# On the Application of Hazard and Operability Method in Patient Safety Context: Opportunities and Challenges

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## Abstract

Patient safety is considered as one of the crucial aspects of the healthcare sector that required improvement. Earlier studies show the high rate of harm to patients and financial losses. In order to improve patient safety, various tools and methods were adopted from other safety-critical industries. While Prospective Hazard Analysis (PHA) tools has proven its effectiveness to enhance the safety and quality of systems and processes in others, now they also gained increased attention in healthcare. One example is the Hazard and Operability (HAZOP) technique to systematically and comprehensively identify hazards and deviations of a system from the intended design in the healthcare sector. The aim of this study is to review HAZOP and identify the potential contribution and challenges of this tool in the healthcare field, in particular patient safety context.

## Keywords
Patient Safety, quality, healthcare operations, HAZOP, Hazard and Operability

## 1. Introduction

There is a growing attention that medical errors harm patients worldwide and impact the healthcare system financially. For instance, improper medication dosage due to unclear instructions are causing financial harm to health care estimated at US $42 billion annum, and severe patient harm, disability, and even death (Atiken 2012; Challenge, 2017; Kurutkan et al., 2015). The evolvement of patient safety has become one of the essential aspects in the healthcare sector during the past years. A vast sum of money spent annum to enhance patient safety. According to the World Health Organization, about 1 out of 10 patients are affected during medical treatment because of errors or harmful effects in developed countries alone (Dhillon, 2012). As the pioneer study in patient safety context, the Institute of Medicine in Washington D.C. conducted two large well-known studies about medical errors 'To Err Is Human: Building a Safer Health System'; the first study in Colorado and Utah and the second study in New York. According to the these studies, from 44,000 to 98,000 people die each year as a result of avoidable medical errors (IOM, 2000). In 2016, another study conducted in the state of Pennsylvania with the participation of 25 hospitals; the study states that around 251,000 patients die due to medical errors (Anderson and Abrahamson, 2017). Another study conducted in Kuwait in 2019 found that 20.9% of the medical errors lead to fatality (Ahmed et al., 2019).

The healthcare sector adopted risk management tools used in other safety-critical sectors to reduce medical errors via identifying the potential risk in the healthcare systems, processes, procedures, devices, medicine, and personnel (Despotou et al., 2014) and improve overall safety culture (Simsekler, 2019). Over a hundred Prospective Hazard Analysis (PHA) techniques for

risk identification are available (Lyons et al., 2004; Simsekler et al., 2015a). Moreover, forty PHA techniques listed in the following study (John Gould Michael, Michael Glossop, Agamemnon Ioannides, 2005). These techniques are categorized to provide better outcomes for a particular process (Gould and Au, 1995; Simsekler et al., 2015b). Moreover, these techniques adopted from different applications such as chemical industries, nuclear power plants, aviation companies, and construction companies (Durand, 2009). There are some popular techniques used in the healthcare sector for risk identification (Simsekler et al., 2018a). These techniques are Failure Modes and Effects Analysis (FMEA), Event Tree Analysis (ETA), Hazard Analysis and Critical Control Point (HACCP), Fault Tree Analysis (FTA), Hazard and Operability Analysis (HAZOP), Human Error Assessment and Reduction Technique (HEART), Structured What-If Technique (SWIFT) and Technique for Human Error Rate Prediction (THERP) (Durand, 2009; Simsekler et al., 2019a).

As one of the common tools used in other safety-critical industries, this paper focuses on how the HAZOP technique used in healthcare to improve patient safety. HAZOP technology was developed at the Heavy Organic Chemicals Division of the Imperial Chemicals Industries (ICI) in Billingham by a team in 1963. Plant production manager assigned them to study the existence of any deviation in the design of phenol plant using the critical examination method, which is a formal methodology to study a process and produce alternatives by asking questions such as 'where it is achieved?' , 'how it is achieved?' and 'when it is achieved?'; however, they used another technique and discovered several unexpected possible risks and operational issues; the used technique was called later HOZOP (Kletz, 1997). In 1973, Herbert Lawley published the first paper on HAZOP at AIChE Loss Prevention Symposium (Kletz, 1997, Lawley, 1974). Over the year, the number of paper on HAZOP steadily rose (Kletz, 1997). While the use of the HAZOP have gained broad use, its application in healthcare is relatively limited. This study, therefore, aims to review the current literature to see how the HAZOP has been used in healthcare, and identify opportunities and challenges.

## 2. Methodology

The introduction gives a brief about the importance of identifying hazards to improve patient safety; in addition, it highlights different hazard identification techniques adopted from the industry sector. The literature review discusses researches and studies that show the contribution of the HAZOP technique to identify the hazards in the healthcare sector.
First, a systematic review search, using keywords "patient safety, HAZOP, hazard and operability" was aimed to identify the relevant articles. This technique was successful in some databases e.g. "Pubmed"; however, it did not yield to a suitable number of articles in other databases e.g. "Scopus". Therefore, the snowballing technique used to trace the relevant articles cited on the important and relevant articles. This technique helped to identify the important authors and references. Overall, the numbers of articles about using the HAZOP technique in healthcare were limited but discussed further for its potential use in future.

## 3. Literature Review

HAZOP technique is a highly effective approach used to identify the possible deviations in a process from the planned design process. It is a team-based brainstorming approach; including multidisciplinary knowledgeable and experienced individuals in the selected process. Moreover,

the team shall be prepared by a detailed training in HAZOP. A list of guidewords such as (more, no, less) is used to identify the deviation in a specific step of the process, then study the possible causes and consequences, finally determine the action required to eliminate or control the causes. The guidewords considered an essential element of the technique that guides the team to ensure complete coverage of all the possible hazards and risks. There are standard guidewords for industrial applications, and some studies had recommended a list of guidewords for healthcare (Despotou et al., 2017). The final step is to document all the identified threats during the study and implement all actions required (Dhillon, 2012, John E. McDonough and Petosa, 2004, Ericson, 2005).

In 1999, a study about adopting proactive hazard analysis to the healthcare sector conducted by the Veterans Health Administration (VHA) and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in the US. The study funded by Emergency Care Research Institute (ECRI) and the Milbank Memorial Fund in the US. The result of the study defined Critical Control Points (HACCP), Root-Cause Analysis (RCA), FMEA and HAZOP techniques as PHA techniques for patient safety. Mainly, FMEA considered as valuable techniques for identifying the risk. Thus, VHA evolved the Health Failure Modes and Effective Analysis (HFMEA) technique using key components of each technique and mainly the component of FMEA (Simsekler et al., 2019b). Another study conducted by the Joint Commission discovered that techniques used to improve the reliability and safety in other sectors could not be implemented directly in the healthcare sector. Moreover, the techniques shall be studied well and conduct necessary changes to suit the applications in the healthcare sector (Liberati et al., 2018).

In 2001, the European Commission had funded a project called CORAS, which is a method for conducting a risk assessment of critical security systems; the project completed successfully in 2003. The project included eleven institutes from the five European countries: Norway five institutes, Greece three institutes, UK two institutes, and Germany one institute. National Center for Telemedicine (NTS) in Norway was one of the participants; NTS considered as the first World Health Organization Collaborating Center for Telemedicine. HAZOP used as an integral part of the CORAS project in identifying the risk in medical databases and telemedicine. Specifically, the areas coved were (1) verification procedures, (2) risk associated with unapproved changes of information while created, conveyed, or stored, (3) risk of the availability of resources, and (4) risk losing connection to the network. The risks identified using the HAZOP technique, then the risks were displayed using FTA. Eva Skipenes, Security Adviser, Norwegian Centre for Telemedicine comments: "*The HAZOP method is very useful to identify and document threats and unwanted incidents, and to gather as much information as possible from different participants. It is easy for non-technologists to follow this method, but it requires good planning (choice of guidewords, choice of which aspects to focus on, and which detail level to us*e". Also, Eva Skipenes added, "NTS is using HAZOP for risk assessment of telemedicine services and information security at primary health care centres in North Norway"(McDonough and Petosa, 2004).

Staff shortage issue leads to overload the staff (physicians, nurses, and pharmacist) and that can lead to medication errors or wrong diagnosis, which may affect patients safety (World Health Organization, 2019) and service quality (Marbouh et al., 2020; Simsekler et al., 2018b). The causes of medication errors and wrong diagnoses are the wrong decisions by the exhausted staff,

and here the needs of IT systems "Decision Support System (CDS)" in healthcare exist. Moreover, the new technologies integrated with healthcare, such as medical software and application software are presenting new hazards. These hazards could also contribute to patient safety. Fox (2003) states that medical error could also occur due to software or application failure. Also, he recommends HAZOP as a method for assuring the safety of the clinical software to be used at the first stage of medical software development. Furthermore, he categorizes the risks of the clinical software into four levels (Fox, 2003, Mankowitz, 2018).

- *Risk level 1.* The CDS may pose serious and preventable risks, e.g. The CDS may prescribe a dangerous drug or procedure.
- *Risk level 2.* The CDS does not pose a clear danger, but it can lead to a situation in which beneficial action is ignored, e.g. The CDS usually recommends the physicians to check lead range in healthy children bodies; however, they fail to do.
- *Risk level 3.* The CDS does not pose a direct or indirect risk, but does not predict future conditions, e.g. the CDS fail to identify that clostridium difficile colitis caused by the prolonged use of antibiotics
- *Risk level 4.* There are no identified risks.

The continuous development in IT brings the attention of the healthcare providers on how to ensure the safety of medical IT system. In the UK, the safety of the medical IT system stipulated in two standards SCCI 0129 (Clinical Risk Management: its Application in the Manufacture of Health IT Systems) and SCCI 0160 (Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems). A research paper 'A Framework for the synthesis of Safety Justification for Digital Enable Healthcare Service' designed and applied a framework on accident and emergency (A&E) to an IT-support clinical emergency services and used the HAZOP technique to study the deviation analysis. Moreover, the authors suggested a set of guidewords with their interpretation (see Table 1). However, they recommend the practitioners to evaluate the guidewords considering the particular domain of the application (Despotou et al., 2017).

Table 1:Shows examples of guidewords with their interpretation (Despotou et al., 2017)

| Guideword | Interpretation |
|---|---|
| Omission | Something missing when expected |
| Early | Something happening earlier than expected |
| Sequence | Something happening out of sequence (when it matters) |
| Lapse | A person not doing something that they were supposed to |
| Slip | A person doing something wrong accidentally |

One of the hazard identification tools in the IT system is Software Hazard Analysis and Resolution in Design (SHARD). It was initially proposed in a paper published at the COMPASS conference in 1994. SHARD technique initiated as a variant of the HAZOP technique in identifying hazards in IT systems. SHARD and HAZOP techniques have close similarities. The main differences between them are the set of guidewords being used, and SHARD does not require a full team to analyze all stages (Pumfrey, 1999). SHARD technique used to identify hazards in software design for the healthcare sector to improve patient safety (Habli et al., 2014).

Durand (2009) conducted a research study in 2008 to evaluate and compare three PHA methods and their contribution to identify the hazards associated with ward-based therapies at Bedford Hospital; the three PHA methods were FMEA, HAZOP, and FTA. The research funded by Cranfield Health Partnership, which included Cranfield University, several nearby hospitals, and Bedford Hospital. The hospital was having some concerns about the unidentified hazard on the oxygen therapy process. Accordingly, it was selected as the subject of the study. The three methods identified a total number of 186 hazards. Only 15% and 13% of the hazards were fully and partially identified respectively by the HAZOP technique ( see Table 2) (Durand, 2009).

Table 2:Shows number of hazards identified by each technique from M. L. Durand research **(Durand, 2009)**

| | FMEA | FTA | HAZOP |
|---|---|---|---|
| Fully Identified | 58 | 58 | 28 |
| % | 31% | 31% | 15% |
| Partially Identified | 55 | 54 | 25 |
| % | 30% | 29% | 13% |
| Not Identified | 73 | 74 | 133 |
| % | 39% | 40% | 72% |
| Total Hazards | 186 | 186 | 186 |

In 2011, The Health Foundation conducted a study called "A pragmatic review of the use of safety cases in industry – lessons and prerequisites for their application in healthcare". The study divided into three phases, and the first phase aimed to conduct a survey safety case in six industries (commercial, automotive, defence, aviation, nuclear, railways, and petrochemical). In the second phase, a systematic literature review conducted on the safety cases of the identified healthcare applications (medical devices, health information, and health system). In the third phase, medical devices selected as the application to be studied, specifically the infusion devices. Therefore, studying the processes of patient infusion and administration of IV fluids. In the third phase, the HAZOP approach utilized to identify the deviation of the processes. As a result of the study, the HAZOP technique recommended to be adopted to healthcare and considered a crucial technique for identifying process or system deviation (NPSA, 2010).

HAZOP technique provides some benefits for patient safety; however, at the same time, it faces some challenges which are presented in Table 3.

Table 3: Opportunities & Challenges of Using the HAZOP Technique in Patient Safety

| No. | Opportunities | Challenges |
|---|---|---|
| 1 | Highly effective in identify hazards during the design stage (Dhillon, 2012; Durand, 2009) | Required team from different multidisciplinary and individuals shall be knowledgeable and experienced in the selected process (Dhillon, 2012) |
| 2 | A useful technique to identify threats, unwanted incident and collect information from different participants (McDonough and Petosa, 2004). | The more familiarity of the team members on HAZOP will yield to better results (Durand, 2009) |
| 3 | It is distinguished from all other PHA techniques (Dhillon, 2012; Ericson, 2005). | Not a one-off technique, required feedback and constant updating to be complete risk |

| | | |
|---|---|---|
| | | management (Durand, 2009) |
| 4 | Recommended as a method for assuring the safety of the clinical software (Fox, 2003; Mankowitz, 2018) | Required more preparation and modification compared to FMEA & FTA (Durand, 2009) |

## 4. Discussion

The literature review discussed earlier studies that evaluated the contribution of the HAZOP technique in improving patient safety. All the studies identified HAZOP as an adequate technique for patient safety, except for one study conducted by VHA and JCAHO, which identified HAZOP as an inadequate technique for patient safety. Three of the studies were focusing on utilizing the HAZOP technique during the development of clinical/medical software to identify the hazards and improve patient safety accordingly. Moreover, they considered HAZOP as an effective technique for the healthcare Information Technology (IT). Nowadays, most of the procedures in the hospitals are carried out and controlled by clinical software and that makes the HAZOP technique an important PHA technique in the healthcare sector. For instance, the first goal in the International Patient Safety Goals (IPSGs) is to identify patients correctly, and this step completed with the help of clinical software. Moreover, clinical software used to remind the physicians and nurses the necessary questions they need to ask the patients. In the industrial sector, the HAZOP technique usually used to identify hazards in processes that included devices and equipment. The Health Foundation has proven that the HAZOP technique is an effective tool to identify hazards in the process of patient infusion, which include usage of devices. Accordingly, the HAZOP technique can be considered an adequate technique to study risks in any other process related to patient safety as long as the study complies with the main guidelines of the technique. As pointed out by Durand (2009), the HAZOP technique was able to cover only 27% of hazards associated with the oxygen therapy process, whereas FMEA and FTA were able to cover 61% and 60 % respectively of the total hazards. Therefore, the FMEA and the FTA techniques may be considered better methods than the HAZOP technique in terms of covering all the hazards associated with the oxygen therapy process. Also, according to the same study, it is recommended for the healthcare sector to combine other techniques along with the HAZOP to ensure the coverage of all potential risks, which can be successfully implemented with recent advancements in healthcare, such as artificial intelligence and machine learning (Ellahham et al., 2019). The HAZOP technique considered as a unique technique that distinguishes it from the other techniques; it has a unique way of identifying the deviates in processes and systems. Overall, the HAZOP technique was found less prevalent in healthcare compared to other techniques such as FMEA, HACCP, and RCA.

## 5. Conclusion

This review paper described the importance of improving patient safety and using proactive tools to identify and mitigate risks. The healthcare field adopted many proactive tools, such as HAZOP, from other industries to improve patient safety by identifying the risk associated with the processes or systems to minimize or eliminate them. In this study, we provided a brief history of the HAZOP and identified earlier studies about the contribution of the HAZOP technique. Though HAZOP has been underused in healthcare, limited studies showed the HAZOP a useful approach to proactively help identify and mitigate risks affecting patient safety.

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