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## An Evidenced-Based Toolkit for the Development of Effective and Sustainable Root Cause Analysis System Safety Solutions

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### Introduction

Despite more than a decade of dramatically intensified efforts to increase the safety of the healthcare system, recent reports have demonstrated that we have been unable to gain a net improvement in our safety - the adverse event rate has remained essentially the same.<sup>1,2,3,4,5,6</sup> Safety scientists believe that this is largely because our tools for change are ineffective.<sup>7,8</sup> The culture in medicine has been criticized for being a “name, blame, and train” environment. This is similar to the safety climate in the aviation industry 40 years ago, before it became one of the main laboratories for the development of the science of safety and the study of human error. Although there is some suggestion that the Root Cause Analysis (RCA) process has led to some improvements, there are still many limitations.<sup>9</sup> For example, RCA teams may not feel empowered to effect change beyond their local unit or hospital, so they elect to train local staff to use a workaround strategy rather than notify the device manufacturer about the need for a redesign.<sup>10</sup> Thus, true root causes (in this example, poor usability of a medical device) are not addressed and clinicians are expected to compensate. This contrasts with system safety engineering practices that have demonstrated that addressing system-level failures is the most effective way to improve safety.<sup>11</sup>

Even before the Institute of Medicine report brought increased attention to patient safety, many hospitals had begun using the RCA process to investigate adverse events and serious near miss events.<sup>12</sup> The RCA process is adapted from other high-hazard industries, where it has been shown to be effective. The goal is to learn from adverse events and near misses, and to implement proactive change in order to reduce future similar events that might

compromise patient safety. The RCA process varies by institution but is generally performed by a multidisciplinary committee and includes the same fundamental steps. An event is analyzed for its causal factors, and changes are recommended that are intended to prevent occurrences of similar events. Traditionally – and too often – these recommendations have included staff training and policy changes. It is much less frequently that system solutions are proposed, such as process and equipment redesign, changes in information display, constraint changes, and reallocation of work functions.<sup>12,13</sup>

Despite the growing popularity of RCA for adverse event review, the efficacy of the current processes has been questioned. The evaluation of RCAs is limited by the fact that there are no peer-reviewed studies that examine the impact of RCAs on patient safety outcomes. Percarpio et al. performed a literature review of RCA-related articles and concluded that there is anecdotal evidence that RCAs improve patient safety but that there is no large study to show this.<sup>12</sup> This study and others describe a number of problems with the RCA framework. These problems include the risk of coming to premature conclusions regarding the root cause when the first “obvious” cause is found, hindsight bias, interpersonal relationships and agendas among committee members, and lack of strong leadership and funding. Additionally, most institutions do not perform follow-up to their RCAs to discover the effects of their interventions.<sup>14</sup>

Additional concerns regarding the RCA process was reported when Wu and colleagues recognized that there is a belief among stakeholders that the RCA process has limited effectiveness, and that hospitals often experience repeat similar events despite having recently completed a similar RCA.<sup>9</sup> The authors further state that a successful RCA focuses on gaps in the system (more than a single cause) and leads to effective and sustained solutions. Many authors have theorized that recommended actions that involve education or policy change are inherently weaker than those that involve redesign of a product or process, as the former are less likely to introduce effective change into the system.<sup>9,15,16</sup> Despite the intent to use RCAs to evaluate system-level problems, some studies have shown that RCAs in medicine often tend to focus on individuals rather than systems and that there are still more ways that the healthcare field can benefit from the integration of the knowledge from system safety engineering fields.<sup>10,17,13,18</sup>

Although the RCA process has been used for many years in medicine, few tools evaluate the actual RCA process outcomes and help hospitals ensure they are producing effective and sustainable results, especially one based on safety science. This research introduces an evidence-based model for assisting hospital-based RCA teams in implementing sustainable and effective RCA solutions.

## Methods

The RCA solution toolkit is based on a multi-institutional dataset of 334 RCA cases and 782 solutions. Through qualitative analysis and an iterative process, a team of safety science experts developed a preliminary model of sustainable and effective solution categories. This model was then modified through interviews of front-line staff regarding the solutions

implemented based on the 32 most recent RCA cases, from one to five years after being implemented.

### Qualitative Analysis

A qualitative analysis of 302 RCA cases, including 499 solutions was performed to identify abstract solution categories representative of all of the safety solutions. These solution categories were then validated by applying them to 32 RCA cases and classifying 283 safety solutions at a different medical institution. All together 334 cases and 782 solutions were reviewed. The solutions were categorized by two physician scientists (AZH,RJF). Disagreements in categorization were discussed and resolved to yield a final data set. An expert panel of three human factors engineering safety scientists (JW,VL,RW) reviewed and scored each of the solutions after reviewing de-identified summaries of the RCA cases. These scores were then used as a basis for a preliminary model of safety solutions, which classified solutions according to their potential for sustainability and effectiveness. This model was then modified based on interview data regarding retrospective assessment of the effectiveness and sustainability of solutions that had been implemented as a result of these RCA cases, from one to five years after the RCA had occurred.

### Interviews

In order to assess the safety solutions, the research team prepared semi-structured interviews to assess if front-line staff were aware of or still performed the safety solutions in daily practice and if they believed them to be effective. For each solution, a set of questions was developed to assess effectiveness and sustainability. In general, the questions were structured such that an open-ended question involving the solution was asked, and then a follow up question in the form of a 5-point Likert scale was used to give a quantifiable answer. The interview questions were grouped such that questions involving radiology staff, operating room staff, inpatient nurses or physicians would only be asked of groups that would be in a position to answer the question. Interviews were conducted at the convenience of participants. This study was approved by the MedStar Health Research Institute Review Board.

### Statistics

Means and standard deviations of scores for each category of solutions were calculated. Regression analysis was done to evaluate the fit between the scores for each category and the order of categories suggested by the expert panel.

### Results

Forty-four participants were interviewed across seven types of units or departments: medical/surgical inpatient units, intensive care unit, operation room, perioperative surgery, interventional radiology, post-anesthesia care unit and transportation. Interviews were performed, and each recorded question received answers from at least two subjects. Thirty-three nurses (including 10 intensive care unit [ICU] nurses), one radiology technician, seven operating room (OR) technicians and three transport staff were interviewed. The distribution of answers per category can be seen in Table 1. It was important to note that because of the

closed nature of some solution categories (contacting third party, counseling, disciplinary action, risk management and vague categories), it was not possible to question front line-staff regarding their effectiveness and sustainability.

The 13 solution categories, with the exception of the *vague* category, were placed on a two-dimensional framework to form a model of sustainability and effectiveness of RCA solutions. The model contains effectiveness along the y-axis and sustainability over time on the x-axis. Each scale is graded from minimally to highly effective (or sustainable) solutions. The initial model was based upon the expert ratings from the qualitative analysis. These original positions in the model were then adjusted based on the average Likert rating by category from the interview questions. Through the expert panel and interview data, the categories were further grouped according to the scale to create combined categories of high, moderate, low and minimal effectiveness and sustainability.

The individual categories are listed below with descriptions and brief examples. Further elaboration on implementation of solutions is contained in the discussion section.

### 1. Institutional

- a. *Description:* Institutional changes are large facility-wide investments that require significant time and resources.
- b. *Examples:* Creating a pediatric inpatient pharmacy or investing in a new magnetic resonance imaging (MRI) scanner with accompanying staff and physical space.

### 2. IT Structure

- a. *Description:* These solutions consist of changes to the IT infrastructure, including reprogramming the software or changing the interface in order to affect change in a process. IT structure changes have the potential to be highly effective and sustainable if implemented after careful analyses to determine how to design the IT to support the cognitive work of the users.
- b. *Examples:* New solutions may include contracting a formal usability evaluation of an existing interface to determine the appropriate changes, followed by changes that include better software integration between systems, allocating more functions to the IT system (e.g., tracking aspiration precautions in an IT system versus pieces of paper in a chart), adding forcing functions to reduce the possibility of making an incorrect data entry (e.g., having the system assist a provider in medication dosing), and changes to displays (e.g., highlighted dosage screen to enhance ease of use during double checks).

### 3. Physical Environment

- a. *Description:* These solutions include any change to the physical environment that medical staff operate within.
- b. *Examples:* These solutions may include posting signs like critical phone numbers, relocating medical devices and equipment, placing equipment of

boom arms so devices are off the floor and easily configurable to accommodate a dynamic work environment.

#### 4. Process

- a. *Description:* Process changes include solutions that are focused on changing the work process and flow of the healthcare workers in an attempt to reduce hazards. These also include the accompanying changes to any protocols and necessary process-change training.
- b. *Examples:* Process changes may include changes in team member responsibilities as well as the addition, elimination or change of particular steps during a healthcare process. For example, the addition of having the ICU physician clear patients for travel from the ICU would reduce the chance of a previously unrecognized unstable patient from leaving the unit. To reduce missed foreign bodies on radiographs, the addition of direct communication between the surgeon and radiologist could aid in the quick and accurate identification of retained surgical equipment.

#### 5. Forms & Paperwork

- a. *Description:* These solutions were categorized by the introduction of new forms or changes to documentation templates and procedures.
- b. *Examples:* Instances may include changes to preoperative checklists to include specific pieces of equipment and not just general categories in order to reduce the instances of retained foreign bodies. Other examples include changing order forms to be more representative of the language that is used for ordering blood products, e.g., “Transfuse when blood products are ready” or “Pre-op transfuse before the patient goes to OR/procedure on [specified date]”.

#### 6. Review

- a. *Description:* Review solutions are where the purpose of the solution is an assessment of a particular system or process with the aim of changing the studied process or environment. This category specifically excluded reviews that are performed solely for compliance purposes.
- b. *Examples:* Review solutions frequently consisted of referring particular cases for review by external practice committees or hand-off committees. Examples of review also include debriefs with staff involved after certain clinical emergencies to identify points in care where interventions could have prevented a deterioration of patient condition and to provide feedback to the staff.

#### 7. Training

- a. *Description:* This category focuses on solutions where education is the primary goal. Training may focus on individuals or groups.

- b.** *Examples:* Training may focus on educating staff regarding a new piece of medical equipment. It may also consist of lectures and testing of residents in a didactic setting. Common examples often focus on adding an educational component to the orientation of new staff members, providing simulated learning environments, providing brief educational session during staff meetings, or providing educational updates regarding existing medical procedures.

## 8. Policy

- a.** *Description:* Policy solutions are focused on either reinforcement of existing policies or isolated change to a policy without significant change to the underlying process, physical environment or IT system. For the purposes of this toolkit, those policies that are changed to reflect underlying systems changes can be bundled as part of those other categories.
- b.** *Examples:* A common example is reminding staff about policies via flyers, emails, newsletters and team meetings. Frequently, staff may be asked to sign a sheet saying that they have been reminded of the policy. For example, hospitals can send a memo to all attending physicians to remind them regarding the policies regarding oversight of house staff to reduce hazardous clinical scenarios due to inexperienced residents.

## 9. Compliance Check

- a.** *Description:* Compliance check solutions are focused on reviews of charts or processes for the purpose of monitoring or regulating a particular process. These solutions often use key words such as audits, chart reviews, and/or secret shoppers to verify that the process in question is being performed according to standards that are put in place.
- b.** *Examples:* Compliance check may consist of audits where staff are observed to verify they are washing hands before patient contact or verifying patient identification before medication administration or procedures.

## 10. Counseling

- a.** *Description:* Counseling solutions are those that focus on individuals involved in a hazardous event and typically involve a “development plan,” providing “feedback” or a practice committee referral.
- b.** *Examples:* These solutions refer to involved individuals and may take on phrasing such as “Coaching and counseling of all involved staff was performed.”

## 11. Contacting Third Party

- a.** *Description:* The involvement of third parties includes hosting manufacturer representatives, motivational speakers and other consultants.
- b.** *Examples:* Third parties may include having a speaker give a didactic lecture about patient safety.

## 12. Risk Management

- a. *Description:* These solutions focus only on the involvement of Risk Management.
- b. *Examples:* These solutions are typically limited to initiating contact with Risk Management.

## 13. Disciplinary

- a. *Description:* These solutions focus disciplinary actions taken towards involved staff members.
- b. *Examples:* These solutions typically end in a staff member being suspended or terminated from their position.

## 14. Vague

- a. *Description:* Vague solutions lack any details or guidance on the purpose, implementation plan or follow-up of the suggested changes.
- b. *Examples:* These solutions may use wording such as “Explore the possibility of changing process X” or “Technology Y may have prevented the event.”

## Discussion

It is important to note that while specific categories are represented as individual points in the model, and groupings have a fixed area, the details of how a specific solution is designed and implemented will have the biggest impact on reducing future hazardous situations that could lead to harm. Changing a process just because it is listed as moderately effective may have little to no impact on reducing the hazard if the process is not well understood and the implications of the changes are not equally well understood. In general terms, any specific solution, regardless of its category could be minimally effective and/or sustainable, whereas many could be made to be at least moderately effective or sustainable. In addition, it is often best to focus on several smaller but more effective and sustainable solutions than to try to fix the entire system at once. Below is a category-by-category discussion of the solutions with guidance and suggestions for RCA teams.

### Category Discussion

**1. Institutional**—Large institutional investments are the exception and not the rule for RCA safety solutions. Although they may reduce or eliminate the hazard, they should be attempted only after a thorough examination of the involved process because there is a significant chance that the same or new hazards will still be present if the process is left in place but performed in a new facility or with a new piece of equipment. Although most hospital-based RCA teams will not possess human factors engineering expertise, they may consider the use of consultants prior to implementing a large institutional solution.

**2. IT Structure**—Because of their perceived sustainability, IT structure changes are often attractive solutions for problems studied by RCA teams. However, as our previous work indicated,<sup>22</sup> an IT solution implemented without appropriate usability analyses to determine



the correct IT solution and the best means to implement it may lead to additional staff workarounds, cause an undue increase in workload, and lead to unintended risks due to a poor redesign. One concept to keep in mind is that of a balanced budget, i.e., for every new task that is created (such as a forcing function, warning message or new step) there is less time to perform other tasks, which may be even more important for patient safety. Furthermore, the heavy-handed use of warning messages may lead to alarm fatigue, where users become immune to the over abundance of alarms and fail to act on the significant alarms when they do occur. IT structure changes have the potential to be highly effective and sustainable if implemented after careful analyses to determine how to design the IT to support the cognitive work of the users.

**3. Physical Environment**—These solutions have the potential to be highly variable in their effectiveness and sustainability depending on the root and contributing causes that are identified and addressed. Solutions that include posting signs that remind staff to do their jobs are unlikely to have a sustained effect on reducing hazardous situations. However, removing an intravenous (IV) pump that created a hazardous situation due to its poor user interface could have a significant impact. Physical changes such as removing a radiolucent piece of surgical equipment will likely eliminate the risk of retained foreign body involving that piece of equipment, but they may not prevent all retained foreign bodies.

**4. Process**—The most likely pitfall would be for the RCA team to identify the wrong process or part of a process for change that will not address the underlying hazard. Specifically, in order to address a wrong patient error in blood transfusions, a process may be adapted to include a double check without addressing how the wrong blood was initially dispensed.

**5. Forms & Paperwork**—The most critical piece of implementing changes to paperwork or additional forms is to make sure they support the work of the end user. Forms that are designed to support the cognitive processes of the individuals involved have the potential to not only improve safety but also improve efficiency. It is important to remember the balanced budget concept and that any new paperwork or checkboxes will take time away from other aspects of clinical care and should be minimized when possible. In general, forms and paperwork should have font styles and sizes that are legible by the staff in the environment that they are working in (e.g., low light). Text that is legible under bright light may be illegible with reduced lighting. Emphasis should be placed on having forms that are self-explanatory and limit the need for training and space devoted to small print instructions. In addition, forms and paperwork changes are often best done with other solutions, such that changes to a process, physical environment, or IT systems are accompanied by changes to the forms and paperwork that assist in caring for the patient.

**6. Review**—Reviews of processes and systems are critical to understanding a challenge; however, the context in which the review is conducted and the expertise of the team conducting the review is paramount to the effectiveness and sustainability of the outcome. Review solutions have a high potential to become referrals of responsibility from the RCA team to another workgroup where the underlying safety issue may be lost to follow-up in



committee discussions. In an environment where it is already challenging to follow-up on specific RCA solutions, attempting to locate the results of reviews by external committees can add an additional level of complexity. When possible, domain experts from areas of concern should be part of the RCA team or potentially asked for assistance in the analysis and development of solutions. The best reviews are performed and shared with front-line staff. These may be performed by a special committee or consist of involved staff in the period right after a safety hazard is identified. Regardless of who performs the review, the critical component is sharing the information with staff to close the feedback loop and create a safety-focused environment. Reviews that are performed in secrecy are unlikely to create sustainable and effective change.

**7. Training**—Training solutions are best reserved where a knowledge deficit was found to have an important role in a hazardous situation. For example, there may be cases in which staff members did not know how to use the recently purchased IV pump, or a resident physician was not aware that high blood pressure in pregnancy is a warning sign for potentially serious complications. On the other hand, training is a poor solution to address a serious system problem such as poor design of equipment, confusing interfaces in Health IT, poorly designed work processes, or inefficient policies. A one-time training session during orientation is unlikely to provide a lasting reduction in hazards if the process taught during training does not match how the process is performed in a clinical unit. Training initiatives should focus on methods that incorporate contexts in which hazardous situations may occur, as well as use simulated environments where it is safe for staff members to learn by experience and failure. When possible, training should not be a one-time event, as skills will not develop, or can erode, if rarely practiced.

**8. Policy**—The most sustainable and effective policy solutions are part of a larger set of changes that are implemented by an RCA team. For example, a policy to solidify a reasoned process change can be implemented along with appropriate education and changes to the physical plant and/or IT structure. Policy changes that happen from the top of the organization down with little supporting effort are unlikely to create effective change. In addition, policy solutions alone typically have a high overhead requirement, meaning that enforcement and compliance with the policy requires significant administrative efforts. Therefore, while some efforts can be sustainable and effective, they are not without a cost. Moreover, if a new priority surfaces for an organization, there is only so much that can be monitored and reported upon without devoting more resources. Policy changes that are made on paper alone, without significant changes to the process or training of individuals, are likely to have limited effectiveness and/or sustainability.

**9. Compliance Check**—While observations give a sense of what is actually being done on the front lines, they frequently suffer from the Hawthorn Effect, in which the rates of compliance increase because staff are aware they are being watched. Thus, any observed rates should assume to be lower in unobserved conditions. The observed rates also typically drop to the baseline rates after the auditing is no longer performed, especially if there was no accompanying change to the underlying process or environment. Chart reviews for compliance are typically retrospective and often give little meaningful feedback to staff on

how to improve the system. Furthermore, they can consume significant administrative resources by attempting to collect data from multiple resources. Organizations should be careful in regards to the downstream effects of any long term auditing commitment. The reporting requirements can quickly trump limited patient safety resources, such that staff spend more time reporting than actively improving safety.

**10. Counseling**—In general these are very weak solutions because they are focused on individuals who are unlikely to repeat the same hazard after being involved in one adverse event. If an individual was acting recklessly or without regard to safety processes, according to Just Culture,<sup>19</sup> then there may be a role for education and training; however, the majority of hazards due to individuals are a result of slips and lapses<sup>20,21</sup> that can only be reduced or eliminated through better design of the system or process. Furthermore, any counseling of an individual will have limited to no effect on other staff members that are at risk of being in a similar hazardous situation. It is also important to note that counseling typically has a negative connotation and may negatively impact staff members' willingness to report unsafe situations that have not yet resulted in patient harm, thus reducing patient safety.

Although there is a strong role for counseling for staff members in a support role for the guilt and depression that they may encounter, these support services should be part of a comprehensive hazard review process and implemented in the immediate post event period. If implemented several months later, it is unlikely to provide the needed support to suffering staff members.

**11. Contacting Third Party**—Although well intentioned, involvement of a third party has a high potential to be an attempt at a quick fix or be a one-time event that has little sustainability on the underlying hazard. A single speaking event will likely raise awareness for a short period of time and then not have sustained impact. Having a large consulting group analyze an entire process may be a large and expensive proposition. The best solutions may include having outside groups focus on a hazard and answer a limited question, such as what is the best way to program the error message on a glucometer to reduce misinterpretations of critical results. The use of research scientists or human factors engineering consultants is likely to give a more complete analysis than one completed by a manufacturer's representatives or general consulting firms.

**12. Risk Management**—Although critical in the overall management of adverse events, the management of risk should be part of the comprehensive approach to any identified hazard, but separate from the mission of the RCA team. Although these processes frequently occur in parallel and may involve some of the same staff members, the notification of Risk Management should occur very early in the process and prior to the publication of solutions by a RCA team. In addition, it may be important for the risk management process to operate independently to garner the most support from clinical staff to focus on increasing safety versus a focus on the management of risk, which can be complimentary or require different paths.

**13. Disciplinary**—It is rare that involved members in hazardous event intend for patients to be injured. Per the Just Culture discussion above, disciplinary actions should be reserved

for the most severe situations, and as above there is a high likelihood that these sorts of actions will have a chilling effect on other staff members' willingness to participate in future RCA or patient safety initiatives. Similar to the involvement of Risk Management as a safety solution, these sorts of disciplinary issues should be handled by Human Resources who are most familiar with labor laws and have a better understanding of a staff member's prior issues. It is also important to note that even if there are concerns about an individual staff member, that individual should not become a distraction from the analysis of the presence of a hazardous situation that maybe only lead to harm in this instance because in prior situations staff members were performing workarounds or otherwise managing the hazard.

**14. Vague**—In general, vague solutions should be avoided in favor of more detailed approaches with clearly defined goals, methods and a way to measure success. If the RCA team is unable to clearly state an approach, then it is unlikely that the front-line staff will be able to implement it or any follow-up or feedback will be accomplished at a later date.

## Limitations

While this study carries a wide breadth to address a number of category types, multiple institutions and multiple years of data, it was not possible to fully explore every solution in every case. To cover the widest range of solution categories, interviews were performed with front-line staff. Interviews, instead of direct observations of workflow and processes, are more susceptible to recall bias. In addition, during several interviews, there was a sense that staff members were reciting what they thought was the right answer and not necessarily what the daily practice was. In attempt to combat this, participation was voluntary and no identifying participant information was recorded. Future research could address this using observation of larger groups of people. Furthermore, it was a challenge to recruit physician staff members on specific clinical units because they typically cared for patients on geographically diverse units. Future studies could explore focused recruitment of physicians or use additional methods. The majority of solutions that were studied were present across many types of staff members, but it is possible that physicians could have added a different viewpoint regarding the sustainability and effectiveness of solutions. Lastly, we did find that front-line staff members attributed a higher level of sustainability and effectiveness to solutions involving training, policy and compliance than was expected by the expert panel. As discussed above, this may have more to do with the perceived effectiveness and requires large amounts of administrative resources to maintain. Different methods, including clinical observations and cost-benefit analysis, may help explore this finding further.

## Conclusion

In conclusion, the RCA process has the potential to produce an effective and sustained improvement in patient safety in the healthcare system. The process starts with having a group of individuals that brings different insight and experience, including those with intimate knowledge of how daily practice works. The group must be committed to exploring the systems-level factors that created the hazardous environment, with an appreciation of Just Culture when evaluating the individuals that were involved with a given event. This toolkit can serve as a template to investigate an event to determine if any of the more

effective and sustainable solution categories can be applied to reduce future hazards. Only through changing system-level factors will we be able to prevent hazardous situations and truly create sustainable and effective change.

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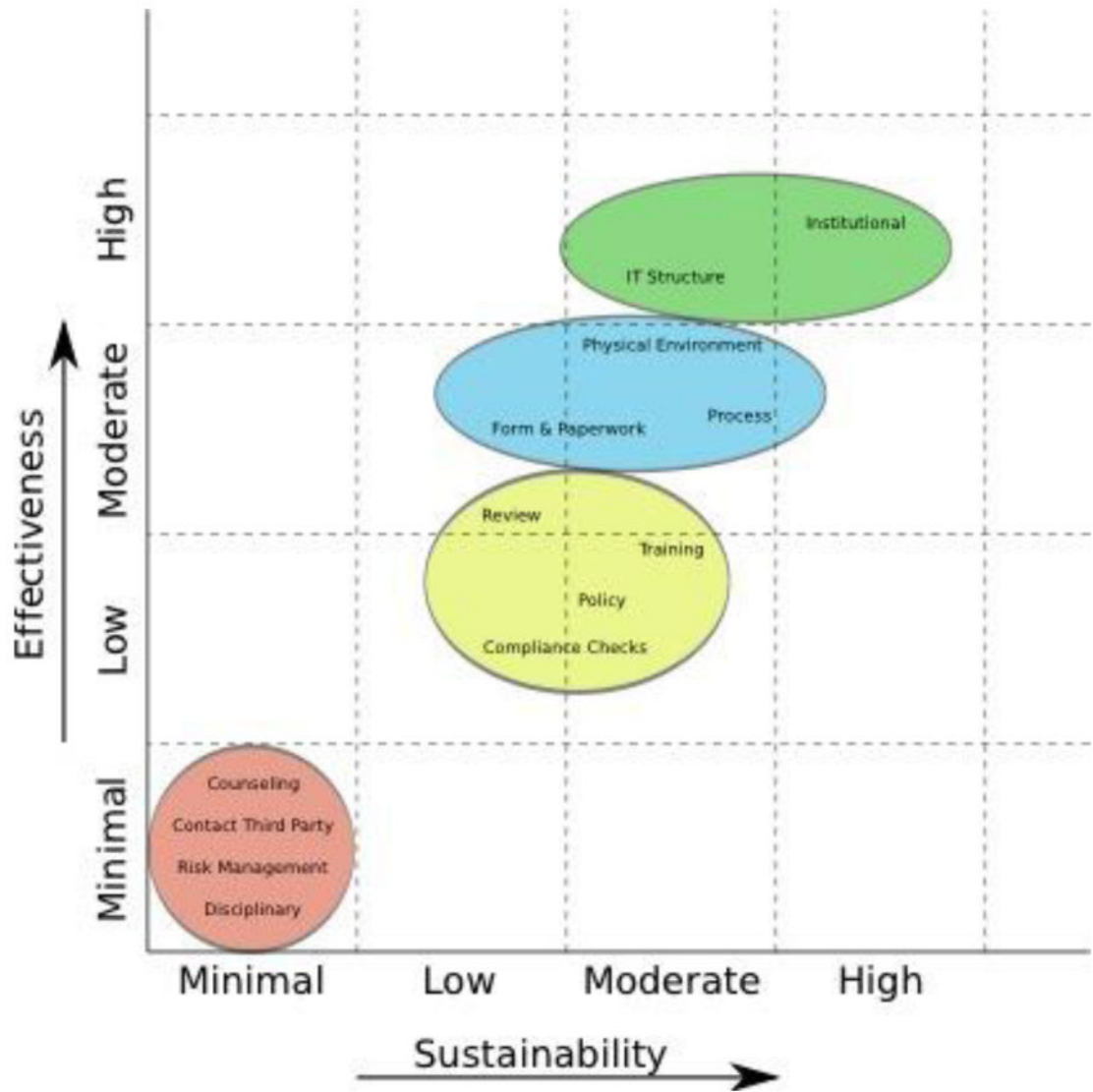


Figure 1. Model of Sustainability and Effectiveness in RCA Solutions

**Table 1**  
**Solution Categories Determined Through Qualitative Analysis**

Category	n
Compliance Check	18
Contact Third Party	0
Counseling	0
Disciplinary Action	0
Forms & Paperwork	91
Institutional	2
Information Technology (IT) Structure	11
Physical Environment	71
Policy	137
Process	183
Review	30
Risk Management	0
Training	156
Vague	0

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