

Leveraging Current Opportunities to Communicate Lessons Learned from Root Cause Analysis to Prevent Foodborne Illness Outbreaks

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SUMMARY

Foodborne illness outbreaks are the result of failures in food systems either to control known hazards or to anticipate novel hazards. Root cause analysis (RCA) is a systematic, analytical approach to identify the underlying reasons why an outbreak occurred. The ultimate goal of RCA is to uncover the systemic weaknesses in the food system that permitted its breakdown so the system can be redesigned in a way that prevents recurrence. Understanding the root causes of foodborne disease outbreaks is essential for a prevention-focused food safety system. Because the same or similar systemic weaknesses may exist in different operations, analysis results can be highly informative for many stakeholders, including food safety professionals in the same or related industries, personnel in regulatory agencies, educators, academic researchers, and consultants. However, the results are often either not shared at all or shared in suboptimal ways, limiting opportunities for learning. The 2017 International Association for Food Protection (IAFP) Annual Meeting represents one way of sharing such results; in fact, this meeting featured a symposium on RCA in the food industry. This article summarizes this symposium and offers recommendations for improving the ways in which lessons learned from RCA can be communicated effectively to a broad food safety audience.

OVERVIEW

Foodborne illness outbreaks are the result of failures in food systems. Failures can be caused by a system breakdown such that interventions designed to control known or anticipated foodborne illness risks can no longer function properly. Failures also can be caused by changes in external factors that impact an operation's food system and overwhelm its ability to effectively control foodborne illness risks, such as unanticipated increases in pathogen prevalence and concentration or the emergence of new and previously unknown food safety hazards. In fact, recent technological advancements in the tools available

to detect foodborne pathogens have led to the recognition of new pathogen-food pairs as food safety threats and to a reevaluation of the food safety risks associated with some previously recognized pathogens and/or foods (7). Hazard Analysis Critical Control Point (HACCP) systems focus on identifying risks that are reasonably likely to occur but may have little ability to control hazards that are not known or anticipated. The 2009 *Escherichia coli* (*E. coli*) O157:H7 outbreak associated with flour in ready-to-eat cookie dough is one example of an outbreak linked to a novel, previously unrecognized pathogen-food pair (10). Information from foodborne outbreaks can provide an opportunity to improve food safety by identifying the factors that led to a food system failure and using lessons learned from investigations to redesign the system so as to prevent recurrence of the same or of a similar issue.

Root cause analysis (RCA)* is a systematic analytical tool used in many different disciplines that can be used to identify the underlying reasons why an outbreak occurred. Because the same or a similar systemic weakness may exist in various systems, analysis results can be highly informative for many stakeholders, including food safety professionals in the same or related industries, personnel in regulatory agencies, food safety educators, academic researchers, and consultants. However, the results are often either not shared at all or presented in suboptimal ways, thereby limiting opportunities for learning.

The 2017 International Association for Food Protection (IAFP) Annual Meeting was a useful venue for the distribution of lessons learned from RCAs of foodborne illness outbreaks. The meeting was attended by more than 3,600 food safety professionals from 59 countries and featured six days of presentations on various food safety issues relevant to various segments of the food industry. At the meeting, a symposium on RCA, its application to the field of food safety, and strategies for information sharing was featured. While there was interest at IAFP in RCA beyond this particular symposium, other presentations at the Annual Meeting focused more

narrowly on the characteristics of agents, food vehicles, and food production environments. The concept of root causes was not a widely discussed theme throughout the 2017 Annual Meeting. Nevertheless, there are a number of opportunities, both at future IAFP meetings and beyond, to enhance communication of RCA findings to help food safety professionals and other stakeholders identify and address important weaknesses in their food systems.

*Note: The term “root cause analysis” is often used interchangeably with “environmental assessment.” Similarly, “root cause” and “environmental antecedent” are also synonyms. For simplicity, the terms “root cause,” “root cause analysis (RCA),” and “root cause investigation” will be used throughout this article.

BACKGROUND ON ROOT CAUSE ANALYSIS

RCA is a collective term that identifies a wide range of tools, techniques, and approaches aimed at identifying the true causes of a problem, as well as how to eliminate them (1). Like HACCP, RCA is based on systems theory and emphasizes the need to understand the underlying interactions within and among multiple interdependent parts of an often complex system (3). The primary goal of an RCA is to go beyond recognizing what went wrong, to identifying *why* it went wrong and how to prevent recurrences. In the food safety arena, RCA can be and is used to examine outbreaks. It can also be used to characterize other significant events, such as finished product contamination events, that could have led to an outbreak (“near misses”). RCA is performed in order to efficiently identify the source of vulnerabilities in the food system and how to address them. These findings should then be communicated to other stakeholders to allow them to learn from them, identify weaknesses in their own food systems and ways to remedy them, and thereby prevent future outbreaks. This understanding is essential for a prevention-focused food safety system (9).

Because the primary goal of outbreak investigations by public health agencies and the food industry is to stop the outbreak, these investigations primarily focus on identifying the food vehicle causing the outbreak and how best to remove it from the market to avoid further illnesses. The root causes of outbreaks may be related to behavioral risk factors, management decisions, social and cultural beliefs (8, 12), as well as economics (12), and therefore go beyond identification of the implicated food vehicle, but they are often not uncovered in the original outbreak investigation.

RCA can vary greatly depending on the context of the outbreak or ‘near miss’ event. The method and purpose can take on different forms, depending on the setting, food industry, and who is conducting the analysis (i.e., government agency vs. company). Although there is variation in the complexity and practical application

of individual investigations, effective root cause investigations share several key properties.

CHARACTERISTICS OF EFFECTIVE ROOT CAUSE ANALYSIS

Because it may be impossible to reconstruct the factors that led to an outbreak after a significant period of time has passed, timely initiation of an RCA is often crucial for an effective investigation. In fact, preliminary analysis of National Environmental Assessment Reporting System (NEARS) data suggests that the factors contributing to an outbreak are more likely to be identified if the investigation begins shortly after an outbreak is identified (4). Timeliness is especially critical for outbreaks involving certain food commodities such as fresh produce because of the short growing season and the fact that fields may be out of harvest and/or plowed under by the time an outbreak is identified and an RCA initiated.

RCAs must be systematic, comprehensive, and focused on continuous improvement based on investigations that seek to identify what went wrong and why it went wrong, as well as what worked in preventing the outbreak from becoming even worse. Additionally, RCAs should be evidence-based and scalable across all levels of the food system. They require an understanding of supply chains, including the source, processing/manufacturing, packing, transportation, distribution, storage, and point of final service/consumption. As such, they require multidisciplinary teams comprised of people with the appropriate technical expertise for the incident being investigated. Depending on the particular facts of the outbreak, the investigation team may consist of microbiologists, epidemiologists, sanitation experts, food scientists, veterinarians, and other experts.

Communicating findings and lessons learned with the appropriate technical audience throughout the course of the investigation, as well as after the root cause(s) have been identified, is key to preventing future outbreaks. Outcomes from RCAs can benefit not only the company or firm conducting the investigation, but also other important stakeholders, including food safety experts in the food industry, governmental agencies, and academia. By collating the findings into a clear, concise, and transparent report at the end of the RCA, even if the investigation fails to identify all, or even any, of the root causes, valuable food safety information can be efficiently shared throughout the industry and beyond to inform the development of internal and external guidance policy, as well as to identify areas of future research. In addition, it is important to keep in mind that the systematic evaluation of a food system during an RCA may uncover other system weaknesses that did not contribute to the current failure but that might give rise to food safety issues in the future and therefore should be addressed.

CHALLENGES TO PERFORMING SUCCESSFUL ROOT CAUSE INVESTIGATIONS AND EFFECTIVELY SHARING RESULTS

While an RCA is a valuable tool for a prevention-focused food system, important practical challenges exist. Root causes are the fundamental reasons that a system failure occurred and therefore are causally related to the event. If it were not for the occurrence of the root cause, the event either would not have occurred or would have had a significantly lower impact. However, root causes can be very difficult to distinguish from contributing factors – issues that may have been necessary to the progression of the event but may not have been sufficient to lead to its occurrence (12). Food systems are complex and consequently can fail in complex ways. There may be multiple root causes, and it may be extraordinarily difficult to identify them. In an analysis of 9,788 restaurant-associated outbreaks, in only 50% of outbreaks was it possible to identify at least one factor that contributed to the outbreak (irrespective of whether it was a root cause or not) (2). Since root cause investigations are typically retrospective, it may be impossible to reconstruct the situation at the time that contamination occurred. Poor or incomplete data, including epidemiologic, microbiologic or logistic records, or sampling logs, may limit the ability to identify a root cause. However, investigations that fail to identify root causes still provide an opportunity to learn from these incidents. Effective and collaborative communication across stakeholders early in an investigation can enhance the ability of investigators to identify contributing factors and root causes and subsequently enhance the opportunities for improvement.

After an RCA is conducted, legal and regulatory challenges can inhibit companies from successfully disseminating key findings and lessons learned. Although food companies may be interested in sharing the results, liability, confidentiality, and brand protection concerns may dissuade them from communicating outcomes. Since root causes can often be related to human or organizational factors, including an organization's food safety culture, companies may be reluctant to discuss these factors out of fear of liability. Discussing findings within an organization may be challenging if the company's leadership does not see the value in an RCA, absent a pressing outbreak or business concern.

Since findings from RCAs have the potential to benefit various stakeholders in government, industry, and academia, lessons learned should be shared systematically within the company, as well as across companies and among key stakeholders. Information should be scalable – shared in formats that are useful for both large and small operations. Dissemination of key findings may require communicating technical information in an accessible

way to non-technical stakeholders within and across companies, and with the public.

HOW TO BETTER COMMUNICATE LESSONS LEARNED FROM ROOT CAUSE ANALYSIS

The 2017 IAFP Annual Meeting demonstrated a growing interest in RCA as a way to continually improve the safety of the food system. However, few presentations beyond this specific symposium shared lessons learned from these types of investigations. Communication about foodborne outbreaks at the IAFP 2017 Annual Meeting focused primarily on characteristics of agents, novel food-pathogen pairs, and contributing factors, and only rarely mentioned the root causes of outbreaks. Similarly, risk or hazard assessments were commonly discussed in symposia and roundtable discussions, but in isolation from systems-based retrospective analyses such as RCA.

Despite barriers to sharing information from outbreak investigations in a timely manner, there is interest in improving communication strategies. Every year, the IAFP Annual Meeting attracts more than 3,000 of the top food safety professionals in industry, government, and academia from all over the world to explore the latest scientific research on today's most pressing food safety issues. The interest in RCA demonstrated at the IAFP 2017 Annual Meeting indicates that there is an opportunity to continue engaging stakeholders to improve communication strategies of key findings from these investigations in order to further enhance food safety systems. Opportunities to improve and enhance sharing of findings from RCA include the following:

1. Recommendations for improving opportunities for information-sharing through IAFP:
 - a. Convene symposia, roundtable discussions, and other sessions at IAFP meetings nationally and internationally that focus on sharing lessons learned from RCAs. The IAFP Annual Meeting provides an opportunity to share information and discuss outbreak investigations and near misses with a large and diverse food safety audience in a timely manner.
 - b. In these sessions, include field investigators, state and local inspectors, and consultants who have been engaged in RCAs to share their experiences. This provides an opportunity to connect those who conduct root cause investigations to those who may be using key findings from these investigations and provides a valuable diversity of perspectives. Field investigators and consultants can talk about experiences in aggregate, which could provide an opportunity to learn from experience without having to name implicated firms, thereby potentially alleviating some confidentiality concerns.

- c. Actively encourage presenters at future IAFP Annual Meetings to incorporate root cause investigations into presentations that may not be explicitly about this topic. Organizers of symposia or other sessions can encourage presenters, especially from industry, to include a discussion of root cause investigations in order to share valuable lessons learned. This approach also may allow for improved harmonization of this tool with other systems-based approaches to food safety.
 - d. Host listening and information-sharing sessions, roundtable discussions or “ask the expert” events at IAFP Annual Meetings and beyond to serve as an opportunity for practitioners to share case studies as well as lessons learned. Informal discussions provide an opportunity to share relevant findings in a timely manner.
2. Recommendations for sharing information beyond IAFP:
- c. Convene regional conferences that include discussions of RCAs in order to share information rapidly among key stakeholders. While the IAFP Annual Meeting is a great opportunity to share findings among food safety leaders, it may not be able to reach everyone who could benefit. Smaller companies may not be able to send representatives to the Annual Meeting. Because numerous sessions occur simultaneously, interested attendees of the Annual Meeting may not be able to participate in RCA sessions. Regional conferences provide an opportunity to share information that may be particularly relevant to those in geographically similar locations and to reach audiences who may not be able to attend larger meetings. Moreover, closer networks of regional food safety experts may be developed and reinforced at regional meetings.
 - d. Leverage or adapt existing forums/tools, such as trade associations, academic centers, and university extension services, to share lessons learned. Sharing information through entities with existing industry relationships such as trade associations, academic centers, and university extension services, which may summarize information from multiple investigations and assure anonymity, could alleviate some concerns about sharing sensitive information and provide an opportunity to reach a broader audience by using existing alert and outreach systems to present case studies.
 - e. Publish findings from root cause investigations in peer-reviewed journals and through other reports, such as trade organization materials and government reports. While publishing full reports is ideal, publishing brief articles in addition to full reports, similar to the Centers for Disease Control and Prevention’s (CDC) *Morbidity and Mortality Weekly Report* “Notes from the Field” articles, also provides the opportunity to share information from recent root cause investigations in a timely manner. “Notes from the Field” articles are abbreviated reports intended to inform readers of ongoing or recent events without waiting to write a full report and may not yet describe conclusions (6). A similar communication strategy could be used for root cause investigations that may have been conducted but for which recommendations have not yet been finalized.
3. Sharing root cause lessons with the broader public:
- d. Create RCA exhibits at The International Outbreak Museum in Portland, OR. The International Outbreak Museum has physical exhibits and online resources that detail outbreak investigations in order to teach audiences about the kinds of foods and products that can cause widespread disease. Even if an investigation does not find the source of an outbreak, the museum encourages submitting information about outbreak investigations (11). This Museum provides an opportunity to share RCAs with a diverse audience, both online and in person.
 - e. Cultivate reporters who cover food policy issues to publish articles about root cause investigation results.

CONCLUSION

RCA has demonstrable value for enhancing prevention-focused food safety systems, and sharing lessons learned can help various food safety stakeholders identify and address systemic weaknesses that can cause a food safety crisis in the future. Yet currently, opportunities to learn from foodborne outbreaks are lost. Leveraging existing opportunities through the IAFP Annual Meeting, as well as exploring new avenues to communicate findings from root cause investigations, can promote such information-sharing throughout industries, governmental agencies, and academia and therefore strengthen food safety systems focused on prevention.

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