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Kuehne + Nagel's PharmaChain: IoT-Enabled Product Monitoring Using Radio Frequency Identification

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Abstract**—**This case study features the Kuehne + Nagel PharmaChain solution for 'cold chain' pharmaceutical and biologic product shipments with IOT-enabled features for shipment temperature and location tracking. Using the case study method and content analysis, this research project investigates the application of the structurational model of technology theory introduced by Orlikowski in order to interpret the firm's entry and participation in the IOT-impelled marketplace.

Keywords**—**Internet of things, IoT, radio frequency identification, supply chain management, business intelligence.

I. Introduction

THIS research features a case study of Kuehne + Nagel (K+N), a global logistics services firm that covers the different transportation modes, which introduced the PharmaChain specialized solution service for "cold chain" shipments belonging to the pharmaceutical and life sciences industries.

The "Internet of Things" or IOT is defined as "…a worldwide information infrastructure for the information society in which physical and virtual 'things' were uniquely identified and connected over the wired or wireless internet. These physical and virtual things could include an object or smart device, such as clothes, a watch, a camera, a washer, a building, a bridge, a car, a suite, an animal or even a person…." [1, pp. 2-3]. In a global survey of 795 firms, Tata Consultancy Services found that four out of the five firms have already deployed IOT initiatives [2]. The four major areas for IOT application are: (a) product monitoring: tracking products by embedding sensors, software, and other technologies in physical products; (b) premises monitoring: installing sensors, digital cameras, and other devices in firms' business operations sites; (c) customer monitoring: tracking wireless mobile devices carried by customers; (d) supply chain monitoring: installing sensors, digital devices, and cameras in the production and distribution facilities [2]. The theoretical framework called the structurational model of technology introduced by Orlikowski [3], [4] is used as the analytical lens through which K+N's implementation experience is investigated and interpreted.

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II. Literature Review

A. Kuehne + Nagel Firm Background

Kuehne + Nagel (K+N) is a based in Switzerland and is a global leader in providing business-to-business sea freight, air freight, overland, and contract logistics services in more than 100 countries [5]. The aerospace, automotive, industrials, high tech, oil and gas, retail, pharmaceutical and healthcare industries are among the key industries served by K+N. In March 2011, K+N introduced the PharmaChain specialized logistics service for the pharmaceutical and health-care industries. K+N guarantees that its pharma cold chain logistics services follow the best practices guidelines of the World Health Organization (WHO) and that its entire network of facilities is GXP compliant, meaning that the firm observes regulations that ensure the delivery of quality high-risk products like pharmaceutical goods and biologics. K+N handles pharma shipments in three categories of facilities: (1) pharma gateways: these have cool zones with temperature ranges of 1-8 and 15-25 degrees Celsius; (2) competence centers: have cooler facilities but do not observe stringent cool zone standards with specific temperature ranges; and (3) pharma branches: do not have special equipment; staff strictly deals with moving goods, but are not allowed to physically handle or touch them [6].

K+N filled a niche in the logistics services marketplace on account of a number of factors. There are multiple stakeholders involved in the shipment of temperature-sensitive pharmaceutical and biologic products. Even for a firm like K+N, delivering logistics services requires coverage of land, air, and water modes of transportation in order to cover the entire world. Traditionally, the pharmaceutical cold chain has been characterized by lack of process visibility leading to serious constraints in the logistics service providers' ability to mitigate shipment delivery problems while the goods are in transit. Limited investment in information technology by different logistics service providers is partly to blame for this lack of visibility. Inadequate equipment performance is also notable --- with more reliable equipment/assets used in logistics found in more developed countries and thus, "breaks" in the cold chain occurs in less developed countries where such assets perform less reliably.

B. Pharmaceutical and Life Sciences Industries' Need for Product Temperature Monitoring

Temperature-sensitive products constitute a "cold or cool chain" and the logistics operations of moving them through a

physical supply chain are regulated by federal law and guidelines of regulatory agencies [7]. Drug or biotechnical testing laboratories and manufacturers, contract manufacturers and packagers, distribution centers, wholesalers, healthcare facilities, pharmacies, etc., are the usual stakeholders who would be concerned about proper product disposition.

A successful "cold chain" supply chain is one that can deliver products to the customer in usable form. Pharmaceutical drug and biotechnology products must arrive unadulterated and with its efficacy fully intact. Organizations such as the U.S. Food and Drug Administration (USFDA) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) act as regulatory arbiters and partners in ensuring the arrival of high quality and safe cold chain products [7].

The pharmaceutical and life sciences industries are faced with two major risks as its physical products traverse its "cold chains": the risk of adulterating the products while in transit and storage and the risk of non-compliance with federal regulations, guidelines, and standards. To date, there is no universal standard, guidance, regulator, arbiter or document with the "final say" on what constitutes a compliant cold chain for a specific geographical area. All affected industries, such as the pharmaceutical and life sciences industries, currently deal with a multitude of recommendations on how to be compliant from many regulations at different levels --- reflecting a totally fragmented regulatory environment for these types of products. Amidst this fragmentation, however, two organizations are preeminent in mandating compliance procedures: the USFDA and ICH.

C. Orlikowski's Structurational Model of Technology

This study applies Orlikowski's "Structurational Model of Technology," [3], [4] to understand how information technology (IT) interacts with organizations. This model draws on Giddens' theory of structuration [8]-[10] which proposed the concept of the "duality of structure," "…which refers to the notion that the structure or institutional properties of social systems are created by human action, and then serve to shape future human action…." [4, p. 147]. "…In Giddens' theory, structure is understood to be an abstract property of social systems. Structure is not something concrete, situated in time and space, and it lacks material characteristics. Structure cannot exist apart from the human actors who enact and interpret its dimensions. Structure has only virtual existence. Interestingly, people readily allow their actions to be constrained by these shared abstractions as social structure…. The ability of organizational structures to elicit compliance and conformity in the absence of material constraints attests to the power of those socially constructed abstractions…. Social structure conditions these social practices by providing the contextual rules and resources that allow human actors to make sense of their own acts and those of other people." [4, p. 147]. Furthermore, Giddens specifies that human interactions are an amalgamation of structures of meaning, power, and moral frameworks enacted in what he calls the "modalities" of these interactions: interpretive schemes, resources, and norms.

"Interpretive schemes…form the core of mutual knowledge whereby an accountable universe of meaning is sustained through and in processes of interaction [9, p. 83]. Orlikowski and Robey [4] translate Giddens' concept of the "interpretive scheme" within the realm of IT and explain that IT represents reality through a set of concepts of symbols embedded in it by which end users understand their world. Thus, IT is not only a medium for the construction of social reality, but also a means of institutionalizing certain "interpretive schemes" or stocks of knowledge within the organization by standardizing, sharing, and taking them for granted.

"Resources" are the media through which power is exercised by human actors because it is through these resources that humans can accomplish their objectives and thus, gain "domination" [4]. Therefore, the deployment of IT institutes a certain order of authority, dictating the way work will be performed, and also, resulting in the differential distribution of power in the organization.

"Norms" are understood as organizational rules that shape "legitimate" behavior. IT is a medium for installing such norms in order to control human behavior in an organization [4].

Orlikowski incorporates the following components in her framework: first, the human agents, consisting of technology designers, end users, and decision makers; second, the material artifacts that constitute IT itself; and third, the institutional properties of organizations --- structural arrangements, business strategies, ideology, culture, control mechanisms, standard operating procedures, division of labor, expertise, communication patterns, and environmental pressures [3], [4].

The structurational model of technology discusses four critical issues [4]. First, IT is the product of human action, which is responsible for the creation, use, and maintenance of different forms of IT. It is only through the human appropriation of IT that it is able to influence human activity. Second, technology is the medium of human action. Since different forms of IT are used by organizational workers, they mediate organizational work either by facilitating it, and in some ways, also constraining it. Third, organizational contexts shape human action within organizations. Human agents are influenced by the institutional properties of their setting which provide the resources, norms, and knowledge they need to work. Furthermore, IT is created and used within certain social and historical circumstances which influence the form and features of this technology. Fourth, human agents either reinforce or transform the institutional properties of an organization when using IT. Weick [11] characterized technology as "enacted environment" whose construction is determined by an organization's structures of signification, domination, and legitimation. Any change in these three structures indicates the "appropriation" and use of technology.

"Structure of signification" refers to the way the concepts and procedures intrinsic to the knowledge embedded in IT directs the manner in which problems are interpreted and work is conducted in the organization [3]. "Structure of domination" refers to IT's ability to control the work of organizational

members once it is deployed. "Structure of legitimation" refers to the ability of IT to sanction a particular mode of conducting the work and thus, propagate a set of norms about what is considered legitimate business practice. Orlikowski also incorporates the three modalities of structuration --- interpretive schemes, resources, and norms --- in her application of the structures of signification, domination, and legitimation in the deployment of IT in an organization

III. Research Method

This study uses the case study approach in aligning the concepts prescribed by Orlikowski's framework to K+N's PharmaChain system. The case study is an appropriate methodology in testing the application of a conceptual framework to a real firm. The primary data used were based on the transcription of the conference presentation of Terry Sell, Pharma and Temperature Controlled Airfreight Services Director, K+N, during the RFID Journal Live! Conference on April 16-17, 2015, San Diego, California, USA. In addition, secondary data sources from academic and trade articles on K+N were content analyzed using key concepts in the model. The following are accepted definitions of the content analysis method:

> "Content analysis is any research technique for making inferences by systematically and objectively identifying specified characteristics within text." [12, p. 5]
>
> "Content analysis is a research technique for making replicable and valid inferences from data to their context." [13, p. 21]
>
> "Content analysis is a research method that uses a set of procedures to make valid inferences from text." [14, p. 1]

In this study, the concepts used for content analysis were derived from the structurational model of technology. This framework forms the "context" of the content analysis method as applied to K+N's PharmaChain system:

> "A context is always someone's construction, the conceptual environment of a text, the situation in which it plays a role. In a content analysis, the context explains what the analyst does with the texts; it could be considered the analyst's best hypothesis for how the texts came to be, what they mean, what they can tell or do. In the course of a content analysis, the context embraces all the knowledge that the analyst applies to given texts, whether in the form of scientific theories, plausibly argued propositions, empirical evidence, grounded intuitions, or knowledge of reading habits…. The context specifies the world in which texts can be related to the analyst's research questions." [15, p. 33]

The secondary data was analyzed within the context provided by the Orlikowski framework, which is considered the "prior theory." "Analytical constructs operationalize what the content analyst knows about the context, specifically the network of correlations that are assumed to explain how available text are connected to the possible answers to the analyst's questions and the conditions under which these correlations could change…. analytical constructs ensure that an analysis of given texts models the texts' context of use…" [15, p. 34].

The following key conceptual elements of the content analysis method as stipulated by Krippendorff [15] were used in this study: (1) body of text selected for the analysis; (2) research question that needed to be addressed; (3) a context of analysis within which interpretations will be made; (4) analytical constructs that operationalize what the analyst knows about the context; and, (5) inferences that will be arrived at to address the research question.

IV. Study Findings

The following findings demonstrate the application of the structurational model of technology in K+N's deployment of PharmaChain in serving its cold chain logistics services clients.

A. Structure of Signification

K+N's PharmaChain was deployed in March 2011 [5]. The specific elements of K+N's PharmaChain that make up the CartaSense wireless monitoring solution by air and ground shipments are the following [16]. First, there are the wireless sensors and in the case of K+N, the "U sensors" used to monitor the pharmaceutical products. The U sensors used for the PharmaChain solution can monitor temperatures ranging from -35 degrees Celsius to + 65 degrees Celsius with both internal and external probes that support relative humidity within the (0-100%) range.

An advanced mesh network enables the connection of innumerable wireless U sensors with each other and with a "gateway." Second, the "gateway" connects the mesh network in a specific spot to a central communication server through the use of either a public or private network. Third, data from all the gateways are gathered real-time by a "communications server," which, in turn, uses some kind of web service technology interface in order to share this data with external applications. Fourth, "technical applications" are software products that allow end users to view the data gathered in a usable format. The data gathered can consist of measurements, mesh network architecture data, or other valuable data. Technical applications may run on any web-enabled device. Fifth, "business analytics software" can do further data analysis in order to produce meaningful reports showing things like warehouse mapping, shipment location, temperature thresholds reached, etc.

The U sensors are attached to the goods/products whose temperature and location are being monitored. Data from these sensors are transmitted to RFID readers when the shipment arrives at a waypoint or its final destination [5].

"U sensors" detect a U sensor gateway within range and start transmitting data to it. Using some kind of network, whether it is a local area network (i.e., Ethernet gateway) or cellular communications network (i.e., general packet radio service or GPRS gateway), the U sensor gateway, in turn, connects with a communications server. The "U sensors" automatically form a dynamic, self-healing mesh network which is resilient even when exposed to rough radio frequency

conditions. Resident sensors can also function as "repeaters" for other wireless sensors that cannot sense a U sensor gateway nearby.

All U sensor data gathered are then transferred to the K+N software which logs temperature data and detects deviation from acceptable thresholds. Other data such as temperature measurements, times of readings, receipt of measurements, whether the tags were connected to the system at the time of measurement, and reader position, among others, are transferred by this software to a database.

K+N's 24/7/365 CareTeam is alerted via a Web-based shipment tracking system when acceptable temperature thresholds are exceeded, and its members then take appropriate remedial action to prevent product spoilage or adulteration. There is also a U sense gateway dashboard that enables K+N workers have supply chain visibility and help manage reader data reception and transmission throughout the journey of the products.

The IT infrastructural elements of this temperature monitoring application is installed in hundreds of points along K+N's global supply chain consisting of warehouses and logistics facilities that oversee the logistics of pharmaceutical and life sciences products of its clients. Chapman, K+N's global pharmaceutical product manager said, "It's not something every company chooses to use or deploys for all products and situations….It's something that's valuable for critical shipments involving high-value products, and the partnership between our customers and our company is constantly expanding." [5].

Operational data from the U sensor mesh network is also linked with K+N's Cargo 2000 system to ensure compliance with air freight delivery standards required by this initiative.

B. Structure of Domination

Moving "cold chain" pharmaceutical products demands thorough scientific knowledge of the product and the nature of the environments where it moves and is stored throughout the delivery journey. A second key requirement is the ability to document data on the operating environments and establishing that they are scientifically sound. Cold chain engineers, packaging engineers, and logistics-related workers should understand these environmental conditions and product parameters better than any inspector. Guidance documents from regulatory agencies spell out valuable criteria for creating tests to ensure the products are protected while in transit and during short-term storage. These tests should accurately represent real-time and real-world shipping environments, primary and secondary shipping containers, transport and storage durations, seasons, and climatic zones. The global supply chain for pharmaceutical products usually include different transportation and several climatic zones, and land, air and water modes of transportation, each with their accompanying temperature fluctuations.

An information system supporting the documentation needs of the peculiar logistics requirements for pharmaceutical products needs to capture detailed records of stability data, geographical data (including climatic zones), and shipping and storage durations at each point in transit, as well as contingency procedures for delivery delays, out-of-specification conditions or other unforeseen exception events.

RFID technology should be able to capture all relevant ambient data regarding the pharmaceutical product shipment in order to fulfill regulatory requirements. In the case of K+N, the CartaSense solution offers end-to-end monitoring and alerting abilities using advanced wireless sensor networking [16]. Vendors need to introduce new paradigms for monitoring assets, providing real-time information, and enabling ad-hoc corrective actions, such as increasing or decreasing the air condition temperature set point while in transit, moving the goods from a warm location back to the fridge room, etc.

The quality of the goods is often related to the remaining shelf life of the product, which is often difficult to predict as complete information is unavailable on the history of the product environment from the product's creation to its actual arrival time. Also, goods on the same pallets coming from the same manufacturing facility, using the same mode of transportation, can have very different environmental profiles. One pallet in the same shipment may have waited longer on the dock and may have been exposed longer to hot sunlight, for instance, than other pallets in the same shipment. Adding a wireless sensor to each pallet enables the capture of the exact temperature history at each point in transit and the product's shelf life can be more accurately calculated.

C. Structure of Legitimation

Standards that govern IOT represent "the structure of legitimation" because they sanction the configuration of the specific elements of the IOT solution used and propagate a set of "norms" about what constitutes a workable IOT solution within different corporate contexts/environments. Observance of IOT standards is important because: (1) standards specify tried and tested solutions which could greatly help a firm deploy IOT solutions under real world conditions; (2) standards require specific IOT solution components provided by vendors and integrators off-the-shelf, thus, helping firms avoid unnecessary development efforts and vendor lock in; and, (3) standards enable solutions that are compatible with related business applications.

At this time, there is no central body of standards that can be applied to all possible IOT applications. The use of industrial IOT standards would be relevant specifically for K+N's temperature monitoring service. The efforts of three bodies would have the most impact on the K+N, though.

The first organization is that of the Open Interconnect Consortium (OIC), which is supported by Intel, Samsung Electronics, Hewlett Packard, Lenovo, Dell, among a total of 50 vendor firms. These firms are working to back up open-source standards covering device discovery, communication, and data exchange, among other functions. The OIC has developed the source code embodying the consortium's specifications for certified IOT products and released it to developers in 2015 [17].

The second organization focusing on enterprise IOT is the Industrial Internet Consortium (IIC) consisting of about 100

members including Microsoft, Samsung, Huawei Technologies, General Electric, Cisco Systems, IBM, and Intel [17]. Its approach is different in that rather than developing IOT standards, it intends to work with different standards bodies to coordinate efforts of industries where IOT and older machine-to-machine technologies have been deployed. In so doing, the IIC will define requirements for standards, design reference structures, and create testbeds for these standards.

The third organization is the IEEE (The Institute of Electrical and Electronics Engineers) P2413, which has a working group devoted to organizing the variety of IOT specifications developed by different industry consortia [17]. It will do so by converting information from different IOT platforms into a commonly understood body of data objects.

With the variety of standards bodies emerging, a good predictor of who might prevail is the size, reputation, and momentum of the firms behind them. These are consortia that will more likely gain greater traction and immediate market recognition and acceptance.

D.Social Consequences

1. Social Structure and Social Consequences of IT

(a) K+N PharmaChain and K+N Login

The supply chain logistics operations of pharmaceutical and life sciences are a complex system of interactions involving multiple parties. Terry Sell from Pharma and Temperature Controlled Airfreight Services – North America, K+N, shared this:

> "[The] current situation is that there are multiple handoffs between different parties. In the freight forwarding world, we don't own [all] assets for the most part. We may have a few trucks here and there, but typically we're not owning our own aircraft. So this is where we have to involve other stakeholders, other providers, and make sure that they are willing to help us in that transit process…." [18].

Relationships among K+N clients and trading partners is supported by a Web-enabled value network platform called K+N Login, thus, enabling a digital horizontal social structure supporting integration among these participants. Functioning as a customer portal, K+N Login is a comprehensive supply chain management platform designed to enable K+N clients to optimize critical logistics, procurement and customer service processes; reduce logistics costs; and provide an "up-to-the-minute quick" view of one's inventory in motion using land, sea, and air transportation [19]. This customer portal links shippers, consignees, third-party service providers like warehousing and distribution center owners, and K+N, enabling always on real-time communications along a firm's entire supply chain.

Achieving supply chain visibility is a critical feature of a customer portal, such as the K+N Login. The portal reports and summarizes important supply chain events and generates exception alerts in cases of critical plan changes or expected or actual service interruptions. In the service of shippers, the portal provides information on the location and status of all products shipped worldwide and across all transportation modes, to allow them to manage them down to the purchase order and item level. The portal's event manager releases a notification message to the appropriate end users once a status or key process step has been reached or is about to be reached. The system also generates a confirmation or pre-advice when conditions set by business parameters designed by clients are reached. The portal also has an escalation mechanism that can identify plan changes and potential or actual service disruptions. If an event is overdue, the escalation mechanism will generate alerts to accelerate the response time of the appropriate parties, and thus, the system is assisting these clients in avoiding complaints from their customers and additional costs they may incur due to product delivery delays.

The portal also assists K+N clients in becoming more effective shipment and logistics planners. The portal has tools that consider a variety of cost factors --- such as transport, handling, and inventory --- in determining budgets. Planners can create and streamline operational plans using information on multiple logistics variables. The portal's interactive delivery planning (IDP) features enables on-line planning, and supports delivery planning and business processes for FCL (full container load) and LCL (less than container load) sea freight shipments. Shipping forecasts based on cargo arrivals and departures can be generated. Deliveries can be prioritized based on the need for a particular product. The portal's booking tool enables clients to place bookings more flexibly. Clients may submit shipping instructions and request equipment, advise pick-up addresses, and cargo-readiness dates. Data collected by the portal can also help clients evaluate the performance of their supply chain trading partners and thus, assist them in deciding whether or not to continue their relationships or contracts with these third parties.

K+N Login has SAP Business Objects integrated into it providing portal members with digital reporting tools --- dynamic performance reports/scorecards, volume statistics, freight spend reports, lead time reports, and fill reports. A built-in portal dashboard presents end users with an overview of logistics activities and order processes in their respective supply chain. Business intelligence tools enable end users to "data mine" collected logistics data for effective planning and decision making.

(b) K+N PharmaChain and Cargo 2000

Because of the complexity involved in logistics operations, this industry is ideal for creating Web-enabled value network electronic environments that can accommodate all necessary entities and participants involved in the process of moving physical goods by land, sea, and air. The PharmaChain solution is integrated with another such Web-enabled environment called "Cargo 2000." [20]. Data captured by PharmaChain is integrated with Cargo 2000.

Terry Sell from Pharma and Temperature Controlled Airfreight Services – North America, K+N, shared this:

> "…And then we also want to make sure it [PharmaChain] was integrating within our systems. Our visibility system, KN Login, and also it also interacted

with the other Cargo 2000 systems which is an industry wide system that gives us information and data so we can match everything up…."

"….We needed to make sure that we had our visibility system in place interacting with industry systems, the Cargo 2000. which gives us data and information, and make sure that that worked with our technology provider with their servers as well so that we could go into the actual monitoring process…." [18].

Cargo 2000 is a collaborative initiative of over 35 of the world's leading airlines, forwarders, and third parties involved in air freight services under the auspices of the International Air Transport Association (IATA) [20]. In response to customer demand for high level of service not previously attained in the air freight industry, Cargo 2000 seeks to create shipping process steps and interfaces for the exchange of shipment data among all parties involved and ensure that door-to-door delivery can be planned precisely and monitored using a master operating plan (MOP). Cargo 2000 consists of a three-pronged approach: planning, controlling, and reporting. In the planning step, the MOP involves calculating a shipment cycle based on the process framework, which subsequently creates a route map. This map defines the "latest by" times for the completion of key processes along the transport chain. All firms involved in a shipment collaboratively plan a route map using the standard data interfaces provided by Cargo 2000 which seamlessly combine the route maps of carrier and forwarder.

In the controlling step, the agreed upon route map is issued and the shipment is monitored against this map from origin to destination. The IT systems of both carrier and forwarded are linked to the Cargo 2000 system and are updated when a milestone is completed. Cargo 2000 generates alerts whenever there is a deviation from the route map. This instigates communication between the forwarder/carrier and the shipper/consignee to enable corrective measures to bring the shipment back on schedule. If the delay is considerable and the original plan cannot be followed, then a new delivery schedule is calculated and the route map adjusted. Exception codes are entered into the Cargo 2000 system to record causes and responsibilities for the shipment delay.

In the reporting step, it is important to establish whether or not the delivery promise was kept and to document reasons when it is not. Cargo 2000 members use standardized procedures and exception codes in reporting their performance. Data submitted by the members are the basis of monthly reports detailing the most frequent causes and responsibilities for shipment delays.

2. Action and Social Consequences of IT

Moving "cold chain" pharmaceutical products demands thorough scientific knowledge of the product and the nature of the environments where it moves and is stored throughout the delivery journey. A second key requirement is the ability to document data on the operating environments and establishing that they are scientifically sound. Cold chain engineers, packaging engineers, and logistics-related workers should understand these environmental conditions and product parameters better than any inspector. Guidance documents from regulatory agencies spell out valuable criteria for creating tests to ensure the products are protected while in transit and during short-term storage. These tests should accurately represent real-time and real-world shipping environments, primary and secondary shipping containers, transport and storage durations, seasons, and climatic zones. The global supply chain for pharmaceutical products usually include different transportation and several climatic zones, and land, air and water modes of transportation, each with their accompanying temperature fluctuations.

An information system supporting the documentation needs of the peculiar logistics requirements for pharmaceutical products needs to capture detailed records of stability data, geographical data (including climatic zones), shipping and storage durations at each point in transit, and contingency procedures for delivery delays, out-of-specification conditions or other unforeseen exception events.

Unlike the previous section that articulated social structure changes, "action" refers to very specific courses of action afforded by the PharmaChain solution for its end users. Terry Sell of K+N aptly described the existence of PharmaChain as providing K+N workers "proactive" action capabilities: "…A paradigm shift within our company is now we have the ability to act on things…." [18].

One important consequence of PharmaChain is K+N's ability to reduce its product release time while in transit by fast-tracking product clearances: "…. So if you have data and information that shows that your product is safe and effective, you can start to pre-clear that. You can start to prepare your downstream supply chain. So that's something where you don't have to wait until information is received from a data recording device that was placed on the freight. It's taken off after it has cleared customs, then they give it to the regulatory authorities, they approve it. You can start that process much more rapidly. So that's kind of an added benefit…." [18].

Another key action possibility is the ability of K+N logistics workers to take corrective actions when there are deviations in the desired temperature levels of pharmaceutical products while in transit: "….When you're talking about if something does happen in transit, whether as a deviation in temperature on the product, now you can have immediate root cause analysis, and this is where it becomes another critical timing factor because if a deviation occurs, the typical deviation can take anywhere from seven to 14 days to take and have a full deviation, full CAPA (i.e., corrective and preventive action) process complete. What that means is that the product is not in the market for sale. So if it's in deviation status or needs to have a CAPA attached to it, …that item is placed in quarantine or [kept] on hold. So if you can speed up that deviation process and take it from 14 days down to five days; that has a profound impact, and again, making sure the market can get that product, making sure you can have cash coming in quicker because you're selling that product quicker…" [18].

In the case of pharmaceutical products, information tracked on deviations from allowable temperature ranges is very important in deciding the disposition of the products. When pharmaceutical product shipments run in the millions of dollars, acting expeditiously to save the shipment from wastage of outright disposal is a significant benefit for the shipper client of K+N:

> "…. But also, when you have a deviation, what's important here, if you have a deviation it doesn't necessarily mean that your product is no good. So if it's frozen, if it's a biologic product, you'll know very quickly that you have to have a disposal process or you're going to bring it back to the origin for disposal. If it's a product that has more stability to it, meaning that it can accept outside of the refrigerated state, 2-8 degrees Celsius maybe to 10 degrees Celsius, then you have what's called time out of range, and you can measure and manage time out of range with this type of system, so you'll know exactly how long it was exposed to temperatures outside of the acceptable range and then you can make a shelf life calculation…." [18].

Another very important entity involved in the logistics process is the regulatory authority like the USFDA. Regulatory agencies need to be apprised about the disposition of the pharmaceutical product shipments that may have been compromised: "…You can give your regulatory authorities, your partner overseas the information so they can make a business based decision. But having that makes it much easier to get these, get these problems cleared up and get it through the CAPA process. You have the ability to mitigate in-transit issues. So again if something is going wrong, if you start to see an alert come out saying hey we're trending too high, well, that's going to be information you can use to make a phone call, so that's how you can be proactive is when you see something happening in real time and it's not correct or doesn't look right, you can make the phone call to make sure things are right. You reduce the product losses. If we know something is not going right, we've got a 24/7/365 team that will sit and monitor these things. They do get push notifications, push alerts, push alarms, and so again it is something where that team can help to reduce product loss, and then again, anytime you have information or data, you can help that to drive business decisions, so many different ways you can drive the business decisions. Are you using the right airlines? Are you using the right process? Can you optimize your packaging? So these are something to consider…." [18].

Going back to PharmaChain's purpose, which is temperature tracking, mitigating actions can be taken by the appropriate workers --- in the case of K+N this would be CareTeam members --- if they have the right information at the right time about the disposition of the pharmaceutical product shipments.

Terry Sell once again shared: "So if we look at the outputs this is, again, we're talking about the ambient temperature outside of a packaging system. So it could be a container, it could be a passive palate shipper, insulated shipper with gel packs, but this would be what the actual shipping system is exposed to, and this is the actual product temperature, so you can have a lot of good data from that. GPS [global positioning system]. Also make sure you see what's going on from the GPS perspective. What is your trucker doing, what routes is he taking? Is he taking a consistent route? If it's high value do you want him taking a consistent route? Do you want him changing routes? So these are all things we can monitor and start to measure as well. The push notifications, so again, talking about having our 24/7/365 CareTeam. They're getting the alerts, temperature alarm. So what are they going to do about it? How are they going to react upon it? Again, we can build processes based upon that as well. So these are some things that are outputs. So, when we talk about the alerts, not only do we get the alerts and the alarms, we can [also] notate that in the system, so it is something where we can say ok we had an alarm on this sensor, temperature was above the upper threshold for 15 minutes, and then say see details. That's where you can have a corrective measure in there, so when you have a deviation your quality departments at your customers' companies will pull that open, they'll see what the corrective measure [were]. It gives them information again to make that immediate decision whether or not you know they can close up the CAPA (corrective and preventive action) based upon that. We also talked about how deviations can be measured, the amount of time. So you have the amount of time out of range, you have where it happened. So, these are all things that we can start to measure and monitor and give [this] information to customers so they can make again business decisions --- so it's very powerful. And, then, [just as] importantly is when we talk about the integration of Cargo 2000 feeds. All these three that are codes here, these are Cargo 2000 feeds [Terry Sell pointing at the slides]. And what that does is it gives who had control of that shipment, where was that shipment in the transport process. So, you've got the temperature information here, you get the dates and times here, now you've got the ownership here. So, when you're talking about who was the stakeholder that had a challenge, whether it was on the aircraft, aircraft departed, it arrived here, was there something that went wrong here? This is what is really powerful is when you can start taking all of the data and crunching it together to create really good information and giving that to your customers so that they can see how they can improve their process. What is going right in the process and what is trending wrong? So even if the packaging is successful, the product was safe, we might find something where we're trending wrong. What's going on there? So again it's using data and information and using it in a good format to try and create business decisions and evaluate where your risk is and where your risk could be. Has something changed?" [18].

3. Measures of Success

K+N's success in providing PharmaChain can be measured in a number of ways. K+N has enabled pharmaceutical supply chain visibility and help clients manage shipments. The firm's notable CareTeam has facilitated proactive remedial action to protect shipments in cases where established temperature

thresholds, for instance, were violated or when shipment deliveries were delayed. K+N has also provided their clients timely, complete, and accurate information to enable them to make the right business decisions concerning their shipments, should they have to supplement or override CareTeam decisions. K+N has reduced product release time and accelerated the movement of the pharmaceutical goods through all clearances points. K+N has been able to fulfill their delivery promises and ensured that products arrive at destination points in a form useful to end customers. In the very end, K+N has helped their clients (shippers) reduce their overall shipping costs, while delivering high-quality specialized logistics services.

V. Conclusions

This study applied Orlikowski's structurational model of technology and has provided us with a better understanding of K+N's deployment of PharmaChain using U sensors. This useful theoretical framework is one of many that clearly illustrates the interactions among information technology, human agents, and the social structures/organizations where these interactions take place.

This framework focuses on four critical issues. First, IT is the product of human action, which is responsible for the creation, use, and maintenance of different forms of IT. Second, technology is the medium of human action. Since different forms of IT are used by organizational workers, they mediate organizational work either by facilitating it and in some ways, also constraining it. Third, organizational contexts shape human action within organizations. Human agents are influenced by the institutional properties of their setting which provide the resources, norms, and knowledge they need to work. Furthermore, IT is created and used within certain social and historical circumstances which influence the form and features of this technology. Fourth, human agents either reinforce or transform the institutional properties of an organization when using IT**.** Weick [11] characterized technology as "enacted environment" whose construction is determined by an organization's structures of signification, domination, and legitimation.

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