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Influenza: The Next Generation

by Marian Rodgers, RN, MPH, Infectious Disease Control Consultant and Mary DiOrio, MD, MPH, Medical Epidemiologist

What can we expect this fall with respect to influenza? The crystal ball always appears foggy at this time of year, but influenza is a dangerous winter visitor whose entry is anticipated and for which we can prepare. Even in a year with a significant influenza vaccine shortage, there is much that we can do to protect ourselves and those for whom we care.

The 2003-2004 trivalent inactivated vaccine virus strains included two influenza A antigens: A/Moscow-like (H3N2) and A/New Caledonia-like (H1N1), as well as one influenza B antigen B/Hong Kong-like. The Fujian strain appeared less of a risk than the chosen strains. As the 2003-04 season passed, however, the Fujian strain spread more rapidly and became the predominant strain of last season's disease activity. When it became apparent that the vaccine did not contain the major circulating virus strain, many individuals questioned whether the vaccine would provide any protection against this strain. This concern increased when a study performed near the end of the season gave the initial impression that the vaccine failed by not preventing influenza-like illness (ILI) among vaccinated health care workers.

Formal studies later showed that the vaccine conferred some protection among both high-risk adults and fully vaccinated children (1). Specifically, the vaccine efficacy for fully vaccinated children compared to unvaccinated children was 25 percent for preventing ILI and 49 percent in preventing pneumonia and influenza. Among adults, the vaccine efficacy was 38 percent among high-risk adults in preventing laboratory-confirmed influenza and 52 percent among those without a high-risk condition.

This season's vaccine contains A/Fujian-like (H3N2) and A/New Caledonia-like (H1N1) as well as B/Shanghai-like antigens. The prevalence of individual influenza strains and how they vary from year to year can be seen in Figures 1 and 2 (following page).

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Figure 1: Prevalence of influenza strains, 2002-2003, by week (2). From: http://www.cdc.gov/flu/weekly/weeklyarchives2002-2003/02-03summary.htm

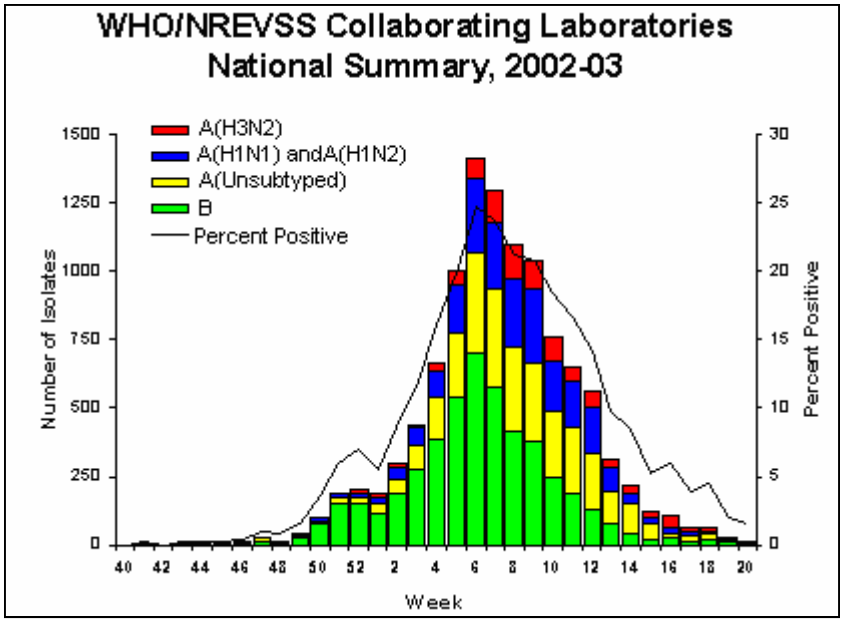
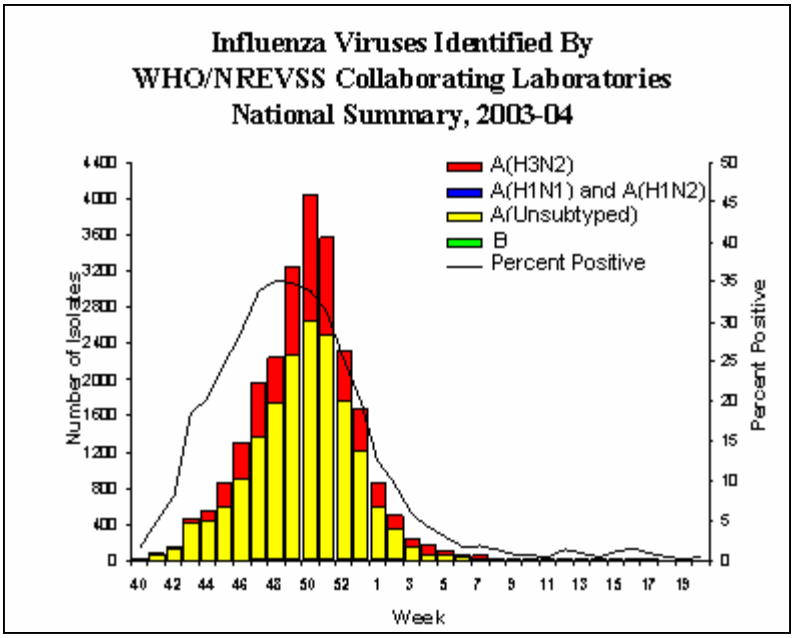


Figure 2: Prevalence of influenza strains, 2003-2004, by week (2). From: http://www.cdc.gov/flu/weekly/weeklyarchives2002-2003/02-03summary.htm



Because influenza vaccine production requires several months, every year's vaccine has a "best educated guess" composition. Every year, sentinel laboratories scattered throughout the world culture and collect viral respiratory cultures, saving influenza isolates. Some of these are forwarded to one of four World Health Organization (WHO) reference laboratories for analysis and testing [the Centers for Disease Control and Prevention (CDC) is one site]. These laboratories also test how well antibodies made to the current vaccine react to circulating virus and new influenza viruses. This information, along with information about disease activity, is summarized and presented to an advisory committee of the U.S. Food and Drug Administration and to a committee at the WHO in January or February of each year. These meetings result in the selection of three virus strains (two subtypes of influenza A viruses and one of influenza B) to go into the influenza vaccine for the following fall and winter influenza season. Usually, one or two of the three virus strains in the vaccine is changed each year. This lengthy influenza vaccine production process also means that when a vaccine shortage occurs, the rapid production of new vaccine is not possible.

Children, especially the very young, have always been at higher risk of serious disease from influenza. Although last year saw more reports of pediatric deaths, whether the increase was real or due to increased attention to the issue

is uncertain. This year's guidelines from the American Academy of Pediatrics and the CDC recommend vaccination for children 6 months to 23 months of age (3). If there had not been an influenza vaccine shortage this year, public health recommendations would have called for the vaccination of family members and care givers of all children under the age of 2 years to prevent these contacts from becoming ill and then exposing the children. Given the severe influenza vaccine shortage, household contacts and care givers of children aged 6 to 23 months are not recommended to receive the vaccine unless they have another reason to be vaccinated. Nevertheless, household contacts and caregivers of children under 6 months of age are recommended to receive the vaccine because these infants will not be able to be vaccinated.

Who should be vaccinated this year?

Given the severe influenza vaccine shortage for the 2004-2005 influenza season, CDC announced the following groups as the intended recipients of the inactivated influenza vaccine:

- all children aged 6 to 23 months;
- adults aged 65 years and older;
- persons aged 2 to 64 years with underlying chronic medical conditions;
- all women who will be pregnant during the influenza season;
- residents of nursing homes and long-term care facilities;
- children aged 6 months to 18 years on chronic aspirin therapy;
- health care workers involved in direct patient care; and
- out-of-home caregivers and household contacts of children aged less than 6 months.

Is avian flu the pandemic strain?

Influenza A can infect a wide variety of animals, including pigs and chickens. Fortunately, for the most part, animal strains do not usually transmit efficiently to humans. Unfortunately, because Asian farmers often live close to their farm animals, mutations can enable animal (including avian) strains to spread to humans. For this reason, Asia is often the source for new influenza strains.

When a new animal strain becomes able to pass efficiently from human to human, previous vaccines are usually ineffective and already existing immunity may be ineffective. The new strain may be more or less pathogenic than previous strains. This past year saw international concern when several farmers in Southeast Asia became infected with an avian strain (H5N1) and became severely ill, including some deaths. Fortunately, H5N1 has not developed the ability to spread efficiently from human to human. Yet, H5N1 spreads easily among chickens and has become difficult to eradicate.

The WHO and the CDC are keeping a close eye on H5N1, as well as other avian strains. Responses to a pandemic may call for the rapid development of a new vaccine, deployment of antiviral drugs from the Strategic National Stockpile, mass vaccination clinics and dealing with vaccine shortages if need and demand overwhelm the supply.

What measures can be taken to protect Ohio communities this year?

1. Vaccinate those in the highest-risk groups:

   With the severe shortage of influenza vaccine, individuals at the highest risk from influenza disease should be prioritized to receive the inactivated influenza vaccine. Those individuals are listed on this page. If you are a healthy Ohioan between the ages of 5 and 49, please consider forgoing your flu shot this year to help stretch the limited supply of vaccine for the most vulnerable among us. Healthy people in this age group may also consider FluMist. This vaccine, which includes attenuated (i.e., weakened), but live, influenza virus, provides protection but is not appropriate for high-risk individuals.

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2. Encourage non-medical protective measures:

   Encourage respiratory hygiene by asking ill individuals to cover their coughs and place tissue supplies in strategic, convenient locations. Everyone should practice healthy self-care: good hand hygiene, proper nutrition, adequate rest and exercise. People should stay home from work when they are ill; when their children are sick, they should keep them home. In addition, high-risk individuals should avoid crowds during the "respiratory season" of October through March.

3. Contribute to surveillance activities:

   When the first positive screening tests for influenza appear in the fall, submit samples for viral cultures either locally or to the Ohio Department of Health Laboratory [there is no charge for this]. Cultures are also needed in the middle of the season and at the end, as strain change (drift) happens.

   Volunteer your outpatient health care facility to become an influenza sentinel surveillance site. To request more information or to enroll in the U.S. Influenza Sentinel Provider Surveillance Network, contact Shannon Rowe, Ohio's influenza surveillance coordinator, at 614-466-0456.

   Screen for influenza and take viral cultures in unusual or clinically severe cases. Last year's influenza season raised questions about influenza-associated encephalopathy, other serious illnesses and deaths. Viral culture results are needed to better understand the etiology and patient characteristics of those with severe disease.

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2. Department of Health and Human Services, Pandemic Influenza Response and Preparedness Plan, http://www.dhhs.gov/nvpo/pandemicplan/ .
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ODH's Appalachian Ridge Oral Rabies Vaccination Program: September 2004

by Kathy Smith, DVM, MPH, State Veterinarian

Rabies is a viral disease that affects animals and people. It is still almost always fatal unless a very expensive and uncomfortable series of vaccinations is initiated soon after the bite. The strain of rabies associated with raccoons is of particular concern because it affects so many other wild animals and our pets, especially cats. This strain of rabies is now endemic from Maine to Florida, and has been spreading westward toward Ohio. In 2003, Virginia reported the first human death due to raccoon rabies. In newly infected areas, raccoon rabies results in a tenfold increase in human rabies exposures and treatments. For these reasons, Ohio does not want this strain of rabies to become established in the state.

In 1997, raccoon rabies made its debut into Ohio. In addition to implementing aggressive wildlife diseases surveillance and public awareness efforts, Ohio used a new tool to fight rabies – an oral rabies vaccine for raccoons. Since May 1997, vaccine-laden baits (Raboral-V @Merial Ltd.) have been distributed along the Ohio, Pennsylvania and West Virginia borders. This has created a 25-mile-wide immune barrier which, until recently, has been successful in stopping further spread.

ODH's Appalachian Ridge Oral Rabies Vaccination Program: September 2004—continued

On July 20, 2004, a raccoon with raccoon rabies was confirmed in Lake County, about seven miles west of the current barrier. Intense surveillance identified additional rabid raccoons in Lake and Geauga counties and one in Cuyahoga County. It is unknown if this occurred through translocation, human conveyance or by natural raccoon movement. As part of Ohio's contingency plan to address an ORV barrier breach, U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) Wildlife Services, with help from the local health departments, initiated rapid and aggressive surveillance. An emergency supplemental vaccine baiting operation was conducted in August 2004 in Lake, Geauga and eastern Cuyahoga counties.

In September, the routine Appalachian Ridge ORV Program was conducted. This is a multi-state partnership coordinated by USDA-APHIS Wildlife Services. In addition to Ohio, baiting is conducted in West Virginia, Pennsylvania, Virginia, Tennessee, and Maryland. About 5 million vaccine baits were distributed over 26,268 square miles. During the Ohio Appalachian Ridge operation, ORV baits were distributed in eight northeast Ohio counties along Ohio's border with Pennsylvania and West Virginia, from Lake Erie south to the Ohio River. Additional targeted areas in Cuyahoga, Portage and Summit counties were baited for the first time.

The baiting operation was begun in early September and completed within two weeks. Baits were delivered at a density of about 75 baits per square kilometer or about one bait per 3.3 acres. Ground teams consisting of local health department personnel delivered vaccine-laden baits in urban and suburban areas, mostly by vehicle. In rural areas, baits were distributed by specially equipped Canadian Twin Otter airplanes flying at an altitude of about 500 feet. USDA, Ohio Department of Health and Ohio National Guard staff filled out the flight crews. The base of the aerial operations was the Youngstown-Elser Metro Airport in North Lima, Ohio. In all, about 880,000 vaccine-laden baits were distributed via airplane and vehicle, covering about 4,526 square miles. The September ORV effort was the result of collaboration among Ohio departments of Health, Natural Resources and Agriculture, the USDA-APHIS Wildlife Services Program and the Centers for Disease Control and Prevention.

Table 1 below shows the number of animals infected with raccoon-strain rabies over the past eight years.

Table 1: Number of Animals Infected with Raccoon-Strain Rabies, Ohio, by Year, 1997—Mid-2004

Year	Raccoon-strain Rabies in Animals
1997	62
1998	26
1999	6
2000	0
2001	1
2002	1
2003	2
2004*	40

***as of 10/8/2004**

For more information about rabies, visit the Ohio Department of Health's Web site at:

http://www.odh.ohio.gov/ODHPrograms/ZOODIS/ZooMain1.htm

Chlamydia and Gonorrhea in Ohio

by Jeff Vasiloff, MD, MPH, Chief, HIV/STD Prevention, the STD Surveillance Team and the STD Prevention Team

In 1997, the Institute of Medicine wrote: "the scope and impact of the STD epidemic are under-appreciated and the STD epidemic is largely hidden from public discourse."

In Ohio, in 2003, there were more than 22,000 cases of gonorrhea and more than 42,000 cases of chlamydia.

Gonorrhea is caused by the gram negative diplococcus, *Neisseria gonorrhoeae*. Chlamydia genital infections are caused by the obligate intracellular bacteria, *Chlamydia trachomatis.* Both are highly transmissible, asymptomatic in many women, and responsible for most cases of pelvic inflammatory disease (PID), which can, in turn, result in infertility and ectopic pregnancy.

Symptomatic gonorrhea usually manifests as urethritis, epididymitis or mucopurulent cervicitis. However, gonococcal infections can also result in pharyngitis, proctitis or disseminated infection, the latter with predominant skin and joint involvement. When symptomatic, chlamydia also manifests as urethritis, epididymitis, mucopurulent cervicitis or proctitis. In addition chlamydia infection can produce Reiter's Syndrome with eye, joint and skin manifestations in addition to genital disease. Ohio gonorrhea and chlamydia data are shown in Tables 1 and 2, respectively.

Ohio ranked seventh-highest in gonorrhea incidence and 11th - highest in chlamydia incidence in 2002 of all 50 states.

Table 1: Gonorrhea in Ohio, 1999 and 2003*:

	1999	2003
Number of cases reported	18,404	22,625
Overall incidence rate per 100,000	162.4	198.1
Incidence rate among 15-19 years of age	700.6	810.2
Incidence rate among 20-24 years of age	763.5	916.0
Proportion of all cases among 15-24 years of age	61.3%	60.6%
Incidence rate among females	168.6	212.3
Incidence rate among males	152.4	177.7
Proportion of cases among women	53.5%	55.1%
Proportion of all cases within Ohio's nine largest cities**	67.4%	64.2%

* STD Surveillance, Ohio Department of Health, 2004.

**Akron, Canton, Cincinnati, Cleveland, Columbus, Dayton, Lima, Toledo, Youngstown

Table 2: Chlamydia in Ohio, 1999 and 2003*:

	1999	2003
Number of cases reported	30,052	42,354
Overall incidence rate per 100,000	265.1	370.8
Incidence rate among 15-19 years of age	1,479.8	1,981.8
Incidence rate among 20-24 years of age	1,379.9	1,960.1
Proportion of all cases among 15-24 years of age	73.7%	74.1%
Incidence rate among females	410.0	569.8
Incidence rate among males	104.0	147.0
Proportion of cases among women	79.6%	78.9%
Proportion of all cases within Ohio's nine largest cities**	51.2%	49.1%

*STD Surveillance, Ohio Department of Health, 2004.

**Akron, Canton, Cincinnati, Cleveland, Columbus, Dayton, Lima, Toledo, Youngstown

Table 1 shows that gonorrhea case counts and rates were higher in 2003 than in 1999. Also, more than 60 percent of all cases occurred among those from 15 to 24 years of age. Yet this proportion may actually be somewhat lower if those 25 years and older were routinely screened. As will be discussed below, Ohio Department of Health's (ODH) partners in the Ohio Infertility Prevention Project routinely use age 22 or 26 as the upper bound for screening of females at family planning sites and STD clinic sites, respectively. Further, the higher incidence rate among females compared to males may be partially explained by the greater emphasis on screening adolescent girls and women than boys and men. However, it is also likely that some adolescent boys and men are treated empirically (on the basis of signs and symptoms) without being cultured (making the case less likely to be reported). Finally, Table 1 also shows that about two-thirds of all reported cases of gonorrhea were restricted to Ohio's nine largest cities.

Table 2 shows that chlamydia case counts and rates were higher in 2003 than in 1999. Also, nearly three-fourths of all reported cases occurred among those 15 to 24 years of age. As is likely with gonorrhea, this percentage may actually be somewhat lower if women 25 years and older were routinely screened. Table 2 also shows that about 80 percent of all cases were reported among females. This is probably explained by the greater emphasis on screening adolescent girls and women compared to boys and men. This emphasis also probably explains the four-fold increase in incidence rate among females compared to males. Finally, Table 2 also shows that only half of all chlamydia cases were reported from Ohio's nine largest cities. Thus, reported chlamydia infections in Ohio are more geographically scattered than gonorrhea infections.

The Spread of STDs

The spread of an STD can be quantified by the following formula:

$R = c \times B \times D$ or $R = c*B*D$

Where: R = Number of new cases arising from an infected partner within a population

c = Rate of partner change within the population

B = Probability of transmission of the microorganism per encounter

D = Duration of infectivity of infected individuals

Chlamydia and gonorrhea are both efficiently transmitted; thus, B is high. Further, because chlamydia infections, especially, can be asymptomatic, if these infections remain undetected (and untreated), the duration of infectivity is prolonged; thus, D is high. Finally, both chlamydia and gonorrhea are transmitted among young, unmarried individuals, a group with an overall high rate of partner change; thus, c is high.

As might be expected, STD prevention and control measures follow from the above formula. That is, the spread of STDs can be attenuated by:

- Decreasing c, by reducing the rate of partner change (e.g., reducing the number of partners, mutual monogamy, delay of sexual debut).
- Reducing the efficiency of transmission (e.g., promoting safer sexual practices, condom use during casual and commercial sex, hepatitis B vaccination).
- Shortening the duration of infectivity (e.g., educating people about early symptoms and signs and the need to seek prompt diagnosis and treatment, routine screening, contact tracing to provide preventive treatment).

The Ohio Infertility Prevention Project (IPP)

Ohio IPP consists of a network of clinical partners throughout the state. The current cohort of collaborators includes 41 family planning clinics, 34 STD clinics and one juvenile detention center. There are plans to recruit other family planning sites and at least two additional juvenile detention centers.

In the first six months of 2004, a total of 34,637 adolescent girls and young women, and their male partners, received screening for

Chlamydia and Gonorrhea in Ohio—continued

chlamydia and gonorrhea. The overall positivity rate for gonorrhea was 4.2 percent.

The overall rate for chlamydia at the 41 family planning clinics was 6.2 percent while the rate at STD clinics was 12.5 percent. At the lone juvenile detention center, the positivity rate for chlamydia was 15.3 percent. With respect to gonorrhea, the overall rate at 41 family planning clinics was 1.5 percent while the rate at STD clinics was 9.9 percent. The positivity rate for gonorrhea at the juvenile detention center was 6.3 percent.

About 10 to 17 percent of untreated chlamydia and/or gonorrhea infections will be complicated by pelvic inflammatory disease (PID). This infection of the Fallopian tubes and adjacent tissues can result in scaring that can lead to infertility or ectopic pregnancy. The IPP prevents PID by detecting asymptomatic antecedent chlamydia and gonorrhea infections so that timely treatment can be administered to adolescent girls and young women at highest risk.

The concurrent treatment of male partners prevents female partner re-infection. In addition, treated males are prevented from infecting other females.

Food-borne Disease Outbreaks, Ohio, 1998-2002

by Ellen Salehi, MPH, Epidemiologist, Bureau of Infectious Disease Control

Food-borne disease appears in some of the earliest writings on medicine. Recognition of the connection between broad bean consumption and favism (i.e., acute hemolytic anemia from fava beans) seems to date back to the time of Pythagoras in the fifth century BC (1). In the Middle Ages (1276 AD) in Augsburg, Germany, meat was inspected for spoilage (2).

In today's world, "ordinary" and naturally occurring events such as food-borne outbreaks are faced daily, but public health workers also have to be alert to potential acts of bioterrorism. Public Health Infrastructure (PHI) funding enables public health staff to rapidly identify diseases and initiate prevention and control activities for response to bioterrorism, other outbreaks of infectious diseases and other public health threats and emergencies. This increased funding for preparedness has improved public health infrastructure with additions of personnel, laboratory and communication upgrades and training opportunities. These have benefited public health and outbreak response. More public health nurses and sanitarians are trained in epidemiologic methods than ever before. Indeed, there are more epidemiologists in Ohio's local health departments than ever before. These positive benefits are regularly seen in Ohio, as public health personnel respond quickly and effectively to outbreak reports.

In the five years from 1998 to 2002, Ohio reported 365 food-borne disease outbreaks. Suspected food-borne and water-borne outbreaks are reportable to local health districts and then to the Ohio Department of Health (ODH) as Class A(2) diseases. That is, they are required to be reported by the end of the next business day, after they are recognized. With the initial report to ODH, on consultation with an epidemiologist, a plan is developed for the investigation, including interviews of ill and well exposed persons, collection of stool and food samples as indicated and review of food preparation. Evaluation of clinical and epidemiologic data determines what kind of specimens and samples to submit to the ODH Lab, and what kind of testing is needed. Some basic forms and reference materials can be found in the Food-borne Disease Outbreak section of the ODH Infectious Disease Control Manual (IDCM), and by clicking on "Forms" in Section 3 (see: http://www.odh.ohio.gov/Resources/publications/IDCManual/ID_Intro.htm). Upon completion of the investigation, local health district personnel complete the Centers for Disease Control and Prevention's (CDC) "Investigation of a Food-borne Outbreak" form#52.13. These

Food-borne Disease Outbreaks, Ohio, 1998-2002—continued

are sent to ODH for review and then to forward to CDC. The 365 outbreaks in this five-year period were classified either as confirmed (161, or 44 percent) or probable (204, or 56 percent). "Confirmed" outbreaks met the CDC agent-specific criteria for outbreaks (see http://www.cdc.gov/foodborneoutbreaks/guide_fd.htm). "Probable" outbreaks did not meet the criteria, but the epidemiologic findings were consistent with and indicated that a food-borne disease outbreak had occurred. See Table 1 for confirmed outbreaks in Ohio during the period of 1998-2002. For national data on causative agents and food vehicles, see the CDC Web site: http://www.cdc.gov/foodborneoutbreaks/report_pub.htm.

In the past five years, there have been a number of changes in the ODH Laboratory's capability for testing in food-borne disease outbreaks. Prior to 1998, Norovirus testing had to be conducted at the CDC. ODH Lab has been able to test bulk stool for Norovirus since early in 1998. Whereas previously, Norovirus outbreaks were left as "probable," they can now be verified in the lab. Other new tests include testing bulk stools for *Clostridium perfringens* toxin. Also, food can be tested for staphylococcal toxin and *Bacillus cereus* toxin.

Table 1. Causative Agents for Confirmed Outbreaks in Ohio from 1998-2002.

Agent	1998	1999	2000	2001	2002
Bacillus cereus	1	1			1
***Campylobacter* spp.**			1	1	
Clostridium botulinum			1		
Clostridium perfringens		2	2	3*	4
Chemical			2		
***E. coli* O157**		2			2
Hepatitis A	2				
Listeria	1	1			
Mushroom poisoning					1
Norovirus (Norwalk Virus)	7	27	29	18	12
***Salmonella* serotype Enteritidis**	2	1	4	2	1
***Salmonella* serotype Typhimurium**	4	1		2	1
***Salmonella* spp (other than Enteritidis or Typhimurium)**	6	2	1	1	
Scombroid fish poisoning				1	
Staphylococcal food poisoning	1	4*		4*	1
Trichinosis	1				
TOTAL	25	41	40	32	23

***This *Clostridia* outbreak also included *Bacillus cereus*.**

Short Notes on Specific Agents/Organisms

Using standard references, preliminary information on incubation period, symptoms and duration can be evaluated and a list of suspected agents compiled. Here is one standard table in use: comfdbr1and2.doc or see also: http://www.cfsan.fda.gov/~mow/app2.html.

If staphylococcal toxin is suspected, it is important to collect a food sample that has been maintained under refrigeration. Stools are not usually evaluated in suspected staphylococcal outbreaks, as *Staphylococcus aureus* is considered normal enteric flora. The ODH Lab can assay the food for staphylococcal toxin.

If *Bacillus cereus* is suspected, likewise, a food sample is important to collect; stool is not usually collected. ODH Lab can culture the food to grow *Bacillus* and do an assay for one of the *B. cereus* toxins. For both *Staphylococcus* and *Bacillus* testing, it is important that the food has been kept refrigerated

as these organisms will easily grow at ambient temperatures.

In outbreaks with an incubation period of nine-14 hours that are principally diarrhea with little vomiting, and in which a meat dish is implicated, *Clostridium perfringens* should be among the suspected agents. Collecting a bulk stool sample while the patient is still having diarrhea is critical to detecting the *C. perfringens* toxin. Once the patient's diarrhea ends, the toxin is no longer excreted. This is a good reason to keep a supply of bulk stool kits ready at all times. Also, food and stool collected in Cary Blair transport media can be cultured for *C. perfringens*. Isolates of *C. perfringens* from food and stool can be compared by pulsed-field gel electrophoresis (PFGE), although sometimes it is of limited usefulness.

Food-borne outbreaks involving *Salmonella, Shigella, Campylobacter* and *E. coli* O157 often include hospitalized cases. A major effort for case finding in area hospitals can be useful and it is important to secure all available isolates for serotyping and PFGE analysis. Food can be cultured, as can stool collected in Cary Blair media from suspected cases. These outbreaks are sometimes recognized retrospectively. Case reports arrive at the health department through the usual channels. Upon interview, a food service operation (or other exposure) is reported in common to unrelated individuals. In this way, a restaurant-associated cluster of cases can be recognized and investigated.

Outbreaks with a Norovirus profile are characterized by an incubation period of 24-36 hours, a high incidence of vomiting and diarrhea among those ill and a relatively mild course with duration of 24-48 hours. They are often also marked by the presence of secondary or tertiary cases. Patients are usually not hospitalized, although dehydration can be a problem, especially for the elderly. Not all Noroviral outbreaks follow a typical course. In some, diarrhea is more prominent than vomiting, or vice versa. Also, secondary cases may not be observed. The incubation period for Norovirus ranges from 10 to 50 hours, but in outbreaks, the median is usually 30-36 hours. The virus is shed while the patient is acutely ill and for an additional 48 hours. After that, the amount of virus shed tapers off rapidly. Bulk stool collected during the acute phase is ideal. ODH Lab tests bulk stool using the RT PCR assay for Norovirus. Stool in Cary Blair media should also be collected to rule out the major bacterial agents whenever Norovirus is suspected, as they have a similar incubation period.

Stool Collection Systems

Stool samples can be collected into Cary Blair transport media when the following bacterial pathogens are suspected: *Salmonella, Shigella, E. coli* O157, *Campylobacter, Clostridium perfringens* or *Yersinia*. They should also be collected when Norovirus is suspected, to rule out these bacterial pathogens which have a similar incubation period.

Ova and parasite (O&P) kits are used when enteric parasites such as *Giardia, Cryptosporidium* or *Cyclospora* are suspected. Three stools within a 10-day period, 24-48 hours apart are recommended. This would require three O&P kits. Each "kit" consists of two vials, PVA and 10 percent formalin, to preserve the different life stages of the parasite.

Supplies of Cary Blair and O&P kits can be obtained at no charge from ODH. To request a supply, contact an epidemiologist in the Bureau of Infectious Disease Control, Investigation Section at (614) 466-0265.

The bulk stool is collected for Norovirus or *C. perfringens* toxin assays. ODH Lab does not supply these. Obtain urine cups and either tongue depressors or plastic spoons to make a supply of bulk stool kits.

Table 2 shows specimen collection guidelines related to food-borne outbreaks.

Food-borne Disease Outbreaks, Ohio, 1998-2002—continued

Table 2. Specimen Collection Guidelines by Organism.

	BACTERIAL			VIRAL	PARASITIC
	Intoxication		Infection		
	Bacillus *Staphylococcus*	*Clostridium perfringens*	*Salmonella, Shigella, Campylobacter, E. coli O157 Listeria, Yersinia*	Norovirus	*Giardia Cryptosporidium Cyclospora*
STOOL	NO	YES Use bulk & Cary Blair	YES Use Cary Blair	YES Use bulk and Cary Blair	YES Use Cary Blair; and O & P x 3
FOOD	YES	YES	YES	YES	YES

With prompt attention to reports of suspected outbreaks, it is often possible to identify the causative agent, mode of transmission and contaminated vehicle. Similarly, timely investigation of reported cases can be important to identifying a common exposure. Questions about the reporting and investigation of food-borne outbreaks in Ohio can be directed to any of the epidemiologists in the Infectious Disease Investigation section of the Bureau of Infectious Disease Control, ODH at (614) 466-0265.

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Rapid HIV Testing in Ohio: Results of a Pilot Study by

Andrew Komensky, RN, BSN, MBA, ACRN, Infectious Disease Control Consultant, HIV Counseling and Testing Site Program Consultant

In early January 2004, the HIV/STD Prevention Program of the Ohio Department of Health began the process of implementing a pilot study using the OraQuick HIV-1 Antibody Test. The implementation process required the program to create a new testing protocol, negotiate with potential pilot sites, request and receive the product and finally, develop an instructional training program. A month later, in February 2004, seven of the 11 counseling and testing sites were up and running with the remaining four sites coming on board by the end of May 2004. The Centers for Disease Control and Prevention (CDC) provided the HIV/STD Prevention Program with a total of 12,000 rapid test kits which were quickly distributed to the 11 sites. The 11 sites are: Canton City Health Department, Cincinnati City Health Department, Violet's Cupboard in Akron, Free Medical Clinic in Cleveland, the Cleveland Department of Public Health, Columbus City Health Department, Combined General Health District of Montgomery County, Youngstown City Health Department, Portsmouth City Health Department, Toledo Lucas Health Department and the Columbus AIDS Task Force.

Advantages and Requirements of HIV Rapid Testing

The OraQuick rapid test has several advantages over the standard HIV antibody test that make this technology worth using. Rapid HIV testing can:

- Increase the number of persons at high risk for HIV who obtain HIV counseling, testing and referral services.
- Increase the number of persons tested for HIV who learn their test results.
- Increase the early identification of new HIV infections and subsequent referral to care, prevention and case management services.
- Decrease the need for follow-up activities for clients who do not return for their HIV test results and associated prevention counseling.
- Provide important information useful for post-exposure treatment decisions in occupational exposure, accidental sexual exposure and childbirth circumstances.

However, even with these advantages, adoption of rapid HIV testing presents health departments and community-based organizations with a number of practical challenges ranging from staff training (to perform the test, document test results, provide preliminary results and deal with biohazardous materials) to the challenges of maintaining environmental control of the test kit procedure as well as modifying prevention counseling strategies and adjusting clinic client flow for this new testing technology. Because of these challenges, agency capacity for staff training, quality assurance of test performance and maintenance of testing procedures and policies are critical elements to consider before implementation.

In general, rapid testing may be an appropriate technology to consider if a setting or agency has:

- Adequate staffing.
- The capacity to provide internal program quality assurance.
- The ability to maintain strict control of confidential information.
- The ability to strictly control testing procedures.
- The ability to control the storing of the test kits.
- Resources to ensure confirmatory specimen collection.
- The ability to provide effective referrals.

However, even with agency capacity, rapid testing may still not be an appropriate technology due to cost factors and the practical challenges of the test.

Agencies with strong capacity may want to consider rapid testing if they serve communities at increased risk for HIV who are not currently availing themselves to HIV counseling, testing, and referral (CTR) services. Rapid testing may be one mechanism for encouraging use of these services. In addition, if low return rates for test results are an agency is-

sue, rapid HIV testing may be a useful tool to improve these rates.

Brief History of HIV Rapid Test Development

The Federal Drug Administration (FDA) approved the OraQuick Rapid HIV-1 Antibody Test in November 2002 and declared the test a waived test in February 2003. This waiver, under the Clinical Laboratory Improvement Amendments (CLIA), allows for OraQuick to be performed relatively easily in a wide variety of non-clinical and outreach settings.

In June 2004, the FDA approved and received CLIA waiver for the new OraQuick Rapid HIV-1/2 Antibody Test. This test has been waived for use in detecting HIV-1 and HIV-2 antibodies in oral fluid, finger stick whole blood and venous whole samples. Results are available within 20 to 40 minutes, although associated procedures related to informed consent and prevention counseling lengthen the time of any session. This rapid test is a screening test. All positive (preliminary reactive) results must be followed up with a confirmatory test. Negative results do not need additional testing. Agencies implementing rapid testing must assure a system of confirmatory testing for preliminary reactive results either through traditional serum testing or through the use of OraSure Swabs.

The test has a high level of accuracy at more than 99 percent sensitivity. Although OraQuick is a highly accurate test, as with any screening test, a risk of false positives exists. The likelihood that a positive result from OraQuick is spuriously false decreases as the prevalence of HIV within the tested population increases.

The test is simple and when the manufacturer's directions are followed correctly, it can provide reliable results. However, mistakes can occur at any point in the testing process. Quality assurance and control of the entire testing process are critical to reduce mistakes and increase reliability of results.

Details of HIV Rapid Testing

The OraQuick Rapid HIV-1 Antibody Test is a single-use, qualitative immunoassay used to detect antibodies to Human Immunodeficiency Virus Type 1 in fingerstick whole blood specimens. The OraQuick rapid test is comprised of a single-use test device and a single-use vial containing a premeasured amount of a buffered developer solution. Each component is sealed in a separate compartment of a single pouch for the test. The OraQuick rapid test utilizes a proprietary lateral flow immunoassay procedure. The plastic housing of the device holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

A fingerstick whole blood specimen is collected with a specimen collection loop and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1.

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen.

OraQuick Rapid HIV-1 Antibody Test kits include the following: a reusable test stand; a single-use specimen collection loop; a vial containing developer solution; and the test device, absorbent packet (to absorb moisture within the test kit packet). Not for use during the testing procedure.

Results of Ohio's Rapid Test Pilot Study: Lessons Learned

By Oct. 13, 2004, a total of 12,557 Ohioans consented for rapid testing. Of that total, 150 (1.2 percent) had preliminary positive results. Of these 150 preliminary positive tests, 143 have so far been followed up with confirmatory testing by Western blot. Of these 143, 139 (97.2 percent) have been confirmed positive. Three preliminary positive tests by the OraQuick Rapid HIV-1 Antibody Test were found to be negative by Western blot and one preliminary positive test was found to be indeterminate by Western blot.

By far, the biggest benefit to rapid testing is that every individual who tests positive knows their status before leaving the testing site. This is significant in that from January through June 2004, nearly 12,955 persons were tested for HIV through traditional means (with serum or OraSure oral fluid testing), and of these, 3,602 (19 percent) persons never returned to receive their HIV results. Furthermore, of the 197 who did test positive for HIV by traditional means, 27 (14 percent) did not return for their results.

Of the five counseling and testing sites that, so far, have had the highest seropositivity rates (ranging from 1.35 percent - 5.88 percent) three are community-based organizations and two are regional health departments. These five counseling and testing sites have, so far, accounted for 73 percent of all the positive test results.

Since the implementation of rapid testing in February 2004 the HIV/STD Prevention Program has seen the number of tests nearly double.

The HIV/STD Prevention Program hopes to increase rapid testing in Ohio; however, the cost of rapid test kits is high ($10-$12 per test kit). It is hoped that the Centers for Disease Control and Prevention will be able to provide some of these test kits to the states at no cost.

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Director of Health: J. Nick Baird, MD

Assistant Director of Health: Anne Harnish, MPA

Assistant Director of Health: James A. Pearsol, M.Ed.

Chief of the Division of Prevention: Deborah Arms, RN, PHD

Chief of the Bureau of Infectious Disease Control: Barbara Bradley, RN, MS

Editors: Jeff Vasiloff, MD, MPH and Amy Bashforth, MPA

Designer: Beverly Henderson

For questions or comments or to add a free subscription,

e-mail jvasilof@odh.ohio.gov or abashfor@odh.ohio.gov

or call Hilary Metelko at 614-752-4315.

Ohio Department of Health

Bureau of Infectious Disease Control

246 North High Street

P.O. Box 118

Columbus, OH 43216-0118

http://www.odh.ohio.gov