Public health response to a large-scale endoscopy infection control lapse in a nonhospital clinic

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J Willmore, E Ellis, V Etches, et al. Public health response to a large-scale endoscopy infection control lapse in a nonhospital clinic. Can J Infect Dis Med Microbiol 2015;26(2):77-84.

OBJECTIVE: To determine whether transmission of blood-borne pathogens (BBPs) (hepatitis B virus [HBV], hepatitis C virus [HCV] and HIV) occurred as a result of endoscopy reprocessing failures identified during an inspection of a nonhospital endoscopy clinic in 2011.

METHODS: The present analysis was a retrospective cohort study. Registered notification letters were mailed to 6992 patients who underwent endoscopy from 2002 to 2011 at one Canadian nonhospital endoscopy clinic, informing them of the infection control lapse and offering BBP testing. Multimedia communications and a telephone line supplemented notification. A retrospective study of patients with BBPs was performed with viral genetic testing and risk factor assessment for eligible patients. Risk for infection among patients whose procedure was within seven days of a known positive patient was compared with those whose procedure was performed more than seven days after a known positive patient. The seven-day period was selected as the period most likely to present a risk for transmission based on the documented cleaning procedures at the clinic and the available literature on virus survival.

RESULTS: Ninety-five percent (6628 of 6992) of patients/estates were contacted and 5042 of 6728 (75%) living patients completed BBP testing. Three were newly diagnosed with HBV and 14 with HCV. Twenty-three and 48 tested positive for previously known HBV or HCV, respectively, 367 were immune to HBV due to natural infection and one, due to immunization. None tested positive for previously known HBV or HCV, respectively.

CONCLUSIONS: Endoscopy reprocessing failures were not associated with an increased risk for BBP among individuals tested.

Key Words: Endoscopy; Infection control lapse; Public health

More than 1.6 million endoscopic procedures are performed annually in Canada (1). The increasing proportion of colonoscopies and other medical procedures being performed in nonhospital (NH) clinics (2) prompted the College of Physicians and Surgeons of Ontario (CPSO) to launch the Out-of-Hospital Premises Inspection Program in 2010 (3). Before this program was implemented, NH facilities performing procedures such as endoscopies were not inspected. The incidence of infections (primarily bacterial) associated with endoscopy has been reported to be one case per 1.8 million (4). This may underestimate incidence due to a lack of postprocedure surveillance and underreporting. Despite the low estimated incidence of infection, several large-scale endoscopy-related outbreaks and notifications have been reported in the literature (5, 6). Few have established transmission of blood-borne pathogens (BBP), such as hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV, as a result of reprocessing errors (7-9). However, HBV and HCV can survive on inanimate surfaces for several days after a known positive patient. The seven-day period was selected as the period most likely to present a risk for transmission based on the documented cleaning procedures at the clinic and the available literature on virus survival.

Funding: The present analysis was supported by a grant from the Canadian Institutes of Health Research (CIHR).
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OPH (23,28).

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of secondary transmission of BBP to others by infected patients
public from harm (26) also supported disclosure, due to the possibility
and/or public health officials was warranted (23,24). Public health
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Principles of patient autonomy, the right to know and the professional

The risk for infection with HBV, HCV and HIV was estimated using
stakeholder communication, risk evaluation and investigation (20).
The risk for infection was estimated to be <1 in 1 million patients for
HBV, <1 in 50 million patients for HCV and <1 in 3 billion patients for
HIV (22). This process is described in more detail in Appendix 1.

Ethics considerations
Clinical and public health ethics principles and values were con-
considered in deciding whether patient notification was indicated (22).
Principles of patient autonomy, the right to know and the professional
duty to disclose led to a conclusion that disclosure by the physician
and/or public health officials was warranted (23,24). Public health
principles of do no harm (nonmaleficence) (25) and protection of the
public from harm (26) also supported disclosure, due to the possibility
of secondary transmission of BBP to others by infected patients
unaware of their infection.

The potential harm of patient distress and anxiety about poten-
tial infection with a BBP (however small the risk) that could arise
with disclosure was considered (27). However, disclosure is ethical
even when the chance of harm is extremely low, although steps must
be taken to minimize patient anxiety. Following the principle of
transparency, disclosing risk information to patients was determined
to be an ethical course of action that would maintain public trust in
OPH (23,28).

Patient identification and notification
A ‘confirmed patient’ underwent an endoscopic procedure in the
clinic between April 1, 2002 and June 1, 2011, based on Ontario
Health Insurance Plan (OHIP) billing records, clinic records for
patients not billed through OHIP, or a plausible history from a self-
identified patient lacking billing and clinic records. OPH compiled
and managed all patient information related to the response in a
secure Microsoft Access database (Microsoft Corporation, USA).

A package was sent by registered mail or personal delivery (to
allow for tracking of package receipt or return) to each patient including a
letter signed by the Ottawa Medical Officer of Health and the clinic
physician. The letter described the infection control lapse (ICL), stated
the estimated numeric risk of BBP infection, offered testing (but did
not specifically recommend testing), provided instructions for obtaining
free laboratory testing using a prepopulated Public Health Ontario
Laboratory requisition (to improve access and facilitate surveillance),
conveyed the clinic physician’s regret for the incident, and provided a
dedicated OPH telephone number and website for further information.
Telephone metrics were tracked through Prairie Fyre, a contact man-
agement software, and patient satisfaction data were logged electronic-
ally by nursing staff who managed the telephones. Local family
physicians, infectious disease specialists, gastroenterologists and emer-
gentologists were also notified. Traditional and social media were used
to inform patients who could not be reached through postal mail.

Case identification
A ‘case patient’ had laboratory evidence of an acute, chronic, occult or
past HBV infection, an HCV infection or an HIV infection, based on
current test results or previously known test results in Ontario’s report-
able disease database. All assays were performed using a chemilumini-
escent microparticle immunoassay (Architect i2000SR, Abbott
Diagnostics, USA). Assays included qualitative detection of antibody
to hepatitis B surface antigen (anti-HBsAg), hepatitis B surface anti-
gen (HBsAg), antibody to hepatitis B core antigen (anti-HBcAg),
antibody to HCV (anti-HCV) and HIV p24 antigen and antibodies to
HIV type 1 and/or type 2 (HIV-1/HIV-2). Patients were classified as poten-
tially infected with HBV (HBsAg positive), or with evidence of previ-
ous or occult infection (HBsAg negative, anti-HBC positive, and
anti-HBs ≤100 mIU/mL) were classified as HBV cases. Patients
were considered to be immune due to immunization if they were anti-
HBsAg positive, HBsAg negative and HBC negative. Patients with
positive anti-HCV were classified as HCV cases. HIV-seropositive
patients were classified as HIV cases. All samples that tested positive
using the initial chemiluminescent microparticle immunoassay were
subject to confirmatory testing.

HBV DNA and HCV RNA testing and sequencing
Patients with HBsAg-positive serum samples and those that were poten-
tially occult cases of HBV infection (in the present study, HBsAg
negative, anti-HBC positive, and anti-HBs ≤100 mIU/mL) were eli-
gible for HBV DNA testing and eligible samples were sent to the National
Microbiology Laboratory, Public Health Agency of Canada for
blinded HBV DNA testing. Anti-HCV serology positive patients
who had not demonstrated undetectable HCV RNA previously were
eligible for HCV RNA testing. Samples were sent to the National
Microbiology Laboratory for blinded HCV RNA testing. If nested
polymerase chain reactions (PCRs) determined viral nucleic acid posi-
tivity (detection limit between 5 IU/mL to 10 IU/mL) in serum sam-
ple, HBV DNA and HCV RNA extracted from clinical samples were
genotyped and sequenced to assess phylogenetic relatedness of viral
samples collected from case patients.

HBV DNA was extracted from 200 μL of sera using silica gel filtra-
tion (easyMAG, bioMérieux, Canada) or phenol/chloroform extrac-
tion methods to optimize sensitivity (29). Extracted DNA was
amplified according to previously published procedures (30,31).
Samples that could be amplified by at least two different region-specific
primer sets and were HBsAg negative, anti-HBC positive and anti-HBs
≤100 mIU/mL were considered to be occult HBV infection positive
(32). A total of 315 base pairs, consistent across all patients, were quer-
yed during phylogenetic analysis. The gene sequence evaluated for
HBV was the surface/polymerase overlapping sequence. Sanger sequen-
cing provided analysis of the dominant population within the patient
quasispecies, which allowed for adequate tracing of transmission events.

HCV RNA was extracted from 250 μL of sera using the automated
nucleic acid extraction system NucliSSENS easyMag (bioMérieux Inc,
USA) and amplified, gel purified, then cycle sequenced with an ABI
Prism 3100 Genetic Analyzer (Applied Biosystems, USA) using BigDye
v3.1 terminator chemistry. Sequence data obtained were used to deter-
mine the HCV genotype of each viral sample and further analysis was

days depending on conditions (10-14) and infections may go undetected
for long periods of time, with serious health consequences (15).

In May 2011, an NH endoscopy clinic in Ottawa, Ontario, was
inspected by the CPSO and significant deficiencies in the cleaning and
disinfection of the endoscopes since 2002 were identified. Specifically,
the inspection found cross-contamination from a dirty endoscope,
inadequate decontamination of biopsy forceps, improper use of endo-
scope processor for high-level disinfection of endoscopes and steriliza-
tion of instruments such as biopsy forceps, and no proper cleaning of
premises between patients (16). CPSO ordered the clinic physician to
tease performing endoscopies at the clinic and notified the Ontario
Ministry of Health and Long-Term Care (MOHLTC) about the issue.
The MOHLTC notified Ottawa Public Health (OPH), the local public
health department. The main objectives of OPH were to assess the risk
of transmission of HBV, HCV and HIV to patients and to determine
whether a public health response was needed.

METHODS
A decision to notify patients was made by OPH based on assessments
of infection risk and ethics considerations, and in consultation with
experts in these areas. Due to the large number of affected patients, the
clinic could not independently undertake notification and follow-up.
An epidemiological investigation, including genetic analysis, was
designed to assess whether there was evidence of patient-to-patient
transmission of BBP.

Infection risk
The risk for infection with HBV, HCV and HIV was estimated using
prevalence estimates (17-19) and the Rutala and Weber methodology
(20,21) recommended by the Public Health Agency of Canada. This
methodology includes a 14-step protocol for situation management in
the event of a possible failure of disinfection or sterilization that could
expose patients to an infectious agent. It includes situational evalua-
tion, stakeholder communication, risk evaluation and investigation (20).
The risk for infection was estimated to be <1 in 1 million patients for
HBV, <1 in 50 million patients for HCV and <1 in 3 billion patients for
HIV (22). This process is described in more detail in Appendix 1.

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performed to determine their phylogenetic relatedness. Genetic distances were estimated by Kimura two-parameter analysis, and a phylogenetic tree was constructed using the maximum likelihood method (33). Significant taxonomic relationships were identified by bootstrap resampling analysis (200 replicates) using the maximum likelihood method. Bootstrap values of ≥70% indicate that the topology of that branch within the phylogenetic tree were considered to be significant or ‘related’.

**Prevalence, risk factor and OR analysis**

To determine whether there was a higher than expected prevalence of any BBP, the prevalence among those tested as a result of the notification was compared with the estimated prevalence in the population of Ottawa (HBV), Ontario (HCV) or Canada (HBV) (as available in the literature), using a Pearson’s \( \chi^2 \) test at \( p = 0.05 \) (17-19).

Public health nurses conducted standardized telephone interviews of case patients regarding any previous test results, HBV immunization and lifetime exposure to recognized risk factors for acute infection (34,35). If the case patient was unavailable and a previous interview record existed, information was abstracted from the provincial reportable disease database. Risk factor responses were collated into mutually exclusive risk factor categories using a previously published hierarchy (35,36).

Odds of infection were calculated using Stata version 12.2 (StataCorp, USA). In this analysis, a case was any confirmed patient who was HBV positive and for whom the HBV status was not known to be positive before their procedure. A control was any confirmed patient who tested negative for HBV. A case or control was considered exposed if they had a clinic visit within seven days after the visit of a known case patient. For the attribution of exposures, confirmed patients who were known to be positive before their endoscopy date were included as transmission exposures: they could act as a source of infection. These confirmed patients were excluded from the analysis because they did not meet case or control definitions. Patients whose laboratory tests indicated they were immune due to immunization were excluded if the vaccination was definitively before their endoscopy procedure. Because some patients had multiple visits, each visit was considered to be an independent case or control visit and the risk analysis was performed on ‘patient-visits’ rather than individual patients.

The seven-day duration for temporal linking was selected by considering the extent to which endoscope cleaning occurred according to clinic records, although insufficient according to the guidelines (37), and evidence of virus survival in the literature (10-14). Given that HBV and HCV can go undetected for long periods of time (15), all case patients were assumed to be infectious at the time of their clinic visit. Exposure periods of 14 days and 28 days were also used as a sensitivity analysis.

### RESULTS

**Notification results**

The notification process resulted in 95% (6628 of 6992) of confirmed patients or estates receiving a package by registered mail or delivery (Table 1). More packages were mailed than confirmed patients due to address changes, and lost or returned packages.

**Viral test results**

Of 6728 confirmed living patients (96% of 6992 confirmed patients or estates of confirmed patients), 5042 (75%) completed viral testing for at least one BBP as of May 11, 2012. Among living patients, 62% (4173 of 6728) were female and the median age (as of January 1, 2011) was 55.2 years (range 15 to 99 years), older than the 2011 Ontario median age of 40.4 (38). Data regarding sex were missing in 319 cases (4.7%) and age in 171 (2.5%). There were 442 (8.8% of 5042) case patients identified who tested positive for a past or current infection with HBV or HCV, including 12 coinfections (Figure 1). No HIV cases were identified. One

**TABLE 1**

| Patient notification results, as of April 2012 |
|-----------------------------------------------|
| **Notification process** | **n (%)** | **Total, n** |
| Confirmed patients identified | 6992 | 6992 |
| Patients confirmed alive at time of notification | 6728 (96.2) | 6992 |
| Packages sent to patients and estates | 7310 | |
| Patients or estates reached by registered mail | 6628 (94.8) | 6992 |
| Patients who received testing for at least one BBP | 5042 (74.9) | 6728 |
| Patients tested for HIV | 5042 (74.9) | 6728 |
| Patients tested for HBV | 4703 (69.9) | 6728 |
| Patients tested for HCV | 4730 (70.3) | 6728 |
| Stakeholders notified (eg, physicians, laboratories, hospitals, public health units) | 1400 | |
| Calls received by OPH from patients, members of the public | 5203 | |
| Calls made by OPH nurses notifying patients of negative laboratory results | 4686 | |
| Calls received by OPH from physicians/other health care providers | 68 | |
| Patients reached by letter to inform them of option for genetic sequencing | 216 | |

**BBP** Blood-borne pathogen; **HBV** Hepatitis B virus; **HCV** Hepatitis C virus; **OPH** Ottawa Public Health

### Case demonstrated immunity to HBV due to vaccination.

Forty-eight of 62 HCV cases (77.4%) and 23 of 26 of those with current HBV infection (88.5%) were known from Ontario’s reportable disease database. Fifty-six percent (247 of 442) of case patients were female, and the median age was 58.2 years (range 24 to 90 years). Results of initial viral testing in the patients tested as a part of the epidemiological investigation were compared with available general population prevalence estimates for HIV (Ottawa estimate), HCV (Ontario estimate) or HBV (Canadian estimate) (17-19) using Pearson’s \( \chi^2 \) test (Table 2). The prevalence of HBV and HIV was significantly lower than expected, past infection with HBV was within the expected range and the prevalence of HCV was not significantly different than expected.

Ninety-three percent (324 of 350) of HBV or HCV case patients who could be interviewed reported alternate risk factors to endoscopy at the clinic. Patients were assigned to the risk factor with the highest risk (Table 3). Decedents (n=34) and patients who could not be reached and did not have a patient file available (n=31) were excluded.

Statistical analysis did not detect increased odds of HBV or HCV infection among patients potentially exposed to a case patient (Table 4). One case was removed from the analysis because this case was definitively immune before their endoscopy. Sixty-three HBV-positive patients and 50 HCV-positive patients were removed from the risk analysis because they were known to be positive before their procedures. Fourteen- and 28-day periods were also used as periods of exposure, and neither detected increased odds of HBV or HCV infection among exposed patients.

### HBV DNA test results

Of HBV cases, 182 were eligible for and were offered DNA testing. A total of 130 HBV DNA tests were performed on 18 HBsAg-positive specimens, 88 HBsAg-negative specimens and 24 specimens in which the HBsAg status was not provided. Twenty specimens were DNA positive according to PCR. Five HBsAg-negative, anti-HBc-positive and anti-HBs-positive (≤100 mIU/mL) specimens, and one specimen in which the HBsAg status was not provided, were considered to be PCR indeterminate because the initial positive PCR result could not be replicated with different primer sets. The 26 sequences were phylogenetically analysed. Three specimens were considered to be occult HBV infection positive (HBsAg negative and PCR positive in different genomic regions). Transmission of HBV related to endoscopy procedures at the clinic was unlikely, as
indicated by insufficient sequence similarity based on genotype and placement on the tree (Figure 2C).

HCV RNA test results

Samples from 27 of 55 eligible anti-HCV-positive patients were tested for HCV RNA; of these, 23 were positive with a viral load ranging from $3.57 \times 10^4$ IU/mL to $2.46 \times 10^7$ IU/mL. Samples from all 23 HCV RNA positive patients were genotyped; subgenotype 1a was the most common (10 cases) followed by subgenotype 1b (six cases). Three cases belonged to subgenotype 3a, three to genotype 4 and one to subgenotype 2a (Figure 2A). One of the three genotype 4 cases belonged to subgenotype 4a, commonly found in Egypt, while the other two were the rarely observed subgenotypes 4v and 4r. A possible transmission event could have occurred only within cases belonging to the same subgenotype.

Analysis of all 1a and 3a cases did not identify clusters of phylogenetically related HCV strains among these patients except for samples H0296/12 and H0501/12; however, these were duplicate samples from the same patient (the laboratory tested all samples in a blind manner). Similarly from the six subgenotype 1b cases, sample pairs H0295/12-H0500/12 and H1284/12-H5899/11 carried identical HCV sequences; however, they were also found to be duplicate specimens from the same patients. Interestingly, these two HCV strains were phylogenetically associated (bootstrap value = 87%); however, the epidemiological data did not confirm possible transmission because the visits of these two patients were one year apart. To further investigate the discrepancy between the phylogenetic and epidemiological data, these two HCV strains were analyzed within the NS5B region.
DISCUSSION

The public health response to a large-scale ICL in an NH endoscopy clinic included a risk assessment and ethics analysis resulting in a decision to notify almost 7000 patients, and to conduct further epidemiological and genetic investigation of case patients. Our investigation found no evidence for an increased risk of BBP acquisition associated with the endoscopy reprocessing failure. Although three new cases of HBV and 14 new cases of HCV were identified, we did not find any related sequences with an epidemiological link among patients with viral genetic analysis results and most case patients identified alternative risk factors. Additionally, the prevalence of BBP in the patient population that went for testing was not clinically higher than expected, particularly given that the median age of the patient population was older than the Ontario population and the fact that some patients were undergoing endoscopic procedures because of their HBV or HCV infection. The odds of infection were not significantly higher for patients who underwent a procedure within seven days after a known HBV or HCV case. These data argue against viral transmission during the endoscopic procedure and confirm what others have found with respect to the extremely low risk of transmission of BBP through endoscopy reprocessing failures (7-9).

Successful contact with 95% of patients was within the range (84% to 99%) achieved in similar notification processes in other jurisdictions (7-9, 15, 39). Factors possibly contributing to the high connection rate included the multipronged communication strategy, as well as repeated attempts to contact patients who did not receive their packages. Patient satisfaction was high on timeliness of services delivered, information provided and staff knowledge, competence and courtesy; the dedicated

Figure 2B and no support for phylogenetic relatedness was found. These observations highlight the importance of using more than one genetic region for phylogenetic analysis.
telephone line was considered to be essential to this outcome and to minimizing patient anxiety. The collaboration between OPH and local, provincial and national laboratories resulted in follow-up of the 75% of patients who chose to get tested. The investigation took almost one year to complete, due to multiple factors including, but not limited to, the lengthy patient identification process, a higher volume of telephone calls from patients than expected, the high number of patients who chose to undergo testing, and the length of time to obtain and report sequential positive and negative results to patients and their physicians. Lack of a predesigned database to manage the large volume of data from various components of the investigation led to data quality and data management problems, which were solved over the course of the investigation.

Limitations to the investigation included the extended risk period (complicating patient follow-up and identification of relevant risk factors among case patients), incomplete clinic patient records, the lack of preprocedure BBP test results for most patients, and having to use general rather than age-specific population prevalence of the BBP to compare with the prevalence found among confirmed patients. Because 25% of patients were not tested, it is possible that associations between case status and exposure may have changed if the status of this group was known. Temporality of case status or viral load and a patient’s endoscopy visit could not be determined, in part because negative results for previously known cases are not reported to OPH. Positive patients were considered to be capable of transmitting infection in the OR analysis. The assumption that all positive patients were infectious may influence our outcomes toward the null. Risk factor information was missing for 8% of case patients, and these may be patients at greater risk for transmitting infection. Misclassification of exposures or case status could also affect the results. Because not all eligible patients underwent DNA/RNA testing, a relationship among cases may have been overlooked.

Knowledge gained from this response will be useful for infection control professionals, public health officials and clinicians planning for or managing a potential ICL or other adverse event. While the infection control risk assessment and ethical assessment pointed to the need for a public health response to disclose the ICL to patients, little guidance was available on the most appropriate methods to use. The notification letters to patients and physicians and the dedicated telephone line proved to be vital components of the response. However, we would not recommend the additional cost of registered mail for a patient whose address is likely reliable (such as their OHIP record). Traditional and social media should be used to capture patients who may have recently moved without notifying OHIP. Genetic analysis was essential to complement the epidemiological investigation once new BBP cases were identified.

Given that our findings support the extremely low quantitative risk of infection from an endoscopy-related ICL, unless clear evidence of transmission is found we recommend others follow the Centers for Disease Control and Prevention (Georgia, USA) guidelines for a Category B breach (40). This approach would use a qualitative description of the risk in patient and public communication, explicitly stating that due to the extremely low risk of having been infected, testing for the infections is not generally recommended, but would suggest that patients may call the dedicated telephone line with questions, or speak to their primary health care provider if they would like to discuss testing. Thus, a prepopulated laboratory requisition would not be needed in the package and staff time spent informing patients of negative results by telephone could be avoided. Public health staff would be notified of positive results for reportable BBP as per local protocol and epidemiological investigations of these cases should include questions regarding endoscopies. If new BBP cases among patients with epidemiological links are identified, genetic analyses of these cases and a recommendation for testing of others who share the link (eg, visit on the same day) may then be warranted.

In addition to regular inspections of NH clinics, requirements for reporting of regular training and retraining for NH staff involved in reprocessing could help to prevent future ICLs. A requirement to document which reusable scope or other instrument is used on which patient could assist in investigations. Because other ICLs had occurred elsewhere in the province, the MOHLTC convened a provincial Task Group on Community Infection Prevention and Control Lapses to make recommendations on how to reduce the number and scale of future lapses, and on consistent public health assessment and management in an ethical and cost-effective manner for ICLs that do occur (41).

ACKNOWLEDGEMENTS: The authors thank members of the Incident Management System and other staff at OPH who contributed to the ICL response, and Epidemiology and Laboratory Services at Public Health Ontario for assistance with laboratory processes and data management.

APPENDIX 1

Estimates for risk of disease transmission

An approach to assessing the risk of disease transmission when there is a failure to follow established infection control procedures has been published by Rutala and Weber (20), and this is the approach is recommended by the Public Health Agency of Canada (21). This method was used to conduct the risk of disease transmission of HIV, HBV and HCV. The following data elements were used to calculate the probability of disease transmission:

- Prevalence of infection (17-19);
- Risk of transmission – risk of transmission for endoscopy alone was calculated using the risk of transmission from mucosal exposure; for endoscopy with biopsy the risk of transmission from percutaneous exposure was used (42,43);
- Likelihood that a nondisinfected instrument was used – various percentages were used to obtain a range of estimates (1%, 10%, 25%, 50%, 75% and 100%);
- Efficacy of cleaning using automated endoscope reprocessor (44);
- Efficacy of disinfection for liquid chemical sterilant (glutaraldehyde). Endoscope reprocessing involves five steps: precleaning with enzymatic detergent, leak testing, manual cleaning and rinsing, high level disinfection and rinsing, and drying and storing. Automated endoscope reprocessors can be used to perform several functions, but manual cleaning must always be performed before placing the endoscope in a reprocessor.
- Data from the manufacturer of the reprocessor used at the facility states that exposure to the disinfectant plus washing in the reprocessor (appropriate length of time and temperature), results in an average log10 reduction in microorganisms (Mycobacterium terrae) of 8.2 to 12.2, depending on which endoscope surface was examined. Reprocessor cleaning alone resulted in a 3.4 to 4.6 log10 reduction (this would be approximately 99.99% effective). No information was available concerning reduction in viruses for this reprocessor.
- There were uncertainties regarding the effectiveness of the glutaraldehyde used because there was not evidence to show that it was tested for efficacy as required. Given this information and the uncertainties around the effectiveness of the glutaraldehyde used in the facility, risk estimates were calculated using the following two scenarios:

Scenario 1: Assume that the exposure to glutaraldehyde was completely ineffective and that any reduction in bioburden of microorganisms was obtained by washing alone; therefore efficacy of ‘cleaning/disinfection’ was a 4 log10 reduction (99.99%).

Scenario 2: Assume that the exposure to glutaraldehyde was effective for inactivating viruses and that the reduction in bioburden was 8 log10 (99.999999%).

Estimates for scenario 1

Endoscopy without biopsy:

- HIV 2.25×10^-11 to 2.25×10^-10
- HBV 4.6×10^-11 to 4.6×10^-9
- HCV between risks for HIV and HBV (no transmission risk available for mucosal exposure for HCV to create an estimate, but this approach agrees with the literature [20])
Endoscopy with biopsy:
- HIV: $2.7 \times 10^{-14}$ to $2.7 \times 10^{-10}$
- HBV: $1.2 \times 10^{-10}$ to $6 \times 10^{-7}$
- HCV: $1.7 \times 10^{-10}$ to $1.7 \times 10^{-8}$

Estimates for Scenario 2
Endoscopy without biopsy:
- HIV: $2.5 \times 10^{-14}$ to $2.5 \times 10^{-15}$
- HBV: $4.6 \times 10^{-13}$ to $4.6 \times 10^{-11}$
- HCV between risks for HIV and HBV (see explanation above)

The highest risk estimate was for HBV when a biopsy took place and assumed that the glutaraldehyde being used was ineffective – $6 \times 10^{-7}$ (6 in 10 million, 0.6 in 1 million).

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