Translating the pharmacovigilance challenge landscape to a lower level of abstraction: The implementation of a value chain analysis, the 5Why method, and fishbone diagrams

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ABSTRACT

While substantial progress has been made over the last decade to address the prevalent challenges faced by pharmacovigilance (PV) systems, many such systems are still experiencing various challenges. Considering that PV challenges identified in literature are often described on a strategic level and that no PV system is the same, there is a failure to understand the influence of these challenges within their specific contexts. Moreover, there is a shortage of research that proposes appropriate methodologies to translate these strategically defined challenges to an operational level, where it would be much simpler to: (i) understand the effects these might have on a PV system, and (ii) realise the potential of leveraging existing technologies to address these challenges.

Thus, the rationale as to why it is important to translate strategic level challenges to an operational level is discussed in this paper. The potential of existing methodologies that can assist and guide this translation process is also investigated. A selected set of methodologies are implemented as an example, describing the influence of strategically defined challenges on the functions in PV and identifying the root causes of these challenges. Lastly, the prospects of existing technologies that can address these challenges are discussed.

Key words: *Pharmacovigilance; challenge landscape; translation; value chain analysis; 5Why method; fishbone diagrams; technological landscape.*

INTRODUCTION: BACKGROUND

In the 1960s, an international health disaster was experienced. A pharmaceutical company introduced Thalidomide, a drug which was marketed as a sedative and anti-emetic in pregnancy. Following the release of Thalidomide, reports of infants being born with severe birth defects flooded the healthcare system. Worldwide, it was reported that nearly 10 000 infants were born with such defects, which affected the development of extremities (Toklu & Uysal (2008) and Isah et al. (2012)). Following these events, it was clear that there was a dire need to develop a system where the effects of newly marketed and existing drugs were constantly monitored to prevent a similar tragedy such as that of the Thalidomide case (Wang et al. (2009); Stolk (2012); and Klausen & Parle (2015)). Subsequently, such a system was developed, and came to be known as pharmacovigilance (PV) (De Abajo 2005).

PV is defined as the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems” (World Health Organization 2002). Ultimately, the goal of PV is to optimise benefits and minimise the risks, of newly marketed and existing drugs, at both the individual and population level. In the last decade, PV has been the recipient of a great deal of research and investment, and has grown to become an important facet of healthcare (World Health Organization 2002). This considerable growth, however, has led to PV becoming a ubiquitous system with an increasing scope.

The expansion of activities have led to numerous challenges that burden modern PV systems (Pan 2014). Challenges from both a systems – and clinical perspective prevent optimal service delivery and resource utilisation within PV systems, and limits the extent to which PV can operate both effectively and efficiently (Strengthening Pharmaceutical Systems 2009). In an effort to identify these challenges, Lamprecht et al. (2017) conducted a systematic review, and prioritised the following challenges: unsupported culture of drug safety, lack of partnerships, lack of transparency, insufficient resources, country specific factors serving as barriers, adverse drug reaction (ADR) under-reporting, and lack of technical capacity.

An investigation of these challenges established that most are described on a high level of abstraction i.e. at a strategic level. In other words, literature tends to argue that these challenges burden PV systems in many countries, but fails to provide additional information as to the specific influences these challenges have on the different functions within PV. The root causes of these challenges in different contexts are also not identified in literature. The subsequent section argues the importance of translating the strategically defined challenges in PV to an operational level in order to realise the influence and root causes of these challenges.

RATIONALE BEHIND THE IMPORTANCE OF TRANSLATING STRATEGICALLY DEFINED CHALLENGES

Strategic management is often the so-called golden child of an organisation, receiving far greater attention than operational management. Executives and managers who have not moved through the ranks of operational management and as a consequence are not familiar with operations, frequently fail to consider the influence of operations on an organisation's overall strategy (Hammer 2004). According to both Croxton et al. (2001) and Hammer (2004), being aware of both the opportunities posed and the limitations associated with various operational strategies will allow these previously mentioned executives and managers to add to their strategic arsenal to become influential market players.

Provided that more effort needs to be shifted towards processes and activities related to operational management (Croxton et al. 2001), there is a need to define and investigate strategic level processes and activities at an operational level. Thus, strategies need to be translated to an operational level to understand how these influence the different functions within an organisation (Naghibi & Baban 2011). Considering this within the PV context, in order to propose actionable solutions to the strategic level challenges that have been identified in the PV landscape, these must be translated to an operational level. Formalising the operational level challenges in this manner will enable knowledge sharing and debate about these in literature, and will enable researchers and practitioners to differentiate between the effects these challenges have on the various functions in PV.

Hewitt-Taylor (2012) argue that, in order for challenges to be described at an operational level, the root causes must be identified. It is argued that it is often more feasible to investigate these root causes, rather than addressing the challenges on an strategic level, because the root causes will deliver tangible problems that can be more easily addressed.

Therefore, the rationale behind the proposition that the PV challenge landscape must be translated to a lower level of abstraction is (i) such a translation will make it clear how strategic challenges influence the different functions in an organisation, or in the case of PV, the stages of which PV systems are composed, and (ii) identifying the root causes of strategic challenges will make it increasingly easier to address such challenges at an operational level.

Such a translation, however, is not always simple, and according to Chmutova (2015), business often struggle severely with this process, given that they fail to leverage existing methodologies in guiding the entire process. Some of the methodologies that have been developed for this translation process are considered in the subsequent section.

TRANSLATION METHODOLOGY ASSESSMENT

In order to identify the different methodologies that can be used to translate the PV challenge landscape, a literature review was conducted in two databases, namely Google Scholar and Scopus, as well as grey literature. Using the search terms "root cause analysis", "translation methodologies and approaches", and "problem solving", the literature review uncovered some of the more widely used methodologies, namely root-cause analyses (RCAs), the 5Why method and fishbone diagrams. Additionally, the 5W2H method, key performance indicators (KPIs), and value chain analyses, methods that are commonly used for analysing and defining systems in the Industrial Engineering profession, are added to the list of methodologies that are considered for application.

Root cause analysis

According to Jones & Despotou (2016), the RCA is by far the most widely used analysis tool for investigating problems, especially in the healthcare environment. RCAs focus on the root cause of problems, while avoiding emphasis on any mistakes made by specific individuals. Ideally, a team-based approach, where teams are composed of individuals from different backgrounds and contexts, is the best approach to conducting a RCA, as this will ensure that a range of root causes to the same problem be identified.

There are different techniques that can be used to conduct a RCA, the most popular being the 5Why method and Fishbone diagrams.

The 5Why method and fishbone diagrams

The 5Why method was developed by Sakichi Toyoda, one of the fathers of the establishment of the car company Toyota in the late 1940s (Warner 2015). Adopted by the global market in the 1970s, the 5Why method became one of the most renowned methodologies, able to identify the root causes of specific problems.

In essence, this form of RCA is completed by asking the Why question, on average, five times (Warner 2015), which will lead to the root cause of a given problem. Additionally, in order to capture the thinking processes during this exercise, a fishbone diagram can be developed, which will provide a visual representation of the possible root causes to a given problem (Pojasek (2000) and Jones & Despotou (2016)).

The 5Why method, in combination with fishbone diagrams, offer several benefits to its users, including (Pojasek 2000): (i) it is a very quick and simple tool to use; (ii) the nature of the Why question is highly relatable, since Why is so often asked in real-life; (iii) fishbone diagrams serve as visual representations to the 5Why method, providing a holistic view of the effects that stem from a certain root cause; (iv) the process initiates a thinking process in the individuals of the team, allowing them to come up with an answer more quickly; and (v) the one right answer syndrome is eliminated since the method is a team-based approach i.e. a broad range of answers from different departments are given.

Regardless of the benefits offered by the 5Why method and fishbone diagrams, there are also some challenges associated with it, namely (Pojasek 2000): (i) facilitation is needed to optimise the results of the method, and the facilitator(s) should have some experience in the method; (ii) it is not always simple to answer the simple question of Why, since many environmental factors may affect the answer; and (iii) when used incorrectly, these methods can lead to finger pointing i.e. one individual or group can be blamed for a mistake.

A number of studies (Pojasek (2000); Bulsuk (2009); Sonkiya (2014); Mpanza (2016); and Brundage et al. (2017)) have endorsed the efficacy of the 5Why method in combination with fishbone diagrams as a mechanism for translating problems that have been defined on a strategic level to a more tactical – or operational level where some of the root causes may exist.

5W2H

The 5W2H method is a highly efficient and simple management tool, constructed of well-defined stages which serve as structures to action planning (Veyrat 2016). The name of this method originates from the questions that are asked. These questions are: "*What will be done?*", "*Why will this be done?*", "*Where will it be done?*", "*When will it be done?*", "*Who will do it?*", "*How will this be done?*", and "*How much will it cost?*" Given that strategies constantly change within the competitive market, strategies must be continuously adjusted, and as a result new strategic challenges come to light. According to Veyrat (2016), going through the process of the 5W2H method will allow organisations to define their strategies, and determine how these goals will be achieved.

The 5W2H method offer many benefits, including (Bau et al. (2012) and Veyrat (2016)): (i) it is a simple method to implement since straightforward questions are asked; (ii) it enables businesses to comprehensively define the problem at hand, which in turn make it simpler to identify areas where improvements are necessary; (iii) the simple questions enables individuals from different backgrounds and experiences to provide their input; and (iv) the simplicity of the method allows it to be used in many different industries.

As with any methodology, there are also some challenges that might burden businesses to effectively use the 5W2H method, which includes: (i) the method is most beneficial when there is a facilitating individual or team who has experience with the method; and (ii) it is not always simple to answer the questions asked by the method, and there may be conflicting views on the correct answer.

It is clear that there are pros and cons to this method, which must be weighed against one another. On balance, however, Veyrat (2016) is of the opinion that when used correctly, the 5W2H method can effectively help businesses translate their strategic goals.

Key performance indicators

Most businesses make use of KPIs to translate their strategy into some quantifiable and measurable objective (Baroudi 2014). For example, a manufacturing business's strategy may be to increase overall productivity. Measuring a business's overall productivity is most likely difficult or infeasible, therefore, operational level KPIs such as the total hours of machine downtime per day, or the total number of defective raw materials per month are used instead. These operational level KPIs can be measured in a direct and standardised manner and enable businesses to determine whether productivity has increased or decreased.

The specific benefits that KPIs offer includes (Baroudi 2014): (i) increasing individual and team focus; (ii) encouraging departments to meet their goals; (iii) serving as a link between individual and departmental goals; (iv) allowing executives, managers, and employees to identify possible areas for improvement; and (v) defining and communicating both the expected and achieved performance levels.

Some potential drawbacks associated with the use of KPIs include (Baroudi 2014): (i) unclear definitions of KPIs can negatively affect other KPIs that are crucial to the measurement of the success of a business; and (ii) employees may sometimes focus more on what is expected of them, rather than focus on how these expectations will be met, leading to possible health and safety risks.

Developing KPIs is often a tedious and difficult process. To avoid this, it is essential that businesses consult the relevant stakeholders as they may have valuable inputs that have not been considered before (Baroudi 2014).

Value chain analysis

A value chain analysis is defined as "a process where a firm identifies its primary and support activities that add value to its final product [or service] and then analyse these activities to reduce costs or increase differentiation" (Jurevicius 2013). It enables businesses to identify underperforming business processes and activities, allowing them to make necessary adjustments. It also highlights influential factors (environmental factors, participating actors etc.) that affect a value chain, delivering a comprehensive image of how a value chain and its components interact.

Value chain analyses offer several benefits, which include (Simister 2011): (i) it is a flexible strategy tool, and can be adapted towards many different industries; (ii) it focusses on the activities needed to deliver value proposition, highlighting the processes and activities that contribute to delivering the customer demand; and (iii) it is a well-known strategic tool, and has delivered insight to many industries as to how and where they need to improve.

It is also important to be aware of the limitations to using value chain analyses, which include (Simister 2011): (i) although the value chain analysis is flexible, it is not a plug and play instrument, therefore necessary changes must be made to adapt the analysis to a specific industry; (ii) knowing that value chain analysis was originally designed for use in the manufacturing industry may deter other industries from using it; (iii) the scale and scope of a value chain analysis can be intimidating, since it considers a value chain in its entirety; and (iv) though many people are familiar with the concept of a value chain analysis, few are experts, and facilitation is therefore often needed to guide the development of such an analysis.

A value chain analysis is a comprehensive strategic tool that offers many benefits, and when implemented properly and the limitations are considered and managed, it can assist businesses in making necessary improvements across its value chain in order to deliver a better value proposition.

TRANSLATION METHODOLOGY SELECTION

In order to select the most appropriate translation methodology for application to the PV system, the methodologies are compared to one another by evaluating their capability of meeting certain qualification criteria. These criteria were developed based on a set of indicators, developed by the World Health Organisation, used to evaluate the inputs, outputs, processes, and impacts of PV systems (World Health Organization 2014), and incorporates some conditions set by the authors of this paper. These qualifying criteria are:

- Stakeholder identification: Does the methodology allow the user to identify the stakeholders that participate in the PV system?
- Distinguishing: Does the methodology distinguish between the different stages in the PV system?
- Flexibility: Does the methodology adapt well to different input data and structures?
- Relationship identification: Does the methodology indicate the effect that different elements may have on the other?
- Reproducible: Can the methodology be reproduced by anyone, regardless of their background?
- Measurable outcome: Does the methodology deliver measurable outcomes?

The sought after translation process consists of two stages, which, in unison, will contribute to the translation of the PV challenge landscape to a lower level of abstraction, where tangible problems can be defined and addressed. These stages are: (1) defining the influence of the PV challenge landscape by differentiating between the different functions, or stages, of a PV system; and (2) identifying the root causes of the differentiated PV challenges within a PV system.

The comparison of the methodologies according to the set of qualifying criteria is shown in Table 1. Based on this analysis, the following two methodologies are selected to address the two stages of the desired translation process: 1) value chain analysis, and 2) the 5Why method and fishbone diagrams. The use of these methodologies are further advocated in the subsequent sections.

Table 1: Comparing the different translation methodologies.

Translation methodology	Stakeholder identification	Distinguishing	Flexibility	Relationship identification	Reproducible	Measurable outcomes
5Why and Fishbone diagrams	**X**		**X**		**X**	
Problem tree analysis			**X**	**X**		
5W2H	**X**		**X**		**X**	
KPIs						**X**
Value chain analysis	**X**	**X**		**X**		

The value chain analysis

A recent report by Franz et al. (2015) discusses a value chain analysis conducted in the energy market system in sub-Saharan African countries. This analysis allowed the developers to comprehensively understand the operation of the current energy market system in sub-Saharan African countries, which in turn allowed them to identify improvement initiatives with regards to specified inputs, services, finances, and enabling factors (Franz et al. 2015). Similarly, the United Nations also implemented a value chain analysis, which focussed on the living conditions of disabled persons. Several influential factors such as disabled rights, policies, and financial structures were identified, indicating problem areas where improvements or adjustments were necessary (United Nations 2012).

The prospects of leveraging the value chain analysis for translating challenges in the PV system that have been defined at a strategic level to an operational level in a specific context is evidenced by these two cases. Moreover, with reference to the qualifying criteria in Table 1, value chain analyses enables the user to differentiate between the stakeholders in PV ("Stakeholder identification"), distinguishes between the different functions of a value chain or in this case a PV system ("Distinguishing), can be adapted towards the PV context ("Flexibility"), and enables the user to identify any possible relationships that might be shared between the different influences in a value chain ("Relationship identification"). The methodology therefore satisfies four of the six qualifying criteria defined in the previous section and this justifies the use of a value chain analysis for the first stage of the translation process i.e. defining the influence of the PV challenge landscape on the functions in a PV system.

The 5Why method and fishbone diagrams

There are many reported cases where the 5Why method and fishbone diagrams have enabled businesses to follow a systematic approach in identifying the root causes of challenges they are experiencing. Myszewski (2013) describes a case where an unknown company used these analyses to identify certain root causes with regards to quality deficiencies found in a product manufactured by this company.

Another reported case of the successful application of the 5Why method and fishbone diagrams is described by Jones & Despotou (2016). A number of hospitals based in the United Kingdom reported numerous unintended consequences from the use of electronic health records. Though these consequences are not named in the article, Jones & Despotou (2016) described that through a combination of the 5Why method and fishbone diagrams, investigators were able to identify the root causes of these consequences, and were subsequently able to address the problems.

These two cases support the rationale that these methodologies are suitable to support the translation of the PV challenge landscape to an operational level. Providing even further justification, the 5Why method, in combination with fishbone diagrams, allows the user to differentiate between the key role players in a PV system ("Stakeholder identification"), can be adapted towards a PV context ("Flexibility"), and can be easily reproduced by someone who might be lacking a certain degree of technical capacity ("Reproducible"). The methodology therefore satisfies three of the six qualifying criteria defined in the previous section and this justifies the use of the 5Why method in combination with fishbone diagrams for the second stage of the translation process i.e. identifying the root causes of the PV challenge landscape.

Subsequently, an example of the application of the two stages of the translation of the PV challenge landscape is provided through a worked example.

STAGE 1: IMPLEMENTATION OF THE VALUE CHAIN ANALYSIS

Following the argument that the value chain analysis can be used for the purpose of the first stage of the proposed translation process, a PV value chain analysis is developed in the subsequent section.

The pharmacovigilance value chain analysis

The PV value chain analysis is shown in Appendix A. Many of the challenges identified in the analysis share relationships with others. Illustrated by double-headed arrows, these relationships indicate that when the one challenge is addressed, there will either be a direct or indirect effect on the other(s).

The PV value chain analysis has been developed in a general context, taking no specific location into consideration. In order to further ensure that the analysis is even more accurate, it can be developed within a specific context where specific challenges to a specific context are investigated.

Regardless, the PV value chain analysis has been validated by a subject matter expert who have sufficient experience in the PV industry, and endorsed the use of such an analysis.

Key points highlighted by the pharmacovigilance value chain analysis

By disseminating the PV challenge landscape in the PV value stream, the PV value chain analysis has highlighted several key points that would have been difficult to identify by simply considering the PV challenge landscape in isolation. The analysis also *sheds some light* on the relationships within the PV challenge landscape, as well as the actual meaning of the influence of challenges in PV. These key points are briefly described in subsequent subsections.

Prominent role players

Governmental bodies, also referred to as regulatory authorities, are key role players in PV. This is because, in most countries, regulatory authorities govern PV systems, developing the necessary policies and investing the required resources for PV systems to operate. Though some countries (e.g. South Africa) are trying to shift a portion of the power held by regulatory authorities outside their jurisdiction, these authorities will still play a major part in PV systems.

Snowballing effect caused by adverse drug reaction under-reporting

Within the ADR under-reporting lane, it is shown that many of the challenges in the downstream PV value stream share relationships with this phenomenon, emphasising the limitations caused by ADR under-reporting that are so often described in literature.

Many challenges faced at the start of the pharmacovigilance value stream

Many challenges are found at the start of the PV value stream i.e. within the data collection and ADR under-reporting, and data collation stages, which highlights the limitations posed by a lack of robust qualitative and quantitative data. Data plays a major part in PV, and it is therefore of great importance that the efforts towards acquiring such data be made as efficient and effective as possible.

Exchanges between country specific factors and insufficient resources

There are frequent exchanges between the challenges associated with country specific factors and insufficient resources, therefore it is worthwhile exploring whether there is a causal relationship between these two strategically defined challenges. In other words, when it is found that there are insufficient resources within a certain country, it is possible that it is a unique case to that specific country i.e. another country may not experience the same problem.

Role played by country specific factors

Many challenges have been identified within the country specific factors lane. This only highlights the rationale that globalisation and standardisation of PV systems on an international scale is not feasible, given that PV systems in different countries are unique, and are influenced by different factors.

Failure to understand the effects of pharmacovigilance

It is often the case that there is a failure amongst those within the PV spectrum, as well as those outside, to fathom the importance of PV, and the major influence it not only has on an individual level, but also the effect it has on the entire healthcare industry.

Lack of access

The lack of access to resources is regularly reported in the analysis. It is not necessarily the case that the expertise, experience, funding, training, technology, and other resources do not exist, but rather that PV systems are not given access to such resources. One of the main reasons for this can be attributed to the fact that PV is not classified as priority within a certain country.

Adoption by the widespread healthcare industry

Disseminating the PV challenge landscape, shows that PV is a large and complex system with much room for problems, and therefore needs to be adopted by the widespread healthcare industry i.e. it must be a priority not only to those actively involved in PV, but also to those outside the spectrum of PV, to aid PV in its activities.

Lack of technical capacity

The lack of training, knowledge, or practice, all of which are attributed to technical capacity, are often limiting factors in PV systems. This can be directly traced back to the pre-entering phase into the healthcare environment i.e. university, college, or any other form of tertiary education. Training needs to start on a tertiary level, where the basics of PV are taught.

Concluding stage one of the translation process

These key point all contribute to the initial translation process i.e. understanding that the PV challenge landscape affects the different stages in the PV value stream in different ways. It is critical to a system such as PV, where drug and patient safety are of primary concern, that researchers understand how the challenges affect a PV system, which will allow them to make the necessary improvements to the system.

In order to identify the root causes of challenges in the PV landscape, the second stage of the translation process proposed in this paper is essential, an example of this second translation step is given in the following section.

STAGE 2: IMPLEMENTATION OF THE 5WHY METHOD AND FISHBONE DIAGRAMS

Up to this point, the translation of the strategically defined PV challenge landscape has reached an intermediate stage. To complete the translation, the root causes of these challenges must be identified, which will translate these challenges to tangible problems that can be addressed at an operational level. In order to do this, the 5Why method, in combination with fishbone diagrams, can be used. To illustrate the implementation of these methodologies, the root causes of three of the challenges in the PV value chain analysis are identified, namely: (i) inadequate access to ADR reporting forms (spontaneous); (ii) failure to develop locally relevant and easily measurable indicators of performance of PV systems; and (iii) the lack of robust local data that limits the extent to which decision-making can be done. Appendix B contains a fishbone diagram illustrating the application of the 5Why method to each of these three challenges. The key findings are briefly discussed in the remainder of this section.

In summary, the possible root causes that have been identified for the inadequate access to ADR reporting forms (spontaneous) are:

i) There is a lack of funding to access software technologies to assist the coordination of the deliveries of spontaneous ADR reporting forms.

ii) There is no existing software technology that can assist the coordination of the deliveries of spontaneous ADR reporting forms.

iii) The individuals responsible for coordinating the deliveries of spontaneous ADR reporting forms are not sufficiently trained in this regard.

iv) There is no designated transportation service to distribute the ADR reporting forms.

v) The person in charge of re-ordering the ADR reporting forms is not sufficiently trained in stock control.

vi) The person in charge of re-ordering the ADR reporting forms is situated in remote location, and as a consequence, users of the forms struggle to notify the person.

vii) The users of the forms have competing priorities, and simply do not have time to notify the person in charge of re-ordering the ADR reporting forms.

The identified potential root causes for the failure to develop locally relevant and easily measurable indicators of performance of PV systems are:

i) Key stakeholders are not aware of the health impact of PV.

ii) There are only globally defined indicators of performance that may not include features of a unique, local PV system.

The possible root causes of the lack of robust local data that limits the extent to which decision-making can be done have been identified as:

i) PV is not sufficiently advocated to the necessary stakeholders.

ii) PV is not included in the undergraduate syllabus of healthcare tertiary education.

iii) The ADR reporting forms are overly complicated and takes too long to complete.

iv) Key stakeholders are not aware of the health impact of PV.

These examples show the systematic thinking process behind the identification of the root causes by using the 5Why method in combination with fishbone diagrams. Subsequently, the key points that were highlighted during this process are discussed.

Key points highlighted by the implementation of the 5Why method, in combination with fishbone diagrams

Certain key points that can be concluded from these analyses, highlighting several distinct features that may not have been known before.

Wide spectrum of possible root causes

When conducting these types of analyses, it is possible to either identify numerous possible root causes of a specific problem, or only a few. This is evident from the wide spectrum of root causes identified in the examples provided. This phenomenon is a result of the nature of answering a simple "Why?" question, which may have more than one possible answer.

Unclear association between root causes and the overall problem

Some of the root causes identified may be deemed as *far-fetched* i.e. it may seem that the root cause and the overall problem may not have anything in common, and this may make stakeholders resistant to using the 5Why methodology. For example, a root cause for the inadequate access to ADR reporting forms is the lack of funding to access software technologies. As Warner (Warner 2015) described, however, these types of analyses have delivered many positive results, and therefore one should at the very least put some effort into investigating the possible interactions these seemingly non-associated root causes and challenges may share.

Shared root causes

As indicated by the analysis of the failure to develop locally relevant and easily measurable indicators of performance of PV systems, and the lack of robust local data that limits the extent to which decision-making can be done, certain possible root causes may affect different problems. This is proof that the challenges in the PV challenge landscape share relationships, as illustrated in the PV value chain analysis.

Concluding stage two of the translation process

In combination with the initial translation process where the influence of the PV challenge landscape on the PV value stream is investigated, the root cause analysis identifies tangible problems that have not been previously known. Further investigations into these root causes can commence, and solutions can be developed in terms of technology, funding, or general managerial strategies.

LEVERAGING THE TECHNOLOGICAL LANDSCAPE

The translation of the PV challenge landscape has delivered tangible problems, many of which are described on an operational level. Some of these operational challenges offer investigators the opportunity to investigate the prospects of the technological landscape and determine how these technologies can be leveraged towards addressing some of these problems. Subsequently, examples of some of these technologies are provided.

Online teaching services

Already proven to deliver desirable outcomes within the educational environment (Lamprecht 2017), online teaching services have been successfully implemented to address the issue of the lack of technical capacity. Frequently found in PV, and emphasised in this paper, the lack of technical capacity refers to the lack of essential theoretical – and practical knowledge. Online teaching services are able to provide these essential skills to individuals in different contexts.

Big data analysis

As highlighted by second stage of the translation process, the lack of existing software to manage data in PV is a challenge affecting different areas in PV. In order to accommodate for the large amount of data circulating in PV, big data analysis software can be used to collect, synthesise, and analyse data. This will enable researchers and practitioners in PV to manage large amounts of data, and identify signals of adverse events much quicker. This will also eliminate the snowballing effect caused by ADR under-reporting, because the necessary data is readily available and analysed.

Cloud technology

Cloud technology, which is essentially an information sharing platform, can be implemented to address the issue of the lack of advocacy of PV systems. One component of this lack of advocacy is the challenge of sharing information with the necessary stakeholders. Cloud technology platforms such are easy-to-use software that can be used to share large amounts of data with many stakeholders, making them aware of the effects caused by PV and the importance of maintaining and supporting these systems.

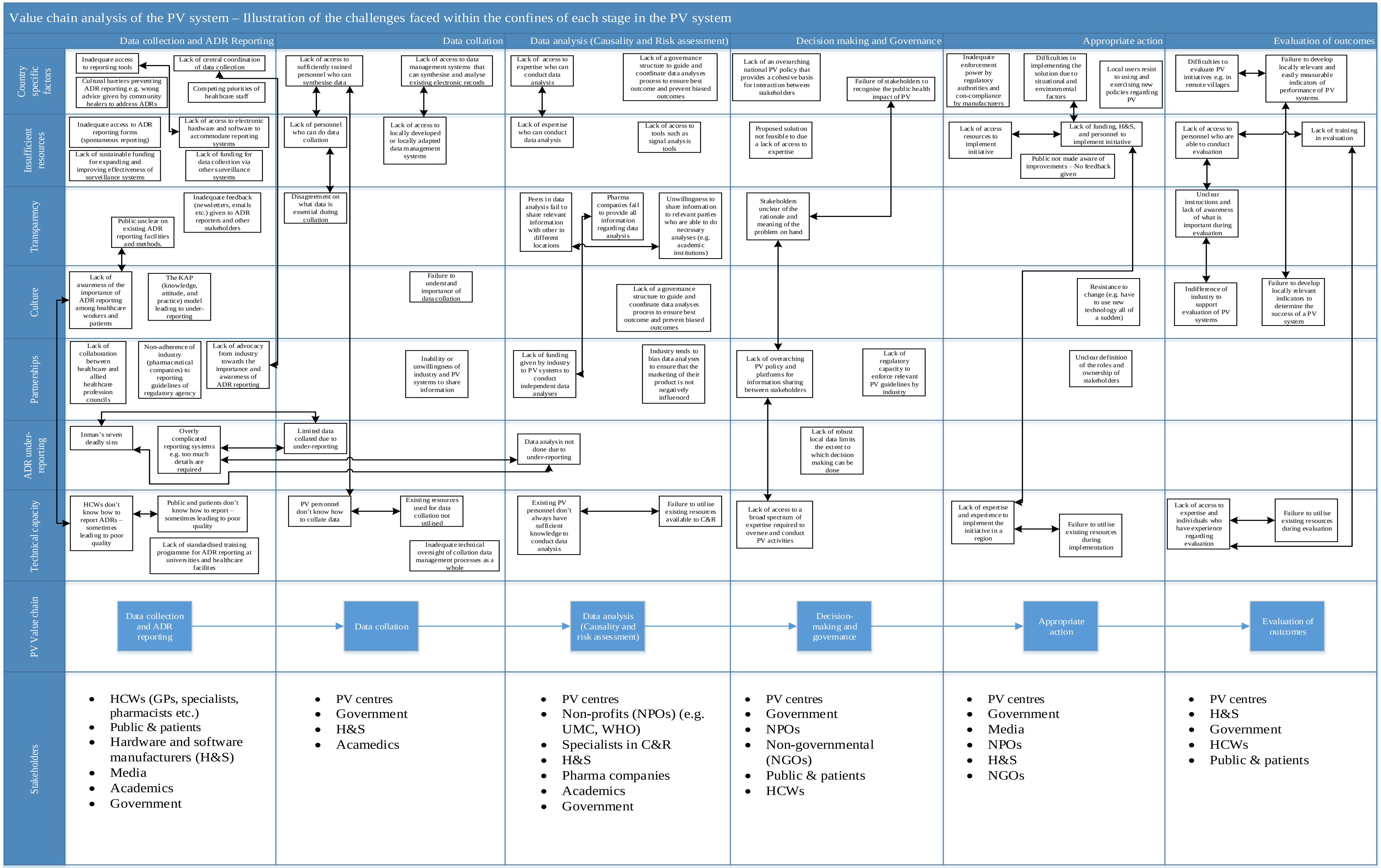
CONCLUSION AND FUTURE RESEARCH

In this paper, the translation of the PV challenge landscape to a lower level of abstraction is the main focus point. It is concluded that this translation process is best achieved via two stages, which are (i) the identification of the influence of the PV challenge landscape in the PV value stream, and, (ii) the identification of the root causes of these challenges. In order to complete these stages, the prospects of several methodologies are investigated, and by making use of a set of qualification criteria, two candidate methodologies are chosen, namely the value chain analysis (used for stage one of the translation process) and the 5Why method in combination with fishbone diagrams (used for stage two of the translation process). As an illustration of the implementation of these methodologies and the associated benefits they offer, examples are provided, followed by a summary of the key points that can be concluded from the application of each of these methodologies to the PV landscape. Finally, candidate technologies are identified that can be leveraged towards addressing the challenges in PV.

Following the two stages of the translation process, is became clear that the methodologies that have been implemented highlighted several key points that may have been difficult, or even impossible, to conclude. As a result, the proposed approach to translating the PV challenge landscape can be used in future studies in an attempt to develop solutions to the many problems that burden PV systems.

Both stages of the translation process of the PV challenge landscape identified several tangible problems and operational challenges that can be addressed with technology. The technologies identified in the paper represent only a portion of the technological landscape, and there are many other technologies that can be investigated. Regardless, the success already achieved by these technologies in other industries such as the educational industry increase the probability that these technologies can be used to address the PV challenge landscape.

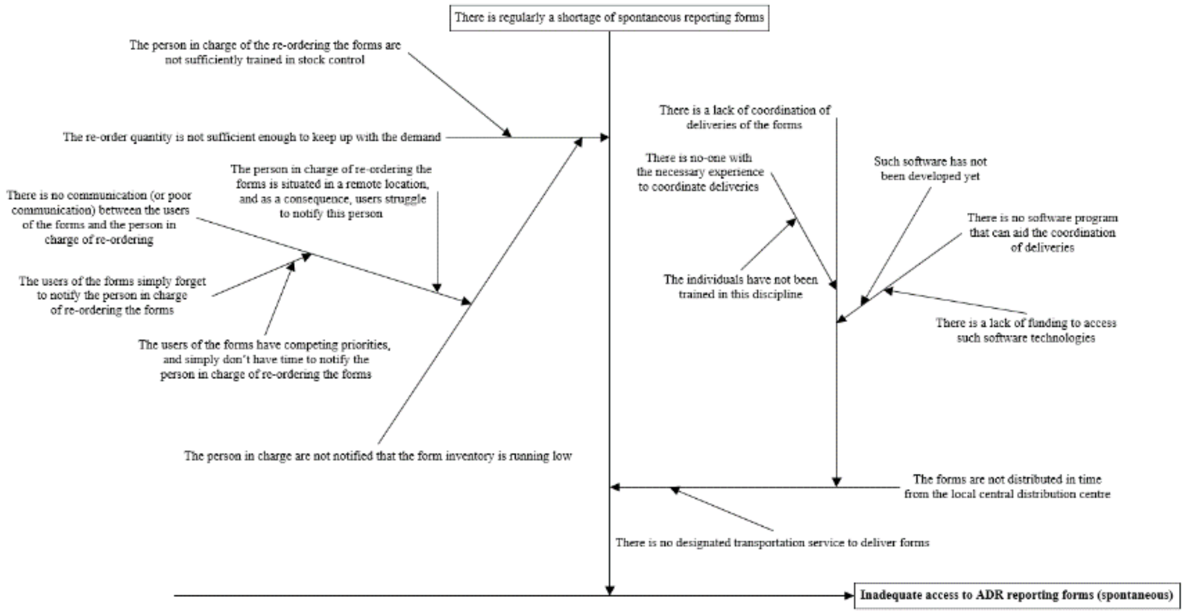
APPENDIX A: THE PHARMACOVIGILANCE VALUE CHAIN



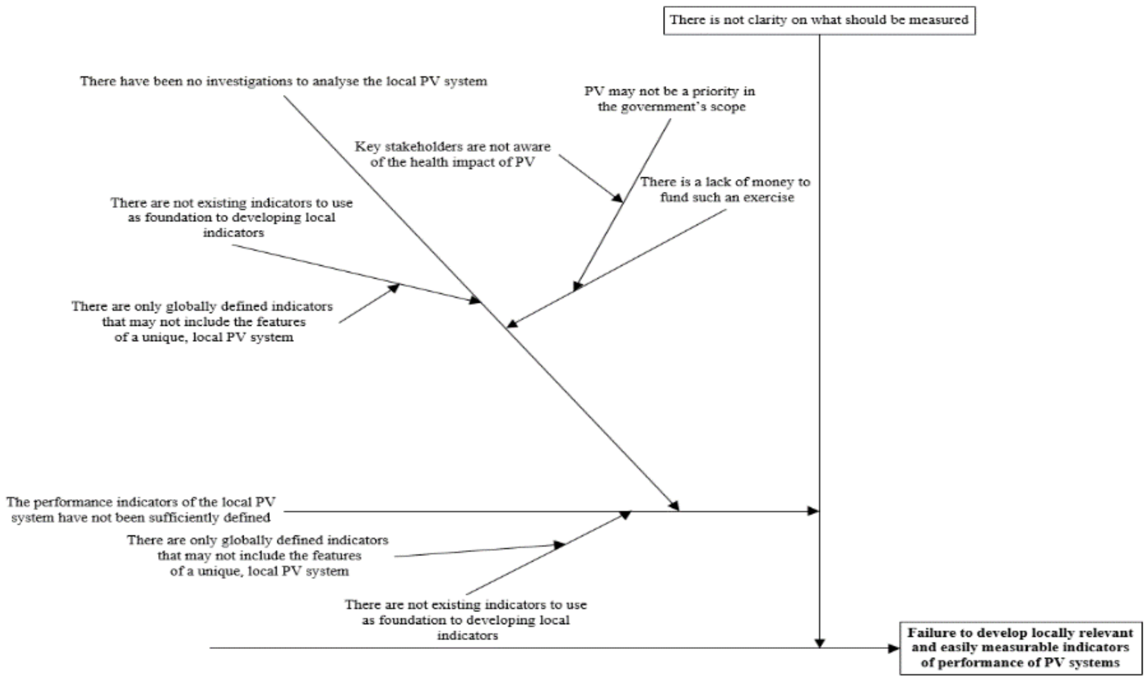
ANALYSIS

APPENDIX B: IMPLEMENTATION OF THE 5WHY METHOD, ILLUSTRATED BY FISHBONE DIAGRAMS

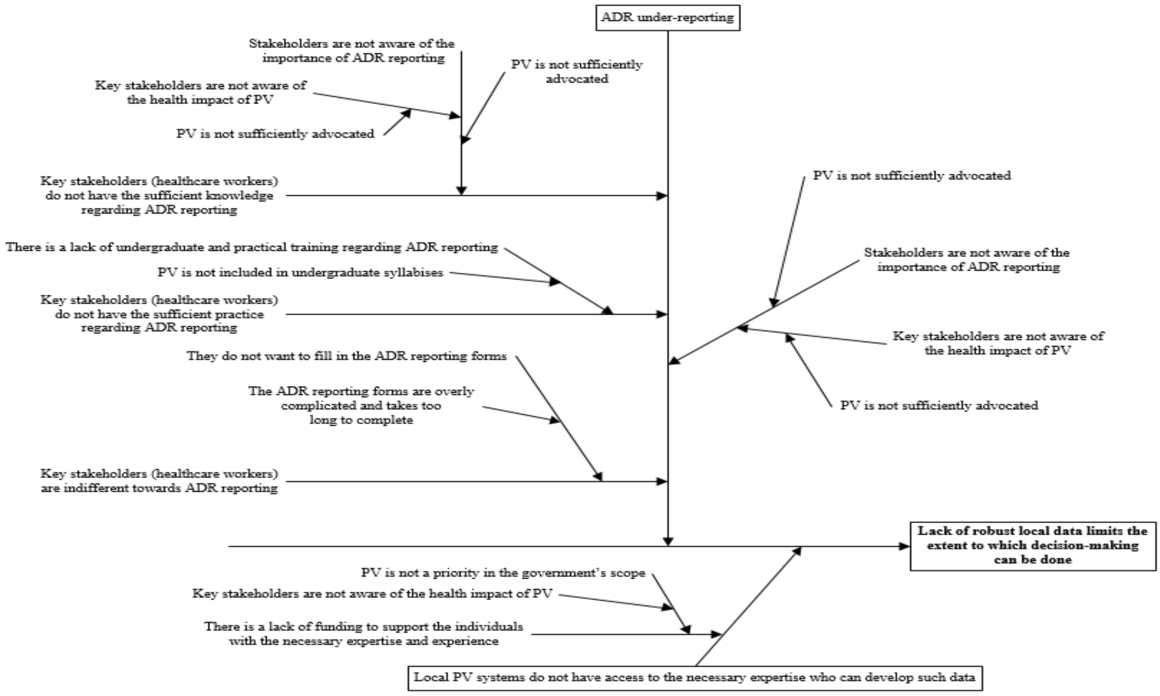
1. Inadequate access to ADR reporting forms (spontaneous).



2. Failure to develop locally relevant and easily measurable indicators of performance of PV systems.



3. Lack of robust local data limits the extent to which decision-making can be done



REFERENCES

De Abajo, F.J., (2005). Improving pharmacovigilance beyond spontaneous reporting. International Journal of Pharmaceutical Medicine, 19(4), pp.209–218.

Baroudi, R., (2014). Key performance indicators: Winning tips and common challenges. EY Performance Journal, 6(2), pp.36–43.

Bau, L.M.S. et al., (2012). Organizational ergonomics of occupational health methods and processes in a Brazilian oil refinery. In Work 41. pp. 2817–2821.

Brundage, M.P. et al., (2017). Smart Manufacturing Through a Framework for a Knowledge-Based Diagnosis System. In M. P. Brundage, ed. ASME 2017 International Manufacturing Science and Engineering Conference. Los Angeles: Research Gate, pp. 1–9. Available at: http://proceedings.asmedigitalcollection.asme.org/proceeding.aspx?doi=10.1115/MSEC2017-2937.

Bulsuk, K., (2009). Using a Fishbone (or Ishikawa) Diagram to Perform 5-why Analysis. Toyota Production System. Available at: http://www.bulsuk.com/2009/08/using-fishbone-diagram-to-perform-5-why.html [Accessed October 4, 2017].

Chmutova, I., (2015). Bank's financial management technologies forming at strategic and operational levels. Economic Annals-XXI, 9, pp.73–77.

Croxton, K.L. et al., (2001). The Supply Chain Management Processes. The International Journal of Logistics Management, 12(2), pp.13–36.

Franz, M. et al., (2015). Building Energy Access Markets: A Value Chain Analysis of Key Energy Market Systems, Eschborn. Available at: http://www.euei-pdf.org/sites/default/files/files/field_pblctn_file/150907_euei_value-chain_en_rz_03_web_0.pdf.

Hammer, M., (2004). Deep Change : How Operational Innovation Can Transform Your Company. Harvard Business Review, (April), pp.1–20.

Hewitt-Taylor, J., (2012). Identifying, analysing and solving problems in practice. Nursing Standard, 26(40), pp.35–41. Available at: https://www.researchgate.net/profile/Eduardo_Cittadini/publication/262911808_Participatory_Analysis_of_the_Sweet_Cherry_Sector_in_Argentinian_South_Patagonia/links/5656edfb08ae4988a7b51232.pdf.

Isah, A.O. et al., (2012). Specific features of medicines safety and pharmacovigilance in Africa. Therapeutic advances in drug safety, 3(1), pp.25–34. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4110828&tool=pmcentrez&rendertype=abstract.

Jones, R.W. & Despotou, G., (2016). Root cause analysis and health informatics. In 14th International Conference on Informatics, Management and Technology in Healthcare. Athens: Studies in health technology and informatics, pp. 131–134. Available at: http://dx.doi.org/10.3233/978-1-61499-664-4-131.

Jurevicius, O., (2013). Value Chain Analysis. Strategic Management Insight. Available at: https://www.strategicmanagementinsight.com/tools/value-chain-analysis.html [Accessed August 18, 2017].

Klausen, S.M. & Parle, J., (2015). "Are we going to stand by and let these children come into the world?": the impact of the "Thalidomide Disaster" in South Africa, 1960–1977. Journal of Southern African Studies, 41(4), pp.735–752. Available at:

http://www.tandfonline.com/doi/full/10.1080/03057070.2015.1047181.

Lamprecht, A.J., (2017). Personal interview. 10 October, Western Cape Department of Education Headquarters.

Lamprecht, I.V.B., Bam, L. & de Kock, I.H., (2017). An investigation into the prospects of existing technologies to address the challenges faced by pharmacovigilance systems. In SAIIE28: Taking up Stewardship. Vanderbijlpark: SAIIE, pp. 1–17. Available at: https://www.saiie.co.za/saiie28.

Mpanza, Z., (2016). Identifying the root causes contributing to defects in order to minimize scrap. In 2016 International Conference on Industrial Engineering and Operations Management. Kuala Lumpur: IEOM Society International, pp. 1139–1146. Available at: http://ieomsociety.org/ieom_2016/pdfs/318.pdf.

Myszewski, J.M., (2013). On improvement story by 5 whys. The TQM Journal, 25(4), pp.371–383. Available at: http://www.emeraldinsight.com/doi/10.1108/17542731311314863.

Naghibi, M.A. & Baban, H., (2011). Strategic Change Management: The Challenges Faced by Organizations. International Proceedings of Economics Development and Research, 4, pp.542–544.

Pan, G.J.D., (2014). Ongoing Challenges in Pharmacovigilance. Drug Safety, 37, pp.1–8.

Pojasek, R.B., (2000). Asking “Why?” five times. Environmental Quality Management, 10(1), pp.79–84.

Simister, P., (2011). Advantages & Disadvantages Of Value Chain Analysis. Differentiate Your Business. Available at: http://www.differentiateyourbusiness.co.uk/the-advantages-disadvantages-of-value-chain-analysis [Accessed August 18, 2017].

Sonkiya, S., (2014). Cause And Effect Diagram- Fishbone Diagram Analysis. Project Quality Management. Available at: https://www.izenbridge.com/blog/cause-and-effect-diagram-fishbone-diagram-analysis/ [Accessed October 4, 2017].

Stolk, R.P., (2012). Screening for diabetes. British Medical Journal, 335(September), p.462.

Strengthening Pharmaceutical Systems, (2009). Supporting Pharmacovigilance in Developing Countries The Systems Perspective, Available at: http://apps.who.int/medicinedocs/en/d/Js18813en/.

Toklu, H.Z. & Uysal, M.K., (2008). The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. Pharmacy World & Science, 30, pp.556–562.

United Nations, (2012). UNPRPD Strategic and Operational Framework, New York. Available at: http://www.undp.org/content/dam/undp/library/Poverty Reduction/Inclusive development/UNPRPD_SOF_web_April2012.pdf.

Veyrat, P., (2016). How did the 5W2H method earn its name? Heflo. Available at: https://www.heflo.com/blog/action-plan/5w2h-method/ [Accessed August 16, 2017].

Wang, X. et al., (2009). Active Computerized Pharmacovigilance Using Natural Language Processing, Statistics, and Electronic Health Records: A Feasibility Study. Journal of the American Medical Informatics Association, 16(3), pp.328–337. Available at: http://dx.doi.org/10.1197/jamia.M3028.

Warner, J., (2015). Is the “5 Why” Method Still a Useful Tool? Ready To Manage. Available at: http://blog.readytomanage.com/is-the-5-why-method-still-a-useful-tool/ [Accessed August 16, 2017].

World Health Organization, (2002). The Importance of Pharmacovigilance - Safety Monitoring of medicinal products, Available at: http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf.

World Health Organization, (2014). WHO pharmacovigilance indicators: A practical manual for the assessment of pharmacovigilance systems. , (1), pp.4–6. Available at: http://apps.who.int/iris/bitstream/10665/186642/1/9789241508254_eng.pdf.