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Methodological Quality Assessment of Review Articles Evaluating Interventions to Improve Microbial Food Safety

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Abstract
Review articles are a means of summarizing the potentially vast volume of research on a topic. However, the methodological quality of review articles varies, and reviews on the same topic may reach different conclusions. We evaluated 65 review articles published between 2000 and 2005 that addressed the effectiveness of microbial food safety interventions, using criteria for methodological soundness developed in the medical field. Overall, the methodological quality of the review articles was poor, with none of the reviews providing information on the method of locating primary research studies or the inclusion/exclusion criteria for selecting primary studies. None of the reviews included a critical appraisal of the methodological quality of the primary studies. Less than half of the reviews stated a focused research question, explored possible reasons for differences in the results of primary studies, discussed the generalizability of results, or proposed directions for future research. There is a need to improve the methodological quality of review articles on microbial food safety interventions if they are to be of use in policy and decision making.

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Disciplines
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Methodological Quality Assessment of Review Articles Evaluating Interventions to Improve Microbial Food Safety

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ABSTRACT

Review articles are a means of summarizing the potentially vast volume of research on a topic. However, the methodological quality of review articles varies, and reviews on the same topic may reach different conclusions. We evaluated 65 review articles published between 2000 and 2005 that addressed the effectiveness of microbial food safety interventions, using criteria for methodological soundness developed in the medical field. Overall, the methodological quality of the review articles was poor, with none of the reviews providing information on the method of locating primary research studies or the inclusion/exclusion criteria for selecting primary studies. None of the reviews included a critical appraisal of the methodological quality of the primary studies. Less than half of the reviews stated a focused research question, explored possible reasons for differences in the results of primary studies, discussed the generalizability of results, or proposed directions for future research. There is a need to improve the methodological quality of review articles on microbial food safety interventions if they are to be of use in policy and decision making.

INTRODUCTION

Foodborne diseases have been estimated to cause 76 million illnesses, 323,000 hospitalizations, and over 5,000 deaths annually in the United States (Mead et al., 1999). The costs associated with foodborne illness include not only medical care, but also the value of lives lost, income lost during illness, and the cost of outbreak investigations (Todd, 1989). The production of food that is safe for human consumption is complex; different livestock species are a source of a large number of microbial pathogens; there are many routes of human exposure; and control efforts may be implemented at numerous stages in the farm-to-fork food production continuum. Thus, there is an enormous and diverse volume of research that describes the biology and epidemiology of the causative agents and investigates methods of controlling or preventing foodborne illness in humans. This volume of literature makes it difficult, if not impossible, for individuals needing to make decisions on the use of intervention strategies or on research needs to read and synthesize all of the available information.

Review articles provide a mechanism to summarize the body of knowledge on a given topic and are thus a potentially important information source for food safety policy and decision makers. Reviews addressing the effectiveness of interventions also might be used as a source of data for food safety risk as-

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sessments. However, review articles on the same subject may reach different conclusions (Antman et al., 1992; Barnes and Bero, 1998; Hoving et al., 2001). As with primary studies (studies that report the results of original research), the validity of a review article should be assessed before applying its conclusions (Oxman et al., 1991). Mulrow (1987) used eight explicit criteria to evaluate 50 review articles published in four major medical journals during 1985–1986. She concluded that the medical review articles published at that time did not routinely use scientific methods to identify, assess, and synthesize information, potentially resulting in invalid conclusions. Subsequently, criteria for conducting and reviewing medical review articles were developed and validated (Oxman and Guyatt, 1988; Oxman et al., 1991; Oxman and Guyatt, 1991) and published in the medical literature (Hutchinson, 1993; Neely, 1993; Oxman, 1994; Oxman et al, 1994). The intent of these criteria was to provide a measure of the extent to which the process of conducting a review guards against bias (Oxman et al., 1991). McAlister et al. (1999) used these criteria to evaluate 158 review articles on clinical topics published in 1996 to determine whether the scientific quality of medical review articles had improved. These authors concluded that, while there were improvements in the methodological quality of review articles, the quality was still highly variable, with many articles not specifying systematic methods.

It is recognized that the approach to food safety policy and decision-making should be science-based (FAO, 2003; WHO, 2002). Therefore, as with other types of research, review articles used in decision-making should be subject to methodological guidelines for quality. Our objective was to evaluate the methodological quality of recent review articles that address the effectiveness of interventions to improve microbial food safety at any point in the food production system, using criteria developed to evaluate medical review articles.

MATERIALS AND METHODS

Review articles evaluating microbial food safety interventions were identified by searching the PubMed, Agricola, and Food Science and Technology Abstracts (FSTA) electronic bibliographical databases. Publication type was restricted to reviews, language type was restricted to English, and the publication date was restricted to 2000–2005. The search words were: "food safety or foodborne" and "meta-analysis or review or overview" and "control or intervention or prevention or mitigation." The PubMed search was conducted in January 2006 and the Agricola and FSTA searches were conducted in March 2006. Abstracts for each of the publications identified by the searches were screened for relevance by one of two reviewers (JMS, JW) to ensure that the abstract described a review article related to microbial food safety and that a consideration of potential interventions was included. Abstracts of book chapters and abstracts describing reviews of antimicrobial resistance, national regulations for food safety, the prevention of deliberate food adulteration with microbial contaminants, and the safety of the inventions in animals were excluded.

A quality assessment checklist was created which included the 10 validated criteria for methodological soundness used by McAlister et al. (1999), with modifications for application to food safety research. McAlister et al. included an assessment as to whether the major clinically relevant outcomes (benefit or harm) were considered. For our purposes, this criterion was divided into two questions: whether the outcomes included the occurrence or severity of disease in humans, and whether the outcomes included detection of the pathogen of interest (as opposed to a proxy such as serological response) within the food production sector. We also included several descriptive questions and a question related to whether the review considered the cost of the intervention. The checklist was pre-tested by having all reviewers independently review four review articles published as book chapters or published prior to 2000. Results were collated and agreement on modifications to improve question clarity was reached by consensus.

Full papers were obtained from abstracts that were deemed potentially relevant. Articles were randomly assigned to one of four reviewers (JMS, MET, AR, AMOC). A single re-

viewer, who was blinded to the author names and affiliations, reviewed each article. The data were stratified by type of review: reviews that addressed a single intervention, reviews that addressed multiple interventions, and general reviews with a section on interventions. Descriptive statistics were performed to describe the characteristics of the studies and to summarize the results of the quality assessment.

RESULTS

The search located 603, 149, and 34 records from PubMed, Agricola, and FSTA, respectively. Relevance screening of abstracts and removal of duplicated records resulted in the identification of 83 abstracts. Upon review of the full papers, a further 18 articles were excluded because they did not contain information on potential interventions. Thus, quality assessment was conducted on 65 review articles. The reviews represented 47 journals; the most commonly cited journals were the *International Journal of Microbiology* and the *Journal of Food Protection*, with 10 reviews from each. Complete citations for the reviews are listed in the Appendix.

There were 17 reviews that addressed a single intervention, 27 reviews that addressed more than one intervention, and 21 general reviews with a section pertaining to interventions. The majority of the reviews pertained to one or more bacterial pathogens, although reviews pertaining to viral foodborne pathogens also were included (Table 1). The majority of the reviews included interventions at the farm or processing sector, although all stages of the farm-to-fork continuum were represented and many reviews covered more than one sector. A wide range of commodity groups was represented.

No single review article met more than 5 of the 10 criteria for methodological soundness (Fig. 1). The median number of criteria fulfilled was 2, and 15 of the 65 reviews did not meet any of the criteria for methodological soundness. None of the reviews provided explicit information on the search strategy to identify primary research studies or the inclusion/exclusion criteria and none reported conducting methodological quality assessment on the primary studies (Table 2). Because quality assessment of primary studies was not conducted in any of the reviews, there were no reviews in which quality assessment could be deemed to be reproducible. There was a range of reporting on the results of primary studies, from qualitative descriptions to extensive detail on individual study results. However, none of the reviews included a quantitative summary measure of the effectiveness of the intervention among studies.

Only 7 articles included a discussion of economic considerations. Of the 52 reviews that did not specifically review consumer level interventions, there were 7 reviews that included the occurrence or severity of disease in humans as an outcome.

DISCUSSION

Using criteria for methodological soundness validated for use with medical reviews, the food safety review articles assessed in this study had major methodological flaws, regardless of whether the review was general in purpose (with a section on interventions) or dealt specifically with interventions. Explicit and widely accepted criteria are available to assess the validity of primary research, including research on the efficacy of interventions (Hutchison, 1993; Sackett et al., 2000). Review articles also may make recommendations on the use of interventions and should therefore be subject to some standard of methodological quality to allow an assessment of their validity. However, review articles have not been viewed as a form of scientific reporting and little effort has been put into ensuring their methodological soundness (Milne and Chambers, 1993).

Less than half of the studies had a focused intervention question, which should provide the basis for the review. All causal questions, including those regarding intervention efficacy, have three key elements: the population, the exposure (or intervention), and the outcome (Oxman and Guyatt, 1988). A clear statement of the review question requires explicit specification of all three elements. A focused

TABLE 1. DESCRIPTIVE STATISTICS OF 65 REVIEW ARTICLES ADDRESSING MICROBIAL FOOD SAFETY INTERVENTIONS PUBLISHED BETWEEN 2000 AND 2005

	Reviews specific to one intervention (n = 17)	*Reviews specific to multiple interventions (n = 27)*	*General reviews with a section on interventions (n = 21)*
Year of publication			
2000	1	2	3
2001	1	4	7
2002	2	3	5
2003	1	1	0
2004	3	9	5
2005	9	8	1
Pathogen type			
Single bacterial species	1	6	11
Multiple bacterial species	10	12	4
Single viral species	0	0	0
Multiple viral species	2	1	2
Multiple bacteria and viruses	3	8	4
Pathogen type not described	1		
Food production sector			
Farm	3	6	2
Processing	9	10	6
Farm and processing	1	3	0
Restaurant	0	0	1
Retail	1	0	0
Storage or preparation	2	1	1
Processing and post-processing	0	3	2
Post processing	0	1	2
Farm to retail	1	0	1
Farm to consumer	0	3	6
Commodity group			
Vegetables or crops	0	1	1
Poultry	3	2	2
Swine	0	2	0
Ruminants	1	4	1
Aquaculture, seafood, shellfish	2	1	3
Consumers	1	0	1
Multiple groups	10	17	13

review question should be clearly stated in the abstract of the review article to allow the reader to quickly determine the relevance of the review to their purpose (Mulrow et al., 1988). Additionally, having a focused question allows the authors of the review to identify appropriate strategies for selecting studies for inclusion in the review and to determine appropriate methods to assess the information (Mulrow, 1987).

Bias in a review article may be introduced by the method of selecting the primary studies for inclusion, by publication bias, or through inclusion of biased results from individual primary studies (Oxman and Guyatt, 1988). The choice of studies that are included in a review contributes to the conclusions (Oxman and Guyatt, 1988) and it is impossible for the reader to know what was done, let alone to evaluate the method of study inclusion, when the decision rules are not explicitly stated (Oxman et al., 1991). None of the reviews provided information on the method of identifying the primary studies or the inclusion/exclusion criteria for including them in the review. Without knowing this, it is impossible for the reader to determine if the review represented all of the information available on the subject or whether there was study selection bias on the part of the author (Mulrow, 1987). Critical appraisals of re-

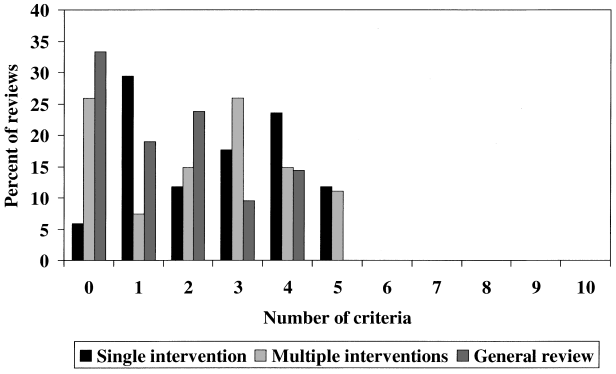

FIG. 1. Frequency distribution of the number of criteria for methodological soundness fulfilled for review articles on microbial food safety that addressed a single intervention ($n = 17$), multiple interventions ($n = 27$), or were general review articles with a section on interventions ($n = 21$).

view articles in the medical literature have found an association between the conclusions of review articles and author affiliations (Assendelft et al., 1995; Barnes and Bero, 1998). Antman et al. (1992) compared the treatment recommendations of clinical experts writing review articles and textbooks to the results of cumulative meta-analyses and found that review articles often did not report therapeutic advances, exhibited delays in recommending preventive measures and, in some cases, recommended treatments that the meta-analysis had determined to be ineffective or even harmful.

None of the reviews included an assessment of the methodological quality of the primary studies. Methodological soundness of the primary literature is essential to the validity of the conclusions. Khan et al. (1996) conducted a meta-analysis of randomized controlled trials of the effect of antiestrogen treatment in subfertile men on pregnancy rate. When all of the studies were included in the analysis, there was a marginal improvement in pregnancy rate. However, sensitivity analysis on the basis of methodological quality revealed that no effect was observed in the analysis of high quality studies whereas meta-analysis of the poor quality studies resulted in a positive treatment effect.

It is possible that authors of the review articles evaluated in this study conducted structured searches, had explicit inclusion and exclusion criteria, and considered the methodological quality of primary studies in making their intervention recommendations, but did

TABLE 2. NUMBER OF REVIEWS ADDRESSING CRITERIA FOR METHODOLOGICAL SOUNDNESS FOR 65 REVIEW ARTICLES ADDRESSING MICROBIAL FOOD SAFETY INTERVENTIONS PUBLISHED BETWEEN 2000 AND 2005

Criteria	*Reviews specific to one intervention* (n = *17*)	*Reviews specific to multiple interventions* (n = *27*)	*General reviews with a section on interventions* (n = *21*)
The review addressed a focused intervention question	3	9	12
The method of locating evidence was described	0	0	0
Explicit criteria were used to select studies	0	0	0
The methodological quality of the primary studies was assessed (critical appraisal was performed and reported)	0	0	0
Assessment of the studies was reproducible (more than one person conducted critical appraisal)	0	0	0
Quantitative summary of intervention effectiveness among studies was presented	0	0	0
Possible reasons for differences between studies were presented (heterogeneity of results was discussed)	3	7	8
The generalizability of the results to the target group was discussed	6	11	16
Directions for future research were proposed	8	9	12
Outcomes included the pathogen of interest within the food production sector	8	14	12

not report this information. However, Oxman and Guyatt (1991) contacted the primary authors of 36 review articles and found that the results of critical appraisal of the review articles were generally consistent with what the authors stated they did in response to inquiries about the methods used to conduct the review.

None of the reviews included a quantitative summary of the intervention effect among studies. Meta-analysis is a technique that statistically combines data from multiple studies to produce a weighted overall estimate of the effect of the intervention (Akobeng, 2005; Deeks et al., 2001). Combining information from multiple studies increases the power and precision of estimates of treatment effects and exposure risk (Akobeng, 2005). Thus, meta-analysis is particularly useful when sample sizes of existing studies are small or when a large trial is too costly or time-consuming to perform (L'Abbé et al., 1987). A valid summary estimate would be of obvious use to decision makers. However, combining data from multiple studies may not be appropriate if there is significant heterogeneity between studies (Akobeng, 2005; Glasziou et al., 2001). Even when meta-analysis is not performed, a qualitative explanation of possible reasons for differences in study results should be provided (Akobeng, 2005).

Fewer than half of the studies discussed possible explanations for differences in results between primary studies (heterogeneity), the generalizability of results, and directions for future research. Possible sources of heterogeneity include study design, chance, and differences in the population, intervention, or outcome (Oxman and Guyatt, 1988). In the food safety area, primary studies have diverse study designs, are conducted in laboratory and commercial settings and, in the on-farm sector, use different populations of animals. All of these factors will impact the ability to generalize the results to the species and food production sector for which the intervention is targeted. Proposed directions for future research are useful for the identification of needed and promising areas of future research and may discourage duplication of research efforts (Mulrow, 1987). However, including suggestions for future research may be difficult to interpret or even misleading if the method of identifying and including literature in the review was not explicitly stated. If the purpose of the review is to provide a general overview on a topic, the inclusion of future research directions may not be warranted or may be framed as knowledge gaps rather than research needs.

We also assessed whether the review considered the occurrence or severity of illness in humans or the cost of the intervention as an outcome. The ultimate goal of food safety interventions is to reduce foodborne illness in humans and yet the review articles rarely considered this as an outcome. This may be a limitation of the ability to collect this type of data in primary studies, but is an issue that ultimately will need to be addressed. Cost may be a consideration in implementing an efficacious intervention, particularly in food production sectors that are market-based, such as the farm and processing sectors. Therefore, some mention of this aspect in review articles dealing with interventions may be warranted.

CONCLUSION

We found that the methodological quality of review articles dealing with microbial food safety interventions was generally poor, regardless of whether the purpose of the review was to provide a general overview of a food safety topic or to specifically review one or more potential interventions. There is a need to incorporate transparency into the methods for selection and inclusion of the primary studies and to provide a critical appraisal of their methodological soundness. While a lack of a systematic approach to conducting a review does not imply that the conclusions of the review are necessarily invalid, it does not provide the reader with the information necessary to evaluate the validity of those conclusions. General review articles may provide a useful overview of a topic and may not be intended to inform policy or decisions on intervention. However, all of the review articles evaluated in this study, whether general or specific to intervention strategies, included a consideration of potential interventions. Decisions on interventions should be based on sound scientific evi-

dence. Our results suggest that review articles on microbial food safety interventions are currently not meeting the criteria for methodological soundness needed to provide that evidence.

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APPENDIX

The 65 review articles evaluated for methodological quality in this study.

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