



## Should we be doing endoscope surveillance cultures?

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Tens of millions of endoscopy procedures are performed each year around the world. These procedures, using flexible endoscopes that are mechanically complex and contain advanced fibreoptics, have revolutionised the diagnosis and management of numerous diseases. Endoscopes typically become heavily contaminated with blood, body fluids and micro-organisms during use, and because each endoscope may be used for multiple different patients even in a single day, it is essential to clean and disinfect them effectively between patients. Unfortunately, most contemporary flexible endoscopes cannot be heat-sterilised and have narrow internal channels that are difficult to clean and disinfect. Failure to effectively reprocess endoscopes has led to hundreds of reported infections complicating gastrointestinal and bronchoscopic procedures, including one report from New Zealand.<sup>1,2</sup> The most common micro-organisms implicated are *Salmonella* species, *Pseudomonas aeruginosa* and mycobacteria; probable transmission of HBV (Hepatitis B Virus) or HCV (Hepatitis C Virus) by endoscopy has been documented in only a few published cases and proven transmission of HIV by endoscopy has not been reported to the authors' knowledge.<sup>3-5</sup> The overall frequency of transmission of infection by gastrointestinal endoscopy has been estimated at 1 in 1.8 million procedures.<sup>6</sup>

Many guidelines for cleaning and disinfection of endoscopes have been written and the risk of transmission of infection is probably negligible when such guidelines are followed. Knowledge of and adherence to up-to-date guidelines is not universal,<sup>7,8</sup> however, and it is likely that inconsistent manufacturers' instructions,<sup>9</sup> automated disinfecting machine breakdowns or contamination, or internal damage to endoscopes will continue to unexpectedly occur, threatening patient safety in the future. In New Zealand, for example, there have recently been two well-publicised incidents in which effective endoscope disinfection and public safety have been questioned: one incident involved an automated disinfection machine malfunction and the other involved the use of an incorrect connector tube between endoscopes and a disinfection machine. In neither instance was there any evidence of infection transmission, despite comprehensive patient testing, but the incidents remind us of the importance of rigorous quality control in our endoscopy units.

Many aspects of endoscope reprocessing may be suitable for quality control monitoring, but none of this monitoring may be sensitive enough to reassure the user that cleaning and disinfection has removed all residual contamination from an endoscope. For example, staff performance errors may occur despite training and compliance checklists, automated disinfecting machine faults may go undetected by function tests and built-in fault detectors, regular maintenance activities (e.g. filter changes) may be interrupted, and tests of disinfectant activity can not be assumed to indicate activity in the internal channels of the endoscope, where damage or organic soiling may be hidden. Surveillance for infections or pseudo-infections following endoscopy may not be a sensitive or practical marker of effective cleaning and

disinfection, because such infections and pseudo-infections are rare, there might be asymptomatic or unrecognised transmission of micro-organisms and it is difficult to obtain patient samples after endoscopy. In contrast, culture of fluid flushed and brushed down the lumens of each endoscope appears to be a sensitive test of the effectiveness of the entire endoscope reprocessing process, from initial flushing to final rinsing.<sup>1,10-12</sup> Such cultures, when performed after inoculating an endoscope with a standardised quantity of a selected micro-organism (the Simulated Use Test),<sup>13</sup> represent the standard test for validation, comparison or post-installation verification of new products or equipment in the endoscopy industry. When performed without a standard inoculum but after patient use, cleaning and disinfection, these cultures lose some validity but are safer and simpler for staff to perform than the Simulated Use Test and may, in addition, detect contamination of an automated disinfecting machine, which the Simulated Use Test will not.

Some data support the use of endoscope surveillance cultures as a quality control tool. Positive endoscope surveillance cultures have been linked with transmission of infection to patients in numerous reports<sup>1</sup> and with breakdowns in cleaning or disinfection.<sup>10,11</sup> In Australia, Deva et al. recently found significant bacterial contamination together with amplified HBV, HCV and HIV nucleic material in endoscopes that were not optimally cleaned.<sup>12</sup>

Endoscope surveillance cultures are formally recommended by two specialist organisations in Australasia<sup>14,15</sup> and the French Society of Gastrointestinal Endoscopy.<sup>16</sup> Personal communications and at least one report<sup>11</sup> indicate that routine endoscope surveillance is performed in many endoscopy units in North America and Europe. The British Thoracic Society Bronchoscopy Guidelines Committee recommend users “consider” bronchoscope surveillance cultures<sup>17</sup> but microbiological endoscope surveillance is not mentioned in recent British Society of Gastroenterology guidelines.<sup>18</sup> Performed regularly, endoscope surveillance cultures have become popular in New Zealand as an accompaniment to other quality control checks in the reprocessing of endoscopes.

Others argue against the use of endoscope surveillance cultures. The tests are time-consuming and expensive, and it is apparent that most published transmission events involving endoscopy could have been prevented if other quality control processes had been followed, particularly those ensuring adequate cleaning and disinfection procedures. The surveillance culture methods currently in use or proposed have not been rigorously validated against reprocessing or patient outcomes; consequently, there is a danger, for example, that results may be mis- or over-interpreted, which could, in turn, lead to unnecessary investigations, patient testing or disruption to activities in endoscopy departments. Unnecessary public recall and testing is especially detrimental, as it can cause needless fear and avoidance of endoscopy in the community, leading to missed opportunities for diagnosis and treatment, and can be costly to the health-care provider in terms of time and other resources. Perhaps because of these arguments, the Association for Professionals in Infection Control and Epidemiology,<sup>19</sup> Centres for Disease Control and Prevention<sup>20</sup> and Society of Gastroenterology Nurses and Associates<sup>21</sup> do not recommend regular surveillance cultures of endoscopes. Instead, they recommend that endoscopes be cultured only if clinical or epidemiological findings suggest endoscopy-related transmission of infection.

These conflicting data and arguments were reviewed by a national-level expert committee, set up in 2000 by Standards New Zealand to review the use of endoscope surveillance cultures in New Zealand. Opinion was also sought from a variety of interested parties in New Zealand. It is clear that some important questions relating to these cultures are currently unanswered, including how well endoscopes are cleaned and disinfected in New Zealand, how effective endoscope surveillance cultures are at identifying problems with cleaning and disinfection, and how high the rate of transmission of infection is by endoscopy when a major failure of cleaning or disinfection occurs. The committee decided on balance to support the current practice of routine endoscope surveillance in New Zealand, provided there are rational guidelines for their performance and interpretation and expert support is available for endoscope users to consult in the case of a significant positive result or major identified failure in endoscope reprocessing. A comprehensive handbook on endoscope surveillance cultures was developed by the committee and published by Standards New Zealand in December 2001.<sup>22</sup> Because of the absence of direct evidence on which to establish authoritative standards, this handbook comprises a series of recommendations based on indirect evidence, principles of infection control and medical microbiology and a consensus of regional expert opinions; therefore, adherence to this handbook is not mandatory. Most importantly, the committee hopes that national-level standardisation of the methods for performing and interpreting these cultures will provide an opportunity for their formal, prospective evaluation. Therefore, the Standards New Zealand endoscopy committee intends to review in 2003 the results of endoscope surveillance cultures performed in New Zealand following the implementation of the handbook and compare these results with those of any concurrent investigations of cleaning and disinfection processes or patient recall and testing undertaken.

**Acknowledgements:** We acknowledge the contribution of the other members of the Standards New Zealand Endoscopy Expert Committee P8149 to the content of this editorial.

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