

## **WEB-BASED SYSTEM FOR MONITORING DIET AND PHYSICAL ACTIVITY AND FOR ACTIVE SURVEILLANCE OF ENTERIC DISEASES**

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**SUMMARY:** This proposal begins with a set of user-friendly interactive Web pages for monitoring diet and physical activity to help individuals control diabetes, obesity, and other health problems. The proposal differs from existing weight-loss Web sites in that it would provide an easy-to-use tool for keeping actual records of foods eaten and exercise received, complete with the means to estimate quantities of food consumed and energy expended. This site will provide instant feedback to respondents, and also allow them to report acute illnesses. Other sites merely provide advice and sample meal plans.

The Web pages are to be part of an Internet-based active surveillance system for reporting and tabulating data from enteric disease outbreak investigations, integrated with environmental health data-processing software for food safety, child day care, and swimming pool inspections. Results from routine inspections, as well as results from outbreak investigations, will be entered with the same system. By integrating the food and illness histories from the diet and exercise Web pages with routine inspection results and outbreak investigations, the system will help local health departments determine the risk of acute enteric disease from specific foods and processing errors in restaurant and home meals, as well as the risk from pets, contaminated water, and child day care facilities. This is also a departure from existing software for public health inspection programs. Existing data processing systems for routine use are geared toward licensing establishments and tabulating code violations; and existing surveillance systems are geared toward identifying hazardous procedures and foods, not ranking hazards. Normally health department inspections are conducted separately from illness surveillance. The proposal also includes use of a hygiene meter and other rapid microbiological tests. Its goal is to help focus prevention activities where they are most needed.

Because the Web pages will take food and health histories, they will have broader applications as well. This surveillance system will provide a framework for epidemiologic studies of the role of diet in health and for community health assessment. Because of its nearly instantaneous data-collection and microbiological analysis capabilities, it will even be capable of detecting a bioterrorism attack.

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## WEB PAGES FOR DIET AND PHYSICAL ACTIVITY

### Obesity and diabetes

According to the *Columbus Dispatch* (2/18/2001), a recent survey by the Columbus Health Department showed that 56% of Franklin County residents are overweight, only 15% eat the recommended 5 or more servings of fruits and vegetables per day, and fewer than 6 in 10 adults exercise regularly. According to the Health Department's medical director, "Obesity makes almost every other health problem worse." **Table 1** lists many of the important diseases associated with obesity.

A Central Ohio Diabetes Association report issued in spring 2001 (*Diabetes in Central Ohio: A Problem We Can't Afford to Ignore*) reports that half of Ohioans beginning treatment for diabetes have already developed complications such as vision problems, neuropathy, or kidney disease. Up to a third are unaware of their condition until they develop complications. African-Americans are twice as likely to have the disease and twice as likely to die from it. Heart disease, cancer and stroke mortality are beginning to decline nationally, but are increasing in Central Ohio. The incidence of diabetes and related complications has been increasing.

Insulin resistance syndrome is characterized by the inability of the body's cells to respond normally to insulin. As the pancreas produces more and more of the hormone, its buildup in the blood contributes to hypertension, glucose intolerance, and abnormal levels of cholesterol and triglycerides. Its prevalence has increased 61% in the past decade (*Columbus Dispatch*, August 28, 2002, p. A4). Now one in five Americans has it (*Columbus Dispatch*, October 20, 2002, p. C3). Recent research reported in the *New England Journal of Medicine* has shown that improving one's diet, losing weight, and increasing exercise can correct insulin resistance and, thus, delay and even prevent Type 2 diabetes. These same interventions can prevent hypertension (*Columbus Dispatch*, October 16, 2002, p. A6).

An article in the journal of the U. S. Public Health Service (Nestle M, Jacobson MF. Halting the obesity epidemic: a public health policy approach. *Public Health Reports* 2001;115 (1): 12-24) declared that the emphasis on modification of individual behavior we have relied on for the last 50 years has failed, and recommended taxes on cars and empty calories to fund a broad range of new public health approaches. However, the traditional approach has been to tell people to eat less and exercise more, without an easy way to compensate for a given day's deviation from established guidelines. Before we give up on changing individual behavior, we should give people the best tools we can devise to assess their performance. Eighty-eight percent of adults and eighty-four percent of adolescents who responded to a survey by the National Association for Sport and Physical Education indicated they were getting enough exercise "to maintain a healthy lifestyle." (*Columbus Dispatch*, October 7, 2002, p. A3.) Most of these people mistakenly believe their level of exercise is adequate, so they probably wouldn't believe messages to the contrary apply to them. Our site would show their levels, and then show adequate levels.

We propose a series of improved interactive Web pages for nutrition and physical activity assessment and modification as a solution to these problems. Any Central Ohio resident will be able to log onto the site and enter a 3-, 5-, or 7-day diet

**Table 1. Obesity-, exercise-, or diet-associated diseases.**

Disease	Co-factors	References
Diabetes		1, 2
Hypertension		1
Hypercholesterolemia		1
Stroke		1
Heart disease		1
Certain cancers		1, 3
Arthritis	Lack of exercise	1, 2
Kidney disease		3
Liver disorders		3
Food sensitivities		3
Celiac disease		3
Bowel disease		3
Osteoporosis		3
Gastroesophageal reflux	Smoking Obesity Lack of exercise	4
Gallbladder disease	Childhood	5
Sleep apnea	Childhood	5
Asthma (?)	Childhood	5
Behavioral disorders (?)	Childhood	5
Depression (?)	Childhood	5
Anorexia nervosa/bulimia		6
Chronic fatigue syndrome	Depression	7

1. Flegel KM et al., Prevalence and trends in obesity among US adults, 1999-2000. *JAMA* 288:14, 10/9/02.
2. Dreyfuss I. Study: Exercise cuts risk of disability from arthritis. *Columbus Dispatch*, 10/29/01, p. E3.
3. Kurtzweil P. Better information for special diets. *FDA Consumer*, January-February 1995, p. 24.
4. Mitchell, T. Have you heard of GERD? *USA Weekend*, June 28-30, 2002.
5. Kotulak R. Obese children suffering ailments once seen typically in adults. *Columbus Dispatch*, May 2, 2002, p. A1.
6. Jacobson S. Therapists know eating disorders strike men, too. *Columbus Dispatch*, December 7, 2000, p. G3.
7. Tanner L. Exercise may relieve syndrome. *Columbus Dispatch*, September 19, 2001, p. A11.

record, one menu item or meal at a time, and/or answer questions about physical activity. Respondents will receive a computer-generated diet and physical activity analysis with custom-generated recommendations for improvement or change. Software available for several years reports the number of calories, amount of magnesium, etc., when a user enters the name of a food item such as “peanut butter sandwich.” This software will be incorporated into a free Web site. The Web site will also explain the importance of diabetes control and highlight available community resources.

### **Present impediments to control of diabetes in Central Ohio**

The CODA report identified seven local conditions that contribute to these high rates of complications and mortality: inability to afford medications, lack of insurance coverage for supplies to test blood sugar levels, inability to afford necessary foods, insufficient instruction on diet, lack of exercise, lack of understanding as to the urgency and benefits of diabetes control and awareness of available community resources, and transportation problems. This project will address all but the first two conditions:

1. Inability to afford medications is beyond the scope of this proposal.
2. Lack of insurance is beyond the scope of this proposal.
3. Two-thirds of local diabetics can't afford necessary foods. This Web site can offer affordable alternatives or substitutions.
4. The Web site will offer exhaustive diet instruction, particularly the self-assessment capability.
5. The proposed site will offer exhaustive exercise instruction, particularly the self-assessment capability.
6. Community resources and the urgency of diabetes control will be highlighted.
7. Many transportation needs will be alleviated by the proposed intervention, because it will reduce the need to travel to see a dietitian. Exercise options will include activities, such as walking, for which transportation is unnecessary.

### **Existing weight control Web sites**

No existing site provides the means for users to conveniently track their actual caloric intake and energy expenditure. In fact, the overriding problem with these sites today is the difficulty in distinguishing fads from facts.

Tufts University created the first on-line rating service for nutrition Web sites, the *Tufts University Nutrition Navigator* (<http://www.navigator.tufts.edu/about.html>, accessed 08/03/03 but no longer available as of September 30, 2007), “the first online rating and review guide that solves the two major problems Web users have when seeking nutrition information: how to quickly find information best suited to their needs and whether to trust the information they find there.” According to *Navigator*,

Most weight management sites now charge a fee, so it's little harder at the moment to find one website that offers comprehensive weight loss advice for free. You can piece together this information from more than one site,

though--try Intellihealth and nutrio.com for basic weight management advice, Nutricise for advice on how to start an exercise program, and Foodfit.com for great low-fat recipes. Then monitor your progress with the tracking tools available on Fitday. These features were free to use at the time this answer was posted. (Fitday requires registration, but it is free.)

According to *Navigator*, to find out how much fat (or fiber, cholesterol, calories, or whatever) is in a specific food,

We actually get this information from a reference book: Bowes and Church's Food Values of Portions Commonly Used, Jean Pennington, Lippincott Publishers. We haven't found a website that provides nutrient data as quickly and completely. If you need an online source, try the USDA's Nutrient Data Lab Click on "Database for Standard Reference" and then on "Nutrient Lists" to search by nutrient. These pages are in PDF format (so they print out well), and are readable with Adobe Acrobat.

A July 2000 supplement to the Tufts University *Health and Nutrition Letter*, "A Guide to Rating the Weight-Loss Web sites" compared and contrasted eight Web sites and recommended improvements they could make. But none of the eight had an interactive self-assessment tool for either diet or exercise. Instead, they provided sample meal plans. **Table 2** summarizes the discussion and gives the current status of these sites according to the Internet Archive, the "Wayback Machine" (<http://www.archive.org/index.php>, accessed September 30, 2007). (See below.)

The Tufts guide said Asimba's computer-generated diet plans, although free of charge, included odd combinations of foods like a lunch of oatmeal, grapes and green beans. Of the two sites charging a fee, Shape Up and Drop 10 was the more expensive at \$10 per week, whereas eDiets charged \$10 per month.

None of the sites listed as "among the best" or "better than most" in the general nutrition category in *Nutrition Navigator* in May 2001 had an interactive self-assessment tool for either diet or exercise except "Nutrition Analysis Tool" (NAT), a product of the University of Illinois Department of Food Science and Nutrition. NAT gives the complete nutrient content of any food or list of foods entered. It has an "Energy Calculator" with an "Activity Record" form that asks for the total number of hours of resting, very light-, light-, moderate-, and heavy-energy activities completed during a day. A strength of the NAT is in providing order forms for paper Daily Food Records and Activity Records participants can take with them when they are away from their computer.

Diet Web sites are a growth industry. **Table 3** lists some sites that appeared after the May 2001 report. Sites also disappear. "Calorie Calendar" appeared in July 2002 and was down by September 2003. The ephemeral nature of Internet sites has prompted the creation of an Internet Archive, the "Wayback Machine" (<http://www.archive.org/index.php>, accessed September 30, 2007).

<b>Table 2. Weight-loss Web sites reviewed by Tufts University in 2000 with current status. Date closed, if applicable, is according to the “Wayback Machine” (see text).</b>					
<b>Site</b> (Site name is in bold)	<b>Features</b> (“personality”)	<b>Fee</b> ?	<b>Diets by</b> <b>R.D.?</b>	<b>Advantages</b>	<b>Disadvantages</b>
<a href="http://www.Asimba.com">www.Asimba.com</a> (Closed 09/02, with Fitrex.com as of 9/30/07)	<ul style="list-style-type: none"> <li>• Computer-generated diets</li> <li>• sports-oriented</li> </ul>	No	No. Diets by Exercise Physiologist	<ul style="list-style-type: none"> <li>• Coaches available (for fee)</li> <li>• individual activity plans</li> <li>• easy walking plan</li> </ul>	<ul style="list-style-type: none"> <li>• May have odd food combinations</li> <li>• Questions went unanswered</li> </ul>
<a href="http://www.cyberdiet.com">www.cyberdiet.com</a> (accessed 9/30/07)	<ul style="list-style-type: none"> <li>• online communities</li> <li>• Easy-to-follow exercises in text and pictures</li> </ul>	No	Yes	<ul style="list-style-type: none"> <li>• 3 meal planners</li> <li>• your recipes OK</li> <li>• chat rooms w/ R.D, trainer, chef</li> </ul>	
<a href="http://www.DietWatch.com">www.DietWatch.com</a> (accessed 9/30/07)	online communities	No	only chat w/ R.D.	<ul style="list-style-type: none"> <li>• chat rooms w/ R.D., trainer, chef</li> <li>• e-mail diet buddies</li> </ul>	most member-to-member contact through chat rooms and bulletin boards
<a href="http://www.eDiets.com">www.eDiets.com</a> (accessed 9/30/07)	Tufts favorite fee site (“great customer service”). Provides exercise routines with animated graphics.	Yes	R.D. by e-mail	<ul style="list-style-type: none"> <li>• convenience foods easily included</li> <li>• e-mail diet buddies</li> <li>• chat rooms w/ R.D, trainer, chef</li> </ul>	most member-to-member contact through chat rooms and bulletin boards
<a href="http://www.eFit.com">www.eFit.com</a> (now <a href="http://dietdetective.com/">http://dietdetective.com/</a> -- accessed 9/30/07)	sports-oriented  Provides exercise routines with video clips.	No	Yes	<ul style="list-style-type: none"> <li>• calorie-controlled meals</li> <li>• shows you 15 lb lighter</li> <li>• individual activity plans</li> </ul>	<ul style="list-style-type: none"> <li>• Substitutions not available (07/2000)</li> <li>• No chats or BB’s</li> </ul>
<a href="http://www.nutrio.com">www.nutrio.com</a> (accessed 9/30/07)		No	Yes	calorie-controlled meals	
<b>Shape Up America</b> <a href="http://www.shapeup.org/">http://www.shapeup.org/</a> (accessed 9/30/07)	Tufts favorite free site (“easy to use”). Operated by Dr. Koop.	No	Yes	<ul style="list-style-type: none"> <li>• Easy-to-use Cyberkitchen to make choices</li> <li>• helps you think around barriers</li> </ul>	

<b>Table 3. Selected Weight-loss Web sites as of 2003.</b>					
<b>Site</b> (Site name is in bold)	<b>Features</b> ("personality")	<b>Fee</b> ?	<b>Diets by</b> <b>R.D.?</b>	<b>Advantages</b>	<b>Disadvantages</b>
<b>Calorie Calendar</b> ( <a href="http://www.womenco.com">www.womenco.com</a> ) (used Fitday for assessments ( <a href="http://www.fitday.com">www.fitday.com</a> (accessed 9/30/07))	(Closed by 09/03)	?	?	?	(not rated by Tufts)
<b>National Health Survey</b> ( <a href="http://www.healthsurvey.org">www.healthsurvey.org</a> ) (accessed 9/30/07)	See text	No			
<b>Nutrition Analysis Tool Version 2.0</b> ( <a href="http://nat.crgq.com/index2.html">http://nat.crgq.com/index2.html</a> ) (accessed 9/30/07)	See text				
<b>Weight Watchers</b> ( <a href="http://www.weightwatchers.com">www.weightwatchers.com</a> ) (accessed 9/30/07)	<ul style="list-style-type: none"> <li>• Weekly meal plans</li> <li>• Uses a "POINTS" system for substitution</li> </ul>	Yes		<ul style="list-style-type: none"> <li>• Has BMI and other assessments</li> <li>• Points for activities</li> </ul>	Substitutions match calories, fat and fiber, but not other nutrients

The University of California and the Lawrence Berkeley National Laboratory are conducting a National Health Study of Nutrition ([www.healthsurvey.org](http://www.healthsurvey.org)) that was described in the *Epidemiology Monitor* in June 1998. Their survey instrument asks for estimates, not records, of food intake and activity levels. It also asks about medical procedures and daily use of dietary supplements. However, it does not clearly and unambiguously ask whether a respondent is initially free of a particular disease. One of its strengths is in providing instant feedback. For example, it provides a graph of high, medium and low body mass index ranges by age and marks each respondent's place in the graph. Another is its provision for follow-up. For example, it asks respondents to name a next-of-kin or other backup source for information in case the respondent dies.

One diet Web site asks participants to weigh themselves daily to measure their sensitivity to calories, and modifies its advice accordingly.

A means of assessing food intake is necessary for quantitative food borne disease risk assessment (see below). A telephone questionnaire developed by the Chicago Department of Public Health for this purpose (not for weight control) requests a statistic that may be

particularly unwieldy for general use: number of bites! The site was at [www.foodriskclearinghouse.umd.edu/Users.htm](http://www.foodriskclearinghouse.umd.edu/Users.htm) but was no longer available as of September 30, 2007.)

### **How this proposal is different**

Two decades ago survey researchers at the University of Washington studied factors determining whether people do or do not respond to surveys, and described what they called the Total Design Method for maximizing response rates. (See Don Dillman, *Mail and Telephone Surveys*. New York: Wiley & Sons, 1978). See **Table 4** for some of the ways to improve response rates for a mail survey. We propose to apply their concepts to our Web-based survey, making it as easy as possible to participate. **Table 5** summarizes the proposed improvements our site will offer over existing sites.

Our proposal is for interactive self-assessment tools for both diet and exercise that keep a running total of all nutrients, rather than requiring users to tally their own (like NAT).

Our Web site will make the accurate estimation of quantities of food consumed a priority. It will provide visual aids to estimate quantities, but might also provide a link to a Web site offering an easy-to-use food scale. Participants could also receive a week's worth of nutritionally balanced calorie-controlled meal plans, but they could make changes. Our entry questionnaire may ask about dietary restrictions, food preferences, food allergies, and activity preferences.

<b>Table 4. Some ways to improve response rates for a mail survey.</b>
<p><b>1. Reward the respondent.</b></p> <ul style="list-style-type: none"> <li>Show positive regard, e.g., by using real “pressed ball point pen signatures.”</li> <li>Use a consulting approach.</li> <li>Support the respondent’s values.</li> <li>Offer tangible rewards (e.g., a copy of the results).</li> <li>Make the questionnaire interesting.</li> </ul>
<p><b>2. Reduce costs to the respondent.</b></p> <ul style="list-style-type: none"> <li>Make the task appear brief.</li> <li>Minimize the physical and mental effort required.</li> <li>Group questions with similar content together, with transitions for continuity.</li> <li>Make topics flow naturally, with questions and answers typed with a vertical flow.</li> <li>Minimize the chances for embarrassment.</li> <li>The first question must be easy, applicable to everyone, and interesting to everyone.</li> <li>Topics that may be objectionable in some way, and demographic questions, come last.</li> <li>Eliminate any implication of subordination.</li> <li>Eliminate any direct monetary cost. For example, provide a self-addressed, stamped return envelope.</li> </ul>

**3. Establish trust.**

- Provide a token of appreciation in advance.
- Capitalize on the legitimacy of the sponsoring agency.
- Build on the relationship begun with a prior letter.

**Table 5. Summary of proposed improvements.**

1. Accurate estimation of quantities of food consumed
2. Accurate, complete estimation of energy expended
3. Emphasis on strength training
4. Free to Central Ohio users
5. Versatile data-entry modes (mail, fax, Palm, etc)
6. Easy recap, reentry
7. Psychological support
8. Links to Web rings

According to Dr. Byron Aoki, physiotherapist at the University of Hawaii, strength training is an important aspect of fitness, because it builds lean muscle. Because a pound of muscle requires 22 calories a day to maintain itself, its presence increases basal metabolic rate. Dr. Aokoi teaches that aerobic conditioning and nutrition are the other crucial elements in fitness. See Harr E., *Columbus Dispatch*, May 20, 2002, p. D1-D2.

The site will make it as easy as possible to calculate and tally energy expended during all daily activities. Some existing sites may ask respondents to fill in a distance walked, requiring them to figure out how to measure it. Our site may provide a link to a Web site offering an easy-to-use pedometer (e.g. <http://www.walk4life.com/home/Default.aspx> ) (accessed 10-10-07). Another option would be a link to the Franklin County Auditor's Web site's city maps, showing the dimensions of the blocks in a respondent's neighborhood, and a calculator to tally block lengths to estimate the total length of a proposed walk. Still another possibility: a global-positioning receiver that plugs into a PDA (personal digital assistant) like Palm Pilot, Handspring Visor, or similar hardware, and provides software (perhaps a ruler) for judging distances. (StarCaddy uses similar technology to get lengths of golf shots. ESRI offers GIS software specifically for PDA's. See [www.esri.com/arcpad](http://www.esri.com/arcpad)) (accessed 10-10-07).

Some 54 million Americans with asthma, arthritis, diabetes, or other disabling or chronic diseases may need special recommendations for exercises that can be performed while sitting on a chair or on the side of a bed, so our site will offer examples.

Anyone in Central Ohio could use our site for free. The cost would be paid from a grant at first and later by fees to be paid by researchers.

Like NAT, we propose to offer the option of ordering or downloading paper forms. Unlike the others, we propose using a mail-in option for the forms to accommodate people without computers, Web access, and/or computer literacy. We also expect to have a fax server, so that people may use paper forms and return them via fax without the need for a clerk to enter the data on receipt. (See Resources Available, below.) Forms submitted by mail would also be scanned into the system by a fax machine. Ultimate ease of use in 2002 might be available to users of hand-held computers on which respondents could enter diet and activity records in almost real time. (In 2001 six percent of households used a palm computer.) This technology is marching forward: Handspring is offering digital cell phone access, e-mail, and Web browsing “in one easy-to-use device”-- their “Treo.” Even voice-recognition software is available, e.g. ViaVoice™.

We plan to offer an immediate recap of food and activity histories for respondents to check for accuracy at the end of each data-entry session. It must allow easy re-entry to enter the next meal or activity. The site will automatically calculate daily totals of energy intake and expenditure. Participants will be invited to re-assess their diet and activity patterns on a regular basis to maintain control, and may sign up for optional reminders. (The National Health Study seems to allow re-entry, but how to do it is unclear.)

We plan to offer copious links to other sites and (ideally) collaborate (synergize) with other sites. Web rings may be appropriate (see [www.webring.org](http://www.webring.org)) (accessed 10-10-07): strings of health, nutrition, recreation, diabetes, and psychological support sites, all leading back to ours, would be available. Psychological support has proven to be critically important in weight-control efforts. Examples of psychological support sites may include [www.depression-screening.org](http://www.depression-screening.org) (accessed 10-10-07). We could follow the lead of [www.geocities.com/HotSprings/Spa/8122](http://www.geocities.com/HotSprings/Spa/8122) (accessed 10-10-07) which offers “Quit Smoking Cards” (phrases to tell yourself when tobacco cravings hit), and offer phrases based on cognitive psychology to debunk negative self-talk that leads to food cravings. Finally, the site will prompt users to save their grocery store and restaurant receipts to facilitate re-creation of custom items, corroborate the time and place of meals eaten out, etc.

Our site will be cleaner looking than most, adding to its ease of use. A site map will help users navigate the site and locate resources.

### **Psychological and behavioral factors**

Accumulating evidence suggests the existence of a physiological response to weight loss that resists and even undoes the change. Overlaid on this is the problem that eating behaviors are closely tied to feelings of psychological well being (or the lack of it). Existing successful weight-loss Web sites deal with psychological issues mostly by offering support groups. Apparently few of them track success and its correlates. This one will.

The World Health Organization has identified depression as the fourth leading cause of disease and disability worldwide. The U. S. Department of Health and Human Services has recommended that primary care physicians screen every patient for depression with a few simple questions.

A National Weight Control Registry was established about eight years ago at the University of Colorado Health Sciences Center in Denver for people who have lost 30 pounds and kept the weight off at least a year. Its URL is <http://www.nwcr.ws/> (accessed 10-

10-07).

The registrants update a questionnaire covering their diet, exercise, and other factors every year. According to the Registry, people who lose weight and keep it off share four traits:

1. They weigh themselves frequently.
2. They eat breakfast every day.
3. “Successful losers” consume a low-fat diet
4. They exercise regularly – an hour a day of moderate activity.

Underlying these traits is an important attitude transformation, a belief that the new habits will improve one’s life. One “successful loser” characterized the change as “taking control, being in charge.” (See Matt Crenson, Associated Press. “Registering a Loss.” *Columbus Dispatch*, September 10, 2001.)

The Trevoze Behavior Modification Program is a 30-year-old weight-loss plan for people who need to lose 20 to 80 pounds and have failed with other programs. Trevoze groups require an hour-long support-group meeting every week, counting calories. (Shari Rudavski, *Columbus Dispatch*, August 28, 2000.)

What we propose is a comprehensive page in the site modeled after the techniques of cognitive psychology: respondents are asked to keep a Daily Mood Log. Every time they get upset, they are asked to record how they feel, identify specific negative “automatic thoughts” contributing to their feelings (like “I’m a loser”), write down more realistic rebuttals to these thoughts, and re-assess their feelings at the end of the process. See David Burns, *Feeling Good* (New York: Avon, 1980).

Use of the Internet for psychological counseling has barely begun; the analogy to telephone counseling, however, suggests that it may be a viable substitute for traditional, in-person, one-on-one or group counseling. Counseling by phone makes it available nights and weekends, without the need for transportation. According to the *New England Journal of Medicine*, “quit lines” for smokers work twice as well as merely providing a packet of self-help information (*Columbus Dispatch*, October 3, 2002, p. A5).

## **ENTERIC DISEASE EPIDEMIOLOGY PROGRAM**

Enteric diseases are an important public health problem. FoodNet, an active surveillance system started by USDA, FDA, EPA and CDC, found the incidence of acute diarrhea from all causes to be 1.4 per person per year in 1996-97, which would translate into 1,400,000 cases annually in Franklin County, Ohio. Mead et al. used data from FoodNet and other sources (see <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm#Figure%201>) (accessed 10-10-07) to estimate that 211 million cases of acute gastroenteritis occur each year in the United States, of which 36% -- 76 million cases -- are foodborne. How much of this is actually due to food is unknown, and FoodNet is not designed to answer this question.

Applying their estimate that 36% of acute diarrhea episodes without respiratory symptoms are due to foodborne disease to Franklin County’s extrapolated burden of 1.4 million cases of

acute diarrhea, county residents actually suffer through 500,000 episodes of foodborne illness every year. Mead et al. estimate that these 76 million cases of foodborne disease result in 5,020 deaths, suggesting that 33 people die from foodborne disease every year in Franklin County.

Control programs for most routes of exposure are in place, but **existing surveillance systems are geared toward identifying hazardous procedures and foods, not ranking hazards**. Existing systems rely on studies of outbreak-associated cases, which are hopelessly selection – biased. So-called sporadic cases have different causes, but are typically reported through a laboratory-based system and studied only after food histories are forgotten, if they are studied at all. Health departments use a risk-based system based on causes of outbreaks to determine inspection frequencies, but it is purely theoretical, and is not based on actual risk. At this time inspectors rely on “professional judgment” to identify critical control point defects that have a likelihood of causing illness. Food inspectors need guidance regarding the magnitude of deviations from accepted parameters that can be tolerated before a hazard exists. This would require knowing the infectious doses for most foodborne pathogens, but this information is not available from the existing system.

Remarkably, we do not know how much enteric illness is due to food or whether it is safer to eat at home or at a restaurant. We do not know the risks attributable to operating salad bars, not wearing gloves, reheating leftovers, or using raw meat, or whether foods prepared in restaurants after daytime hours are riskier. We do not know whether viruses or bacteria pose a larger hazard.

The diet and exercise web site will make it possible to conduct prospective active surveillance. We will study individual (sporadic) cases of infectious intestinal diseases (typically diarrhea, vomiting, etc.) prospectively (i.e., beginning with a cohort of initially disease-free people) with methods usually reserved retrospectively for outbreaks. This will make it possible to **determine the actual risks presented by specific foods and food-processing steps**, in order to concentrate inspections on the riskiest procedures. Its quantitative risk assessment will eliminate the guesswork.

### **Routes of exposure.**

**Foodborne disease** appears to be just as much a public health problem today as it was 50 years ago in spite of efforts at all levels of government to control it, according to the *New York Times* (03/18/01). The U. S. Centers for Disease Control and Prevention and the Ohio Department of Health consider it to be “emerging” because its incidence has increased in the last 20 years or threatens to increase in the near future. The amplification of human errors through mass production and distribution of food products is partly responsible for this increase. Other causes include increased use of fresh (not cooked or canned) fruits and vegetables, the popularity of precooked foods like seafood salads and deli meats, and overtaxed federal inspection programs. According to a General Accounting Office report, 85% of cases are caused by these FDA-regulated foods, but FDA inspects food-manufacturing plants an average of once every eight years. See. *New York Times* 03/18/2001.

Over the last 20 years the HACCP (hazard analysis-critical control point monitoring)

approach has become the industry standard for ensuring food safety; however, a lot of work remains to be done if HACCP is to reach its full potential. All good HACCP programs start with a risk assessment. But at this time microbiological risk assessment is largely guesswork. The prospective active surveillance system described below will enable food processors to judge the likelihood and results of mishandling of their products, providing guidance on the critical limits they should set for their food safety programs. USDA has also said this data will help processors involved in international trade by establishing the safety equivalence of different products.

**Child day care facilities** also spread enteric pathogens. There are more than 10.5 million children under age six in the U. S. whose mothers work outside the home; at least two million of these children are in day care centers while their parents work. Working parents with a sick child may still have to rely on a day care center, and the center may have an economic incentive to care for the child. A study of a community shigellosis outbreak in Lexington, Kentucky showed that 91% of cases among children younger than six years of age were attributable to their attendance at licensed child day care centers. In another study, 39% of toy balls and 21% of environmental surfaces in centers at which an outbreak of diarrhea was taking place had detectable rotavirus, compared to 5% of toy balls and 2% of swabs in centers without outbreaks. Hand washing by staff and children, exclusion of sick children from day care, and other hygienic measures are important to control these outbreaks; their relative importance, however, is unknown.

In the notorious 1995 *E. coli* outbreak involving undercooked hamburgers from Jack-in-the-Box restaurants, one child who died never ate a hamburger from the chain, but merely stayed at the same day care center as a child who did.

**Pets, water, and person-to-person spread.** Pet-related acute enteric illnesses include salmonellosis from reptiles and campylobacteriosis from healthy cats. Cat-associated gastroenteritis may depend on whether the cat is allowed outside. Pet-associated illness may be infrequent, but may be important in persons with AIDS. In 1991 there were 121.2 million dogs, cats, birds, and other animals in the U.S., and there were 249.6 million people in the U.S. in 1990 (World Book), or 0.5 pet per person. In addition to domestic pets, farm animals at petting zoos may be a source of Salmonella, *E. coli* O157:H7 and other enteric infections. Water used for drinking or recreation may become contaminated with enteric pathogens. According to the U.S. Geological Survey, as reported in the *Columbus Dispatch* on June 27, 2002, 56% of samples of the Cuyahoga River taken between Akron and Cleveland in 2000 contained infectious enteroviruses. Person-to-person spread is the ‘default’ explanation for enteric infections; that is, if health officials can find no other explanation for an outbreak, there’s always the person-to-person theory.

### **Existing enteric disease surveillance systems.**

There are three passive surveillance systems in use for enteric diseases in the United States (i.e., they operate without solicitation, intervention, or contact by a health agency). Two are for outbreaks (defined as the occurrence of two or more cases of a similar illness resulting from a common exposure), and one is for individual “sporadic” illnesses (isolations of reportable disease agents by laboratories). There is also a special active surveillance system for foodborne diseases – FoodNet – for which health personnel collect data for a

limited geographic area.

One of the two outbreak surveillance systems is for foodborne disease outbreaks; the other is for waterborne outbreaks. The Centers for Disease Control and Prevention (CDC) operates the Foodborne Disease Outbreak (FBDO) Surveillance System. The CDC reviews the data, but state and local public health departments have primary responsibility for identifying and investigating foodborne disease outbreaks. To be counted by the National Foodborne Illness Reporting System, individuals or their physicians have to realize they may have been in an outbreak due to food or water and report it to their local health department. There is a similar but separate passive system for waterborne outbreaks.

Laboratories and physicians report cases of culture-confirmed salmonellosis, shigellosis, listeriosis, botulism, campylobacteriosis, trichinosis, cholera, typhoid fever, and hepatitis A to local health departments through a passive reporting system. Obviously this system starts with collection of a stool culture for analysis, and may pick up both so-called sporadic, or individual, cases and outbreak-associated cases. Although the distinction is blurry between epidemic cases and the far more common sporadic cases, the definition of an outbreak obviously focuses on epidemics and is meant to exclude sporadic cases.

Nevertheless, practically all studies of foodborne illness outbreaks are case-control studies. Likewise, most risk factor studies (e.g., studies of pet-associated illness) are ad-hoc, clinic-based case-control studies.

#### **Limitations of passive and retrospective systems.**

There is a theoretical problem with using retrospective methods to estimate the rate or probability of disease associated with a risk factor. There is also a difficulty with using studies of epidemic cases to try to identify means to control the vastly more common sporadic cases. Underreporting hopelessly biases the official incidence data from the passive reporting systems. Common misperceptions by patients, doctors, and even public health officials contribute to this underreporting. By the time the organism responsible for an illness is identified, if it ever is, it is generally impossible for patients to remember possible exposures. For all these reasons the existing surveillance systems are unable to show the relative importance of various food processing defects, etc., in causing illness

Mausner and Bahn (p. 169 in their 1985 textbook, *Epidemiology—an Introductory Text*) summarize the differences between retrospective (case-control) and prospective studies. Almost all prospective studies entail very costly long-term follow-up of a large number of subjects. Retrospective studies have problems with recall bias and with the selection of control groups. They can yield only a relative risk, but cannot ascertain incidence rates or the absolute risk due to a factor. The odds ratio from a case-control study can only estimate the relative risk of disease due to the study factor if the controls are representative of the general population, the cases are representative of all cases, and the frequency of the disease in the general population is small.

There is a problem with using outbreak surveillance to identify faulty practices: outbreaks and individual cases may not have the same causes. Outbreaks feature short incubation periods and high attack rates (50%), whereas sporadic cases have longer incubation periods and lower attack rates (5%). The Minnesota Department of Health has detected a decrease in outbreak-associated cases, caused by bacteria incubating in foods, and

an increase in sporadic cases, caused by lower-level contamination. Intermittent contamination of food products caused by infected workers (especially multiply infected workers) is occurring more frequently; examples are salmonellosis associated with previously unlikely vehicles such as cantaloupes, tomatoes, shredded cheese, shell eggs, and wrapped hamburgers merely touched by an infected employee. Passive surveillance is becoming less and less appropriate because recognizing food as the cause of an illness is becoming even more difficult. Practices identified as hazardous through outbreak surveillance have been prohibited, but the actual risk associated with such a violation is not known.

**Underreporting and other selection biases.** The most salient feature of the official incidence data is that only a tiny fraction of all outbreaks is reported. The fraction of total cases represented by the reported cases is likely to be high for severe diseases like botulism, but low for milder ones like listeriosis. The overall ratio is said to be 25:1. The usefulness of this data is limited by its biases because, as the CDC points out, “large outbreaks; interstate outbreaks; restaurant-associated outbreaks; and outbreaks involving serious illness, hospitalizations, or deaths are more likely to come to the attention of health authorities than cases of mild illness after a family cookout.” The CDC data is also skewed in favor of diseases with short incubation periods caused by the more common bacterial pathogens (as opposed to viral and other agents).

As noted above, according to 1996-97 FoodNet population survey estimates there are 1,400,000 cases of acute diarrhea from all causes annually in Franklin County. Applying the estimate that 36% this is foodborne suggests that county residents actually suffer through 500,000 episodes of foodborne illness every year.

However, between 1993 and 1997 an average of 550 outbreaks (only 17,212 cases) of foodborne disease were reported per year in the entire United States. Although the Columbus Health Department receives only a handful of reports of outbreaks a year, the inadequacy of the existing passive reporting system was demonstrated during a recent *E. coli* O157:H7 outbreak when the Department received 200 calls a day from individuals with bloody diarrhea.

**Knowledge gap.** Most patients presume their symptoms were caused by the last meal they ate. Most complaints of illness the Columbus Health Department receives about restaurants and grocery stores are not credible because they allege a combination of symptoms, incubation period, or other details inconsistent with accepted characteristics of these illnesses.

A study has shown that public health professionals frequently misunderstand the importance of certain agents such as viruses in causing outbreaks of gastroenteritis; this leads to inappropriate testing of samples and the institution of inappropriate control measures.

**Memory problem with retrospective studies.** Most people have difficulty remembering what they ate yesterday, and find it virtually impossible to re-create a food history during the likely incubation period of an illness by the time it is identified by a laboratory.

**Laboratory-based surveillance** for individual cases of enteric disease relies on the collection of stool cultures. Stool cultures, necessary for confirmation of the etiologic agent in an outbreak, are frequently not done because they rarely influence treatment. Public health officials often complain that the United States spends vast sums of money on medical care, but most of the money is for acute care, and only five percent of the expenditure is for prevention. The low frequency of stool culture collection is a small part of this emphasis on treatment versus prevention. Furthermore, not all agents capable of causing outbreaks are reportable as individual cases.

**Complexity.** The “knowledge gap” referred to above is embodied in the inability of many local health departments to respond appropriately to sporadic and outbreak-associated gastrointestinal illness. More than 200 acute infectious diseases capable of causing symptoms of foodborne illness have been identified. The variability in etiology and routes of exposure strains the expertise of many health departments.

**Unknown pathogens** appear to account for 81% of all cases of foodborne illness. (See Mead et al. (<http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm#Figure%201>)). Among outbreaks that are investigated, for 68% the agent is never identified. See <http://www.cdc.gov/mmwr/PDF/ss/ss4901.PDF> (accessed October 11, 2007). As Dr. Mead points out, this is cause for concern because many of the organisms of greatest concern today were unknown just 20 years ago.

Unknown pathogens distort the data from reported outbreaks because of “positive results bias:” researchers are less likely to report an outbreak for which the agent was never identified.

### **Proposal for Prospective Active Surveillance.**

Diet records from the Web site for nutrition and physical activity assessment may serve as a relatively unbiased source of cases for surveillance of sporadic foodborne illness. When clients enter their 3-day diet records, they will be asked to identify commercial sources of foods. When they log back onto the site after a 2-day lag to receive their results and recommendations, they will be asked to report any subsequent symptoms (e. g. diarrhea) suggestive of foodborne illness. Respondents will be asked to save and refrigerate small samples of foods they consume on a daily basis. Symptomatic individuals (or a subset of them with symptoms most likely to lead to positive stool cultures), as well as controls matched to them, may be offered cash payments for stool and food samples. The cash might overcome the usual squeamishness that reduces cooperation in outbreak investigations. We will provide convenient, free, state-of-the-art microbiological testing of these samples, and link any diagnoses with food and illness histories.

Essentially the website will allow us to use these symptoms of foodborne illness to schedule most of the regular, routine inspections mandated by law, both of the establishments suspected of causing the illness and of “control” restaurants. (See “Enhanced Inspections” section below.) The inspections will reveal faulty practices associated with the illnesses.

The goal of this part of the program is to fine-tune the existing risk-based inspection program. At the present time Ohio mandates more frequent inspections in operations with a higher *theoretical* risk of causing an outbreak. This study will enable us to focus prevention activities on food operations and processing defects epidemiologically linked to recent sporadic illness in the local community.

**Case-control study.** This proposal could be conceptualized as a case-control study in which cases are people who subsequently experience symptoms suggesting foodborne illness. Controls would be people who remained symptom-free. Obviously controls could be selected from Web site clients who did not subsequently become ill. Controls could be matched to cases; e.g., controls could be best friends, neighbors, age-matched to cases, etc. The exposure of interest would be one to three foods listed in the food records of cases or controls.

An example: suppose the case had cramps and diarrhea and a stool test revealed the presence of *Bacillus cereus* toxin. As **Table 6** shows, attention would focus on foods eaten 7-12 hours earlier (International Association for Food Protection (IAFP). *Procedures to Investigate Foodborne Illness – 5th Edition*. 1999: Des Moines, IA (see [www.foodprotection.org](http://www.foodprotection.org)) (accessed 10/18/07). **Table 7** suggests focusing attention on starchy food that may have been held at incubating temperatures (Weingold SE, Guzewich JJ, Fudala JK. Use of foodborne disease data for HACCP risk assessment. *Journal of Food Protection*, September 1994; 57:9, pp. 820-830). Under the theory that improper hot holding of starchy food caused the illness, such a food would either not appear in the food history of any controls matched to this case, or such foods would have been held at safe temperatures.

Under this program many routine standard inspections would be more in-depth than they usually are now, focused in this way on foods matched to foods eaten by cases. **Table 8** (in the subsection on electronic forms under “Environmental Health Data Processing System” below) shows the data capture necessary. Obviously this would be a significant departure from the amount of data captured in almost any other inspection program. Normally health department inspections are conducted separately from illness surveillance. The only known precedents for this approach – comparing restaurants implicated in complaints of sporadic illness with other restaurants --are a program in Seattle-King County, Washington and a risk-based restaurant inspection system in Los Angeles County. (See Buchholz U et al., A risk-based restaurant inspection system in Los Angeles County. *Journal of Food Protection*, February 2002, Vol. 65, No. 2, pp. 367-372. Buchholz et al. used as cases restaurants implicated in credible but unconfirmed complaints alleging foodborne illness. Their data can't show the risk of such a complaint due to a specific violation, because not marking a violation may mean “that the item was either observed and found to be in order or that it was not observed at all.”

<b>Table 6. Classification of acute enteric diseases by symptoms, incubation periods, and agents.</b>			
<b>Disease group</b>	<b>Predominating or initial symptoms</b>	<b>Incubation (hours)</b>	<b>Likely etiologic agents</b>
Upper GI	Nausea, vomiting	<1	heavy metals
		1-6	<i>Bacillus cereus</i> <sup>a</sup>
			<i>Staph. aureus</i>
7-12	Mushrooms <sup>b</sup>		
Sore throat & respiratory	Sore throat, fever, nausea	<1	Lye
		24-72	<i>Strep. pyogenes</i>
Lower GI	Cramps, diarrhea	7-12	<i>B. cereus</i>
			<i>Cl. perfringens</i>
		13-72	Campylobacter
			Pathogenic <i>E. coli</i>
			<i>Salmonella</i>
			<i>Shigella</i>
>72	Norwalk virus		
	Other viruses		
	Entamoeba <i>Giardia</i>		
Neurological	Vision problems, tingling, paralysis	<1	Insecticides
		1-6	Ciguatera fish
		18-36	<i>Cl. botulinum</i>
		>72	Mercury <sup>c</sup>
Generalized infection	Fever, chills, aches	>72	Listeria
			<i>Salmonella typhi</i>
			Hepatitis A <i>Toxoplasma</i>
Allergic	Facial flushing, itching	<1	Scombroid fish
			Monosodium glutamate
		1-6	Hypervitaminosis A <sup>d</sup>

- a. Exo-enterotoxigenic strains.
- b. Endo-enterotoxigenic strains.
- c. Grain fungicides; meat of animals fed contaminated grain.
- d. Disease is due to consumption of liver and kidneys of animals from cold regions.

<b>Table 7. Classification of acute foodborne disease outbreaks by preparation method, significant ingredient, agent, and contributing factors, New York State, 1980-1991.</b>						
<b>% (a)</b>	<b>Significant ingredient</b>	<b>% (b)</b>	<b>Agent</b>	<b>% (c)</b>	<b>Contributing factors</b>	<b>% (d)</b>
<b>14%</b>	<b>Eaten raw or lightly cooked</b>					
	Shellfish	95%	General viral Norwalk virus Hepatitis A	59% 31 2	Unapproved source Eating raw meat Contaminated ingredient	60% 53 49
<b>6%</b>	<b>Solid masses of potentially hazardous food</b>					
	Starchy food	58%	<b>B. cereus</b>	79%	Improper hot holding Improper cooling	42% 23
	Beef	21	<i>C. perfringens</i>	72	Improper reheating	50
	Egg	16	<i>Salmonella</i>	100	Inadequate cooking Contam. ingredient	39 100 49
<b>5%</b>	<b>Cook/serve foods</b>					
	Egg	31%	<i>Salmonella</i>	95%	Inadequate cooking	82%
	Poultry	21	<i>Salmonella</i>	33	Inadequate cooking	33
	Beef	20	<i>Salmonella</i>	36	Inadequate cooking	29
<b>5%</b>	<b>Natural toxicant</b>					
	Finfish	83%	Scombroid toxin	99%	Inadequate refrigeration	79%
<b>5%</b>	<b>Roasted meats and poultry</b>					
	Poultry	41%	<b>Salmonella</b>	52%	Inadequate cooking	41%
	Beef	41	<i>C. perfringens</i>	34	Improper hot hold.	28
	Pork	16	<i>C. perfringens</i>	27	Improper cooling	45
<b>1%</b>	<b>Salads with one or more cooked ingredients</b>					
	Poultry	35%	<b>Salmonella</b>	50%	Inadequate refrigeration	50%
<b>1%</b>	<b>Liquid or semi-solid mixtures of potentially hazardous foods</b>					
	Poultry	33%	<b>Salmonella</b>	50%	Inadequate refrigeration	50%
<b>1%</b>	<b>Chemical contamination</b>					
	Beverages	42%	Heavy metals	58%	Added poison	33%

- Percentage of 1,528 reported outbreaks involving food with given method of prep.
- Percent of reported outbreaks for given significant ingredient in above category.
- Percent of reported outbreaks for the specific agent in a significant ingredient category.
- Percentage of outbreaks where specific contributing factor was reported in significant ingredient category.

**Smaller categories are not represented.**

### Sample sizes necessary for results.

A prior estimate for the proportion of survey respondents expected to have gastrointestinal symptoms and a specification of a likely range or an acceptable level of precision are required to determine how large the survey would have to be.

Incidence (risk) can be viewed as the proportion  $p$  of respondents in the survey who become ill during follow-up. Daniel (Daniel WW. Biostatistics: a foundation for analysis in the health sciences. 4th ed. New York: John Wiley & Sons, 1987, p. 155) gives a formula for estimating the sample size  $n$  for estimating a population proportion in this situation. A normal-curve approximation may be used if  $n > 20$  and  $np > 5$ . The length of the interval from the point estimate  $p$  to the lower estimate is  $d$ . The usual technique results in a sample size large enough that 95% of samples drawn at random from a population of cases and controls would contain a proportion of cases within the expected range of proportions. The  $z$ -score corresponding to this ( $\alpha = 0.05$ ) is 1.96.

The sample size needed is given by:

$$n = \frac{z^2 (1 - \alpha / 2) pq}{d^2}$$

Mead et al. (see <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm#Figure%201>) (accessed 10/17/07) started with the age-adjusted rate of 0.75 episodes of disabling diarrhea (3 loose stools per 24-hour period lasting more than a day or interfering with normal activities) per person per year from the FoodNet population survey. To this they added the rate of 0.30 episodes of vomiting without diarrhea from Cleveland and Tecumseh, Michigan community health surveys, and reduced the total by 25% to remove symptoms associated with respiratory illness. In this way they estimated the overall rate of acute gastroenteritis in the United States to be 0.79 episodes per person per year  $((0.75 + 0.30) * .75 = 0.79)$ . The corresponding diarrhea rate from the Tecumseh study was 0.52 episodes per person per year, so using the same method would put the overall rate of acute gastroenteritis at  $(0.52 + 0.30) * .75 = 0.62$  episodes per person per year.

It bears noting that illness caused by *Listeria*, *Toxoplasma*, and hepatitis A virus typically are not characterized by gastrointestinal symptoms.

**1. To estimate overall incidence.** Using the estimates suggested by Mead et al., the overall rate of acute gastroenteritis (disabling diarrhea or vomiting, or both, without respiratory symptoms) is 0.79 but may be as low as 0.52 episodes per person-year. This suggests that the risk of developing symptoms on a given day is  $0.79/365 = 0.00216$  down to  $0.52/365 = 0.00142$ . Over three days of follow-up the probability of developing symptoms would be three times as high, or 0.00648 to 0.00426. So  $p = 0.00648$  and  $d = 0.00648 - 0.00426 = 0.00222$ . The box shows details of the calculation. The minimum number of respondents to estimate the incidence of symptoms in the general population is 5,032. Other assumptions result in different sample sizes.

variable	calculations	values	variable	calculations	values
point est for rate / pers-yr		0.79	duration of follow-up (days)		3
lower lim for rate / pers-yr		0.52			
z	1.96	1.96	d	$(3/365)*(0.79-0.52)$	0.0022192
p	$(3/365)*0.79$	0.0064932	n	$z^2*p*q/d^2$	5032
q	1-p	0.9935068	np	n*p	32.674554

The formula is based on a normal-curve approximation to the binomial distribution that is not accurate if  $np < 5$ . In this case it works, because  $np = 32$ .

**2. To estimate the relative risk of restaurant meals.** In a national sample taken in March 1986, 16.5% of respondents did not eat out in a two-week period, so 83.5% ate out at least once. A somewhat larger percentage, perhaps 20%, would not have eaten out in one week. Therefore, perhaps 80% did eat out in a one-week period. Sample-size tables for case-control studies (Schlesselman JJ. Case-Control Studies. New York: Oxford University Press, 1982, p. 169) can be summarized in graphic form as in **Figure 1**. A study involving 681 cases and 681 controls would be sufficiently large to detect a relative risk of 1.5 or above with  $\alpha = 0.05$  (two-sided) and  $\beta = 0.20$ , assuming an 80% exposure rate among controls. However, if the exposure rate among controls is 85%, each group must be 871.

The normal-curve approximation to the binomial distribution can not be used to calculate the sample size needed to estimate the incidence of foodborne illness because if 1/3 of gastrointestinal symptoms is due to food,  $np < 5$ . This project will at least serve as a pilot. A Washington State study to identify risk factors for campylobacteriosis succeeded with 218 cases and 526 controls.

We will have a sufficient number of neighborhood controls to estimate the incidence of symptoms, as well as the 681 cases needed to determine the relative risk of restaurant meals.

By comparison, one study of campylobacteriosis involved only 45 pairs of cases and controls (Deming, M. S., R. V. Tauxe, P. A. Blake, S. E. Dixon, B. S. Fowler, T. S. Jones, E. A. Lockamy, C. M. Patton, and R. O. Sikes. Campylobacter enteritis at a university: transmission from eating chicken and from cats. American Journal of Epidemiology 1987; 126:526–34).

**3. To estimate the risk of acute gastroenteritis due to consumption of improperly cooled solid masses of food.** Analysis of smaller and smaller subgroups of exposures will require larger and larger samples. This portion may be conceived of as a pilot until a number of subjects accumulates.

**Table 7** shows that 6% of outbreaks in New York State during a recent decade were caused by improper temperature control of solid masses of potentially hazardous foods. However, lightly cooked shellfish, not a popular item in Ohio, caused 14% of the rest. Removing the 214 shellfish outbreaks, solid masses of food caused  $(.06)(1528) / (1528 - 214) = 7\%$  of outbreaks, the likely figure for Ohio.

If 36% of 0.52 to 0.79 episodes of gastroenteritis are due to food, and 7% of the 36% are due to improper temperature control, this factor would be responsible for 2.5% of the illnesses, or 0.013 to 0.020 person-years of illness. Substituting these values in the box

yields a sample size of 191,000

**Enhanced inspections.** Under this proposal food service inspectors will conduct a hazard analyses (preparation review) for one to three foods consumed by cases during the likely incubation period of their illness, based on symptoms. (See **Table 6** and **Table 7.**) Hall et al recently refined the classification system it uses. See *Epidemiology and Infection* (2001), 127, 381-387.) Results will be compared to those from a similar series of evaluations associated with controls. Both “case” and “control” inspections will include the standard inspections required by law, but they will also review the preparation of specific foods implicated by **Table 6** (for cases) or matched to foods implicated by **Table 7** (for controls). Item 3 in **Table 8** (in the section on electronic forms, below) corresponds to data from “control” inspections.

Under the theory that restaurant food causes some of the illness, more defects should be observed in the case series than in the control series. This will reveal the absolute risk of illness due to processing defects. Integration of food histories with illness histories will allow analysis of inspection results and laboratory analyses of food samples according to the case or control status of the respondent.

County extension agents will evaluate meal preparation, exposure to sick pets, contaminated water, and other factors in homes, and educate principal meal preparers about food safety. We will also investigate child day care facilities and person-to-person spread. Evaluation of home meal safety may include testing food safety knowledge of the cook and observations of food preparation. Ideally, as many routine inspections as possible would be “enhanced.”

Extension agents will collect food, clinical, and pet stool samples during home visits.

### **Microbiological testing program for food and clinical samples**

Food samples may be of any foods left over from the respondent's meal, "check samples" of foods prepared in a similar fashion, or ingredients. Environmental samples from restaurants may include drippings on refrigerator floors, dried deposits on equipment, and swabs of slicers, cutting boards, and other surfaces. Samples from day care centers may include swabs of the surfaces of toys. Samples from homes may include kitchen sponges and towels and stool samples from pets. Clinical samples from respondents or food service workers may include vomitus, feces, urine, nasal swabs, rectal swabs, throat cultures, cultures of skin lesions, or "glove juice" samples of germs on hands. Food, environmental and clinical samples will be collected using established methods, sometimes in return for cash bounties.

Traditional culture techniques for identification of bacteria in food samples and clinical specimens take two days of “pre-enrichment” to grow enough germs to work with, followed by a purification step that may take an additional day. The complete process typically takes about a week to complete. By the time public health agencies receive results of clinical tests for reportable enteric diseases, patients tend to forget what they ate. Restaurants no longer have leftovers. Surfaces have been cleaned. This proposal solves all these problems; stool test results are available the same day the stool is collected.

Test results must be available quickly for this proposal.

In keeping with the near-real-time data capture on the diet analysis and morbidity

history Web pages, we propose to use rapid microbiological tests: a bioluminescence meter for food contact surfaces and immunomagnetic separation followed by genetic testing for food and clinical samples. Unlike traditional cultural methods for detecting foodborne pathogens, a bioluminescence meter gives results almost instantaneously. Immunomagnetic separation can be used in place of, or in addition to, the standard pre-enrichment step, and is suitable for microorganisms that can not be grown in culture. The immunomagnetic separation and genetic testing we propose to use require 4 hours or less, are more sensitive than cultural methods, and are the only tests available for some viruses. However, they have not been fully developed and validated for some pathogens, a process that may take 12 months.

PCR equipment is widely available. Kits are even available for use by high school students -- see [www.carolina.com](http://www.carolina.com) (Stratagene robocycler, Thermal Cycler, etc.) (accessed 10/18/07).

Nucleic acid sequence-based amplification (NASBA) has received less attention than PCR but may be a simple and rapid alternative. (Compton J. Nucleic acid sequence-based amplification. *Nature*, March 7, 1991, pp. 91-92.) Because NASBA does not require rapid changes in temperature in samples under analysis, less specialized equipment is required. It is faster, less susceptible to contamination, and, because infectious material is inactivated, NASBA is less of a hazard to laboratory workers.

This genetic testing is being automated. Whereas the cost per test of multiplexed PCR by hand was once estimated at \$475, the cost of testing a food or clinical sample for all known microbial pathogens at once with the GeneChip™ system would be less than \$100. Again, a significant development cost would be involved, but the “chip” would be a lasting legacy of the Project for years to come. Eventual addition of microbiological testing would allow quantitative microbiological risk assessment, revealing the absolute risk of illness due to specific pathogens.

Researchers at the Mayo Clinic developed a PCR-based test for anthrax that can be completed in an hour, including definitive identification, and costs only \$50 per test. (See *Columbus Dispatch*, November 6, 2001.)

Still other testing formats are being commercialized. Portable fiber-optic biosensors capable of detecting as few as 200 bacterial cells in 20 minutes in the original sample are available (see FSNet for March 22, 2001).

A certain amount of perspective is necessary when using and interpreting different tests. Differing sensitivities and specificities of different kinds of tests, and the differing prevalence of agents, result in differing predictive values for different tests for the same pathogen. For a brief discussion of problems with interpreting rapid tests (for bioterrorism agents specifically), see <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5048a5.htm> (accessed 10/18/07).

### **1. A bioluminescence meter.**

This technology may be helpful for rapid screening of surfaces and products to identify the most heavily contaminated ones for further testing under the theory that they may be more likely to carry the pathogen of interest.

The area is still experimental. Data from these meters correlates well with traditional culture methods for swimming pool water – see Lee et al., Rapid determination of bacteria in

pools. Environmental Health, July/August 2001, pp. 9-13. No link has been shown between bioluminescence test results and contamination with a specific pathogen.

## **2. Immunomagnetic separation.**

IMS technology uses microscopic paramagnetic beads coated with monoclonal antibodies to bind to the pathogen of interest and draw it out of a food or clinical sample.

Agricultural Research Service (USDA) scientists have developed a rapid, easy-to-use test to detect and count *E. coli* O157:H7 bacteria in natural and constructed bodies of water. ARS microbiologists Dan Shelton and Jeff Karns in the Animal Waste Pathogen Laboratory, Beltsville, Md., developed the test, which uses magnetic beads to detect the pathogen. The magnetic beads are coated with anti-*E. coli* monoclonal antibodies that bind to the bacteria, making it possible to count them. See <http://www.foodtechsource.com/emag/022/know.htm> (accessed 10/18/07). Current testing methods are designed only to detect the bacteria, but not to measure how many are present.

IMS has been used to advantage with PCR. Kang et al. (Research note: screening bovine carcass sponge samples for *Escherichia coli* O157 using a short enrichment coupled with immunomagnetic separation and a polymerase chain reaction-based (BAX) detection step. October 2001: Journal of Food Protection: Vol. 64, No. 10, pp. 1610-1612) developed a bovine carcass sponge sample screening protocol for detecting *Escherichia coli* O157:H7. It was composed of a short selective enrichment followed by an immunomagnetic separation (IMS) and target detection using the BAX *E. coli* O157 polymerase chain reaction assay. This screening protocol compared favorably to a culture-based method for detection of the organism in carcass sponge samples.

## **3. Microarrays for genetic testing.**

A U.S. company, Affymetrix, has automated the production of DNA probes. The DNA chip array will permit the detection and accurate identification of dozens of microorganisms at low concentrations in food, water, or other samples, reducing the time necessary for results (currently 48 hours on average) to just 4 hours, and cutting the cost per test ten-fold compared to traditional culture methods. The GeneChip technology is a multidisciplinary system that combines microbiology, photolithography, chemistry, image analysis and bioinformatics. It enables the production of a "biochip" designed to identify fluorescent-labeled DNA or RNA fragments through their hybridization to oligonucleotide probes, short DNA sequences. The probes are synthesized on a miniaturized glass substrate, measuring approximately 1 cm<sup>2</sup>, on which hybridization occurs. Each hybridization surface may contain a very large number of unique oligonucleotide probes (up to 400,000), permitting several thousand individual nucleotide positions to be characterized at the same time. A positive hybridization result is detected by the intensity of the fluorescence, which reflects the stability of the hybridization between the oligonucleotide probe and the target sequence of the microorganisms potentially presents in a sample. Unlike conventional screening methods based on morphology and physiology characteristics, molecular testing identifies one or several DNA sequences of any microorganism, including bacteria, viruses and parasites.

Lyonnais des Eaux, a water management firm, and bioMérieux, an in vitro

diagnostics company, formed a research and development partnership program to develop Affymetrix GeneChip arrays for drinking water quality control and consumer safety. Lyonnaise des Eaux is a water management company, currently supplying 77 million people around the world with drinking water and 52 million people with wastewater services. bioMerieux specializes in infectious disease diagnostics and industrial microbiology control. See

[http://www.biomerieux.com/servlet/srt/bio/portail/dynPage?open=PRT\\_NWS\\_REL&doc=PART\\_NWS\\_REL\\_G\\_PRS\\_RLS\\_9&crptprm=ZmlsdGVyPQ](http://www.biomerieux.com/servlet/srt/bio/portail/dynPage?open=PRT_NWS_REL&doc=PART_NWS_REL_G_PRS_RLS_9&crptprm=ZmlsdGVyPQ) and [http://www.biomerieux.com/servlet/srt/bio/portail/dynPage?doc=PRT\\_NWS\\_REL\\_G\\_PRS\\_RLS\\_5](http://www.biomerieux.com/servlet/srt/bio/portail/dynPage?doc=PRT_NWS_REL_G_PRS_RLS_5) (both accessed 10/20/07).

We propose to use this technology (but not necessary these companies) for rapid identification of pathogens..

**4. Ribotyping for bacteria.** After DNA probe detection of a bacterial pathogen in food, environmental, and clinical samples related to a single case, standard enrichment, selective, or differential methods will be used to isolate pure cultures of bacteria from the individual (not pooled) samples. We envision performance of a Gram stain and examination under a microscope for all samples to select similar colonies for comparison. Immunofluorescent stains are also available to help identify pathogens microscopically.

We propose to follow up the above methods with use of technology like DuPont's, fully automated RiboPrint™ system for food microbiology. It can identify a pure culture of virtually any bacteria and characterize it below the species level using RiboPrint™ images. Obviously a match between isolates from different sources would suggest epidemiological relatedness. Results are available in about 8 hours. Reagents for one sample cost about \$45.00.

The October 2001 issue of the *Journal of Food Protection* (vol. 64, no. 10, pp. 1617-1620) contains a report by Gendel et al. in which automated ribotyping with a Qualicon (Du Pont) Riboprinter was used to show that clinical isolates of *Vibrio parahaemolyticus* O3:K6 recovered during two U.S. outbreaks of oyster-associated gastroenteritis in 1998 were related to each other and to a previously identified highly virulent Asian clone of this serotype.

The relative lack of biodiversity among some strains of microbe presents a difficulty in differentiating among strains.

### **Environmental Health Data Processing System**

The goal of this part of the program is to fine-tune the existing risk-based inspection program. At the present time Ohio mandates more frequent inspections in operations with a higher theoretical risk of causing an outbreak. This study will enable us to focus prevention activities on food operations and processing defects epidemiologically linked to recent sporadic illness in the local community.

**Electronic forms for outbreak investigations and routine inspections.** The food record and acute illness history collection features of the Web site will be integrated with an

electronic data collection and management system for both routine inspections and foodborne illness outbreak investigations. The food record forms for use in diet control will double as food history forms for outbreak investigations. See **Table 7**.

In collaboration with a local health department and a software company, we plan to computerize the paper (static) outbreak investigation forms developed by the International Association for Food Protection (IAFP), reproduced in *Procedures to Investigate Foodborne Illness – 5th Edition*, used around the world (see [www.foodprotection.org](http://www.foodprotection.org), accessed 10/20/07). We have IAFP's permission to reproduce and computerize these forms.

We also plan to computerize Ohio's inspection forms for routine inspections and outbreak investigations. These forms are used by every local health department in Ohio. Ohio adapted the U.S. FDA's 1999 Food Code in March of 2001, so they conform to similar forms used by more than 25 other states that have adapted the Food Code. (Ohio's CCP form, while not a HACCP form, notes violations of parameters that could be critical control points.) This will require classification and tabulation of the process defects noted on the CCP Inspection Form.

The next step will be to reorganize a significant fraction of routine inspections as enhanced inspections (see above). These inspections will reveal food consumption patterns for controls (necessary for exposure assessment) and pathogen levels that are insufficient to cause disease (for dose-response assessment).

**Table 8.** Electronic forms for outbreak investigations and routine inspections.

1. Computerize Ohio's inspection forms for routine inspections:
  - The IAFP complaint form (Form A)
  - The IAFP food history form (Form B).
  - The IAFP Food Preparation Review form.
  - The clinical specimen and food and environmental sample collection forms.
  - Computerize the outbreak investigation summary forms for reporting investigation results to the Ohio Department of Health and Centers for Disease Control.
2. Computerize Ohio's inspection forms for routine inspections:
  - Ohio Department of Agriculture/ Ohio Department of Health Standard Inspection Report form for both Food Service and Retail Food Establishments.
  - Ohio Department of Agriculture Retail Food Establishment Process Review
  - Ohio Department of Health Critical Control Point Inspection Report
3. Classify foods as eaten by cases or controls.
4. Classify foods by preparation method, significant ingredient, agent, and contributing factors. (See **Table 7.**)
5. Compare the frequencies of each processing defect for cases and controls to determine the actual risks presented by specific foods and food-processing steps, in order to concentrate inspections on the riskiest procedures.
6. Adapt the whole process to the investigation of exposures other than food:
  - Exposures in the home, to be evaluated by county extension agents.
    - person-to-person spread
    - home meal preparation
    - exposure to sick pets, contaminated water, etc.
  - Exposures associated with child day care, to be evaluated by Ohio Department of Human Services day care inspectors.
7. Integrate the IAFP and other forms with Laboratory Information Management System (**LIMS**) forms.
8. Tie clinical and environmental test results together with LIMS.
9. Integrate all of the above into a microbiological risk assessment.

Columbus Public Health (formerly Columbus Health Department), following a national trend among food regulatory agencies, is posting inspection results on the Web. Columbus Public Health has not yet computerized CCP inspections.)

### **Microbiological risk assessment**

The food intake records, with quantities consumed, provide an opportunity for quantitative microbiological risk assessment of the foods involved and their preparation methods. Intake data for controls will allow for exposure assessment. Predictive modeling was once considered too complex.

The major microbial risk assessments conducted to date generally rely on conservative "fail-safe" assumptions rather than model more mechanistically the impact of the microbial ecology of foods on growth and decline of pathogenic organisms. Food inspectors need guidance regarding the magnitude of deviations from accepted parameters that can be tolerated before a hazard exists. Epidemiological and microbiological information (e.g. the number of pathogens per gram of food implicated in outbreaks) will improve the basis for dose-response assessments.

Microbiological risk assessment has been recommended to assure equivalency of sanitary standards among different countries as a prerequisite to introduction of foods into international trade. The World Health Organization has recommended that "the scientific community should consider risk assessment data and information needs when planning experiments or surveys. These aspects should also be considered when reporting results to ensure that the information generated is available for microbiological risk assessments." See <http://www.who.int/foodsafety/micro/en/> (accessed 10/20/07).

## **FRAMEWORK FOR OTHER EPIDEMIOLOGIC STUDIES**

### **Nutrition research**

The on-line collection of food records creates an opportunity for research into the associations between nutrition and the prevention and management of chronic diseases other than diabetes and obesity, such as cancer and cardiovascular disease. An Institute of Food Technologists report in the May 2001 issue of *Food Technology* identified as research priorities the elucidation of the roles, interactions and optimum levels of hundreds of bioactive "functional" food components not considered essential now.

### **Other Web-based epidemiologic studies**

This framework is well suited to some of the first Web-based epidemiologic studies. The Web site will be able to conduct an ongoing version of CODA's survey of impediments to control of diabetes. The site will be able to estimate the risk of having or developing diabetes, eating disorders, and even alcoholism.

The psychological aspects of the site open up avenues of exploration that may otherwise be challenging. If the Web site tabulates psychological status, it could help test the postulate that stress suppresses the immune system. By screening entries for levels of

alcohol consumption as well as behavior problems that may suggest alcoholism, it could gently offer referrals to treatment.

### **Bioterrorism surveillance**

Most bioterrorism proposals to date have relied on doctors, not patients. For example, see the request for applications for the Rapid Response Grant Program On Bioterrorism-Related Research, <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-02-002.html> (accessed 10/20/07). (Application due date was February 15, 2002.) We propose to use the symptom-reporting capability of our Web site to enlist all participants in disease surveillance. “Use of automated ambulatory-care encounters for detection of acute illness clusters, including potential bioterrorism events” has been proposed by Ross Lazarus and others (See *Emerging Infectious Diseases*, v. 8, no. 8, 2002, pp. 753-760.) The important concern that panic could elicit spurious reports could be addressed by mapping cases with similar symptoms with use of geographic information systems (GIS). Geographic proximity of cases and rates of new episodes of illness above historical limits would alert authorities to a potential toxic release.

CDC provides public domain epidemiology software (Epi Info™ Version 3.4.1, Release Date: July 9, 2007) that includes GIS –see <http://www.cdc.gov/epiinfo/> (accessed 10/20/07).

Guidelines issued by the CDC for distinguishing inhalational anthrax from influenza-like illness (see [www.cdc.gov/mmwr/preview/mmwrhtml/mm5044a5.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5044a5.htm)) (accessed 10/20/07) could be adapted for use on the Web site. Presence of a runny nose favors a diagnosis of influenza-like illness, whereas nausea or vomiting and shortness of breath may increase suspicion of inhalational anthrax among people who handle quantities of mail.

The purpose of terrorism is to produce fear and anxiety. “Combating the Terror of Terrorism,” by Ezra Susser, Daniel Herman and Barbara Aaron, discusses the psychological aftermath of the September 2001 terrorist attacks on the United States. (*Scientific American*, August 2002, pp. 70-77. Symptoms of post-traumatic stress disorder appeared in 7.5% of 67,000 Manhattan residents south of 110<sup>th</sup> Street within 2 months of the World Trade Center attacks – a rate three times normal. Yet mental health considerations have mostly been missing from public health responses to terrorism. Health and disability insurance may not pay for mental health assessment or treatment. Susser et al. recommended establishing a reserve corps of part-time and retired mental health professionals to administer cognitive-behavioral therapy, pharmacotherapy, family therapy, etc. They also called for emergence of a leader like Mayor Giuliani, someone to deliver clear, consistent messages and inspire people with a sense of control and optimism. A related feeling of belonging to a group (*esprit de corps*) is also important. Our Web site will not be able to provide the reassurance of a Giuliani, but it could offer on-line counseling, in-depth information, and a sense of involvement in surveillance activities.

A Mid-Ohio Regional Planning Commission committee is coordinating bioterrorism response in the Central Ohio area. We propose to collaborate with MORPC.

## RESOURCES AVAILABLE

MicrolifeUSA ([www.microlifeusa.com](http://www.microlifeusa.com)) (accessed 10/20/07) distributes BalanceLog Software, easy-to-use diet and exercise software for weight management, and portable handheld calorimeters for use with it.

Nutritionist Pro, nutrition analysis software (<http://www.nutritionistpro.com/>) (accessed 10/20/07), performs thorough nutrient analysis of diets, recipes and menus using a knowledge base that includes over 20,000 foods and ingredients and more than 80 nutrients and food characteristics for each food. The software's client tracking program maintains detailed, specific information on an unlimited number of clients—multiple addresses and phone numbers, historical information, chart notes, dietary and weight goals and fitness evaluations and plans. The diet analysis program provides nutrient analysis for professional nutrition counseling and research. Through diet recall or food frequency, it will evaluate an independent diet or compare it against specific nutrient requirements. The menu-planning program will plan a menu for one or more days and analyze for average daily nutrient intake by individual meal or single day.

The Web-based infrastructure would facilitate data entry from supplemental sources such as mail, fax, or telephone. For example, some people may complete paper forms that could be fed into a fax machine. Biscom (<http://www.biscom.com/>) (accessed 10/20/07) can provide a fax server to convert this input into the same form as submissions via the Internet.

Decade Software Company of Fresno, California (<http://www.decadesoftware.com/>) has created Envision for Windows, a 32-bit, multi-user, client server data management system designed specifically to track all aspects of food regulatory inspections and other activities of environmental health agencies. Other Decade products include software for a Field Inspection System in which inspectors use PDA's or Pen Tablet PC's to enter violations during inspections. Envision promotes the automated publishing of inspection results on the Web. The weight-loss website would have to access an establishment profile file maintained at the Health Department to link case histories to the local health department's inspection program. Decade's External Database Lookup or Web Inspection Query Tool enable site visitors to call up establishments by name and/or address, review possible matches, call up a particular inspection and view violations cited on-line, etc. Envision allows the creation of user-defined fields and forms integrated with the standard database forms. The outbreak data collection, CCP inspection, and other forms described above may be created as custom Envision forms.

Another Decade product, Epitome for Windows, would be particularly useful for clinics operated by local health departments. Epitome tracks patient information such as health assessment results at each clinic visit and links the medical history to patient demographics, including family / head-of-household and socioeconomic status.

Decade now has several competitors. One is SMOOware, Inc. ([www.smooware.com](http://www.smooware.com)), which focuses on applications for field use with hand-held computers.

The *Columbus Dispatch* may help publicize this project. A *Dispatch* editorial ("Keeping track," July 16, 2001) recommended a national chronic disease network to track associations between environmental hazards and illness. "Even a pilot effort, starting at \$60 million, would allow such a program to get off the ground."

## Potential Grantors

Diet advice, exercise promotion and food safety are all related to national health promotion and disease prevention objectives for which funding is potentially available from the National Institutes of Health under Healthy People 2010. See [www.health.gov/healthypeople/sitemap](http://www.health.gov/healthypeople/sitemap) (accessed 10/20/07).

The U. S. Government has expressed interest in many aspects of this proposal in the past. For example, a request for proposals for “Environmental Approaches to the Prevention of Obesity” (e.g. by facilitating exercise) closed in March 2002 – see <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-02-021.html> (accessed 10/20/07). Similarly, FDA made \$750,000 available in FY 2002 for research to develop and implement a framework for systematically ranking the threats posed by microbiological agents, toxins, and chemicals in food and to evaluate control points during production, processing, and retail. (Source: [www.content.sciencewise.com/content/index.cfm?objectid=11013](http://www.content.sciencewise.com/content/index.cfm?objectid=11013), accessed 4/23/02.)

Several established foundations have ongoing programs supporting food safety research, use of the Internet for health interventions, or local (Central Ohio) high-technology startups. The Kellogg Foundation’s ongoing Grants Program might provide funding for all or part of this initiative. The Pew Charitable Trusts have called for a chronic disease tracking and monitoring system. See [www.pewtrusts.com/ideas/index.cfm?issue=14](http://www.pewtrusts.com/ideas/index.cfm?issue=14) (accessed 5/23/02). The Greater Columbus Chamber of Commerce and others have made support of “high tech” ventures a priority and have established Columbus Venture Network to link entrepreneurs, service providers (such as attorneys and accountants) and investors.

The Marshfield Clinic in Marshfield, Wisconsin, has expanded its Food Safety Services program by making PCR testing for foods available to the meat industry. Marshfield may be interested in many aspects of this proposal.

## POTENTIAL PROBLEMS

An obvious impediment to widespread use of a weight control Web site is the fact that Internet access is not universal. In April 2001, 71 million people used the Internet; adults logged on an average of 15 days. Not long ago the typical person with Internet access was an educated white male 26-30 years of age. But the demographics are changing rapidly.

Non-whites may be more likely to use the net for health information. Our solution to lack of Internet access is to allow individuals without Internet access to submit data by mail, fax, or telephone. This potential problem could also be controlled by adjusting study groups to the general population on variables such as age, marital status, distribution of occupations, etc.

Self-selection bias may be another problem with Internet-based epidemiologic studies. It could be controlled by adjustment of responses by comparison to supplemental mail, fax, or telephone surveys.

The potential also exists for false responses; these could be controlled through internal monitoring protocols.

The potential mess involved with collecting and saving food samples, and the squeamishness many people feel when contemplating collection of stool samples, may not be overcome by the promise of cash for their samples. The samples would be helpful, but not necessary for the success of the program. Microbiological testing is not necessary for the risk assessment of processing defects.