

Leveraging a Bayesian network approach to model and analyze supplier vulnerability to severe weather risk: A case study of the U.S. pharmaceutical supply chain following Hurricane Maria

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ABSTRACT

The United States government has identified the health care sector as part of the critical infrastructure for homeland security to protect citizens against health risks arising from terrorism, natural disasters, and epidemics. Citizens also have expectations about the role that health care plays in enjoying a good quality of life, by providing response systems to handle emergencies and other illness situations adequately. Among the systems required to support desired performance levels is a robust and resilient pharmaceutical supply chain that is free of disruption. Shortages of drugs place undue pressure on healthcare providers to devise alternative approaches to administer patient care. With climate change expected to result in increasingly severe weather patterns in the future, it is critical that logistics engineers understand the impact that a catastrophic weather event could have on supply chain disruption to facilitate the design of supply systems that are robust and resilient. This study investigates the main causal and intermediate events that led to risk propagation in, and disruption of, the U.S. pharmaceutical supply chain following Hurricane Maria. A causality Bayesian model is developed to depict linkages between risk events and quantify the associated cumulative risk. The quantification is further examined through different advanced techniques such as predictive inference reasoning and sensitivity analysis. The general interpretation of these analyses suggests that port resilience is imperative to pharmaceutical supply chain performance in the case of Puerto Rico.

1. Introduction

A nation of healthy people is the bedrock of a productive national economy. Good health is also indicative of a good quality of life. In this regard, both governments and citizens have expectations about the role and function of the health care system as an intervention mechanism in saving and preserving life [1]. United States citizens expect to receive the care that they need when administered to a hospital or health care facility to address an emergency situation or chronic disease. Part of these expectations includes access to prescribed drugs that support care and recovery in an expedient manner. Shortages of critical drugs in the pharmaceutical supply chain pose a national security threat [1]. In June 2018, the American Medical Association (AMA) published a statement indicating that continuous shortages of pharmaceutical products present a health care crisis [2]. Whenever drug shortages arise, both treatment

options and quality of care are compromised. To ensure an effective health care system that is capable of responding to the medical requirements of its citizens, a robust and resilient pharmaceutical supply chain is essential.

Seventy percent of commonly used drugs carried by U.S. pharmacies are produced overseas, in countries including Australia, Canada, China, France, Germany, India, Japan, Malta, Singapore, Sweden, UK, and USA [3]. Several factors can lead to disruptions in global pharmaceutical supply chains, resulting in shortages in the U.S. These risks can be classified into two broad categories: (i) operational risks and (ii) disruptive risks [4]. Operational risks refer to uncertainties inherent in everyday supply chain activities that impede the delivery of customer requirements. Examples include price volatility, demand fluctuation, equipment breakdown, and quality failures. Disruptive risks are those events that lead to major interruptions in the supply chain, negatively

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impacting delivery of requirements to the customer. Catastrophic events such as earthquakes and hurricanes, as well as man-made disasters such as cyber-crime and political protests fall into this category.

In recent years, climate change, and the resulting extreme weather events, have been identified as major disruptive risks by supply chain risk managers. In a survey on supply chain risks, natural disasters that impact supplier facilities were counted among the top risk concerns of supply chain managers [5]. With climate change events predicted to increase ten-fold in the future [6], understanding the risks posed to supply chains is imperative. Extreme weather events lead to serious consequences in supply chains, particularly those with a global span. If an extreme weather event precedes or coincides with another risk event, the situation becomes extremely dire. For instance, in September 2017, Hurricane Maria hit Puerto Rico as a Category IV storm and exposed the vulnerability of the island's pharmaceutical supply chains to the consequences of extreme weather risk. Simultaneously, one of the most severe influenza seasons on record was beginning and within weeks escalated to levels that exceeded twice the national baseline, increasing the demand for intravenous normal saline to treat patients.

Approximately 10% of drugs used by U. S. citizens are produced in Puerto Rico [7], which is home to 49 facilities approved by the Food and Drug Administration (FDA) for producing pharmaceuticals and medical devices [8]. The impact of the storm on the U.S. pharmaceutical supply chain became obvious as disruptions in pharmaceutical manufacturing and delivery led to severe shortages of saline solution in hospitals on the U.S. mainland [7,9]. In the U.S., 40 million bags of saline solution packaged in two sizes (250 ml and 500 ml) are used in hospitals per month [10,11]. In the event of a shortage of either size, some substitution with accommodation can be made. However, in the absence of bagged saline solution, other methods have to be devised to treat patients. This comes at a price to health care quality as issues, such as contamination or dilution errors, can arise, propagating even further risk in the system [10].

The impact of Hurricane Maria on the pharmaceutical supply chain led to serious negative consequences on the U.S. health care system which lasted for several months [7,12]. About fifty percent of hospitals suffered shortages of saline solution [13]. Moreover, there were only three FDA-approved suppliers for saline in the U.S., with half of the requirements produced by one supplier, Baxter, which had located the majority of its production operations, including all of the mini-bag size, in Puerto Rico [10,14]. The other two suppliers were unable to increase production to buffer the shortage, as these facilities were already operating at full capacity [10,15].

Following the disaster and in response to other factors that cause supply shortages, a summit to discuss the security of the national healthcare system recommended the use of historical data and manufacturing input to identify drug shortages and develop strategies to create more resilient supply chains [1]. Among the strategies recommended was the establishment of production centers in multiple global locations to hedge the risk of natural disasters. Thus, if this approach is recommended as a best practice in pharmaceutical supply chain design, it would be beneficial to develop risk models that help to evaluate the risk associated with a supplier location in the event of severe weather risk. Using the risk event of Hurricane Maria as a case study, this paper seeks to answer the following questions:

- (i) What were the *main causal factors* and *intermediate events* that led to the disruption of the U.S. pharmaceutical supply chain following Hurricane Maria's devastation of Puerto Rico?
- (ii) What is an appropriate *estimate of the risk exposure* of disruption to U.S. hospitals?
- (iii) Where should *risk mitigation strategies* be targeted to minimize post-catastrophic disaster consequences to the pharmaceutical supply chain?

To answer the aforementioned questions, a detailed model for the

specific case of the pharmaceutical supply chain following a natural disaster was developed using the Bayesian network (BN) approach. This model contributes to the supply chain risk management literature by developing a more detailed approach to quantify the risk associated with extreme weather events, based on an actual situation. The outcome of this research will provide high level insights into reducing the exposure of natural disasters and corrective susceptibilities on the pharmaceutical supply chain and evaluating the applicability of countermeasures based on the types of weather risk.

The exposition of the paper is as follows: Section 1 discusses the selection of supplier locations and considerations in designing supply chains to minimize the effects of disaster risk. Section 2 discusses the fundamental principles of Bayesian networks and applications. Section 3 describes the causality Bayesian network model developed for the case of Puerto Rico following Hurricane Maria and describes the causal factors. Section 4 addresses the modeling and quantification of the Bayesian network. Section 5 discusses the results and analysis, and Section 6 ends with concluding remarks.

1.1. Review of the literature

A supply chain is a network of entities, integrated from initial supplier to final customer to effectively and efficiently synchronize demand and supply across companies, while providing value to all stakeholders [16]. Supply chain management is an umbrella term that captures both operational and strategic functions to meet the needs of customers. Operational activities include routine sourcing, conversion, production, and logistics, while strategic functions focus on coordination, collaboration, and integration of key functions and processes within and across companies [17]. Logistics management is defined as "that part of supply chain management that plans, implements, and controls the efficient, effective forward and reverse flow and storage of goods, services, and related information between the point of origin and the point of consumption to meet customers' requirements" [17]. Both operational and strategic factors are critical considerations in designing high performing supply chains. Fig. 1 provides a simplified illustration of the pharmaceutical supply chain to depict the relationship between the two terms.

This section is designed to pursue three objectives: (i) to describe how supplier locations are selected; (ii) to discuss the interrelationships between risk, vulnerability, and resilience; and (iii) to review the methods developed and approaches used to evaluate supplier and supply chain network risk. These three factors are critical to developing a disruption free supply chain network.

1.2. Selection of supplier locations

Supplier selection to minimize cost and risk and meet customer expectations is a fundamental responsibility of procurement managers [18]. Suppliers are often selected from geographic regions that allow companies to derive cost and benefit advantages [19]. Cost is critical in the pharmaceutical sector because of the large investments made in research and development, limited patent protection, and regulatory requirements [20]. To mitigate losses once patents expire, companies locate manufacturing plants in low cost regions and consolidate companies into fewer larger firms. Puerto Rico has become a pharmaceutical manufacturing hub because of the tax incentives offered [21–23], strategic geographic location between North and South America and Europe, globally approved manufacturing sites [23], highly trained workforce [24], relatively low wages [22], stable political climate, and legal infrastructure that supports U.S. FDA regulatory requirements and intellectual property. Most companies, however, place little emphasis on evaluating the associated risk [25]. One of the downsides of Puerto Rico as a location is its exposure to severe weather risk.

1.2.1. Supply chain risk, vulnerability, and resilience

Supply chain risk, vulnerability, and resilience are three interrelated

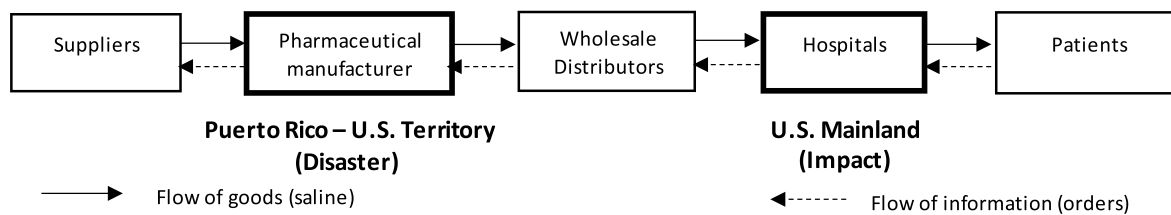


Fig. 1. A simplified diagram of the pharmaceutical supply chain for saline.

terms used in reference to the performance of supply chains that are subject to negative shocks. However, important distinctions exist between these three terms.

Supply chain risk is a broad area encompassing events that arise due to uncertainty or unpredictability, and which lead to supply chain disruptions that have a negative impact on supply chain financial performance [4]. In general, risk is measured quantitatively by combining the probability of occurrence and the severity of impact [26]. Because of the links that exist between supply chain nodes in one supply chain and those in other supply chains [27], understanding the source and nature of supply chain risks is important to effectively mitigate risk and manage supply chain performance. Supply chain risks stem from myriad sources, including offshore manufacturing, terrorism, political unrest, natural disasters, economic cycles, fluctuations in demand, infectious diseases, infrastructure, man-made disasters, currency volatility, price risks, information systems risk, quality risks, pilferage, lean supply chain strategies, outsourcing and sole sourcing, forecasting, intellectual property theft, customer payment default, inventory policies, capacity limitations, and delays due to disruptions, [4,28–31]. Supply chain risk (SCR) and supply chain risk management (SCRM) definitions vary and include both customer and firm perspectives. For example, Chase and Jacobs [29] define supply chain risk as the probability that a disruption will reduce a supply chain's capability to deliver customer orders without delays. Zsidisin and Ritchie [32] define supply risk as “the probability of an incident associated with inbound supply from individual supply failures or the supply market occurring, in which its outcomes result in the inability of the purchasing firm to meet customer demand or cause threats to customer life and safety” Benton [33] supports these definitions by defining supply chain risk in terms of the likelihood of an event occurring that results in negative consequences. Tang [4] takes a more corporate perspective by defining supply chain risk management as the “coordination and collaboration among supply chain partners to meet profitability requirements and ensure continuity.” From these definitions it becomes obvious that management of risks in pharmaceutical supply chains is necessary to support the delivery of efficient, effective, and timely health care to patients.

Supply chain vulnerability is defined as “an exposure to serious disturbance, arising from risks within the supply chain as well as risks external to the supply chain” [34]. Pettit (2010) extends this definition from merely an “exposure” to “susceptibility” of a supply chain to internal and external risks [35]. Rousseau (2003 in Ref. [36]) provides a more general definition of vulnerability, which nonetheless is applicable in understanding the linkages between risk and vulnerability in a supply chain context. The author describes vulnerability in terms of the risk faced compared to the capacity to mitigate the risk, or in mathematical terms, $Vulnerability = Risk/Capabilities$ (Rousseau, 2003 in Ref. [36]. Laville [37] notes that supply chain vulnerability has increased with globalization and modularization.

Supply chain resilience is somewhat under-explored in the academic literature [38,39] and among scholars, a common definition is still lacking [40]. The term “resilience” is used to refer to the ability to return to a former state after being subjected to a period of stress. Ponomarov and Holcomb [41] describe supply chain resilience as the ability to adapt to unforeseen conditions, respond to disruptions, and recover to the desired level of performance to ensure business continuity [41].

Three dimensions of resilience are robustness, resources, and recovery [38]. Supply chain resilience includes preparedness, reaction, recovery, and growth [40]. The emphasis in the literature appears to be on recovery rather than preparedness, but proactiveness is critical for recovery and growth [40]. Some proactive measures discussed in the literature to ensure supply chain resilience include building buffer inventories; hedging currencies; developing rapid means of communication with supply chain partners; strategic staging of resources; resource pooling across supply chain echelons; identifying, evaluating, and approving alternative suppliers; redesigning products to facilitate the interchange of component parts; ensuring redundancy is built into digital networks; and designing supply chain networks such that the concentration of supply sources within a specific geographical area is reduced [4,29,30].

From these definitions, it becomes obvious that to reduce supply chain vulnerability, the development of capabilities to manage risk is important. Since it is impossible to eliminate all risk, supply chains must be designed to be resilient [40]. Thus, there is a need to deploy a systemic approach to deal with the possibility of disruption consequences [42–44].

1.2.2. Considerations in selecting locations to minimize the effects of disaster risk

Risks associated with supplier selection tend to be described broadly and specified in terms of common metrics such as cost, quality, delivery, flexibility, and reputation risks [45]. However, according to a report published in Homeland Security Affairs, at least three factors that interplay in the consequences of disaster risk need to be considered: (i) dependencies within the system, (ii) distance between demand and supply points, and (iii) capacity of substitute networks to meet requirements [46]. These factors have been highlighted in regard to civilian risks following a disaster but are equally applicable to supply chain node risk. With regard to the first point, the dependencies within the supply chain system must be understood, including those factors that impact supply and demand balances within the supply chain. In reference to the second, transportation networks and logistics and supply chain relationships must be known and foreseen to understand where system failures are likely to occur in the movement of goods from supply to demand points. For the third point, critical infrastructures must be identified to enable redundancies, e.g., in the electric power, water, transportation, and telecommunications systems. The 2017 Atlantic hurricane season revealed several factors of importance in designing resilient supply chains to minimize failures and recovery delays in the event of a large-scale natural disaster.

While the pharmaceutical plants in Puerto Rico suffered minimal damage from Hurricane Maria, failure in the electric grid infrastructure prevented the immediate resumption of production. Failures in the transportation and logistics infrastructure also presented challenges in moving employees and materials to and from manufacturing plants [47] and materials through the main port [48,49]. Other infrastructural failures also impacted the pharmaceutical supply chain due to the ripple effect on factors that ultimately impacted supply chain performance. Based on the impact and the risk events that propagated from the storm, the FDA identified 10 companies and 40 critical drugs that were at risk of being supplied to the U.S. mainland, some of which had only one

supplier [50].

1.3. Approaches used to assess supply chain risk

A search of the academic literature revealed that methods used to assess supply chain risk include quantitative, qualitative, and combination methods. Common supplier evaluation methods used by practitioners include the cost-ratio and linear averaging methods [33]. The cost-ratio method evaluates supply risk by calculating all the costs associated with acquisition of a product and ranks suppliers based on total cost. The linear averaging method uses a simple weighted average to compute a score based on defined criteria, to which weights are attached based on a company's competitive priorities.

Sharma and Pratap [51] discuss the use of Failure Mode and Effects Analysis (FMEA) to identify and prioritize supply chain risks, with broad categories of risk identified within the firm, the industry, and the broader environment. Using this method, supply chain risk is computed by calculating a risk priority number (RPN) that incorporates the probability of a risk event occurring, the likelihood of detection, and the severity of the consequences. FMEA has also been used in combination with other methods. Arabsheybani et al. [45] propose an approach that combines FMEA in combination with Fuzzy MOORA to minimize supplier sustainability risk, while maximizing profits through order allocation. Other methods have been used to select suppliers, while also considering supplier risk factors. De Felice et al. [18] used Analytic Hierarchy Process (AHP) to evaluate the factors that are critical to supplier performance that could become a risk if performance falls below expectations. The authors evaluated seven factors: quality system, performance, technical capability, reputation, price and cost, financial stability, and geographical location. Kirytopoulos et al. [19] applied an Analytic Network Process (ANP) approach to evaluate pharmaceutical suppliers. Pourhejazy et al. [52] used Data Envelopment Analysis (DEA) to rank alternative supply chain networks for a Liquefied Petroleum Gas company. More robust quantitative approaches include mathematical programming models and stochastic methods. Fuzzy TOPSIS has been applied to quantify risk factors in pharmaceutical supply chains [53]. Govindan and Jepsen [54] applied ELECTRE TRI-C approach to classify suppliers based on risk exposure. Simulation has been employed to evaluate supply chain cost and lead times under different network design configurations [4].

The application of Bayesian networks to calculate supply chain risk exposure or predict disruptions is an emerging area of research [25]. Lockamy and McCormack [55] developed a Bayesian network to assess risk in automotive supply chains [55]. Nepal and Yadav [56] combined FMEA and Bayesian networks to evaluate sourcing risks in the pharmaceutical sector across four countries. The study focused on evaluating operational risks related to sourcing effectiveness, e.g., seaport efficiency, port equipment availability, documentation accuracy, length of supply chain, worker strikes that disrupt the supply chain, wage fluctuations, quality issues, and price and cost changes. Sharma and Sharma [25] developed a conceptual Bayesian network model that integrated a variety of risks based on data collected across a number of industries. They incorporated eight categories of risk – process, supply, demand, environmental, relationship, catastrophe, logistical, and control risk – which were ranked using a pairwise comparison. In their model, the relative importance of catastrophe risk was ranked among the least important. Table 1 provides a synopsis of existing themes to evaluate suppliers. These general themes serve as a baseline snapshot in developing the proposed model.

After surveying the literature, one important gap is identified and needs to be addressed. There is a lack of risk assessment models that design and quantify the impact of severe weather risk on pharmaceutical supply chain disruption. To address this gap, this research proposes the following:

Table 1

Quantitative methods used to evaluate suppliers.

Authors	Types of Risk	Method(s)	Sector(s)
Blackhurst et al. [57]	Supplier risk factors, product risk factors	Risk Index/ Probability and Severity	Automotive
Chan et al. [58]	Supplier risk	Fuzzy Analytic Hierarchy Process (Fuzzy-AHP)	Manufacturing
Lockamy [59]	Supplier risk – external, internal, network	Bayesian Network	Electronic
Lockamy and McCormack [55]	Supplier risk – misalignment of interest, leadership, product, logistics, human, financial risks	Bayesian Network	Automotive
Mehralian et al. [53]	Supplier risk – quality, flexibility, environmental, delivery, technology, cost, reputation, information	MADM/Fuzzy TOPSIS	Pharmaceutical
Nepal and Yadav [56]	Supply chain risk - port logistics, documentation, price, wages, currency, quality, labor, time	FMEA and Bayesian Networks	Chemical Distributor
Sharma and Pratap [51]	Supply chain risk – product, planning, environmental, industry, leadership	FMEA	Manufacturing
Benton [33]	Supplier risk - cost, lead time, quality defects	Cost Ratio Method Linear Averaging	Any
De Felice et al. [18]	Supplier risk - technical, quality, financial, location, reputation, cost	Analytic Hierarchy Process (AHP)	Swedish/Iranian firms
Dweiri et al. [60]	Supplier risk – price, quality, delivery, service	Analytic Hierarchy Process (AHP)	Automotive
Govindan and Jepsen [54]	Supplier risk	ELECTRE TRI-C	Electrical
Hosseini et al. [61]	Resilience-based supplier selection	Bayesian Network (BN)	Any
Sharma and Sharma [25]	Supply chain risk – macroecon., disaster, demand, supply, process, control, relationships, logistics,	Bayesian Network (BN)	Textile
Pourhejazy et al. [52]	Supply chain risk, supplier network	Data Envelopment Analysis (DEA)	Liquid Petroleum Gas
Sener et al. [62]	Supplier risk-quality, time, financial, price, capacity	Fuzzy Linear Programming and Fuzzy regression/ Boolean approach	Non-specific (conceptual)
Arabsheybani et al. [45],	Supplier risk - sustainability	FMEA in combination with Fuzzy MOORA	Electrical, Automotive, Chemical, other

- Identification of potential factors that are responsible for pharmaceutical supply chain disruption under severe weather conditions.
- Development of a probabilistic graphical model, a Bayesian network (BN), to quantify the potential risk of supply disruption in a hospital's inbound pharmaceutical supply chain from exposure to a Category IV hurricane.
- Perform a set of advanced analyses, such as predictive inference reasoning and sensitivity analysis, to provide deeper insights into the impact of the results of the proposed model.

- Demonstrate the efficacy of the proposed model as a risk assessment tool for identifying the supply chain vulnerabilities that need to be prioritized to minimize pharmaceutical supply chain disruption.

2. Fundamentals of Bayesian Network and its application

A Bayesian model is an acyclic graphical depiction of risk or uncertain events, illustrated as a system of nodes connected via arrows called “edges” to show the direction in which risk cascades from a main causal event to the affected nodes [63,64]. The visual structure of a Bayesian network indicates where a risk event originates as a main causal event and the flows to dependent variables that eventually determine the consequences of the risk.

In a Bayesian network model, any event that arises from a previous event is called a child node, while the event which causes the impact is designated as the parent node [65,66]. Probabilities of occurrence are associated with all nodes, whether a main causal event or an event conditioned on a main causal event. Bayesian networks can utilize either deterministic or probabilistic data and are unique in allowing risk assessments using either historical data or expert judgment [25]. All nodes have an associated node probability table (NPT). The probability of each event happening is indicated in the node probability table for each risk event. Parent nodes state the prior probabilities for the node state, whereas child nodes indicate the posterior probabilities of the node state as a condition based on the parent node states. Node states can take on a variety of probability distributions such as Boolean, continuous, and discrete.

A diagrammatic example of a Bayesian model is shown in Fig. 2 below. Node A is the parent node, representing the main causal event and Nodes B and C are intermediate events that derive their states from the parent Node, A. Conversely, we can say that the probability of Nodes B and C happening are conditional upon Node A's state. Node D is a consequence of the events represented by Nodes B and C. The direction of the arrows shows how the information propagates.

Based on the above Figure, the Bayesian equation can be streamlined as follows:

Everything seems fine, but please make those two big parenthesis (before “D” and before “node”) small – like the regular one. (1)

Bayes Rule extends this theory further to allow for the assignment of probabilities to one event occurring on condition that another prior event has occurred. An example would be the probability that the country's electric grid could go down (B), given that a catastrophic hurricane (A) has occurred. This is denoted as follows [67,68]:

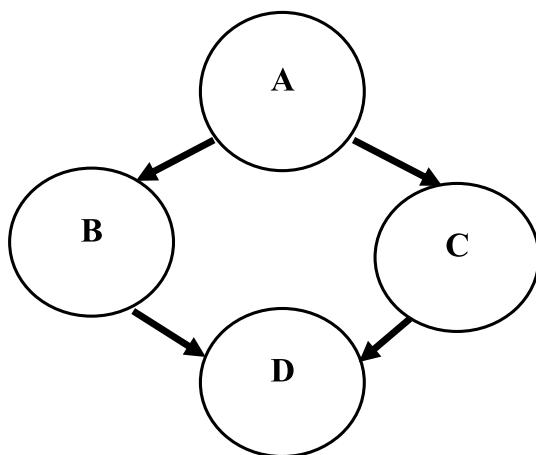


Fig. 2. Diagrammatic depiction of a bayesian model.

$$P(A|B) = \frac{P(A \cap B)}{P(B)} \quad (2)$$

Bayesian networks allow risk assessment in complex systems, such as supply chains, which have multiple interdependencies and interrelationships. Bayesian networks have been applied to predict extreme events that occur very rarely or which are “unusual in nature” [69].

There are several advantages of using a Bayesian network model in risk analysis. First, by observing the structure of a Bayesian model, one can determine the causal relationships without further computations [25,65]. Another advantage is that it allows a better assessment of risk because it is flexible in accommodating more detailed information on the causes and propagation events of the risk as new information is received. Bayesian networks incorporate conditionalities, so that risk is computed based on a series of prior events that impact the outcomes. Bayesian networks have been applied to multifarious problems, e.g., to evaluate risk and reliability; diagnose the source of faults; prevent the likelihood of failures; assess how managerial interventions impact sustainability; predict uncertainty and metrics in manufacturing; and categorize data and manage projects. Bayesian networks are also useful where the risk associated with a particular event cannot be treated solely on the basis of historical incidents of the event and expert opinion is required.

To further explore the versatility of Bayesian networks in multiple areas, readers should consider the works of Perez-Minaña [70], (natural resource management); Zhou et al. [71] (safety risk analysis); Hossain et al. [72] and Hossain et al. [73] (waterway port); Neil et al. [74] (legal arguments); Kabir et al. [75]; Hossain et al. [76] (supply chain); Ghosh et al. [77] (project management); Hossain et al. [78] (electrical infrastructure); Hosseini and Sardar [79] (electric vehicle); Shin et al. [80] (cyber risk); Saldao et al. [81] (information dependencies); Alipio et al. [82] (vehicle traffic and flood monitoring); Goyal and Chanda [83] (financial institution); Hossain et al. [84]; and several others.

3. Problem description and model formulation

This section describes the Bayesian network (BN) model depicting the impact of severe weather risk on the U.S. pharmaceutical supply chain. The research methodology used to develop the model is illustrated in Fig. 3. The top view of the proposed BN model is depicted in Fig. 4.

To develop a detailed model for the specific case of the pharmaceutical supply chain following the rare event of Hurricane Maria, the first step was to conduct an extensive search of the public literature domain. To construct a model with a high degree of confidence, multiple sources were used to gather details of the events that unfolded after the disaster. Information was extracted from news articles, videos, government and other reports to develop a picture of the situation that unfolded following the disaster. From the data gathered, the trigger event, main causal events, intermediate events, and consequences were determined.

The model was constructed using AgenaRISK Version 10 software. Boolean logic was applied to design all nodes (see Table 2). The Boolean nodes can have only two possible states, for example, True/False or Yes/No. Alternatively, the states can be customized based on the circumstance such as Failed/Functional. Probability tables were developed for all 34 nodes included in the model. For some nodes, such as the probability of a severe hurricane or influenza outbreak, historical data were used. For others, such as the financial distress of the electric utility company, bankruptcy information from court documents was used in combination with information in the public domain. Probabilities for other nodes were based on news reports, academic papers and official reports following the disaster. Advanced analyses, such as predictive inference reasoning and sensitivity analysis, were performed and the

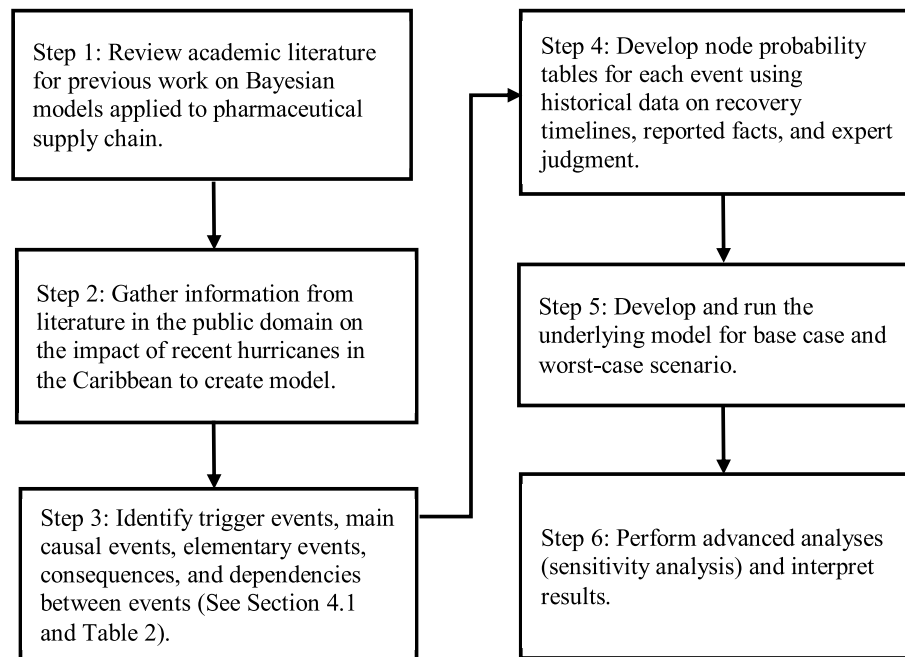


Fig. 3. Methodology used to develop the model.

model was propagated to develop insights on how to decrease the overall vulnerability to U.S. hospitals and pharmaceutical supply chains following severe weather risk.

3.1. Description of the factors

The main and intermediate causal factors were established by extracting information from secondary sources, including data archives, reports, websites, newspaper articles, videos, and published stories. The events that unfolded following Hurricane Maria, Hurricane Irma and other recent hurricanes and storms provided a rich source of information for identifying the risk events. In a similar way, the onset and impact of the influenza outbreak in the United States and the impact of the number of approved suppliers was determined. In each case, the causes and consequences of the risk event were ordered to indicate parent and child relationships.

3.1.1. Identification of main risk factors

The main risk events identified in pharmaceutical supply chain disruption are: (i) a Category IV or V hurricane hitting Puerto Rico and damaging critical infrastructure, (ii) factory buildings not constructed to withstand Category IV or V hurricanes, (iii) employees' housing not constructed to withstand Category IV or V hurricanes, (iv) a utilities company in financial distress with limited resources to invest in and maintain a resilient electric grid, (v) a significant percentage of the product supplied by a single supplier (Baxter) located in Puerto Rico, (vi) the amount of product supplied by other suppliers combined, and (vii) an outbreak of influenza in the United States that increases demand for the product (saline) above requirements for average hospitalization rates. The occurrence of these risk events simultaneously presents a unique situation that could lead to disruptions in supplies to U.S. hospitals.

The following sources were used to identify the main causal events: Association for Financial Professionals [85]; AMA [2]; AON Benfield [86]; ASHP [1]; Bartley [87]; Becker [88]; Becker [89]; Bonner [90]; Buchanan [91]; Byrd [92]; Centers for Disease Control [93]; Chandler [6]; Cision PR Newswire [94]; Cullen and Walton [95]; CNN News [96]; Daily Market Update [97]; Dept. of Homeland Security [98]; Department of Homeland Security [7]; EIA [99]; Elvidge [100]; Entralgo [101];

FEMA [102]; FEMA [103]; Ferris [104]; Fiegerman and Murphy [105]; Fox News [106]; Gillespie [107,108]; Jarvis [109]; Harris and Olson [110]; Healy [111]; Inside Towers [112]; Hinojosa and Melendez [113]; Isidore et al. [114]; National Hurricane Center [115]; Oxfam Report [116]; Palin [117]; Paavola [118]; Puerto Rico Report [14]; Reardon [119]; Resnick and Barclay [120]; Schmidt [121]; Science Friday [12]; The Guardian [122]; Viglucci, [123]; Weather Underground Archives [124]; Weise [125]; Center for Puerto Rican Studies [126].

3.1.2. Identification of intermediate risk events and dependencies

The direct (immediate) factors that could potentially cause disruptions in the pharmaceutical supply chain to U.S. hospitals are an *increase in product demand*, and a *shortage in product supply*. These factors and dependencies are described further below.

• Increase in Product Demand States

Hospital supply disruptions are impacted by unique risks posed by pharmaceutical *product demand states*. During outbreaks of disease, demand requirements could rise above normal seasonal patterns. The influenza season runs from October to March, with the beginning coinciding with the end of the hurricane season, which runs from June to November. If the number of symptomatic cases of influenza increases after a severe hurricane, leading to increased hospitalizations, product demand requirements for saline could increase to levels significantly higher than that for the average season. Information to establish this state was derived from the following sources: [7,13,93,127–129].

• Product Supply States

Product supply states are impacted by several factors that emerge in post-hurricane disaster situations. Two input nodes that could pose potential risks to *product supply states* are (i) *delays in outbound logistics* and (ii) *reduced total production capacity*.

I. Delays in Outbound Logistics: An agile and reliable supply chain is critical to ensure an uninterrupted supply of products to hospitals. One factor that could impact product supply is *logistics delays of outbound products* caused by *reduced port operations efficiency*. Five risk factors that could cause *reduced port operations efficiency* are (i) *employees failing to*

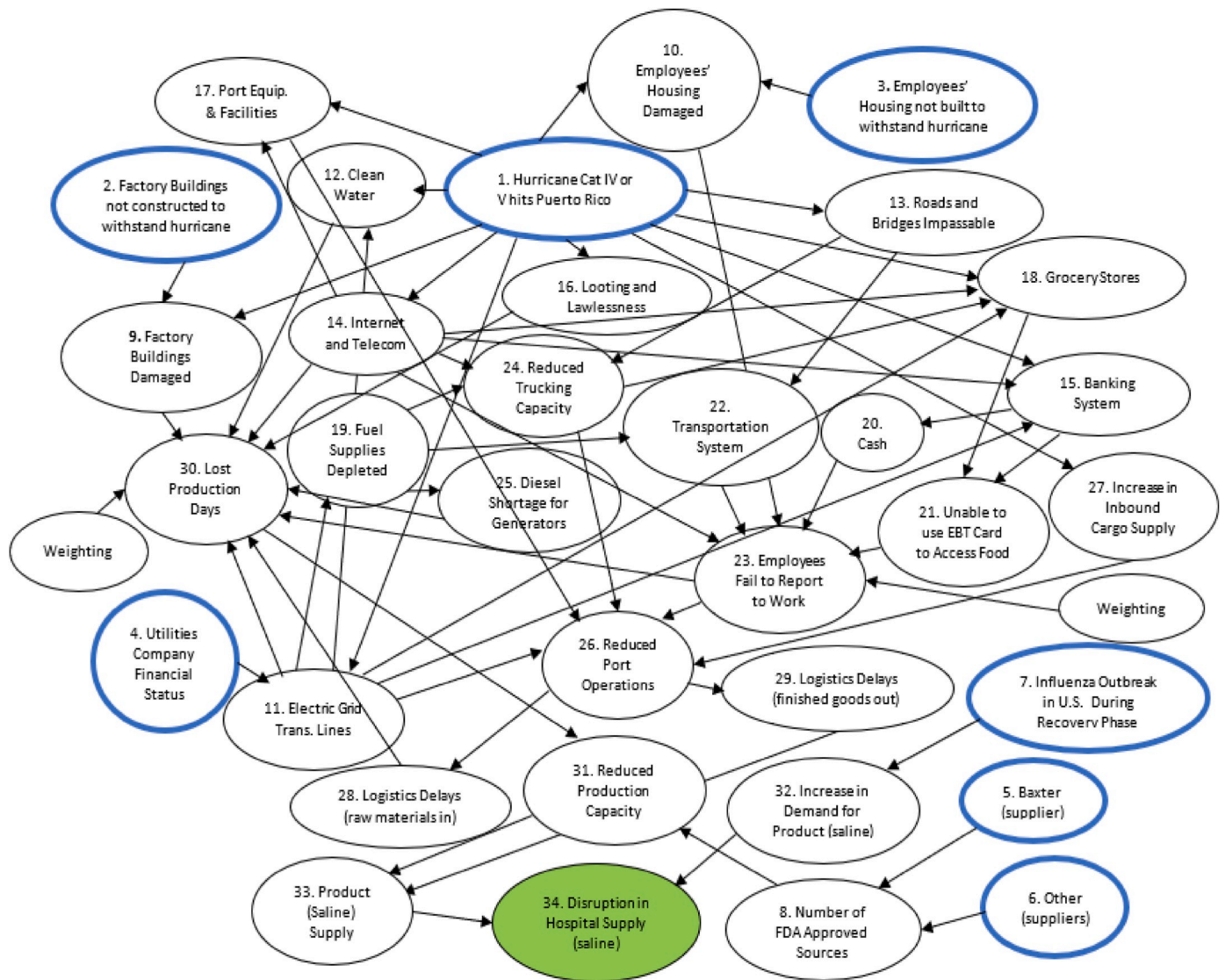


Fig. 4. Top View of the proposed Bayesian network (BN) model. *Blue-outlined oval represents main risk events, black-outlined oval represents intermediate risk events, and green-filled oval represents consequence.

report to work, (ii) port equipment and facilities damaged, (iii) electric grid down, (iv) reduced trucking capacity between factory and port, and (v) increased inbound cargo.

- (i) The potential causal factors of *employees failing to report to work* are (a) a *transportation system not functioning* due to *fuel supplies depleted* because of increased demand for diesel to run home generators as a result of the *electric grid going down* following a *Category IV or V hurricane*, and *impassable roads and bridges* due to a *Category IV or V hurricane* (b) infeasible employer-employee communication due to the *Internet and telecommunications system not operational* following a *Category IV or V hurricane*, (c) *employees' housing damaged* due to a *Category IV or V hurricane* and *employees' housing not constructed to withstand a Category IV or V hurricane*, resulting in damaged roofs and walls, personal injury, and local or overseas displacement; (d) *employees unable to access cash* for transportation and other needs due to a failed banking system that is caused by a *Category IV or V hurricane*, which results in the *electric grid down* and the *Internet and telecommunications system down*; (e) *employees unable to use Electronic Benefit Transfer (EBT) cards* (payment cards issued under a federal nutrition assistance program to assist qualifying families with the purchase

of food) at *grocery stores* to purchase food due to inoperability of ATM systems caused by a *failed banking system* and *grocery stores closed* due to a *Category IV or V hurricane* that results in the *Internet and telecommunications system down*, *electric grid down*, and *reduced trucking capacity*. Based on US Census data, just under half of Puerto Ricans live below the poverty line; therefore, it is reasonable to assume that a percentage of lower paid factory workers would be dependent on EBT cards to stock up on groceries.

- (ii) Causal factors for *port equipment and facilities damaged* or not functioning are a direct hit by a *Category IV or V hurricane* that damages or destroys material handling equipment and facilities, and also results in *Internet and telecommunications down*.
- (iii) If a *Category IV or V hurricane hits*, there is a high probability of the *electric grid going down*, particularly when these lines are above ground because of a lack of investment by a *utilities company in financial distress*.
- (iv) Three causal factors that have the potential to result in *reduced trucking capacity* for moving products between factory and port are (a) *roads and bridges impassable* due to a *Category IV or V hurricane* that results in debris and destruction; (b) *fuel supplies depleted* because of increased demand for running private

Table 2

Risk events following Hurricane Maria.

Node ID	Description	Types	Parent Node ID
0	Climate Change	Trigger	
1	Hurricane Category IV or V hits Puerto Rico	Main Risk Event	
2	Factory buildings not constructed to withstand Cat. IV or V hurricanes	Main Risk Event	
3	Employees' housing not built to withstand Category IV or V hurricanes	Main Risk Event	
4	Utilities company financial status	Main Risk Event	
5	Baxter (supplier)	Main Risk Event	
6	Other (suppliers)	Main Risk Event	
7	Influenza Outbreak	Main Risk Event	
8	Number of FDA approved sources (suppliers)	Intermediate Risk Event	5, 6
9	Factory buildings damaged	Intermediate Risk Event	1, 2
10	Employees' housing damaged	Intermediate Risk Event	1, 3
11	Electric grid	Intermediate Risk Event	1, 4
12	Clean water	Intermediate Risk Event	1, 11
13	Roads and bridges	Intermediate Risk Event	1
14	Internet and telecommunications infrastructure	Intermediate Risk Event	1
15	Banking system	Intermediate Risk Event	1, 11, 14
16	Looting and lawlessness	Intermediate Risk Event	1
17	Port equipment and facilities	Intermediate Risk Event	1, 14
18	Grocery stores	Intermediate Risk Event	1, 11, 14, 24
19	Fuel supplies depleted	Intermediate Risk Event	11
20	Cash accessibility	Intermediate Risk Event	15
21	Employees unable to use EBT cards at grocery stores	Intermediate Risk Event	15, 18
22	Transportation system	Intermediate Risk Event	13, 19
23	Employees fail to report to work	Intermediate Risk Event	10, 14, 20, 21, 22
24	Reduced trucking capacity	Intermediate Risk Event	13, 14, 19
25	Diesel shortage for generators	Intermediate Risk Event	19
26	Reduced port operations efficiency	Intermediate Risk Event	11, 17, 23, 24, 27
27	Increase in inbound cargo from overseas	Intermediate Risk Event	1
28	Logistics delays – raw materials inbound	Intermediate Risk Event	26
29	Logistics delays – finished goods outbound	Intermediate Risk Event	26
30	Lost production days	Intermediate Risk Event	9, 11, 12, 14, 16, 23, 25, 28
31	Reduced production capacity	Intermediate Risk Event	8, 30
32	Increase in demand for product (saline)	Intermediate Risk Event	7
33	Product (saline) supply	Intermediate Risk Event	29, 31
34	Disruption in hospital supply (saline)	Consequence	32, 33

*ID = unique identification number [Node 0: Trigger; Nodes 1–7: Main Risk Events; Nodes 8–33: Intermediate Risk Events; Node 34: Consequence].

residential generators due to the *electric grid down*; and (c) *Internet and telecommunications down*, preventing communication with truckers. When truckers have limited fuel supplies and communication between factory and truckers is infeasible, there is a possibility that fuel will be conserved by avoiding futile commutes to facilities that are not operating, particularly if attempts to report to work have already been previously made.

- (v) If a *Category IV or V hurricane hits* an island location like Puerto Rico, there will be an influx of humanitarian supplies alongside regular imports that result in *increased inbound cargo*, thereby constraining limited resources and *reducing port efficiency*.

II. Reduced Production Capacity: Reduced production capacity states are dependent on (i) the number of Food and Drug Administration (FDA) approved sources and (ii) lost production days in the aftermath of a hurricane.

- (i) *Number of FDA Approved Sources:* One of the main risk factors for *reduced production capacity* in the pharmaceutical industry is the *number of FDA approved sources*. On site- and production line-specific approvals granted by the Food and Drug Administration (FDA) are required for pharmaceutical manufacturers to supply U.S. healthcare facilities. Within the same pharmaceutical company, production cannot be shifted from one site to another without FDA approval certifying compliance with current Good Manufacturing Practice (cGMP). Without alternative FDA approved sites prior to a disaster, total production capacity remains fixed at best or reduced in the aftermath. The situation is exacerbated when manufacturers require high volume production to achieve economies of scale, leading to a single supplier situation. Risk factors for the number of FDA approved sources are (a) the percentage of product supplied by a *single supplier (Baxter)* and (b) the percentage of product supplied by *other suppliers*.
- (ii) Eight potential risk factors for lost production days are: (a) *factory buildings damaged*, (b) *electric grid transmission lines destroyed*, (c) *diesel shortage for running factory generators*, (d) *clean water unavailable* (e) *Internet and telecommunications infrastructure down*, (f) *looting and lawlessness* that could lead to curfew hours, restricting employee work time, (g) *employees failing to report to work* due to injury or local/overseas displacement, and (h) *delays in inbound logistics* due to port congestion from accumulation of containers due to an increase in *inbound cargo from overseas* and *port equipment and facilities damaged*.
- (a) *Factory buildings damaged* could result from a direct hit by a *Category IV or V hurricane* and *factory buildings not constructed to withstand a Category IV or V hurricane*, resulting in roof damage, wall collapse, broken doors and windows, equipment damage, and contamination due to flooding and entry of debris.
- (b) Risk factors for the *electric grid down* include inadequate investment in and maintenance of a resilient electric grid structure due to the *utilities company's financial status*.
- (c) *Diesel shortage for generators* could result due to *fuel supplies depleted* caused by a surge in fuel demand for residential home generators, grocery store freezers, and port generators due to the *electric grid down* following a *Category IV or V hurricane*, coupled with insufficient reserves at filling stations due to delays in *inbound supplies* from overseas.
- (d) Clean water unavailable could result from a *Category IV or V hurricane* that damages water lines and causes the electric grid to go down, resulting in water pumps not being powered.
- (e) If *Internet and telecommunications system fails* due to a *Category IV or V hurricane*, factories will likely resort to manual operations, decreasing production efficiency.

- (f) Curfews are imposed in disaster situations if there is anticipation or exhibition of lawlessness. If a curfew is imposed due to *looting and lawlessness* following a Category IV or V hurricane, factory production hours could be limited. In the case of Puerto Rico, the initial curfew imposed on September 20 was lifted within three days of the hurricane.
- (g) *Employees failing to report to work* could be caused by the *transportation system down*, *employees housing damaged*, *cash non-accessible*, *employees unable to use EBT cards* to obtain personal needs, or the *Internet and telecommunications system down*, hindering communication between the factory and employees.
- (h) *Delays in inbound logistics* could occur due to *reduced port operations efficiency*. Five causal factors for *reduced port operations efficiency* are (i) *increased inbound cargo supply* (relief and other supplies) due to a surge in vessel calls, (ii) *employees failing to report to work*, (iii) *port equipment and facilities not functioning* due to damage and *Internet and telecommunications down*, resulting in manual operations, (iv) *reduced trucking capacity*, and (v) *electric grid down*.

Data for product supply states were compiled from the following: [1, 2,20,130–133], [13,48,49,99,114,134–141], [109], , , [14,21,46,47, 116,118,122,142–146], [147],[148], [149] .

3.1.3. Disruption in hospital supplies (consequence)

Ultimately, disruption in the U.S. hospital supply chain is directly influenced by two factors: (i) the potential *increase in demand for the product (saline)* and (ii) the risk of a *reduced supply (of saline)*. The major risk factor for an *increased demand for saline* is an *outbreak of disease (e.g., influenza)* in the United States, which leads to an increase in hospitalization rates, resulting in the demand for saline above average season requirements to treat patients. Potential risk factors for a *reduction in supply* stem from *reduced production capacity* due to *lost production days* and a lack of redundancy in the *number of FDA-approved suppliers*. Another risk factor for supply shortage is *delays in outbound logistics* due to *reduced port operations efficiency*.

Information on increased demand for saline was compiled from [7, 93,142], [149].

The description of the trigger event, main causal events, and intermediate (elementary) events that have the potential to impact supply chain performance in the aftermath of a hurricane are summarized in

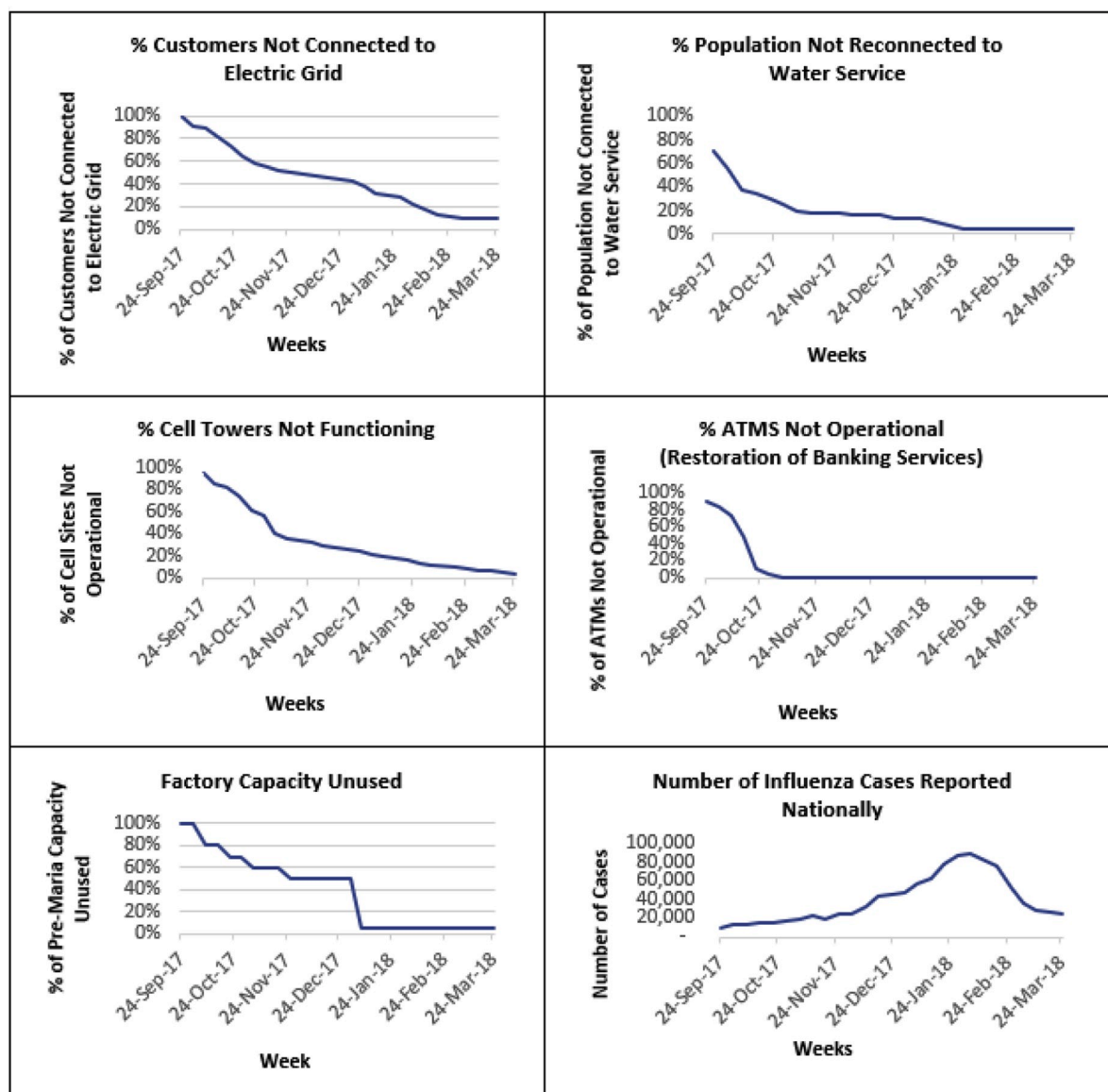


Fig. 5. Examples of estimated timelines of nodal activities in the aftermath of hurricane maria.

Table 2.

4. Parameter modeling and quantification with Bayesian network

In this section, we employ a Bayesian network (BN) to quantify *disruption in hospital supply* as a function of the various factors and subfactors related to the pharmaceutical supply chains of Puerto Rico. The simulated base model of the proposed BN is depicted in Fig. 6. The probabilities entered for each node represent the likelihood of the event occurring at a specific time point/time slice in the immediate aftermath of the hurricane. In each case, the probabilities were determined by developing recovery timelines over several weeks following the hurricane from data in the public domain. While the model includes probability data for the immediate aftermath, it could be adapted to accommodate probabilities at future time points based on recovery progress. Examples of recovery timelines for specific nodes are shown in Fig. 5 below.

Timelines were developed from the following sources: AFP [85]; Aon Benfield [86]; Bartley [87]; Becker [88]; Becker [89]; Bonner [90]; Buchanan [91]; Byrd [92]; Centers for Disease Control [93]; Daily Market Update [97]; Dept. of Homeland Security [98]; Elvidge [100]; Entralgo [101]; FEMA [102]; FEMA [103]; Ferris [104]; Fiegerman and Murphy [105]; Gillespie [107]; Jarvis [109]; Harris and Olson [110]; Healy [111]; Inside Towers [112]; Oxfam [116]; Palin [117]; Cision PR Newswire [94]; Reardon [119]; Resnick and Barclay [120]; Schmidt [121]; Weise [125].

The Parameter Modeling and Quantification for the Bayesian

Network is described below.

4.1. Severe weather occurrence

• Hurricane Category IV or V hits Puerto Rico Directly (Node 1)

Historical data from 1980 to 2018 indicate that two catastrophic hurricanes (Category IV or higher) hit Puerto Rico out of 495 storms formed in the North Atlantic during that period. Based on this data, the likelihood that Puerto Rico will be hit by a Category V storm is 0.004 or 0.40%. Predictions based on the impact of climate change in the future indicate that Category V Hurricanes will increase from one every 800 years to one every 80 years by the end of the century [6]. Taking both the historical data and the predictions into consideration, the probability of a Category IV or higher hurricane hitting Puerto Rico immediately after Hurricane Maria was estimated at approximately 0.80% True, 99.20% False. The Node Probability Table (NPT) for this parameter is designed using Boolean logic as shown in Table 3.

Table 3

NPT of Hurricane Category IV or V (direct) hits Puerto Rico.

False	0.9920
True	0.0080

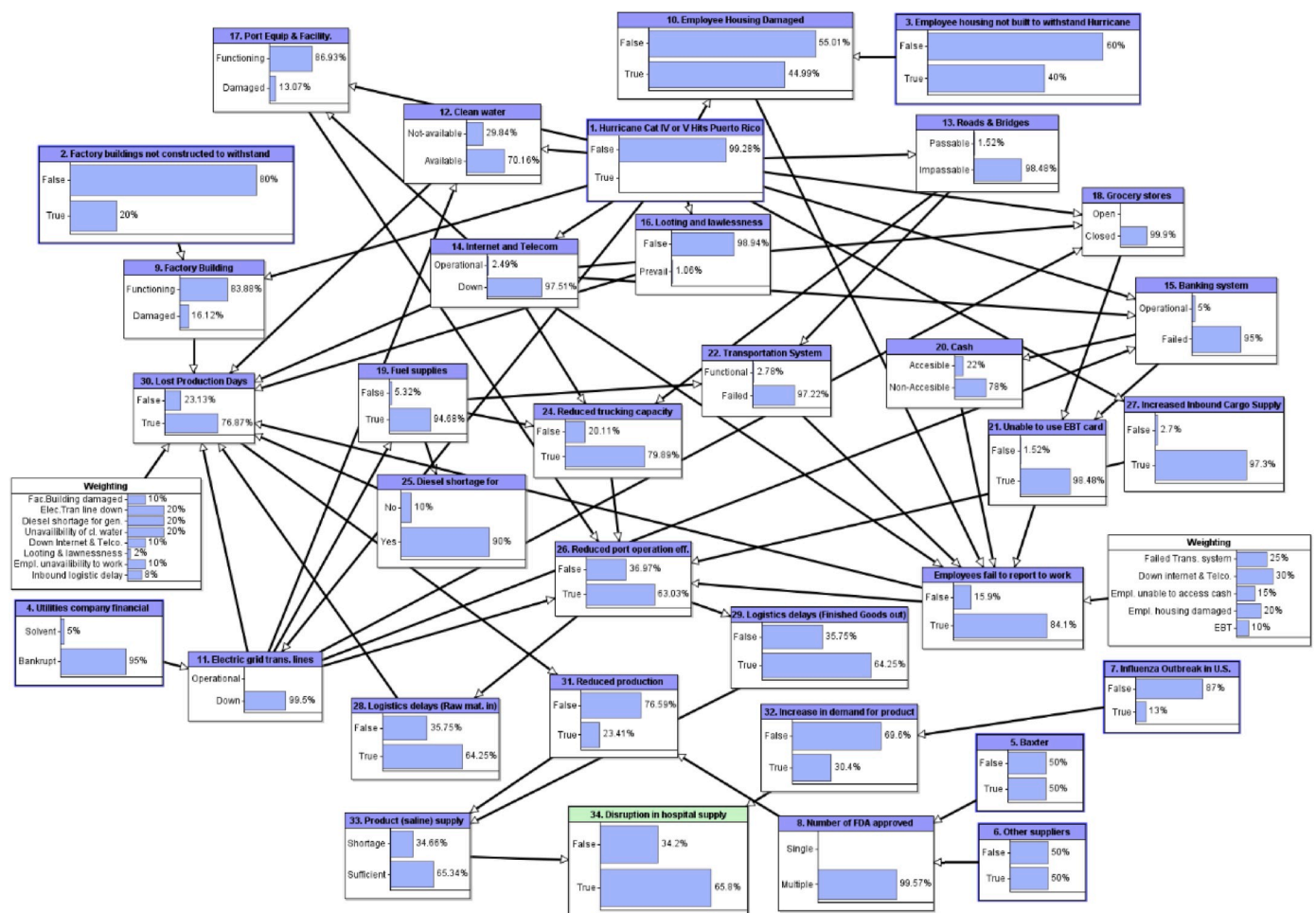


Fig. 6. The proposed BN model for scenario 1 (base case).

4.2. Damage to buildings

- **Factory Buildings Not Constructed to Withstand Category IV or Higher Hurricanes (Node 2); Factory Buildings Damaged After Hurricane (Node 9)**

The main type of roof construction for civilian and military buildings in Puerto Rico is 3- to 6-inch reinforced concrete slab [95]. Reports following Hurricane Maria indicate that factories, commercial buildings, and warehouses suffered minimal damage [21,109,114,150], although water leakage due to loss of roof cladding proved to be a problem [109, 150]. Based on these reports, the likelihood that factory buildings were not constructed to withstand Category IV or higher hurricanes (Node 2) was estimated at 20% True (inability to withstand), 80% False (ability to withstand). Boolean logic was entered in an NPT similar to that shown in Table 3. The posterior probability calculations for Factory Buildings Damaged after Hurricane (Node 9) propagated at 83.87% functioning, 16.13% damaged.

- **Employees' Housing Not Built to Withstand Category IV or Higher Hurricanes (Node 3); Employees' Housing Damaged After Hurricane (Node 10)**

According to reports, approximately 50% of homes in Puerto Rico were built informally without permits at the time Hurricane Maria hit [86,123]. Forty-four percent of the Puerto Rican population lives below the poverty line [146], which inevitably includes a percentage of lower paid factory workers. Based on this data, the probability that employees' housing was not constructed to withstand a Category IV or higher hurricane (Node 3) was estimated at 40% True (inability to withstand), 60% False (ability to withstand). This data was entered into the NPT table in a similar manner as shown in Table 3. Post-hurricane reports indicated that 22–30% of homes were damaged or destroyed due to wind and water [86,113,123], with a number of informal homes taking the hardest hit. Taking into consideration the large number of lower paid workers in a factory setting, the updated NPT probabilities for employees' housing damaged after the hurricane (Node 10) were propagated to develop two states: 45% True (damaged), 55% False (not damaged).

4.3. Damage to utilities

- **Utilities Company Financial Status (Node 4); Electric Grid (Node 11)**

If a financially distressed utilities company fails to invest in or maintain a resilient grid, there will be greater damage and destruction during a Category IV or higher hurricane. At the time the hurricane hit, Puerto Rico's power generators were on average 28 years older than those of U.S. mainland utility companies and Puerto Ricans experienced 12 times as many blackouts [99]. Furthermore, Puerto Rican Power Utility (PREPA) filed for bankruptcy two months prior to Hurricane Maria [86,120,151]. Given this information, the Boolean node states for Utilities Company Financial Status (Node 4) were set at 95% bankrupt, 5% solvent. This signifies that there is a 95% chance that the utility company's poor financial status could have contributed to the failure of the electric grid, resulting in transmission lines down. Following landfall of the hurricane, a 100% blackout was experienced due to destruction of the electric grid transmission lines, towers, and hydro-electric dams [86, 88,102,152]. Based on the causal factors, the NPT table probabilities for the electric grid (Node 11) resulted in 0.5% operational, 99.5% down.

- **Clean Water (Node 12)**

Clean water availability is conditioned on the extent of damage caused by a Category IV or V hurricane hitting Puerto Rico and the

availability of electricity to power the water pumps. According to the statistics, 50–70% of the island had no water service following Hurricane Maria [92,102,116,120,153]. Given this information, the NPT for clean water availability is modeled as approximately 30% available, 70% not available.

- **Internet and Telecommunications Infrastructure (Node 14)**

Most organizations in Puerto Rico had one Internet Service Provider (ISP), but even in situations where two ISPs were used, the second ISP did not provide the expected redundancy because the cables were run on the same poles [91]. Reports indicate that 85%–91% of cell towers were destroyed by Hurricane Maria, critically impacting the Internet and telecommunications service [87,89,102,109,120,125, 154]. Based on this data, the NPT for this node was modeled at approximately 10% operational, 90% down.

4.4. Access to cash

- **Banking System (Node 15); Cash (Node 20)**

Based on the causal factors of a hit by a Category IV or V hurricane, Internet and telecommunications system down, electric grid down, the posterior probability of the banking system (Node 15) calculated as 11.17% operational, 88.83% down following Hurricane Maria. These probabilities are supported by reports following Hurricane Maria [49]. Failure of the banking system highly impacted the liquidity of the monetary system in Puerto Rico at a time when cash was required for transactions [49,108,155,156]. Based on this information, the posterior probability for Cash (Node 20) is calculated at 20% accessible, 80% non-accessible for cash withdrawal.

4.5. Port operations

- **Port Equipment and Facilities (Node 17); Reduced Port Operations Efficiency (Node 26)**

The main causal factors impacting the functioning of port equipment and facilities are a direct hit by a Category IV or V hurricane and Internet and telecommunications going down. The primary infrastructure at the Port of San Juan, the main port in Puerto Rico, sustained some damage from Hurricane Maria, although reports indicate that this was not extensive due to repairs performed by Crowley on one of the major terminals earlier in the year [136,157]. Ports could receive cargo vessels, but operations were affected due to damaged infrastructure. One potential "hidden" factor that could have an impact on the functioning of port equipment and facilities but was not included in the model because of the emphasis on pharmaceutical supply chain resilience is depletion of fuel supplies. Based on the above information, port equipment and facilities are predicted to be functional 87% of time, whereas 13% of time these might be down due to the Hurricane attack.

Based on a decision taken by the Treasury Department prior to the storm, which authorized the "manual release" of goods in the event of non-functioning or damaged equipment and facilities, port operations deployed in the aftermath of Hurricane Maria were less efficient [46]. The Reduced Port Operations Efficiency node (Node 26) is conditioned upon five factors, namely: Reduced Trucking Capacity, Port Equipment and Facilities Damaged, Electric Grid down, Increased Inbound Cargo Supply, and Employees Failing to Report to Work. Thus, if we design this variable using Boolean logic, it requires $2^5 = 32$ entries, which is quite tedious and error prone as well. Moreover, many of those 32 entries may be unnecessary and have minimal impact on the Reduced Port Operations Efficiency node. As an alternative, the "NoisyOR" concept was used to design the posterior probability of this node. In addition, it is possible that there are other hidden factors that could influence the likelihood of a disruption. To account for these hidden or "leak" factors, a NoisyOR

function is a convenient choice, where the leak factor is the extent to which factors absent from the model could contribute to the outcome being *true*. For example, this situation would apply if there are n variables designated as A_1, A_2, \dots, A_n that are conditioned on B , with the probability of B being *true* when only one of the variables, A_1 , is *true* and all causal variables other than A_1 are *false*, whereas leak factors are denoted by l . Following is the NoisyOR function:

$$\text{NoisyOR}(A_1, S_1, A_2, S_2, \dots, A_n, S_n, l) \\ \text{where } S_i = P(B = \text{True} | A_i = \text{True}, A_j = \text{false}; \text{for all } j \neq i)$$

The modeling equation of the above factor is presented in equation (5).

$$\text{NoisyOR}(\text{Reduce trucking capacity}, 0.25, \text{Electric grid transmission line}, 0.30, \text{Port equipment and facility}, 0.25, \text{Increased inbound cargo supply}, 0.15, \text{Employees fail to report to work}, 0.15, 0.10) \quad (5)$$

• **Increase in Inbound Supplies (Node 27); Logistics Delays – Raw Materials In (Node 28); Logistics Delays – Raw Materials Out (Node 29)**

Following Hurricane Maria, an increase in vessel calls [133,158], due to an influx of relief and rebuilding supplies, resulted in a surge in inbound cargo [46,109,136,159]. This is confirmed by reports indicating a 20–67% increase in vessel fleets [136]. Based on reports and historical data, the posterior probability for Increase in Inbound Cargo (Node 27) was calculated as 97% True, 3% False, meaning that there is a 97% chance of an increase in inbound cargo significantly above current import levels with the potential to lead to logistical bottlenecks. Reduced port operations efficiency due to manual operations as a result of damaged port equipment and facilities, congestion arising from a surge in inbound container volumes, and the unavailability of truckers, precipitated a backlog that led to logistics delays for inbound raw materials [48,109,152,159–162]; [5,143]; [163]. Due to the slowdown in inbound logistics, the posterior probabilities for this NPT (Node 28) are calculated at around 65% True, 35% False, implying a 65% chance of logistics delays in inbound raw materials. Due to the slowdown in outbound logistics for the same reasons mentioned above the conditional probabilities of this node are calculated close to 65% True, 35% False, implying a 65% chance of logistics delays in inbound raw materials (Node 29).

4.6. Access to transportation

• **Roads and Bridges Impassable (Node 13); Transportation System (Node 22); Reduced Trucking Capacity (Node 24)**

Following a hit by Category IV Hurricane Maria, reports indicated that roads and bridges were impassable [86,109,164]. The posterior probability of Node 13 resulted in 1.53% Passable, 98.47% Impassable. Based on reports by Aon Benfield [86]; and Respaut et al. [157]; impassable roads and bridges, coupled with depleted fuel supplies, greatly impacted the availability of transportation. With a limited number of public bus lines running [165] to accommodate workers out of gas, the posterior probability of inaccessibility of transportation (Node 22) was calculated at 2.78% functional, 97.22% failed. Finally, it is obvious that if the Internet and telecommunications system goes down preventing communication with truckers, roads and bridges are impassable, and depleted fuel supplies are widespread, there will be a scarcity of drivers, resulting in reduced trucking capacity [48,49]. Based on reports indicating that only 20% of drivers reported for work [49,

140], and in order to calculate the posterior probability of the reduced trucking capacity, the same NoisyOR logic has been applied as discussed above.

4.7. Access to food

• **Grocery Stores (Node 18); Employees Unable to Use EBT Cards at Grocery Stores (Node 21)**

The consequences of a catastrophic hurricane, which included damaged infrastructure, combined with a disrupted Internet and telecommunications system, non-functional electric grid, and insufficient

trucking capacity to move groceries from the port to the stores led to almost 100% closure of the grocery store system (Node 18) [49,91,106,159,160,166,167]. Forty-four percent of the Puerto Rican population lies below the poverty line [168]. This implies a high probability that lower paid factory employees will fall within this bracket, requiring food assistance. A failed banking system and failed grocery system impeded the use of EBT (grocery subsistence) cards [116,155], potentially increasing the trauma to employees, and impacting the ability of employees to return to work. On the basis of this information, the contributing factors resulted in the possibility of 97.31% True, 2.69% False for the usage of EBT card (Node 21).

4.8. Access to fuel

• **Fuel Supplies Depleted (Node 19); Diesel Shortage for Generators (Node 25)**

With the electricity grid down, fuel demand for powering residential and commercial generators (e.g. port, grocery stores) increased, leading to a rapid shortage of fuel supplies for trucking and factory generators [49,50,157,160]. Based on these insights, there is an almost 95% chance that fuel supplies might be depleted as a consequence of the Hurricane (Node 19). With the electric grid down and a surge in demand for fuel to power personal and commercial generators [157], fuel supply availability for running factory generators rapidly depleted, impacting fuel availability to run factory generators [7]. All of these factors led to a 90% chance of a shortage of diesel to power factory generators (Node 25).

4.9. Law and order

• **Looting and Lawlessness (Node 16)**

Unlike other islands affected by Category IV and V hurricanes, reports indicate that looting and lawlessness were not widespread in Puerto Rico [106][138]. Therefore, the conditional probability of this node calculated at around 1% Prevail, 99% False, meaning that there was only a 1% chance that looting and lawlessness would result in measures such as the imposition of curfew hours that could potentially limit factory production hours.

4.10. Factory productivity

• **Employees Fail to Report to Work (Node 23)**

During the disruptive event, several factors impacted employees

reporting to work. With the Internet and telecommunications systems down and a lack of satellite phones, communication with manufacturing plant employees and truckers was severed [109]. In the aftermath of the disaster, personal trauma related to damaged housing, unavailability of cash, inability to use EBT cards to access groceries, a failed transportation system, as well as migration of approximately 400,000 Puerto Ricans to the U.S. mainland are contributory factors expected to result in employees failing to report to work [91,132]. In order to compute the posterior probability of the node titled “employees fail to report to work” of the proposed model, a labelled node named “weighting (weighted average)” is introduced to demonstrate the weight of each variable responsible for “employees fail to report to work”. The weights were estimated based on subjective judgment and personal anecdotes of professionals with expert knowledge in the areas of supply chain management, port operations, and risk management. Two of the experts were able to provide real life experiences in dealing with severe post-hurricane disaster situations. Labelled variables can have a number of discrete states. Simply, the weighted average is the weighted mean probabilities of all the parent nodes of the aforementioned node as represented in the following equation (3).

$$WMEAN = \sum W_i A_i = 1, 2, \dots, n, \quad \forall i = 1; 0 < W_i < 1; \sum_i W_i = 1 \quad (3)$$

where “i” represents the number of variables (nodes) directly connected to the weighted average node of *employees fail to report to work* (see Fig. 4) and W_i denotes the weight associated with the i th variable.

• Lost Production Days (Node 30); Reduced Production Capacity (Node 31)

Several factors contributed to lost workdays, including damaged factory buildings [147], shortage of diesel to run factory generators, electric grid down, employees failing to report to work due to personal calamities [49,132], Internet and telecommunications systems down [109], delays in inbound supplies due to port congestion [49,136], looting and lawlessness, and unavailability of clean water [109]. The previously discussed “weighted average” concept was adopted to compute the posterior probability of the lost production days node. Reduced production capacity is predicated on two factors: lost production days [14,118] and available capacity among FDA approved suppliers following Hurricane Maria. Prior to Hurricane Maria, FDA approved plants were already operating at near full capacity with no supply redundancy [10]. This is supported by reports that indicate Baxter, which supplied approximately half of U.S. hospital saline, reduced order fulfillment quantities by 50% in the aftermath of Hurricane Maria [131]. Based on these contributing factors and reports, the posterior probabilities for reduced production capacity are calculated close to 24% True, 76% False.

4.11. Suppliers

- Baxter (Node 5); Other Suppliers (Node 6); Number of FDA Approved Sources (Node 8)

At the time Hurricane Maria made landfall, the FDA had approved three companies to supply saline to U.S. hospitals. Of these, Baxter supplied almost 50% of U.S. hospital requirements [10,169]. Baxter was also the only supplier for the mini-bag size, with the majority of

production located in Puerto Rico and no supply redundancy [9,10,13,122,131]. Based on this information, the Boolean values that represent Baxter’s supply to U.S. hospitals were set at 50% True, 50% False as in Table 3 (Node 5) and the probability values for the combined supply of other FDA suppliers was set at 50% True, 50% False (Node 6). This implies that 50% of U.S. hospital requirements for saline were supplied by other suppliers and 50% by Baxter. Entries were similar to that shown in Table 3. Based on the probability values for the two parent nodes, Baxter (Single Supplier) and Other (Multiple Suppliers), the posterior probabilities for the number of FDA approved sources (Node 8) propagated at 99.57% multiple, 0.43% single. The NPT indicating how this variable was modeled is shown in Table 4.

4.12. Demand and supply for saline

- Influenza Outbreak in the United States (Node 7); Increase in Demand for Product (Node 32)

An outbreak is defined as a sudden increase in the number of disease cases above the endemic level [170]. Following Hurricane Maria, the U. S. suffered an influenza outbreak, with data from the Centers for Disease Control for the 8-year period 2010 to 2018 indicating 960,000 hospitalizations in 2018 compared to 473,750 in an average season. Assuming that an influenza outbreak is considered to have occurred when the hospitalization rate exceeds 125% of the average hospitalization rate, then the 2017 influenza season represents a 1/8 or 13% chance of occurrence based on eight years of data. The NPT data for this Boolean type was set at 13% True (possibility of outbreak), 87% False in a similar manner as shown in Table 3 (Node 7). Based on this data, the posterior probabilities for Increase in Demand for Product Saline (Node 32) resulted in approximately 30% True, 70% False, meaning that given an influenza outbreak in the United States, there is a 30% likelihood that demand for saline will increase.

- Product Supply (Shortage of Saline) (Node 33)

The consequences that led to reduced production capacity [10,14,118,131] coupled with delays in outbound logistics due to port congestion [48,49,109,152,159–162] led to a decrease in the inventory flows of saline through the supply chain to hospitals on the U.S. mainland. Based on the causal factors for this node, propagation led to posterior probabilities of around 35% shortage, 65% sufficient.

- Disruption in Hospital Supplies (Shortage of Saline in U.S. Hospitals) (Node 34)

Reports indicate that FDA approved suppliers of U.S. hospitals were operating near full capacity prior to Hurricane Maria [10]. With the immediate causal factors of a shortage in the supply of saline from Puerto Rico following Hurricane Maria and a simultaneous increase in demand for saline by U.S. hospitals, it is obvious that the supply flow of saline to U.S. hospitals would be disrupted [118,130,131]. Based on information propagation in the model, a disruption risk exposure of 65.73% True, 34.27% False was obtained. This implies that there is a 65.73% chance of a disruption in hospital supplies of saline.

5. Results and analysis

In this section, we discuss different types of advanced analyses such as predictive inference reasoning and sensitivity analysis to derive further insights into the proposed model.

5.1. Predictive inference reasoning

Bayesian networks can be used for two types of predictive inference reasoning: (i) prognostic reasoning, which allows data on causes to be

Table 4
NPT for FDA approved sources (to U.S. Hospitals).

Baxter (Supplier)	False		True	
Other (Suppliers)	False	True	False	True
Single	0.001	0.010	0.005	0.010
Multiple	0.999	0.990	0.995	0.990

entered and forward propagation conducted to determine the effect, and (ii) diagnostic reasoning, which allows data on effects to be entered and propagated backwards to arrive at conclusions regarding the causes [64]. An example of prognostic reasoning is the entering of data on an extreme weather event, e.g., a hurricane, and predicting the resulting risk exposure to an object or system. In our study, we consider *prognostic inference reasoning* also known as *forward propagation analysis* to predict the likelihood of disruption in hospital supplies under a combination of influential factors modeled using historical data and expert opinion based on the events following Hurricane Maria. The forward propagation of the model seeks to evaluate the outcome of the target node, *disruption in hospital supplies*, given the nodal probabilities of the causal factors.

For instance, if a message is imparted from node A to its child node B , then it is known as *prognostic inference reasoning* from A to B and denoted by $\varepsilon_B(A)$, whereas if the message is disseminated from node C to B , it is known as *diagnostic support reasoning* and represented by $\Gamma_C(B)$. In order to show the functionality of the inference reasoning, the joint probability distribution for node B with its parent node A and child node C can be demonstrated through the following equation, where $\theta_{B|A}$ signifies the conditional probability for node B given its parent A . $\varepsilon_B(C)$ and $\Gamma_A(B)$ represent the prognostic and diagnostic reasoning respectively [171].

$$P_r(BA, e) = \Gamma_e(B)\theta_{B|A}\Pi_i\varepsilon_B(A_i)\Pi_j\Gamma_{C_j}(B)$$

The simulated base model, which was developed based on a thorough examination of the post-disaster literature and depicted in Fig. 6, predicts a 65.73% shortage of saline solution in U.S. hospitals (See Table 5). The trade literature suggests that approximately 50% of hospitals across all 50 states suffered a shortage of saline [13]. Taking into consideration that there might be other unknown or “leak” factors that can influence the posterior probability of the target node, the model provides a reasonable computation of the risk exposure based on available information.

A pessimistic case (scenario 2) was further developed by means of forward propagation analysis to examine the extent to which the pharmaceutical supply chain might be disrupted if three critical factors that impact supply chain continuity are defined in terms of the most severe state: (i) the product supplied by Baxter to U.S. hospitals increases from 50% to 100%, meaning that the entire supply to U.S. hospitals is produced by a single FDA-approved manufacturer, Baxter; (ii) the probability of port equipment damaged is 100%, meaning that the port is unable to perform any port related works; and (iii) the demand for saline reaches its peak due to an influenza outbreak (see Fig. 7). The three variables were selected because these factors exacerbated an already strained production situation following Hurricane Maria. The unique requirements of the pharmaceutical industry for cGMP compliant facilities and economies of scale in manufacturing encourage large scale production by a few suppliers. This could lead to a precarious single source situation. Epidemics are also likely risks faced by the healthcare sector. In the event of a major epidemic, product demand could rise sharply above existing requirements. Port failure could highly impact the pharmaceutical transportation network to carry the product (saline) from the supplier to the customer (hospitals) within the stipulated time frame. All of these observations together have a negative impact on the

hospital supply chain and the results of the propagation analysis indicate that disruption in the hospital supply chain could rise from 65.73% to as high as 89.18%.

5.2. Validation of the model using sensitivity analysis

Sensitivity analysis is an approach used to validate a Bayesian network model by examining the impact of contributory nodes on the outcome of the target node. In this study, the aim was to identify which nodes are likely to have the greatest impact on the probability of hospital supply chain disruption. This is represented by the length of the bars in the Tornado chart (see Fig. 8). The longer the bars, the greater the impact on disruption in hospital supplies when the causal factor contributes to a risk state. The numerical range represents the smallest and largest values of the posterior or outcome probability for each node state for which data is entered.

Causal factors evaluated included (i) reduced port operations efficiency, (ii) electric grid, (iii) diesel shortage for factory generators, (iv) Internet and telecommunications system, and (v) employees failing to report to work. Of these five factors, the results indicate that reduced efficiency in port operations is the factor with the greatest impact on disruption in hospital supplies, while employees failing to report to work is the factor with the least impact. This can be viewed in the Tornado chart in Fig. 8, which indicates a value range of 0.620–0.722 for reduced port operations efficiency and 0.655 to 0.658 for employees failing to report to work, with other factors falling in between.

When compared to a real-world scenario, the results seem logical, as employees alone are unable to improve the target node state if the electric grid and telecommunications systems are not operational, diesel is in short supply, and port operations are slowed. Puerto Rico is an island territory that is isolated from the U.S. mainland, with a high concentration of pharmaceutical manufacturing plants. In the event of a disaster, the flow of hospital supplies to the mainland could be quickly severed if the port's primary infrastructure is destroyed forcing a shut-down or if operations are slowed to a pace that fails to synchronize supply with demand. Moreover, the port is a critical juncture in the flow of both inbound raw materials for pharmaceutical manufacturing and outbound finished goods, signifying that any bottleneck in operations will seriously hamper supplies to U.S. hospitals. Based on the criticality of the health care sector, the highest emphasis should be placed on developing robust and resilient port infrastructure and operations.

6. Concluding remarks

This research paper proposes a static Bayesian network model to quantify the impact of severe weather risk on pharmaceutical supply chain performance to support the development of effective risk control and mitigation strategies. Although the Bayesian network is a static model, by understanding the probability of recovery at different points in time following a major hurricane disaster (see Fig. 5), a risk manager can use the model for decision-making in three ways: (i) proactively, to guide the design of a resilient pharmaceutical supply chain network, including the selection of supplier locations to minimize severe weather risk, (2) proactively, to perform scenario analysis to support the development of a risk response contingency plan to minimize the impact of adverse events on supply chain performance, and (iii) reactively, to update the Bayesian model in crisis management situations as data on recovery progress becomes available, to determine the impact on supply chain performance to the end customer. The model can be adapted to include other concurrent non-weather risk events as indicated in the case of the influenza outbreak in the United States. This would allow supply chain managers to more effectively plan for risk management in the pharmaceutical supply chain. The Bayesian network model can also be adapted for the dynamic case by dividing the recovery timeline into time slices and using the associated probabilities in each case to make a prediction.

Table 5

A comparison of the risk exposure of the base scenario and worst-case scenarios.

Scenario	Baxter	Port Equipment and Facility damaged	Increased in Demand due to Epidemic	Hospital Disruption
Scenario 1 (Base Case)	50%	13.22%	30.4%	65.73%
(Scenario 2) (pessimistic case)	100%	100%	100%	89.18%

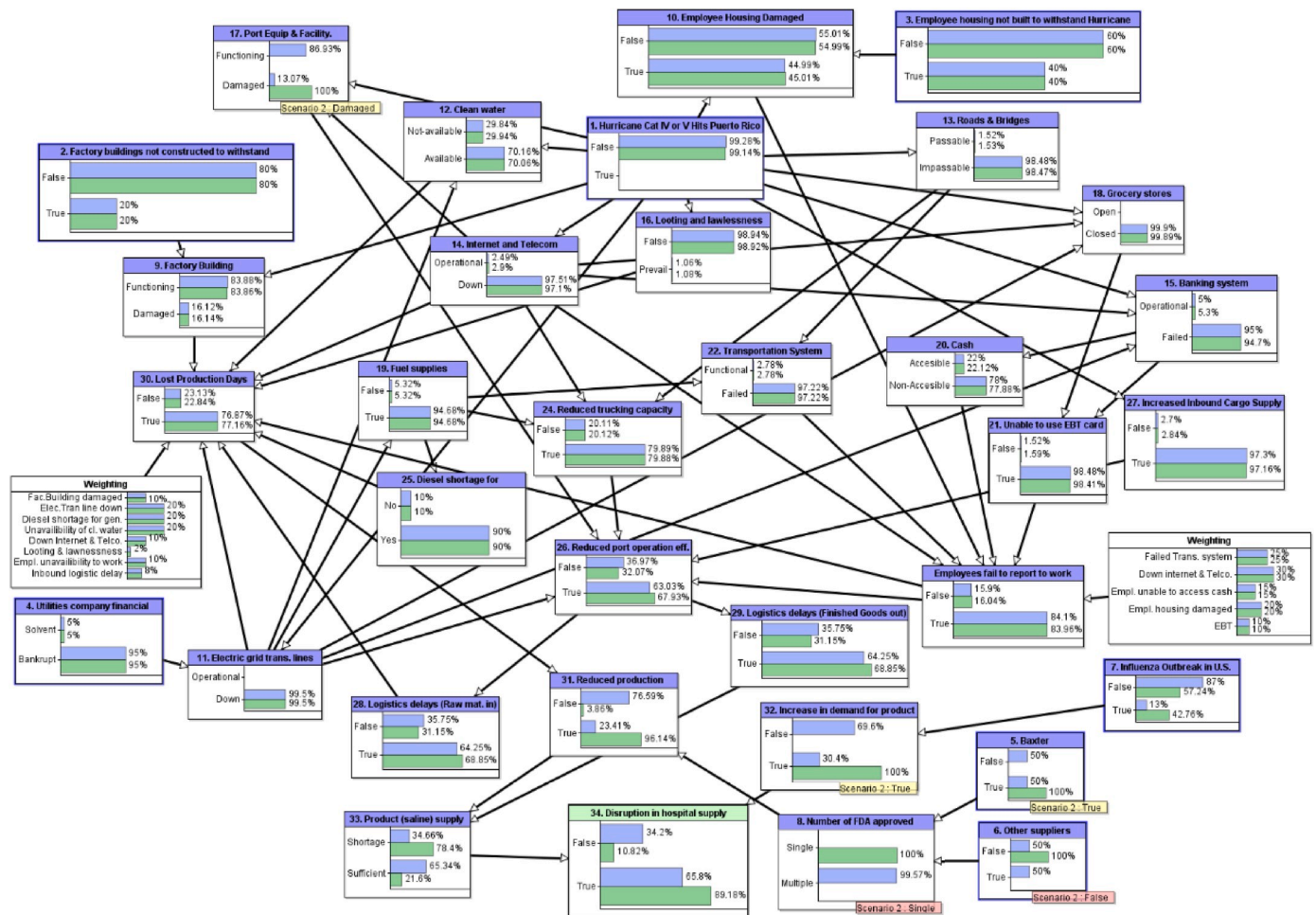


Fig. 7. The developed BN model for scenario 2 (pessimistic case).

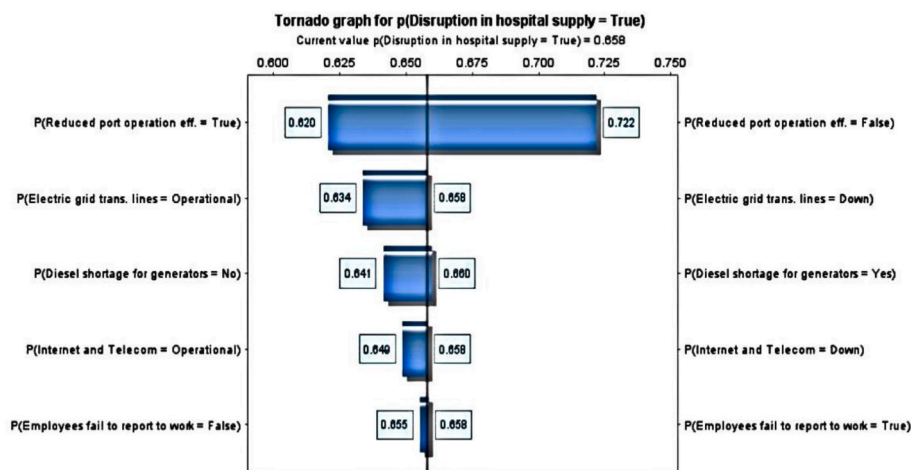


Fig. 8. Sensitivity analysis of disruption in hospital supply and its salient causal factors.

This Bayesian network model was customized for the situation following Hurricane Maria's landfall in Puerto Rico and the subsequent impact on U.S. mainland hospitals, but the model can be modified for other supply chains in supplier locations that are prone to catastrophic weather risk. The model provides high level insights into a series of hidden risks that unfolded following the disaster, leading to a shortage of saline in U.S. hospitals. It also demonstrates the fragility of the U.S.

pharmaceutical supply chain to the onset of known recurrent risks that coincided with the event, e.g., the influenza outbreak, which increased the severity of the outcome and delayed supply chain recovery.

The advanced analyses indicate that reducing the risk of having a single source, increasing the resilience of port infrastructure, and developing robust methods to manage the impact of an increase in demand would significantly decrease the chances of supply chain failure.

However, the model does not suggest how these control measures should be implemented. The investigation of strategies and efficient methods would be the subject of a separate study.

Some suggestions that could be further investigated include evaluating the impact of reducing the concentration of production in Puerto Rico and dispersing manufacturing at FDA approved plants worldwide; investing in additional manufacturing capacity; designing flexibility into production plants; holding buffer inventory at strategic points in the supply chain during the hurricane season; constructing private port facilities to serve manufacturing plants; negotiating port agreements that can be exercised in the event of a disaster, and applying new technologies to the generation of electricity and manufacturing of the product. Other examples of risk mitigation strategies include holding sufficient fuel for backup generators for at least two months; arranging post-disaster transportation for employees prior to the storm; ensuring cash reserves on site for employees; and developing more robust communication strategies.

The information from various news sources indicated that approximately 50% of U.S. hospitals suffered stockouts in the months following Hurricane Maria [13]. This figure reflects the situation shortly after the storm and provides an estimate of the situation in the ensuing weeks as Baxter's supply to U.S. hospitals was disrupted for a prolonged period of time. At least up to November 2017, a rationing system was required since orders could only be partially filled due to Baxter not being fully reconnected to the electric grid and the persistence of operations and logistics problems [172–174]. At the same time, one of the most severe influenza seasons was beginning, which resulted in an increase in the demand for saline. The model predicts an exposure of approximately 65.8% risk of shortages, which seems reasonable in light of the events that unfolded following the disaster.

Some possible reasons for the difference include (i) the availability of data used to make preliminary estimates, (ii) lack of knowledge of actual hospital usages and shortages, and (iii) operations-related “leak” factors within the pharmaceutical industry. Other factors to consider include the fact that all node types were specified as Boolean, with clear true or false outcomes. However, these outcomes can be further refined to more closely reflect the actual situation. In determining the probabilities of the various node states, Sharma and Sharma [25] further recommend that if there are more than a few node states, expert judgment would be better replaced by using Saaty's Pairwise Comparison method to determine the relative weightings. As noted previously, the model was developed for the static case, but a dynamic Bayesian model would improve predictive insights along the recovery timeline.

Finally, as this paper concludes, another unforeseeable risk, the SARS-CoV-2 pandemic (COVID-19), again raises the issue of the vulnerability of the U.S. pharmaceutical supply chain to rare disruptive events. The authors recognize the potential to adapt the Bayesian network model developed in this paper to evaluate the impact of this risk event on the U.S. health care system and are currently in the process of investigating this area.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijdr.2020.101607>.

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