Models of Community-Based Hepatitis B Surface Antigen Screening Programs in the U.S. and Their Estimated Outcomes and Costs

David B. Rein, PhD[a]
Sarah B. Lesesne, BS[a]
Bryce D. Smith, PhD[b]
Cindy M. Weinbaum, MD, MPH[b]

ABSTRACT

Objectives. Information on the process and method of service delivery is sparse for hepatitis B surface antigen (HBsAg) testing, and no systematic study has evaluated the relative effectiveness or cost-effectiveness of different HBsAg screening models. To address this need, we compared five specific community-based screening programs.

Methods. We funded five HBsAg screening programs to collect information on their design, costs, and outcomes of participants during a six-month observation period. We categorized programs into four types of models. For each model, we calculated the number screened, the number screened as per Centers for Disease Control and Prevention (CDC) recommendations, and the cost per screening.

Results. The models varied by cost per person screened and total number of people screened, but they did not differ meaningfully in the proportion of people screened following CDC recommendations, the proportion of those screened who tested positive, or the proportion of those who newly tested positive.

Conclusions. Integrating screening into outpatient service settings is the most cost-effective method but may not reach all people needing to be screened. Future research should examine cost-effective methods that expand the reach of screening into communities in outpatient settings.

[a]RTI International, Atlanta, GA

[b]Centers for Disease Control and Prevention, Division of Viral Hepatitis, Atlanta, GA

Address correspondence to: David B. Rein, PhD, RTI International, 2951 Flowers Rd., Ste. 119, Atlanta, GA 30341; tel. 404-234-5035; fax 404-234-5030; e-mail <drein@rti.org>.

Between 800,000 and 1.4 million people in the United States are chronically infected with the hepatitis B virus (HBV),[1] leading to approximately 2,000–4,000 annual deaths from HBV-related chronic liver disease.[2] Chronic hepatitis B viral infections can result in decompensated cirrhosis or hepatocellular carcinoma (HCC). If detected early, chronic hepatitis B can be treated with antiviral therapy, leading to successful viral suppression among up to 70% of those who initiate therapy, as well as vaccination of household contacts.[3]

Chronic hepatitis B surface antigen (HBsAg) prevalence is approximately 8.9% among foreign-born Asian American, Native Hawaiian, and other Pacific Islanders (AA/NHOPIs) in the U.S. and 1.4% among U.S.-born AA/NHOPIs.[4] However, one-third or more of AA/NHOPIs remain unaware of their infection. The Centers for Disease Control and Prevention (CDC) currently recommends hepatitis B screening for all U.S. residents born in countries with ≥2% prevalence of HBsAg.[1] Despite CDC's recommendations and the consequences of HBV infection, no federally funded program exists to screen immigrants for HBsAg.

At least two studies describe the outcomes of the screening initiatives, but information on the process and method of service delivery is comparatively sparse.[5,6] To provide such information, a previous study identified, documented, and surveyed community screening programs to understand what services they provided and to gather demographic information on the populations they screened.[7] In this study, we present data from a pilot effort to describe five specific community-based screening programs that were given financial support to provide screening data and programmatic information for analysis. The results of this analysis can be used to inform additional research on screening activities and suggest options for expanding research on screening for hepatitis B in the future.

METHODS

Data collection

We awarded small grants to five community-based organizations that planned to conduct screening to collect demographic data, test results, and follow-up data during screening events between July 2008 and January 2009. We provided a data collection tool developed using CSPro® 4.0.[8] We trained each organization to enter participant-level data and to submit data in de-identified form. The project was approved by the Institutional Review Boards at RTI International and each participating program.

Program staff collected participant information on age, gender, country of birth, insurance status, source of primary health care, number and type of household contacts, HBsAg screening history, knowledge of current infection status, serologic test results (HBsAg), whether results were delivered, and whether HBsAg-seropositive participants intended to seek care.

Screening structure and costs

We conducted site visits at three programs and interviewed two others by telephone to understand each program's screening activities and costs. We asked program staff to describe the activities involved in planning, promoting, setting up, implementing, and following up on screening. We asked program administrators to describe the mix of personnel (i.e., program employees, contracted organizations, and volunteer labor) who performed each activity and the hours required to perform it. Program administrators reported the time and staff needed to complete each activity, the supplies used for screening, and the facilities used for screening and administration. Each program processed tests locally using a Clinical Laboratory Improvement Amendments certified laboratory with reported costs per test (including blood draw, kit, and processing) ranging from $14 to $38.

We calculated labor time per person screened by dividing total time required by each activity by the number of participants screened or by asking clinic staff to directly report the amount of time spent screening each person. We estimated labor costs by multiplying staff time per person screened by the expected hourly wage for an employee in that labor category as reported by the Bureau of Labor Statistics wages for each program's metropolitan area.[9] We calculated total cost per person screened by summing all component costs.

Data analysis

We analyzed how programs used paid staff, community outreach, contracts, and partnerships to accomplish each component of screening and used this information to create four categories to describe our data. Using SAS® version 9.1.3,[10] we calculated the HBsAg prevalence by screening program type and country of birth. Among those testing positive, we calculated the proportion who intended to seek care, who would like care but could not afford treatment, and who did not intend to seek care.

Using the total costs and total number of participants screened, we calculated several cost-per-outcome measures for each model. We calculated the cost per complete screen, the cost per positive result, and the cost per newly identified HBsAg-positive person by dividing total costs by the number of participants in each of these categories. We defined a complete screen

as one in which a patient was tested for HBsAg on the day of screening and received test results by mail, by telephone, or in person. We adjusted these results to account for differences in prevalence across the sites and tested whether this adjustment made any difference in our interpretation.

RESULTS

Model characteristics

We identified three unique screening models across the five sites: one Community Clinic Model (CCM), one Community Outreach Model (COM), and one Partnership and Contract Model (PCM). The remaining two programs used elements of COM and PCM and were categorized as the Outreach and Partnership Model (OPM).

In the CCM, screening was integrated into the clinic's routine primary care services with indications for screening determined by the patient's risk for chronic hepatitis B infection. The clinic we observed created standing orders instructing physicians to screen all of their patients born in Bangladesh, Cambodia, the Philippines, Thailand, and Vietnam for HBsAg at the time of their next regularly scheduled visit. As part of the visit, physicians performed pretest education and counseling and sent patients to the in-facility laboratory for phlebotomy. HBsAg serologic testing was performed by a laboratory, with follow-up communication and referral activities performed by clinic staff.

In the COM, screening was performed in community, nonclinical settings by a not-for-profit organization, a university-based dedicated project director, a few staff, and volunteers. This organization targeted Asian immigrants by screening at Asian-oriented health fairs and community centers, but still tested anyone who requested screening. In the planning and recruitment stages, the director identified venues, hired a laboratory to provide phlebotomists and testing, allocated staff, and recruited volunteers to promote the screening event. Program staff and volunteers coordinated participant transportation, reviewed educational materials, and helped participants complete forms. Following screening, the COM staff received results from the laboratory, sent results to participants, and referred HBsAg-positive patients for medical evaluation.

The PCM contracted with for-profit general health screening companies to include HBsAg screening alongside other health screenings at Asian-oriented employee wellness campaigns or large trade events and conventions. The PCM also used subcontracts to community programs similar to but not including the COM we observed. The subcontracted programs performed screening at Asian-oriented community events and reported data back to the PCM manager. The PCM was responsible for identifying events at which to hold screenings, securing funding (primarily from charitable pharmaceutical corporation donations), and establishing contractual relationships. Planning, screening, follow-up, and referral activities were performed by subcontracted programs.

The OPM mixed the direct involvement aspect of the COM with the partnership and contract services element of the PCM. While these programs conducted screenings in settings similar to the COM, the planning and setup activities were completed by partnering with a separate community organization that had direct links to targeted community. The OPM hired phlebotomists and laboratory services to draw blood and process results and organized screening paperwork and materials. The OPM paid a partnering community organization to promote, plan, and set up the location of the screening. Their recruiting and screening locations included Asian-oriented community organization sites, civil associations, and churches. The OPM received completed test results and sent notification and referral letters to participants. Further follow-up with participants was completed by the partner organizations.

The models used different combinations of staff, volunteers, and contracted workers to perform the component tasks for each phase of screening, planning, implementation, and follow-up. The CCM did not require planning, promotion, or setup activities and used clinic staff for almost all component tasks except those involving laboratory services. Similarly, the COM used a combination of organization staff to perform all activities except for blood draws and laboratory processing. The PCM set up the contracts and partnerships, but the activities involved with screening were completed solely by contracted organizations. Finally, the OPM organized the clinical elements of screening but contracted with community groups to promote and implement the screening events.

Participant characteristics

As shown in Table 1, the five programs screened 1,623 participants during the period observed, the majority (94.7%) of whom were foreign-born, with 31.6% from South Korea, 21.6% from Vietnam, and 16.3% from China. More than half of the participants screened did not have insurance (54.2%) or a regular doctor (55.6%), and only 13.2% reported previously being tested for hepatitis B.

HBsAg prevalence rates varied according to participant country of birth. The prevalence was 1.7% among U.S.-born participants compared with 6.3%

among foreign-born participants from countries with an HBV prevalence of ≥2%. Participants from China, Cambodia, Taiwan, and Vietnam had the highest prevalence rates (range: 7.4%–9.9%). We found no positive cases among the foreign-born participants who reported being born in a country with <2.0% prevalence. HBsAg prevalence ranged from 5.6% to 6.6% across the programs. Newly identified HBV prevalence was 4.9% in the CCM, 4.1% in the COM, 3.2% in the OPM, and 4.5% in the PCM (Table 1). Newly identified people comprised 55.2% to 73.9% of the HBsAg-positive participants screened by each program (data not shown).

A total of 291 participants reported prior to

Table 1. Characteristics of people screened for HBsAG by five observed hepatitis B screening organizations: U.S., July 2008 to January 2009

	Screened for HBsAg		*Prevalence*	
Parameter	N	*Percent (95% CI)*	*HBV Percent (95% CI)*	*Newly identified HBV Percent (95% CI)*
Total	1,623			
Country of origin				
U.S.	59	3.6 (2.8, 4.6)	1.7 (0.2, 11.1)	1.7 (0.2, 11.1)
Foreign-born in country with				
HBV prevalence ≥2%	1,514	93.3 (92.0, 94.4)	6.3 (5.2, 7.6)	4.3 (3.4, 5.5)
Cambodia	76	4.7 (3.8, 5.8)	7.9 (3.6, 16.5)	5.4 (2.1, 13.4)
China	264	16.3 (14.6, 18.2)	9.9 (6.8, 14.1)	7.1 (4.6, 10.9)
India	28	1.7 (1.2, 2.5)	NA	NA
Indonesia	50	3.1 (2.4, 4.1)	4.0 (1.0, 14.6)	4.0 (1.0, 14.6)
Philippines	32	2.0 (1.4, 2.8)	3.1 (0.4, 19.1)	3.2 (0.5, 19.1)
South Korea	513	31.6 (29.4, 33.9)	4.9 (3.3, 7.1)	2.8 (1.7, 4.6)
Taiwan	106	6.5 (5.4, 7.8)	7.6 (3.9, 14.4)	4.9 (2.1, 11.1)
Thailand	28	1.7 (1.2, 2.5)	3.6 (0.5, 21.4)	0.0 (NA)
Vietnam	351	21.6 (19.7, 23.7)	7.4 (5.1, 10.7)	5.3 (3.4, 8.2)
All others	66	4.1 (3.2, 5.2)	1.5 (0.2, 10.0)	1.6 (0.2, 10.0)
Foreign-born in country with				
HBV prevalence <2%	22	1.4 (0.9, 2.1)	NA	NA
Missing	28	1.7 (1.2, 2.5)	NA	NA
Insurance				
Yes	696	42.9 (40.5, 45.3)	4.2 (2.9, 6.0)	2.7 (1.7, 4.2)
No	879	54.2 (51.8, 56.6)	7.4 (5.9, 9.3)	5.3 (4.0, 7.0)
Unsure	29	1.8 (1.3, 2.6)	3.5 (0.5, 20.8)	NA
Missing	19	1.2 (0.8, 1.9)	NA	NA
Regular doctor				
Yes	646	39.8 (37.4, 42.2)	4.2 (2.9, 6.1)	2.9 (1.9, 4.5)
No	902	55.6 (53.2, 58.0)	7.2 (5.7, 9.1)	5.0 (3.8, 6.6)
Do not know	36	2.2 (1.6, 3.0)	5.6 (1.4, 19.7)	2.9 (0.4, 17.3)
Missing	39	2.4 (1.8, 3.3)	NA	NA
Previous hepatitis test				
Positive	66	4.1 (3.2, 5.2)	45.5 (34.0, 57.5)	0.0 (NA)
Negative	148	9.1 (7.8, 10.6)	2.7 (1.0, 7.0)	2.7 (1.0, 7.0)
None	1,293	79.7 (77.7, 81.6)	3.6 (2.7, 4.8)	3.6 (2.7, 4.8)
Missing/don't know	116	7.1 (6.0, 8.5)	NA	NA
Models				
Model 1: Community Clinic Model	106	6.5 (5.4, 7.8)	6.6 (3.2, 13.2)	4.9 (2.1, 11.1)
Model 2: Community Outreach Model	233	14.4 (12.8, 16.2)	6.4 (3.9, 10.4)	4.1 (2.2, 7.6)
Model 3: Outreach Partnership Model	519	32.0 (29.8, 34.3)	5.6 (3.9, 7.9)	3.2 (2.0, 5.1)
Model 4: Partnership Contract Model	765	47.1 (44.7, 49.5)	6.0 (4.5, 7.9)	4.5 (3.2, 6.2)

HBsAG = hepatitis B surface antigen

HBV = hepatitis B virus

CI = confidence interval

NA = not applicable

screening that they had previously been tested for HBsAg. Of these, 22.7% self-reported that they were HBsAg positive, 50.9% reported that they were HBsAg negative, and 26.5% reported that they did not know their HBsAg status (77 respondents categorized as missing/don't know did not remember their HBsAg status). Of the 22.7% of participants who self-reported they were positive, 45.5% actually were determined to be positive based on the newly administered screening test. Of those who self-reported that they were negative, 2.7% tested positive; of those who reported that they did not know their status, 7.1% tested positive.

On the day of screening, all participants were asked whether they intended to seek care if they tested positive. Among those screened, 71% intended to seek care, 27% wanted to seek care but did not know if they could afford it, and 2% did not intend to seek care. The intention to seek care varied by setting: of participants testing positive for HBsAg, >85% in the CCM intended to do so, 58% in the COM intended to do so, 71% in the PCM intended to do so, and 72% in the OPM intended to do so. Of those who went on to test negative for HBsAg, 71% had indicated an intention to seek care if they tested positive compared with 58% for those who went on to test positive. When the analysis excluded individuals who were aware of their status prior to screening, the difference between intention to seek care among those who tested negative (71%) and those who tested positive (63%) was smaller. Because of inadequate follow-up data, we were unable to determine whether there were changes in intention to seek care after receipt of test results or whether intention to seek care predicted who sought medical evaluation and treatment.

Cost and outcome measures

The organizations screened varying numbers of participants during the six-month data collection period (Table 2). The CCM program screened the fewest participants (n=106) followed in increasing order by the COM program (n=233), the two OPM programs (n=519: 237 at Site A and 282 at Site B), and the PCM program (n=1,308; 765 observations used in cost analysis). Cost-per-outcome estimates for the PCM program were based on data from 765 participants for whom data were considered reliable. Those participants who would not have been recommended for screening by CDC recommendations but who were screened anyway were primarily participants born in the U.S. or participants who had been screened before and were aware of their HBsAg status.

Screening costs per outcome varied substantially across program models. The CCM had the lowest cost per complete screen ($40) followed by the COM ($102), the OPM ($176, calculated by taking the weighted average costs across the two OPM organizations), and the PCM ($280). The costs per positive person identified varied widely, from $609 in the CCM to $4,657 in the PCM. Adjusting the results for differences in prevalence did not meaningfully alter these results.

DISCUSSION

We observed five different programs that organized screening in three primary ways: clinical protocols, direct community outreach, and not-for-profit and commercial contracts. The structures did not differ meaningfully in the outcomes achieved among those who were screened, as each structure identified a similar proportion of positive patients and newly identified positive patients after adjusting for differences in prevalence rates. The models differed substantially in the number of people screened over the observation period and the cost per person screened. Because we were only able to collect case study data and because we were unable to collect information on the size of the targeted population, additional research will be needed to determine if these differences were caused by the structure of organizing screening services or if they were merely reflective of the programs observed.

When comparing the sites that we observed, integrating hepatitis B screening into clinical care, as practiced by the CCM, was the least costly of the models but also reached the fewest people. The lower costs were attributable to the CCM's lack of programmatic planning or promotional activities. It is unclear whether the low number of participants screened was an inherent characteristic of the passive nature of screening in clinical settings or if it resulted from the attributes of the CCM site. This CCM was located in a densely populated urban neighborhood with a very large AA/NHOPI population, although we do not know how many of those patients used the clinic for care.

In our observations, extending screening outside the clinic and into community settings resulted in increased costs; however, it reached more than twice as many people in the same period. The majority of these extra costs were incurred in planning and organizing the screening event, in securing a space for the event, and in the uncompensated time of volunteers who helped with the event. The hybrid OPM models screened a similar number of participants as the COM but at a higher cost per screening.

The PCM screened more people than the other models but at a substantially higher cost per person

Table 2. Number of people screened, positive cases identified, and costs per screening and case identified observed among four hepatitis B screening models: U.S., July 2008 to January 2009

Program	*Screened for HBsAg* N	*Indicated for screening by CDC guidelines Percent (95% CI)*	*Positive cases* N *(percent)*	*Newly identified positive cases* N *(percent)*	*Cost per complete screen*	*Cost per positive case identified (adjusted for prevalence)*[a]	*Cost per newly identified positive case (adjusted for prevalence)*[a]
Model 1: Community Clinic Model	106	80 (75.5)	7 (6.6)	5 (4.7)	$40	$609 ($639)	$854 ($895)
Model 2: Community Outreach Model	233	171 (73.4)	15 (6.4)	9 (3.9)	$102	$1,584 ($1,619)	$2,641 ($2,698)
Model 3: Outreach Partnership Model	519[b]	361 (69.6)	29 (5.6)	16 (3.1)	$176[c]	$3,150 ($2,794)	$5,709 ($5,063)
Model 4: Partnership Contract Model	765[d]	578 (75.6)	46 (6.0)	34 (4.4)	$280[e]	$4,657 ($4,444)	$6,300 ($6,013)

[a]Assumes the average prevalence for all programs

[b]Combined number screened across the two Outreach Partnership Model (OPM) sites. The individual OPM sites screened 237 at Site A and 282 at Site B.

[c]Uses weighted average of costs from two OPM programs

[d]The Partnership Contract Model screened 1,308 participants during the time period, but accurate and usable data were collected for only 765 participants. Because we estimated costs on a per-screen basis, the lack of inclusion of these data does not affect our cost-per-screen estimates.

[e]Uses the costs involved in the second year

HBsAG = hepatitis B surface antigen

CDC = Centers for Disease Control and Prevention

CI = confidence interval

than the other programs. These additional costs resulted from the development of a data system to track information, the convening of a medical advisory board to establish guidelines for contracted screening activities, and the higher costs charged by commercial testers as compared with the costs incurred by the not-for-profit COM.

We observed no HBsAg-positive cases among participants born in a country not indicated for screening except among those who reported being HBsAg positive prior to screening. Our research confirmed that screening should not be recommended for this group, although declining to screen these individuals may prove difficult to implement in screening settings. In contrast, our findings suggest that screening should be recommended for patients who report having been screened in the past regardless of their self-reported HBsAg status. Among participants who reported being tested before, 2.7% of those who reported being negative and 7.1% of those who reported not knowing their HBsAg status subsequently tested positive for HBsAg. Among those who self-reported being HBsAg positive prior to screening, only 45.5% subsequently tested positive.

We estimated the HBsAg prevalence rates of U.S. residents born in nine Asian countries with rates ranging from a low of 0.0% among those born in India to a high of 9.9% among residents born in China. These values are instructive and to some degree in line with the confidence intervals of other recent estimates, though in most cases the estimates we observed were higher.[7,11,12] Rates are likely higher than actual prevalence rates because people who suspect they are infected are likely more willing to participate in voluntary screening.

Limitations

This study had several limitations. Because it was an exploratory pilot study, the data are descriptive in nature and reflective only of the programs we observed. As such, they are not generalizable to other programs. If this research generates interest, future studies should undertake a more scientifically rigorous observation of multiple implementations of each of the three primary categories of screening and evaluate the reach, costs, and quality across each group. The prevalence rates observed were calculated from a convenience sample of participants in hepatitis B screening programs. Furthermore, our results reflect only the current time period. In future decades, the benefits of global vaccination against HBV infection will likely result in lower prevalence rates of HBsAg observed among future foreign-born populations in the U.S.

CONCLUSIONS

In our observations, integrating screening into clinical services was the least costly means of screening in terms of the costs per person screened, but it also reached the fewest people. Increasing the number of people screened by bringing screening out of the medical setting and into the community increased costs but also increased the number of people who could be rapidly screened. Expanding community-based screening to include multiple groups further increased the costs per screening because of additional management costs.

Future studies should test whether our case study findings apply to a broader group of screening operations. If so, efforts could be made to combine the low costs achieved by clinical integration of screening services with the greater reach of community outreach screening events. Concurrent research may wish to examine which populations are likely to be reached during a reasonable period of time through clinical integration approaches and which populations warrant the additional costs of community outreach.

The authors thank Laura Danielle Wagner, MPH, for help with revising the manuscript, and Susan Murchie for editing support.

This study was funded by the Centers for Disease Control and Prevention's (CDC's) Division of Viral Hepatitis (DVH) under Public Health Service contract #200-2009-F-30515. The views expressed in this article are those of the authors and do not necessarily represent the official positions of CDC and the DVH.

REFERENCES

1. Weinbaum CM, Mast EE, Ward JW. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. Hepatology 2009;49(5 Suppl):S35-44.
2. Vogt T, Wise ME, Shih H, Williams IT. Hepatitis B mortality in the United States, 1990–2004. Abstract presented at the 45th Annual Meeting of the Infectious Diseases Society of America; 2007 Oct 4–7; San Diego.
3. Khokhar A, Afdhal NH. Therapeutic strategies for chronic hepatitis B virus infection in 2008. Am J Med 2008;121(12 Suppl):S33-44.
4. Cohen C, Evans AA, London WT, Block J, Conti M, Block T. Underestimation of chronic hepatitis B virus infection in the United States of America. J Viral Hepat 2008;15:12-3.
5. Lin SY, Chang ET, So SK. Why we should routinely screen Asian American adults for hepatitis B: a cross-sectional study of Asians in California. Hepatology 2007;46:1034-40.
6. Screening for chronic hepatitis B among Asian/Pacific Islander populations—New York City, 2005. MMWR Morb Mortal Wkly Rep 2006;55(18):505-9.
7. Rein DB, Lesesne SB, Leese PJ, Weinbaum CM. Community-based hepatitis B screening programs in the United States in 2008. J Viral Hepat 2010;17:28-33.
8. Census Bureau (US). Census and Survey Processing System (CSPro®) 4.0.004. 2010 [cited 2011 Feb 14]. Available from: URL: http://www.census.gov/ipc/www/cspro/doc.html
9. Bureau of Labor Statistics (US). May 2007 metropolitan and nonmetropolitan area occupational employment and wage estimates [cited 2011 Feb 14]. Available from: URL: http://www.bls.gov/oes/2007/may/oessrcma.htm
10. SAS Institute, Inc. SAS®: Version 9.1.3 for Windows. Cary (NC): SAS Institute, Inc.; 2008.

11. Chang ET, Sue E, Zola J, So SK. 3 For Life: a model pilot program to prevent hepatitis B virus infection and liver cancer in Asian and Pacific Islander Americans. Am J Health Promot 2009;23:176-81.

12. Rein DB, Lesesne SB, O'Fallon A, Weinbaum CM. Prevalence of hepatitis B surface antigen among refugees entering the United States between 2006 and 2008. Hepatology 2010;51:431-4.