

ABSTRACT

The identification of laboratory-confirmed Hepatitis A in a food worker at a local restaurant typically requires the testing and prophylaxis of other food workers in the establishment as well as community residents depending on the scope of the illness and risk to the community. After identification of a confirmed case, the Greenfield Health Department successfully utilized the Point of Dispensing (POD) model to conduct a Hepatitis A testing and vaccination clinic for over 90 food workers from a local restaurant. This poster highlights the department's outbreak response and containment while examining the cost to contain this potential outbreak. The cost analysis indicates a significant savings with pre-exposure vaccination of food workers versus the costs required for outbreak investigation and control, however, the endemic rate of Hepatitis A must be considered. In time, universal vaccination of all children with Hepatitis A vaccine will lessen the epidemiological investigation and required prophylaxis for future outbreaks.

INTRODUCTION

Hepatitis A Epidemiology ^{2,3}

- Liver disease caused by an acute infection of Hepatitis A virus (see Figure 1)
- Hepatitis A is prevalent in much of the world, except for the USA, western Europe, Japan, New Zealand, and Australia (for incidence in US see Figure 2)
- Varies in severity from a mild illness lasting 1-2 weeks to a more disabling disease persisting several months
- Transmitted by the fecal-oral route through person-to-person contact or consumption of contaminated food or water
- Risk factors are varied, but most cases have unknown etiology (see Figure 4)

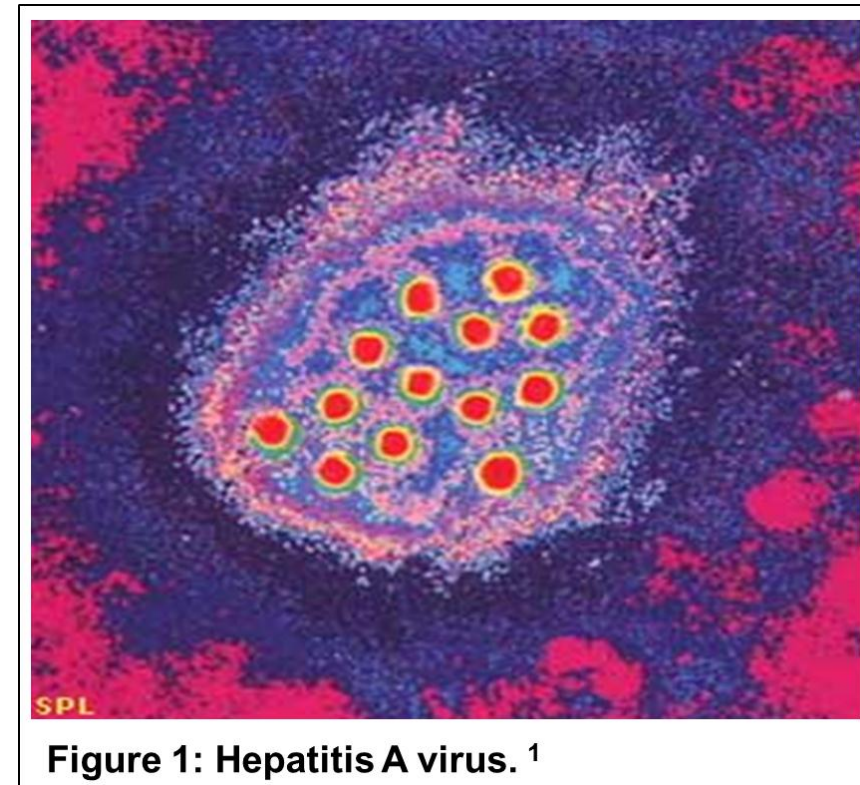


Figure 1: Hepatitis A virus. ¹

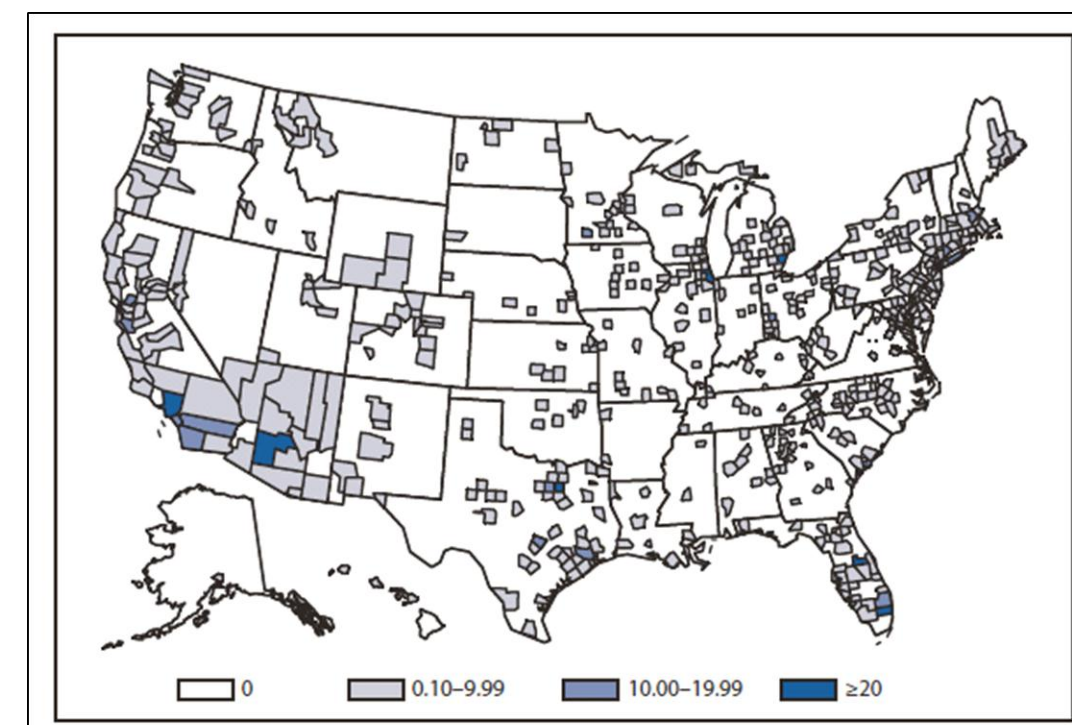


Figure 2: Hepatitis A Incidence, by county — United States, 2010. ⁴

Hepatitis A Epidemiology in Wisconsin ^{2,3}

- Disease is not uncommon
- 30-40 cases reported annually in Wisconsin
- Approximately one case annually in Greenfield since 2007
 - Range, 0-3 cases
 - 2010 Census population = 36,858 residents
- Disease occurs most frequently in children and international travelers

Hepatitis A Vaccine

Licensure & Recommended Use ³

- First licensed in 1995, and responsible for decreasing incidence every year since (see Figure 3)
- Two single-antigen vaccines exist, Vaqta (Merck) and Havrix (GSK), and a combined Hepatitis A/Hepatitis B vaccine, Twinrix (GSK)
- Incremental Vaccine Recommendations since licensure:
 - 1996 = children living in areas with highest rates of disease
 - 1999 = children (> 2 years) living in counties with historical disease rates higher than national average
 - 2005 = Food and Drug Administration (FDA) lowers minimum age for vaccination from 24 months to 12 months
 - 2006 = recommended for all children at one year of age, international travelers, or for any individuals who are at increased risk of infection or complications from Hepatitis A

Immunogenicity ^{3,5}

- 1st dose confers approximately 95% immunity after one month
- 2nd dose induces virtually 100% immunity
- Vaccine less effective in those with chronic liver disease, immune-compromising conditions, transplant recipients, and elderly

Efficacy and Effectiveness ^{3,5}

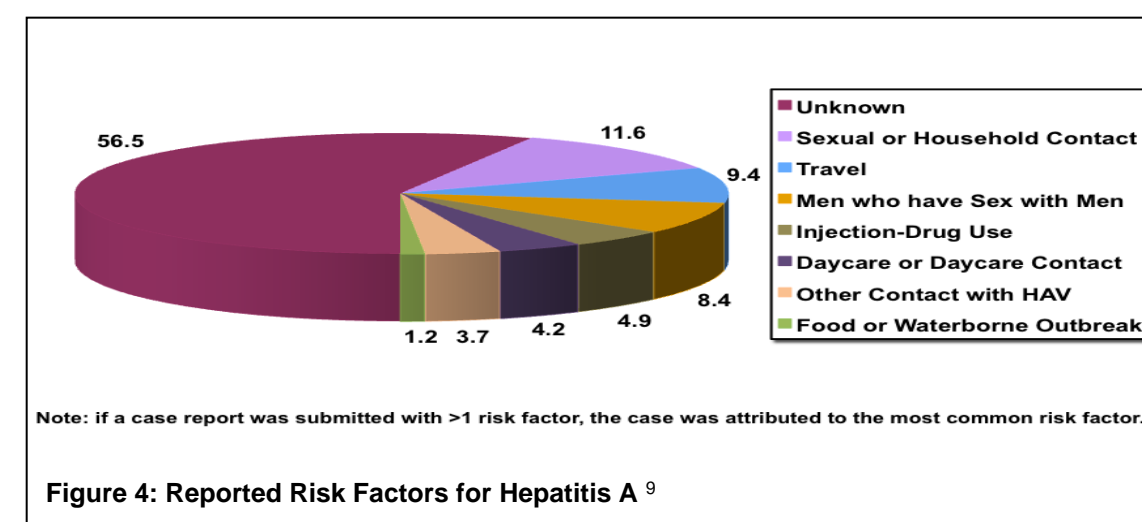
- 97 percent of children developed significant titer response within 1 month of vaccination
- Over a 1-year observation period the efficacy was calculated at 94 percent
- Models indicate that the protection will continue for nearly 25 years following completion of two-dose vaccine series

Cost-Effectiveness ^{3,5}

- Routine vaccination of children at 1 year would reduce 184,000 infections and 32 deaths in each annual birth cohort
- Routine childhood vaccination eliminates public health costs associated with surveillance, contact tracing, and outbreak response

Hepatitis A in Food Workers

- Hepatitis A cases have been confirmed following exposure to a myriad of sources from restaurants and retail stores: glazed donuts, lettuce, green onions, oysters, raspberries, and others
- Food workers not at greater risk of disease but are highly likely to spread disease to large number of patrons ⁷
- Food-borne outbreaks account for approximately 10 percent of all Hepatitis A cases ⁸
- Typically, 38 persons with Hepatitis A are linked to one confirmed case ¹⁰, although one food worker was identified as infecting up to 230 customers
- Costs of an outbreak to restaurant may be substantial considering lawsuits and negative publicity ⁸
- Several jurisdictions have implemented or have considered implementing mandatory food worker vaccination ⁷
- Cost-effectiveness studies have largely supported the benefits of mandatory food workers vaccination ¹¹, while others have not ⁸



Note: If a case report was submitted with >1 risk factor, the case was attributed to the most common risk factor.

Figure 4: Reported Risk Factors for Hepatitis A ⁹

METHODS

Epidemiological Investigation

- November 29, 2011: Received report of 20-year old female with positive IgM Hepatitis A laboratory test results
- Client hospitalized on November 28th following visits to an area clinic on both November 26th and November 28th
- Symptom onset November 22nd and included body aches, diarrhea, vomiting, hot/cold flashes, and fatigue
- Confirmatory Hepatitis A laboratory serology performed at Wisconsin State Laboratory of Hygiene was also positive
- Worked as bartender and food server at a local restaurant (Restaurant A) while symptomatic

Environmental Health Investigation

- During the ten days prior to symptom onset, when she may have been communicable, the client worked five days at Restaurant A
- Client identified as food handler (primarily as a bartender with food service duties) and had considerable potential for illness transmission
- Manager described client as "conscientious" with her personal hygiene at workplace
- Two other food establishments inspected due to close contact and potential spread due to their food service positions
 - Mother (non-household contact with significant exposure) worked at local retail deli (Retail Food Store A)
 - Friend (non-household contact with significant exposure) worked at another local restaurant (Restaurant B)

Consultation with Wisconsin Division of Public Health

- Risk of spread to the public considered significant if client met three criteria:
 - Worked while symptomatic = YES
 - Worked with food = YES
 - Worked with diarrhea = YES
- Recommended testing and vaccination of food workers who handled food
 - Vaccination provided to food workers 49 years and under
 - Immune Globulin provided to food workers 50 years and older
- Recommended testing and vaccination of close contacts who were also food workers
- Vaccine and Immune Globulin provided by Wisconsin Division of Public Health, Immunization Program
- Serological testing will be fee exempt at Wisconsin State Laboratory of Hygiene (WSLH) per Basic Agreement with Wisconsin local health departments
- Prophylaxis to the general public pending documented disease transmission or laboratory-confirmed illness(es) at Restaurant A

Consultation with Restaurant A and Corporate Regional Consultant

- Coordinated all public health messages and all on-going situational updates to food workers
- Identified employees with significant food handling responsibilities (all employees except busboys and dishwashers)
 - 98 total employees identified with potential for transmission to customers
 - Immunization history of identified employees assessed using Wisconsin Immunization Registry (WIR)
 - Six employees with documented evidence of at least one Hepatitis A containing vaccine did not require further testing or vaccination

Testing and Vaccination Clinic

- Utilized modified Point of Dispensing model previously used for 2009 Novel Influenza H1N1 pandemic
- Clinic scheduled over two-day period (Friday afternoon and Saturday morning)
 - Clinic attendance mandatory prior to next work shift
 - Those unable to attend clinic had blood drawn at laboratory clinical draw site followed by vaccination at the Health Department
- Venipuncture and sample preparation obtained locally through contracted laboratory
- Samples sent to Wisconsin State Laboratory of Hygiene for testing; rapid turnaround expected (within 1-2 days of receipt)

RESULTS

A total of 98 food workers from Restaurant A were identified as having direct contact with the index case. Six food workers had documented evidence of Hepatitis A vaccination according to the Wisconsin Immunization Registry and therefore did not need to undergo any laboratory testing or vaccination. All other food workers (92) were required to attend the Hepatitis A testing and vaccination clinic prior to their next work shift. Eighty-seven (95%) of staff attended one of the two clinic dates; those who couldn't attend visited a laboratory clinical blood draw site followed by vaccination at the Health Department, both in close proximity to one another.

Per Wisconsin Division of Public Health policy, food workers were provided either Hepatitis A vaccine or Immune Globulin (IG), depending on their age. Food workers under 50 years-old received a single dose of Hepatitis A vaccine (Havrix, GSK); those over 50 years-old received IG (Immune Globulin, Talecris) with education about the benefits to Hepatitis A vaccination in the future. The Wisconsin Department of Health Services, Immunization Program, provided the Hepatitis A vaccine and the IG as part of the overall outbreak control.

Four food workers received IG and the remaining eighty-eight food workers were vaccinated with Hepatitis A vaccine through the Health Department clinic. Additionally, the 92 food workers had venous blood drawn by a local contracted laboratory to test for Hepatitis A antibodies. The contracted phlebotomist collected the blood on-site at the Health Department clinic, transported the samples to the central laboratory for processing, and the samples were sent via courier to the Wisconsin State Laboratory of Hygiene for fee-exempt testing due to the potential outbreak.

Hepatitis A IgM Antibody test results were negative for all 92 food workers, indicating that no workers had evidence of current infection. Twenty (22%) samples tested positive for Hepatitis A Total Antibody, an indication that the individual was either immune to Hepatitis A following a previous infection and/or vaccination. All laboratory results were disseminated directly to each food worker in a sealed envelope; non-confidential results were shared with Restaurant A management and the corporate regional consultant.

The Health Department epidemiological and environmental health investigation was conducted over a two-week period and required an estimated 135 hours. The cost to investigate this potential outbreak and control the spread through the Hepatitis A testing and vaccination clinic included over \$5,630 in staff time alone; the costs related to phlebotomy and specimen preparation were roughly \$4,100 (see Table 1). Due to an existing arrangement between the Wisconsin State Laboratory of Hygiene and local health departments in Wisconsin, Hepatitis A serodiagnostic laboratory testing was provided fee exempt, with the value of this in-kind contribution equaling \$3,680.

Table 1: Costs Associated with Investigation and Control of Hepatitis Case in Food Worker, Greenfield, WI. November-December, 2011.

Expense	Cost
Staff Time (Hourly Wage & Fringe)	\$ 5,364.61
Phlebotomy & Specimen Preparation	\$ 4,136.81
	<i>subtotal</i> \$ 9,501.42
Hepatitis A serodiagnostic laboratory testing*	\$ 3,680.00
	Total \$ 13,181.42

* In-kind contribution due to fee-exempt agreement between Wisconsin State Laboratory of Hygiene & Wisconsin Local Health Departments.

DISCUSSION

This outbreak effectively utilized the Point of Dispensing (POD) model for the Hepatitis A testing and vaccination clinic. The model was embraced during Novel Influenza H1N1 response, and the model was easily adapted to include both blood draw and Hepatitis A vaccination or administration of IG to contain this potential outbreak. This need for clinic continued to emphasize the importance of point of dispensing planning and exercising within the department, as well as the complementary, dual-use nature of public health preparedness and communicable disease outbreak investigation.

The system for tracking costs associated with this outbreak was handled as typically done within the department. Staff were encouraged to track their time early in the outbreak investigation to reduce the impact of recall bias. The two largest costs associated with containing this potential outbreak included total staff time (including hourly wages and fringe benefits) and phlebotomy and specimen preparation; the costs were computed to be approximately \$5,365 and \$4,137, respectively, for a total cost of roughly \$9,501. The cost of outbreak containment increases by \$3,680 to a overall total of \$13,181 when including the value of in-kind laboratory testing for Hepatitis A (provided by the Wisconsin State Laboratory of Hygiene through a prior fee-exempt arrangement with local health departments), or the equivalent of \$143 per food worker tested and vaccinated. The cost analysis does not include the cost of Hepatitis A vaccine or IG provided by the Wisconsin Division of Public Health, Immunization Program.

The cost associated with this potential outbreak is very high compared to the costs of a hypothetical pre-exposure Hepatitis A vaccination effort. Ironically, the Health Department conducted an outreach to local restaurants and retail food establishments in 2010 offering Hepatitis A vaccine to food workers at a reduced cost. The vaccine cost was covered by the American Recovery and Reinvestment Act (ARRA), leaving food workers responsible for only the administration cost (\$10); very few food workers took advantage of this opportunity despite the marked savings. By comparison, the usual cost of Hepatitis A vaccine through the Health Department is \$30 per dose.

Table 2: Comparison of Costs for Two Hypothetical Models of Pre-Exposure Hepatitis A Vaccination with Actual Total Costs to Investigate and Control Hepatitis Case in Food Worker, Greenfield, WI. November-December 2011.

Option	Number	Cost	Total	Compared to Outbreak Costs
ARRA-funded Hep A Vaccination	92	\$ 10.00	\$ 920.00	7.0%
Health Department Hep A Vaccination	92	\$ 30.00	\$ 2,760.00	20.9%

Compared to the two options for hypothetical pre-exposure Hepatitis A vaccination scenarios, and considering the parameters used, the cost to contain this potential outbreak was 5- to 14-fold higher. In 2010, the ARRA scenario would have vaccinated the 92 food workers for \$10 per dose at a total cost of \$920. In 2011, without the ARRA-funded vaccine, the Health Department privately purchased Hepatitis A vaccine for adults within the community; the cost for vaccinating 92 food workers at \$30 per dose would equal \$2,760 (see Table 2).

Based on this research it may be sensible to encourage pre-exposure hepatitis vaccination of food workers, a practice implemented in several health jurisdictions nationally. While the endemic rate of Hepatitis A in Greenfield, Wisconsin, may not support a large pre-exposure vaccination effort, some areas of the country with high disease rates may choose to do so.

Future outbreaks will be positively impacted by increasing rates of Hepatitis A vaccination in the community. Despite the universal call for Hepatitis A vaccination in all children in 2006, adult vaccination rates remain low. Among adults 19-49 years old, a 2007 national survey indicated that only 12% had received two doses of Hepatitis A vaccine ¹², while in 2010 the survey data indicated that 11% had received two doses of vaccine ¹³. The adult survey data is consistent with the findings of this research since 7% of the food workers had evidence of at least one vaccination. High vaccination rates among Wisconsin children 19-35 months based on 2011 National Immunization Survey data indicate that 77% have received one dose of Hepatitis A vaccine and 49% have received both doses ¹⁴; this data would indicate that the necessity of pre-exposure vaccination against Hepatitis A will not be needed forever, but may achieve significant herd immunity within a few decades.

The research described herein is not without limitations. The primary limitation is that this research centers on a small suburban health department (approximately 37,000 residents served by 6.7 full-time equivalent staff in 2011). It is quite possible the cost structure of the Greenfield Health Department is dissimilar to other local public health agencies in the country which either over- or under-estimates the true costs of outbreak investigation and control thereby altering the cost-benefit of pre-exposure Hepatitis A vaccination of food workers.

Despite the limitations in scope, this research indicated a significant cost associated with the containment of this outbreak. Specifically, the total costs required to contain the potential outbreak were nearly five times the cost of vaccinating restaurant food workers before the outbreak occurred. While restaurant and retail food stores may not directly realize the benefits of such vaccination, tailored messages about business impact – both direct and indirect – and including mention about lost work time may be enough to impact their decisions. Ideally, the cost of the vaccination should be borne by the business and not the food worker. All health departments may consider outreach to food workers for pre-exposure vaccination, but especially those departments serving jurisdictions with high Hepatitis A incidence. Ultimately, increasing vaccination of children will address this limitation but will likely have a direct impact for decades.

ACKNOWLEDGEMENTS

I humbly thank all Greenfield Health Department staff. Each staff member played an important role in the investigation and control of this potential outbreak; they are owed a great deal of thanks for making all aspects of the investigation and control of this potential outbreak seemingly effortless. Additional credit should be given to the management of Restaurant A and the corporate regional consultant; their concerns were well aligned with those of the Health Department and their efforts to communicate and coordinate with staff made our job immensely easier.

I am indebted to Kelsey Blumer, Public Health Intern (Summer 2012), for her patience and diligence in assembling the early drafts of this poster. A big thank you also goes to Lisa Forsch, Public Health Specialist and MPH student, for her assistance with editing and formatting the final version of this poster.

REFERENCES

- Hepatitis A blog. Surveillance and analysis on hepatitis news and outbreaks. Seattle, WA: MarlerClark. Available at www.hepatitisblog.com. Accessed on October 12, 2012.
- American Public Health Association. Hepatitis, Viral. In: Heymann DL, ed. Control of Communicable Diseases Manual, 19th ed. Washington, DC: American Public Health Association; 2008. 278-84.
- Committee on Infectious Diseases. Hepatitis A Vaccine Recommendations. *Pediatrics* 2007;120:189-99. Available at www.pediatrics.aappublications.org. Accessed August 6, 2012.
- CDC. Summary of Notifiable Diseases – United States, 2010. *MMWR* 2012; 59: 66. Available at <http://www.cdc.gov/mmwr/pdf/wk/mm5953.pdf>. Accessed October 10, 2012.
- American Academy of Pediatrics. Hepatitis A. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009: 329-37.
- Rein DB et al. Cost-Effectiveness of Routine Childhood Vaccination for Hepatitis A in the United States. *Pediatrics* 2007;119:e12-21. Available at www.pediatrics.aappublications.org. Accessed August 6, 2012.
- Jacobs RJ et al. Cost-effectiveness of vaccinating food service workers against Hepatitis A infection. *J Food Prot* 2000; 63: 768-74.
- Meltzer MI et al. The economics of vaccinating restaurant workers against Hepatitis A. *Vaccine* 2001; 19: 2138-45.
- University of Washington. Hepatitis web study. Seattle, WA: University of Washington. Available at <http://depts.washington.edu/hepstudy/hepA/clindx/acute/discussion.html>. Accessed on October 11, 2012.
- Dalton CB et al. The cost of a food-borne outbreak of Hepatitis A in Denver, Colo. *Arch Int Med* 1996; 156: 1013-6.
- Anonychuk AM et al. Cost-effectiveness analyses of Hepatitis A vaccine. A systematic review to explore the effect of methodological quality on the economic attractiveness of vaccination strategies. *Pharmacoeconomics* 2008; 26 (1): 17-32.
- CDC. Adult vaccination coverage reported via National Health Interview Survey (NHIS). Atlanta, GA: US Department of Health and Human Services, CDC; 2008. Available at <http://www.cdc.gov/vaccines/stats-sur/nhis/default.htm>. Accessed October 10, 2012.
- CDC. Adult vaccination coverage reported via National Health Interview Survey (NHIS). Atlanta, GA: US Department of Health and Human Services, CDC; 2011. Available at <http://www.cdc.gov/vaccines/stats-sur/nhis/default.htm>. Accessed October 10, 2012.
- CDC. National, state, and local area vaccination coverage among children aged 19-35 months – United States, 2011. *MMWR* 61(35): 689-696.