Risk of Hepatitis C Virus Exposure in Orthopedic Surgery: Is Universal Screening Needed?

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Abstract

The aging baby boomer generation will soon start using tremendous orthopedic surgical resources. This group has also been identified as a group at high risk for having undiagnosed hepatitis C virus (HCV) infection.

We conducted a study to assess the prevalence of HCV among orthopedic surgery patients at our institution—using their demographic data to determine whether they represent a unique cohort at high risk for having undiagnosed HCV. We estimated that we operated on as many as 233 patients with undiagnosed HCV in 2011.

A cost-effective, universal preoperative HCV screening program may reduce the risk for occupational exposure in orthopedic surgery and significantly benefit public health by bringing undiagnosed patients to treatment. A robust screening program requires several ethical considerations. By offering routine screening to patients, orthopedic surgeons have an opportunity to maintain intraoperative safety and improve the health of the public.

Orthopedic surgeons face an elevated risk for occupational exposure to blood-borne pathogens because of the nature of the procedures they perform.[1-5] The pathogens of concern historically have included hepatitis B virus (HBV), hepatitis C virus (HCV), and the human immunodeficiency virus (HIV). In recent years, fear of occupational exposure appears to have waned, likely because of the widespread use of an effective HBV vaccine and the exceedingly rare occupational transmission of HIV.[6]

HCV, however, continues to be a cause for concern: an effective vaccine is lacking, medical therapies are poorly tolerated, and the transmission rate is relatively high, ranging from 0.31% to 4.2% per percutaneous exposure from a hollow-bore needle.[7-9] Estimated prevalence of HCV in the United States is 3.2 million (1.3%), according to the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES).[1-5,10] In addition, the CDC has demonstrated that HCV recently surpassed HIV as a cause of death in the United States, and that the burden of disease is highest among Americans born between 1945 and 1965—the baby boomers.[6,11,12] Further complicating the issue is the low rate of HCV diagnosis among Americans; reports indicate that anywhere from 25% to 75% of patients with HCV infection lack a diagnosis.[7-9,13-15]

These statistics are concerning because patients older than 65 years disproportionately seek orthopedic care for musculoskeletal disease, and orthopedic surgical procedures carry a high risk for occupational exposure to blood.[1,2] One projection of primary total knee arthroplasty (TKA) suggests an increase from 450,000 procedures performed in 2005 to nearly 3.5 million in 2030, more than half on baby boomers (born between 1945 and 1965).[16] Based solely on an empiric age group analysis, the future arthroplasty population appears to be at high risk for having undiagnosed HCV infection.

We conducted a study to quantify the burden of HCV among orthopedic surgery patients at our institution. In this article, we report our findings and briefly review the history and efficacy of standard precautions in the operating room, and the risks that HCV exposure poses for surgical teams. We then present an argument for a comprehensive and ethical preoperative HCV screening program at orthopedic institutes and discuss the challenges of universal screening.

Materials and Methods

The finance division of our institution keeps patient-level data for all orthopedic surgery patients in a deidentified database. This database includes information regarding procedures performed (eg, inpatient, outpatient, arthroplasty, arthroscopy, spine) and demographic information (eg, age, race, sex). We stratified the database into groups of patients based on procedure, age, sex, and race. Patients were stratified by race into 3 groups in accordance with NHANES, the CDC-maintained

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Table I. New York University Langone Medical Center Orthopedic Patient Demographics, 2011

Characteristic	n
Sex	
Male	7338
Female	7434
Total	14,772
Race/Ethnicity	
Non-Hispanic white	8701
Non-Hispanic black	1856
Other	4215
Age, y	
≤ 19	1341
< 40	3120
< 50	2464
< 60	3226
< 70	2756
< 80	1362
≥ 80	503

national survey that tracks the health and nutritional status of US citizens. Each year, NHANES examines a representative sample of about 5,000 patients, stratifies them by age, race, and sex, and then determines the prevalence of major diseases and risk factors for those diseases, including HCV infection. These groups are non-Hispanic white, non-Hispanic black, and other, which includes all races that do not fit into the first 2 categories. Patients were stratified into the age groups defined by NHANES: 19 years or younger, 20 to 39 years, 40 to 49 years, 50 to 59 years, 60 to 69 years, 70 to 79 years, and 80 years or older. We directly compared demographic groups from our orthopedic population and calculated the prevalence of HCV among those groups by extrapolating from the HCV prevalence of all NHANES participants between 1999 and 2002. This was done in accordance with previously published methods.[10] Ages were corrected to account for the fact that orthopedic patients in 2011 were roughly 10 years younger when the initial NHANES data were collected. One patient was excluded because demographic information was unavailable at time of analysis.

HCV prevalences were calculated for all orthopedic patients at our institution. In addition, prevalence was calculated for all inpatient and outpatient procedures and for our entire total joint arthroplasty (TJA) and spinal fusion (SF) patient population. These 2 procedure classes are considered to be at especially high risk for occupational exposure to body fluids.[3-5] The prevalence values were then used to calculate the absolute number of HCV patients who had surgery at our institution in 2011. Because literature reports indicate 25% to 75% of patients with HCV remain undiagnosed, this percentage range was used to estimate the number of patients with undiagnosed HCV who had surgery at our institution in 2011.

All statistical analyses were performed with SAS version 9.3 (SAS Institute, Cary, North Carolina). Differences between estimated prevalence for inpatients and outpatients were assessed with Pearson χ^2 analysis with significance set at $P < .05$. Confidence intervals (CIs) were defined as 95% and were determined for all groups.

Results

In 2011, 14,773 patients underwent orthopedic surgery at our institution (**Table I**). Of their cases, 5,756 (39%) were classified as inpatient procedures, and 9,017 (61%) as outpatient. With respect to high-risk procedures, 4,083 patients (27.6%) underwent TJA and SF procedures. Our patient population included 7,338 males (49.6%) and 7,434 females (50.4%), 8,701 non-Hispanic Caucasians (58.9%), 1,856 non-Hispanic blacks (12.6%), and 4,215 other races (28.5%). Patients within each age group are delineated within **Table I**. There were 8,446 patients (57.1%) who had surgery and were between 41 and 69 years old.

The weighted prevalence of HCV among all patients at our institution was calculated to be 2.11% (95% CI, 1.10-5.21), yielding 311 patients who had HCV and underwent orthopedic surgery in 2011 (**Table II**). Using the reported diagnosis rate of

Table II. Institutional HCV Burden for Orthopedic Surgery Procedures, 2011

		Estimates		
Procedures	No. of Patients	HCV Prevalence[a] (95% CI)	No. of Patients With HCV	Range of Patients With Unknown HCV Status
All	14,772	2.11 (1.10-5.21)	311	78-233
Outpatient	9016	2.12 (1.13-5.48)	191	48-144
Inpatient	5756	2.09 (1.07-5.80)	120	30-90
Arthroplasty and spinal fusion	4083	2.33 (1.19-5.32)	95	24-72

[a]Calculated from National Health and Nutrition Examination Survey HCV prevalence data.

25% to 75%, we calculated a range of 78 to 233 patients with undiagnosed HCV who had orthopedic surgery at our institution in 2011. Patients who had outpatient, inpatient, and TJA/SF procedures had HCV prevalence of 2.12% (CI, 1.13-5.48), 2.09% (CI, 1.07-5.80), and 2.33% (CI, 1.19-5.32), respectively. There were no statistically significant differences between any of these groups (odds ratio, 1.02; 95% CI, 0.81-1.28). All these prevalences were empirically higher than the national prevalence (1.3%) reported by NHANES, though these results did not reach statistical significance. These prevalences were also not significantly different from those reported for our geographic region (2.2%).[14]

Discussion

This study estimated the burden of HCV among orthopedic surgery patients at a single institution in an urban environment. Using our cohort, we were unable to identify an increased risk for HCV among an orthopedic surgery population. However, as many as 233 patients with undiagnosed HCV underwent surgery. Our estimates may be conservative considering that the NHANES data do not account for the US incarcerated population of nearly 1.5 million.[17]

This study is important because of significant changes in the medical community's understanding of HCV. The CDC recently reported that, between 1999 and 2007, HCV surpassed HIV as a cause of mortality in the United States, and that the largest number of deaths attributable to HCV had occurred among baby boomers, making them a generation at high risk for HCV-related morbidity and mortality.[12] As baby boomers continue to age, there will be a significant increase in the annual number of orthopedic surgeries they undergo.[16,18] More than 50% of the estimated 3.5 million TKAs that will be done in 2030 will be performed on baby boomers who are currently 45 to 54 years old—a group now shown to be at high risk for HCV infection and HCV-related morbidity and mortality.[16] At our institution alone, there has been a 180% increase in the number of primary TKAs performed for all age groups within the past 5 years.[19] All these data demonstrate a very real and unacceptable risk for HCV exposure for our surgical teams and signal a call to action for improvements in safety practices and screening. To begin, we must review the history and efficacy of our current system of standard precautions.

Current Standard Precautions in the Operating Room

The concept of "blood and body fluid precautions" was first introduced by the CDC in 1983 in response to the acquired immunodeficiency syndrome (AIDS) epidemic in the United States.[20,21] Initially, these precautions were risk based, or recommended for health professionals interacting with patients thought to be at high risk for carrying a bloodborne disease. By 1988, however, this guideline was expanded and applied to all patients regardless of perceived infection risk. Thus, a system of "standard precautions" was created, with the hope that a safety mechanism that was based on the universal assumption of infectivity would be effective in preventing transmission of bloodborne infections.

Table III. Known Risk Factors for HCV Infection[a]

Present or past injection drug users
Recipients of donated blood, blood products, and organs prior to 1992
People who received coagulation factor transfusions prior to 1987
Present or past hemodialysis patients
People who received body piercings or tattoos with nonsterile instruments
Health care workers injured by needle sticks
Persons infected with HIV
Children born to mothers infected with HCV
Having sexual contact with a person infected with HCV
Sharing personal care items (eg, razors, toothbrushes) that may have come in contact with blood of an infected person

[a]Adapted from Centers for Disease Control and Prevention.[25]

The CDC recognized that standard precautions did not completely prevent occupational exposures to blood, and there were several reports of surgeons transmitting HBV to their patients despite the recommendations.[4,22] Therefore, in 1991, the CDC began defining some surgical procedures as *exposure-prone*, or having a "definite risk of bloodborne virus transmission from surgeon to patient" even with the surgeon adhering to standard precautions. The list of exposure-prone procedures includes many common orthopedic surgeries, such as total knee arthroplasty, total hip arthroplasty, open spine surgery, and open pelvic surgery.[22] This is due in part to long procedure times, use of sharp power tools, and surgeon manipulation of sharp bone fragments.

Although a full performance evaluation of the effectiveness of standard precautions is beyond the scope of this article, it is noteworthy that strict adherence to standard precautions and to reporting percutaneous-exposure cases to institution-based occupational health officials has been a subject of much study and debate. Some studies have demonstrated modest adherence by orthopedic surgeons to both standard precautions and reporting.[3,4,23,24] The shortcomings of our current standard precautions raise the question of whether a policy intervention focused on the safety of the surgical team could improve surgeon vigilance, adherence to standard precautions, rates of exposure reporting, and public health.

A Universal Approach to Safety

One viable option for decreasing the risk for occupational exposure to HCV is to adopt a risk-based approach. Such an approach would involve preoperative assessment of patient risk factors for past HCV exposure (**Table III**), the results of which could influence intraoperative safety protocols (**Table IV**).[25-27] However, this approach may prove inadequate because patient reports may be accidentally or intentionally inaccurate.[28,29] An alternative to the high-risk approach is a non–risk-based

approach in which a protocol is applied universally to all patients. This is the approach that the CDC took when developing standard precautions during the 1980s. New York state has implemented equitable and non–risk-based interventions that mandate offering HIV and HCV screening.

Table IV. Interventions That Reduce Exposure Risk[a]

Double-gloving
Kevlar surgical gloves
Impervious personal isolation gowns that enclose mucous membranes
Blunt needle sutures to close fascia
Staples to close skin
Knotless suture products that minimize needle handling
Hands-free passing of sharp objects

[a]Adapted from Bennett and Duff[26] and Parantainen and colleagues.[27]

Universal screening would medically benefit preoperative patients and is in accord with the most recent Institute of Medicine and CDC recommendations and with New York state law.[28,30,31] Increasing patient awareness of HCV infection would help patients to seek appropriate medical treatment for this chronic and potentially fatal disease. Readily available laboratory testing has simplified the screening process, and the prospect of new HCV pharmacotherapy with excellent efficacy and tolerable side-effect profiles suggest that HCV may soon become an infection with a long-term cure in many patients.[32-35] Similar screening programs have already been evaluated and were determined to be cost-effective.[36,37]

Universal screening before elective orthopedic surgery may decrease the surgical team's risk for occupational HCV exposure. Preoperative knowledge of HCV serostatus and viral load

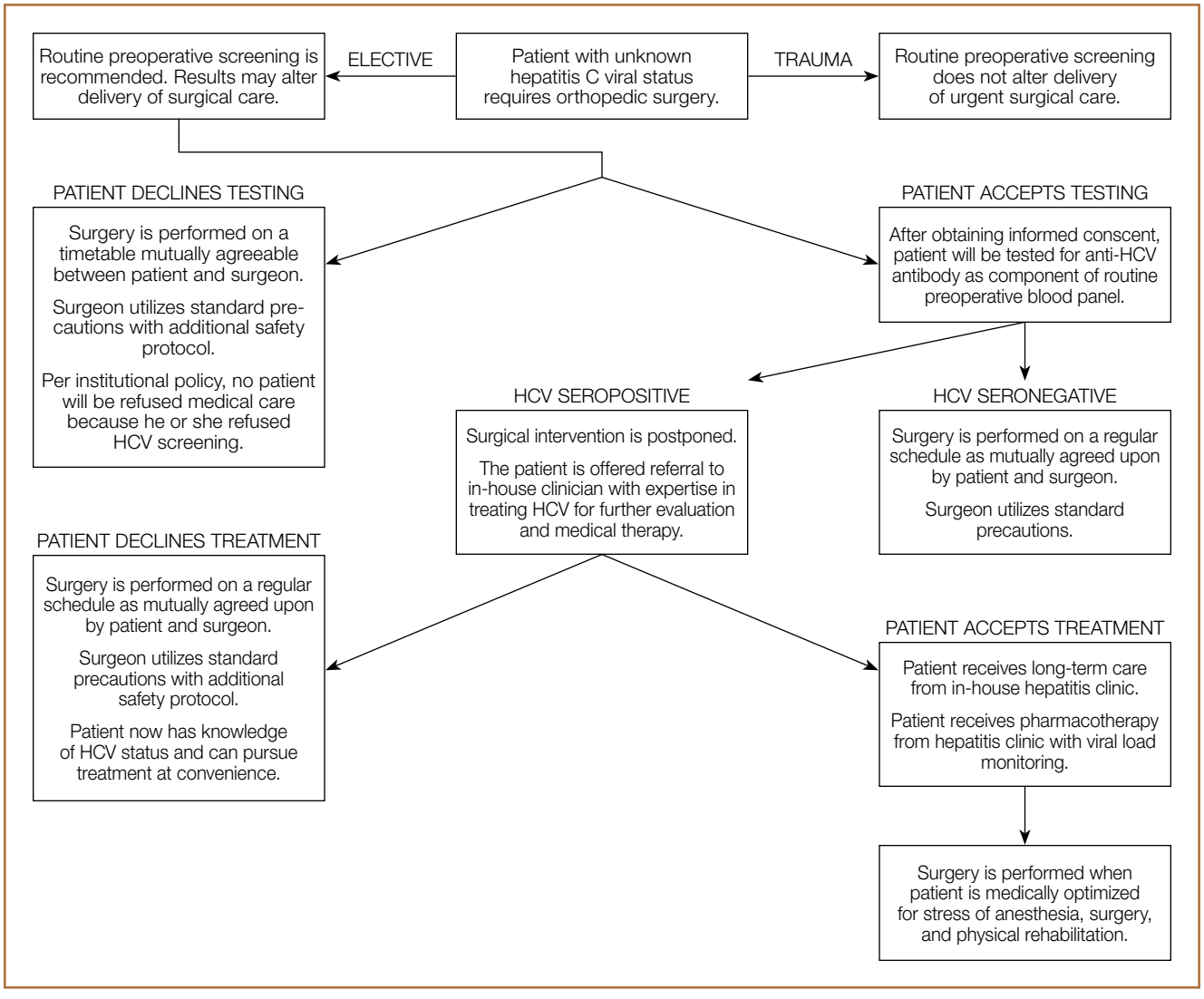

Figure. Proposed workflow for preoperative HCV screening.

eliminates the weaknesses of patient-reported risk stratification and could instill in the surgical team a new procedural vigilance that would inherently lower the risks for occupational exposure by improving intraoperative safety and postexposure reporting. Last and most important, knowledge of HCV status may be useful in risk-stratifying a patient for arthroplasty, as HCV has been associated with longer hospital stays and higher rates of surgical and mechanical complications, reoperation, and need for revision among this group.[38]

A Universal Preoperative HCV Screening Program

A preoperative screening program for HCV must not violate the foundational principles of bioethics—namely, autonomy, beneficence, nonmaleficence, justice, and confidentiality. In addition, a screening program must embrace an egalitarian protocol that removes the decision making from surgeons and staff, thereby eliminating the potential for unjust variability on a case-by-case basis (ie, the screening process is standardized). Our proposed protocol is outlined in the **Figure**, described in the next paragraphs, and guided by several tenets set forth by the CDC, which are listed in **Table V**.

Patients scheduled for elective orthopedic surgery will be offered hepatitis screening and viral typing and will be asked to provide consent. Patients who are admitted for trauma-related injuries and require emergency surgery, and patients who require urgent surgery, such as hip fracture surgery, will not be offered preoperative screening because the results would not change the timing of surgery. Patient autonomy will be respected; patients can forgo screening and continue to have uninterrupted orthopedic interventions. When a patient refuses screening, the surgeon should try more aggressive safety interventions.

Patients who undergo screening and test seronegative for HCV will proceed to surgery with the benefit of both patient and surgeon knowing the patient is HCV-negative. In contrast, patients found to be HCV-seropositive will be offered referral to an in-house clinician with expertise in treating HCV. This clinician can provide further evaluation and possible medical therapy. Preoperative planning, choice of anesthesia, intraoperative safety protocols, postoperative recovery, orthopedic surgery complication rates, and length of hospital stay are all affected by many interrelated factors, such as HCV genotype, serum viral load, degree of liver injury, plans for medical treatment, and side effects of medical treatment.[38,39] Therefore, all plans for elective surgery should be postponed pending full workup and medical clearance by an in-house clinician specializing in the treatment of hepatitis.

Because this protocol temporarily delays the surgical plan for patients who test positive for HCV, any institution using such a protocol would benefit from having an in-house or affiliated clinic staffed by clinicians with expertise in treating HCV, thereby allowing close coordination of care. This would afford patients the services of hepatologists, laboratory testing, and access to hepatitis pharmacotherapy. By creating a subdivision of hepatitis care, orthopedic surgery facilities will not abandon their patients. Rather, they will continue to monitor the musculoskeletal disease of its preoperative patient population and coordinate care with the hepatitis clinic such that surgery is performed when the patient is medically optimized for the physiologic stress of anesthesia, surgery, and physical rehabilitation. The goal is to establish direct communication between a patient's orthopedic and hepatologic caregivers so that the patient can get appropriate care with maximal safety for both the patient and operative staff.

Respect for bioethical principles should be maintained. Patients should be allowed to opt out of the process at any point. For example, a patient who undergoes testing and is found to be HCV-seropositive may refuse referral for HCV care and instead continue with regularly scheduled elective orthopedic surgery. In this instance, the orthopedic surgeon is obligated to provide uninterrupted care pending traditional preoperative evaluation from medical and anesthesia teams. In certain exceptional cases in which the surgeon thinks the patient's HCV seropositivity would pose significant harm to both the patient and the surgical team, the case can be referred to the institution's ethics committee.

Table V. Recommendations for Ethical HCV Screening[a]

Consent must be obtained for testing
Patients must be informed of test results, and seropositive patients should be provided counseling by properly trained persons
Patients should be assured that confidentiality safeguards are in place
Patients should be assured that, if found to be infected, they are not denied needed care and are not provided suboptimal care
Prospective evaluation should be performed of (A) the efficacy of the program in reducing the incidence of parenteral, mucous membrane, or significant cutaneous exposures of health care workers to the blood or other body fluids of patients infected with HCV and (B) the effect of modified procedures on these patients
Patients cannot be refused surgical care based on screening results
Patients cannot be refused surgical care if they refuse to proceed with screening or treatment for HCV as long as otherwise medically cleared to undergo surgery

Abbreviation: HCV, hepatitis C virus.

[a]Adapted from Centers for Disease Control and Prevention.[20,21]

Challenges to Preoperative Screening

Our proposed universal HCV screening program may lead to substantial delays in elective orthopedic care. Once HCV is diagnosed in a patient, a medical workup must be performed to establish the need for anti-HCV therapy, which may require liver biopsies, psychiatric referrals, and optimization of other medical comorbidities. Anti-HCV treatment itself may then be quite time-consuming, with months of treatment and close follow-up to demonstrate viral clearance. It is unclear at what time an HCV-seropositive patient would be deemed "fit for the operating room": during treatment, after treatment, after a predefined disease-free period, and so forth. Furthermore, new HCV therapies (eg, oral protease inhibitors) are revolu-

tionizing the treatment of HCV and eliminating the need for poorly tolerated interferon treatments.[32,33,35] Yet, with any new treatment comes uncertainty about how that treatment should interface with major surgical procedures, such as TJA and SF. It may be too early for medical and surgical providers to integrate these factors into a universal HCV screening program, but orthopedic surgeons have an opportunity to address these challenges and lead surgical subspecialties in this arena.

Furthermore, the results of this study may not be generalizable outside other major US urban centers because of the unique patient population at our institution. For this reason, universal screening may be unjustified in community practice settings. However, it is interesting that our institutional rate of HCV is similar to other HCV estimates for the local geographic area, and that none of these HCV estimates differs significantly from the NHANES estimates for the United States at large.[10,14] Finally, because of the retrospective nature of our study and our deidentified source data, we were unable to estimate how many patients with already diagnosed HCV underwent surgery at our institution in 2011—information with the potential to have influenced our findings.

Conclusion

Orthopedic surgeons in the United States will soon find themselves performing many exposure-prone procedures on baby boomers, who are known to shoulder a large HCV disease burden, and many of whom will not know their infection status. Although we were unable to demonstrate an increased prevalence of HCV among our orthopedic population, a universally applied preoperative HCV screening program implemented at orthopedic surgery facilities may still benefit the health and safety of both patients and surgical teams. This presents the field of orthopedic surgery with a unique opportunity to change the public health of the United States for the good for decades to come. With this opportunity also comes the responsibility to tackle the challenges that implementation of a screening program presents.

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This paper will be judged for the Resident Writer's Award.