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As hep B outbreaks continue, CDC may urge HBV shot for millions of diabetics

Landmark recommendation expected from ACIP

By Gary Evans, BA, MA

Mr. Evans is Executive Editor of the Infectious Disease Group at AHC Media LLC, in Atlanta, GA; he writes for Hospital Infection Control & Prevention *and the HICprevent blog at http://hicprevent.blogs.ahcmedia.com/. This article originally appeared in the October issue of* Hospital Infection Control & Prevention.

A key advisory committee to the Centers for Disease Control and Prevention (CDC) is expected to recommend that millions of diabetics be immunized against hepatitis B virus (HBV), a move that could finally halt the recurrent and deadly HBV outbreaks linked to needles and devices used in glucose monitoring in a variety of health care settings. The CDC Advisory Committee on Immunization Practices (ACIP), which has been mulling the issue for more than a year, will likely make the recommendation to immunize diabetics for HBV at an Oct. 25-26, 2011, meeting in Atlanta, says **William Schaffner**, MD, an ACIP liaison member representing the National Foundation for Infectious Diseases.

"These outbreaks of hepatitis B occurring in hospitals and other health care facilities have really come to the attention of ACIP," he says. "If that is the way the vote goes, this [importance of HBV vaccination] will have to be intensely educated to people with diabetes and everyone taking care of patients with diabetes," he says. "It will have to be put on the list of quality assurance measures for the care of diabetic patients so we know that doctors actually do this."

In addition to HBV, outbreaks linked to blood glucose testing carry the threat of hepatitis C virus and HIV, neither of which have a vaccine. Though accurate surveillance data for these kinds of outbreaks are notoriously elusive, it does appear from the ongoing outbreaks that HBV is the prime threat of being transmitted via reused or improperly handled equipment. HBV is the most efficient transmitter of the common blood-borne viruses, its high-titer virus in blood residue easily persisting in the environment for days on inadequately disinfected equipment and surfaces.

"In patients who have diabetes it's important that they monitor their blood glucose level to determine the correct concentration and frequency of insulin administration," explains **Alice Guh**, MD, MPH, a medical epidemiologist in the CDC's Division of Healthcare Quality Promotion. "The concern is when devices used to administer insulin and check for blood glucose are not appropriately handled."

It must be duly noted that the CDC has had a standing recommendation that glucose fingerstick devices be restricted to individual use for more than 20

years. Yet this advice is ignored all too frequently, most recently in a clinic in Madison, WI, where thousands of patients are being evaluated for testing. It's a familiar, traumatic refrain: infection control breaches include reusing spring-loaded barrels of fingerstick devices for multiple patients, sharing the fingerstick devices among patients, and/or staff routinely administering the sticks without wearing gloves or performing hand hygiene between patients.

"Insulin pens really should be viewed in the same way that we see syringes and needles — this type of equipment should be dedicated to single patients use," Guh says. "The fingerstick device should really be a single-use, disabling type of device where the lancet could retract and provide an extra layer of safety and [ensure] the device can't be used again."

Though the threat of other blood-borne viruses would remain, a large HBV vaccination campaign in the diabetic population could disable a great threat to patient safety.

"I think it would be very substantial — it ought to essentially eliminate many of these outbreaks," says Schaffner, chairman of the department of preventive medicine at Vanderbilt University School of Medicine Nashville.

"While we at Vanderbilt and other places are doing a better job with infection control with these glucometers, the general sense is 'OK that's very good — but it's not sufficient,'" he adds. "The number of outbreaks that have occurred — particularly among older people — both in hospitals and in other health care facilities is substantial."

While most of the reported outbreaks have occurred in non-hospital settings, state and federal authorities are ratcheting up pressure in acute care — demanding strict infection control policies with glucose monitoring equipment. Though Vanderbilt thought they had an adequate program in place, Tennessee state health department inspectors decided the hospital needed to upgrade cleaning and documentation for blood glucose meters.

"That [state] survey brought this home to us in a very explicit fashion," Schaffner says. "We knew that glucometers were being used and we made the assumption that they were being used appropriately, but we clearly had to demonstrate to the surveyors that we had a very rigorous program in place on glucometer use and glucometer disinfection between patients. We had to be able to document that. We really jumped on that and put a lot of energy into it."

At the top of the agenda

The HBV immunization issue tops the agenda for the upcoming ACIP meeting, with the first two items listed being "HBV risk among adults with diabetes" and "assisted blood glucose monitoring." The latter term may essentially be a surrogate for higher risk of infection, as "assisted monitoring of blood glucose is typically performed in health care settings such as clinics, hospitals, and long-term care settings (e.g., skilled nursing facilities and assisted living facilities). Individuals who perform blood glucose monitoring either for themselves or on others must be aware of basic safe practices to protect against infection transmission," the CDC states.

There have been numerous jarring exceptions to that rule, resulting in at least 16 outbreaks of HBV infection in the United States since 2004 — all linked to sharing or other inappropriate reuse of blood glucose monitoring

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equipment in assisted-living facilities.[1] However, earlier this year the CDC reported an outbreak that may have tipped the scales. To put it bluntly, six diabetics who died of HBV complications would likely be alive today if they had been vaccinated against the virus. On Oct. 12, 2010, the North Carolina public health officials were alerted by a local hospital that they had four residents of a single assisted-living facility admitted with suspected acute HBV infection. The resulting investigation found unsafe practices at the facility, including sharing of reusable fingerstick lancing devices approved for single patient use only and shared use of blood glucose meters without cleaning and disinfection between patients. And here, another telling point: None of the 25 residents who had not been assisted with blood glucose monitoring were infected. However, eight of the 15 residents whom facility staff had assisted with blood glucose monitoring had HBV infections.

HBV prevalence across broad spectrum

In the North Carolina case, safety single-use devices were required at the facility and HBV vaccine was offered to all susceptible residents. Now ACIP is poised to recommend that CDC do the same thing nationally, but something has also bubbled to the surface as the data were gleaned. While one of the original discussion points on this issue was whether to just vaccinate diabetics in long-term care, ACIP has found a striking HBV prevalence throughout all age groups.

"As they have investigated this further, [ACIP found] that at every age going down to young adulthood, diabetics have a higher rate of HBV than their non-diabetic counterparts, [even when] controlled by age, demographics, and every other way you can control," Schaffner says.

Why? It may have something to do with the small part of an iceberg at its highest point above water. As infection preventionists are well aware, the reported outbreaks of HBV and HCV are dwarfed by the unreported ones and the sporadic transmission moving under the radar. These infections may be counted among hepatitis cases of unknown origin, though some health departments and IPs at times make heroic efforts to try to find a health care connection. For example, the CDC reports that in 2006, national viral hepatitis surveillance data revealed that 50% of patients with acute HBV and HCV were reported without accompanying risk factor data.[2] Among patients for whom risk factor data were reported, 56% with acute HBV infection and 32% with acute HCV infection could not specify a known risk factor for their infection (such as injection drug use, sexual or household contact with another infected person, occupational exposure to blood, or needlestick injury.) A published CDC review of outbreak information revealed 33 outbreaks in non-hospital health care settings in the prior decade, including 12 in outpatient clinics, six in hemodialysis centers, and 15 in long-term care facilities, resulting in 448 people acquiring HBV or HCV infection.[3] The data did not include specific information on the subset of diabetics, but one is tempted to conclude that much of the HBV prevalence in the population may be linked to health care settings.

"It has been a struggle to understand this — obviously diabetics as a group have much more exposure to needles," Schaffner says. "There is this sense of needle sharing, [is that] where does this increased risk of HBV come from? That remains an enigma, but every way you parse it, these

CDC recommendations for HBV vaccination

Who should be vaccinated against hepatitis B? The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices currently recommends that the following persons be vaccinated against hepatitis B:

- All infants, beginning at birth
- All children aged < 19 years who have not been vaccinated previously
- Susceptible sex partners of hepatitis B surface antigen (HBsAg)-positive persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., > 1 sex partner during the previous 6 months)
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sex with men
- Injection drug users
- Susceptible household contacts of HBsAg-positive persons
- Health care and public safety workers at risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease, including predialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to regions with intermediate or high rates of endemic HBV infection
- Persons with chronic liver disease
- Persons with HIV infection
- **All other persons seeking protection from HBV infection — acknowledgment of a specific risk factor is not a requirement for vaccination** ■

investigations have found the increased risk remained."

The prevalence of HBV in diabetic populations will no doubt be detailed at the ACIP meeting, but unpublished CDC data provided to the committee previously reveals that diabetics comprise some 10% of all HBV infections in adults age 25 years and older. The other compelling factor for vaccination is the bad outcome in patients when these diseases converge. Increases in liver-associated hospitalizations and all-cause mortality with chronic HBV are reported among adults with diabetes and hepatitis. Knowing that at least some of these disturbing patient outcomes were caused by viral transmission in medical or long-term care settings, puts an ethical onus on ACIP to act. For Schaffner, it's a no brainer. Hepatitis vaccination should include diabetics and everybody else.

"There isn't any doubt about it — we ought to immunize young adults [for HBV] universally," he says. "We have kind of a schizophrenic immunization policy in the United States. Up until the 19th birthday we immunize universally for HBV and then beyond that it remains a traditional risk-based immunization program."

Though the latest CDC recommendations state that anyone can be immunized that wants to get the vaccine, Schaffner says for all practical purposes a perfectly good vaccine has been historically undermined by unnecessary risk assessments prior to administration.

"You have to, in effect, 'qualify' for hepatitis B immunization," he says. "It seems kind of paradoxical because young adults are just entering that period of more widespread sexual activity. You have to go to the doctor and say I have multiple sex partners or one thing or another. You have to qualify by having had some exposure before you can get immunized."

Despite such concerns, he concedes that ACIP is not likely to go beyond diabetics in recommendations to the CDC. "I don't think ACIP is ready yet to just advance universal immunization until age 30 or 40 or whatever it might be established more or less arbitrarily," Schaffner says. "But [a recommendation to immunize diabetics] would extend the protection against HBV to a very large and obviously growing segment of the population." ■

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Medication Poisonings Are Increasing in Children

In this issue: Medication poisonings in children; rosuvastatin vs atorvastatin for atherosclerosis; saw palmetto for prostate symptoms; using atypical antipsychotics for off-label indications in adults; and FDA actions.

More medications, more poisonings

Medication poisonings among young children have increased in frequency in recent years despite safety measures to prevent them, according to a new study from *Pediatrics*. Researchers used patient records of more than 450,000 children 5 years old or younger from 2001-2008. The rate of poisoning increased by about a third during this time span compared to the prior decade. Child self-exposure was responsible 95% of the time with ingestion of prescription drugs causing more than half of the poisonings and more than 70% of significant injuries. The most dangerous drugs were opioids, sedative-hypnotics, and cardiovascular agents. The authors conclude that the number of children visiting emergency departments after medication exposure is increasing, with the majority of ingestions caused by children finding and ingesting medications by themselves. They suggest that efforts at poison-proofing homes with young children "may be a good, but insufficient, strategy." They further suggest that the increase in poisonings is in part due to the rise in number of medications in the environments of young children, with the number of adults taking medications, especially opioid medications, rising dramatically in the last 10 years. Other possible explanations include more siblings on medications, especially ADHD meds, as well as exposure to grandparents' homes where child-proofing may not be as rigorous. They further conclude that current preventive efforts are inadequate and new measures, such as efforts targeting home medication safety (including storage of medications and child-resistant closures) and repackaging (such as blister packs and flow restrictors on liquid medications), should be considered. (*Pediatrics* published online September 16, 2011.) ■

Rosuvastatin no better than atorvastatin

Rosuvastatin is no better than atorvastatin in slowing progression of coronary atheroma, according to AstraZeneca, the manufacturer of rosuvastatin and sponsor of the study. Researchers compared rosuvastatin 40 mg to atorvastatin 80 mg in the Study of Coronary Atheroma by Intravascular Ultrasound: Effect of Rosuvastatin vs Atorvastatin (SATURN) trial. The primary efficacy endpoint was change from baseline in percent atheroma volume in a targeted coronary artery as assessed by intravascular ultrasound. After 104 weeks of treatment in some 1300 patients, there was a numerical greater reduction in favor of rosuvastatin, but the reduction did not reach statistical significance (astrazeneca.com/Media/Press-releases). The full results will be presented at the American Heart Association meeting in

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November. The results come as a blow to the manufacturer of rosuvastatin (Crestor) who had hoped to gain a marketing advantage before the introduction of low-cost generic atorvastatin into the market, slated for December. ■

Saw palmetto for prostate symptoms

Saw palmetto is ineffective for treating lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH), even at higher doses, according to a new study. Previous studies have shown no benefit from saw palmetto, but researchers in this current study set out to test the efficacy of 2-3 times the normal daily dose on men over the age of 45 with significant LUTS. The main outcome was the difference in American Urologic Association Symptom Index score between baseline and week 72. Both saw palmetto and placebo led to an improvement in symptoms with a favorability toward placebo regardless of the dose of saw palmetto. Doses tested were a single 320 mg tablet per day with dose escalation to 2, then 3, tablets per day. The authors conclude that increasing doses of saw palmetto root extract did not lower LUTS more than placebo in men with BPH (*JAMA* 2011;306:1344-1351). This is the second rigorously controlled trial after the Saw Palmetto Treatment for Enlarged Prostates study (*N Engl J Med* 2006;354:557-566) to show no benefit from the supplement on LUTS in men with BPH. ■

Off-label use of atypical antipsychotics

Controversy surrounds the use of atypical antipsychotics for off-label indications in adults, especially the elderly with dementia. A new meta-analysis reviews the evidence of efficacy of these drugs for various off-label uses. Of more than 12,000 studies considered, 162 were included in the analysis. Drugs reviewed included risperidone (Risperdal), olanzapine (Zyprexa), quetiapine (Seroquel), aripiprazole (Abilify), ziprasidone (Geodon), asenapine (Saphris), iloperidone (Fanapt), and paliperidone (Invega). For elderly patients with dementia, a small but statistically significant improvement in symptoms such as psychosis, mood alterations, and aggression were seen with aripiprazole, olanzapine, and risperidone. For generalized anxiety disorder, quetiapine was the most effective, while for obsessive-compulsive disorder, risperidone was associated with a 3.9 greater likelihood of favorable response, compared with placebo when used with antidepressants. There was no benefit seen with any of the drugs used in treating eating disorders, substance abuse, or insomnia, and only marginal benefit in personality disorders or posttraumatic stress disorder. All of these drugs have a boxed warning regarding increased mortality in elderly patients with dementia and increased risk of suicidality. Increased risk of death was seen in elderly patients with a number needed to harm (NNH) of 87. Also noted was increased risk of stroke, especially with risperidone (NNH = 53), extraparametal symptoms (NNH = 10 for olanzepine, NNH = 20 for risperidone), and urinary tract symptoms (NNH range = 16-36). Weight gain was also a problem in non-elderly adults, particularly with olanzapine (incidence of more than 40%), while akathisia was more common with aripiprazole. Other common side effects included fatigue, sedation, and extrapyramidal symptoms. (*JAMA* 2011;306:1359-1369). ■

FDA actions

The FDA has issued a warning regarding the potential for arrhythmia associated with the antinausea drug ondansetron (Zofran). The drug should be avoided in patients with QT prolongation as they are at particular risk of developing torsade de pointes. Ondansetron should be used with caution in patients with congestive heart failure, bradyarrhythmias, those predisposed to low potassium or magnesium, and in those taking drugs that cause QT prolongation. These patients should have electrocardiogram monitoring if ondansetron is indicated. The FDA is requiring new labeling changes to reflect these warnings.

The FDA is reminding physicians and patients that epinephrine inhaler (Primatene Mist), the only over-the-counter inhaler for asthma, will be removed from the market on December 31. The withdrawal is due to an international ban on chlorofluorocarbon propellant. The FDA is recommending that physicians ask their patients with asthma if they use Primatene Mist and talk to them about prescription alternatives.

The FDA has approved infliximab (Remicade) to treat moderate-to-severe ulcerative colitis (UC) in children 6 years and older who have had inadequate response to conventional therapy. The drug is already approved for adults with UC. The approval was based on a randomized, open-label trial of 60 children ages 6 to 17 with moderate-to-severe UC. The drug carries a boxed warning for serious infections and cancer. Infliximab is manufactured by Janssen Biotech. ■