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ORIGINAL PAPER

Hepatitis B Evaluation and Linkage to Care for Newly Arrived Refugees: A Multisite Quality Improvement Initiative

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Abstract

A quality improvement collaborative evaluated Hepatitis B virus (HBV) care for resettled refugees and identified strategies to enhance care. 682 of the 12,934 refugees from five refugee health clinics in Colorado, Minnesota, and Pennsylvania had chronic HBV. Timely care was defined relative to a HBsAg + result: staging (HBV DNA, hepatitis Be antigen, hepatitis Be antibody, alanine transaminase testing) within 14 days, comorbid infection screening (hepatitis C virus and HIV) within 14 days, and linkage to care (HBV specialist referral within 30 days and visit within 6 months). Completed labs included: HBV DNA (93%), hepatitis Be antigen (94%), hepatitis Be antibody (92%), alanine transaminase (92%), hepatitis C screening (86%), HIV screening (97%). 20% had HBV specialist referrals within 30 days; 36% were seen within 6 months. Standardized reflex HBV testing and specialist referral should be prioritized at the initial screening due to the association with timely care.

Keywords Hepatitis B · Refugees · Linkage to care

Introduction

Problem Description

Hepatitis B virus (HBV) infection is a leading cause of cirrhosis and hepatocellular carcinoma [1]. Worldwide, approximately 2 billion people are infected with or have a history of HBV infection [2]. Of these, 240 million suffer from chronic HBV infection [2]. Approximately 45% of the world's population live in areas in which ≥ 8% of the local population has chronic HBV infection (high HBV endemicity), and 43% live in areas of intermediate HBV endemicity (2–7% chronic HBV infection prevalence) [3]. Most refugees who resettle to the United States are from regions with intermediate to high HBV endemicity [4–6]. Therefore, screening refugees for HBV is a priority. Furthermore, HBV screening of refugees is cost-effective [7].

Available Knowledge

HBV screening rates for newly arrived refugees are generally high. Previous evaluations have found that HBV screening of newly arrived refugees has been over 90% in adults [8–11]. Ongoing care is necessary for all patients with chronic HBV infection to mitigate associated morbidity and mortality.

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Initial evaluation for patients with chronic HBV infection includes disease staging and screening for comorbid infections, hepatocellular carcinoma (HCC), and hepatitis A virus (HAV) immunity. Disease staging includes comprehensive expanded laboratory testing for hepatitis Be antigen (HBeAg), hepatitis Be antibody (anti-HBe), HBV DNA, and alanine transaminase (ALT), which provides information regarding the potential need for treatment [12]. Initial evaluation should also include screening for comorbid infections, such as hepatitis C virus (HCV) and human immunodeficiency virus (HIV), because of the increased risk of infection due to the shared modes of transmission. Furthermore, coinfections could lead to serious medical conditions, and treatments for one virus may affect the other virus [12–15]. HCC screening with ultrasound (US) is recommended every 6 months for high risk individuals [12, 16, 17]. HAV immunity should be evaluated, and the hepatitis A immunization should be given if not immune [12]. Linkage to care for chronic HBV infection and comprehensive evaluation should include referral to an HBV specialist (gastroenterology or infectious disease specialist). Despite high HBV screening rates for newly arrived refugees to the United States, less is known about follow-up care after identification of HBV infection.

Rationale

The United States Centers for Disease Control and Prevention (CDC) recommends that all newly arrived refugees receive a domestic medical examination (DME) to introduce them to the United States health care system and to evaluate their health post-arrival [18]. The DME is widely conducted with high screening rates for HBV (96%) because the DME is recommended by the CDC and resettlement agencies are requested to complete the DME within 30 days of resettlement [19]. CDC provides guidelines for the DME to assist state public health departments and medical professionals/clinicians in determining the best tests to perform based on evidence. HBV screening, vaccination, and appropriate linkage to care are recommended in CDC's guidelines as part of the DME because they allow for implementation of interventions to reduce morbidity and mortality associated with chronic HBV infection. The procedures for implementing the CDC's guidelines for examination can be modified at state and local levels.

Specific Aim

Five refugee screening clinics established a multi-site quality improvement (QI) collaborative to evaluate HBV care and identify strategies to enhance linkage to care for resettled refugees with chronic HBV.

Methods

Context

DME were conducted in four primary care clinics (sites 1–4) and one public health department clinic (site 5). Sites 1–4 are primary care clinics that perform initial DME and serve as medical homes to provide ongoing care. Site 5 followed the public health department directed screening model used in multiple states. In this model, the public health department performed screening and then referred refugees for ongoing primary care at medical homes outside of the public health department system. Varying screening recommendations, based on CDC and the United States Office of Refugee Resettlement guidelines, were in place at state levels during the evaluation period.

The patient population included newly arrived refugees who underwent DME at one of the sites during 2006–2016. Patients included children and adults from all sites except site 3, a pediatric site that included only children. For site 5, children under 18 were screened according to risk factors including close contact with a case or prior residence in an intermediate to high prevalence country.

Interventions

Five geographically dispersed clinics with expertise in performing refugee DMEs formed a collaborative QI working group in 2015. The goal was to improve care for refugees diagnosed with chronic HBV infection by examining existing practices, reviewing baseline data, and sharing lessons learned for ongoing improvement of care. The QI working group members included primary care and public health professionals with expertise in refugee health in Colorado, Minnesota, and Pennsylvania; they talked by phone twice per month to discuss data systems and clinic workflows at different sites.

The QI process started by conducting a retrospective review of HBV screening and chronic HBV care among resettled refugees at the five sites. The process used the health system Model for Improvement, focusing on the three fundamental questions that lay the groundwork for "Plan-Do-Study-Act" (PDSA) cycles: "What are we trying to accomplish?" "How will we know the change is an improvement?" and "What change can we make that will result in improvement?" [20]. Participating sites began the process by sharing site-specific protocols for HBV screening and care and then collaboratively discussed how to standardize data and measurements such as the timing of HBV staging. After establishing metrics, sites collaboratively reviewed baseline data to identify strategies for

change. Each site individually developed and managed its own hepatitis B registries. The datasets generated during these quality improvement efforts are not publicly available to prevent deductive identification given the low prevalence of chronic Hepatitis B Virus within certain sub-groups.

Study of the Intervention

Each site retrospectively conducted chart reviews and collected data from the DME that were completed during the following years: 2008–2016 (site 1), 2007–2016 (site 2), 2013–2016 (site 3), 2014–2016 (site 4), and 2006–2012 (site 5) (Table 1). Each site was retrospectively able to go back to different time points for data collection based on available data. When possible, data collection was standardized across sites.

Site 1 (2008–2016): site 1 performed reflex hepatitis B testing after a positive HBsAg result. A reflex test is an automatic laboratory test performed from the same specimen after an initially ordered and resulted test. HBV reflex testing included HBeAg, anti-HBe, and HBV DNA. Site 1 also routinely collected ALT, HCV, HIV, and HAV antibody screening for all refugee patients ≥ 18 years using a standard order set concurrent with HBV screening. A standard order set is a group of lab orders that standardizes and automates orders based on evidence-based practice. Chronic HBV infection was commonly managed by primary care providers at site 1 without referral to an HBV specialist if the HBV DNA level remained low and ALT within normal range during routine monitoring.

Site 2 (2007–2016): site 2 conducted universal HBV testing using HBsAg. Universal hepatitis A vaccination/confirmation of immunity was performed concurrently. Starting in 2009, universal screening for HIV was also performed concurrently using a standard order set. A reflex HBV panel was not automatically drawn for patients with positive HBsAg. Instead, patients with positive HBsAg were asked to return to the office for HBeAg, anti-HBe, HBV DNA, and ALT per the judgment of their health care provider.

Site 3 (2013–2016): site 3, a pediatric primary care clinic, conducted universal HBV testing using HBsAg, anti-HBs, and anti-HBc. Universal hepatitis A vaccination/confirmation of immunity and screening for HCV and HIV were performed concurrently with HBV screening using a standard order set. A reflex HBV panel was not automatically drawn for patients with positive HBsAg. Instead, patients with positive HBsAg were asked to return to the office for HBeAg, anti-HBe, HBV DNA, ALT, and HCC screening per the judgment of their health care provider and without using a standard order set. Similarly, patients with chronic HBV were referred to HBV specialists within the same health care system (and using a shared electronic health record) per the judgment of their health care provider. Patients referred shortly after arrival in the United States typically received support from resettlement agency staff who assisted with scheduling and attending HBV specialist appointments as part of a local refugee health partnership. The clinic protocol also included a routine follow-up appointment in primary care (typically 1 to 3 months after the initial appointment to review screening laboratory results) for vaccination and care management.

Site 4 (2014–2016): site 4 tested universally for HBV using HBsAg; however, complete HBV serologies were not conducted. Reflex testing for HBV DNA, HBeAg, anti-HBe, ALT, and HAV was adopted from site one's model approximately 6 months into the QI collaborative; reflex testing also included testing for liver function, HCV, and HAV immunity.

Site 5 (2006–2012): site 5 conducted universal HBV screening for resettled refugees ≥ 18 years. With parental permission, children under 18 were screened based on HBV risk (including residence in an intermediate or high prevalence country or identification as a close

Table 1 Profiles and HBV screening and follow-up protocols of five US sites providing care to newly arrived refugees

Site	1	2[c]	3[d]	4	5[e]
Time frame (years)	2008–2016	2007–2016	2013–2016	2014–2016	2006–2012
Universal HBV screening[a]	Yes	Yes	Yes	Yes	No
Reflex HBV panel if positive HBsAg[b]	Yes	No	No	Yes	No
Universal hepatitis C virus and HIV screening	Yes	Yes	Yes	Yes	No
Universal hepatitis A virus vaccination or confirmation of immunity	Yes	Yes	Yes	Yes	No

[a]Hepatitis B virus (HBV) screening involves testing for hepatitis B surface antigen (HBsAg)

[b]Reflex HBV panel automatically sent by laboratory if initial HBsAg positive and includes HBeAg, anti-HBe, and HBV DNA

[c]Site 2: Initiated universal HIV screening in 2009

[d]Site 3: Pediatric site

[e]Site 5: HIV screening universal in individuals 13 years and over

contact with a person with HBV). If HBV screening was performed, HAV vaccination was administered in children ≥ 12 months of age, HIV screening was conducted in children ≥ 13 years, and HCV screening was performed in adults ≥ 18 years. Patients with positive HBsAg were offered HBeAg, anti-HBe, HBV DNA, ALT, and HCC screening; referred to public health for case follow-up; and referred for case management to primary care providers, near the patient's home.

Measures

HBsAg, antibody to HBsAg (anti-HBs), and hepatitis B core antibody (anti-HBc) were collected for all patients, except at sites 4 and 5. The HBV disease status for patients was determined based on serologic test results as follows: HBV infection, immune due to HBV vaccination, immune due to natural infection, isolated core antibody, and susceptible. IgM antibody to hepatitis B core antigen was not routinely obtained, and therefore chronic HBV infection was defined as a positive HBsAg result during DME.

Refugee characteristics evaluated included sex, age (percent less than 18 years old, median age at arrival, and interquartile range in years), and birth country. We determined the percentage of refugee patients with chronic HBV infection with the following laboratory tests or imaging performed within 14 days of a positive HBsAg result: HBV staging (HBV DNA, HBeAg, anti-HBe, and ALT); HCC screening (ultrasound or alpha-fetoprotein); HAV evaluation (hepatitis A virus vaccination or demonstration of immunity against hepatitis A); screening for comorbid infections (HCV and HIV). Linkage to care for chronic HBV infection was defined as patients referred to an HBV specialist (gastroenterology or infectious disease specialist) within 30 days and seen by that specialist within 6 months of a positive HBsAg result. The 14-day, 30-day, and 6-month cutoffs were determined by the QI working group as expected and appropriate timing for chronic HBV care for a migratory population at risk for loss to follow-up because of language, cultural, and healthcare navigation barriers.

Analysis

Research electronic data capture (REDCap) was used at sites 2, 3, 4, and 5 to collect and manage data [21]. Site 1 extracted data from the electronic medical record and analyzed the data using SAS version 9.3 (SAS Institute Inc., USA). Descriptive statistics were performed including frequencies and percentages for categorical variables and median and interquartile range for age using Microsoft Excel.

Ethical Considerations

This project was designated by ethics review committees as non-research at all sites: Denver Health, HealthPartners, Thomas Jefferson University, Children's Hospital of Philadelphia, Colorado Department of Public Health and Environment, and CDC. Denver Health, Children's Hospital of Philadelphia, and Thomas Jefferson University determined the work to be quality improvement.

Results

HBsAg screening results were available for 12,934 newly arrived refugees across the five sites (Table 2); 682 (5%) had a positive HBsAg. The percentage of HBsAg-positive patients ranged from 1 to 6% among sites. Across the five sites, the median age of newly arrived refugees with positive HBsAg was 28, 29, 12, 27, and 31 years respectively (Table 3). The vast majority of refugees diagnosed with chronic HBV infection were > 18 years; there were more HBV-infected males than females.

Follow-up evaluation and linkage to care for newly arrived refugees with a positive HBsAg varied across the sites with available data (Table 4). For these sites, testing within 14 days of HBsAg result was completed as follows: HBV DNA 100%, 55%, 50%, and 100%; HCC screening (ultrasound or alpha-fetoprotein) 44%, 15%, 50%, 100%, and 1% respectively. There was variation between sites related to reflex testing protocols and standard order sets. Sites with reflex HBV laboratory testing (sites 1 and 4) had higher rates of appropriate and timely laboratory panel completions within 14 days of chronic HBV infection identification than other sites. Sites 1 and 3 concurrently screened patients for

Table 2 Hepatitis B virus (HBV) infection or immunity status among screened, newly arrived refugees at five US sites

Site	1	2	3[a]	4	5
HBsAg results available, N	5229	1371	173	641	5520
Positive HBsAg	6%	4%	2%	1%	6%
Complete HBV serologies available	96%	96%	100%	NA	NA
HBV status for patients with complete serologies					
Infected (acute or chronic)	6%	4%	2%	1%	6%
Immune due to HBV vaccination	42%	19%	61%	NA	NA
Immune due to natural infection	22%	15%	3%	NA	NA
Isolated core antibody	4%	4%	1%	NA	NA
Susceptible	26%	55%	33%	NA	NA

NA data not available

[a]Hepatitis B Virus (HBV) status was based upon hepatitis B surface antigen (HBsAg), antibody to HBsAg (anti-HBs), and hepatitis B core antibody (anti-HBc) laboratory results

Table 3 Demographic characteristics of newly arrived refugees with positive hepatitis B surface antigen identified during domestic medical exam at five US sites

Site	1 (n = 310)	2 (n = 53)	3[a] (n = 4)	4 (n = 9)	5 (n = 206)
Gender, female	37%	30%	50%	22%	37%
Age < 18	15%	2%	100%	11%	5%
Age at arrival: Median (years)	28	29	12	27	31
Interquartile range (years)	20–40	25–40	9–13	23–41	24–42
Country of birth					
Afghanistan		6%			
Benin				11%	
Bhutan	1%	6%			6%
Burma	40%	51%		44%	50%
Cuba				11%	
Democratic Republic of Congo	1%	11%		11%	3%
Eritrea	1%	2%			4%
Ethiopia	3%	2%		22%	3%
Russia					3%
Somalia	14%				14%
Other (< 2% per country)[b–d]	40%	22%			17%

[a]Site 3 is a pediatric center. Data on country of birth are redacted to prevent deductive identification given the low prevalence of chronic Hepatitis B Virus at this site

[b]Other at site 1 includes Cameroon, Kenya, Laos, Liberia, Nepal, Syria, Thailand, Vietnam, and unknown

[c]Other at site 2 includes Indonesia, Iraq, Ivory Coast, Senegal, Sudan, Thailand, Vietnam, unknown

[d]Other at site 5 includes Burundi, Central African Republic, Iran, Iraq, Ivory Coast, Kenya, Liberia, Mauritania, Mongolia, Nepal, North Korea, Rwanda, Sierra Leone, and Sudan

Table 4 Follow-up laboratory testing and linkage to care information for newly arrived refugees with positive HBsAg at five US sites

Site	Overall (N = 582)	1 (n = 310)	2 (n = 53)	3 (n = 4)	4 (n = 9)	5 (n = 206)
Laboratory testing performed within 14 days of initial positive HBsAg[a] result (%)						
HBV[b] DNA testing	93	100	55	50	100	NA
Hepatitis Be antigen testing	94	100	55	100	100	NA
Hepatitis Be antibody testing	92	100	43	100	100	NA
ALT[c] testing	92	99	55	75	100	NA
Hepatocellular carcinoma screening (ultrasound or alpha-fetoprotein)	41	44	15	50	100	1
Hepatitis A initiated vaccine series or confirmed immunity	93	95	79	75	89	NA
Confirmed immunity (+IgG)	91	95	79	75	33	NA
Hepatitis A vaccination (if − IgG or not tested)	3	2	0	0	56	NA
Hepatitis C antibody testing	86	99	92	100	100	65%
HIV testing	97	98	96	100	100	94%
Referral to HBV specialist within 30 days of initial positive HBsAg results (%)						
Referred to chronic HBV specialist	20	16	28	100	100	NA
Linkage to care within 6 months of initial HBV screening (%)						
Seen by chronic HBV specialist[d]	36	27	13	75	89	16

[a]Hepatitis B surface antigen

[b]Hepatitis B virus (HBV)

[c]Alanine transaminase

[d]Some sites managed HBV within primary care; therefore, referral and clinical visits to a chronic HBV specialist may underestimate the true number of patients being managed for HBV

HIV using a standard order set, and site 2 adopted this model in 2009; sites 1–3 had 98%, 96%, and 100% completion of HIV screening within 14 days. Sites 1 and 3 concurrently screened patients for HCV using a standard order set, and site 4 included HCV in reflex testing performed following a positive HBsAg; sites 1, 3, and 4 had 99%, 100%, and 100% completion of HCV screening within 14 days.

Referral to an HBV specialist within 30 days of positive HBsAg result occurred for 16%, 28%, 100%, and 100% of patients among sites 1–4, respectively. For sites 1–5, the percent of patients with chronic HBV infection who had a clinic visit with an HBV specialist within 6 months of a positive HBsAg result was 27%, 13%, 75%, 89%, and 16%, respectively. Sites 1, 2, and 5 used a primary care-based HBV management protocol.

Discussion

Summary

Chronic HBV prevalence ranged from 1 to 6% in newly arrived refugees across the five screening sites. This variation is likely multifactorial, including changing HBV prevalence of resettled populations over different periods, differences in populations resettled in each state, and increasing HBV vaccine prevalence among children [11, 22]. Collection of complete HBV serologies at sites 1 through 3 provided a wide range of results with refugees shown to be immune because of prior HBV vaccination or cleared HBV infection, and those who were not immune. Clinical sites vaccinated refugees who were neither immune nor chronically infected with HBV according to the CDC DME guidelines [23].

Although CDC and state guidelines outline screening recommendations for newly arrived refugees and persons identified with chronic HBV infection, there was variation in use of these screening guidelines across five diverse refugee screening sites [12, 24]. Site 1 had a reflex laboratory testing panel for HBV when a positive HBsAg was identified. Adoption of this approach by site 4 during the QI collaboration was associated with high rates of additional HBV laboratory testing within 14 days of HBsAg result. Standardized changes to clinical processes can improve the appropriate and timely completion of HBV workup. These services are usually covered by health insurance as they are considered a best practice, and early treatment has been found to be cost effective [25].

Interpretation

This evaluation of existing practices for chronic HBV infection management demonstrated that current models for HBV specialist referral are not effective for resettled refugee populations served by the included sites. The QI collaborative group has discussed strategies to improve HBV specialist referral and ongoing management for chronic HBV infection. More clinics should explore the use of referrals as standard in their clinical protocols for all patients identified with chronic HBV infection and reflex HBV testing at the time of the initial screening test. However, referrals do not ensure linkage to care. Previous research has shown that 32% of a sample (N = 1162) of primarily foreign-born, chronic HBV patients living in California were referred to a specialist [26]. This is comparable to our sample, as 20% were referred to a specialist within 30 days, and 36% were seen by the specialist within 6 months. Other research has shown that chronic HBV adult patients are more likely to receive management in primary care (37%) compared to a specialist (14%) [27]. Some sites managed adults with inactive chronic HBV in the primary care setting; some patients were not linked to specialist care because they did not need treatment. For sites managing adult HBV patients in primary care, ongoing management strategies such as HBV disease registries need to be considered to close gaps in care.

Chronic HBV in adults may be managed by primary care or specialists. Primary care providers often initially identify adult HBV infected patients, especially among high-risk populations [28, 29]. A previous study among primary care providers (N = 393) indicated that 83% perceived HBV to be a serious disease, but 62% were unaware of treatment guidelines [29]. Previous research has shown that labs were more likely to be ordered and completed when adult patients saw specialists (62% and 90%) compared to primary care providers (33% and 47%) [27, 28]. Adult primary care providers can be trained to manage HBV [30]. Resettled refugees have more trust in providers trained in cultural competency and with whom they have continuity of care; primary care providers have the opportunity to build strong connections with refugees [31, 32]. Additionally, refugee clinics in our study had more experience and resources for medical interpretation compared to specialists in the same network. Furthermore, scheduling an appointment with a specialist and long wait times were barriers for recently resettled refugees at some sites. Other barriers included inaccurate contact information, difficulty accessing transportation to subspecialist offices, patient lack of understanding of HBV infection, and patient lack of understanding for ongoing follow-up for a disease with no current symptoms. Collaboration between primary care providers and specialists is important; novel programs for

managing adults with chronic HBV in primary care with specialist oversight should be further explored [33].

Limitations

Limitations to this QI work include the retrospective, observational design of the planning stage, which does not allow for evaluation of causality. Prevalence data was not evaluated by country of origin, which could provide valuable comparisons to previous data [11]. Additionally, we were unable to monitor refugee follow-up outside the health systems included in the QI collaborative. Thus, linkage to care may be underestimated if some refugees sought care for chronic HBV infection at other institutions or outside the timeframes for data collection. Some sites managed HBV within primary care; therefore, our data focused on HBV specialist referral and clinical visits may underestimate the number of patients being managed for HBV. Some sites had fewer patients with a positive HBV screen, which limits the referral comparisons to larger sites. Results may not be generalizable to all clinics that complete the refugee DME. Linkage to care was limited to 6 months; future research should expand longitudinal follow-up to longer timeframes.

Conclusions

HBV vaccination, screening, and linkage to care is cost-effective [7, 34]. Unique strategies to address language, cultural, and healthcare navigation barriers faced by recently resettled refugee populations could be implemented to improve HBV care. QI collaborative sites recommend further exploration of the following strategies: (1) Partnerships that provide transportation supports to refugees attending specialist appointments; (2) Evaluation of culturally competent provider training materials for primary care and specialist providers; (3) Electronic medical record prompts to flag HBV patients; (4) Implementation of HBV reflex testing and standard order sets; (5) Development of HBV patient registries including phone outreach; and (6) Partnerships between public health and medical providers to provide HBV screening for household contacts of patients with HBV infection. Future work could investigate the effectiveness and economics of implementing these approaches. More research is also needed to systematically determine which refugees are candidates for treatment and the rate of treatment among those who test positive. Future quality improvement work will focus on developing clinical decision support tools to enhance timely staging for chronic HBV infection, HCC surveillance, and retention in care. Next steps in our PDSA cycle include planning standard referral protocols and iteratively measuring timely HBV staging and HCC screening rates following implementation of improved standard order sets and laboratory protocols.

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Compliance with Ethical Standards

Conflict of interest All authors report no conflicts of interest.

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