Achieving a resilient response to crisis: a case study from the pharmaceutical industry

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Abstract
Based on a Grounded Theory approach, the paper outlines a qualitative case study of the operational response of a pharmaceutical goods manufacturer following the impact of a crisis event. Drawing on relevant theory, attention is placed on the mechanisms of organizational resilience through the development of a causal network model.

Keywords: Resilience, Crisis, Response

INTRODUCTION

Given the increasing demands of the world around us, organisations must strive and continually adapt the way in which they operate in order to sustain competitiveness and drive development within an increasingly uncertain environment. Organisations are continually threatened by a diverse and changing range of risks and threats. The challenges that this environment poses vary in both severity and magnitude. Events and impacts may also originate across an organisational network. Through turbulent economic, social and environmental periods; organisations and their wider networks will experience disruptions and discontinuities. Subsequently, understanding the features that allow for successful adaption and response to these conditions is essential within the volatile business environment in which modern organisations operate. This research forms an investigation into the concept of resilience within organisations. Utilising evidence from a single case study within the UK pharmaceutical industry, the paper explores the concept of resilience within the response of an organisation to crisis events.

LITERATURE REVIEW

The concept of 'resilience' has continually developed within both academia and practice over recent years (Bhamra et al, 2011). Resilience relates to the adjustment of an element or system following the influence of an event or disturbance (Holling, 1996). As highlighted by several authors (Seville et al, 2006; Crichton et al, 2009; Gibson and Tarrant, 2010; Lengnick et al, 2010), through focusing on the development of resilience within a system, it may be possible to not only effectively address and overcome crisis events but transcend these events and develop towards a more robust system. As such, resilience can be viewed as the emergent property of systems that relates to the inherent and adaptive qualities and capabilities that enable a system's adaptive

capacity during turbulent periods. The mechanisms of organisational resilience thereby strive to improve situational awareness, reduce organisational vulnerabilities to systemic risk environments and restore efficacy following the events of a disruption (Burnard and Bhamra, 2011).

Resilience based literature has been largely conceptual. The literature based within the context of resilience, as well as the literature within related areas, can be grouped broadly into three general areas of classification. These correlate to the elements of resilience as identified by Ponomarov and Holcomb (2009). These include the elements of 'Readiness and Preparedness', 'Response and Adaption' and 'Recovery or Adjustment'. Increasing publications and literature have developed following the community level resilience (Norris *et al*, 2008) and supply chain resilience (Rice and Sheffi, 2005) perspectives. Although the importance of organisational resilience is recognised within these areas, there has been little specific focus on the organisational level.

Looking at the wider context of resilience and the response of organisations to crisis events, areas such as crisis management provide a keen insight into the dynamics that influence the ability of organisation's to effectively mitigate disruptive events. Crisis management relates to four activity areas of risk reduction, readiness, response and recovery through which organisations address the complexity and impact of disruptive events (Evans and Elphick, 2005). Crisis management therefore forms a multidisciplinary activity that encompasses all aspects of an organisation's operations and forms a critical component within strategic management (Gundel, 2005). Crisis management within organisations relates to preparations and activities both before and after the onset of an event. Crisis management involves a concerted effort to initially prevent a crisis from developing and establishing prior preparations towards limiting an events impact. The initial stages of crisis management thereby relate to an organisation's ability to effectively interpret events, recognising both the potential impact and scale of the event. Following the onset of an event, crisis management activities must focus on supporting an effective organisational response to the demands of the situation and provide plans and resources towards the recovery of the organisation (Rosenthal and Pijenburg, 1990). Reilly (1993), purports however, that crisis management actually relies on three fundamental processes: problem perception, analysis, and decision making.

METHODOLOGY

The focus of this paper is to explore the response of organisations to crisis events. As a result, a qualitative based methodology was considered the more appropriate approach as this allows for the meaning individuals ascribe to a certain phenomena to be addressed (Creswell, 2009). The research followed a single case study approach and formed part of a larger research study related to organisational level resilience (Yin, 2009). Organisational resilience was explored through focusing on the response of an organisation to disruptive events. The organisational case study was developed over the course of a one year period and involved the analysis of semi-structured interviews, observations and a review of supplemental organisational documents.

In order to ensure a robust approach, a case study protocol was developed to guide the interviews through relevant areas related to resilience and crisis management (Yin, 2009). A total of 10 semi-structured interviews were conducted across the organisation. Each interview was then transcribed and analysed through multiple stages of coding and review. A coding database was developed to support this analysis. Through this, the research follows a theory building approach within data analysis and triangulates the collected qualitative data with different literature streams

towards developing an improved understanding of organisational resilience. The transcripts and coding was then independently reviewed to ensure consistency.

CASE STUDY

The case study focuses on the response of a pharmaceutical organisation following a high impact event. The organisation is composed on multiple business units, with operations and facilities located across the globe. This includes research and production facilities for healthcare and pharmaceutical goods within the United Kingdom. Given the scale of the organisations operations globally, the performance of operational divisions could potentially be significantly impacted by fluctuations and changes within international markets. In addition, the organisation is also subject to a diverse range of threats and events that could impact operations. Within the organisation, an incident or severe threat is any event that threatens safety or has the potential to cause a business interruption. Any incident or event that cannot be resolved effectively has the potential to escalate into a crisis. Within the organisation a severe event is considered to be any event that threatens the safety of employees or eventual patients or end users. The risk of faulty products entering the market is of critical concern and as a result production and distribution operations are governed by strict regulatory and quality procedures. An event which threatens the safety of potential patients could result in a product recall and carry significant legal and liability consequences, as well as threatening the reputation of the organisation.

Given the nature and end use of pharmaceutical products, quality assurance is of paramount concern. The production of medical equipment and pharmaceutical products are governed by strict regulatory requirements and legislation. As such, each product requires full traceability from sellers and distributors to suppliers of individual components and materials. The compete supply chain of the organisation is subsequently closely monitored. This approach is required to ensure operating licences and to support the recall of any defective or dangerous products. If a defect is identified, affected products can be identified and associated batches and components reviewed to establish the cause. This system is in place to ensure the safety of patients and end users.

Disruptive events, such as those experienced by the case study organisation, can create significant barriers and operational constraints. These constraints must be identified and managed effectively if an organisation is to ensure operational continuity. Within the case study organisation, the effective management of an event lies in establishing a response team. Events are then managed and coordinated by the respective members of the response team. The severity and potential consequences of an event drives ownership within response activities. The team is then required to review the organisational crisis preparations and implement an appropriate plan of action. As a result, threats and risks related to people and skills are considered a severe threat. The performance and ability of the organisation to operate is dependent on the knowledge, skill and competencies of employees and management functions.

In mid-2012, flash floods caused by heavy rainfall halted production and resulted in a large scale evacuation of the organisations production facility in the central region of the UK. The extreme weather resulted in lightning strikes, high winds, heavy rainfall and hail; impacting both businesses and the local community. The local drainage system was unable to cope with the sudden and large amount of rainfall. The large ingress of water into the organisation’s facilities had immediate implications on production. The site was subsequently evacuated following personnel safety concerns. Following the evacuation of the site, the facilities were secured from a health and safety perspective, ensuring electrical and mechanical safety of individuals and equipment.

Impacted and affected products were then identified, secured, inspected and quarantined. Physical recovery and clean-up operations were then implemented and within 36 hours the site had restored operations in a limited capacity. Following a full review, the organisation recovered and was able to return to full operations within 14 days.

Focusing on the response of the organisation to the event, three themes emerged that encompass the majority of the identified factors within the response of the organisation. These themes include Crisis and Risk Management, Activation and Detection, and Response. These are discussed within following sections.

Crisis and Risk Management

Following the experience of the organisation through previous exposure to risk and crisis events, the organisation utilises risk management tools and techniques in order to identify issues and develop corrective or preventative action plans. These are then developed and used to identify and realise opportunities, drive improvements and enhance health and safety performance. Within the organisation's approach to crisis and risk management it is imperative that organisational elements recognise the nature of risk and identify and raise issues as soon as possible. The organisation operates with an established risk register procedure across all organisational functions. The risk registers are continually updated and reviewed in accordance with current operations and projects. The resulting databases are used to communicate risks, highlight potential risks, identify possible threats, establish improvements and monitor performance.

Following the identification of individual risks or the classification of a risk factor, the risks are quantified and rated. Through this, risk management functions are able to quantify potential risks and prioritise correction actions. This approach allows for the respective management functions to meaningfully discuss risk and the associated implications; addressing both low and high probability events. The identified risks and features can then be communicated across organisational levels through a standard platform. The risk registers form an electronic database. The risk management function within the organisation operates as a collective group, allowing for the open discussion of risk from different perspectives and experiences. The limitations within the use of a risk register, rest within the accumulation and aggregation of risks. However, through the classification of risks, organisational elements are able to provide a robust platform towards the development of the organisation. The development of risk registers within the organisation is supported by regular reviews and continual communications and information exchange about risk.

Activation and Detection

The detection and classification of risks and threats forms the initial stages within the response of the organisation to any disruptive event. Detection forms a continual process within the functioning of the organisation. The classification of risk and threats prior to the onset of any disruptive event allows the organisation to develop an understanding of inherent vulnerabilities and establish associated risk tolerances or thresholds. The organisation then focuses on establishing both major and minor risk factors towards supporting the routine functioning and operation of organisational elements. As such, detection is linked to effective risk management within the organisation.

Following the onset and immediate impact of an event, regardless of cause, reports from different areas are channelled to the senior management team. These reports may contain varying

information about the severity of events or the extent of the impact. Subsequently, the first stage within the response to an event is gaining visibility of the event and establishing the as many details as possible. A critical element within the detection of a potential threat or event is gaining visibility of the issue. As such, detection of an event is often based on circumstances. Certain events will raise immediate alarms, however predominantly detection is based on individuals promptly reporting incidents. To support this, the organisation seeks to establish clear operational bounds and follow established protocols. Through this individuals are able to recognise potential indicators or discontinuities outside of routine operations and effectively escalate the response. The limitations and constraints related to the detection of potentially disruptive events are therefore linked to an inability to effectively identify or interpret signals.

The period of activation links the detection of an event to response activities. The main functions during this period involve identifying the event and its associated impacts, coordinating an event response team and then developing a suitable response plan and strategy. The organisation must assess the scale of the event and establish the events' impact. It is through this assessment that the organisation is able to address an. Following this, the response plan can then be developed. Rather than follow a predefined response routine, the event management team develops an event specific plan or strategy towards responding to and mitigating the consequences of the event. The response strategy provides a stepwise approach to response activities, utilising available information and resource.

Response

The organisation's response to severe and large scale events is based on the formation of an event response team and the development of a specific response plan. Physical response activities are then coordinated and facilitated by the members of the event response team. The senior manager on site assumes responsibility. Initial response activities may be enacted prior to or run concurrently with the establishment of the response team.

The response of the organisation to an event is support through achieving several critical success factors. These relate to the operational priorities set within the organisation. The central concern following the onset of a disruptive event is the safety of employees and impacted individuals. Externally, given the nature of pharmaceutical products, the impact of patients is also a critical concern. Quality assurance and regulatory compliance are central across all organisation functions in regards to the development and manufacture of products. There are several critical success factors within response activities. These extend throughout the various stages of response, and involve both the identification and resolution of event impacts. The critical success factors of response include:

- Containment
- Leadership
- Communication
- Speed of response
- Access to resource and expertise

The organisation seeks to establish a controlled approach within the management of disruptive events. This is in turn is supported by the emergency response plan and procedures. The first objective within response activities is to ensure the safety within impacted areas. As a result, events physically impacting the organisation will result in a halt to production and a site evacuation. This

allows responders to access and secure the site. Response activities must also ensure that health and safety is not compromised and that there are no implications for potential patients. However, within the response of the organisation, several challenges are presented. These include:

- Understanding what skills and expertise are available
- Identifying where these skills and expertise lie within the organisation
- Establishing access to skills and expertise
- Connecting available skills and expertise to response activities
- Recognising opportunity
- Access to information

The end point of a crisis or disruptive event is largely subjective. The initial impact of an event is typically the most severe, however extenuating circumstances and resolved issues can cause significant long-term implications. A return to routine operation and function does not always signify the recovery from an event. Dependent on the type, scale and impact of an event, the end point or recovery may vary significantly. Small scale events may also carry significant consequences. Instead, response operations focus towards a point of stability within the functioning of the organisation. It is at this point that the organisation is able to focus on recovery operations.

CONCLUSION

Following the evidence of the case study, several insights can be gained into the effective response of an organisation to a crisis event. A proactive approach within the response of an organisation limits the opportunity for the escalation of impacts following disruptive events. Within the case study organisation, this approach is supported through the integrated monitoring of organisational elements and functions. These monitoring systems include production, supply chain, safety, strategic objectives and environmental monitoring. Given the nature of the products being produced, the monitoring of the production area is critical. However, these systems extend throughout the operations and functions of the organisation and monitor changes and operational fluctuations. Through setting both operational and risk tolerances within organisational elements, the organisation is able then to recognise discontinuities. The systems also support the organisation's ability to identify the potential causes of discontinuities.

Through the immediate identification of a threat and the potential impact of an event, the organisation is able to constrain and restrict the potential consequences and implications of an event to a certain extent. Although, it is almost impossible to completely limit the impact of an event, through immediate action the organisation is able to limit certain factors. For example, restricting a faulty product entering the market. As such, a proactive approach to the management of disruptive events relies on an organisation's taking a proactive approach within crisis event and not waiting for the full impact of an event to be realised before responding. This should be supported through an established chain of authority within the escalation of response activities.

Following the detection of an event, in order to respond effectively, organisations are required to anticipate a broad range of issues. The need to anticipate wider issues allows an organisation to appropriately resource response activities and establish the initial extent of the impacts. Although this assessment may change as response activities progress. The ability to effectively identify impacted individuals, areas (physical infrastructure), supply chain, stakeholders, operating market, environmental concerns and economic impacts quickly is critical within response activities.

Organisations must also identify the wider issues linked to events such as issues within the market or if the events may be linked to a broader issue.

Through investigating the case study organisation's response to crisis events and reviewing relevant literature, resilience and an organisation's ability to overcome disruptive events stems directly from the capabilities of organisational members and the structures and support provided across organisational networks. In order to support a resilient response to crisis events, organisations must look to effectively establish structures and robust systems during routine functioning through which the organisation is then able to draw upon when required.

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