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Implementation of Birth-Cohort Testing for Hepatitis C Virus: Lessons Learned From Three Primary Care Sites

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Abstract

Hepatitis C virus infection affects approximately 2.2 to 3.2 million Americans. In 2012, the Centers for Disease Control and Prevention recommended a one-time antibody test of all persons belonging to the 1945–1965 birth cohort. Efforts to implement this recommendation in clinical settings are in their infancy; this case study report therefore seeks to share the experiences of three sites that implemented interventions to increase birth-cohort testing through participation in the Birth-cohort Evaluation to Advance Screening and Testing for Hepatitis C. At each site, project managers completed standardized questionnaires about their implementation experiences, and a qualitative analysis was conducted of the responses. The testing interventions used in-person recruitment, mail recruitment, and an electronic health record prompt. Sites reported that early efforts to obtain stakeholder buy-in were critical to effectively implement and sustain interventions and that the intervention required additional staffing resources beyond those being used for risk-based testing. In each case, administrative barriers were more extensive than anticipated. For the electronic health record–based intervention, technological support was critical in achieving study goals. Despite these barriers, interventions in all sites were successful in increasing rates of testing and case identification, although future studies will need to evaluate the relative costs and benefits of each intervention.

Keywords

health promotion; program planning and evaluation; process evaluation; community intervention; public health laws/ policies; health research

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INTRODUCTION

Hepatitis C virus (HCV) infection affects approximately 2.2 to 3.2 million Americans and was the underlying or contributing cause of at least 15,000 deaths in 2007 (Denniston et al., 2014; Ly et al., 2012). Prior to the development of clinically significant liver disease, HCV infection is largely asymptomatic and remains undiagnosed in at least 43% of infected individuals (Spradling et al., 2012). Since 1998, the Centers for Disease Control and Prevention (CDC) has recommended routine HCV testing of individuals with a high risk of exposure (CDC, 1998). More recently, studies have demonstrated the cost-effectiveness of one-time antibody testing of all members of the 1945 to 1965 birth-year cohort without the need for evaluating exposure risk (McEwan, Ward, Yuan, Kim, & L'Italien, 2013; McGarry et al., 2012; Rein et al., 2012). In 2012, both the CDC and the U.S. Preventive Services Task Force (USPSTF) expanded testing recommendations to include all individuals born from 1945 to 1965—in addition to testing those with exposure risks or clinical indications of infection (Moyer, 2013; Smith et al., 2012). These recommendations could significantly increase identification of HCV infections in the United States.

BACKGROUND

Significant barriers may impede implementation of birth-cohort testing in primary care (PC) settings. For example, implementation of previous CDC and USPSTF infectious disease testing recommendations have been hindered by lack of physician knowledge about the new recommendations, organizational barriers, reimbursement concerns, patient resistance, and provider disagreement; Implementation has been facilitated, however, by systematic reminders, provider education, and low implementation costs (Cabana et al., 1999).

Four large PC clinical networks were involved with the Birth-Cohort Evaluation to Advance Screening and Testing for Hepatitis C (BEST-C)—University of Alabama at Birmingham in Alabama; Henry Ford Health System in Detroit, Michigan; the Mount Sinai Icahn School of Medicine in New York, New York; and the University of Texas in Houston. To understand current HCV birth-cohort testing barriers and facilitators, these four networks completed a previous study of the baseline conditions and characteristics through interviews conducted in June and July 2011 with primary care providers (PCPs), hepatologists, and administrators (Jewett et al., 2014). At this time, providers faced many of the same barriers described by Cabana et al. (1999), including lack of PCP knowledge about testing recommendations, organizational barriers such as delays in scheduling appointments at the liver clinic, and concerns about financial barriers to treatment.

Starting in December 2012, three of the BEST-C sites developed interventions to increase HCV testing and diagnosis among members of the 1945 to 1965 birth cohort. Each intervention used a randomized controlled design to compare the number of patients tested and diagnosed from a birth-cohort approach with the number found using a risk-based approach (Smith et al., 2014).

POLICY CASE STUDY

These three BEST-C interventions, which were implemented from December 2012 to March 2014, are some of the earliest systematic interventions to increase HCV testing among the 1945 to 1965 birth-cohort; they therefore can provide information that may be helpful to others wishing to implement similar interventions in clinical settings. Each site encountered unforeseen barriers to, and opportunities for, implementation, which resulted in modifications to the initial design. This case study provides information about the barriers and facilitators of birth-cohort testing learned during the BEST-C research project with the intent of helping those who might wish to implement similar interventions within their own clinical practice.

Structured Questionnaire Responses

To explore lessons from the BEST-C sites, we collected data via e-mail from the three sites. We used a structured questionnaire to ask study coordinators about the conception, methodology, and implementation of their intervention, implementation barriers faced, solutions to barriers, and additional lessons learned. Respondents were chosen based on their roles as implementation coordinator and their ability to report organizational details of the study. Initial questions were sent via e-mail, and ambiguous or incomplete responses were later clarified as needed by phone and e-mail (Table 1).

Although a single representative from each site responded to the initial e-mail, this representative gathered and incorporated the experiences of various project team members, including study coordinators, physicians, nurses, medical assistants (MAs), and technology support teams. Each site implemented a unique intervention tailored to the rules and customs of its health system and the capacity of its research team (Table 2).

Data Analysis

We sought to evaluate each BEST-C design through four key stages: conception, implementation, modifications, and final approach. Interview data were qualitatively summarized to identify common themes that could be helpful for future institutional implementation of birth-cohort testing interventions. A multidisciplinary team that included a research analyst, a project director, and a research assistant performed the data coding and quality assurance. Themes and subthemes were identified and validated by peer triangulation and confirmed by site leads.

Findings

Changes in Provider Practice due to BEST-C—The BEST-C intervention and its implementation of the birth-cohort testing strategy generated interest at all three sites. The site that implemented the best practice alert (BPA) prompt continues to use it after the end of the BEST-C timeframe and has expanded BPA use to all eligible patients at their clinics. This site also reported that BEST-C provided the opportunity for provider education on the internal process for referral after a positive HCV antibody test result, linking patients to the appropriate care for treatment. Previously published articles have highlighted the challenge of the treatment cascade following an HCV positive diagnosis, making this a noteworthy

accomplishment (Holmberg, Spradling, Moorman, & Denniston, 2013; Yehia, Schranz, Umscheid, & Lo Re, 2014).

Resource Burden—All sites reported that implementing a birth-cohort testing intervention was more complicated and required greater resources than initially anticipated, although some of this greater burden was attributed to the experimental design of the BEST-C study. One site estimated dedicating more than 1,200 hours of staff time to execute all elements of the study. Another used clinical research staff to approach patients for HCV testing—operating under the belief that highly skilled personnel would best ensure acceptance of and cooperation with the intervention within PC offices. The final site had to devote resources to continual redesign of its intervention, first when it was unable to implement an electronic health record (EHR) prompt as an intervention strategy due to the EHR transitioning from one system to another, and later when its subsequent mail-based intervention required modification due to low rates of testing uptake in the pilot.

Earning Support From Stakeholders—Obtaining stakeholder buy-in to implement the intervention was more challenging than the sites expected. At two of the sites, providers, MAs, and other clinical staff were skeptical of having a role in conducting research and lacked commitment to the study. Intervention adherence was further complicated by frequent turnover of study and clinic personnel. Nonintervention staff reported difficulties accommodating intervention tasks in addition to their usual job responsibilities. Also, the personnel at each site—and at each clinic within the sites—had varying levels of knowledge and comfort in recommending HCV testing, which produced an unanticipated staff education issue to address.

In line with findings from implementation of other interventions, early and continued engagement of providers and other medical staff was critical to intervention adoption and success. All three sites found that holding discussions on the design and importance of the study with providers, MAs, and other team members facilitated provider participation. The site implementing the EHR prompt anticipated physician-reported “pop-up fatigue”—when physicians ignore or delete prompts because they receive too many alerts—and held a focus group with physicians and MAs to determine how an EHR prompt could be included while minimizing the impact on work flow. MAs reported that an alert would require two clicks or fewer for it to be accommodated. Physicians were provided a preloaded order and were permitted to bypass the standard BPA to save time when appropriate.

Two sites reported considerable support from physicians and staff including leadership. One found “lunch and learns” and one-on-one trainings to be successful in educating providers about the intervention. The site using mail-based intervention reported that managing the volume of the testing workload on laboratory services was essential to acquiring the acceptance of laboratory management staff and approval of their intervention. It solved the problem by staggering the implementation geographically over time. This regional staggering reduced the overall volume of new tests coming to the lab at any one time while preserving the goal of testing the entire birth cohort.

Patients at sites with in-person interventions did not uniformly accept HCV testing. Staff reported that patients were wary of receiving an HCV test due to stigma or distrust of the health system. It was unclear if this skepticism resulted from distrust of physicians, of research and/or government collaboration, or out of a concern over the possible consequences of receiving a positive test result. Site coordinators speculated that patients might have been reluctant to be tested based on prior experience with rejection from insurance companies due to preexisting conditions. Some patients did not want to know if they were living with HCV infection, and others saw no financial benefit or other reasons for study participation.

Administrative Barriers—All sites faced a number of administrative hurdles that slowed implementation. One site found it difficult to obtain access to provider schedules for training and planning purposes and to acquire sufficient access to computing resources to facilitate patient identification at the clinic site. Each site initially intended to implement an EHR prompt for testing. In all cases, hospital medical board approval was required to implement an EHR-based prompt for testing. The lengthy approval process delayed implementation in the EHR-prompt site, and, subsequently, the other two sites abandoned, at various stages of development, an EHR prompt intervention.

Additionally, one site reported that its EHR system limited what MAs (the staff charged with triggering the BPA) could access and therefore limited how the BPA could be used. Because this was a research study, even after board approval, the site's institutional review board required consent from each provider that would be exposed to the BPA. If patients changed providers, caution had to be used to determine whether the alert was activated in their medical record so that nonconsented providers did not receive the alert. This became increasingly complicated as the "scheduled" provider may have differed from the attending provider who signed off on the lab request. It was difficult to discern from the EHR which provider was in the room with the patient and therefore saw the BPA. However, the issue of provider consent would not likely be a problem in nonresearch implementations.

Since the intervention was designed as a research study rather than as routine clinical care, one site faced difficulties in educating the laboratory staff to complete the appropriate test and bill the specific research account accordingly. To resolve this issue, the head of laboratory services and the staff held a meeting to devise a plan for implementing the project. The laboratory site managers were then individually instructed regarding study procedures and the correct codes to use for billing.

Technological Challenges—Two sites attempted to use EHR technology to implement their intervention. While one was able to overcome the technological challenges and implement an EHR prompt, these barriers were too great to allow for EHR-based implementation in the other. The site that implemented the BPA found that its EHR was unable to retrospectively examine prior claims to determine if an individual had a prior HCV test or diagnosis at the time of service. To resolve this, the EHR would check patient history and flag ineligible patients prior to a scheduled patient visit. Incorporating this flagging delayed the implementation of the BPA and may have resulted in some repeat testing among unscheduled walk-in patients.

The EHR alert site also found that the BPA had to be customized to fit the workflow at each clinic. The timing of the BPA had to be altered, as initially it appeared when the attending physician was reviewing their residents' patient charts, rather than when the resident was seeing the patient. The EHR intervention also had a number of challenges related to the timing of data reported from the EHR. The site noted that more frequent data checks would have supported continuous quality improvement during implementation by enabling adjustments in the intervention as needed.

Future Changes to Interventions—All sites reported a desire to continue implementing interventions to increase birth-cohort testing in the future, though each planned to alter its intervention for future practice. The site using the EHR prompt plans to compare effectiveness of targeting a BPA to MAs versus clinicians. The site that mailed prompts to patients noted that although the operational implementation was simple, an EHR alert would be less expensive and more efficient and therefore more sustainable outside the context of a research project. An EHR-based system also facilitates direct discussion with care providers and a blood draw during a scheduled visit. The site that implemented the EHR-based prompt reported that the birth-cohort strategy was effective in increasing testing but that the yield of HCV-positive cases identified through testing was lower than initially expected. The site would like to incorporate an additional risk-based component to the intervention to increase the number of positive cases identified by the intervention. The in-person intervention site does not intend to continue their direct patient recruitment following the end of the intervention period and will instead rely on physician awareness and implementation of birth-cohort testing as the standard of care.

One site noted that state law changed during the period of the intervention. This law, effective January 1, 2014, requires PCP to offer HCV testing to the 1945 to 1965 birth cohort. However, this site also noted that the change in law did not appear to result in an immediate increase in the number of HCV tests performed in their control group.

DISCUSSION

Our case study findings suggest that implementation of birth-cohort testing was feasible and successful in increasing testing rates in all three sites observed. Meta-analysis of effect estimates showed that anti-HCV+ patients were four times more likely to be identified using birth-cohort testing versus usual care (Smith et al., 2014). Additional data on the efficacy of birth-cohort testing in BEST-C will be presented in future analyses. To be successful, implementation in each site required planning and preparation as well as negotiation and discussion with providers and system administrators to obtain systematic approvals and adherence with intervention protocols. Each intervention was successful in increasing testing rates over the control as well as increasing the overall yield of new cases identified (Smith et al., 2014). Future analyses will also determine the cost-effectiveness of each intervention.

Barriers to testing implementation in these three sites were similar to those common to any change in practice patterns. These barriers included a lack of adequate knowledge about updated HCV screening recommendations and the absence of formal policies supporting systematic implementation of birth-cohort testing (Jewett et al., 2014). Other sites and

clinics wishing to implement a birth-cohort testing intervention may face similar barriers in gaining organizational approval and should plan to dedicate resources to staff, provider, and administrator education about the CDC and USPSTF birth-testing recommendation and its relevance to the local patient population.

Other interventions, beyond the case studies of BEST-C, have also been successful in increasing HCV testing rates among the 1945 to 1965 birth cohort. First, an intervention to test medically stable persons born between the years 1945 to 1965 in two urban emergency departments demonstrated high testing rates and yield in this population. This study identified a prevalence of 9.9% to 11.0% among persons who self-reported that they were unaware of their antibody status (Galbraith et al., 2013; Galbraith et al., 2014; Galbraith et al., 2015).

A second intervention, which focused on increasing risk-based testing rather than birth-cohort testing, used clinical reminder stickers to prompt physicians at urban PC clinics to screen for HCV risk factors and order an HCV test if patients had one or more risk factors. This study resulted in 25.3% of patients being tested; of those tested, 5.0% were HCV-antibody positive (Drainoni et al., 2012). A third intervention conducted at three community-based PC clinics used on-site education sessions for PCPs, regular communication with the research team, and environmental reminders, including pocket cards and posters. The study team placed stickers on progress notes prompting either risk-based screening or birth-cohort testing, evaluating each as a separate intervention. Both interventions led to a significant increase in identifying HCV-infected persons. Compared with a 6.0% testing rate at baseline, 13.1% and 9.9% of patients meeting selection criteria were tested during the risk-based screening and birth-cohort testing phases, respectively. The prevalence of anti-HCV positivity was 5.3% in the risk-based screening interventions and 5.8% in the birth-cohort period (Litwin et al., 2012).

This case study has several notable limitations. First, we received responses from site representatives but did not directly interview providers or patients. We specifically asked about the experiences of providers and patients observed throughout the study time frame, and although each site appeared to be forthcoming about problems that providers and patients described, it is likely that additional challenges and issues were not captured. Second, this study refers only to interventions intended to increase birth-cohort testing in PC settings. Barriers to implementation might differ in other settings such as emergency departments, inpatient facilities, specialty care, and outpatient drug testing centers. Third, each of our interventions was implemented as part of a formal research protocol. Many of the barriers faced by these sites, such as difficulties related to consenting patients and providers, would not apply to an organization adding birth-cohort testing as a component of routine care.

During the time of the experimental interventions, the USPSTF released their birth-cohort testing recommendation, affecting all the sites. However, during our period of observation, the USPSTF recommendation did not have a demonstrable impact on testing rates in terms of increasing birth-cohort testing in the intervention control groups. Nevertheless, it is premature to draw any conclusions about the long-term impact of the USPSTF

recommendations. While recommendations from CDC and the USPSTF were an essential first step in facilitating birth-cohort testing nationwide, in the three sites we observed, the publication of recommendations alone did not trigger a noticeable change in testing frequency within the control sites during the time the study was conducted.

CONCLUSIONS

Each of the three sites involved in this case study were successful in its implementation of an intervention that increased HCV testing rates. While this research represents the experience of only these three sites, their experiences can be leveraged to avoid shortcomings in future implementation. Although a BPA was the preferred intervention at all three sites, site-specific challenges prevented the success of this solution in two of the sites. To implement birth-cohort screening, each site developed a separate intervention that met its specific capabilities. All three sites encountered unanticipated barriers at start up, and all of the sites reported the need to perform continuous quality improvement and minor alterations to their interventions throughout the study. Despite these challenges, the success of these three sites indicates that implementing birth-cohort testing in PC settings is feasible and likely to be successful given dedicated resources, buy-in, and support from hospital administration.

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TABLE 1

Questions Asked of Each Study Coordinator

Questions	
1	What was your idea and original conception of the intervention?
2	Why was this the best model for your specific location?
3	How did you go about implementing the intervention?
4	What resources were necessary to implement your intervention (staff, type of EHR, etc.)?
5	What were major barriers or difficulties you encountered?
6	How was the intervention adjusted, or what steps did you take to overcome these barriers?
	For more detail, please discuss barriers in terms of the following:
	Administration
	Providers (clinicians and staff)
	Patients
	Technical/operational difficulties
7	What, if anything, was easier than you expected?
8	What are some of your lessons learned? What would you do differently?
9	Did the intervention generate interest in birth-cohort testing more generally, beyond the population involved in the trial?
	a. Among health care providers/clinic staff?
	b. Among the patient population? Has BEST-C raised community awareness for birth-cohort testing?
10	Has there been any lasting impact of implementing a short-term intervention to improve birth-cohort testing?
	a. Have providers participating in the intervention continued to offer birth-cohort testing after the end of the intervention?
	b. Has any of the information learned from BEST-C been disseminated throughout your organization? Have other parts of your organization used those lessons learned to implement birth-cohort testing on a wider scale?
11	Did your intervention reduce the burden on the medical provider?

NOTE: EHR = electronic health record; BEST-C = Birth-Cohort Evaluation to Advance Screening and Testing for Hepatitis C.

TABLE 2

Summary of Intervention Design by Site

Site	Patient inclusion criteria	Outreach methodology	Randomization
1	Patients born between 1945 and 1965 who had previously visited a site 1 clinic and who had no prior evidence of HCV testing in their medical records	In-person recruitment by study coordinators at four internal medicine clinics	Cluster randomized crossover design: two intervention clinics and two control clinics which switched midway through the study (Rietbergen & Moerbeek, 2011)
2	Patients identified in the EHR system born between 1945 and 1965 who had made at least one primary care visit to a system-affiliated physician in the past year and who had no prior evidence of HCV testing in their medical records	Repeated mailing outreach at weeks 0, 1, 4, 8, and 12, based on a Dillman Total Design Survey Method (Hoddinott & Bass, 1986)	Stratified multiclinic, individually randomized—within each clinic, patients were randomized to intervention or control
3	Patients born between 1945 and 1965 and who had no prior evidence of HCV testing in their medical records	EHR best practice alert targeted to medical assistants indicating patients eligible for a test	Cluster randomized design among 10 semiautonomous primary care practices

NOTE: HCV = hepatitis C virus; EHR = electronic health record.