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Systematic risk assessment methods for the infection control professional

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Microbial and infectious disease risk models and tools are used to assess infectious hazards in the environment and to identify strategies to prevent or reduce these hazards. Although risk modeling of infectious threats represents a promising approach in applied epidemiology, there are inherent limitations to most models because of the multifactorial nature of the transmission of infections, the dynamic environment in which transmission takes place, and a paucity of available data to more fully specify model parameters. For example, the causal evidence for a link between hand hygiene and reduction in transmission of health care-associated infections is strong. Nevertheless, even though a simple mathematical model has been used to predict that very small increases in hand hygiene could bring endemic organisms under control,[1] it is still impossible to assess precisely the extent to which an incremental change in hand hygiene will increase or decrease risk of disease transmission because of the complexity and ever changing transmission factors that arise within varying health care settings.

Despite these limitations, predictive tools such as models or other systematic processes to assess transmission risk can be used to help structure decision making and to identify the need for further research. A model is similar to a working hypothesis in which unknowns exist, and outcomes will depend on the interaction of these unknowns. Models can serve to predict what and where the control points will be, and subsequent studies to test the ''fit'' of the model will help to measure the magnitude of each point's contribution to control. Hence, simple risk assessment processes can be useful tools for the infection control professional.

The purposes of this paper are to (1) introduce several processes adapted from the food and consumer industries, which could be applied to assess the risk of microbial transmission and the potential impact of interventions to prevent or control transmission in health care settings and (2) describe criteria to assess the usefulness of such tools. The Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) use several risk assessment formats for issues as far ranging as food safety, carcinogens, medical devices, radiation risk, pharmaceuticals, and biologics.[2,3] The use of such systems in these agencies illustrates the potential wide-scale utility of risk assessment. This report concludes with a discussion of how components of various risk assessment processes could be applied to the health care environment.

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PROCESSES USED TO ASSESS MICROBIAL RISK

Hazard analysis and critical control point

Widely used in the food service industry for years, the Hazard Analysis and Critical Control Point (HACCP) is a quality assurance system designed to provide a structure for developing a plan to identify and remove a risk. HACCP has also been used to investigate outbreaks and assess risks in the home and hospital.[4,5] Some of the hospital-based applications of HACCP include evaluating the cleanliness of a hospital laundry,[6] assessing hospital cleanliness in general and determining where the critical control points are,[7] developing a set of protocols to prevent postoperative

Table 1. Application of HACCP and microbial risk assessment frameworks to infection control practice*

Model	Phase	Process
Hazard Analysis and Critical Control Point (HACCP)	(1) Analyze hazards	(1a) Document an association between an infection and the presence of an organism in the environment. Assess epidemiologic evidence regarding severity of health consequences if potential hazard is not properly controlled
	(2) Identify critical control points	(2a) Review transmission modes of organism in question. Identify points at which transmission can be prevented or controlled
	(3) Establish preventive measures with critical limits for each control point	(3a) Implement preventive measure(s) and define a minimal level of adherence (eg, zero tolerance, at least 80% compliance, and others)
	(4) Establish procedures to monitor the critical control points	(4a) Develop surveillance plan to monitor adherence to the preventive measure(s) (eg, hand hygiene, aseptic technique for central line insertion, private rooms for infected patients, use of gowns and gloves)
	(5) Establish corrective actions to be taken when monitoring shows that a critical limit has not been met	(5a) Work with appropriate administrators to select appropriate corrective actions and assure that they will be implemented
	(6) Establish procedures to verify that the system is working properly	(6a) Continue surveillance/monitoring plan on an ongoing basis (eg, prevalence surveys)
	(7) Establish effective recordkeeping to document the system.	(7a) Develop electronic databases; assure that plan and surveillance data are also summarized in minutes of infection control/safety/quality control committee or other administrative meetings
Microbial risk assessment	(I) Risk assessment:	
	(1) Hazard identification	(1a) Document an association between an infection and the presence of an organism in the environment
	(2) Exposure assessment	(2a) Evaluate the level of the organism in the environment
	(3) Dose-response assessment	(3a) Determine whether the degree of exposure is likely to result in an infection
	(4) Risk characterization	(4a) Integrate the above information to make an estimate of the risk in the population of concern
	(II) Risk communication	Involve relevant others in risk assessment as well as plans for managing the risk in an interactive exchange of information and opinions
	(III) Risk management:	
	(1) Assess alternatives	(1a) Consider various prevention and control strategies
	(2) Select and implement appropriate options	(2a) Choose strategies which are practical, cost effective, and sustainable

*Adapted from Voysey and Brown[15] and Lammerding and Paoli.[22]

Table 2. Categories of environmental site-associated contamination risks and need for decontamination*

Category	Examples of sites in the health care setting	Probability of significant contamination (%)†	Risk of contamination transfer‡
Reservoir	Wet sites: humidifiers, ventilators, sinks	High (80-100)	Occasional
Reservoir/disseminator	Mops, sponges, other cleaning materials	Medium (24-40)	Constant
Hand and food contact surfaces	Chopping boards, kitchen surfaces, cutlery, cooking utensils	Medium (4-40)	Constant
Other sites	Environmental surfaces, floors, curtains	Low (3-40)	Occasional

*Adapted from Bloomfield and Scott.[17]
†The probability of risk of contamination was confirmed by an analysis of 70 environmental sites in 200 homes in the United Kingdom.
‡Note: This represents estimated risk of TRANSFER of contamination from environmental sources, not risk to individual patients.

endophthalmitis when traditional infection control measures failed,[8] identifying measures to decrease risk of further infection during a salmonella outbreak in a German hospital,[9] evaluating environmental and procedural sources of contamination in enteral feedings,[10] and assessing the quality and microbiologic safety of expressed breast milk on a neonatal unit.[11]

The 7 steps of HACCP are as follows: (1) analyze the hazards, (2) identify critical control points, (3) establish preventive measures with critical limits for each

Table 3. Criteria for evaluating the relevance of a risk assessment process*

Internal	
Logical soundness	Degree to which method can be justified theoretically and/or empirically.
	Operational validity: Are there problems with underlying methodologic assumptions?
Completeness	Theoretic comprehensiveness: Ability to account for all problem aspects.
	Operational comprehensiveness: Extent to which method purposely ignores certain considerations and information because they are hard to accommodate.
Accuracy	Precision: What confidence level can be associated with results?
	Bias: Is the method likely to give undue weight to any specific interest or consideration?
	Sensitivity to assumptions: Are results highly sensitive to untested or untestable assumptions?
External	
Acceptability	Compatibility with existing institutions and processes.
	Compatibility with social norms: Is the method viewed as ethical, rational, fair?
	Understandability: Are nontechnical people able to understand it?
	User confidence, familiarity, and experience with method.
Practicality	Level of expertise required to apply technique.
	Computational resources required to apply technique.
	Time required to apply technique: Can the method be applied in the time allowed?
	Input data availability: Are required inputs available? Is the method flexible in its ability to use different types of data?
Effectiveness	Usefulness of results: Do the results support important tasks or decisions?
	Range of applicability: Is the method applicable to different risks and problem areas?
	Generalizability: Are insights and conclusions generalizable to other problem areas?
	Does the method link effectively and efficiently with other types of methods?

*Adapted with permission from Covello and Merkhoffer[21] Figure 35, p. 240.

control point, (4) establish procedures to monitor the critical control points, (5) establish corrective actions to be taken when monitoring shows that a critical limit has not been met, (6) establish procedures to verify that the system is working properly, (7) and establish effective recordkeeping for documentation. For those interested in the potential application of HAACP to infection control problems, the system is described more fully on the FDA Center for Food Safety and Applied Nutrition Web site: http://vm.cfsan.fda.gov/~lrd/haccp.html.

Microbial risk assessment

In the 1990s, prompted by several US outbreaks of cryptosporidiosis and other pathogens in the water supply, the International Life Sciences Institute Risk Science Institute collaboratively with The EPA Office of Water convened a working group to develop a framework for assessing the risks associated with microorganisms in aqueous environments.[3] Because of increasing recognition that the HACCP system was limited because the considerations of hazards and their control were qualitative rather than quantitative, they developed a conceptual framework that used a more quantitative microbial risk assessment to determine standards for enteric microbes allowed in drinking water.[12,13] This quantitative risk assessment involves 3 phases: problem formulation (ie, clearly defining the purpose of the risk assessment), analysis (identifying the potential for human exposure and health effects), and final characterization of the risk. The analysis phase includes describing the characteristics of the pathogen (eg, virulence and prevalence) as well as the host (eg, susceptibility, dose response, potential seriousness of the exposure). In the final phase, the data obtained are combined to estimate and quantitatively describe the risk.

Quantitative microbial risk assessment[14] has been used in the United States, Canada, and the United Kingdom as a tool for stepwise analysis of health risks associated with an exposure and reaching risk management decisions based on the probabilities of infection.[3,12,15,16] The essential components for microbial risk assessment include not only the risk assessment itself but also communication and management regarding the environmental risk. The steps of HACCP and microbial risk assessment are outlined in Table 1, along with an explanation of how they might be applied to the practice of infection prevention and control in health care settings. Buchanan and Whiting have recommended that quantitative microbiologic risk assessment be integrated with HACCP to form a more dynamic, quantitative method of risk assessment.[12]

RISK CATEGORIES

The same concept of an incremental scale to define categories of infection hazard was used by Bloomfield and Scott,[17] Bloomfield,[18] and Bloomfield and Scott[19,20] to develop a schema for measuring risk of contamination in homes and for suggesting levels of

decontamination and disinfection. Their schema was based on 2 factors: the frequency of occurrence of major contamination at an environmental site as well as the probability of transfer from that site. Hence, even if a particular environmental site were highly contaminated, unless there was a high probability of transfer from that site, the risk of cross transmission would be low. An example in the hospital setting would be water in flower vases, which is highly contaminated but unlikely to be a source of transmission, unless, for example, it is discarded into a sink, which is subsequently not cleaned and used by a patient. Although we found no published reports of these risk categories being used in a health care setting, the schema adapted for the hospital environment in Table 2 may be useful for assessing the levels of risk from various potential fomites and vehicles of cross transmission.

ASSESSING THE UTILITY OF A RISK ASSESSMENT MODEL

Many infection control professionals may have already developed or adopted structured methods for assessment of the risk of infectious disease transmission from environmental sources. Other infection control programs have been integrated into broader quality assurance, risk management, or patient safety programs, which provide a structure for risk assessment. For those who have not yet adopted a formal structure for risk assessment, however, the tools described above may be useful. In addition, it is helpful to have criteria to assess any risk assessment system, model, and/or tool that are being used.

Covello and Merkhoffer[21] have proposed 6 criteria for evaluating risk assessment processes. These include logical soundness, completeness, accuracy, acceptability, practicality, and effectiveness. These terms are defined in Table 3. Such models and frameworks can be helpful to assure that all aspects of a problem are considered and to structure intervention plans and follow their progress in a systematic way. If a risk assessment strategy that meets these evaluative criteria is used to quantify risks and assess preventive strategies, it should be possible to move to a more sophisticated understanding of the complex interactions between the microbial environment and our own behavior and physiology that, in combination, results in various health outcomes. Although such models do not substitute for sound judgment, they are tools that can lead to a logical and effective course of action.[12]

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