Investigating the Causes of Adverse Events

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If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask, for once I know the proper question, I could solve the problem in less than five minutes.—attributed to Albert Einstein

Despite remarkable advances in surgical care, unintentional harm and suboptimal outcomes persist in the health care environment [1–7]. Many serious events are not attributable to the natural course of the patient's underlying condition or illness but, rather, to system and process failures, many of which share common characteristics. Organizational learning and continuous improvements resulting from the thoughtful and systematic analysis of such events are of vital importance in preventing their recurrence and keeping in patients safe.

Organizations and their cardiothoracic surgical teams must determine the causes of errors and develop solutions that address the inherent systems problems that lie at the root of these events. When they occur, however, the causes are not readily apparent to front-line staff because of the affective and cognitive distortions these failures engender as well as the complexity of the environment. Several analytic tools and methods are available for this purpose that have been widely used in other industries to learn from mistakes and mitigate identifiable hazards [8]. Many health care systems and regulatory agencies have embraced these methods to complement other strategies aimed at reducing events that can be "reasonably prevented" [9]. The Joint Commission (TJC), for example, maintains that meaningful improvements in patient safety are dependent on each organization's ability to identify errors and analyze their contributing factors to prevent similar errors from occurring again at the same institution [10]. Furthermore, the information learned about error frequency, type, and root causes support continuous improvement efforts as organizations redesign systems of care to improve outcomes and enhance patient safety. The purpose of this paper is to highlight the utility of event investigation and analysis to identify the causes and prevent the occurrence of adverse events.

Identifying Causal Factors

The conceptual model for evaluating the quality of medical care, proposed by Donabedian in 1966, contains three components of medical care from which to derive information regarding quality: structure, process, and outcomes [11]. The structure of care involves the settings and context of medical care delivery. Individual processes of care—the actions and activities of delivering medical care—can be examined and compared with best known standards of practice. The processes that can readily be examined, however, are not always those that have the most direct impact on outcomes. For example, the timing of preoperative antibiotic administration can more easily be measured than the performance of a surgeon. Although many other factors (antecedent conditions), such as a patient's comorbidities, influence the result of health care, it is ultimately the outcomes that are the most important indicators of quality [9]. In this framework, undesirable outcomes are a consequence of defects in either the structure (ie, system design) or the incorrect application of processes. The root causes of poor quality can be found by exploring the gap between optimal and suboptimal results. This gap is the object of root cause analysis (RCA) methods.

Individual behavior is influenced by an organization's structure, set of processes, and values [12]. Understanding human performance is critical to identifying causal factors. Error-prone conditions are usually predictable and preventable. Errors, accidents, and adverse events can only be avoided by understanding the reasons they occur and by applying lessons learned from similar past events. Unfortunately and too often, human error is the conclusion of a poorly performed accident investigation. Errors are usually a symptom of deeper (systemic or "latent") conditions. To understand the basic, root causes of events, human error must be the starting point rather than the end of an investigation to truly understand causation, systemic hazards, and gaps in organizational performance.

Organizational learning in health care is a necessary characteristic for teams to improve [13]. An organization must be skilled at extracting "learning," not only from major errors, but from all available growth opportunities such as minor events, real or perceived safety risks, near misses, and precursor events. For learning to occur, however, organizations must also be able to systematically aggregate and widely disseminate the results of all its problem-solving activities. Because most adverse

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events rarely have a single cause, the ability to identify a number of contributing conditions can yield a number of possible solutions for correcting system flaws and process failures. Identifying causal factors should follow certain rules (Table 1) so that investigations do not fall short of reaching true causal factors.

Monitoring

The ideal safety-conscious clinical environment has systems in place to monitor for potential problems so that, when they occur, a prompt response can be mounted, data collected, and hazards neutralized. Protocols and procedures should be implemented to immediately respond to critical events. Crisis management algorithms and simulation exercises with frequent training are important components of risk management for a safety-focused clinical team. When accidents happen, however, this heightened predisposition to action may not lead to capturing critical information. The use of incident reporting systems, although widely available in hospitals and ambulatory settings, have had a poor track record of capturing safety events due to several factors such as a poor reporting culture, poorly designed reporting tools, inadequate feedback to those who report, and persistent lack of evidence for the application of learning from investigations [14].

Although the immediate causes of patient safety events may be evident to those frontline clinicians at the "sharp end," root causes may be tied to decisions made remotely in the past or elsewhere. The complexity of modern health care organizations may obscure causal and contributing factors that are far removed from frontline operations. Among these are such factors as educational and training requirements, staffing ratios, level of support services, workflow design, and composition of work teams.

Root Cause Analysis

An RCA is a formalized, indepth process for investigating an incident with the goal of identifying the most basic factors contributing to error or poor performance. It is an

impartial, interdisciplinary approach involving both individual persons uninvolved with the event as well as those who are the most familiar with the situation. By digging deeper at each level of cause and effect using an iterative and systematic approach, basic and contributing causes are surfaced with the ultimate goal of preventing recurrence and supporting human performance by the judicious application of "human factors engineering" methods. Excellent resources are available for conducting an RCA, such as "Root cause analysis in health care: tools and techniques from Joint Commission Resources" [10] and "VA National Center for Patient Safety: root cause analysis (RCA) step-by-step guide" [15].

Although relatively new in the health care context, RCAs were developed by industrial psychology and systems engineering to identify causal factors underlying variations in performance [8]. They have been used in many other industries successfully in uncovering latent errors, particularly in high-reliability organizations such as aviation and nuclear power [16, 17]. This approach may identify causes of a problem in either processes or structure, and the findings can aid in developing strategies to prevent its recurrence.

There are three fundamental components of an RCA: (1) identification of causal and contributory factors associated with the event (including upstream and downstream factors and individual persons); (2) causal analysis and prioritizing corrective actions; and (3) development of preventive strategies and effective countermeasures. The overarching goal is to find out what happened, why it happened, and how it can be prevented in the future. Once causal and contributory factors have been identified, their root causes can be elucidated so that teams can generate effective responses.

To identify possible process flaws and potentially unsafe conditions, highly reliable organizations and teams also examine near misses and conduct forward-looking exercises such as "failure mode and effects analysis" (FMEA) [18]. Unlike the retrospective analysis done through an RCA, the FMEA technique is a systematic way to analyze potential failures [19]. It is often the initial method used to study a system's reliability and involves reviewing all components and subsystems to identify potential failure points and their consequences on the rest of the system (ie, the causes and effects).

Fundamentally, an RCA attempts to correctly frame each problem and identify all contributory factors. Once the chronology of events is established, information is gathered directly from the persons involved. Given the complexity of multidisciplinary surgical care, it is important that information and narratives are collected while it is fresh in everyone's mind. Asking key questions in a structured format assists in analyzing the situational factors surrounding the event.

The "5 whys" approach, developed and used extensively by Toyota Motor Corporation during the early evolution of their manufacturing processes, is able to outline the causal chain in which one event or set of conditions causes the next [20]. The technique of asking "why?" for each subsequent response allows the

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Table 1. The Five Rules of Causation

Rule 1. Clearly show the "cause and effect" relationship to each contributing factor.

Rule 2. Use specific and accurate descriptors for each action rather than vague, negative words. Avoid descriptors such as poor, inadequate, wrong, bad, failed, careless.

Rule 3. Human errors must have a preceding cause.

Rule 4. Violations of procedure are not root causes but must have a preceding cause.

Rule 5. Failure to act is only causal when there is a preexisting duty to act.

When these rules are used, causal statements resulting from a properly conducted root cause analysis focus on correcting actual system issues and will increase the likelihood that those corrective actions will be supported and sustained. (Modified from National Patient Safety Foundation [21].)

investigator to dig deeper until fundamental causes for the incident are identified with the assumption that, if they are fixed, the problem will not recur. It is imperative that a causal process or behavior is identified during the course of the "5-whys dive." This tool is simple to use, requires no advanced training, and can quickly separate symptoms from causes. The exercise also promotes teamwork and can shift a team's culture to one of action. The number of "why?" layers necessary to reach the root cause depends on the depth of the causal chain in the problem.

There are a number of useful tools that can assist an event investigation, such as cause-and-effect diagrams (Fig 1), process maps, affinity diagrams, and Pareto charts (see Recommended Resources) that provide a "big picture" visual of how various causal factors are related and grouped. These tools are complementary and work to flesh out how actions, behaviors, and contributing factors relate to each other.

Before undertaking an investigation, it is important to ensure that immediate action has been taken to avoid compounding a problem that has or may cause further harm. Key steps should be taken in the short term to eliminate any hazardous conditions that can affect another patient. An RCA should be conducted in a timely manner but only after patients are out of danger. The cardiothoracic surgical environment has unique characteristics in which events are not linear as in an assembly line but, rather, where effects can amplify quickly and result in harm before detection. As such, the identification of unsafe conditions requires urgent action.

RCA Squared

Many organizations spend significant resources investigating adverse events. These efforts, at best, have been uneven. The RCA method is often applied inconsistently, leading to missed opportunities to improve those systems contributing to events. A panel of experts from the National Patient Safety Foundation has assembled best-practice guidelines (see Recommended Resources) to help health professionals standardize the RCA process and improve the way organizations investigate medical errors, adverse events, and near misses with the ultimate goal of implementing sustainable change [21]. The goal of RCA squared (RCA^2) is to help organizations learn to identify and implement sustainable, systems-based actions to improve safety. The process is called RCA^2 to emphasize the need for action once an analysis is completed.

As with many other high-reliability industries such as aviation, the solutions to hazards are prioritized using a scoring system based on severity of harm and probability of occurrence. With such a risk-based prioritization system, organizations can address hazards before they occur. In addition to the standardization of the RCA process, this approach guides the development of process and outcome measures to track improvements, verifying that actions and responses are effective.
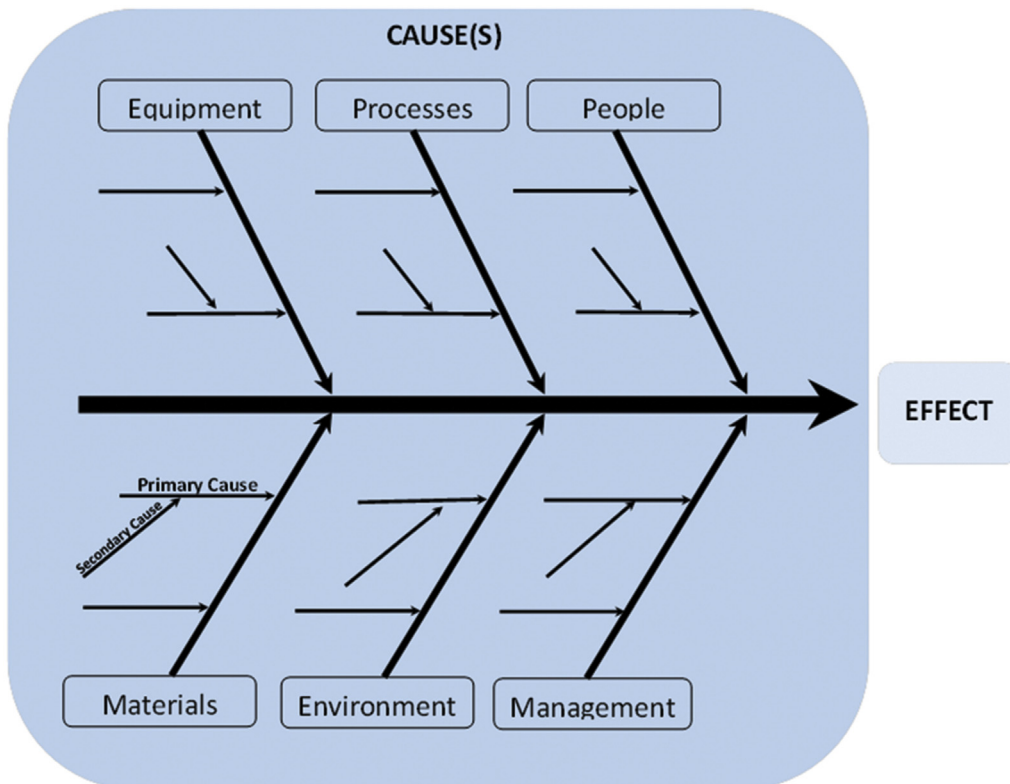

Fig 1. The cause-and-effect (or Ishikawa) diagram is one of several basic tools that can be used in a root cause analysis to show causal relationships and contributory factors leading to an adverse event [10, 15, 21].

The RCA[2] process also underscores the responsibility of an organization's leaders in future risk mitigation by providing clarity around their role in patient safety and in system improvement overall. It stresses the involvement of an organization's governance body and senior management in the oversight and review of the effectiveness of solutions. Team members are tasked to identify all corrective actions necessary to prevent patient safety events only with the full engagement and support of the hospital's board and chief executive officer. Action items derived from the RCA[2] process are discussed at the highest levels of the organization, including board meetings, so leaders can truly understand the types of events occurring and the importance of a robust investigative process.

Common Cause Analysis

RCAs are carried out in response to a single event or a cluster of events. The findings and corrective plans generated from these activities apply only to specific areas, service lines, or work teams, particularly in larger organizations [22]. Unless a higher level view is taken periodically, organizations are not able to synthesize the learning achieved from individual investigations preventing their dissemination to other areas. A "common cause analysis" aggregates the findings identified from multiple event investigations to determine whether they share systemic factors that need to be addressed through organizational policy changes, major workflow redesign, staffing decisions, and so forth. Organizations should periodically conduct common cause analyses to identify the degree to which individual action plans have been effective and to detect patterns and trends at the organizational level that may reveal system vulnerabilities. The focus of this work is on institution-wide change and the shaping of institutional policies. Through this process, organizations can also assign priorities to the various activities to make strategic and resource allocation decisions that can effect sustainable change.

Pitfalls and Challenges of Event Investigations

Ending Up With a Narrow Set of Facts

Because most people are not trained to consider system failures and neglect to dig beyond proximate causes, it is easy to generate a narrow set of facts that can miss more hidden, systemic contributions to events. Investigations that consider only the actions and omissions of particular persons are incomplete and misleading. The analysis must involve a wide range of sources of information related to the processes or areas to be investigated. The absence of a wider set of inputs, particularly from those upstream and downstream from the problem, often results in a low resolution investigation, leading to weak solutions and a recurrence of the precipitating event. Homogeneity in rank and role of the members of the RCA team and those being interviewed may result in "group think" from a lack of diversity of perspectives and must be avoided.

The use of forms and computer programs to collect incident data has many advantages, particularly when using systems that can aggregate and analyze discrete data elements from a large set of investigations. However, when context-rich causal factors are reduced to a list of generic conditions on a dropdown menu or checkboxes on a form, the ability to develop a deep understanding of the nuanced and complex set of conditions contributing to accidents may be lost.

Cognitive Biases

Organizational leaders and managers tend to possess an unconscious bias in believing that their organization is fundamentally safe, discounting systemic problems and tending to assign errors to specific persons without considering latent conditions or system effects. Furthermore, surgeons and surgical staff are subject to cognitive factors that inaccurately assess the probability of an event occurring, making it difficult to synthesize data and learn from the experience [23]. Such cognitive biases as the availability heuristic, ego bias, hindsight bias, confirmatory bias, and counterfactual thinking can influence one's interpretation of adverse events during an investigation [23–25].

Heuristics, or "rules of thumb," are mental shortcuts that are frequently used in cases when quick decisions or predictions are necessary [23]. Although they simplify the task of assessing probabilities, such "intuitive" behaviors can lead to errors in judgment. The availability heuristic, for example, is a tendency to assign greater value to immediate or recent examples that come to a person's mind. Recent cases are seen as more probable to occur than other possibilities and can lead to errors in judgment. Additionally, when reviewing an adverse event, it is common to seek only evidence that confirm one's own hypotheses and ignore negative evidence. This confirmatory bias can derail the process of information gathering and synthesis during an RCA by skewing data collection and interpretation [23].

With hindsight bias, one is more likely to state that they could have predicted the event beforehand. That is, we tend to overestimate the inevitability of an outcome once it is known. This is a common bias encountered during many investigations as well as in morbidity and mortality and other case review conferences. Egocentric bias distorts the probability estimation of an event as a result of overconfidence in one's own perspective. In the presence of missing data points, persons may assume that their interpretation of existing information is correct, leading to a higher level of confidence in their judgment and abilities than would be predicted mathematically [23, 26]. To reduce ego bias or unwarranted confidence, one should always consider the possibility that one's perspective may be incorrect.

Another factor that can influence an event investigation is regret or value-induced bias, which occurs when we allow the degree of undesirability of an outcome to alter our assessment of its likelihood [23]. In reviewing a serious adverse event, for example, we overestimate its probability of occurrence to avoid the

unpleasant feelings associated with decisions made leading to the event.

Counterfactual thinking involves conjectures that begin with "if only" and is often seen during RCAs and other quality assurance activities [24, 25]. Counterfactual thinking can be either upward (better than reality) or downward (worse than reality) and may be either outward focused (outside of one's control) or self-focused (within one's control) [23, 25]. Counterfactuals that are both downward ("it could have been worse") and outward focused ("it was out of my control") are effective coping mechanisms in dealing with the stress of an adverse event but may lead to minimizing the significance of the event and blaming others.

The Blame Game

In surgical specialties, the culture of high expectations and decisiveness contributes directly to the difficulties in disclosing errors and conducting incident investigations [24]. Too often, the approach taken during an investigation devolves into assigning culpability to an individual person or a group. Usually, the blame is aimed at persons with lower standing along the power gradient or at other specialties and professions. The attribution of causation to factors other than self during an investigation is quite common, particularly among surgeons. In the search for root causes, a person may defend against culpability by blaming someone or something else, including staff, other health care providers, a patient's noncompliance, or the illness itself. It is important that the investigative team prevents the use of blame at any point by any person regardless of rank or authority and maintains a strong focus on understanding the systemic factors and conditions that precipitated the event.

The Second Victim

In the course of an incident investigation, the emotional impact on team members is quite significant and underappreciated, particularly after serious harm has occurred. Such events and errors cause increased stress, loss of confidence, guilt, anger, reduced job satisfaction, depression, and fear of potential litigation [24, 27, 28]. After such an event, those health care providers at the "sharp end" are considered "second victims" (subsequent patients who are harmed by them are "third victims") [27]. The willingness of a person to share this distress is affected by the perceived level of competition with coworkers. In addition, providers are known to be more likely to experience distress after a serious error when they are dissatisfied with how the error was disclosed to the patient.

Moulton and coworkers [24] have defined four phases of response to a serious event among "second victim" surgeons: kick, fall, recovery, and long-term impact. The first phase, or the kick, occurs when a surgeon is first informed of the event. The result is physiologic stress, anxiety, and sadness. The kick is followed by the fall, when surgeons feel a downward spiral of emotions as they try to find out details of the case in the hope that

they are exonerated. The uncertainty as to the root cause of events results in extended periods of information searching and an inability to focus on other tasks. Although blame is not a major theme in this phase, participants studied have demonstrated a tendency to blame others in an attempt to feel better about the situation. The beginning of the recovery phase is marked by a return to feeling normal and undistracted by the thoughts of failure.

The long-term impact or cumulative effect of these reactions varies among individual persons. In some cases, the long-term result is poor and may not improve over time, resulting in considerable personal and professional difficulties [24]. After an adverse event, a person may have trouble reflecting on what has been learned from the event to be able to prevent its recurrence [29]. Discussing a serious error in a supportive and collegial environment is an effective coping strategy. However, seeking counseling from peers is not common in surgical practice owing to the stigma involved [27, 28]. Frank discussions about medical errors with colleagues and mental health professionals can be extremely helpful and should be part of our culture. Persons who feel emotionally supported by their organizations are known to be more likely to feel comfortable talking to patients after an error and to address those issues surfaced during an RCA. The impact of these events on second victims is becoming better defined, and directed support services are increasingly being offered by health care organizations even though only a small fraction of physicians believe that their organizations adequately support them in coping with error-related stress [28].

Disclosure

Transparency and disclosure of medical errors and a strategy of prospective risk management in dealing with medical errors is vitally important in the reporting phase of an investigation and may result in a substantial reduction in medical malpractice lawsuits, lower litigation costs, and a more safety-conscious environment. In what is now referred to as communication-and-resolution programs, health systems and liability insurers have encouraged the disclosure of adverse events, proactive seeking of resolution, apology, and where appropriate, compensation. In a study of six such systems to embrace communication-and-resolution programs, several factors were found that contributed to the success of such a program and included having a strong institutional champion, marketing the program to skeptical clinicians, and making the results transparent [30]. A transformative culture change is required to integrate these programs into daily work to achieve the benefits of early disclosure of events and any subsequent settlement.

The American Medical Association code of ethics helps render clarity to the physician's professional obligation to disclose to patients when errors occur: "Situations occasionally occur in which a patient experiences significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the

physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred" [31]. Moreover, the American College of Physicians ethics manual states that "Physicians should disclose to patients information about procedural or judgment errors made during care, as long as such information is material to the patient's well-being. Errors do not necessarily imply negligent or unethical behavior, but failure to disclose them may" [32]. This statement also leaves no ambiguity that physicians are obligated—it is their professional duty—to disclose the error of another surgeon once it has been discovered. Every patient is entitled to truly informed care. Patients and families should not have the burden of trying to discover "what happened" and any additional financial burden to a patient as a result of the error should be relieved. Although this topic continues to be controversial, there remains an ethical responsibility to families and patients to disclose all information that is pertinent to their care [33].

Regulatory Requirements

Depending on the nature and seriousness of the event, there are duties, both from an ethical and regulatory perspective, to report certain types of events to local, state, and other regulatory agencies. This series of requirements, however, is heavily influenced by state law [34]. Currently in the United States, 26 states and the District of Columbia have reporting systems that collect information from hospitals and other facilities about adverse medical events resulting in patient death or serious harm [35].

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that have serious adverse events improve safety and learn from these sentinel events. As such, accredited organizations are strongly encouraged, but not required, to report sentinel events to TJC. However, all sentinel events must be reviewed by the hospital and are subject to subsequent review by TJC. The perceived benefits of this reporting are increased access to additional expertise during the review, and that public reporting raises the level of transparency in the organization, and that reporting conveys the health care organization's message to the public that it is proactively doing everything possible to prevent similar patient safety events in the future. A timeframe of 45 days to complete an entire RCA and start the implementation phase is recommended by TJC [36]. Accredited hospitals are expected to identify the event and formalize a team response that stabilizes the patient, discloses the event to the patient and family, and provides support for the family and the staff involved (in addition to notifying the hospital's leadership and conducting an immediate investigation). The Joint Commission provides standards that relate specifically to the management of sentinel events [37]. For instance, standard LD.04.04.05, EP 7 requires that each accredited hospital define the term "patient safety event" for its own purposes and communicate this definition throughout the hospital. Similarly, standard MS.05.01.01, EP 10 requires hospitals to include sentinel event data among the information used in performance improvement activities to improve the quality of care and patient safety.

Although self-reporting a sentinel event is not required, there is no difference in the expected response, timeframes, or review procedures whether the hospital voluntarily reports the event or TJC becomes aware of the event by some other means. If a hospital wishes to report an occurrence of a sentinel event, the hospital will be asked to complete a form accessible through its Joint Commission Connect extranet site under "continuous compliance tools." If, however, TJC becomes aware of a sentinel event (eg, through the complaint process) that was not reported by the hospital, the hospital's chief executive officer (or designee) is contacted and a preliminary assessment of the sentinel event is made if the event has occurred within the past year. That can result in either a mandated formal response to TJC or a day-long interview at TJC headquarters.

Conclusion

Preventable adverse events in health care are common. Understanding the systemic conditions under which errors occur is vitally important to keeping patients safe, continuous quality improvement, and sound risk management. Incident investigation and causation analysis are important components of an overall strategy to improve patient safety and reduce errors. Surgical teams and their organizations must approach the investigation of these events in a thoughtful and systematic way to understand how the structure and processes of an organization can be redesigned to prevent errors and improve outcomes.

Recommended Resources

The Joint Commission. Root Cause Analysis in Health Care: Tools and Techniques. 5th ed. Oak Brook, IL: Joint Commission Resources; 2015.

National Patient Safety Foundation. RCA^2: improving root cause analyses and actions to prevent harm. Version 2. January 2016. Available at http://www.npsf.org/?page=rca2&hhsearchterms=%22rca2%22. Accessed April 11, 2017.

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