanto echoed Marciano's statement. "Since the allegation came to us, we have formed a team to delve into it. The team comprises of BIN and the Health Ministry, among others," he said.

Djoko agreed that it was possible that the virus might have been "engineered" for certain interests. "The allegations represent good input for us to stay vigilant to the possibility," he said.

The government has asked regions across the country to begin taking measures to anticipate the new bird flu virus, identified as H5N1 clade 2.3.2.

In Bantul, Yogyakarta, the new virus strain has killed more than 1,000 ducks. The same strain also reportedly killed hundreds of ducks in Central Java and in East Java.

The Central Java provincial administration has recorded nearly 200,000 cases of duck deaths in 28 regencies and cities since September 2012.

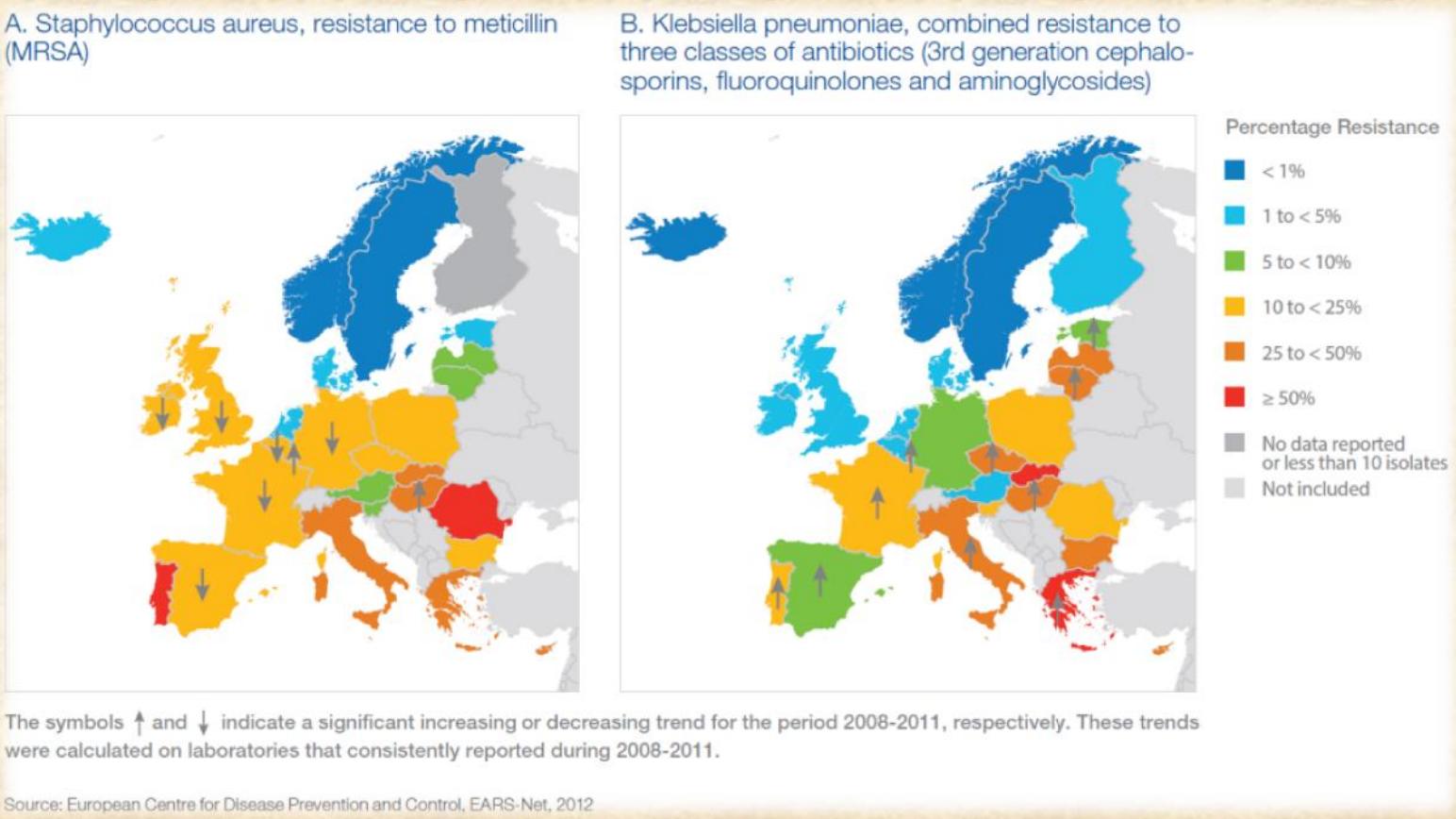
Over 6,000 ducks were reported to have been infected with the virus in the regencies of South, Central and East Lampung.

In Payakumbuh, West Sumatra, known as the province's main production center of poultry products,

the virus killed nearly 2,000 ducks in December 2012, while in Sidenreng Rappang, South Sulawesi, some 25,500 birds have reportedly died since December 2012.

Bloodstream Infections Showing Multi-Drug Resistance

Source: http://www3.weforum.org/docs/WEF_GlobalRisks_Report_2013.pdf



Rapid DNA: Coming Soon to a Police Department or Immigration Office Near You

Source: https://www.eff.org/deeplinks/2012/12/rapid-dna-analysis

In the amount of time it takes to get lunch, the government can now collect your DNA and extract a profile that identifies you and your family members.

Rapid DNA Analyzers—machines with the ability to process DNA in 90 minutes or less—are an operational reality and are being marketed to the federal government and state and local law enforcement agencies around the country. These machines, each about the size of a laser printer, are designed to be used in the field by non-scientists, and—if you believe the hype from manufacturers like IntegenX and NetBio—will soon "revolutionize the use of DNA by making it a routine identification and investigational tool."

From documents we received recently from US Citizenship and Immigration Services (USCIS) and DHS's Science & Technology division, we've learned that the two agencies are working with outside venders NetBio, Lockheed Martin and IntegenX (i.e. RapidHIT 200 – picture below) and have "earmarked substantial funds" to develop a Rapid DNA analyzer that can verify familial relationships for refugee and asylum applications.

In the refugee context—where people are often stranded in camps far from their homes with little access to the documentation needed to prove they should be granted asylum in the US—DNA identification could be useful for both the federal government and the asylum seeker. However, DNA samples contain such sensitive, private and personal information that their indefinite storage and unlimited sharing create privacy risks far worse than other types of data. The United Nations High Commissioner for Refugees (UNHCR) stated in a 2008 Note titled *DNA Testing to Establish Family Relationships in the Refugee Context* that DNA testing "can have serious implications for the right to privacy and family unity" and should be used only as a "last resort." The UNHCR also stated that, if DNA is collected, it "should not be used for any other purpose (for instance medical tests or criminal investigations) than the verification of family relationships" and that DNA associated with the test "should normally be destroyed once a decision has been made."

It seems USCIS is not heeding the UNHCR's recommendations; the documents show that USCIS wants to use Rapid DNA analysis for much broader purposes than just verifying refugee applications. The agency notes that DNA should be collected from all immigration applicants—possibly even infants—and then stored in the FBI's criminal DNA database. The agency also supports sharing immigrant DNA with "local, state, tribal, international, and other federal partners" including the Department of Defense and Interpol on the off-chance the refugee or asylum seeker could be a criminal or terrorist or could commit a crime or act of terrorism in the future. This flow chart shows USCIS's ideal DNA collection and sharing process.

USCIS is not alone in wanting to get the most out of DNA collection. Another document we received shows that the intelligence community and the military are interested in DNA analysis to reveal ethnicity, health status, age, and other factors. And while Rapid DNA analyzers are not currently set up to extract enough data to reveal this information, IntegenX representatives at the Biometrics Consortium Conference this past September said that setting up the machines to extract additional loci would not be difficult.

Some federal agencies interested in Rapid DNA may not be able to implement it widescale for some time. Currently USCIS "does not have the authority to require DNA testing, even when fraud is highly suspected." For that to happen, the agency would have to update 8 C.F.R. 204.2(d)(vi),1 which it has discussed doing but hasn't yet done. And although the FBI is also very interested in Rapid DNA analyzers, legal rules prevent the Bureau from using the machines to process any DNA that wil go into its CODIS (Combined DNA Index System) database.

This hasn't stopped Rapid DNA manufacturers from aggressively marketing their products to state and

local law enforcement agencies across the country. IntegenX and Lockhead Martin are both pushing local governments (pdf p.3) to create their own local DNA databases instead of relying on CODIS. This has pluses and minuses—it means some chunk of the DNA collected by state or local cops may not end up in the FBI's massive DNA database and become subject to repeated nationwide searching. However, it also means that cops may not follow the stringent DNA handling procedures currently required by the FBI2 and that, without oversight, collection procedures could become based on little or no real suspicion of criminal activity.

Whether the technology itself is accurate and appropriate to use for immigration populations may also be an issue. According to the documents, scientists at the National Institute of Standards and Technology are uncertain whether the "Likelihood Ratios"3 currently used by accredited labs would be applicable "to an immigration population, since the largest reference groups, whose characteristics feed into the calculations of the ratios, are American Caucasians and Hispanics." DHS's own Science & Technology Division noted at a January 4, 2011 Working Group meeting that it was concerned "that prototype equipment may not provide totally reliable results." Science & Technology staff stated they could not "yet predict how accurate the non-match findings will be, since the error rate for the machines remains unknown." This means that people could be excluded from refugee programs just because the machine determined—inaccurately—that their DNA did not match their family member's DNA.

DHS and USCIS acknowledge that "DNA collection may create controversy." One USCIS employee advocated for "DHS, with the help of expert public relation professionals," to "launch a social conditioning campaign" to "dispel the myths and promote the benefits of DNA technology." Another document feared that "If DHS fails to provide an adequate response to [inquiries about its Rapid DNA Test Program] quickly, civil rights/civil liberties organizations may attempt to shut down the test program."

However, the real issues with expanded DNA collection—and the issues these documents don't answer—are whether DNA collection is really necessary to solve the challenges inherent in proving refugee entitlement to benefits; what standards and laws will govern expanded federal, state and local DNA collection and subsequent searches; how DNA will be collected, stored and secured; who will have access to it after it's collected; and what processes are in place to destroy the DNA sample and delete data from whatever database it's stored in after it's served the limited purpose for which it was originally collected. Without answers to these questions, no amount of "social conditioning" can convince those concerned about privacy and civil liberties that expanded DNA collection is a good idea.

New way to design vaccines: modifying antibodies to trigger immune response

Source:http://www.homelandsecuritynewswire.com/dr20130108-new-way-to-design-vaccines-modifying-antibodies-to-trigger-immune-response

In an approach with the potential to aid therapeutic vaccine development, Whitehead Institute scientists have shown that enzymatically modified antibodies can be used to generate highly targeted, potent responses from cells of the immune system.

The approach, referred to as "sortagging," relies on the bacterial enzyme sortase A to modify antibodies to carry various payloads, such as peptides, lipids, fluorophores, and proteins. In this case, the scientists, whose findings are reported online this week in the *Proceedings of the National Academy of Sciences*, attached a variety of small antigens to an antibody directed at the surface of key immune cells. A Whitehead Institute release reports that through sortagging, the scientists were quickly able to prepare various antibody-antigen fusions and to deliver the antigens to their intended targets and track them as the immune cells mounted their intricate responses.

"Sortagging is remarkably specific and efficient," says Lee Kim Swee, first author of the PNAS paper and a postdoctoral researcher in the lab of

Whitehead member Hidde Ploegh. "We were able to create 50 different constructs (antibody-protein attachments), which wouldn't have been feasible if we had relied on the more traditional approach of genetic fusion."

Swee and colleagues tested the approach in a mouse model of herpes virus, sortagging nineteen known viral epitopes to a cell-specific antibody. They created a vaccine cocktail and immunized a group of mice. Upon subsequent re-exposure to the virus, vaccinated mice showed a 10-fold reduction in the amount of circulating virus.

"This is proof of principle that one could in fact use sortagging on antibodies to easily attach a tailored set of antigens, toward which the immune system can be educated," Swee says. "This technique also helps us understand how to design better antibody-based vaccines."

For paper co-author Carla Guimaraes, sortagging's value is bolstered by its flexibility. She likens it to "playing with Legos," because it allows "you to mix and match" proteins of diverse shapes, sizes, and functions. The process can be used, for example, to attach the relatively large green fluorescent protein (GFP) to antibodies without hindering GFP's desirable fluorescing activity or the binding of the conveying antibody to its intended target.

"Imagination is really your only limitation," says Guimaraes, who is also a postdoctoral researcher in the Ploegh lab.

"You could for example, use sortase to attach a toxin to an antibody and use that antibody to deliver the toxin to specific cells." Such an approach, she notes, would be an appealing strategy for developing better-tolerated cancer therapies.

— Read more in Lee Kim Swee et al., "Sortase-mediated modification of αDEC205 affords optimization of antigen presentation and immunization against a set of viral epitopes," Proceedings of the National Academy of Sciences (7 January 2013)

Abstract

A monoclonal antibody against the C-type lectin DEC205 (αDEC205) is an effective vehicle for delivery of antigens to dendritic cells through creation of covalent αDEC205–antigen adducts. These adducts can induce antigen-specific T-cell immune responses or tolerance. We exploit the transpeptidase activity of sortase to install modified peptides and protein-sized antigens onto the heavy chain of αDEC205, including linkers that contain non-natural amino acids. We demonstrate stoichiometric site-specific labeling on a scale not easily achievable by genetic fusions (49 distinct fusions in this report). We conjugated a biotinylated version of a class I MHC-restricted epitope to unlabeled αDEC205 and monitored epitope generation upon binding of the adduct to dendritic cells. Our results show transfer of αDEC205 heavy chain to the cytoplasm, followed by proteasomal degradation. Introduction of a labile dipeptide linker at the N terminus of a T-cell epitope improves proteasome-dependent class I MHC-restricted peptide cross-presentation when delivered by αDEC205 in vitro and in vivo. We also conjugated αDEC205 with a linker-optimized peptide library of known CD8 T-cell epitopes from the mouse γ-herpes virus 68. Animals immunized with such conjugates displayed a 10-fold reduction in viral load.

Hydrogen peroxide vapor kill superbugs dead

Source: http://www.homelandsecuritynewswire.com/dr20130102-hydrogen-peroxide-vapor-kill-superbugs-dead

Infection control experts at the Johns Hopkins Hospital have found that a combination of robot-like devices that disperse a bleaching agent into the air and then detoxify the disinfecting chemical are highly effective at killing and preventing the spread of multiple-drug-resistant bacteria, or so-called hospital superbugs.

A study report on the use of hydrogen peroxide vaporizers — first deployed in several Singapore hospitals during the 2002 outbreak of severe acute respiratory syndrome, or SARS, and later stocked by several U.S. government agencies in case of an anthrax attack — was published 1 January in the journal *Clinical Infectious Diseases*.

A Johns Hopkins University release reports that in the study, the Johns Hopkins team placed the devices in single hospital rooms after routine

cleaning to disperse a thin film of the bleaching hydrogen peroxide across all exposed hospital equipment surfaces, as well as on room floors and walls. Results showed that the enhanced cleaning reduced by 64 percent the number of patients who later became contaminated with any of the most common drug-resistant organisms. Moreover, researchers found that protection from infection was conferred on patients regardless of whether the previous room occupant was infected with drug-resistant bacteria or not.

"Hydrogen peroxide vapor, as spread around patients' rooms by these devices, represents a major technological advance in preventing the spread of dangerous bacteria inside hospitals and, especially, from one patient occupant to the next, even though sick patients were never in the same room at the same time," says infectious disease specialist and study senior investigator Trish Perl, M.D., M.Sc.

Of special note, researchers say, was that enhanced cleaning with the vapor reduced by 80 percent a patient's chances of becoming colonized by a particularly aggressive and hard-to-treat bacterium, vancomycin-resistant enterococci (VRE).

In what is believed to be the first head-to-head comparison between traditional hand-cleaning and mopping with bleaching agents and robotic vaporizers, researchers routinely tested patients and their surroundings not only for VRE, but also for the more common methicillin-resistant Staphylococcus aureus, or MRSA, and lesser-known bacteria, including Clostridium difficile and Acinetobacter baumannii.

The release notes that some 6,350 patient admissions to JHH were closely tracked as part of the two-and-a-half-year analysis, as patients moved into and out of 180 private hospital rooms. Almost half the rooms received enhanced cleaning with hydrogen peroxide vapor in between patients, while the rest did not. Overall, multiple-drug-resistant organisms were found on room surfaces in 21 percent of rooms tested, but mostly in rooms that did not undergo enhanced cleaning.

Perl says that patients bringing in or picking up drug-resistant organisms while undergoing treatment in hospitals is a persistent and growing problem, and previous research has shown that patients who stay in a hospital room previously occupied by an infected patient are at greater risk of becoming infected.

"Our study results are evidence that technological solutions, when combined with standard cleaning, can effectively and systematically decontaminate patients' rooms and augment other behavioral practices, such as strict hospital staff compliance with hand-washing and bathing patients in disinfecting chlorhexidine when they are first admitted to the hospital," says Perl, senior hospital epidemiologist for the Johns Hopkins Health System and a professor at the Johns Hopkins University School of Medicine.

"Our goal is to improve all hospital infection control practices, including cleaning and disinfection, as well as behavioral and environmental practices, to the point where preventing the spread of these multiple-drug-resistant organisms also minimizes the chances of patients becoming infected and improves their chances of recovery," says Perl.

The paired robot-like devices, each about the size of a washing machine and weighing nearly 60 pounds, as well as supplies used in the study, were provided by their manufacturer, Bioquell Inc. of Horsham, Pennsylvania.

After the room has been cleaned, the vents are covered and the two devices are placed inside. The sliding door is closed, and the room is sealed. Then, the larger of the two devices disperses hydrogen peroxide into the room, leaving a very tiny, almost invisible layer (only 2 microns to 6 microns in thickness) on all exposed surfaces, including keyboards and monitors, as well as tables and chairs.

Because hydrogen peroxide can be toxic to humans if ingested or corrosive if left on the skin for too long, the second, smaller device is activated to break down the bleach into its component water and oxygen parts. The combined operation takes the devices about an hour and a half to complete.

"What is so exciting about this new method of infection control is that the devices are easy to use and hospital staff embrace it very quickly," says surgeon and study co-investigator Pamela Lipsett, M.D., M.H.P.E. Lipsett, a professor and director of surgical and critical care fellowship training at Johns Hopkins, says that during the study and before room cleanings, staff were "wheeling in" other pieces of equipment so these, too, could be decontaminated by the hydrogen peroxide vapor.

As a result of the study and the researchers' recommendation, JHH has purchased two of the Bioquell

decontaminating units, which cost more than $40,000 per pair. The devices, already in use at some twenty other hospitals across the country, will be used at Johns Hopkins to decontaminate rooms typically housing high-risk patients under strict isolation precautions because of severe infection with a multiple-drug-resistant organism.
Researchers say they next plan to study the devices' effectiveness at decontaminating the outside packaging of unused but potentially exposed hospital supplies, which are typically discarded even though their seals remain intact. The research team also wants to coordinate study testing among other hospitals to validate their Johns Hopkins findings. Larger and longer studies may also be planned, to precisely measure and determine how well the devices work against the spread of each hospital superbug. The current study had only sufficient numbers to statistically validate the paired unit's effectiveness against VRE.

Noma

Cancrum oris; Gangrenous stomatitis
Source: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002318/

Noma is a type of gangrene that destroys mucous membranes of the mouth and other tissues. It occurs in malnourished children in areas of poor cleanliness.

Causes, incidence, and risk factors
The exact cause is unknown, but may be due to bacteria called fusospirochetal organisms.
This disorder most often occurs in young, severely malnourished children between the ages of 2 and 5. Often they have had an illness such as measles, scarlet fever, tuberculosis, cancer, or immunodeficiency.

Risk factors include Kwashiorkor and other forms of severe protein malnutrition, poor sanitation and poor cleanliness, disorders such as measles or leukemia, and living in an underdeveloped country.

Symptoms
Noma causes sudden, rapidly worsening tissue destruction. The gums and lining of the cheeks become inflamed and develop ulcers. The ulcers develop a foul-smelling drainage, causing breath odor and an odor to the skin.
The infection spreads to the skin, and the tissues in the lips and cheeks die. The process can eventually destroy the soft tissue and bone. Eventual destruction of the bones around the mouth cause deformity and loss of teeth

Noma can also affect the genitals, spreading to the genital skin (this is sometimes called noma pudendi).

Signs and tests
Physical examination shows inflamed areas of the mucous membranes, mouth ulcers, and skin ulcers. These ulcers have a foul-smelling drainage. There may be other signs of malnutrition.

Treatment
Antibiotics and proper nutrition helps stop the disease from getting worse. Plastic surgery may be necessary to remove destroyed tissues and reconstruct facial bones. This will improve facial appearance and the function of the mouth and jaw.

Expectations (prognosis)
In some cases, this condition can be deadly if left untreated. Other times, the condition may heal over time even without treatment. However, it can cause severe scarring and deformity.

Complications
- Disfigurement
- Discomfort

Calling your health care provider
Medical care is needed if mouth sores and inflammation occur and persist or worsen.

Prevention
Measures to improve nutrition, cleanliness, and sanitation may be helpful.

References

Chow AW. Infections of the oral cavity, neck, and head. In: Mandell GL, Bennett JE, Dolin R, eds. *Principles and Practice of Infectious Diseases*. 7th ed. Philadelphia, Pa: Elsevier Churchill Livingstone; 2009:chap 60.

New Anthrax Drug Approved

Source: http://www.homelandsecurity.org/node/691

Dr. Nicole Lurie, the assistant secretary for preparedness and response at the Department of Health and Human Services, has called the Food and Drug Administration's (FDA) approval of raxibacumab, an antibody approved for use with antibiotics to treat inhalational anthrax in children and adults, "a major step forward in the nation's preparedness against bioterrorism."
The new drug, the first FDA-approved drug for anthrax treatment and the first countermeasure developed and procured under Project BioShield to receive approval from the FDA, prevents the anthrax toxins from promoting harmful effects and increases the survival rate of people infected with anthrax. Dr. Lurie said, "Under Project BioShield, our Biomedical Advanced Research and Development Authority, has procured all these drugs [more than a dozen products available under emergency use authorization] for the Strategic National Stockpile.

The goal, however, is to have drugs that have completed the FDA approval process and therefore will not require FDA emergency authorization before they can be used. Today we have reached the goal with raxibacumab. Our success rate shows BioShield is an effective tool in bringing our nation drugs we will need to protect health and save lives in an emergency".

FDA approves raxibacumab to treat inhalational anthrax

First monoclonal antibody approved using the Animal Efficacy Rule

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm332341.htm

The U.S. Food and Drug Administration today approved raxibacumab injection to treat inhalational anthrax, a form of the infectious disease caused by breathing in the spores of the bacterium *Bacillus anthracis*. Raxibacumab also is approved to prevent inhalational anthrax when alternative therapies are not available or not appropriate.

Raxibacumab is a monoclonal antibody that neutralizes toxins produced by *B. anthracis* that can cause massive and irreversible tissue injury and death. A monoclonal antibody is a protein that closely resembles a human antibody that identifies and neutralizes foreign material like bacteria and viruses. Anthrax is a potential biological terrorism threat because the spores are resistant to destruction and can be easily spread by release in the air.

The FDA granted raxibacumab fast track designation, priority review, and orphan product designation. The drug demonstrated the potential to fill an unmet medical need, has the potential to provide safe and effective treatment where no satisfactory alternative therapy exists, and is intended to treat a rare disease, respectively.

Raxibacumab is the first monoclonal antibody approved under the FDA's Animal Efficacy Rule, which allows efficacy findings from adequate and well-controlled animal studies to support FDA approval when it is not feasible or ethical to conduct trials in humans. In this case, because inhalational anthrax is a rare and lethal disease, it is not possible to conduct adequate efficacy trials in humans.

"In addition to antibiotics, raxibacumab will be a useful treatment to have available should an anthrax bioterrorism event occur," said Edward Cox, M.D., M.P.H, director of the Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research. "Although antibiotics are approved to prevent and treat anthrax infection, raxibacumab is the first approved agent that acts by neutralizing the toxins produced by *B. anthracis*."

Raxibacumab's effectiveness for inhalational anthrax was demonstrated in one study in monkeys and three studies in rabbits. All animals were administered aerosolized *B. anthracis* spores, and efficacy was determined by survival at the end of the studies. Animals received varying doses of raxibacumab, placebo or antibiotics normally used to treat anthrax.

More animals treated with raxibacumab lived compared to animals treated with placebo. Sixty-four percent of animals in the monkey study and 44 percent of animals in one rabbit study receiving the 40 milligrams per kilogram dose of raxibacumab survived exposure to anthrax, compared with none in the placebo groups. All surviving animals developed toxin-neutralizing antibodies. Another study in rabbits showed that 82 percent of animals treated with antibiotics and raxibacumab survived exposure to anthrax compared with 65 percent of animals receiving antibiotic treatment alone.

The safety of raxibacumab was evaluated in 326 healthy human volunteers. Common side effects included rash, extremity pain, itching and drowsiness.

Raxibacumab was developed by Rockville, Md.-based Human Genome Sciences, in conjunction with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority. Human Genome Sciences has since been acquired by GlaxoSmithKline.

Use of Medical Simulation to Teach Bioterrorism Preparedness: The Anthrax Example

By Olsen, Martin E. MD

Source:http://journals.lww.com/smajournalonline/Fulltext/2013/01000/Use_of_Medical_Simulation_to_Teach_Bioterrorism.12.aspx

Abstract

The 2001 anthrax bioterrorism attacks demonstrated vulnerability for future similar attacks. This article describes mechanisms that can be used to prepare the medical community and healthcare facilities for the diagnosis and management of a subsequent bioterrorism attack should such an event occur and the fundamentals of medical simulation and its use in teaching learners about the diagnosis of management of anthrax exposure.

Key Points

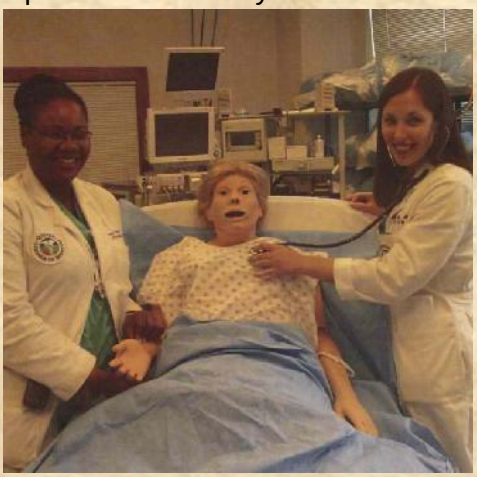
* The concept of medical simulation has existed for centuries, but its use has increased during the past decade.
* Medical simulation has been confirmed as an excellent medical education tool in peer-reviewed studies.
* Anthrax infection is a medical condition that carries an extremely high mortality rate with late diagnosis, but a significantly improved mortality rate when the diagnosis is made early after exposure.
* Medical simulation allows physicians and medical learners to have contact with a diagnosis that they will not likely see in the developing world unless a bioterrorism event occurs.
* If an anthrax attack does occur, then physician familiarity with anthrax infection may be lifesaving for patients.

Medical simulation has become a standard tool in many medical education programs. Bioterrorism events are rare but potentially catastrophic, and medical simulation provides an opportunity to teach capabilities in the diagnosis and management of these events. This article describes the use of a high-fidelity simulator as the patient, but some educators may prefer a standardized patient.

What Is Medical Simulation?

The use of medical simulation has increased dramatically in the past decade. Medical simulation adapts technology to the educational environment and provides a mechanism to rehearse critical patient care events. Aspects of learning that may carry risks for patients at the bedside can now be moved to a laboratory environment.[1]

As stated by the *Accreditation Council for Graduate Medical Education Bulletin* Editor Ingrid Philibert, "Budding and experienced musicians, actors, lawyers giving closing arguments, clergy preparing sermons… would not consider engaging in these activities without some form of rehearsal, either as an explicit trial of the activity in a 'low-stakes' setting, or at least as a deliberate 'mental walk-through' of all the steps that will go into the actual performance."[1] Simulation-based medical education may allow consistent trainee exposures to unusual medical conditions, critical incidents, near misses, and crises.[2]



Simulation has been used unsystematically for centuries.[3] In the 16th century mannequins, referred to as "phantoms," were developed to teach obstetric skills.[4] Current high-fidelity simulators involve human-shaped mannequins with electronically controlled parameters. These simulators actively depict both normal and abnormal pulses, pupillary examinations, cardiac sounds, pulmonary sounds, and other parameters depending on the individual mannequin's design and capabilities. Advanced simulation-based medical education can provide realistic representations of patient care issues and clinical environments.

Educators can alter simulated patient reactions and responses in ways that are not possible with actual patients, and this can increase the precision and relevance of training and competency assessment.[5] With medical simulation, trainees are able to have their first contact with real patients, and practicing clinicians can use medical simulation to improve their proficiency when learning new procedures or when developing their existing skills.

Simulation is an important tool for improving the safe delivery of medical care. Medicine, however, has lagged behind other high-technology and high-risk professions such as aviation in the use of simulators. The possible reasons for this delay include cost, limits to the accurate modeling of complex human pathophysiology, demands for rigorous scientific evidence of effectiveness, and resistance to change.[2] Medical trainees need live patients to hone their professional skills, and this requirement could at times have an impact on patient safety. Simulation-based learning can develop health professionals' knowledge, skills, and attitudes while protecting patients from unnecessary risk.[2]

The use of medical simulation in residency training programs has been well described across multiple disciplines,[6–8] and the effectiveness of simulation-based training in disaster preparedness also has been described.[9–14] Learning from errors is a key component in improving expertise; future behaviors are changed as a result of this experience.[15] Mistakes made during simulation exercises are more easily exposed and discussed than mistakes involving actual patients. In a simulation environment, instructors can actually provoke errors, allowing trainees the opportunity to cope with desired conditions. Simulation protocols can involve actors posing as family members of the simulated patient. Trainees can be taught and evaluated on their approach in dealing with the families of the simulated patients.[2]

Disaster training comparisons of high-fidelity simulators versus trained actors in a simulation disaster have been undertaken. One study demonstrated that high-fidelity simulators, when compared to live actor-patients, have equivalent results in prompting critical actions in mass casualty drills, and increased perceived reality of the exercises also was noted.[16]

During the response to a bioterrorism attack, meaningful communication must involve the right information delivered at the appropriate time in an effective manner from trusted sources. A simulation model of the hypothetical response to anthrax bioterrorism indicated that predicted mortality increases significantly the longer the amount of time from the attack's detection to its announcement. Timeliness, accuracy, and precision of communication, in addition to instructions for obtaining prophylaxis and treatment, are critical.[17]

Anthrax as a Disease and as a Bioterrorism Agent

The first modern experience with aerosolized anthrax pertains to 42 deaths accidental release of material in Sverdlovsk, Russia, in 1979.[18] The deaths resulted from the inhalational form of anthrax after a 1- to 4-day illness, which occurred several days after exposure. The first reported use of anthrax as a bioterrorism agent occurred in the United States, the autumn 2001 attacks in which 22 cases and 5 fatalities were reported. Half of the cases were inhalational and half were cutaneous.[19] Jernigan et al described 10 of the inhalational anthrax cases.[20] Seven of the victims were postal employees, and the median age of the patients was 56 years (range 43–73 years). The median incubation period from the time of exposure to onset of symptoms was 4 days (range 4–6 days). Symptoms included fever or chills (n = 10), sweats (n = 7), fatigue or malaise (n = 10), nausea or vomiting (n = 9), and dyspnea (n = 8).[20] Cough was minimal or nonproductive in nine of the subjects, and all of the patients with inhalational anthrax had abnormal chest x-rays. The abnormalities included infiltrates, pleural effusions, and mediastinal widening.

Patients sought care a median of 3.5 days (range 1–7 days) after the onset of symptoms. Eight of the patients were in the initial phase of illness when they first sought care; six of them received antibiotics with activity against *Bacillus anthracis* and all survived. Four patients who had fulminant disease when they received their antibiotics died. Pleural effusions were a consistent clinical feature and occurred in all of the patients.[20] Evaluation of these first 10 inhalational cases reported suggests that survival may be markedly improved by the combination of antimicrobial therapy begun during the initial phase of the illness along with aggressive supportive care such as drainage of pleural effusions.[20]

Historically, naturally acquired inhalational anthrax has been described as having a presentation of an initial 1 to 4 days of malaise, fatigue, fever, myalgias, and nonproductive cough, which is then followed by a fulminant phase of dyspnea, cyanosis, and profuse diaphoresis.[21] In the initial phase of the 2001 anthrax outbreak, patients experienced profound and often drenching sweating and nausea and

vomiting. Abnormalities on initial chest x-rays included mediastinal widening, paratracheal fullness, hilar fullness, pleural effusions, and parynchemal infiltrates. The total white blood cell count was normal or only slightly elevated at the time of initial visit in these patients.[20]

Inhalational anthrax occurs 2 to 43 days after exposure in humans.[22] The bacteria multiply and produce exotoxins that quickly cause mediastinal edema and necrosis. These conditions can be followed by bacteremia, toxemia, and sepsis, which subsequently cause death. Inhalational anthrax is therefore bimodal; a nonspecific prodromal period is followed by a fulminant course.

During the prodromal period, inhalational anthrax may be difficult to distinguish from pneumonia or influenza. In cases of anthrax, the presenting complaints include nausea, vomiting, pallor/cyanosis, diaphoresis, altered mental status, tachycardia >110 beats/min, a temperature >100.9°F, and an increased hematocrit.[23,24]

Because the first symptoms of inhalational anthrax are nonspecific, the diagnosis requires a high degree of suspicion. After the incubation period, patients may have dyspnea, cough, headache, chills, vomiting, weakness, or chest pain,[20] and many of these symptoms were prevalent in the 2001 anthrax attacks. Physical examination findings included fever, tachycardia, and hypoxemia. Early treatment with two or more antimicrobial agents, one of which is either ciprofloxacin or doxycycline, may improve the survival in people exposed to anthrax.

Cutaneous anthrax is the most common form of the naturally acquired anthrax contagion; approximately 2000 cases are reported worldwide each year. None of the cutaneous cases of anthrax diagnosed in 2001 attacks were fatal.[19] With treatment, <1% of cutaneous anthrax cases should be fatal, whereas data from before the antibiotic era show that 10% to 40% of untreated patients with cutaneous anthrax may die from exposure. A well-developed anthrax lesion can be recognized easily by a physician familiar with the disease; unfortunately, few physicians in developed countries have ever seen this clinical picture.[25]

Gastrointestinal anthrax results from the ingestion of bacilli from undercooked meat and, to the author's knowledge, has not been used as a bioterrorist weapon, although autopsy results from Sverdlovsk revealed hematogenously spread gastrointestinal anthrax in victims who died of inhalational anthrax.[18]

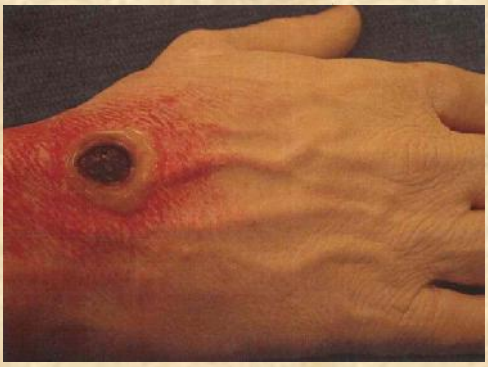
The challenge of identifying anthrax is illustrated by an Israeli study that assessed the ability of emergency departments (EDs) to make an accurate diagnosis.[26] Biologic drills were instituted and hospital and emergency physician managers were informed at the beginning of the calendar year that a drill using a surrogate patient with a clinical picture of inhalational anthrax would occur at some point, although the exact date for each hospital was not announced.[26] Surrogate patients presented with symptoms consistent with anthrax. They complained of a dry cough, chest tightness, pleuritic pain, shortness of breath, myalgia, nausea, headache, and drenching sweats. These patients induced a factitious elevated oral temperature using a warm liquid. As part of the drill, chest x-rays consistent with anthrax infection were provided to the ED staff as replacements for the x-rays taken of the surrogate patients. The ED staff admitted 91% of the surrogate patients and included anthrax in the differential diagnosis 61% of the time. Only 43% of institutions notified relevant local and state officials.[26]

Pregnant women and their infants are thought to be more vulnerable to bioterrorism than other population groups.[27–29] Ciprofloxacin is the first-line drug prophylaxis for women exposed to anthrax; however, the prophylactic treatment of pregnant or lactating women should be limited to those exposed to a high-risk source of contamination. Few controlled studies have been conducted on the use of ciprofloxacin in pregnancy, but the morbidity and mortality of anthrax clearly outweigh the risk of ciprofloxacin.[30] Prophylaxis for asymptomatic pregnant or lactating women is 500 mg of ciprofloxacin orally every 12 hours for 60 days. If the anthrax bacteria are found to be sensitive to penicillin, then the patient can be switched to amoxicillin.[30]

Anthrax as a Teaching Model for Disaster Preparedness

The first potential healthcare providers to come in contact with victims of an anthrax attack include family physicians, ED physicians, pediatricians, internal medicine physicians, and obstetrician/gynecologists. Given the lack of familiarity of medical students and obstetrician/gynecologist trainees with an anthrax diagnosis, the author established a residency program medical simulation educational format at East Tennessee State University in 2005 (anthrax is one of many scenarios taught in the program). Crisis management has been an important component of this simulation program. Residents and medical students do not know the diagnosis before they begin participation in the

scenario. For this exercise, a patient simulator presented symptoms of both cutaneous and inhalational anthrax. Although it is understood that none of the patients in the 2001 anthrax attack had both forms, it was believed that combining the clues could be appropriate for the trainees' educational level. The moulage on the mannequin's hand to simulate the anthrax lesion is shown in picture; the trainees also may be shown a picture of an actual anthrax lesion. In this exercise, the lesion is usually covered by a bandage that the learners must remove to examine. It is interesting to note that medical student learners have noticed the bandage but have failed to look under it until prompted. This is an opportunity for them to learn about thoroughness when performing a physical examination.



In the author's experience, trainees appreciate the opportunity afforded by the simulation laboratory and exposure to infections with which they are unfamiliar. Trainees are advised that patients in the simulation laboratory have a higher mortality rate than in the general population. This is certainly the case with the anthrax scenario in that the diagnosis usually is missed. Thus far, only residents given a patient with both cutaneous and inhalational anthrax have made a successful diagnosis, and this observation highlights the value of the exercise.

The Table (at the end of this article) is the instructor's template for the scenario run and is the suggested tool for educators who wish to use it when training medical personnel. A previous version of the Table has been published elsewhere.[31]

Conclusions

Bioterrorism threats will remain a concern for the healthcare system for the foreseeable future. In the case of anthrax, early diagnosis can be lifesaving for exposed patients and can allow for the rapid implementation of protocols to protect the community at large. Simulation has been shown to be an educational format superior to lecture. The use of a simulation-based educational program to prepare healthcare providers and healthcare systems for bioterrorism events such as anthrax has the potential to significantly improve outcomes for future bioterrorism victims and the communities in which they reside.

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References

1. Leach DC. Simulation and rehearsal. In: Philibert I, ed. *ACGME Bull* 2005; 1–10.
2. Ziv A, Wolpe PR, Small SD, et al.. Simulation-based medical education: an ethical imperative. *Acad Med* 2003; 78: 783–788.
3. Owen H. Early use of simulation in medical education. *Simul Healthc* 2012; 7: 102–116.
4. Buck GH. Development of simulators in medical education. *Gesnerus* 1991; 48: 7–28.
5. Ziv A, Small SD, Wolpe PR. Patient safety and simulation-based medical education. *Med Teach* 2000; 22: 489–495.
6. Deering S, Brown J, Hodor J, et al.. Simulation training and resident performance of singleton vaginal breech delivery. *Obstet Gynecol* 2006; 107: 86–89.
7. Binstadt ES, Walls RM, White BA, et al.. A comprehensive medical simulation education curriculum for emergency medicine residents. *Ann Emer Med* 2007; 49: 495–504.
8. Rowe R, Cohen RA. An evaluation of a virtual reality airway simulator. *Anesth Analg* 2002; 95: 62–66.

9. Summerhill EM, Mathew MC, Stipho S, et al.. A simulation-based biodefense and disaster preparedness curriculum for internal medicine residents. *Med Teach* 2008; 30: e145–e151.
10. Subbarao I, Bond WF, Johnson C, et al.. Using innovative simulation modalities for civilian-based, chemical, biological, radiological, nuclear, and explosive training in the acute management of terrorist victims: a pilot study. *Prehosp Disaster Med* 2006; 21: 272–275.
11. Heinrichs WL, Youngblood P, Harter P, et al.. Training healthcare personnel for mass-casualty incidents in a virtual emergency department: VED II. *Prehosp Disaster Med* 2010; 25: 424–432.
12. von Lubitz D, Carrasco B, Fausone C, et al.. Bioterrorism: development of large-scale medical readiness using multipoint distance-based simulation training. *Stud Health Technol Inform* 2004; 98: 221–227.
13. Phelps S. Mission failure: emergency medical services response to chemical, biological, radiological, nuclear, and explosive events. *Prehosp Disaster Med* 2007; 22: 293–296.
14. Franc-Law JM, Ingrassia PL, Ragazzoni L, et al.. The effectiveness of training with an emergency department simulator on medical student performance in a simulated disaster. *CJEM* 2010; 12: 27–32.
15. Blumenthal D. Making medical errors into "medical treasures." *JAMA* 1994; 272: 1867–1868.
16. Gillett B, Peckler B, Sinert R, et al.. Simulation in a disaster drill: comparison of high-fidelity simulators versus trained actors. *Soc Acad Emerg Med* 2008; 15: 1144–1151.
17. Brandeau ML, Zaric GS, Freiesleben J, et al.. An ounce of prevention is worth a pound of cure: improving communication to reduce mortality during bioterrorism responses. *Am J Disaster Med* 2008; 3: 65–78.
18. Abramova FA, Grinberg LM, Yampolskaya OV, et al.. Pathology of inhalational anthrax in 42 cases from the Sverdlovsk outbreak of 1979. *Proc Natl Acad Sci U S A* 1993; 90: 2291–2294.
19. Inglesby TV, O'Toole T, Henderson DA, et al.. Anthrax as a biological weapon, 2002 updated recommendations for management. *JAMA* 2002; 287: 2236–2252.
20. Jernigan JA, Stephens DS, Ashford DA, et al.. Bioterrorism-related inhalational anthrax: the first 10 cases reported in the United States. *Emerg Infect Dis* 2001; 7: 933–943.
21. Brachman PS. Inhalation anthrax. *Ann N Y Acad Sci* 1980; 353: 83–93.
22. Wright JG, Quinn CP, Shadomy S, et al.. Use of anthrax vaccine in the United States. *MMWR Morb Mortal Wkly Rep* 2010; 59 (rr06): 1–30.
23. Dixon TC, Meselson M, Guillemin J, et al.. Anthrax. *N Engl J Med* 1999; 341: 815–826.
24. Swartz MN. Recognition and management of anthrax—an update. *N Engl J Med* 2001; 345: 1621–1626.
25. Doganay M, Metan G, Alp E. A review of cutaneous anthrax and its outcome. *J Infect Public Health* 2010; 3: 98–105.
26. Leiba A, Goldberg A, Hourvitz A, et al.. Lessons learned from clinical anthrax drills: evaluation of knowledge and preparedness for a bioterrorist threat in Israeli emergency departments. *Ann Emerg Med* 2006; 48: 194–199.
27. James DC. Terrorism and the pregnant woman. *J Perinat Neonat Nurs* 2005; 19: 226–237.
28. White SR, Henretig FM, Dukes RG. Medical management of vulnerable populations and co-morbid conditions of victims of bioterrorism. *Emerg Med Clin N Am* 2002; 20: 365–392.
29. American College American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women. ACOG Committee opinion no. 457: preparing for disasters: perspectives on women. *Obstet Gynecol* 2010; 115: 1339–1342.
30. ACOG Committee on Obstetric Practice. ACOG Committee Opinion number 268, February 2002. Management of asymptomatic pregnant or lactating women exposed to anthrax. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2002; 99: 366–368.
31. Olsen ME. Anthrax, in Eason MP, Olsen ME (eds): *Workbook of OB/GYN Simulation*. Miami, Gaumard Scientific, 2010, pp 136–138.

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Learning objectives	• Increase understanding of potential bioterrorism weapons • Increase understanding of the criteria for diagnosis of anthrax • Increase understanding of the treatment of anthrax • Be able to discuss challenges in dealing with someone who may be identified as an important person
Simulation overview	The patient is a 37-year-old pregnant woman at 22 weeks' gestation who is visiting from out of town. If asked, she is the administrative assistant to the governor. He is in town making a speech. She had a previous negative experience at a facility where she was overtreated as a result of her political connections. She therefore will not volunteer the information that she works for the governor unless questions are specific. Three days ago, the governor received a mail gift from a constituent that the patient dropped. The item dropped was a box of powdered sugar doughnuts. Given the business of the office and the travel plans, the patient did not attach significance to this event. The patient did pick up the box of doughnuts and threw them away. She inhaled anthrax which was on the doughnuts and she touched the doughnuts. The simulator will have a black coal-appearing eschar with edema at the site of cutaneous anthrax exposure The patient also has inhalational anthrax. The patient's symptoms are nonspecific but will include fever, dyspnea, cough, headache, chills, vomiting, weakness, and chest pain. An x-ray should be available for this scenario that shows mediastinal widening. Possible additional findings in the x-ray include infiltrate or pleural effusions. As the scenario progresses, altered mental status could develop. Tachycardia could develop. Increased hematocrit could be found on laboratory analysis. For an advanced group of learners, meningoencephalitis could develop at the discretion of the simulation director.
Patient history and examination	The patient is a 37-year-old professional woman at 22 weeks' gestation who is visiting from out of town and does not hav prenatal records available. She was in good health until this morning, when she felt symptoms of chest pain, cough, nausea, dyspnea, and headache. This is her first pregnancy. She has had no surgeries. She had one 2-day admission 2 years ago with a discharge diagnosis of upper respiratory infection. Patient believes that the admission was unwarranted and the high cost of the admission, including the expense of magnetic resonance imaging, is a source of irritation to the patient. She is taking prenatal vitamins and no other medications. She has no known drug allergies, denies tobacco use, and denies alcohol use and street drug use. Physical examination shows tachypnea at 28 breaths per minute, tachycardia at 118 beats/minute, and a temperature of 102.4°F. The patient appears generally uncomfortable with diaphoresis. She may cough or vomit. As the scenario progresses, she will develop confusion and have trouble answering some questions. The physical examination also shows pulmonary findings consistent with infiltrates and/or pleural effusions. Fetal status will remain unremarkable until the patient deteriorates.
Laboratory values	• White blood cell count: 22,000 • Hemoglobin: 16 • Hematocrit: 48 • Platelets: 204,000 • Chest x-ray: shows mediastinal widening and pleural effusion and/or infiltrates
Simulation parameters	• Simulator should have a lesion on the hand consistent with cutaneous anthrax exposure. This will be a black coal-colore eschar with edema around it. • Tachypnea is present. • Tachycardia is present. • Patient is febrile. • As the scenario progresses, the patient develops respiratory distress with appropriate changes in her pulmonary settings.
Expected actions by participants	• Careful history, including social history, taken • Identification of the lesion on the hand and inquiry into its cause • Order of chest x-ray and diagnosis of the mediastinal widening and infiltrates/effusions • Diagnosis of anthrax exposure is made • Initiation of supportive therapy, including appropriate antibiotics; the first choice is ciprofloxacin. Doxycycline or penicillin, if the anthrax strain is sensitive, could also be considered. Some authors recommend 2 antibiotics for initial therapy. • Recommendation of corticosteroids in patients who have pulmonary edema, respiratory failure, and meningitis
Personnel/Props	• High-fidelity simulator • Cutaneous eschar on mannequin • Actress—voice of patient • Actress—nurse • Chest x-ray of anthrax victim • Picture of cutaneous anthrax-exposed patient
Additional literature	Inglesby TV, O'Toole T, Henderson DA, et al. Anthrax as a biological weapon, 2002 updated recommendations for management. *JAMA* 2002;287:2236–2252. Jernigan JA, Stephans DS, Ashford DA, et al. Bioterrorism-related inhalational anthrax: the first 10 cases reported in the United States. *Emerg Infect Dis* 2001;7:933–943.
Competencies addressed	• Patient care • Medical knowledge • Interpersonal communication skills
Debriefing goals	• Discuss cutaneous anthrax. Pustules arrive 1–12 days after exposure, toxin production results in local edema. After 1–2 weeks, the eschar dries and falls off. In the 2001 terrorist attacks, none of the cutaneous cases of anthrax were fatal • Discuss inhalational anthrax. This is seen as an ideal biologic weapon. Cases arise 2–43 days after exposure in humans. The initial symptoms are nonspecific but may include fever, dyspnea, cough, headaches, chills, vomiting, weakness, or chest pain. Confusion can occur, and the condition can progress to meningoencephalitis. • Recognize that suspicion of anthrax should prompt immediate notification of local and state health departments. A chest radiograph is of great help in establishing the diagnosis of inhalational anthrax. Mediastinal widening is common; infiltrates and pleural effusions are also frequently seen. • Review treatment of anthrax, which usually (in nonpregnant patients) consists of ciprofloxacin or doxycycline. Alternative drugs that have in vitro activity against anthrax include rifampin, vancomycin, imipenem, clindamycin, aminoglycocides, chloramphenicol, cefazolin, and the macrolides. Blood cultures should be drawn before antibiotic administration. • Corticosteroids are recommended in patients who have pulmonary edema, respiratory failure, and meningitis. Complications of medications in pregnancy also could be discussed. In the 2001 cases of bioterrorism, patients experienced either inhalational anthrax or cutaneous anthrax, but no victims experienced both conditions. In this simulation scenario, both conditions were simulated to enhance the learning process. • Discuss very important person treatment issues. This patient's care was compromised by the fact that she had been seen as a very important person and had a negative experience in that regard. She was therefore reluctant to admit that she worked for the governor's office. Had she been forthcoming with that information, the learners may have been more suspicious of bioterrorism at an earlier time than they were as a result of the delay in receiving this information.

Introducing the BioWeapons Monitor

Editors, Gerald Walther and Simon Whitsby

Source: http://news.cbrnresourcenetwork.com/newsDetail.cfm?id=143

The BioWeapons Monitor is an initiative of the BioWeapons Prevention Project (BWPP)—a global network of civil society actors dedicated to the permanent elimination of biological weapons and of the possibility of their re-emergence—to help monitor compliance with the international norm prohibiting biological weapons, laid down chiefly in the 1972 Biological Weapons Convention (BWC).

Note: The CBRN Resource Network would like to thank the editors, authors, and the BWPP itself for this contribution to the Responder Rundown. This article is the first in a series.

About the BioWeapons Monitor

The *BioWeapons Monitor* is an initiative of the BioWeapons Prevention Project (BWPP)—a global network of civil society actors dedicated to the permanent elimination of biological weapons and of the possibility of their re-emergence—to help monitor compliance with the international norm prohibiting biological weapons, laid down chiefly in the 1972 Biological Weapons Convention (BWC). Particularly, it aims to increase the transparency of activities relevant to the BWC, and thereby complement the current treaty regime. Preventing states and non-state actors from acquiring and using biological weapons is an urgent need. The *BioWeapons Monitor* seeks to provide factual information that will enhance discussions on strengthening the effectiveness and improving implementation of the BWC and other national and international measures relating to the prohibition of biological weapons. Its objective is to benefit the international community as a whole.

The *BioWeapons Monitor* seeks to complement and work with governments in their activities to effectively implement the BWC and to fulfill their obligations to permanently eliminate biological weapons and prevent their re-emergence. Following the Seventh Review Conference in 2011 and its agreement of Standing Agenda items on international cooperation and assistance, developments in science and technology and strengthening national implementation, the *BioWeapons Monitor* will seek to provide relevant national information that will assist the States Parties in developing approaches that will enhance the effectiveness and improve the implementation of the BWC. A key starting point is the information submitted by the BWC States Parties annually under the BWC confidence-building measures (CBMs). The proposals submitted by Canada and Switzerland to the Seventh Review Conference to explore a broader concept of compliance assessment based on examining and assessing the national regulatory programme that has been implemented to ensure compliance with a regulatory/legislated requirement provide an interesting approach.

The *BioWeapons Monitor 2012* contains country reports on BWC-relevant activities in eight states: Brazil, Germany, India, Japan, Kenya, Switzerland, the United Kingdom, and the United States. In-country authors collected and analysed relevant information that is distributed through this publication. The authors used open sources and actively sought information from government departments, research institutions, industry, scientific societies and other entities. This wide range of sources helps to ensure that the project is as comprehensive as possible and draws on as many reliable sources as possible. The *BioWeapons Monitor 2012* is based on the model for 2011: For future years the intention is to extend the coverage to include all three of the Standing Agenda items of the Intersessional Process.

The *BioWeapons Monitor* takes the Landmine Monitor – a product of the International Campaign to Ban Landmines, which is a global network of civil society organisations – as its role model. Although a civil society initiative, the Landmine Monitor is regarded as the de facto monitoring regime for the 1997 Mine Ban Treaty, reporting on States Parties' implementation of, and compliance with, that accord. The country reports in the *BioWeapons Monitor 2012* provide factual information and are constructive in their analysis. As a rule, any potentially controversial piece of information is backed by two different sources.

More importantly, States Parties are invited to advice on and comment on the information prior to publication.

This third edition of the *BioWeapons Monitor* builds on experience obtained during work on the second issue in 2011. The Third edition was, and future editions will be, able to build on relationships established by the in-country authors with relevant experts on the ground and experience of finding and using data sources, allowing, over time, reports to be more comprehensive and presenting a more complete picture of BWC-relevant activities. The *BioWeapons Monitor* is a work in progress, being constantly updated, corrected and improved. We welcome comments from governmental and non-governmental actors.

Origins of the *BioWeapons Monitor*

The *BioWeapons Monitor* idea grew in response to the wish to find a way forward to strengthen the effectiveness and improve the implementation of the Convention in the early twenty-first century. Over time, its aims have become more concrete. In 2008, a group of four civil society organisations – the Institute for Security Studies in South Africa, the Research Group for Biological Arms Control in Germany, the Society for the Study of Peace and Conflict in India, the Verification Research Training and Information Centre in the UK – took up the challenge of increasing transparency in areas related to the BWC by monitoring the activities of states. With the input of the BWPP Board of Directors, the *BioWeapons Monitor* was further developed and initial funding secured in early 2010. The first edition of the *BioWeapons Monitor* was released on 10 December 2010.

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Introduction

State of the biological weapons disarmament regime

The centrepiece of the multilateral biological weapons disarmament regime is the Biological Weapons Convention (BWC) of 1972, which entered into force 1975. In total, there are 166 members and 12 signatories to the BWC. Nineteen countries remain outside of the Convention. Compared to other multilateral treaties on weapons of mass destruction, the BWC has a long way to go towards achieving universality.

States that signed the BWC but have yet to ratify

1. Central African Republic
2. Cote d'Ivoire
3. Egypt
4. Guyana
5. Haiti
6. Liberia
7. Malawi
8. Myanmar
9. Nepal
10. Somalia
11. Syrian Arab Republic
12. United Republic of Tanzania

States not members of the BWC

1. Andorra
2. Angola
3. Cameroon
4. Chad
5. Comoros
6. Djibouti
7. Eritrea
8. Guinea
9. Israel
10. Kiribati
11. Mauritania
12. Micronesia (Federated States of)
13. Namibia
14. Nauru
15. Niue
16. Samoa
17. South Sudan
18. Tuvalu

Efforts to strengthen the effectiveness and improve implementation of the Convention by adding compliance / verification measures ended unsuccessfully in summer 2001 after 6.5 years of negotiations. States Parties were unable to reach a consensus on the drafting of a Final Declaration.

Instead, subsequent to the Fifth Review Conference States Parties agreed to hold meetings on an annual basis to discuss a range of issues, including national implementation, disease surveillance, and the role of the scientific community.

The intersessional meetings took place twice a year and continued up to and after the Sixth BWC Review Conference in 2006. They have led to the opening of proceedings in Geneva, Switzerland, that include contributions from both international and nongovernmental organisations (NGOs), and bring into the process of strengthening the Convention a broad range of expertise, especially from the public health sector. The intersessional process has increased common understanding on a range of issues, but thus far discussions have produced little in the way of effective action, such as multilaterally agreed decisions or guidelines.

At the Seventh Review Conference in December 2011, State Parties recognized the need for the Intersessional Process to go ahead with sustained and continuing considerations of three Standing Agenda items: a review of developments in the field of science and technology, to strengthen national implementation, and cooperation and assistance, specifically under Article X. Furthermore, a biennial topic to be considered in the Intersessional Process in 2012 – 2013 is how to enable fuller participation in the CBMs.

Article I on the BWC defines the scope of the Convention which states that: 'Each State Party to this Convention undertakes never in any circumstance to develop, produce, stockpile or otherwise acquire or retain:

(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflicts'

Whilst a number of State Parties voiced general concerns at the 2006 Review Conference about the use of biological weapons by non-state actors such as terrorist groups or individuals, currently there are no states that admit to having or developing biological weapons, nor are there allegations of non-compliance with the BWC under investigation in international fora.

Why transparency is important

All States Parties are expected to be in compliance with the Convention as they are legally bound to implement the Convention fully and comprehensively. It is important to demonstrate such compliance with the Convention by providing transparency about the activities in the life sciences being carried out within the State Party whether by government, industry or academia. The importance of such transparency is underlined because of the inherent "dual-use" nature of activities in the life sciences.

In regard to the Convention, it is important to provide transparency about the programmes within a State Party to counter outbreaks of disease – whether natural, accidental or deliberate – in humans, animals or plants. States Parties are committed under Article IV of the Convention "to take any necessary measures to prohibit and prevent" biological weapons. It has become apparent over the past decade that more attention needs to be given to effective biosecurity and biosafety as well as to education and outreach of all those engaged in the life sciences. Transparency about

such steps taken nationally to ensure the effective implementation of all Articles of the Convention is vital to build confidence that States Parties are in compliance with the Convention.

Existing transparency-building efforts under the BWC

One example of States Parties promoting transparency in issues of BWC compliance can be found in the working paper submitted to the Meeting of Expert in July 2012, Geneva, by Canada and Switzerland.(1) The working paper is part of an earlier effort by Canada to show how States Parties could show compliance by providing information about their national legislation as well as evidence of implementation of the Convention. In addition, year specific information is also given, for example, the number of announced and unannounced inspection visits to facilities. Annex I and II of the working paper provide exemplars based on Canada and Switzerland, respectively.

Besides this concerted individual effort to show how BWC compliance could be assessed, the biological weapons control regime includes a number of multilateral mechanisms to foster transparency. The consultative mechanism under Article V of the BWC allows for multilateral meetings to consider problems and to clarify ambiguities regarding BWC compliance. The current annual BWC meetings are a forum for face-to-face information exchanges. States Parties are invited to report on their own compliance every five years to the BWC Review Conferences. Most importantly, there are annual data exchange measures, the so-called confidence-building measures (CBMs).

Confidence-building measures

The existing transparency enhancement measures have, however, limited utility. Only one state has taken advantage of the consultative process under Article V in a multilateral setting;(2) many states do not submit the politically-binding CBMs; and there appears to be little follow-up after the initial data-gathering step. However, as agreed at the Seventh Review Conference, the issue of how to enable fuller participation in the CBMs is being addressed by States Parties during the Intersessional Process in 2012 – 2013.

CBMs are the only permanent transparency mechanism and every State Party to the BWC is under a politically-binding obligation to submit a CBM declaration by 15 April of each year, providing information on a range of activities and facilities. As of 22 November 2012, 66 states had submitted their CBM for the year, a few less than in 2011, and still less than half of the 165 BWC State Parties. The BWC Implementation Support Unit collects the CBM returns and makes them available to State Parties.(3) CBMs were agreed in 1986 'to prevent or reduce the occurrence of ambiguities, doubts and suspicions'(4) and were extended in 1991. In later years, states made a number of proposals to improve them and to cover more topics, but, by and large, these did not result in changes to the CBM mechanism. At the Seventh Review Conference in 2011, State Parties agreed to increase the scope of the CBMs in order to promote cooperation and exchange of

information between life scientists.(5) The following topics are to be covered within a CBM submission:

A. Part 1: Exchange of data on research centres and laboratories; Part 2: Exchange of information on national biological defence research and development programmes.

B. Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.

C. Encouragement of the publications of results and promotion of use of knowledge.

E. Declaration of legislation, regulations and other measures.

F. Declaration of past activities in the offensive and/or defensive biological research and development programmes.

G. Declaration of vaccine production facilities.

CBM declarations are largely made available to BWC States Parties only. A limited but increasing number of states – 22 out of the 66 that have submitted them as of 22 November 2012 – have made them publicly available.(6)

States and topics covered in the country reports

The eight country reports in this publication contain information from open sources that is relevant to the compliance with the BWC. The objective is to demonstrate that confidence in compliance can be increased through transparency of relevant activities available from open-source information. We selected countries (Brazil, Germany, India, Japan, Kenya, Switzerland, the UK, and the US) that are biotechnology leaders in their geographical subregions. An advanced biotechnological capability is a necessary, even if by no means a sufficient, precondition for a large-scale biological weapons programme. No widely accepted global ranking of the biotechnological capabilities of states exists, however. While abundant data are available on biotechnology research, development and production capabilities in individual countries, global comparative overviews based on common methodology are extremely rare. One effort to develop such a ranking system was published in 2005.(7) The *BioWeapons Monitor* has used the methodology suggested in that publication and updated the listing.

We selected one country each from Africa, South America and North America as well as two countries and Asia and three from Europe to sustain the *BioWeapons Monitor's* principle of global distribution.

Selection of topics

Transparency is fostered by collecting, processing, analysing and distributing relevant information. The challenge is to define what information is relevant in the context of biological weapons disarmament. The country reports focus on capabilities that would be important to any biological weapons effort, particularly if the intended product is a weapon with massive destructive or disruptive force.

Each country report opens with information on the status of the BWC and the Geneva Protocol in the country in question, as well as on the national contact point for biological weapons issues and general national policy towards biological arms control. Because information can only be properly assessed if it is put in context, each country report has some basic information on the national life-science and biotechnology industry landscape.

A country's capacity for working with agents of particular biological weapons concern or conducting activities with high misuse potential is covered by providing information on:

- Biodefence activities and facilities;
- Maximum and high biological safety level (BSL-3 and BSL-4) facilities and their activities;
- Any work on smallpox, and other dual-use research of immediate misuse potential; and;

A country's capacity for producing biological agents in large quantities is covered by supplying information on vaccine production facilities.

Biological weapons-related accidents or cases of use will manifest themselves in unusual disease outbreaks. The following disease outbreaks are covered:

Outbreaks of particularly dangerous and rare diseases (anthrax, botulism, plague, smallpox, tularaemia, and viral haemorrhagic fevers such as –

- Ebola, Lassa, and Marburg); and
- Suspicious disease outbreaks.

States are under the obligation to implement the international norm prohibiting biological weapons into national laws and regulations. This is also an important aspect of countering the threat of terrorist use of biological weapons. The country reports provide information on:

- Relevant national laws, regulations and guidelines; and

- Codes of conduct, education and awareness-raising efforts.

To indicate how committed a state is towards the well-being of the BWC, the *BioWeapons Monitor* covers:

- CBM participation; and
- Participation in BWC meetings in Geneva.

Finally, the country reports examine past biological weapons activities and accusations thereof, from both governmental and non-state actors, with a focus on the post-1972 period. Bioterrorism hoaxes also are covered.

References

(1) Canada and Switzerland 'National Implementation of the BTWC Compliance Assessment', BWC/MSP/2012/MX/WP.17

(2) Cuba requested a consultative meeting in 1997 to receive clarification about an outbreak of *Thrips palmi*, an insect pest, on its territory, which it suspected was connected to the overflight of a US agricultural airplane. The US presented information on why there was no connection between the two events. For more information, see, for example, Report of the Formal Consultative Meeting to the BWC, 29 August 1997, BWC/CONS/1, http://unog.ch/1997-08-FCP/BWC_CONS_01.pdf; and Zilinskas, R.A. (1999) 'Cuban Allegations of Biological Warfare by the United States: Assessing the Evidence', Critical reviews in Microbiology, Vol. 25, No. 3, pp. 173 – 227.

(3) Detailed guidelines on how to collect information, complete the forms and submit the CBM declaration to the United Nations are available at http://www.unog.ch/bwc/cbms

(4) See http://bwc.unog.ch/1986-09-2RC/BWC_CONF.II_13.pdf, Part II, p. 6.

(5) See the Annex I of the Final Document of the Seventh Review Conference, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/600/60/PDF/G1260060.pdf?OpenElement

(6) See http://www.unog.ch/__80256ee600585943.nsf/%28http-Pages%29/4fa4da37a55c7966c12575780055d9e8?OpenDocument&ExpandSection=26#_Section26

(7) See http://www.biological-arms-control.org/publications/hunger_CBM.pdf , pp. 46 – 51.

Gerald Walther *and* ***Simon Whitsby*** *are the editors for BioWeapons Monitor 2012, a publication of the BioWeapons Prevention Project (BWPP) at the Bradford Disarmament Research Centre, University of Bradford (UK).*

History of Experimentation on Human Guinea Pigs

By Fred Burks

Source: http://anthonycolpo.com/the-long-history-of-experimentation-on-human-guinea-pigs/

1932 to 1972 – In the infamous Tuskegee syphilis study, 200 black men diagnosed with syphilis are never told of their illness, are denied treatment. They are used as human guinea pigs in order to follow the progression and symptoms of the disease. They all subsequently die from syphilis, their families never told that they could have been treated. The study continues for four decades. (MSNBC, Time Magazine, Wikipedia)

1939 – At an orphanage in Iowa, 22 children are the subjects of the so-called "monster" experiment, which attempts to use psychological abuse to induce children who spoke normally to stutter. The experiment is designed by Dr. Wendell Johnson, one of the nation's most prominent speech pathologists, for the purpose of testing one of his theories on the cause of stuttering. (CBS News, San Jose Mercury News, Wikipedia)

1940 – In Chicago, 400 prisoners are infected with malaria in order to study the effects of new and experimental drugs to combat the disease. Nazi doctors later on trial at Nuremberg cite this American study to defend their own actions during the Holocaust. (Life Magazine, Life 2nd photo, Wikipedia, medlibrary.org)

1940 to 1979 – The U.K. Ministry of Defence conducts open air tests using disease-producing bacteria and viruses. Many of these tests involved releasing potentially dangerous chemicals and micro-organisms over vast swaths of the population without the public being told. (BBC News, Guardian)

1943 – In response to Japan's full-scale germ warfare program, the U.S. begins research on biological weapons at Fort Detrick, MD. (NPR, Wikipedia)

1944 – The U.S. Navy uses human subjects to test gas masks and protective clothing. Individuals are locked in a gas chamber and exposed to poisonous mustard gas and lewisite. By the time the war is over, more than 60,0000 U.S. servicemen have been used as human subjects in chemical defense research programs. They are told that they should never reveal the nature of the experiments. (Telegraph, Institute of Medicine)

1945 – Project Paperclip is initiated. In this top secret program, the U.S. State Department, Army intelligence, and the CIA recruit Nazi scientists and offer them immunity and secret identities in exchange for work on secret government projects in the United States. (BBC News, New York Times, MSNBC/AP)

1945 – "Program F" is implemented by the U.S. Atomic Energy Commission. This is the most extensive U.S. study of the health effects of fluoride, which was a critical chemical component in atomic bomb production. The use of fluoride in drinking water, it is found, causes adverse effects to the central nervous system. But much of the information is squelched in the name of "national security" because of fear that lawsuits would undermine full-scale production of atomic bombs. (Project Censored, BBC producer, Fluoride Action Network)

1946 to 1953 – In an experiment sponsored by the U.S. Atomic Energy Commission and the Quaker Oats corporation at the Walter E. Fernald State School in Massachusetts, 73 mentally disabled children are fed oatmeal containing radioactive calcium and other radioisotopes, in order to track "how nutrients were digested." The children are not told that they are being fed radioactive chemicals and are instead told by hospital staff and researchers that they are joining a "science club." (CBS News)

1950 – In an experiment to determine how susceptible an American city would be to biological attack, the U.S. Navy sprays a cloud of bacteria from ships over San Francisco. Monitoring devices are situated throughout the city in order to test the extent of infection. Many residents become ill with pneumonia-like symptoms. At least one man dies. (San Francisco Chronicle, Wall Street Journal)

1950s – In Project GABRIEL and Project SUNSHINE, researchers in the U.S. and the U.K. attempt to determine how much nuclear fallout would be required to make the Earth uninhabitable. Examination of human bodies could reveal how readily fallout from already exploded bombs was taken up and hence how much damage it caused. Researchers secretly collect human bodies and bones from all over the world without permission, with a particular focus on infants. (Guardian, Deseret News, Wikipedia)

1950s to 1960s – The CIA and British military study LSD as a potential weapon for use by intelligence services. Human subjects (both civilian and military) are used with and without their knowledge. At least one subject dies as a result. (New York Times, Time Magazine, Guardian, US Dept. of Energy)

1951 – The French town of Pont-Saint-Esprit likely has bread spiked with LSD by the CIA as part of a mind control experiment which leaves five people dead and many seriously ill. (BBC News, Telegraph)

1953 – CIA initiates Project MKULTRA. This is an eleven year research program designed to produce and test drugs and biological agents that will be used for mind control and behavior modification. Six of the subprojects involve testing the agents on unwitting human beings. (Washington Post, New York Times, Wikipedia)

1953 to 1970s – The CIA and Department of Defense implement Project MKNAOMI, designed to maintain, stockpile and test biological and chemical weapons. It establishes a robust arsenal within the CIA's Technical Services Division

(TSD) consisting of various lethal and incapacitating materials. (Time Magazine, Wikipedia)

1960 to 1971 – Dr. Eugene Saenger, funded by the Defense Atomic Support Agency, performs whole body radiation experiments on more than 90 poor, black Americans. He forges consent forms, and does not tell them what he is doing (they think they are receiving medical care). He exposes their chests to the equivalent of about 7,500 x-rays, which cause intense pain, vomiting, and bleeding from their nose and ears. At least eight, and as many as 20 of the subjects die as a result. (Los Angeles Times, New York Times)

1963 – The CIA Inspector General completes a report on the MKULTRA program stating, "A final phase of testing of MKULTRA products places the rights and interests of U.S. citizens in jeopardy. Public disclosure of some aspects of MKULTRA activity could induce serious adverse reaction in U.S. public opinion." Only one copy of the report is made due to its "unusual sensitivity." (Declassified CIA document #17748)

1963 – Researchers inject prisoners and terminally ill patients with live cancer cells to test their immune responses. They are told only that it is a "skin test." (Time Magazine)

1965 – The CIA and Department of Defense begin Project MKSEARCH, a program to develop a capability to manipulate human behavior through the use of mind-altering drugs. (US Dept. of Defense, Wikipedia)

1966 – The U.S. Army dispenses Bacillus subtilis variant Niger throughout the New York City subway system. Many thousands of civilians are exposed when army scientists drop lightbulbs filled with the bacteria onto ventilation grates. (Wall Street Journal, New York Post)

1970 – The United States intensifies its development of "ethnic weapons" (Military Review, Nov., 1970), designed to selectively target and eliminate specific ethnic groups who are susceptible due to genetic differences and variations in DNA. (Project Censored, Telegraph)

1973 – The last of more than 2,000 volunteers, nicknamed the "white coats," pass through Fort Detrick, where they have offered up their bodies for science since 1954. The volunteers are conscientious objectors who agree to be infected with debilitating pathogens. Many are Seventh Day Adventists who choose to become human guinea pigs rather than serve on active duty. (BBC News, PBS, Wikipedia)

1977 – Senate hearings on Health and Scientific Research confirm that 239 populated areas had been contaminated with biological agents between 1949 and 1969. Some of the areas included San Francisco, Washington, D.C., Key West, Panama City, Minneapolis, and St. Louis. (Wall Street Journal)

1978 – Experimental Hepatitis B vaccine trials, conducted by the CDC, begin in New York, Los Angeles and San Francisco. Advertisements for research subjects specifically ask for promiscuous homosexual men. (Medical Knowledge Base)

1980 – The U.S. Department of Defense completes 35 years of detonating nuclear weapons at various sites around the world, sometimes monitoring downwind residents for medical problems and mortality rates. A Centers for Disease Control and Prevention/National Cancer Institute study claims that nuclear fallout from these radiation tests may have caused approximately 11,000 deaths. (CDC Study, Wikipedia)

1981 – The first cases of AIDS are confirmed in homosexual men in New York, Los Angeles and San Francisco, triggering speculation that AIDS may have been introduced via the Hepatitis B vaccine trials started in 1978 in these same cities. (Medical Knowledge Base, Journal of Medical Hypotheses)

1985 to 1986 – According to the journal *Science*, HTLV and VISNA, a fatal sheep virus, are very similar, indicating a close taxonomic relationship. The Proceedings of the National Academy of Sciences states HIV and VISNA are highly similar and share all structural elements, except for a small segment which is nearly identical to HTLV. This leads to speculation that HTLV and VISNA may have been linked to produce a new retrovirus to which no natural

immunity exists. (Science, National Academy of Sciences)

1986 – A report to Congress reveals that the U.S. Government's current generation of biological agents includes: modified viruses, naturally occurring toxins, and agents that are altered through genetic engineering to change immunological character and prevent treatment by all existing vaccines. (Citation needed)

1987 – The U.S. Department of Defense admits that, despite a treaty banning research and development of biological agents, it continues to conduct such research at 127 facilities and universities around the nation. (Science Magazine, New Internationalist)

1990 – More than 1,500 six-month old African-American and Hispanic babies in Los Angeles are given an experimental measles vaccine that has never been licensed for use in the United States. The CDC later admits that parents were never informed that the vaccine being injected to their children was experimental. (Los Angeles Times, New Scientist)

1994 – U.S. Senator John D. Rockefeller issues a report revealing that for at least 50 years the Department of Defense has used hundreds of thousands of military personnel in human experiments and for intentional exposure to dangerous substances. Materials included mustard and nerve gas, ionizing radiation, psychochemicals, hallucinogens, and drugs used during the Gulf War. (Rockefeller Report)

1994 to 1995 – Dr. Garth Nicolson at the MD Anderson Cancer Center in Houston, TX discovers that many returning Desert Storm veterans are infected with an altered strain of Mycoplasma incognitus, a microbe commonly used in the production of biological weapons. He then uncovers evidence that biological agents used during the Gulf War were manufactured in Houston, TX and Boca Raton, Fl and tested on prisoners in the Texas Department of Corrections. (Journal of the American Medical Association, Capt. Joyce Riley, USAF)

1995 – The U.S. Government admits that it had offered Japanese war criminals and scientists who had performed human medical experiments salaries and immunity from prosecution in exchange for data on biological warfare research. Some of these scientists had tortured to death the humans on which they experimented. (Los Angeles Times, USA Today/Associated Press)

1996 – The U.S. Department of Defense admits that Desert Storm soldiers were exposed to chemical agents. A scientific review finds a strong association between exposure to certain chemicals and the Gulf War illness suffered by many veterans. (CNN News, CNN 2nd article, Washington Post, New York Times)

1999 – Jesse Gelsinger dies as a result of a University of Pennsylvania's gene-therapy trial. The principal investigator in the study, James Wilson holds a 30% equity stake in Genovo, which owned the rights to license the drug being studied; the university owned 3.2% of the company. When Targeted Genetics Corp. later acquires Genovo, Wilson reportedly earns $13.5 million and Penn $1.4 million. (Time Magazine)

2000 – Experimental artificial blood is transfused into research subjects across the United States without their consent. Later studies show that the artificial blood causes a significant increase in the risk of heart attacks and death. (ABC News, 2nd ABC News article)
2002 – North Carolina's Shearon Harris nuclear plant contains the largest radioactive waste storage pools in the US. If the cooling system malfunctions, the resulting fire could trigger a nuclear meltdown. In 2002, plant managers are forced to manually shut down the reactors four times. Between 1999 and 2003, there are twelve major problems requiring the shutdown of the plant. Yet the U.S. Nuclear Regulatory Commission ignores the potential risks. (Counterpunch, ABC affiliate, Associated Press)

2007 – Texas governor Rick Perry makes the vaccine Gardasil mandatory for all Texan schoolgirls. The vaccine is designed to prevent the sexually transmitted cervical-cancer virus, yet even girls not sexually active are forced to take the new vaccine. Perry defends his relationship with Merck & Co., makers of the vaccine. The safety of the vaccine is also

increasingly questioned. (MSNBC/AP, Los Angeles Times)

2008 – Nanotechnology, with risks to health still unknown, is being widely used in consumer products. Some experts say the microtubules which can easily enter our bodies may pose health and environmental risks. Researchers in Scotland say we may be facing the same health risks as asbestos. Yet industry is rapidly embracing this risky technology with little oversight. (New York Times, Project Censored, Science News)

2009 – The American Academy of Environmental Medicine calls for a moratorium on genetically modified foods. Their report states, "GM foods pose a serious health risk in the areas of toxicology, allergy and immune function, reproductive health, and metabolic, physiologic and genetic health." Yet the US threatens a trade war against any country which opposes these frankenfoods. The US media fail miserably to even present a debate on this crucial health topic. (American Academy of Environmental Medicine, Guardian, Scientific Summary)

2011 – Researchers suspect the military's High Frequency Active Auroral Research Program (HAARP), which frequently disturbs the ionosphere using powerful directed energy beams, is placing humanity at high risk due to unintended consequences. Some believe HAARP may even be influencing some natural disasters like earthquakes and hurricanes. (CBC documentary [Canada's PBS], Prof. Michel Chossudovsky)

2011 – Three nuclear design specialists employed by General Electric come forward stating that they resigned in 1976 after becoming convinced that the nuclear reactor design they were reviewing — the Mark 1 — was so flawed that it could lead to a devastating accident. Five of the six reactors at the Japan's nuclear facility which experiences a melt down in March 2011 are Mark 1s. (CBS News)

From 1988 to 2008, the number of overseas clinical trials for drugs increases by 2,000%, to approximately 6,500 trials. These trials are often conducted in areas with large numbers of poor and illiterate people who grant their consent by signing an "X" or making a thumb print on a form. The tests are rarely monitored by the FDA, and have in some cases proved deadly. 49 babies die in New Delhi, India during a 30-month trial. The cost of testing in countries without safety regulations is much lower; and, due to lax or nonexistent oversight, pharmaceutical corporations (or research companies they've contracted out to) are able to more easily suppress research that demonstrates harmful effects and only report positive results. (Vanity Fair)

Fred Burks *served as a language interpreter for Presidents Bush and Clinton, Vice Presidents Gore and Cheney, Secretaries of State Powell and Albright, and numerous other top officials. He resigned from the State Department in 2004 after the introduction of an oppressive new secrecy clause. In the article below, he lists government, military, and medical experiments in which human subjects were shamelessly used as guinea pigs.*

More can be read at:
http://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States#cite_note-15

Biological attack early warning system developed in IRAN

Source: http://isna.ir/fa/news/91110402429/سیستم-هشدار-زودهنگام-حملات-بیولوژیک-برای-مقابله-با-حملات-بیولوژیک

This Early warning system is able to analyze Biological particles suspended in the air to protect against biological attacks and identifying biological pollutants in urban areas or hospitals.
The air sampling device collects and evaluates biological agents in terms of the frequency of biological aerosols
This early warning devices of biological agents detects the presence of biological agents (microorganisms) suspended in the air using a vacuum pump automatically, a certain volume of air sampled and the mechanical mechanism of particle from 1 to 10

micrometer suspended in the air is detected after passes on ultraviolet laser light and data is analyzed electronically. Simultaneously to increase the accuracy of the optical system, the particle size is also measured in terms of the size. The Biological monitoring system detects the presence of biological particles on time and sends optical signal to the operator or designed to prepare network of biological detectors in the field. It is also capable to monitor environmental parameters. The detector size is 50X30X20 centimeter and weights 17 kilogram.

Use cells' suicide alarm to fight bioterrorism

Source: http://www.futurity.org/health-medicine/use-cells-suicide-alarm-to-fight-bioterrorism/

The alarm system that helps immune system cells destroy invading bacteria points to a potentially new way to protect people from biological weapons, researchers report.

Cells in the immune system called macrophages normally engulf and kill intruding bacteria, holding them inside a membrane-bound bag called a vacuole, where they kill and digest them.

Some bacteria thwart this effort by ripping the bag open and then escaping into the macrophage's nutrient-rich cytosol compartment, where they divide and could eventually go on to invade other cells.

Research from the University of North Carolina School of Medicine shows that macrophages have a suicide alarm system—a signaling pathway to detect this escape into the cytosol.

The pathway activates an enzyme, called caspase-11, which triggers a program in the macrophage to destroy itself.

"It's almost like a thief sneaking into the house not knowing an alarm will go off to knock down the walls and expose him to capture by the police," says study senior and corresponding author Edward Miao, assistant professor of microbiology and immunology.

"In the macrophage, this cell death, called pyroptosis, expels the bacterium from the cell, exposing it to other immune defense mechanisms."

Miao says the new findings, reported in the journal *Science*, show that having this detection pathway protects mice from lethal infection with the type of vacuole-escaping Burkholderia species: *B. thailandensis* and *B. pseudomallei*.

Both are close relatives. But they differ in lethality.

B. pseudomallei is potentially a biological weapon. Used in a spray, it could potentially infect people via aerosol route, causing sickness and death. Moreover, it also could fall into a latent phase, "essentially turning into a 'sleeper' inside the lungs and hiding there for decades," Miao explains.

In contrast, *B. thailandensis*, which shares many properties with its species counterpart, is not normally able to cause any disease or infection

These environmental bacteria are ubiquitous throughout South East Asia, and were it not for the caspase-11 pathway defense system, that part of the world could be uninhabitable, Miao points out.

This grim possibility clearly emerged in the study. Mice that lack the caspase-11 detection pathway succumb to infection not only by *B. pseudomallei*, but also to the normally benign *B. thailandensis*.

"Thus caspase-11 is critical for surviving exposure to ubiquitous environmental pathogens," the authors conclude.

Miao points to research elsewhere showing that the pathway's abnormal activation in people with septic shock, overwhelming bacterial infection of the blood, is associated with death.

"We discovered what the pathway is supposed to do, which may help find ways to tone it down in people with that critical condition."

As to bioterrorism, the researcher says it may be possible to use certain drugs already on the market that safely induce the caspase-11 pathway.

"Since this pathway requires pre-stimulation with interferon cytokines, it is conceivable that pre-treating people with interferon drugs could ameliorate a bioterror incident.

"This could be quite important in the case of Burkholderia, since these bacteria are naturally resistant to numerous antibiotics.

"But first we have to find out if they would work in animal models, and consider the logistics of interferon

stockpiling, which are currently cost prohibitive."

Additional research contributors are from Seattle Biomedical Research Institute and the University of California, Berkeley. The National Institutes of Health, Burroughs Wellcome Fund, Cancer Research Institute, and the National Science Foundation supported the research.

The D222G Mutation and Severe Influenza

By Amesh A. Adalja, MD, FACP

Source: http://www.upmc-biosecurity.org

During the 2009 H1N1 influenza pandemic, a variety of clinical presentations occurred, ranging from asymptomatic infection to fulminant respiratory failure that required extra-corporeal membrane oxygenation (ECMO). An interplay between host and viral factors is the likely answer to the question of why some but not all patients developed severe illness. Early in the pandemic, one viral factor postulated as having a role in disease severity was the D222G mutation on the HA1 subunit of the viral hemagglutinin. This mutation, which was present in the 1918 H1N1 virus, is known to alter binding properties by permitting replication of the virus in the lower respiratory tract. In 2009, officials from Norway announced that the mutation was found in isolates from 3 patients, at which point the need for case control studies to confirm the severity of associated clinical disease was noted. A new article by authors from the Norwegian Institute of Public Health provides this information.[1]

Characteristics of the D222G Mutation

Rykkvin and colleagues analyzed 462 respiratory samples from pandemic patients with ordinary and severe cases of influenza, including 52 samples from severe nonfatal cases and 26 from fatal cases. Severe cases included those with lower respiratory tract disease or other end organ complications of influenza.

Through pyrosequencing, the D222G mutation was found in 13 samples--in 31% of fatal cases, 10% of severe cases, and none of the mild cases. The mutation was more likely to be present in specimens collected 8 days or more after symptom onset. In samples collected from the upper and lower respiratory tracts of the same patient, the mutation was found in both.

Of samples that underwent full genetic sequencing, phylogenetic analysis revealed that the isolates did not form a distinct cluster. Instead, each was on a separate genetic branch, indicating that sporadic development occurred rather than transmission of the mutated virus. Most of the D222G-containing viruses existed as quasi-species--or minor variants--that represented less than 50% of the proportion of the circulating virus. In serial samples, the wild type allele preceded detection of D222G in 80%, implying the mutation arose after infection.

Incorporating D222G into Clinical Practice?

The results of this study are important because they offer another clue to the etiology of severe influenza. By changing its binding preference via the D222G mutation, the influenza virus is able to access deeper sites of replication (via targeting of type II pneumocytes and alpha 2,3 linked sialic acid residues) and cause more severe disease. However, the implications for clinical decision making are not clear. The mutation was not found in initially infecting viruses (likely because of known inefficient transmission of alpha 2,3 binding preference viruses); instead it occurs during infection. Since serial sampling is not typically performed with influenza patients, it would be difficult to track development of the mutation.

Because viruses with this mutation are sporadic mutants and do not form one lineage, D222G-containing virus is not likely to become widespread in the population unless further mutations occur. Nonetheless, given its association with severe disease, D222G screening should become part of influenza surveillance. This would allow for tracking of the mutation's prevalence and identification of other mutations that may render the virus more transmissible.

References

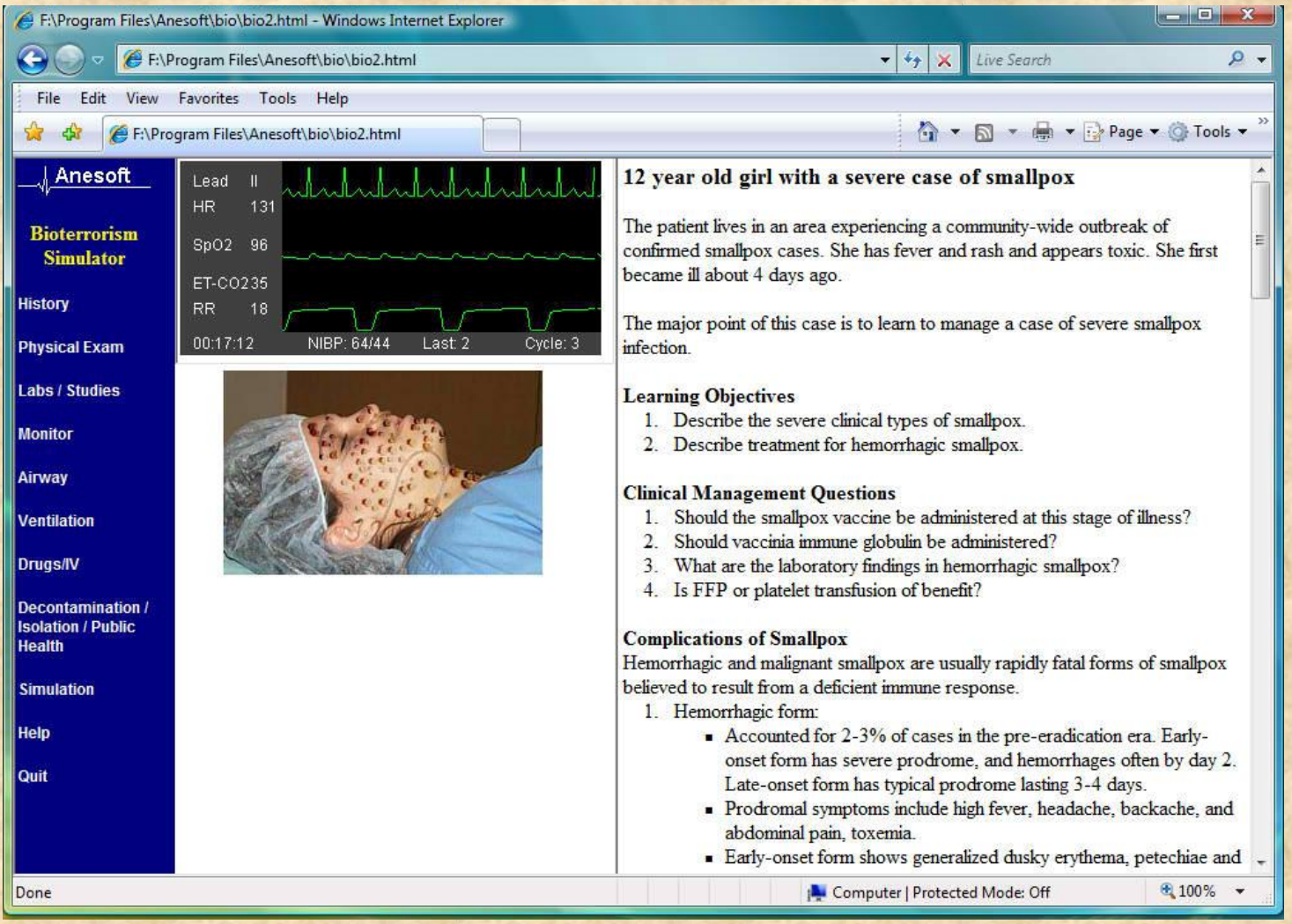
1. Rykkvin R, Kilander A, Dudman SG, et al. Within-patient emergence of the influenza

A(H1N1)PDM09 HA1 222G variant and clear association with severe disease, Norway. *Eurosurveillance*. 2013;18(3):pii-20369. http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20369. Accessed January 22, 2013.

Bioterrorism Simulator

Source: http://anesoft.com/bioterrorism-simulator.aspx

Improve your management of patients exposed to biological or chemical agents



Works on Windows and Macintosh

- 24 patient exposure scenarios, including:
  - Anthrax
  - Botulism
  - Ebola
  - Plague
  - Smallpox
  - Nerve agents
  - Toxic agents and vesicants
- Useful for physicians, nurses and first-responders
- Designed in conjunction with infectious disease and military experts
- Demonstrate proficiency for Joint Commission

- Earn up to 12 AMA PRA Category 2 CME credits

Easy to use real-time simulator

- Recognize the signs and symptoms of each exposure.
- Order appropriate isolation and decontamination
- Order and interpret the appropriate lab studies
- Manage the patient's cardiopulmonary status
- Order appropriate medications

Bioterrorism Preparedness – The Forgotten Patient Population

Source:http://globalbiodefense.com/2013/02/05/bioterrorism-preparedness-the-forgotten-patient-population/?goback=.gde_3711808_member_211359636

*Contributing author **Saskia van Rijn**, MPH highlights the gaps in hospital bioterrorism preparedness for the pediatric population and the crucial need to address the unique care paradigm of these patients in emergency planning.*

Bioterrorism and preparedness have been highlighted topics since the 2001 "Amerithrax" attacks. The reality that the United States is particularly vulnerable to these attacks, while not a new notion, has become increasingly sensationalized in the media. The forefront to these initiatives, apart from prevention, is patient care and first responders. Hospital preparedness is being considered a source for vulnerability, which has ignited agencies like CDC's National Bioterrorism Hospital Preparedness Program and the Hospital Preparedness Program (HPP) on a national level. Federal funds are trickling down via FEMA, DHS, and state health departments, aiding hospitals in their efforts to become better prepared for emergency situations. While these efforts are appreciated, there is a residual effect being seen across hospitals. The general issues identifying bioterrorism agents, communication, and pediatric care is slowly being realized.

Bioterrorism preparedness is by no means, a novel concept, but the involvement of hospitals has started to reveal a great deal of vulnerability within the public health system. Since hospitals are most likely to see the first wave of cases, their ability to detect, respond, and communicate this information is crucial. The unfortunate reality is that detecting these cases of Category A agents is extremely difficult. Aside from the diagnostic hurdles, most of the medical guidelines and emergency response protocols for disaster situations are adult specific.

The Arizona Department of Health Services recently hosted a hospital preparedness workshop. While informational and extremely beneficial, it became obvious that the protocols in place are directed at the adult patient, not the pediatric. Firstly, pediatric patients require specific medical attention, they are simply not "little adults". Stankovic *et al.* emphasize that children are particularly vulnerable to biological agents, as they have higher respiratory minute volume, larger surface area to body mass, smaller blood volume, and are unable to fully communicate their symptoms given limited cognitive and motor skills.[1] The difficulty communicating symptomology is highlighted by Place *et al.*, stating that this may greatly impact screening and triage capabilities for physicians.[2] A 2004 study performed in Washington D.C. assessed the ability for physicians to correctly diagnosis category "A" agents in patient cases. The investigators found that 50.7% were able to correctly diagnose smallpox, 70.5% anthrax, 49.6% botulism, and 16.3% plague.[3] Interestingly, after the first testing, a training module was given, which led to an increase in correct diagnosis by about 70%. While this was not aimed at pediatric patients, it highlights several things; recent bioterrorism attacks emphasize knowledge regarding pertinent pathogens, educational workshops are beneficial, and communicable diseases appear to have lower diagnoses. From an epidemiological standpoint, each pathogen presents and is transmitted in such a diverse manner, any delay in identification would be detrimental to care and isolation.

The range of patients in a pediatric hospital is extremely diverse. A neonate in an intensive care unit may

be on ECMO (extracorporeal membrane oxygenation), which requires constant supervision and during transport, up to 6 specific health professionals. Secondly, pediatric patient have the "family component". Adult patients may have a spouse or children with them, but in pediatric cases, it is very common to have an entire family present. Pediatric patients have larger groups accompanying them for support and medical decisions, thus making their transport and movement more time consuming and burdensome. A large visitor population poses concern for exposures, as well as supplies. Lastly, the current supplies and protocols in place are for an adult population. During the aforementioned training, it was noted that for every 100 beds/stretchers available, only 1-2 were pediatric capable.

Pediatric care is uniquely complex, in that this is an entirely separate population of patients that need to be treated with specialized care. Given the complexities that have been demonstrated with identifying bioterrorism agents in children, the vulnerabilities and lack of specialized support for pediatric hospitals in emergency situations particularly biosecurity threats, are astounding. Hospitals seek to prevent exposures and outbreaks, but like most things in public health, it is very downstream. Active surveillance depends upon physician diagnosis and lab detection, all of which take time, especially with a patient population that may not be able to communicate their symptoms.

Hospitals are uniquely vulnerable in emergency situations, especially bioterrorism events. Given their role as first responders for the initial wave of patients, their ability to identify and respond to these events is crucial. Pediatric hospitals are especially vulnerable to these disasters, as children are a highly susceptible patient population during bioterrorism events. The current protocols and initiatives in place, while aiming to close the gaps of communication, fail to focus on the unique needs of a patient population that has limited diagnostic guidelines in place, as well as difficultly communicating their symptomology. Epidemiological and preparedness groups focus on either material management, disease characteristics, whereas a combination of the two, with focus on the uniqueness of certain patient populations, would provide a strong foundational response and prevention system. Current emergency response and preparedness methodologies are generally lacking in the pediatric capabilities. It is crucial to incorporate hospital pediatric patients and their unique needs into preparedness protocols, especially in biosecurity plans.

References:

[1]Stankovic C, Mahajan P, Hong Y, Dunne R, Knazik S. Evaluating the Preparedness of Pediatricians in Michigan. *Pediatric Emergency Care*. 2009. 25(2).

[2] Place R, Hanfling D, Howell J, Mayer T. Bioterrorism-Related Inhalational Anthrax: Can Extrapolated Adult Guidelines Be Applied to A Pediatric Population? Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. 2007. 5(1).

[3]Cosgrove S, Perl T, Song X, Sisson S. Ability of Physicians to Diagnose and Manage Illness Due to Category A Bioterrorism Agents. *Arch Intern Med.* 2005;265:2002-2006.

[4]Veltri K, Yaghijian V, Morgan-Joseph T, Prlesi L, Rudnick E. Hospital emergency preparedness: Push-POD operation and pharmacists as immunizers. *J Am Pharm Assoc.* 2012; 52:81-85.

[5] Bravat, *et al.* Pediatric Anthrax. *Evidence Reports/Technology Assessments*. 2006. 141.

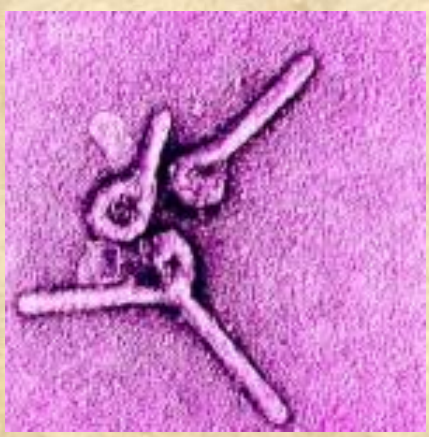
[6]Centers for Bioterrorism Preparedness Planning Pediatric Task Force Initiative. Hospital Guidelines for Pediatric Preparedness. 2008. 3rd edition.

Canadian Study Shows Airborne Transmission of Ebola

Source:http://globalbiodefense.com/2012/11/19/canadian-study-shows-airborne-transmission-of-ebola/#more-3136

Breakthrough research from the Canadian National Centre for Foreign Animal Disease and the National Microbiology Laboratory has raised concerns about possible airborne inter-species transmission of the deadly Ebola virus.

The researchers demonstrated transmission of the Zaire strain of Ebola from pigs to macaques without direct contact between them. Pigs inoculated with the Ebola virus were kept physically separated but in close proximity to the monkeys, all of which contracted the illness.



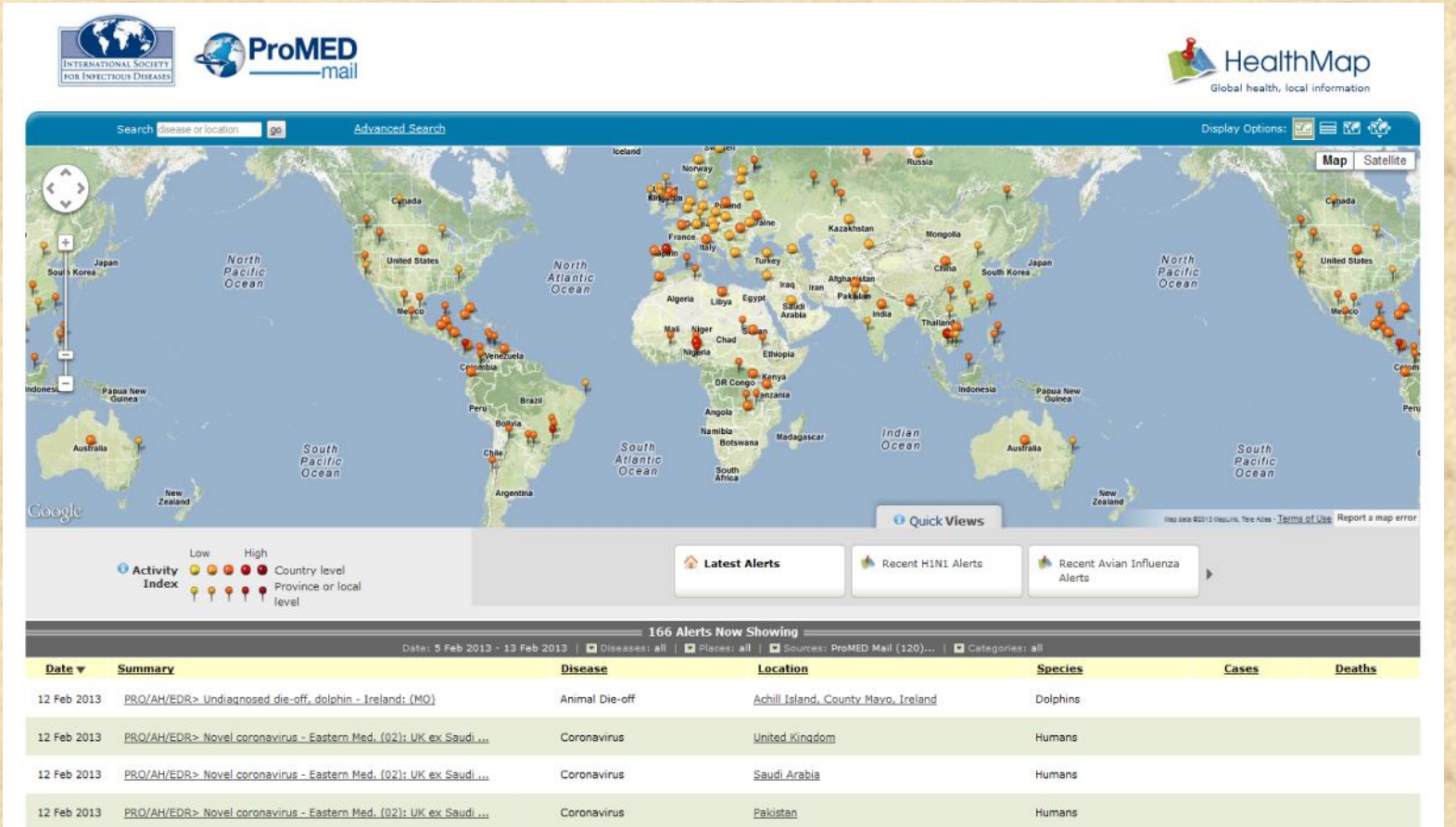
"What we suspect is happening is large droplets – they can stay in the air, but not long, they don't go far," states Dr Gary Kobinger of the National Microbiology Laboratory at the Public Health Agency of Canada. "But they can be absorbed in the airway and this is how the infection starts, and this is what we think, because we saw a lot of evidence in the lungs of the non-human primates that the virus got in that way." The statements were made in response to questions from *BBC News*.

While primates develop systemic infection associated with immune dysregulation resulting in severe hemorrhagic fever, the Ebola infection in swine appears to primarily affect the respiratory tract, implicating a potential for airborne transmission. The researchers are concerned that pigs might be a natural host for the lethal virus and that limited airborne transmission might be contributing to the spread of the disease in some parts of Africa.

Surveillance system identifies, tracks emerging infectious diseases

Source: http://www.homelandsecuritynewswire.com/dr20130211-surveillance-system-identifies-tracks-emerging-infectious-diseases

A team of researchers has developed a method to identify the cause of infectious disease outbreaks based on online reports about the symptoms, the season, and the ratio of cases to fatalities. Using data from the Internet outbreak reporting system ProMED-mail, the researchers applied this method to more than 100 outbreaks of encephalitis in South Asia, recently identified as an emerging infectious disease "hotspot," to



determine which of ten infectious diseases was causing symptoms of encephalitis, and whether Nipah — a serious emerging infection — could be reliably differentiated from the others.

A release from the Columbia University's Mailman School of Public Health reports that the findings showed that three quarters of the disease outbreaks formed distinct clusters, and that previously unknown disease outbreaks could be correctly identified 88 percent of the time. For Nipah virus encephalitis that number rose to 100 percent.

Results of the study are published in the *Journal of the Royal Society, Interface*.

Particularly noteworthy according to author Dr. Stephen S. Morse, professor of Epidemiology at Columbia University's Mailman School of Public Health and an originator of ProMED-mail, was that unknown outbreaks in resource-poor settings could be evaluated in real time, leading to more rapid responses and reducing the risk of a pandemic. The model provides a quick and inexpensive means to assess outbreaks and allows for the tracking of infectious disease outbreaks in the earliest stages of an epidemic.

"Our approach is especially beneficial in resource-poor countries because of their limited surveillance capacity and lack of laboratories to diagnose unusual outbreaks," said Dr. Morse, who is also founder of ProMed. "Such countries are often where new infectious diseases emerge."

The study was supported by USAID Emerging Pandemic Threats PREDICT and by the National Institutes of Health.

— Read more in Tiffany L. Bogich et al., "Using network theory to identify the causes of disease outbreaks, of unknown origin," Journal of the Royal Society Interface 10, no. 81 (6 April 2013) (published online: 6 February 2013)

Monoclonal Antibodies for Biodefense

By Gigi Kwik Gronvall, PhD

Source: http://www.upmc-biosecurity.org

Monoclonal antibodies (mAbs) have become a blockbuster drug platform with the biggest portion of sales growth in the pharmaceutical industry.[1] Nearly all large pharmaceutical companies have at least one mAb-licensed product and more candidates in their pipelines. However, the concentration of effort in mAb development has been to address oncological indications and immunological diseases, such as rheumatoid arthritis (RA).[2] For infectious diseases, there are just 2 licensed mAbs: one for prevention of respiratory syncytial virus (RSV) in premature babies and another recently approved to treat inhalational anthrax.

A Larger Role in Biodefense

Now the Center for Biosecurity has released a report in which the case is made for a larger role in biodefense for mAbs.[3] For Department of Defense personnel, in particular, and other special populations, the possibility of using mAbs that target traditional bioweapons agents offers great promise. mAbs have several advantages that other medical countermeasures do not: they provide near-instant immunity regardless of prior immune status, immunity is not permanent, the rate of adverse reactions is relatively low, and the pathway to development may be faster as compared with vaccines or small-molecule drugs.

One of the challenges to using mAbs for medical countermeasures is that they are specific and require a specific disease diagnosis. A mAb that targets botulinum toxin, for example, cannot be used to treat a tetanus infection. In contrast, broad-spectrum antivirals and antibiotics do not require specific diagnoses. Further, the broad-spectrum therapeutics tend to be more effective than mAbs later in the course of disease.[4] In spite of the current lack of commercial attention to mAbs for infectious disease, there are a number of reasons to believe they may be more desirable in the future.

Post Antibiotic Era Treatments

The increased prevalence and rising costs of treatment for methicillin-resistant *S. Aureus* (MRSA) and resistant nosocomial and community-based infections have prompted experts to declare that we are entering a "post-antibiotic era."[5,6] The commercial pipeline for new

classes of antibiotics is not projected to offer a solution to this problem any time in the near future, which necessitates development of alternative approaches to treating infectious diseases.[4]

Treatment for Immunocompromised People

There are at least 10 million people in the United States (3.6% of the population) who are considered immunocompromised.[7,8] This has implications for treatment of naturally occurring infections and for response to a biological attack, as this population may be more adversely affected and may not benefit from vaccination. Conceivably, a mAb could provide protection for this population without exposing immunocompromised people to the risks of live virus vaccines.

More Effective Prophylaxis

Many childhood diseases are not confined to children, and mAbs may be beneficial as treatment or post-exposure prophylaxis for exposed adults.[9] For example, adults who have not been vaccinated against pertussis in many years may benefit from a mAb to boost their immune response if they are at risk for whooping cough.[10] With mumps, there is diminished herd immunity, leaving college students particularly at risk.[11] Influenza vaccine is less effective for the elderly, who are more likely to suffer the effects of the disease.[12] For all of these diseases, a mAb may be more effective than vaccine as prophylaxis or to aid those who have become infected or are at risk of developing the disease.

Protecting the Microbiome

There is increased scientific understanding of the health maintenance role of the microbiome--the collection of microbes that live in or on the human body, including in the gastrointestinal tract, mouth, skin, nose, and urogenital tract.[13] However, the microbiome is disrupted by broad-spectrum antibiotics, which kill many microbes, alter the body's ecosystem, and affect health. There is evidence that alterations of the microbiome may contribute to disease and even to obesity.[14] As these disease pathways become better understood, reluctance may grow to using broad-spectrum antibiotics as a first-step prophylaxis.[4] A specific medical countermeasure, such as a mAb, may protect the microbiome while limiting an infection.

Increased Availability of Diagnostics

In contrast to broad-spectrum antibiotics, the specificity of mAbs requires a diagnosis of disease before treatment. This has been a clear barrier in the past, but recent government efforts to develop and promote diagnostic tests for infectious diseases may allow the more widespread use of mAbs for early treatment of disease.[15] If diseases are diagnosed routinely and quickly, there may be more opportunities to use a specific medical countermeasure such as a mAb, and more commercial interest in providing specific therapeutics.

Improvements in Environmental Detection

Fielded environmental biological detection capabilities offer more rapid recognition of biological agent exposures than has been available in the past. These detection systems are increasing the range of agents that can be detected and are decreasing the time from collection to identification and confirmation. Faster identification of exposures could boost the effectiveness of a mAb therapy.

Regulatory Allowance of Cocktails

There is some evidence that mAbs are more effective against infectious diseases when administered as a cocktail--a mix of 2 or more mAbs administered at once.[4] However, if each mAb in a cocktail had to attain FDA licensure individually, the burden and cost of clinical testing would be prohibitive. The FDA has allowed one combination product, a cocktail of mAbs against rabies (developed by Crucell/Sanofi and currently in phase II clinical trials) to be tested and regulated as one product.[16] This approach will be advantageous for licensing mAbs for other infectious disease that require multi-mAb treatment.[4]

The Center for Biosecurity of UPMC conducted this study to provide leaders in the US Department of Defense with an expert assessment of the technical feasibility and strategic implications of next-generation monoclonal antibodies as medical countermeasures for DoD personnel. The full report includes recommendations for potentially appropriate DoD investments in mAb technologies.

References
1. Datamonitor. Monoclonal Antibodies: 2010. October 7, 2010.
2. Nelson AL, Dhimolea E, Reichert JM. Development trends for human monoclonal antibody therapeutics. *Nat Rev Drug Discov*. 2010;9(10):767-774.
3. Gronvall GK, Rambhia KJ, Adalja AA, Cicero A, Inglesby T, Kadlec R. *Next-Generation Monoclonal Antibodies: Challenges and Opportunities*. 2013. Available at http://www.upmc-biosecurity.org/website/resources/publications/2013/2013-02-04-next-gen-monoclonal-antibodies.html.
4. Saylor C, Dadachova E, Casadevall A. Monoclonal antibody-based therapies for microbial diseases. *Vaccine*. 2009;27 Suppl 6:G38-46.
5. Alanis AJ. Resistance to antibiotics: are we in the post-antibiotic era? *Arch Med Res*. 2005;36(6):697-705.
6. The 10 x '20 Initiative: pursuing a global commitment to develop 10 new antibacterial drugs by 2020. *Clin Infect Dis*. 2010;50(8):1081-1083.
7. Kemper AR, Davis MM, Freed GL. Expected adverse events in a mass smallpox vaccination campaign. *Eff Clin Pract*. 2002;5(2):84-90.
8. Kahn LH. The growing number of immunocompromised. *Bull At Sci*. January 6, 2008. Available at http://www.thebulletin.org/web-edition/columnists/laura-h-kahn/the-growing-number-of-immunocompromised. Accessed August 22, 2012.
9. Weinberger B, Herndler-Brandstetter D, Schwanninger A, Weiskopf D, Grubeck-Loebenstein B. Biology of immune responses to vaccines in elderly persons. *Clin Infect Dis*. 2008;46(7):1078-1084.
10. Gidengil CA, Sandora TJ, Lee GM. Tetanus-diphtheria-acellular pertussis vaccination of adults in the USA. *Expert Rev Vaccines*. 2008;7(5):621-634.
11. Barskey AE, Glasser JW, LeBaron CW. Mumps resurgences in the United States: A historical perspective on unexpected elements. *Vaccine*. 2009;27(44):6186-6195.
12. Osterholm MT, Kelley NS, Sommer A, Belongia EA. Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. *Lancet Infect Dis*. 2012;12(1):36-44.
13. The Human Microbiome: Me, myself, us. *The Economist*. 2012. Available at http://www.economist.com/node/21560523. Accessed September 10, 2012.
14. Zimmer C. Tending the Body's Microbial Garden. *The New York Times*. Science. June 19, 2012. Available at http://www.nytimes.com/2012/06/19/science/studies-of-human-microbiome-yield-new-insights.html?pagewanted=all. Accessed August 22, 2012.
15. Jennifer B. Nuzzo, Kunal J. Rambhia, Samuel B. Wollner, et al. *Diagnostics for Global Biosurveillance: Turning Promising Science into the Tools Needed in the Field*. Center for Biosecurity of UPMC; September 2011.
16. Crucell. *Developing a Rabies Antibody Combination*. 2012. Available at http://www.crucell.com/R_and_D-Clinical_Development-Rabies_Antibody_Product. Accessed August 21, 2012.

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Southern California Plans Defenses against Bioterror Attack

By Leslie Evans

Source: http://www.international.ucla.edu/article.asp?parentid=1917

► Editor's Note: Although this is a 2002 paper, it contains some very interesting information!

More than 200 doctors, state and local officials, police, hazardous materials specialists, germ warfare scientists, and scholars met at the University Synagogue in West Los Angeles for a two-day conference May 29 and 30 on how to prepare for the threat of bioterrorist attacks. Participants ranged from the top State of California and Los Angeles County officials in charge of crisis management in the event of an attack to the chief Russian and American scientists who had run each country's bioweapons programs until they were shut down some decades ago.

The conference was sponsored by Center of Medical Multimedia Education Technology (COMMET), and cosponsored by UCLA's Burkle Center for International Relations as well as several other concerned groups including the Los Angeles Terrorism Early Warning Group (TEW).

"There have been major disturbances in the 'force.' The Oklahoma City bombing, the first World Trade Center bombing in 1993, sarin gas in Tokyo. We are witnessing a paradigm shift, a period of global instability: Eastern culture vs. Western, rich vs. poor, Judeo-Christian vs. Muslim, America lovers vs. America haters."

Peter Katona

The conference was chaired by Dr. Peter Katona, assistant professor of Clinical Medicine at UCLA and a member of the Los Angeles County Bioterrorism Task Forces. In his opening remarks Katona noted that "fanatics have always been around, but today there are new technologies, and a new religious fervor that lacks the constraints of previous decades."

He noted that only 2% of 14,000 cargo containers entering the United States every day are inspected. That 15-20 of about 100 potential microbial agents have actually been developed, and 18 countries have them. "They are very cheap to produce compared to nuclear weapons."

"There have been major disturbances in the 'force'": The Oklahoma City bombing, the first World Trade Center bombing in 1993, sarin gas in Tokyo. We are witnessing a paradigm shift, a period of global instability: Eastern culture vs. Western, rich vs. poor, Judeo-Christian vs. Muslim, America lovers vs. America haters."

Katona pointed out that diseases, even when not deliberately spread, have had a devastating impact in the past, greater than any war. Most people know about the Black Death in Europe in the 14th century, that killed 25 million people, or the smallpox Cortez gave to the Aztecs in Mexico, that killed 4-7 million. But how many have heard of Justinian's plague, that killed 100 million in Asia minor and southern Europe in the 6th century, or the native-based hemorrhagic fevers in Mexico that killed up to 80% of population--12-15 million--a generation after Cortez?

Smallpox is a prime candidate for deliberate terrorist use. It was eradicated by the World Health Organization in 1967-1977. The last recorded case in the world was in 1977 in Somalia; the last case in the United States was in 1949. In the Middle Ages a quarter of the population was killed by smallpox, and as late as 1951, 64,000 died of it in India.

Peter Katona pointed out how the fear of bioterrorism far exceeds its actual impact: 4 letters, 22 cases of anthrax, and 5 deaths created public health chaos. Tens of thousands of courses of antibiotics were prescribed, there were massive decontamination headaches, and lots of money was spent, all without any of the mass deaths that this kind of bioagent is capable of.

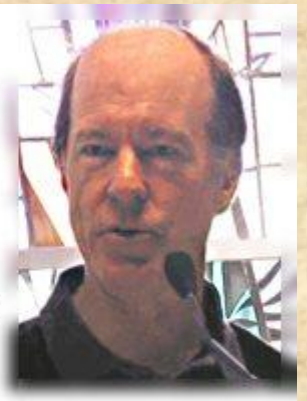
Thus far the countries that have bioweapons have been reluctant to use them. Japan in 1936 to1945 had a bioweapons program and killed 3,000-5,000 U.S. POWs with anthrax. Russia had enough anthrax to kill the whole population of the earth, but never used it. Iraq had 19,000 liters of botulinum toxin and 8,500 liters of anthrax, but didn't use them for fear that the United States or Israel would use nuclear weapons on Baghdad. The United States has not used biological weapons against humans, but it has killed half a million Cuban hogs with bioweapons, Katona reported. Washington ran an offensive biological program until 1969--and one of the leading scientists who operated it, Bill Patrick, spoke at the conference.

More ominously, with the democratization of technology, its cheapening to the point that small groups or even individuals can afford it, entities less accountable than states are coming into posession of biological warfare materials. "The Aum Shinrikyo cult in Japan used chemical, not biological, weapons in their sarin gas attacks on the Tokyo subway. But they also purchased a ranch in Australia to experiment with biological agents," Dr. Katona told the conference. "They had tried to use anthrax but they were unskilled. They tried to kill a judge by shooting anthrax into his apartment from the next building, but the attempt failed." It is presumed that private terrorist groups such as Al Qaeda are capable of purchasing or developing infectious agents that can be used for attacks in the United States. How to prevent this, or how to respond if prevention fails, was the business of this meeting.

Gregory Treverton: The Typology of the New Terrorist

The first speaker of the day was Gregory Treverton, a senior policy analyst at the RAND Corporation, who has worked with the Senate Select Committee on Intelligence, the National Security Council, and has been vice-chairman of the National Intelligence Council.

"In the 1970s and 1980s the terrorists were secular, they had an agenda to negotiate. Bin Laden's aims are so apocalyptic that they cannot be negotiated. We have seen a shift from secular-political to apocalyptic, from defined, limited purpose, want something, to very grand purposes or revenge, from violence for stun but limited, to no limit on violence."



Gregory Treverton

We were taken by surprise on September 11, he said, despite some advance warning from intelligence agents, because interpreting data depends on the current mind set. "We were looking for bombs on planes, not planes as bombs. Even those of us who wrote terrorist scenarios really didn't think the terrorists would do it. We had relatively happy endings to previous terrorist attacks. The worst things that could happen didn't. So we didn't see the evidence of the people in flight schools. It is easier to see it in hindsight."

Terrorism is the tactic of the weak against the strong. "Hence it is asymmetric," Treverton said. "It involves the deliberate targeting of noncombatants. It seeks a stun effect, terrorism as theater." Terrorism is an element in many conventional struggles. "There is a continuum, not a sharp break, the context does matter. One person's terrorist is another's freedom fighter."

Still, there is something new in the current generation of terrorists. "In the 1970s and 1980s the terrorists were secular, they had an agenda to negotiate. Bin Laden's aims are so apocalyptic that they cannot be negotiated. We have seen a shift from secular-political to apocalyptic, from defined, limited purpose, want something, to very grand purposes or revenge, from violence for stun but limited, to no limit on violence."

Understanding our adversary is key: "We need to not turn them into cardboard characters. Bin Laden is a good manager and charismatic, very patient, he learns from his failures. Remember that World Trade Center 1 was 8 years earlier. He had ABC teams: The A team hit on September 11. His B teams were turned loose with some money to free lance--perhaps Reid the shoe bomber. The C teams received venture capital, to fund initiatives from other terrorists. Al Qaeda has sent money to other terrorists to go out and do bad things."

Treverton examined possible responses to the terrorists. He suggested 4 possibilities: Accommodation, punishment, blocking recruitment, and increased surveillance.

"First is **accommodation.** This is a nonstarter. There is no way to accommodate the objectives of the present terrorists."

Punishment. "Perhaps this is also a nonstarter. If it only creates martyrs then it plays into the hands of the terrorists. Courts and jails have little effect and they are costly and time consuming. Then there is punishment for harboring terrorists. This can be counterproductive in the case of many states that may do so unwillingly. It can be accompanied by a carrot to help them build more open societies."

Possible **block points.** "We could try to cut off recruiting. This is inherently hard. While the source of recruits is not infinite, it is large, even in the United State. It is said we should work on the sources of terrorism, but this is iffy and very long term. For example, improving the position of women in the Arab world can result in more Arab men ready to get on airplanes and crash into our buildings."

Monitoring movement of new recruits can be more promising. "We can watch their bases and staging areas. The European staging areas were very important, not only the camps in Afghanistan. Are there U.S. equivalents? Apparently not yet. Afghanistan will be a powerful lesson. But it was as much co-opted by Al Qaeda as having decided to harbor it. We will need to have a long-term presence in the area as a carrot."

Treverton pointed to sensitive issues in attempting to monitor potential terrorist staging in the U.S.: "There are concerns about civil rights in monitoring. Profiling. The key is looking for combinations of people and activities, especially outside the box. This raises thorny issues.

Our existing capacity is very weak-- giving Mohammad Atta a visa after he was a martyred terrorist is one example."
This is new terrain for us as a nation, he said. "Past successes set us up to fail now. Distinctions such as foreign vs. domestic are more problematic today. The CIA is barred from domestic intelligence and law enforcement. This worked fairly well during the cold war but doesn't work well now. In late August the CIA sent a cable saying 2 of the (later) hijackers were in the country. The FBI said, what should we do about it? The FBI didn't do much. No one told the FAA to look for them, since it is not a law enforcement agency. No one told the airlines, since they are private companies, not government."
Treverton said that he expected little useful to come from Office of Homeland Security headed by Tom Ridge. "The fate of all government czars is to have enormous responsibility but no authority and very little budget. They have a bully pulpit but nothing more. If this is serious it should be made a cabinet post."
Gregory Treverton was asked a question much on the minds of many Americans: "Should the U.S. be more sensitive to injustices and inequalities that promote hatred abroad?"
"Yes," he replied, "but this is very long term. And it is difficult to untangle the elements. Some of the hatred against Americans is because we are top dog. Some is also a clash of civilizations. Some of this comes from a general resentment because of a number of bad centuries for Islam, going back to declines and defeats that we could not possibly have been responsible for."

Miriam Cotler: The Ethics of Counterterrorism

Miriam Cotler is chair of the Department of Health Sciences at California State University, Northridge. "I have been teaching medical ethics for 17 years," she said as introduction some moral questions: "How can we counter terrorism ethically? Given terrorist attacks, why shouldn't we violate our own laws in order to win?"

Miriam Cotler

"We are a nation of laws and due process. It is our strength, not our weakness. There is always a temptation to invoke security as a reason to abridge liberty."

Answering her own questions, Cotler said that some acts are permissible under some circumstances, but some are morally wrong and should never be committed. "This is unlike a war. In a real war there are rules of engagement, we have expectable behaviors, we know who the enemy is, there are rules to not kill civilians, and even though this is often broken, it is the rule that is supposed to govern war."
Terrorism, she said, "is always a violation of law and of the rules of war. Terrorists do not want to coexist. They do not differentiate the innocent from the enemy. They are for their good but do not recognize our good. So there is no basis for negotiation. This makes them criminals. But countering them is a slippery slope -- a little bit of this and a little bit of that. How do we define the boundaries?"
Cotler suggested that there is a Western bioethical health model. It begins with the recognition that we are "a society of moral strangers. We come from different ethnic, religious, and ethical beliefs. There is not a commonly shared moral standard. Our rules are designed to honor the individual while letting the institution function. In medicine this includes informed consent, reporting requirements, the right of people to give permission to be touched. The relation between human rights and patients' rights is obvious to those of us involved in medical practice."
Public health involves both protections of individuals and protections of society. "When should someone's driving privileges be revoked? When should businesses be closed as a public hazard? Courts ruled that public interest overrode the right to refuse to be vaccinated. This precedent was later used to justify sterilization of a woman erroneously diagnosed as an imbecile.... We have not much progress where community and individual rights differ."
War raises these issues to a different, more violent, level. "In war soldiers have a right to kill. The rules are about how and who they should kill. A basic rule is, kill if you have to but don't

inflict unnecessary suffering. Soldiers are instructed not to kill civilians. These rules have as their purpose the ability to resume normal relations after the war. Terrorism is different. Its aim is annihilation and its goals do not include peaceful coexistence after the struggle. There is no acknowledged need to live together. There is no prospect of living together in peace in the future."

Bioterrorism is unusual in that countering it requires cooperation between the criminal justice system, a law enforcement agency, and the public health system, which is not.

"At one extreme there is good intelligence, cooperation between agencies. We also look to employ an effective spy network able to respond promptly. We need to be able to retaliate quickly to destroy infrastructure.

"At the extreme other end are detainment of persons, searches without authorization, trials without legal safeguards. We have seen noncitizens detained without due process. Terrorists seek to provoke such extreme reactions. It is unwise for us to suspend civil liberties. We need to counter terrorism with the pubic health model."

The Emergency Health Powers Act of October 2001 states that a declaration of an emergency by a state government can place all medical facilities under state control. "It also criminalizes refusal to be tested. Authority under this act is much too broad. Health care professionals, not political functionaries, are trained to handle medical emergencies. There should be a new cooperation but this law is one way only."

One problem with mandatory treatment, Colter said, is that many of the most vulnerable who do not want to be compelled to accept treatment just disappear, with the opposite of the result intended.

When Is Torture Justified?

Cotler examined the reasons why torture might be justified in trying to stop a terrorist attack. "Alan Dershowitz has advocated the right of the state to use torture in terrorism cases. Suppose you know that a bomb is about to go off and you have detained suspects who could tell you where it is? Do you torture them?"

Cotler says no. "Don't make this decision based on whether or not it will work. First, this is the rationale of torturers everywhere. It falsifies the problem. Having done it once, you are soon asked to repeat the act. Soon it becomes commonplace. How can we protect people from excesses if torture warrants are issued? How does the judge know how much torture is enough?"

The ticking bomb theory assumes the suspect will talk. "They may not do so. They may be ready to become martyrs. Torture becomes a means of spreading fear, not gathering information. It will lose us the war for legitimacy. Over time torture means losing empathy for our victims and our souls die. We are a nation of laws and due process. It is our strength, not our weakness. There is always a temptation to invoke security as a reason to abridge liberty."

The Makers of the Plague

In the course of the conference two of the scientists most responsible for creating the agents of "germ warfare" offered their secrets on what bio agents are, how they are made, and what they can do. These were Kenneth Alibek (nee Kanatjan Alibekov), former First Deputy Director of Biopreparat, the Soviet offensive bioweapons program, and Bill Patrick, his American counterpart, former head of product development for the U.S. offensive biological weapons program. Their reports were equally chilling.

Kenneth Alibek

"If used in an explosive anthrax will produce an infected zone, with a wider contaminated zone. In case of plague, the infected zone is followed up by additional new infection zones. Not everyone in the zone gets infected. In the case of smallpox, however, it is highly contagious. There would be a huge number of secondary foci, and the great majority in the aerosol cloud will get infected."

Kenneth Alibek: From Plaguemeister to the Search for a Universal Antidote

Ken Alibek spoke on the first day. Now a mild-mannered professor of microbiology at George Mason University, he once headed the operations side of the supersecret Soviet biological warfare program. He worked under the sinister General Kalinin. The American biowarfare program was ended in 1969 by Richard Nixon. The Soviets responded by making their efforts more secret. One of Alibek's coworkers was murdered when he tried to quit, and this was after the collapse of USSR in 1991. Alibek visited the United States shortly afterward and had the opportunity to see first hand that the U.S. program was really dead--something strongly denied by his superiors in Russia. At great personal risk, Alibek then went public with revelations about the secret Russian installations, forcing Yeltsin to admit the existence of the program. Hundreds of tons of bioweapon material were destroyed and the majority of facilities have been verified to have been closed down. But General Kalinin remains an active figure in Russia and some Russian facilities have not been inspected. More worrisome, some 6,500 Russian bioweapons technicians and scientists left the project and have gone on to other jobs. They remain a potential talent recruitment pool for well-financed terrorist groups in other countries.

Alibek began by enumerating six types of biological agents that can and have been weaponized: bacterial, viral, rickettsial, fungal, toxins, and bioregulators. Examples of bacterial agents include bubonic plague, Ebola, and hemorrhagic fever. Viruses include smallpox. Rickettsial diseases include louse-borne typhus fever. Toxins include botulism. Bioregulators are less common as potential weapons. The Soviet Union tried to weaponize certain neurotransmitters, which can suppress particular reactions. The actual stable of Soviet bio weapons included smallpox, plague, anthrax, Q fever, Marburg, tularemia, glanders (a bacterial disease of domestic animals, weaponizable because it requires very few organisms to produce an infection), and VEE (Venezuelan equine encephalitis, an alphavirus).

Tularemia, glanders, and VEE were operational and meant for use close to front lines. They were not meant to kill but to incapacitate enemy troops.

"Anthrax," Alibek said, "was developed by the USSR in huge amounts. Q fever was produced until 1990, after which it was replaced by Marburg." Marburg is a hemorrhagic filo virus, similar to Ebola.

Alibek divided bio weapons into dry and wet types, as the delivery systems for the two are quite different. Among dry varieties he listed tularemia (a bacterial infection transmitted by a very small number or organisms, which can be but usually is not fatal), anthrax, brucellosis (a bacterial infection of farm animals), and Marburg.

Liquid types are mainly smallpox, plague, a wet version of anthrax, and VEE.

"Dry weapons are more effective," Alibek declared. "They can be stored for long periods of time, and have a low decay level. But dry is more difficult to manufacture. Liquid is easier to manufacture but difficult to deploy."

Alibek listed the principal means a standing army would use to deploy these materials:

"There can be aviation bombs with biological bomblets for strategic and medium bombers. Or spray tanks installed on medium bombers. Then there are multiwarhead ballistic missiles with bomblet warheads or Cruise missiles with special disseminating devices. Typically a bomblet group contains 100-110 bomblets, each containing half a kilo of payload."

Soviet Capacity for Megadeath

The Soviet biowarfare program, Alibek said, was organized under the Ministry of Defense. It produced a numbing 1,000 plus tons of anthrax annually, of which about 200 tons were usually stockpiled. Some 100 tons a year were produced and 20 tons stockpiled for plague and smallpox. Some 200 tons a year were produced of tularemia; and 100 plus tons each of brucellosis and VEE.

Compared to these quantities, the October-November anthrax attacks in the United States "involved maybe 5 grams of anthrax." Biological weapons, Alibek added without apparent intentional irony, "have a large psychological effect also in terrifying people."

Of all the available bioagents, Ken Alibek felt that smallpox was probably the most devastating. Historically it could kill as much as 30% of the population in an affected area, and even those people today who were vaccinated in childhood have long since lost their immunities.

The most effective way to spread a bio agent, he said, is if it is airborne. Aerogenous infections include anthrax, plague, epidemic typhus, Marburg, and smallpox. "Effectiveness

depends on several factors," Alibek said. "These include choice of agent, deployment method, formulation, and manufacturing process."
Anthrax, though potentially deadly on inhalation, is not contagious between people. In Sverdlovsk in a 1979 accident, 64 people died by direct inhalation. "If used in an explosive anthrax will produce an infected zone, with a wider contaminated zone. In case of plague, the infected zone is followed up by additional new infection zones. Not everyone in the zone gets infected. In the case of smallpox, however, it is highly contagious. There would be a huge number of secondary foci, and the great majority in the aerosol cloud will get infected."
These effects could be compounded if civil authorities were slow to recognize that this was a bioweapon attack. "The target population could be large and poorly defined. The scale may not be immediately apparent. The biological agent used may not be immediately identified. It would take time to identify what agent was used."

Defense against Bioweapons
Ken Alibek laid out steps for defending after an attack. "Technical steps," he said, "include detection, identification, physical protection, disinfection, and vector control: disinsection [eliminating insects pests], and deratization [eliminating potentially infected rodents and other small animals]. On the medical level there is a need for prophylaxis, urgent pre- and post-exposure prophylaxis, and treatment."
Alibek further divided the needed response into several sub steps, which he called scientific, medical, tactical, and logistical. As an example, he took anthrax. "The scientific response is the vaccine. The medical response is to side effects--some people will die from vaccination. Tactically, it must be decided at what time point do we make the decision to vaccinate everybody? It takes multiple shots over six months. Logistically, do we have the capability to manufacture multiple doses for the entire population, that is, billions of doses?"
Clearly it would take a huge number of scientists to make serious preparation for each of the major bio warfare agents that might be used. "It has not happened so far. Now there is about $80 million devoted to this, but it is not enough."
Realistically it may not be possible to prepare against all of the potential agents. "It might take 10 years to develop a vaccine against plague; it might take 15 years to develop a vaccine against Marburg. This could cost tens of billions of dollars and still not guarantee protection, as once a vaccine is developed the terrorists can move on to the next agent for which you do not have a vaccine."

The Universal Antidote
Kenneth Alibek is looking for an end run around this cul de sac. The approach he is studying is nonspecific immune stimulation and immunomodulation. In effect, boosting the immune system to such high defense levels that it can resist almost any bacteria or virus, the universal antidote. "This would also make a contribution in therapy of cancer and sepsis," Alibek said.
With total funding of $15 million he and his collaborators have developed a common defense against anthrax and smallpox, using a biomodulator. "We have reached a 90-100 percent protection. The immune system has specific immunity and nonspecific immunity. If we can modulate nonspecific immunity to the point of eliminating the pathogen it can prevent infection from a wide range of agents. This is something you do in advance; it is not possible as a treatment after infection has happened. We think modulating nonspecific immunities has the greatest promise."
A questioner in the audience then asked if nonspecific immunities could be raised through nutrition without the use of special drugs. Alibek replied that this could be done to a limited degree. "Betacarotine, vitamins B and C, affect the immune system. Selenium and zinc also, among minerals; copper sometimes. If you take them it doesn't say that you can resist all possible pathogens, but when you are older it can re-raise your baseline to what it was when you were younger. The great majority who died of Japanese encephalitis in Europe were elderly with compromised immune systems."

The Anthrax in the Letters
Kenneth Alibek expressed a high level of professional contempt for the skills of the anthrax mailer who hit the Hart Office Building and suggested that the quality of their product was greatly exaggerated by the press. "I was given samples of the anthrax," he said. "It is not true

that only a highly sophisticated lab could produce the quantities used. I know some very primitive production techniques that can produce the large volume of spores that was used in the U.S. mail attacks."

As for the small size of the particles as evidence of weaponization, Alibek suggested that this happened in the Post Office itself after the letters arrived. "There was an additional milling process: it took place in the mail cancellation machine itself as the product went through the rollers. The product at the end was more sophisticated than what arrived in the letter." There was a claim at one point that one of the letters may have come from a different, higher level, source because the particles were smaller. Alibek said of this, "One of the letters was misdelivered, to the State Department, and was run through the roller machine a second time when it came back. Naturally, it contained smaller particles afterward."

Bill Patrick: The Secret of a Good Bioweapon

Although he spoke on the second day of the conference, the comments by Bill Patrick, folksy doyen of the American germ-warfare establishment, really belong here with his Russian counterpart. Patrick is a microbiologist who worked as a central figure in America's bioweapons program from 1951 to 1986. The offensive section of the program was closed down in 1969. He is now a germ-warfare consultant (his business card displays a skull and crossbones). The New York Village Voice refers to him irreverently as Dr. StrangeBug.

Bill Patrick

"Particle size is the key to biological warfare. You have to have small particles.... Why is this? Because the lung has defense mechanisms and you need the right particle size to get past it! You need 5-micron or smaller particles if you are going to infect."

Grandfatherly and gravel voiced, Patrick eschewed the computerized Power Point presentations favored by all of the other speakers. He described himself as a dinosaur as he pulled out a sheaf of hand-scrawled overhead transparencies on the kill radius of various deadly toxins and slapped them down on the old-fashioned projector.

"There are four issues in success of BW [the insider's jargon for biological warfare]," Patrick said for openers. The four are agent, meteorology, munition, and delivery. "In the anthrax letter scare," he said with a chuckle, "delivery and munition were the post office."

The secret of a good bioweapon, he confided to the audience, is in the munition, in the physics of the primary aerosol. "After an initial period of equilibration, large particles fall out. The small particles, 1 to 5 microns, remain airborne and behave as a gas, can enter lungs."

On the whole, he said, there has been a tendency in the past to exaggerate the danger of contamination of an area hit by a bio agent. "Not too long ago the army believed that any object downwind of the aerosol would have to be decontaminated. As long as a primary aerosol is airborne it passes over equipment. They do not need to be decontaminated. You breathe it in because you are a vacuum, an air pump."

Patrick had some suggestions if you are caught outside when a germ warfare attack takes place. He described a test the military conducted with noninjurious spores: "For test subjects standing in the open 100 meters downwind of release, there were large numbers of spores on the nose, but not on their clothes. Unless they are breathed in, particles tend to flow around objects. When the subjects turned their backs to the aerosol and used a handkerchief over their noses, there were no spores around the nose, just one spore on an eyebrow. Turning your back to the aerosol reduces the probability of infection. Using any cloth to breathe through further reduces infection. Five layers of toilet paper is very efficient in screening the primary aerosol. The difficulty, of course, is knowing when the primary aerosol is coming."

The next lesson is that the smaller the particle the more deadly it is. "In the case of tularemia, using 1-micron particles, it takes 2.5 cells of tularemia to kill a guinea pig; a monkey will die with 14 cells; for human, 10-52 cells is an infecting dose, giving a 50% infection rate. As particle size increases, larger numbers are needed. It's the small particles that will get you."

Wherever the primary aerosol has passed through before it settles or disperses, the ground and objects on it are relatively free of particles. "They verified this by having helicopters stir up

the dust after the aerosol passage. When they tested dust raised, they found no secondary reaerosolization of the residue."
Patrick reported another test, 20 miles upwind of naval ships. "There was no contamination on the outside of the ships, but they found high concentrations in the ships' air handling systems for a while, then it dissipated. So there was a spike at the 12 minute mark. Within 32 minutes there was nothing in the atmosphere of the ship. Air handling is very efficient in ships. The aerosol acts as a gas and is dispersed."
Fire fighters, he said, have been told to turn off the air system in a building if an aerosol is suspected. "That's not necessarily a good idea. When we tested with 8 grams of particles in the air handling system of a government building, it built up for an hour and a half, but was cleared out in about 2 hours. There was no residue on walls and surfaces, it behaved as a gas. You should let the air system run to clear the building out."
If the spores came in through a letter, however, "the pattern would be entirely different--it's not an aerosol issue then."

What Happens to Big Particles that Precipitate Out at the Outset?
Bill Patrick described studies in 1950s on inefficient, large-particle aerosols. In one test, 60 liters of contaminant were disseminated in an outdoor area. "They tested one hour after contamination by driving a tractor with a beater through the contaminated area and testing at various heights. They found 67 spores at the 1 foot level, 2 at 3 feet, 1 at 5 feet. There was nothing at any level after 5 hours. Using a denser contaminant, at 60 million spores per liter, contamination at 1 foot at 1 hour was 2,150, at 3 feet 62, at 5 feet, 22. So contamination depends on the density of the original aerosol. Adhesive force binds particles to terrain, which reduces infectiousness." Even denser concentrations are possible, which have a longer dispersal time, but generally aerosol contaminants disperse within 48 hours. This is not true of powders in contained spaces.

The Magic of Freeze Dried Bioweapons
In 1959 it was discovered how to create a freeze-dried powder of agents. Unlike ordinary powders, the freeze dried powders "have secondary aerosol characteristics. They continue indefinitely to be easily blown into new clouds because of their secondary aerosol characteristics. In contrast liquid had almost no secondary aerosol characteristics."
A liquid agent requires a great deal of energy to disseminate, compared to a powder.
"Particle size," Patrick said, "is the key to biological warfare. You have to have small particles." 53 1-micron particles equal just 1 5-micron particle. And not only do you have fewer particles in the same volume, but it takes many more of the bigger particles to infect. The larger the particles, the larger the number of particles needed for infections; at 11.5 microns it takes 23,000 particles to infect a guinea pig.
"Why is this?" Bill Patrick asked rhetorically. "Because the lung has defense mechanisms and you need the right particle size to get past it! You need 5-micron or smaller particles if you are going to infect."

Another Take on the Anthrax Letters
Bill Patrick also had some professional disdain for the press accounts of the anthrax contained in the letters to Senate Majority Leader Tom Daschle and Sen. Patrick Leahy. "They claimed the material was milled to get a smaller particle. You don't mill, because milling causes rough surfaces that lead to reagglomeration!"
As for the claimed improvement in the quality of the anthrax between the Daschle and Leahy letters, "The labs that did the analysis had no experience with biological warfare. Suspending the powder in water, as they did, destroys the integrity of the original agent." Patrick's opinion was that the anthrax in the Leahy and Daschle letters was high quality but not weapons grade, and was produced on a small scale.

How Do You Clean the Stuff Up?
Bill Patrick offered a short film of himself instructing first responders on how to clean up a freeze dried bioagent powder. "This stuff is free flowing, electrostatic free, small particles. It has beautiful flow characteristics." Here is a man who takes pride in his work.

Weapons grade powder, he warned, is very hard to wet, but that is the first step. In the film he demonstrated, first using an ordinary garden hose ("You'd better be wearing protective clothing if you ever have to try this," he cautioned).
As the water hit the powder on the ground it immediately rose into the air in a new dust cloud. He repeated the effort with a little garden sprayer, and finally with a watering can. In each case the dust cloud reappeared, although smaller each time. "Good weapons grade powder is hydrophobic," he concluded.
The way to do it is to prepare a strong soapy solution containing bleach, and to gently lay towels wet with the solution over the powder. "Leave the towels on the powder for 2 hours, then pour more of the solution over the towels, let stand for 2 hours. Now the powder is fully wet."
If the contamination is inside a building, Bill Patrick proposed the use of paraformaldehyde. "Then use a buddy system to decontaminate each other with a garden sprayer with soap and water. The runoff does not need to be captured. The dilution factor in an ordinary drain will take care of the problem."

Dr. Jonathan Fielding: New Initiatives in Disease Surveillance and Preparedness Training for Los Angeles County

The conference got down to the meat of its business with Dr. Jonathan Fielding, MD, Director of Public Health, Los Angeles County Department of Health Services. Fielding reported on the state of preparedness of County medical personnel.

"We have a highly mobile population. We will have challenges. Victims may disperse after an attack. We need to have a strategy to use the news media to alert victims. We have to expect that victims may present at geographically dispersed medical offices and hospitals."

Jonathan Fielding

"Our job is health assessment and epidemiology," he said. "The critical issues are planning, surveillance, and getting an early warning." The County started its Bioterrorism Unit in 1999. It is part of the Terrorism Early Warning (TEW) Group with the FBI and local law enforcement.
"Our first response is likely to be analysis of data to determine if the situation is unusual. If we get a lab confirmation, then we alert the medical community, identify the source of the outbreak and the at-risk persons." Most doctors in Los Angeles have never seen a case of anthrax, smallpox, or plague. "We need to train special response teams," Fielding said. "We have to participate in exercises for different scenarios, develop interagency protocols."
The key first step is the speed with which an attack can be confirmed. "We need to do rapid assessment, rapid confirmation of the agent, then mobilize the laboratories, alert the medical community, the ERs, other labs. Then we have to determine possible quarantine, assess environmental contamination, and access biological stockpiles as necessary."
"We have to maintain pharmaceutical stockpiles and medications," Fielding said. "We must ensure emergency medical support and staff, and know where they are and how to call them to the location where they are needed. We also have to manage hospital diversion during an emergency."
There are 4,000 square miles in Los Angeles County, from very dense to very rural areas. "We have a highly mobile population. We will have challenges. Victims may disperse after an attack. We need to have a strategy to use the news media to alert victims. We have to expect that victims may present at geographically dispersed medical offices and hospitals."

New Levels of Surveillance of Reports of Suspicious Illness

An expected complication is that early signs and symptoms are often nonspecific. The medical and lab community are not familiar with rare bioterror diseases. Fielding reported that the County "has been establishing syndromic surveillance, providing training to increase awareness, enhancing collaboration between the medical community and public health agencies."

The County has set up obligatory reporting on suspicious illness by all County medical facilities, with twenty-four hour a day staffing to receive the reports and initiate a response. They have also established coordination with the coroner to get reports of suspicious deaths.
Four large hospitals are participating in the Volume-based County Hospital Surveillance System. They log visits in 4 syndromes: respiratory (possible anthrax), acute rash with fever, neurologic syndromes, and encephalitis.
"We are also developing a project to look at animal illness and death surveillance," Fielding reported. His agency plans to increase veterinary surveillance through a web-based reporting system. He outlined still more extensive options for data gathering being considered for the future. These include monitoring school absenteeism, 911 calls, and pharmacy dispensing of pharmaceuticals, starting with agents for the treatment of influenza.

Lessons from the Anthrax Letters
Fielding said that his office has drawn a number of conclusions from the national scare around the 4 anthrax letters. "They had an inadequate internal communication system. You need real time communication with most physicians. Further, a public communication strategy is essential, and you have to have fulltime central coordination. We are spending a lot of effort on communication. For example, we are collecting the email addresses of all doctors in Los Angeles County."
The Los Angeles County Department of Health Services is also developing questionnaires that can standardize information received so that it can be quantified rapidly. And they are doing this in many of the languages spoken in the County. They have appointed a full time central coordinator to bioterror preparedness.

Enhancing Preparedness
In addition to knowing when you have been hit, you also have to have materials to respond with and personnel trained in their use. The County authorities have recently enlarged their pharmaceutical stockpiles and decontamination capacity, as well as lab capacity.
"We now schedule regular disaster exercises involving several County departments and the mobilization of public health nurses, health centers, communicable disease specialists, lab, and medical staff. Recent exercises have focused on chemical and biological agents. We are also training nurses--we don't want to sound the alarm and have nobody show up to serve because they are scared for themselves."
The County has received funding of $24.6 million to improve its assessment, surveillance, and epidemiology. One target has been to expand laboratory capacity. The county now has the capability to do rapid testing and identification of biological agents. They are also training local labs for bioterrorism preparedness. There are plans to relocate and renovate County Health's own primary lab. To promote public awareness the agency has set up a website on Bioterrorism Preparedness and Response: www.labt.org.

Will Victims Be Quarantined?
Several people in the audience asked questions about the County's policy on forcible quarantine of persons exposed to a bioterror agent. Dr. Fielding responded, "This is very difficult. We have thought about having a single hospital to take the largest group of victims in such an emergency. Private hospitals are reluctant to agree because of the contamination and exposure of their staffs. The County hospitals are understaffed. One possibility it to use a nonhospital to take a large number of people and call the medical personnel to that location."
He concluded by saying, "I can assure you that the first smallpox case would not be a local matter, it would be an international matter. But we would still be the ones on the spot who would have to handle it."

Laurene Mascola: Every White Powder in the World Was Anthrax

From this point on the conference focused closely on how to respond in a bioterror emergency. The next speaker was Dr. Laurene Mascola, chief of Acute Communicable Disease Control for Los Angeles County. Her first advice was "Don't smoke. All those who died of anthrax were long-term smokers."

"The response procedure is to vaccinate and monitor a ring of people around each suspected and confirmed case. Those infected should be quarantined in a facility. Their close contacts should be sent home and instructed to stay there for 17 days."

Laurene Mascola

The problem with bioterror agents, she said, is that they are not detectible by ordinary senses. "They can be used in enclosed spaces--sporting events, subways, convention halls. They are the most toxic thing there is per weight, and go undetected until there are numerous insidious casualties. They have the potential for widespread illness in unprecedented numbers."

Depending on the size of the strike, there are limited therapeutic stockpiles. "Treatment is complicated by the need for special protective measures for medical care, clinical lab, and autopsy. And the event itself sows panic among the ill, the exposed, and healthcare providers."

Public fears are an important part of the aftermath of a strike. "After Washington," Mascola said, "every white powder in the world was anthrax. The cornstarch put in some magazines to make the pages turn, the talcum powder on baby changing tables, the powdered dust from opening Kleenex boxes--my office was overwhelmed with calls for 3 months, when anthrax had not been seen west of the Mississippi."

How Anthrax Works

Prior to October 4 it was assumed that it took 8,000 to 10,000 spores to cause an anthrax infection. After October 4, she said, it is assumed that very low numbers, even one spore, can cause anthrax. Pre-October 4, "policy was not to decontaminate a building after exposure. After October 4, offices are scrubbed and fumigated before they are deemed safe enough to enter. No one proposes to leave the anthrax residue in place."

Dr. Mascola traced the course of an anthrax infection. "Spores enter the skin, GI tract, or lung. The spores germinate in macrophages, the core of the body's immune system. Once that obstacle is destroyed, the spores are transported to regional lymph nodes where they begin the local production of toxins. This leads to edema and necrosis, bacteremia and toxemia. You have to stop it at the macrophages stage or no antibiotic can help you. Overwhelming sepsis leads to death."

Before October 4 there had been no suggestion that spores could leak through paper (envelopes). "Post Oct 4, cross contamination of mail was one of the most unexpected epidemiological findings." Previously the Post Office used blowers to clean mail handling equipment. "This just spread the spores. Now the blowers have been replaced with a vacuum process."

Dr. Mascola had some suggestions for anyone who might be infected. She recommended doxycycline rather than cipro as a more effective antibiotic. Given the usual long wait time to see a dermatologist, she suggested that people with lesions suspected to be anthrax use a digital camera to send pictures by email to a dermatologist to get a quick diagnosis.

Smallpox: The Biggest Threat

The United States is holding 95 million doses of smallpox vaccine. The starting point for assessment, Dr. Mascola said, is that no one can count on any existing immunity. "Even those of us who were vaccinated probably are not safe. Ten years is the safe life of a vaccine. Smallpox historically killed about 30% of those exposed, and today we have a more immunocompromised population than in the past."

The vaccine is clearly not worse than the disease, as some diehards have argued in the past. But it is not completely without risk. Approximately 1 person per million who is given the smallpox vaccine will die of it. Mascola said that people who have been exposed need to be vaccinated within 4 days to have a chance of preventing or lessening the effect of the disease.

Smallpox runs its course in 17 days. Patients, she said, remain infectious until all scabs have separated. This also means that those who have been exposed to the disease need to be isolated for 17 days afterward before they can be given a clean bill of health.
"The response procedure," Mascola said, "is to vaccinate and monitor a ring of people around each suspected and confirmed case. Those infected should be quarantined in a facility. Their close contacts should be sent home and instructed to stay there for 17 days. Household members are at the greatest risk. All household members should be vaccinated unless there are strong health contraindications."
It is not common, she said, for this kind of infection to be spread by casual contact on planes or buses.
And the contacts of the contacts? The boyfriend of a household member? Mascola recommended waiting until the first level contact showed symptoms before extending the ring out another level.

Two Elected Officials

City Councilman Jack Weiss and County Supervisor Zev Yaroslavsky both addressed the conference. Both have been involved in local disaster preparedness, including for the possibility of various kinds of terrorist attacks. "There is no upside to being involved in threat preparedness," Weiss said. "There are substantial downsides: money for this comes from things your local constituency want. If something bad does happen, the fingers get pointed at you if anything is less than optimal in the response."
He reported that the City of Los Angeles has purchased thousands of escape masks for the fire department and allocated funding to allow the police and fire departments to each have a full-time representative on the staff of the Terrorism Early Warning Group.
Zev Yaroslavsky was cautious in what he could promise. "Our capability to respond to a public health crisis is very limited," he said. Before September 11, "the public health people were relegated primarily in our mind to restaurant inspections. On September 10 if you had asked me what preparations we had made for smallpox or anthrax I would have had to laugh because it was not even on our minds. Now it is on everybody's mind. I think it is just a matter of time before we experience suicide bombings in our country. It is likely we will see a biological attacks here in our country. We have to think way outside our box. We are vulnerable in a number of areas."

Steven E. Koonin: There would Be Casualties in the Thousands

A final speaker of the day was Steven E. Koonin, provost and professor of theoretical physics at the California Institute of Technology and an adviser to the federal government on civilian biodefense.

On the possible effects of an anthrax attack on 10 stations of the New York subway system: "Four million people use the system every day. At a 1% infection rate, we estimated that 40,000 people would be infected, and, if the attack were covert and antibiotics were not given promptly, most would die. We also expected that all 4 million would show up for screening."

Steven E. Koonin

Koonin participated in a team that drafted a 1999 report for the Defense Advanced Research Projects Agency (DARPA), the central research and development organization for the Department of Defense, on possible scenarios for a bio attack in the United States.
"Most of our scenarios remain highly pertinent to the current threat level today," he said. Koonin recounted three of their disaster suppositions. The first envisioned the release of anthrax at 10 stations in the New York subway system. "Four million people use the system every day. At a 1% infection rate, we estimated that 40,000 people would be infected, and, if the attack were covert and antibiotics were not given promptly, most would die. We also expected that all 4 million would show up for screening."
The second scenario supposed that smallpox was released in an air duct of an airplane. "There would be no event, no responders. The passengers would disperse to their destinations and connecting flights, and 30% of those who were unvaccinated would die, along with the same percentage in new foci created where they went."

The third scenario imagined a ricin attack by a domestic militia on a government building in Minneapolis. "There is no known treatment. Victims die in 3 days after inhaling. The effects are very rapid. There would be casualties in the thousands."
Koonin offered a few points: "Often there is no 'event.' Threats may be frequent, but we will only know when one was real a considerable time afterward." Public health, he said, "is ill-prepared to detect or respond. Moreover, there is no surge capability. Most hospitals are already run at capacity."
The best defense, he suggested, was better intelligence. His 1999 report had advocated strengthening the public health information system to aid in prompt detection of a bio agent. Much of the data needed to recognize an emerging threat already exists, collected for some other purpose. "We need to do data mining in the existing health system. This means emergency room admissions, school absences, pharmacy sales, workplace absences. Look for anomalies."
Koonin suggested two improvements on existing systems. First, that there be units established that would conduct regular sampling in public places: of drinking fountains, public phones, public bathrooms. Second, that it was important to find ways to rapidly tell people that they are not infected. He proposed cheap disposable sampling kits including nasal swabs, urine, feces, and saliva testing, with whatever new technology is needed to offer quick presymptomatic diagnosis.

John Sullivan: The Terrorism Early Warning Group

On the second day of the conference those in the audience who were not familiar with this initiative had a chance to get a close look at the Terrorism Early Warning Group. A report on its structure and activities was made by Sergeant John P. Sullivan, TEW's Officer in Charge.

"TEW has been a cooperation of some 40 agencies: FBI, police, fire, public health. We watch for telltale signs of planned attacks and want to interdict them if possible."

John Sullivan

The TEW was founded in 1996 as an interdepartmental organization to improve preparedness against terror attacks in Los Angeles County. Today it has a full-time staff of 16, each made available to TEW by an existing agency. It has 70 part-time staff members. Its headquarters is in the Emergency Operations Bureau of the Los Angeles County Sheriffs Department.
Sullivan began by saying that there are aspects of the current wave of terrorism that confound the traditional response community. "The terrorism that most of us know came together in the 1970s, political terrorism, they used guns and bombs. The older groups could have had the capability for more serious attacks. The IRA could have used chemical attacks, but their aims were more limited and they chose not to. We will see bombs, like the suicide bombers, which are very difficult to detect. Large vehicle bombs. There is the example in Israel where a truck bomb was detonated at a natural gas facility. That is a low tech attempt that could have a large impact."
Today's no holds barred terrorists have different origins than most of those in the past. "States are rational actors and can be restrained even when they use these methods. Terrorism is changing. There is a variety of actors, not just separatists or state sponsored agents. Now there are religious terrorists, and political guerrillas linked to drug trafficking, and millenarian cults. The religious nexus may be the most dangerous because of mass validation of its goals. If you can say it is a sacramental act to go forth and kill, you can have people embrace a higher order of devastating acts. In postmodern terrorism there is a blurring of the distinction between crime and war. The military is not designed to operate within the United States. This is a truly profound conflict with people who want a total change in our society, and the fight is domestic as well as foreign. The distinction between domestic and foreign has less and less meaning."
Sullivan examined some of the organizational problems of responders to an event. "Knowing if it is intentional or not is problematic, especially in the early stages. There is a lack of personal

protective equipment (PPE) and internalization of the doctrine for its use: we neither have it nor are we prepared to wear it for any prolonged period of time. Unless gas masks are a very good fit they are no use against aerosol biological agents."

There are issues of crowd control. "You can't quarantine Los Angeles County. What amount of force is appropriate to keep victims in one place? In an anthrax hoax event in the Van Nuys courthouse it cost $500,000--for the fire department, bulldozers, and police. It is problematic to shoot victims to keep them from leaving. It is more efficient to use prophylaxis. There is a federal quarantine authority, but it has generally been used on animals or on people entering the country."

In a real attack the forces of public order will have to be prepared to act with imperfect information. "We have 8,000 cops in my department and about 45,000 in L.A. County. In an event of this size this is a small force. In the fog of war it is hard to know what is happening. Commanders want perfect knowledge, but you can't wait to make decisions. It requires a high level of self-confidence to act with very limited information. 70% accuracy in intelligence is the gold standard, but you may have only 40% knowledge when you have to act."

Networking Law, Fire, Health, and Emergency Management

Sullivan described the TEW as a network that integrates local and federal agencies for the purpose of critical infrastructure protection. "Our adversary is networked. They are pulling together groups that are linked and can go through their decision process rapidly. We do not have a single hierarchy."

The TEW is working to develop localized as well as coordinated sources of information. "Most information comes from the bottom up, not from the government: this guy next door has funny smelling boxes and strange people coming in at all hours. We need to fuse surveillance by police with that by public health agencies, and on one computer screen, not fifteen. We need to fuse epidemiological intelligence with other intelligence streams. We have tried to do that in L.A. County with the TEW Group."

Public health officials are the first to declare the existence of an outbreak, but they need to have regular ties with the police and sheriff's department so they know who to call in law enforcement who have an emergency structure of action in place. "Decontamination needs to be provided quickly not only at the scene of initial contamination but at the hospitals where people will go."

"From its first meeting," Sullivan said, "TEW has been a cooperation of some 40 agencies: FBI, police, fire, public health. We watch for telltale signs of planned attacks and want to interdict them if possible. In Israel you couldn't predict the first suicide bombing, but you could then predict number 2 and 3."

TEW at this point is a Los Angeles County organization, but new groups are being organized in San Diego, Sacramento, and other cities. TEW has subgroups for water supply, for nuclear, for chemical, and for biological. They are starting a suicide bomber group and are bringing in Israeli police to provide advice. They are producing "playbooks" -- standardized response information folders -- on each of these eventualities that can be used to provide orientations to people and officials elsewhere.

Sullivan reported that TEW has its own field teams ready to deploy as well as hazmat technicians with video equipment to bring feed of an event back to headquarters for analysis. It collects intelligence from multiple sources, and does extensive training, exercises, and gaming. "We have done a live agent exercise at the Dugway Proving Grounds in Utah, and do exercises in Los Angeles with simulated agents. We have a civil battlelab for simulating national strategy for emerging threat issues, including riots and disturbances as well as terrorist attacks."

Dr. John Celentano: "He Asked to Be Patched Up and He Returned to the Pit"

What medical facilities does Los Angeles have and how adequate are they for a serious emergency. Dr. John Celentano, Disaster Medical Officer for the County of Los Angeles Emergency Medical Services Agency, tried to answer the question.

"We need to take clothes off people, giving showers with detergent soap, scrub with a closed cell sponge (no brushes to avoid skin abrasion), use detergent to dissolve fat-soluble adherents."

John Celentano

"There are 80 acute care hospitals in the County," he said, "that is, 911 receiving hospitals, where paramedics take patients. Five of those are owned and operated by the County. There are 40 or 50 more that are not 24 hour and do not have emergency services. We have 300 medical intensive care units (paramedics) in the County."

Looking beyond local resources there are 40 Disaster Medical Assistance Teams (DMATs) in the country. These are local teams, usually 35-person field-deployable volunteer medical personnel, under the control of the U.S. Public Health Service. DMATs are deployed to disaster sites with sufficient supplies and equipment to sustain themselves for a period of 72 hours. "DMATs can be deployed anywhere in the country," Celentano said. "Ten were sent to Los Angeles County after the Northridge earthquake."

At a still higher level there are three federal National Medical Response Teams (NMRTs) trained to deal with weapons of mass destruction. One is in Los Angeles.

Medical Supply Caches

Dr. Celentano reported on a variety of caches of emergency pharmaceuticals. "There are 2 local caches, one owned by the federal government through the Veterans' Administration; the other is owned by the County. These are sufficient to handle 1,000 plus casualties of a terrorist incident. They can handle more for certain kinds of incident."

There are three still larger caches of pharmaceutical/medical supplies maintained by the federal government. "One is on the West Coast, one in the Midwest, one on the East Coast. These are very large. The West Coast has prophylaxis for 2-3 million people. It is huge. It occupies 5,000 square feet of floor space in a warehouse. It can be delivered by truck to a county unit in case of serious emergency."

Since 9-11 Los Angeles County has received funds from the Board of Supervisors for 5 more caches including decontamination and personal protective equipment gear. One cache is at each county hospital. "With these we can handle the first 24 hours before the federal pharmaceutical cache arrives. We also have about $30,000 for each of the acute care hospitals to develop decon capabilities and Personal Protective Equipment."

Public Health: Hospitals and Medical Services

The County Department of Health Services is broken into two pieces, hospitals and medical services.

"The problem with the hospitals in an emergency is saturation," Celentano said. "Today there is a 95% bed occupancy compared to 75% 12 years ago, as well as there being fewer beds. We will fill the beds that are available and try to maintain standards by using the military to evacuate to hospitals in other counties or states, rather than overcrowding by setting up folding cots or anything like that."

Training for Decontamination

"We expect to need to wear protective gear in a bio emergency," Celentano said. "This means learning how to wear it, and then learning how to decontaminate casualties before admitting them to the hospital to avoid shutting the hospital down. OSHA regulations and EPA regulations have standards for workplace safety gear, but they say nothing about gear for hospital personnel in emergency situations."

The first job has been to choose among several levels of available protection. "Level A is a moon suit, completely sealed with its own atmosphere. Hazmat people wear these, they are not usable for hospital personnel."
Level B decon suits are made of materials that provide heavy splash protection and include an air tank. The County has chosen Level C gear for hospital emergency decontamination units. This provides a face mask with a blower and HEPA filter, but not self-contained air, and a light-weight suit that offers full skin protection. "Hospital receiving areas--the parking lots--have this head to foot gear to receive victims," Dr. Celentano said. "There are at least 4-5 suits per hospital. We are buying this equipment."
In an emergency the hospital receivers will set up a decon corridor in the parking lots. "We need to take clothes off people, giving showers with detergent soap, scrub with a closed cell sponge (no brushes to avoid skin abrasion), use detergent to dissolve fat-soluble adherents. We will strip clothing off and hose people over inflatable yard pools, the small kind that children set up on summer days. We chose Level C gear rather than the heavier types because personnel have to be able to don and doff skin protection equipment and respiratory gear frequently and on short notice. Our Level C gear has a hood with a powered air sucker. This provides positive pressure in the hood to keep stuff out. The body of the gear is chemical protective suits, throwaway afterward."

Three Weeks at Ground Zero

John Celentano knows this stuff from life as well as training exercises. He and his wife served for three weeks at Ground Zero at the World Trade Center in New York beginning October 28. 20 of the 40 national DMAT teams rotated into the area for shifts. Dr. Celentano and his wife were there with the Los Angeles team.
"The cloud from the Trade Center could asphyxiate people who were caught in it," he recalled. "The fire burned for almost 12 weeks. The Los Angeles team got there 4 weeks after it started. Everybody had to wear a filter mask. One aftermath was the 'WTC cough.'"
The mission objective of the DMAT was to provide health care services to all personnel at the WTC site, and to prophylax 8,000 postal workers in the New York Post Office.
"We staffed two field clinics in tents at the edge of site. We treated them for minor injuries, or sent them to a local hospital. We had a 5-bed capacity of our 'Liberty Street Clinic.'"
One fire fighter came in with one finger almost torn off. "He asked to be patched up and he returned to the pit." The Los Angeles DMAT also did vehicle maintenance for electric vehicles, generators, and heaters. It provided hourly reports to federal and New York authorities.
"We treated about 40 patients a day, most for dust and fume irritation, cuts, scrapes, and eye injuries--there were lots of those. We also sent postcards and letters to American children who wrote to "Ground Zero."

David Pegues: UCLA Hospital in a Potential Emergency

UCLA was represented at the conference not only by the conference chair, Dr. Peter Katona, but by the chair of the UCLA Hospital's Task Force on Bioterrorism Preparedness. Dr. David Pegues reported on how the hospital, one of the largest in the region, could respond in a serious emergency.

"UCLA Hospital has 10 rooms for isolation of respiratory communicable disease. These 10 rooms are on 8 floors.... We can only isolate 10 individuals and would still have to vaccinate several thousand workers because of routine cleaning and handling.... We might put smallpox patients in tents outside."

David Pegues

"Los Angeles health care is already stretched to the breaking point," he said. "Nevertheless, health care workers have gone out of their way to learn a lot in the last few months about responding to terrorist threats."
There are 34 million people in California, one eighth of the entire U.S. population. There are 480 hospitals in the state, half of which are nonprofit, a third of which are for profit, and the rest run by one or another level of the government.

"Bed availability is very low, almost a crisis." Even a comparatively small crisis can put a great strain on public health resources. "In October and November, 2001," Dr. Pegues said, "1,500 samples of suspicious substances were analyzed by public health labs nationally; 6,000 samples were triaged without having to undergo lab analysis. Public health labs were overwhelmed across the country. It is clear that a big influx of victims would overwhelm the UCLA health care system."

The hospital has been actively evaluating its capacity to triage, isolate, quarantine, and decontaminate and treat victims of a biologic attack. One question that hospital administrators have been looking at is how to increase staff in an emergency. "We are in a physician rich area, but nurse poor," Pegues said. The UCLA Hospital is part of a 19 clinic network of primary care providers. But while in an emergency the other 18 may send patients on to UCLA, the UCLA Hospital is the high end of its associated medical providers and has no one else to refer patients to.

The Task Force on Bioterrorism Preparedness has examined what kind of demands may be placed on its existing medical equipment. For example, inhalation anthrax and plague can induce respiratory failure. Normally patients who cannot breathe on their own are intubated and placed on a respirator. "There are 1,100 mechanical ventilators in L.A. County," Pegues said. UCLA has about 100 of them. "They cost $35,000 each for additional ones. We can't afford them and have no place to put them." What would they do, then? "Patients with these conditions need short-term intubation. We are buying $6 disposable air bags. This is the standard of care in many developing countries, where patients are kept alive by family members who hand operate the air bags. UCLA has bought 100 and will expand to 1,000. We will have staff members or volunteers squeeze the bags for the needed time."

In most cases decontamination won't be necessary for BT agents, Dr. Pegues said. "It is unlikely that victims will present immediately following an exposure event. An exception would be if the release was announced in advance."

The hospital plans if there is a need for decontamination to have the victims remove their clothing and put it in plastic bags, then shower with soap and water. Personnel would use disinfectant or bleach for environmental decontamination. Vaccination is appropriate for only a few bio agents--inhalation anthrax and smallpox. Others use antibiotics.

What Do You Do with Highly Contagious Patients?

One of the most difficult problems is treating patients with a disease that is contagious through the respiratory tract. Inhalation anthrax, tularemia, and botulisms are not contagious. The big problems are with the bugs that are: smallpox, plague, and HFV (viral hemorrhagic fevers such as Ebola).

"UCLA Hospital has 10 rooms for isolation of respiratory communicable disease," Pegues said. These special rooms have an air system that can generate negative pressure to precipitate exhaled particulates. "These 10 rooms are on 8 floors. There is no isolation ward for multiple patients. We can only isolate 10 individuals, and would still have to vaccinate several thousand workers because of routine cleaning and handling. We need special biocontainment facilities for disposal of materials that have been in contact with smallpox." Dr. Pegues suggested that his hospital "might put smallpox patients in tents outside, as even one would be very difficult to care for inside and ten is the absolute limit."

There are 550 beds at the UCLA medical center and an additional 220 beds at affiliated Santa Monica Hospital. "We already have outstripped capacity. We have on occasion had to set up extra beds in halls," Pegues said.

Dr. Pegues raised other concerns for which there are not yet answers: "Where does the water go after decontamination? Who will perform autopsies? The L.A coroner says they will not participate in autopsies of persons who have died of contagious diseases. How will we maintain security or isolation of contagious patients when there are 100 entrances to CHS [UCLA's Center for Health Sciences]?"

The UCLA Hospital is conducting training in using personal protective equipment and the use of decontamination systems. There is special training for high risk employees: mail, security, and emergency management personnel.

In reply to a question, Dr. Pegues affirmed that it is UCLA policy to provide vaccinations where this is the indicated treatment for families of all UCLA employees if they are able to get to the campus in an emergency situation.

Alvin Toffler: We Need Smaller, More Diverse Institutions to Survive

The sobering conference closed with a videotaped interview with futurist Alvin Toffler, author of the influential book Future Shock, by conference organizer Dr. Peter Katona.

Attempts to predict the future shape of things have generally been notoriously off the mark, but Toffler remains game to try. He began by suggesting that we are seeing "an emerging third wave civilization colliding with the old first and second wave civilizations." He explained that the first wave was preindustrial agrarian. "Fighting was constant and short, face to face, fighters had to go back to the soil." The second wave was our own familiar industrial society, where "the machine age gave us the machine gun."

Toffler defined the new third wave as knowledge based. He predicted a lengthy period of violence in this transition. What is different about the third wave formation, in Toffler's view, is the centrality of small, mobile, international groups in place of fixed states and their ponderous bureaucracies. "The second wave type of conflict was based on the massed forces of state to state warfare aimed at mass destruction. In the third wave we will see pinpoint warfare, small teams, small groups, a lot of different types of conflict."

Toffler suggested that the rapid electronic communication and high speed travel that permit small groups to strike suddenly in distant parts of the globe are symptoms of a new form of decentralized organization that is the natural type for "third wave" civilizations and should be deliberately adopted by our domestic institutions.

"Max Weber," he said, "saw bureaucracy as a very efficient way to organize people. It was, as long as things were linear, but their response time is too slow. Their efforts to continually enlarge the organization are misplaced. They cannot cope with these disparate on-again off-again threats. The obverse of this is smaller, more diverse. Corporations set up cost centers, subunits that have decision-making responsibility.

"There have been many cases like the Phoenix FBI agents of predictions ignored. The hierarchy has grown so tall with so many gatekeepers who refuse to pass information up the line as needed that the system is choking on its own internal complexity. I think we'll make it but we'll make it a lot better if we are prepared to restructure our institutions. Particularly our intelligence agencies, but the same is true of our political systems, our hospitals, our police forces. These systems worked well as long as we were an industrial society and economy. We are no longer that, we are something new that the world has not seen before."

Bioweapons Country Report: Brazil

By Kai Ilchmann

Source: http://news.cbrnresourcenetwork.com/newsDetail.cfm?id=152

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General policy statements on bioweapons and bioweapons/bioterrorism threat perception

On 5 September 1991, Brazil, together with Argentina and Chile, signed the Mendoza Agreement in which it expressed its 'total commitment not to develop, produce or acquire in any way, stockpile or retain, transfer directly or indirectly, and not to use chemical or biological arms'.(1)

At the 7th Review Conference Brazil has stated that it is concerned about possible misuse of biological research, especially considering rapid advances in the life sciences. Brazil supports the review, simplification and updating of the CBMs to enhance participation. For Brazil the "full, effective and non-discriminatory" exchange of equipment, materials and scientific and technical information for peaceful uses of biological agents under Article X of the convention is "essential for the realization of the objectives and purpose of [the] Convention".(2) Brazil has also voiced concern about the BWC's lack of means for assuring that States parties were in compliance with the convention, stating that it "is critically important for States parties to be collectively reassured that the provisions of the Convention are being realized".(3)

Status of the life science and biotechnology industry

Brazil's biotechnology industry shows considerable breadth and Brazil has identified biotechnology as a priority sector for growth for the government although that trend appears to be in the decline. (4) A recent report indicated that Brazil has more than 820 biotechnology companies employing almost 100,000 people working to serve the world's tenth largest biopharmaceutical market.(5) All major biotechnology and pharmaceutical companies now have a foothold in this emerging market.(6)

Brazil has a strong focus on plant biotechnology and is the second biggest producer of genetically modified (GM) crops in the world.(7) A break-down of the biotechnology industry shows that the leading segment is human health, which accounts for 32 percent of its firms. Reagents and animal health account for another 16 and 15 percent, respectively. Brazil's strong focus on agrobiotechnology, and agriculture-related companies only make up 11 percent of the country's biotechnology industry. Environmental and bioenergy sectors comprise 7 and 3 percent of the Brazil's biotechnology firms, respectively. Other sectors (bioinformatics, molecular diagnostics and contract research organizations) account for 16 percent of the firms.(8) Bibliometric research on life science activities shows Brazil to be linked strongly in international coauthorship of scientific publications.(9)

Brazil, amongst other BRIC countries, is supporting innovation in biotechnology through approaches including increasing investment, building infrastructure, strengthening intellectual property protection and improving education. Brazil has become the third largest source of venture capital for inventions involving medical technology behind China and the US.(10) New legislation – including the 2004 Innovation Law, and policies, such as the 2008 Productive Development Policy – aim to foster interaction and collaboration between academia and the industrial sector, which have traditionally been isolated from one another.(11) Other legislative changes have opened up some research avenues, for example the 2005 Biosafety Act, which allows human embryonic stem cells to be obtained for research purposes.(12) Brazil has invested into the development of science and biotechnology, although recently this trend has been reversed – despite growing GDP and political assurances for continued investment.(13) Bureaucracy and red tape is still a hurdle, considerably hampering research.(14)

Biodefence activities and facilities

Three branches are involved in biodefence activities. The Brazilian Army Chemical, Biological and Nuclear Defence Company (Companhia de Defesa Química, Biológica e Nuclear (Cia DQBN)), under the Directorate of Specialized Extension (Diretoria de Especialização Extensão), reports to the Land Forces Command. Cia DQBN is charged with the assessment and support in CBRN-related matters, as well as to offer support to the Land Forces, the other Special Forces and/or Auxiliaries and civil defence. The Brazilian Special Forces maintain a platoon charged with CBRN defence (1º Pelotão de Defesa Química, Biológica e Nuclear). The platoon trains to perform support operations in operational risk assessment and decontamination activities; as well as guiding the use of non-lethal weapons for crisis management. The platoon has participated in emergency exercises of nuclear power plants and provided security detail for VIP events.

The Brazilian Army Biology Institute (Instituto de Biologia do Exército (IBEx)) is the primary provider of laboratory support for the health system of the Army. However, agent identification and analysis is carried out by the civilian public health laboratory FIOCRUZ.(15) IBEx develops and carries out research projects in partnership with various civil institutions in several areas, such as: medical bacteriology, medical mycology, medical virology, immunology, tropical medicine, human physiology, snakes venoms, entomology and human genetics.(16)

The third branch involved in biodefence activities is a section of the Army's science and technology centre (Centro Tecnológico do Exército - CTEx). CTEx carries out basic and applied research and development for defence against chemical, biological and nuclear attacks. In particular in the following areas: analytical methods for the identification of chemical and biological warfare agents; methodologies and

procedures for care of emergencies involving CBRN; environmental impacts of CBR agents.(17)

Maximum and high biological safety level (BSL-3 and 4) facilities and their activities

There are a total of 12 BSL-3 laboratories under the responsibility of the Ministry of Health and 8 BSL-3 laboratories under the responsibility of the Ministry of Agriculture (see Table 1).18 Brazil currently has no BSL-4 laboratories, although there has been ongoing discussion for several years about building one. The BioWeapons Monitor has found that the absence of BSL-4 laboratories does not preclude research with pathogens that produce serious and transmissible disease normally handled in BSL-4 laboratories.

This research is carried out in University research laboratories where little regulation, or reporting requirements exist, according to information provided to the BioWeapons Monitor.

Research on smallpox, allegations of smallpox outbreaks, policy on smallpox destruction

Research on smallpox (variola major) could not be detected in Brazil during the report time frame.

Other dual use research of immediate misuse potential

No research of immediate misuse potential could be detected in Brazil during the report time frame.

Vaccine Production

Four vaccine production facilities haven been identified for the present report (see Table 2 below).(19)The Brazilian government states that domestic production delivered 128.7 million doses of viral and bacterial vaccines to the public health system in 2009, with supply rising by 11% in 2010. Excess production is transferred to institutions including the World Health Organization (WHO), the Pan-American Health Organization (PAHO), and UNICEF.(20)

The Butantan Institute is the largest domestic producer of vaccines and serums and the leading developer of scientific research into venomous animals responsible for over 93% of serums and vaccines produced in Brazil.(21)

The Research, Innovation and Dissemination Centers (RIDC) of the São Paulo Research Foundation, FAPESP includes the Center of Applied Toxinology (CAT). CAT focusses on the synthesis of molecules that can be used for new drugs—obtained from snake poison, from the bristles of the caterpillar *Lonomia oblique* and from the saliva of the tick *Amblyomma cajennense*(22) Natural extracts are also investigated by scientists linked to BIOprospecTA, a network of researchers, institutions and labs working on the identification of molecules or processes of economic interest in microorganisms, macroscopic fungi, plants, invertebrates (including marine) and vertebrates.(23)

Outbreaks of particularly dangerous diseases

In June 2012 a suspected outbreak of tick-borne Spotted fever killed one woman and infected three of her family members.24 In 2011 the state of Minas Gerais reported 8 cases, 3 of them lethal; in 2010 the number of confirmed cases was 15 with 6 fatalities.25Other states also report Spotted Fever occurrences. Between 6 and 27 fatal cases per year wereregistered nationally during 2007 to 2010.26 National figures for confirmed cases and fatalities could not be ascertained.

In April 2012 two cases of hantavirus infections were confirmed in Uberaba, Minas Gerais. 2 people, one 22 and the other 18, were infected and died.(27) In 2010 Regional Directorate of Health of Minas Gerais confirmed 14 cases of the disease half of these were lethal.(28)

In February 2012 Secretariat of Health (SESA) of the State of Parana confiscated all lots of a manufactured sausage, about 400 kg, distributed in the Alto Piquiri area, due to the suspicion of the presence of the bacterium that causes botulism (*Clostridium botulinum*). 2 people died, 2 were symptomatic, and 10 others are suspected cases of the disease.(29) This episode followed an outbreak of botulism in Santa Catarina in the 1st half of March 2011. Six people received medical attention and recovered, a seventh died.(30)

A number of outbreaks of glanders (i>Burkholderia mallei) have been reported in horses in several Brazilian states in early 2012.(31) In 2011, there were 9 outbreaks of glanders reported from 3 states in the Northeast Region – Pernambuco, Paraiba, and Rio Grande do Norte. The disease is fairly common, 209 outbreaks have been reported

between 2005-2011 across a number of Brazilian states.(32)
A disease control initiative worth noting here is the release of genetically modified *Aedes aegypti* which carry a gene that causes their offspring to die before reaching adulthood. The mosquito, *A. aegypti*, is the carrier of dengue, yellow fever, which are prevalent in Brazil. The Brazilian National Biosafety Technical Committee has approved the control method and its roll out in several cities.(33)

Suspicious outbreaks of disease

The BioWeapons Monitor has not detected any outbreaks of disease to raise suspicion of biological terrorism or warfare in Brazil during the reporting period.

Allegations and hoaxes

The BioWeapons Monitor has not detected any allegations of biological weapons use or hoaxes perpetrated in or by Brazil during the reporting period.

National legislation and regulations

Brazilian national legislation and regulations pertaining to *aspects* of BW is extensive. The national implementation database counts 57 different instruments.(34) These 57 instruments include, besides the instruments for the Geneva Protocol and the BWC(35), penal legislation criminalising intentional spread of disease(36), manufacturing and/or selling counterfeit or adulterated products(37); notification regulations for disease; regulation of export of goods and services with possible military applications or dual use(38); regulation of transport of dangerous products(39); financial detection and hindering of illicit activities connected to the development of weapons of mass destruction and their means of delivery(40); definitions of the National Sanitary Surveillance System(41); regulations for agrotoxins(42); financing of terrorism; establishes best practice for production of medical goods; and a whole host of regulations, decrees and laws concerned with GMOs.
Relevant sections of the Federal Constitution(43) have been extended with interpretations to include prohibitions to the access to any element of the Brazilian genetic patrimony or its use in connection with chemical or biological weapons.(44)

Biosecurity is covered by the 1995 National Biosecurity Law (Lei Nacional de Biossegurança (nº 8974/95)), which was updated in 2005 (Lei de Biossegurança (Lei nº 11.105 de 24/03/2005). However, this Biosecurity law ostensibly covers safety standards and enforcement mechanisms of the construction, cultivation, production, handling, transportation, transfer, import, export, storage, research, marketing, consumption, release into the environment and disposal of genetically modified organisms (GMOs) and their derivatives for the protection of life and health of humans, animals and plants; and observance of the precautionary principle to protect the environment. The Biosecurity Law thus implements the provisions of the Cartagena Protocol on Biosafety. Under the provision of the Biosecurity Law (1995) authorised creation of the National Technical Commission on Biosafety (CTNBio) and outlines its responsibilities, structure, staffing, functioning and standards. The Law requires any organization using genetic engineering techniques and methods to create an Internal Biosafety Commission (CIBio) and outlines their responsibilities.
The General Coordination Office for Sensitive Materials, within the Ministry of Science and Technology (CGBE/MCT) is the organ responsible for controlling imports, exports and re-exports of sensitive goods.(45) The CGBE implements controls and authorizes transfers of items contained in the National Lists of Control of Sensitive Goods and Technologies, after necessary consultations with other governmental organs involved. This activity is undertaken through the Foreign Trade Integrated System (SISCOMEX). This system aims to automatically detect non-authorized imports, exports and re-exports, by centralizing all information on transfers.
Brazil's legislation for the control of export of sensitive goods and technology and services related to WMD, as well as items of dual use, is implemented and maintained by the Interministerial Committee for the Control of Sensitive Goods (CIBES)(46) and the Interministerial Committee for the Implementation of the Directives of the Chemical Weapons Convention (CIAD-CWC). The Brazilian Intelligence Agency (Abin) works together with CIBES as an advisory agency to the General-Coordination of Sensitive

Goods of the Ministry of Science and Technology (CGBE/MCT) Executive Secretariat. CIBES maintains a list of controlled agents and equipment linked to WMD or dual-use. The list is divided into 5 sections:
(i) Agents of relevance for animals (26 bacteria, 13 rickettsia, 5 fungi, 79 viruses or prions, 1 protozoan group and related agents)
(ii) Agents of relevance for plant (23 bacteria, 7 phytoplasma, 50 fungi, 10 viruses or prions, 6 nematodes)
(iii) Toxins (19 entries)
(iv) Genetic elements (associated with pathogenicity and encoding toxins contained in the list in section (iii))
(v) Equipment
a. Containment and protection equipment.
b. Aerosol inhalation chambers
c. Cross (tangential) flow filtration equipmentd. Fermenters, bioreactors (>20 litres) as well as chemostats and continuous-flow systems
e. Steam sterilisable freeze-drying equipment
f. Spray drying equipment with droplet dispersal <50microns and flow above 2l/min

Codes of conduct, education and awareness raising

In 2004 the National State-Private Industry Integration Programme for Sensitive Goods (PRONABENS)(47) was created by the Brazilian Intelligence Agency (ABIN) in response to address the provisions of UN Security Council Resolution 1540. The focus of PRONABENS is on the implementation of outreach activities for industry and public bodies involved in the development of sensitive equipment or dual-use equipment, offering guidance on government controls regarding the transfer of sensitive goods and services. PRONABENS activities led to the development and approval of the "List of Sensitive Goods and Controlled Equipment in the Biological Area" in Resolution no. 10 of March 13, 2008. The BioWeapons Monitor has learned that this initiative has been suspended recently. The reasons for this suspension could not be identified. Efforts are underway to instigate educational programmes and outreach activities by NGOs; foremost amongst these is the National Association for Biosecurity (ANBio).(48)

CBM participation

Brazil has submitted 17 out of 26 CBMs since 1987, although on an irregular basis. Brazil first submitted in 1991, then from 1993-99, 2001 and 2002, 2004-07, and 2010-2012. Brazil has repeatedly called for reviewing, updating and simplifying CBMs to increase participation and transparency; most recently these calls were made at the 7th Review Conference.(49) Despite calls for greater transparency in various Brazilian statements over the past few years, Brazil has yet to make its CBM submission publically available.

Participation in BWC meetings

Brazil has participated in all relevant meetings since the Sixth Review Conference of the BWC in 2006, the period under investigation here (see Table 4 below). In addition to formal meetings Brazil was also represented at the meetings preparing for the 7th Review conference in Montreux, Switzerland organized and co-hosted by Norway, Indonesia and the BWC Implementation Support Unit (ISU); and two meetings in Beijing, China: one organised by the Chinese Academy of Sciences (CAS), the US
National Academy of Sciences (NAS) and the InterAcademy Panel (IAP) Biosecurity Panel together with the International Union of Microbiological Sciences (IUMS) and the International Union of Biochemistry and Molecular Biology (IUBMB) and entitled Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention, and the second workshop was organised by the Government of China and the Government of Canada together with the Implementation Support Unit (ISU) of the Biological Weapons Convention (BWC) and entitled Strengthening International Efforts to Prevent the Proliferation of Biological Weapons: The Role of the Biological and Toxin Weapons Convention. Brazil attended both workshops.

Past bioweapons development and use, and accusations of bioweapons development and use

Brazil has neither conducted nor been accused of conducting a biological weapons programme and has made no submission under CBM Form F.

Endnotes

(1) cns.miis.edu/inventory/pdfs/aptmendoza.pdf
(2) BWC/CONF.VII. Statement by Brazil (December 2011)
(3) States News Service, Statement by Luiz Filipe De Macedo Soares to the First Committee. 22 October, 2010. & BWC/CONF.VII. Statement by Brazil (December 2011)
(4) Luisa Massarani. "Innovation is 'imperative,' says Brazil science minister." Nature (online) 25 January 2012. doi:10.1038/nature.2012.9903; and Luís Amorim. "Scientists protest against fresh S&T budget cuts" 6 March 2012. SciDev.net
(5) Global Health Progress (2010) Report: Biopharmaceutical sector Brazil. See press release on: http://www.globalhealthprogress.org/brazil%E2%80%99s-biopharmaceutical-sector-contributes-economic-growth-expands-access-healthcare, accessed June 2012.
(6) Mike May. (2011) "Brazilian drug companies hope to benefit from foreign investment". Nature Medicine 17, 1171 doi:10.1038/nm1011-1171a. Published online 11 October 2011
(7) Brazil, number two on the list behind the US, was planting just over 30 million hectares with GM crops in 2011. See: Nature (2012) Seven Days. Vol 482, Iss 7385. 15 February 2012. Based on 2011 data from the International Service for the Acquisition of Agribiotech Applications (ISAAA).
(8) BrBiotec Brasil and Centro Brasileiro de Analise e Planejamento - CEBRAP (2011) "Brazilian Biotech Mapping 2011". Available at: www.cebrap.org.br, accessed July 2012
(9) See for example various papers by: Ilchmann, Revill, McLeish & Nightingale (2011) on the United Nations Disarmament ThinkZone, on "Synthetic Biology & the BWC", "Vaccine Development & the BWC", "Nanotechnology & the BWC"
(10) PricewaterhouseCoopers (PwC)—"Medical Technology Innovation Scorecard: The race for global leadership", January 2011. Available at: http://pwchealth.com/cgi-local/hregister.cgi?link=reg/innovation-scorecard.pdf, accessed July 2012.
(11) Scientific American (2011) Worldview – Deconstructing the BRICs. Available at: http://www.saworldview.com, accessed July 2012
(12) Elie Dolgin. (2011) "In Brazil, basic stem cell research lags behind clinical trials" Nature Medicine 17, 1172 doi:10.1038/nm1011-1172 Published online 11 October 2011
(13) Luís Amorim. "Scientists protest against fresh S&T budget cuts" 6 March 2012. SciDev.net
(14) Luisa Massarani (2011) "New framework needed to thwart Brazil's crippling bureaucracy". Nature Medicine vol 17, iss 1171. doi:10.1038/nm1011-1171b. Published online 11 October 2011
(15) Personal communications with FIOCRUZ & CTEx.
(16) Instituto de Biologia do Exército (IBEx) website: www.ibex.eb.mil.br
(17) Research group profile: Grupo de Defesa Química, Biológica, Nuclear e Radiológica. Information available at: http://dgp.cnpq.br/buscaoperacional/detalhegrupo.jsp?grupo=0992106U2BNX4D, accessed May 2012
(18) National Academy of Sciences and National Research Council. (2012) Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories. E1: Brazil. National
(19) Previously, according to CBMs up to 2004 Brazil declared ten vaccine production facilities, seven of which were active in 2003. Iris Hunger (2005) "Confidence Building Needs Transparency - A summary of data submitted under the Bioweapons Convention's confidence building measures 1987 - 2003" The Sunshine Project.
(20) http://www.brasil.gov.br/sobre/science-and-technology/health-technology/vaccines/br_model1?set_language=en
(21) http://www.butantan.gov.br
(22) Scientific American (2012) Worldview – Searching for the next wave. Available at: http://www.saworldview.com, accessed July 2012
(23) www.bioprospecta.org.br
(24) Jornal do Cruzeiro do Sul. 29 June 2012. http://www.cruzeirodosul.inf.br/acessarmateria.jsf?id=398752, via ProMED-mail: 20120630.1185436
(25) Estado de Minas. 9 Nov 2011. http://www.em.com.br/app/noticia/gerais/2011/11/09/interna_gerais,261017/divinopolis-registra-primeiro-caso-de-febre-maculosa.shtml, via ProMED-mail: 20111125.235743
(26) Spotted fever , fatal - Brazil (02): background. ProMED-mail post: 20110404.1045
(27) Correio. 28 Apr 2012. http://www.jornalcco.com.br/noticia/1680/Secretaria-da-Saude-confirma-dois-casos-de-hantavirose-em-Uberaba--MG, via ProMED-mail: 20120501.1119924
(28) Jornal da Manha. 13 Jan 2011. http://www.jmonline.com.br/novo/?noticias,7,SA%DADE,40022, via ProMED-mail: 20110115.0170
(29) Gazeta do Povo. 23 Feb 2012. http://www.gazetadopovo.com.br/vidaecidadania/conteudo.phtml?id=1226353, via ProMEDmail: 20120305.1060430
(30) Radio Criciuma. 6 Apr 2011. http://www.radiocriciuma.com.br/portal/vernoticia.php?id=17414, via ProMED-mail: 20110407.1090
(31) World Animal Health Information Database(WAHID), weekly disease information 2012; 25(21)
(32) ProMED-mail, additional information on WAHID report. ProMEDmail archive number: 20120528.1147807
(33) Helen Mendes. "Brazil tests GM mosquitoes to fight dengue". 10 April 2012. SciDev.net
(34) National Implementation Database. http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622EC1257777004DA382/$file/BWC_NID_Report.htm#br
(35) These include, for example, decree No. 5459, 7 June 2005 which establishes sanctions for the development of biological weapons.
(36) Penal Code of Brazil, 1940 Article 131 (intentional disease transmisison); 1940, Article 267 (cause a disease outbreak); 1940, Article 270 (poison drinking water); 1940, Article 129 (jeopardize the physical integrity or the health of another person); 1940, Article 259 (disseminate an illness or plague that may cause damage to forests, plantations or animals of economic relevance)
(37) E.g. Law No. 9.677, 2 July 1998

(38) E.g. Law No. 9.112, 10 October 1995
(39) E.g. Resolution No. 420/2004, 12 February 2004 updating Regulation No. 204, 20 May 1997
(40) E.g. Law No. 9613, 3 March 1998
(41) Law No. 9.782, of January 26, 1999 & Provisional Remedy No. 2.039-20, 25 August 2000
(42) E.g. Decree No. 4.074, 4 January 2002
(43) Constituição de 1988 da República Federativa do Brasil, Capítulo VI, Artigo 225
(44) Provisional Decree 2186-16, 2001
(45) As established under Regulation No. 49, 16 February 2004
(46) Established in Law No. 9.112, 10 October 1995, Decree No. 4.214, 30 April 2002 defined the composition and responsibilities
(47) PRONABENS - Programa Nacional de Integração Estado-Empresa na Área de Bens Sensíveis http://www.abin.gov.br/modules/mastop_publish/?tac=PRONABENS
(48) ANBio - Associação Nacional de Biossegurança, http://www.anbio.org.br/
(49) BWC/CONF.VII. Statement by Brazil. See also: BWC/CONF.VI/WP.12

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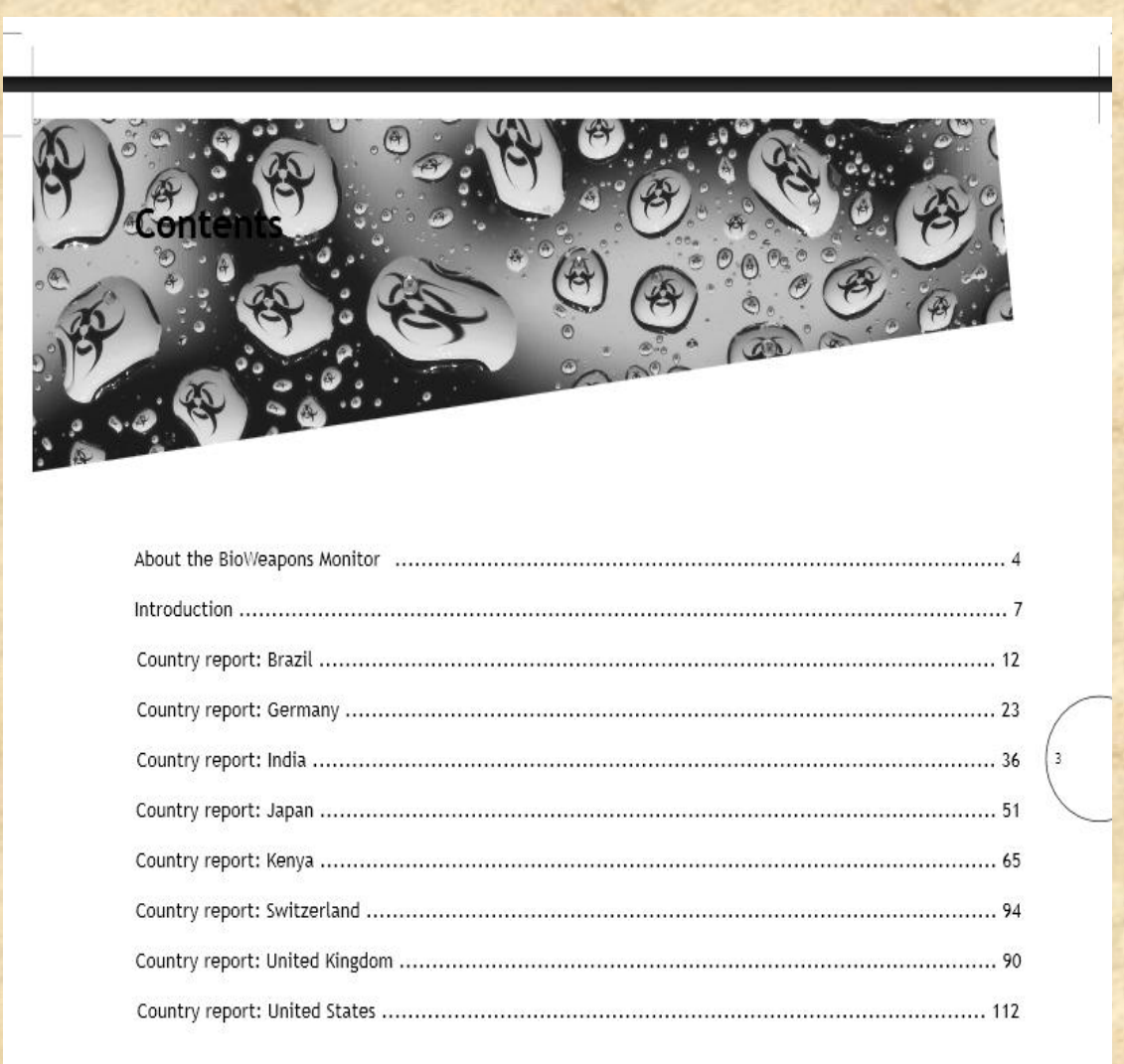
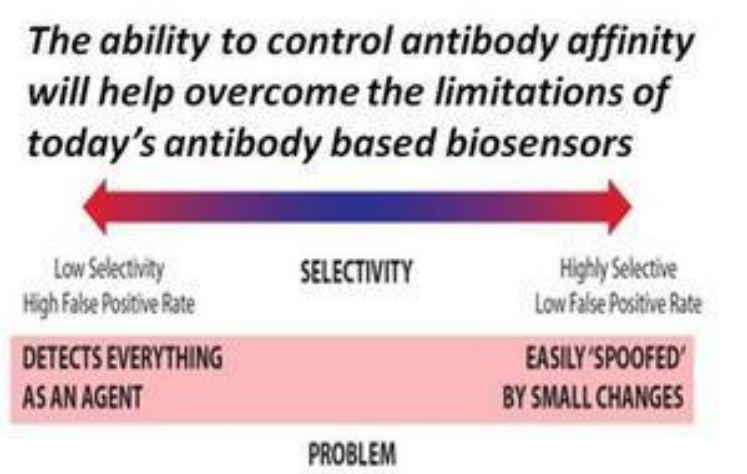
► **Read BioWeapons Monitor 2012 at:** http://www.bwpp.org/documents/BWM%202012%20WEB.pdf

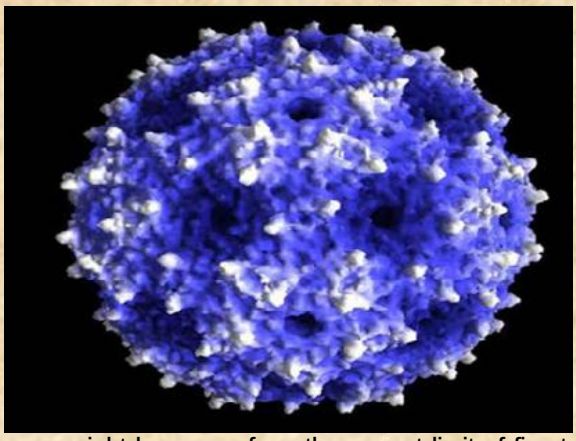


Improving detection of, responses to biological warfare

Source: http://www.homelandsecuritynewswire.com/dr20130221-improving-detection-of-responses-to-biological-warfare

Biological warfare agents pose more than a hypothetical threat to U.S. soldiers. Troops operate in hostile areas where they could come under attack from adversaries wielding bio-agents like anthrax and toxins. The first step in reacting to any such attack is knowing that it occurred. Quickly and accurately identifying the presence of airborne antigens can be difficult given their complexity, the presence of numerous similar microorganisms in the environment, and the fact that even minute quantities of a threat agent can cause infection.*





MS2 bacteriaphage

A DARPA release reports that the Department of Defense (DoD) employs antibody-based biosensors as its immediate tool for quickly detecting antigens — antibodies bind to antigens — but these sensors have functional limitations that can leave soldiers at risk. The two biggest liabilities involve stability and affinity. Stability refers to a sensor's ability to continue functioning as required over time and despite environmental conditions. Affinity refers to the tightness of the bond between an antibody and an antigen; the higher the affinity, the more sensitive a biosensor is over a wider range of threats. Existing DoD biosensors, while effective, have restricted shelf lives, are quickly rendered inoperable by high temperatures, and offer limited affinity.

DARPA launched the Antibody Technology Program (ATP) in 2009 to address the technological limitations of current antibody-based biosensors. The program set out with two primary goals: achieve revolutionary improvements in the stability of antibodies over time, even in extreme conditions; and control affinity in biosensors to enable detection of numerous antigens by a single unit. ATP ended in 2012 having achieved both goals and with a plan in place to transition the technologies to DoD's Critical Reagents Program, part of the Joint Program Executive Office – Chemical and Biological Defense (JPE-CBD), for biosensor deployment throughout the military services.

Specifically, DARPA performers demonstrated the ability to increase antibody temperature stability at 70 degrees Celsius (158 degrees Fahrenheit) to forty-eight hours, up from the current limit of five to ten minutes. When transitioned to DoD biosensors, these results are projected to eliminate the need for refrigeration while increasing the shelf life by a factor of 36, extending survivability at room temperature (approx. 25 degrees Celsius or 77 degrees Fahrenheit) from one month to approximately three years. DARPA also increased antibody affinity by a factor of 400, thus opening the door to vastly more sensitive, multiplexed biosensors that can test for numerous antigens.

Mildred Donlon, theDARPA program manager for ATP, explained the implications of the breakthroughs: "When you consider the locations of

warfighters who have the most potential for biological weapons to be used against them, they are typically environments with extreme temperatures and harsh conditions, and the warfighters themselves are probably operating in small groups. If it's going to be useful to these teams, DoD equipment needs to be ruggedized to survive conditions and be easy to use by non-experts. The ATP technology hits these goals.

"By removing temperature stability as a limiting factor, troops will now be able to carry sensors with them without worrying about refrigeration and wondering if the sensor will return an accurate reading. According to the Chemical Biological Medical Systems Joint Project Management Office at JPE-CBD, eliminating the need for cold-chain logistics in transport and deployment of sensors is estimated to save DoD in the range of $10 million per year," Donlon said. "The new stability also means antibodies can be attached to new materials to make potentially more practical sensors to take the place of current beads and strips. Most importantly, by pairing more stable sensors with a huge increase in sensitivity, DARPA is giving troops the confidence to trust the results of what can be literally life-or-death measurements."

ATP achieved these results by altering the amino acid sequences within the antibody molecules. Rather than creating an additive stabilizing material, ATP performers devised methods to make the altered amino acids an integral part of the structure of the antibody molecule.

"Antibody-based biosensors have been in use for roughly 30 years," Donlon said. "DARPA used recent advances in understanding of protein structure and analysis to determine new ways to alter amino acids, integrate them into an antibody structure, and do so at a sustainable scale."

The release notes that DARPA partnered with the U.S. Army's Edgewood Chemical Biological Center (ECBC) from the beginning of ATP, to first assist with evaluation of performer research proposals, then later in the program to provide ATP performers with unaltered antibodies, conduct testing on the performers' altered antibodies, and validate results. To ensure that the production methods for modifying antibodies are scalable and cost effective, performers had to submit one-gram samples for testing. The positive results mean that existing DoD antibody stockpiles can be altered to incorporate the new properties of stability and high affinity.

Program performers for ATP included: Affomix Corp. (Branford, Conn.), purchased by Illumina, Inc. (San Diego, Calif.); AnaptysBio, Inc. (San Diego, Calif.); the Naval Research Laboratory (Washington, District of Columbia); StableBody Technologies, LLC (Lemont, Ill.); The University of Texas at Austin (Austin, Texas); and the ECBC (Aberdeen, Md.), which participated as the validation laboratory. AxioMx, Inc. (Branford, Conn.) was created to rapidly generate high-quality recombinant antibodies.

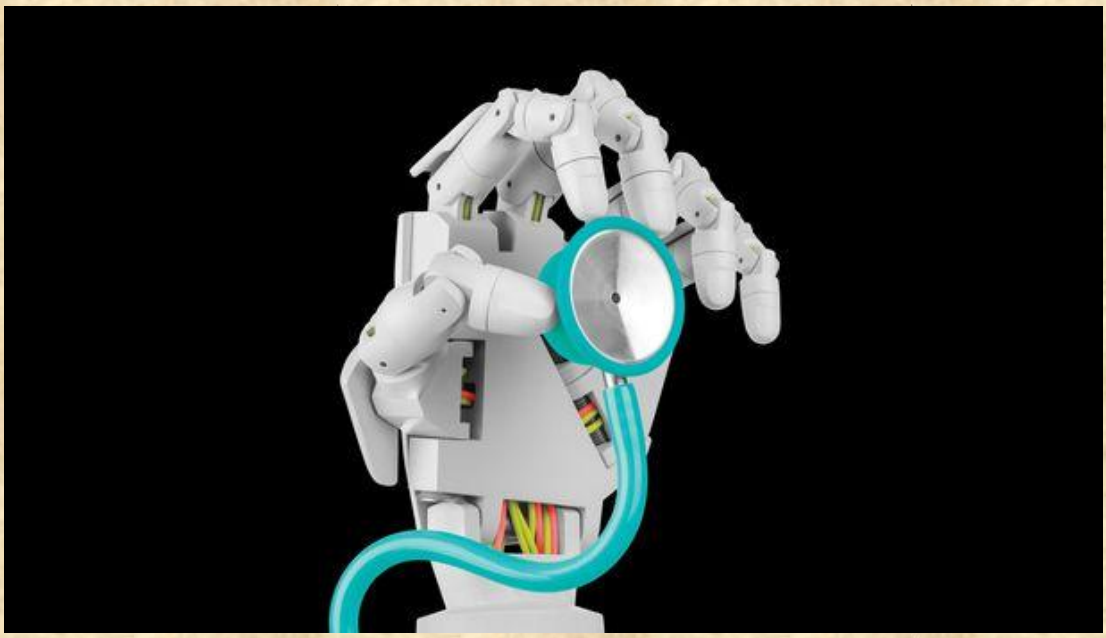
The Robot Will See You Now

By Jonathan Cohn

Source:http://www.theatlantic.com/magazine/archive/2013/03/the-robot-will-see-you-now/309216/?single_page=true

IBM's Watson—the same machine that beat Ken Jennings at *Jeopardy*—is now churning through case histories at Memorial Sloan-Kettering, learning to make diagnoses and treatment recommendations. This is one in a series of developments suggesting that technology may be about to disrupt health care in the same way it has disrupted so many other industries. Are doctors necessary? Just how far might the automation of medicine go?

Charley lukov didn't need a miracle. He just needed the right diagnosis. Lukov, a 62-year-old from central New Jersey, had stopped smoking 10 years earlier—fulfilling a promise he'd made to his daughter, after she gave birth to his first grandchild. But decades of cigarettes had taken their toll. Lukov had adenocarcinoma, a common cancer of the lung, and it had spread to his liver. The oncologist ordered a biopsy, testing a surgically removed sample of the tumor to search for



particular "driver" mutations. A driver mutation is a specific genetic defect that causes cells to reproduce uncontrollably, interfering with bodily functions and devouring organs. Think of an on/off switch stuck in the "on" direction. With lung cancer, doctors typically test for mutations called EGFR and ALK, in part because those two respond well to specially targeted treatments. But the tests are a long shot: although EGFR and ALK are the two driver mutations doctors typically see with lung cancer, even they are relatively uncommon. When Lukov's cancer tested negative for both, the oncologist prepared to start a standard chemotherapy regimen—even though it meant the side effects would be worse and the prospects of success slimmer than might be expected using a targeted agent.

But Lukov's true medical condition wasn't quite so grim. The tumor did have a driver—a third mutation few oncologists test for in this type of case. It's called KRAS. Researchers have known about KRAS for a long time, but only recently have they realized that it can be the driver mutation in metastatic lung cancer—and that, in those cases, it responds to the same drugs that turn it off in other tumors. A doctor familiar with both Lukov's specific medical history and the very latest research might know to make the connection—to add one more biomarker test, for KRAS, and then to find a clinical trial testing the efficacy of KRAS treatments on lung cancer. But the national treatment guidelines for lung cancer don't recommend such action, and few physicians, however conscientious, would think to do these things.

Did Lukov ultimately get the right treatment? Did his oncologist make the connection between KRAS and his condition, and order the test? He might have, if Lukov were a real patient and the oncologist were a real doctor. They're not. They are fictional composites developed by researchers at the Memorial Sloan-Kettering Cancer Center in New York, in order to help train—and demonstrate the skills of—IBM's Watson supercomputer. Yes, this is the same Watson that famously went on *Jeopardy* and beat two previous human champions. But IBM didn't build Watson to win game shows. The company is developing Watson to help professionals with complex decision making, like the kind that occurs in oncologists' offices—and to point out clinical nuances that health professionals might miss on their own.

Information technology that helps doctors and patients make decisions has been around for a long time. Crude online tools like WebMD get millions of visitors a day. But Watson is a

different beast. According to IBM, it can digest information and make recommendations much more quickly, and more intelligently, than perhaps any machine before it—processing up to 60 million pages of text per second, even when that text is in the form of plain old prose, or what scientists call "natural language."

That's no small thing, because something like 80 percent of all information is "unstructured." In medicine, it consists of physician notes dictated into medical records, long-winded sentences published in academic journals, and raw numbers stored online by public-health departments. At least in theory, Watson can make sense of it all. It can sit in on patient examinations, silently listening. And over time, it can learn. Just as Watson got better at *Jeopardy* the longer it played, so it gets better at figuring out medical problems and ways of treating them the more it interacts with real cases. Watson even has the ability to convey doubt. When it makes diagnoses and recommends treatments, it usually issues a series of possibilities, each with its own level of confidence attached.

Medicine has never before had a tool quite like this. And at an unofficial coming-out party in Las Vegas last year, during the annual meeting of the Healthcare Information and Management Systems Society, more than 1,000 professionals packed a large hotel conference hall, and an overflow room nearby, to hear a presentation by Marty Kohn, an emergency-room physician and a clinical leader of the IBM team training Watson for health care. Standing before a video screen that dwarfed his large frame, Kohn described in his husky voice how Watson could be a game changer—not just in highly specialized fields like oncology but also in primary care, given that all doctors can make mistakes that lead to costly, sometimes dangerous, treatment errors.

Drawing on his own clinical experience and on academic studies, Kohn explained that about one-third of these errors appear to be products of misdiagnosis, one cause of which is "anchoring bias": human beings' tendency to rely too heavily on a single piece of information. This happens all the time in doctors' offices, clinics, and emergency rooms. A physician hears about two or three symptoms, seizes on a diagnosis consistent with those, and subconsciously discounts evidence that points to something else. Or a physician hits upon the right diagnosis, but fails to realize that it's incomplete, and ends up treating just one condition when the patient is, in fact, suffering from several. Tools like Watson are less prone to those failings. As such, Kohn believes, they may eventually become as ubiquitous in doctors' offices as the stethoscope.

"Watson fills in for some human limitations," Kohn told me in an interview. "Studies show that humans are good at taking a relatively limited list of possibilities and using that list, but are far less adept at using huge volumes of information. That's where Watson shines: taking a huge list of information and winnowing it down."

Watson has gotten some media hype already, including articles in *Wired* and *Fast Company*. Still, you probably shouldn't expect to see it the next time you visit your doctor's office. Before the computer can make real-life clinical recommendations, it must learn to understand and analyze medical information, just as it once learned to ask the right questions on *Jeopardy*. That's where Memorial Sloan-Kettering comes in. The famed cancer institute has signed up to be Watson's tutor, feeding it clinical information extracted from real cases and then teaching it how to make sense of the data. "The process of pulling out two key facts from a *Jeopardy* clue is totally different from pulling out all the relevant information, and its relationships, from a medical case," says Ari Caroline, Sloan-Kettering's director of quantitative analysis and strategic initiatives. "Sometimes there is conflicting information. People phrase things different ways." But Caroline, who approached IBM about the research collaboration, nonetheless predicts that Watson will prove "very valuable"—particularly in a field like cancer treatment, in which the explosion of knowledge is already overwhelming. "If you're looking down the road, there are going to be many more clinical options, many more subtleties around biomarkers … There will be nuances not just in interpreting the case but also in treating the case," Caroline says. "You're going to need a tool like Watson because the complexity and scale of information will be such that a typical decision tool couldn't possibly handle it all."

The Cleveland Clinic is also helping to develop Watson, first as a tool for training young physicians and then, possibly, as a tool at the bedside itself. James Young, the executive

dean of the Cleveland Clinic medical school, told *The Plain Dealer*, "If we can get Watson to give us information in the health-care arena like we've seen with more-general sorts of knowledge information, I think it's going to be an extraordinary tool for clinicians and a huge advancement." And WellPoint, the insurance company, has already begun testing Watson as a support tool for nurses who make treatment-approval decisions.

Whether these experiments show real, quantifiable improvements in the quality or efficiency of care remains to be seen. If Watson tells physicians only what they already know, or if they end up ordering many more tests for no good reason, Watson could turn out to be more hindrance than help. But plenty of serious people in the fields of medicine, engineering, and business think Watson will work (IBM says that it could be widely available within a few years). And many of these same people believe that this is only the beginning—that whether or not Watson itself succeeds, it is emblematic of a quantum shift in health care that's just now getting under way.

When we think of breakthroughs in medicine, we conjure up images of new drugs or new surgeries. When we think of changes to the health-care system, byzantine legislation comes to mind. But according to a growing number of observers, the next big thing to hit medical care will be new ways of accumulating, processing, and applying data—revolutionizing medical care the same way Billy Beane and his minions turned baseball into "moneyball." Many of the people who think this way—entrepreneurs from Silicon Valley, young researchers from prestigious health systems and universities, and salespeople of every possible variety—spoke at the conference in Las Vegas, proselytizing to the tens of thousands of physicians and administrators in attendance. They say a range of innovations, from new software to new devices, will transform the way all of us interact with the health-care system—making it easier for us to stay healthy and, when we do get sick, making it easier for medical professionals to treat us. They also imagine the transformation reverberating through the rest of the economy, in ways that may be even more revolutionary.

Health care already represents one-sixth of America's gross domestic product. And that share is growing, placing an ever-larger strain on paychecks, corporate profits, and government resources. Figuring out how to manage this cost growth—how to meet the aging population's medical needs without bankrupting the country—has become the central economic-policy challenge of our time. These technology enthusiasts think they can succeed where generations of politicians, business leaders, and medical professionals have failed.

Specifically, they imagine the application of data as a "disruptive" force, upending health care in the same way it has upended almost every other part of the economy—changing not just *how* medicine is practiced but *who* is practicing it. In Silicon Valley and other centers of innovation, investors and engineers talk casually about machines' taking the place of doctors, serving as diagnosticians and even surgeons—doing the same work, with better results, for a lot less money. The idea, they say, is no more fanciful than the notion of self-driving cars, experimental versions of which are already cruising California streets. "A world mostly without doctors (at least average ones) is not only reasonable, but also more likely than not," wrote Vinod Khosla, a venture capitalist and co-founder of Sun Microsystems, in a 2012 TechCrunch article titled "Do We Need Doctors or Algorithms?" He even put a number on his prediction: someday, he said, computers and robots would replace four out of five physicians in the United States.

Statements like that provoke skepticism, derision, and anger—and not only from hidebound doctors who curse every time they have to turn on a computer. Bijan Salehizadeh, a trained physician and a venture capitalist, responded to reports of Khosla's premonition and similar predictions with a tweet: "Getting nauseated reading the anti-doctor rantings of the silicon valley tech crowd." Physicians, after all, do more than process data. They attend at patients' bedsides and counsel families. They grasp nuance and learn to master uncertainty.

For their part, the innovators at IBM make a point of presenting Watson as a tool that can help health-care professionals, rather than replace them. Think Dr. McCoy using his tricorder to diagnose a phaser injury on *Star Trek*, not the droid fitting Luke Skywalker with a robotic hand in *Star Wars*. To most experts, that's a more realistic picture of what medicine will look like, at least for the foreseeable future.

But even if data technology does nothing more than arm health-care professionals with tablet computers that help them make decisions, the effect could still be profound. Harvey Fineberg, the former dean of the Harvard School of Public Health and now the president of the Institute of Medicine, wrote of IT's rising promise last year in *The New England Journal of Medicine*, describing a health-care system that might be transformed by artificial intelligence, robotics, bioinformatics, and other advances. Tools like Watson could enhance the abilities of professionals at every level, from highly specialized surgeons to medical assistants. As a result, physicians wouldn't need to do as much, and each class of professionals beneath them could take on greater responsibility—creating a financially sustainable way to meet the aging population's growing need for more health care.

As an incidental benefit, job opportunities for people with no graduate degree, and in some cases no four-year-college degree, would grow substantially. For the past few decades, as IT has disrupted other industries, from manufacturing to banking, millions of well-paying middle-class jobs—those easily routinized—have vanished. In health care, this disruption could have the opposite effect. It wouldn't be merely a win-win, but a win-win-win. It all sounds far too good to be true—except that a growing number of engineers, investors, and physicians insist that it isn't.

One of these enthusiasts is Daniel Kraft, age 44, whose career trajectory tracks the way medicine itself is evolving. Kraft is a physician with a traditional educational pedigree: an undergraduate degree from Brown and a medical degree from Stanford. He trained in pediatrics and internal medicine at Harvard-affiliated hospitals in Boston. Then he returned to the West Coast, to Stanford University Hospital, to complete fellowships in hematology and oncology.

But Kraft always had a flair for entrepreneurship and a taste for technology: While in medical school, he started his own online bookstore, selling texts to his classmates at a discount. (He later sold the business, for considerable profit.) At Stanford, Kraft says he used his knowledge of social media to develop a better method for communication among doctors, allowing them to exchange pertinent information while making rounds, for instance, rather than simply texting phone numbers for callbacks. "Here we are at Stanford, heart of Silicon Valley, and all we had were basic SMS text pagers—they could only do phone numbers," Kraft recalls. "So I hacked into a Yahoo Groups thing, so we could send actual text messages through servers. Then it spread to the rest of the hospital."

"In Brazil and India, machines are already starting to do primary care, because there's no labor to do it. They may be better than doctors. Mathematically, they will follow evidence—and they're much more likely to be right."

Thus began Kraft's second, parallel career as an inventor, an entrepreneur, and a professional visionary. He audited classes in bio-design and business, hanging out with computer nerds as much as doctors. Today he holds several patents, including one for the MarrowMiner, a device that allows bone marrow to be harvested faster and less painfully. (Kraft is the chief medical officer for a company that plans to develop it commercially.) Kraft is also the chairman of the medical track at Singularity University, a think tank and educational institution in Silicon Valley. Initially, Kraft's primary role at Singularity was to offer a few hours of instruction on medicine. But Kraft says he quickly realized that "a lot of people, in gaming, IT, Big Data, devices, virtual reality, psychology—they were all converging on health care, and interested in applying their skills to health care." That led Singularity to establish FutureMed, an annual conference on medical innovation that brings together financiers, physicians, and engineers from around the world. Kraft is the director.

Exponential improvements in the ability of computers to process more and more data, faster and faster, are part of what has drawn this diverse crew to medicine—a field of such complexity that large parts of it have, until recently, stood outside the reach of advanced information technology. But just as significant, Kraft and his fellow travelers say, is the explosion of data available for these tools to manipulate. The Human Genome Project completed its detailed schematic of human DNA in 2003, and for the past several years, companies have provided personal genetic mapping to people with the means to pay for it. Now the price, once prohibitive, is within reach for most people and insurance plans. Researchers have only just begun figuring out how

genes translate into most aspects of health, but they already know a great deal about how certain genetic sequences predispose people to conditions like heart disease and breast cancer. Many experts think we will soon enter an era of "personalized" medicine, in which physicians tailor treatments—not just for cancer, but also for conditions like diabetes and heart disease—to an individual patient's genetic idiosyncrasies.

A potentially larger—and, in the short run, more consequential—data explosion involves the collection, transmission, and screening of relatively simple medical data on a much more frequent basis, enabling clinicians to make smarter, quicker decisions about their patients. The catalyst is a device most patients already have: the smartphone. Companies are developing, and in some cases already selling, sensors that attach to phones, to collect all sorts of biological data. The companies Withings and iHealth, for example, already offer blood-pressure cuffs that connect to an iPhone; the phone can then send the data to health-care professionals via e-mail, or in some cases, automatically enter them into online medical records. The Withings device sells for $129; iHealth's for $99. Other firms sell devices that diabetics can use to measure glucose levels. In the U.K., a consortium has been developing a smartphone app paired with a device that will allow users to test themselves for sexually transmitted diseases. (The test will apparently involve urinating onto a chip attached to the phone.)

AliveCor, a San Francisco–based firm, has developed an app and a thin, unobtrusive smartphone attachment that can take electrocardiogram readings. The FDA approved it for use in the U.S. in December. While the device was still in its trial phase, Eric Topol, the chief academic officer at Scripps Health in San Diego and a well-known technology enthusiast, used a prototype of the device to diagnose an incipient heart attack in a passenger on a transcontinental flight from Washington, D.C., to San Diego. The plane made an emergency landing near Cincinnati and the man survived.

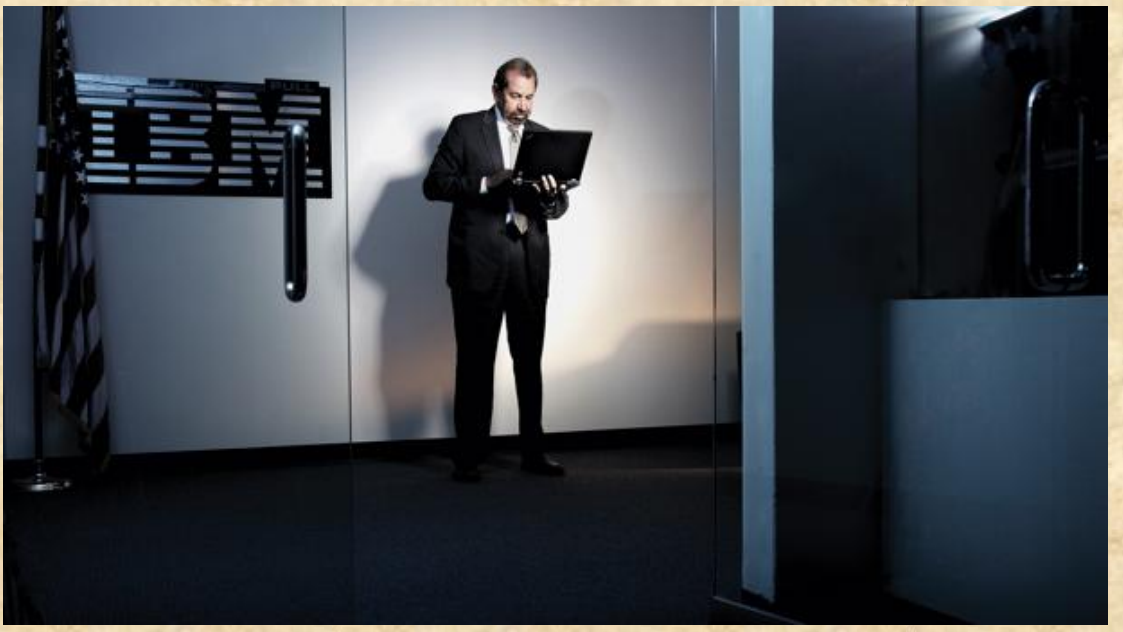
Ari Caroline and his colleagues at Sloan-Kettering are leading Watson's training in cancer care. "You're going to need a tool like Watson," he says, given the rapidly increasing complexity of the field. (Kareem Black)

As sensors shrink and improve, they will increasingly allow health to be tracked constantly and discreetly—helping people to get over illnesses faster and more reliably—and in the best of cases, to avoid getting sick in the first place. One group of researchers, based at Emory University and Georgia Tech, developed a prototype for one such device called StealthVest, which—as the name implies—embeds sensors in a vest that people could wear under their regular clothing. The group designed the vest for teenagers with chronic disease (asthma, diabetes, even sickle-cell anemia) because, by their nature,

teenagers are less likely to comply with physician instructions about taking readings or medications. But the same technology can work for everyone. For instance, as Sloan-Kettering's Ari Caroline notes, right now it's hard for oncologists to get the detailed patient feedback they need in order to serve their patients best. "Think about prostate surgery," he says. "You really want to check patients' urinary and sexual function on a regular basis, and you don't get that when they come in once every three or four months to the clinic—they'll just say generally 'good' or 'bad.' The data will only get collected when people are inputting it on a regular basis and it captures their daily lives."

As more and more data are captured, and as computers become better and faster at processing them autonomously, the possibilities keep expanding. One medical-data start-up getting some buzz is a company called Predictive Medical Technologies, based in San Francisco. It is developing a program that sucks in all the data generated in a hospital's intensive-care unit, plugs the information into an algorithm, and then identifies which patients are likely to experience a heart attack or other forms of distress—providing up to 24 hours of warning. A trial is under way at the University of Utah's hospital in Salt Lake City. The eventual goal is to expand the program's capabilities, so that it can monitor conditions throughout the hospital. "You don't just want more data," Kraft says. "You want actual information in a form you can use. You need to be able to make sense of this stuff. That's what companies like Predictive Medical do."

Watson "fills in for some human limitations," says IBM's Marty Kohn, a physician, who emphasizes that Watson is being developed to support doctors, not replace them. (Kareem Black)



So how would all these innovations fit together? How would the health-care system be different—and how, from a patient's standpoint, would it *feel* different—from the one we have today? Imagine you're an adult with a chronic condition like high blood pressure. Today, your contact with the health-care system would be largely episodic: You'd have regular checkups, at which a doctor or maybe a nurse-practitioner would check your blood pressure and ask about recent behavior—diet, exercise, and whatnot. Maybe you'd give an accurate account, maybe you wouldn't. If you started experiencing pain or had some other sign of trouble, you'd make an appointment and come in—but by then, the symptom might well have subsided, making it hard to figure out what was going on.

In the future as the innovators imagine it—"Health 2.0," as some people have started calling it—you would be in constant contact with the health-care system, although you'd hardly be aware of it. The goal would be to keep you healthy—and any time you were in danger of becoming unhealthy, to ensure you received attention right away. You might wear a bracelet that monitors your blood pressure, or a

pedometer that logs movement and exercise. You could opt for a monitoring system that makes sure you take your prescribed medication, at the prescribed intervals. All of these devices would transmit information back to your provider of basic medical care, dumping data directly into an electronic medical record.

And the provider wouldn't be one doctor, but rather a team of professionals, available at all hours and heavily armed with technology to guide and assist them as they made decisions. If, say, your blood pressure suddenly spiked, data-processing tools would warn them that you might be in trouble, and some sort of clinician—a nurse, perhaps—would reach out to you immediately, to check on your condition and arrange treatment as necessary. You could reach the team just as easily, with something as simple as a text message or an e-mail. You'd be in touch with them more frequently, most likely, but for much shorter durations—and, for the most part, with less urgency.

Sometimes, of course, office or hospital visits would be necessary, but that experience would be different, too—starting with the hassle of dealing with insurance companies. Watson has a button for submitting treatment proposals to managed-care companies, for near-instant approval, reducing the time and hassle involved in gaining payment authorization. The transformation of the clinical experience could be more profound, although you might not detect it: someone in a white coat or blue scrubs would still examine you, perform tests, prescribe treatment. But that person might have a different background than he'd have today. And as the two of you talked, your exam information would be uploaded and cross-referenced against your medical record (including the data from all those wireless monitors you've been toting around), your DNA, and untold pages of clinical literature.

The evolution toward a more connected system of care has already begun at some large organizations that use team models of care. One such institution is the Group Health Cooperative of Puget Sound, a nonprofit, multi-specialty group practice. Matt Handley, the medical director for quality and informatics, says that about two-thirds of Group Health's patients now use some form of electronic communication, and that these methods account for about half of all "touches" between patients and the group's doctors or nurses. "They set up their own appointments … They don't need to call somebody and ask when I'm free," Handley says. "They send messages to doctors; look up lab tests and radiology results; and order refills … The fascinating thing is that people of all ages are using it … I have people in their 90s who secure-message me."

It's a long way from Group Health to Health 2.0, and Handley is among those who are wary of the hype. Sure, the demos for products like Watson look great. They always do. But can such tools really winnow down information in a way that physicians will find useful? Can they effectively scour new medical literature—some 30,000 articles a month, by Handley's reckoning—and make appropriate use of new evidence? Will they actually improve medicine? "While Watson could sometimes be helpful, it may actually drive up the cost of care," Handley says, by introducing more possible diagnoses for each patient—diagnoses that clinicians will inevitably want to investigate with a bevy of expensive tests. A study in the journal *Health Affairs*, published in March 2012, found that physicians with instant electronic access to test results tended to order more tests—perhaps because they knew they could see and use the results quickly. It's the same basic principle Handley has identified: if new tools allow providers to process far more information than they do now, providers might respond by trying to gather even more information.

Another reason for skepticism is the widespread lack of good electronic medical records, or EMRs, the foundation on which so many promising innovations rest. Creating EMRs has been a frustratingly slow process, spanning at least the past two decades. And even today the project is a mess: more than 400 separate vendors offer EMRs, and the government is still trying to establish a common language so that they can all "speak" to one another. "Our doctors have state-of-the-art electronic health-record systems," says Brian Ahier, the health-IT evangelist (yes, that is his real title) at the Mid-Columbia Medical Center, in northern Oregon, and a widely read writer on medical innovation. "But for clinical communication" outside the medical center, "they have to print it out, fax it, and then scan" what they get back.

But despite these risks and stumbling blocks, there are reasons to think the next wave of innovations might really

stick. One is legislation enacted by the Obama administration. The 2009 Recovery Act—the $800 billion stimulus designed to end the economic crisis—set aside funds for the creation of a uniform standard for electronic medical records. It also made changes to Medicare, so reimbursement to doctors and hospitals now depends partly on whether they adopt EMRs and put them to "meaningful use." The incentives seem to be working: according to a September 2012 survey by the consulting firm CapSite, nearly seven in 10 doctors now use EMRs. The trade publication *InformationWeek* called this tally a "tipping point."

Under the Affordable Care Act, a.k.a "Obamacare," Medicare will also begin rewarding providers who form integrated organizations, like Group Health Cooperative of Puget Sound, and groups that accept "bundled" payments, so that they are paid based on the number of patients in their care rather than for each service rendered. In theory, this financing scheme should encourage medical practices and hospitals to keep patients healthier over the long term, even if that means spending money up front on technology in order to reduce the frequency of patient visits or procedures. In other words, the new, digital model for health care should eventually become more economically viable.

One sign that medical care is in the midst of a massive transformation, or at least on the cusp of one, is the extraordinary rise in demand for information-technology workers within the health-care sector. All over the country, hospitals are on a hiring binge, desperate for people who can develop and install new information systems—and then manage them or train existing workers to do so. According to one government survey, online advertisements for health-IT jobs tripled from 2009 to 2010. And the growth is likely to continue. The Bureau of Labor Statistics estimates that in this decade, the health-IT workforce will grow by 20 percent. Most experts believe that such growth still won't be nearly enough to fill the demand. But it's the data revolution's ability to *change* jobs within health care—to alter the daily workflow of medical assistants, nurses, doctors, and care managers—that might have the most far-reaching effects not just on medicine, but also on the economy.

Economists like to say that health care suffers from a phenomenon called "Baumol's disease," or "the Baumol effect," first described half a century ago by the economist William Baumol, in collaboration with a fellow economist named William Bowen. In most occupations, wages rise only when productivity improves. If factory workers get an extra dollar an hour, it's because they can produce extra value, thanks to better training or equipment. Baumol and Bowen observed that certain labor-intensive occupations don't operate by the same principle: job productivity doesn't rise much, but wages go up anyway, because employers need to keep paying workers more in order to stop them from pursuing other lines of work, in other sectors where productivity is rising quickly. That forces the employers to keep raising prices, just to provide the same level of service.

Over time, industries afflicted with Baumol's disease tend to consume a larger and larger proportion of a nation's income, because their cost, relative to everything else, climbs ever upward. The health-care industry has a textbook case of Baumol's disease, and so far, technology hasn't made much of an impact. Just as it still takes five string players to play a Mozart quintet (Baumol's famous example), so it still takes a highly trained surgeon to operate on somebody. "We do now have robots performing surgery, but the robot is under constant supervision of the surgeon during the process," Baumol told a reporter from *The New York Times* two years ago. "You haven't saved labor. You have done other good things, but it isn't a way of cheapening the process." Likewise, a doctor in a clinic still sees patients individually, listens to their problems, orders tests, makes diagnoses—in the classic economic sense, the process of an office visit is no more efficient than it was 10, 30, or 50 years ago.

Now technology could actually change that process, not by making the exam faster but by enabling somebody else to conduct it—or to perform the test, or carry out the procedure. The idea of robots performing surgery or more-routine medical tasks with less supervision is something many experts take seriously—in part because, in the developing world, burgeoning demand for care is already pushing medicine in this direction. As part of an experimental program in Tanzania, rural health workers, many of whom have relatively little medical training, have access to a "decision-support

tool" that can help them diagnose and treat illness based on symptoms. And thanks to an initiative called the Maternal Health Reporter, similar caregivers in India can submit patient information to a central data bank, then receive regular reminders about care for pregnant women.

"In Brazil and India, machines are already starting to do primary care, because there's no labor to do it," says Robert Kocher, an internist, a veteran of McKinsey consulting, and a former adviser to the Obama administration. He's now a partner at Venrock, a New York venture-capital firm that invests in emerging technologies, including health-care technology. "They may be better than doctors. Mathematically, they will follow evidence—and they're much more likely to be right." In the United States, Kocher believes, advanced decision-support tools could quickly find a home in so-called minute clinics—the storefront medical offices that drugstores and other companies are setting up in pharmacies and malls. There, the machines could help nonphysician clinicians take care of routine medical needs, like diagnosing strep throat—and could potentially dispense the diagnoses to patients more or less autonomously. Years from now, he says, other machines could end up doing "vascular surgery, fistulas, eye surgery, microsurgery. Machines can actually be more precise than human hands."

Nobody (including Kocher) expects American physicians to turn the keys of their practices over to robots. And nobody would expect American patients accustomed to treatment from live human beings to tolerate such a sudden shift for much of their care, mall-based minute clinics notwithstanding. But because of a unique set of circumstances, the health-care workforce could nonetheless undergo enormous change, without threatening the people already working in it.

Between the aging of the population and the expansion of health-insurance coverage under Obamacare, many more people will seek medical attention in the coming years—whether it's basic primary care or ongoing care for chronic conditions. But we don't have nearly enough primary-care doctors—in practice today or in training—to provide this care. And even if we trained more, we wouldn't have enough money to pay them. With the help of decision-support tools and robotics, health-care professionals at every level would be able to handle more-complicated and more-challenging tasks, helping to shoulder part of the load. And finding enough nurses or technicians or assistants would be a lot easier than finding enough doctors. They don't need as many years to train, and they don't cost as much to pay once their training is finished. According to the Bureau of Labor Statistics, doctors' median annual salary is $166,400, while nurses' is $64,690 and medical assistants' is $28,860.

Health professionals at all levels tend to guard their turf ferociously, lobbying state officials to prevent encroachments from other providers. But the severe shortage of professionals to provide primary care means there should be plenty of work to go around. Already today, there's a push within health-care-policy circles to more consistently allow providers to "practice at the top of their licenses"—that is, to let the people at each level of training do as much as their training could possibly allow them to do. That would enable higher-wage, more-highly-skilled professionals to focus on work that's truly commensurate with their education. It would also reduce the cost of care. Watson and its ilk could help us take this concept further, by augmenting the capabilities of workers at every skill level. Physicians could lead large teams of mid- and low-level providers, delegating less complicated and more routine tasks. "Having nurses, with the assistance of these artificial-intelligence tools, [do more] frees physicians to perform the higher-level interventions, allowing everyone to practice at the top of their license," Brian Ahier says.

That model actually isn't so different from the collaborative approach that institutions like Group Health have been deploying with such success. "We focus on developing teams—teams of several doctors, physician assistants, nurse-practitioners, and/or nurses," Matt Handley says. "Every day starts with a huddle: the team talks about the day and reviews a couple of topics and cases, figures out who is going to need what, from which provider, and so on."

The providers with less medical training can be more technologically adept, anyway. "The doctor or clinician of course has the high analytic skills, makes the judgment calls, the diagnoses, prescribes medications," says Catherine Dower, an associate director at UC San

Francisco's Center for the Health Professions. "But the medical assistants are frequently the ones who can actually use this new technology really well, including tele-health—they can get bio-feeds from patients sitting at home, they can tap insulin and cardiac rates. And then, as this information is fed into a central site, the medical assistant can read and make a decision on which patient should come in and be seen by the doctor, and which one needs some minor modification"—whether that means adjusting medication or scheduling a visit to discuss more-significant changes in treatment or therapy.

For the health-care system as a whole, the efficiencies from the data revolution could amount to substantial savings. One estimate, from the McKinsey Global Institute, suggested that the data revolution could yield onetime heath-care savings of up to $220 billion, followed by a slower rate of growth in health-care costs. Total health-care spending in the U.S. last year was $2.7 trillion, so that would be roughly the equivalent of reducing health-care spending by 7.5 percent up front. That's the best reason to believe that the data revolution will make a difference, even if it never lives up to the hype of its most enthusiastic proponents. The health-care system is so massive, so full of waste, so full of failure, that even a marginal change for the better could save billions of dollars, not to mention quite a few lives.

And, in a small way, it could help us begin to fill the hole that's developed in the middle class. David Autor, an economist at MIT, has noted that for the past generation, technological change in the U.S. has tended to favor highly skilled workers at the expense of those with mid-level skills. Routine clerical functions, for instance, have been automated, contributing to the hollowing-out of the middle class. But in the coming years, health care may prove a large and important exception to that general rule—effectively turning the rule on its head. "Look at physician-assistant positions," Dower says. "They don't require college or a bachelor's degree, just a technical program." And once you're certified, "you come out with a pretty good salary, up in the $75,000-to-$80,000 range." If technological aids allow us to push more care down to people with less training and fewer skills, more middle-class jobs will be created along the way.

"I don't think physicians will be seeing patients as much in the future," says David Lee Scher, a former cardiac electrophysiologist and the president of DLS Healthcare Consulting, which advises health-care organizations and developers of digital health-care technologies. "I think they are transitioning into what I see as super-quality-control officers, overseeing physician assistants, nurses, nurse-practitioners, etc., who are really going to be the ones who see the patients." Scher recognizes the economic logic of this transition, but he's also deeply ambivalent about it, noting that something may be lost—because there are still some things that technology cannot do, and cannot enable humans to do. "Patients appreciate nonphysician providers because they tend to spend more time with them and get more humanistic hand-holding care. However, while I personally have dealt with some excellent mid-level providers, they generally do not manage complex diseases as well as physicians. Technology-assisted algorithms might contribute to narrowing this divide."

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Even Watson, which has generated so much positive buzz in medicine and engineering, has its doubters. "Watson would be a potent and clever companion as we made our rounds," wrote Abraham Verghese, a Stanford physician and an author, in *The New York Times*. "But the complaints I hear from patients, family and friends are never about the dearth of technology but about its excesses."

Marty Kohn, from the Watson team, understands such skepticism, and frequently warns enthusiasts not to overpromise what the machine can do. "When people say IT can be transformative, I get a little anxious," he told me. Partly that's because he thinks technology can't change an industry, or a culture, if the professionals themselves aren't committed to such a transformation—Watson won't change medicine, in other words, if the people who practice medicine don't want it to change. As a physician, Kohn is careful to describe Watson as a "clinical support" tool rather than a "decision making" tool—to emphasize that it's a machine that can help health-care professionals, rather than replace them. "Some technologies are truly transforming health care, providing therapies that never existed before. I

don't view IT that way. I view IT as an enabler." Still, Kohn has reconciled himself to hearing people talk about Watson as if it were a person—he says he's now used to answering the question "Who is Watson?" rather than "What is Watson?" He also likes to tell a story about a speech he gave in Canada, one that, like the Las Vegas presentation, attracted more people than the room could hold. That evening he called his wife, to tell her about the enthusiasm. "That's really great, Marty," he recalls her saying. "Just remember, they were there to meet Watson, not you."

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