

## **SOCIOTECHNICAL CONSIDERATIONS FOR HEALTH INFORMATION TECHNOLOGY DESIGN AND IMPLEMENTATION IN COMPLEX AND ADAPTIVE HEALTH SYSTEMS**

### **ABSTRACT**

Pharmacovigilance (PV) is based on the medical assessment of adverse medical events or drug-related problems, collected within organised health programmes. Pharmacovigilance monitoring systems are examples of Health Information Technologies (HITs), a subset of ICTs (Information and communications technologies) which exist within health systems specifically. Traditional approaches to introduce ICTs into complex systems have been plagued with multiple shortcomings. Research has shown that there exists potential for standardisation to add significant value within PV. The seemingly obvious mechanism to achieve standardisation when taking a traditional systems engineering approach would be through the implementation of HITs. The successful design and implementation of HITs would be of demonstrable value in terms of improving the delivery of patient care and, in the context of PV, improving patient safety. The need for a sociotechnical approach to studying Health Information Technologies (HITs) in complex adaptive health systems is explained and motivated in this paper. PV systems involve complex interactions between healthcare professionals, computer hardware and software, as well as the physical work environment within which they operate, all the while being exposed to external pressures from ever changing political, technological, cultural and social factors. Sociotechnical approaches focus on the nature of health care work and working with information technologies as a social process. The design approach aims to find the synergy between specific characteristics of healthcare work, and the potential benefits of ICT. To assist with the successful design and implementation of HITs, the notion of a sociotechnical transition must be considered. One must delve into the operational level of the system and consider relationships amongst and between technology and its users across multiple system boundaries.

**Key words:** Sociotechnical Systems; Sociotechnical transition; Health Information Technology; Standardisation; Pharmacovigilance.

“If we want safer, higher-quality care, we will need to have redesigned systems of care, including the use of information technology to support clinical and administrative processes.” (Corrigan *et al.*, 2005)

## INTRODUCTION

Pharmacovigilance (PV) is based on the medical assessment of adverse medical events or drug-related problems, collected within organised health programmes. An adverse drug reaction (ADR) is defined as being any undesirable effect of a medication beyond its intended therapeutic effect (Pirmohamed *et al.*, 1998). PV is a responsibility that is shared across all stakeholders of the health system, from pharmaceutical multinationals and regulatory agencies, to healthcare professionals (HCPs) and the patients themselves (Schurer *et al.*, 2017). Pharmacovigilance activities contribute to the prevention of unnecessary patient harm, improved clinical practices, and support research and education activities. Patient safety remains the central focus among all PV activities; with the end goal of assisting healthcare providers in making more informed therapeutic decisions for their patients.

The activities relating to pharmacovigilance form part of what is essentially an extended health system-wide quality management system (Santoro *et al.*, 2017) which falls under the category of patient safety. Patient safety relies on data systems and data systems rely on data standards.

Pharmacovigilance monitoring systems are examples of Health Information Technologies (HITs), a subset of ICTs (Information and communications technologies) which exist within health systems specifically. These PV systems involve complex interactions between healthcare professionals, computer hardware and software, as well as the physical work environment within which they are implemented. Traditional approaches to introduce ICTs into complex systems have been plagued with multiple shortcomings. This has highlighted the need to change the approach to introducing ICTs into such complex healthcare systems.

A review of literature on the reporting of adverse drug reactions shows that under-reporting of ADRs is as high as 94% (Hazell *et al.*, 2006). An investigation into the value of a standardised pharmacovigilance reporting system by Schurer *et al.* (2017) showed that there exists potential for standardisation to add significant value within PV. The seemingly obvious mechanism to achieve standardisation when taking a traditional systems engineering approach would be through the implementation of HITs. However, the actual standardisation of processes along with the successful design and implementation of HITs is not as straightforward as one would expect (Schurer *et al.*, 2017).

The need for a sociotechnical approach to studying Health Information Technologies (HITs) in complex adaptive health systems is explained and motivated in this paper. A comparison is drawn between a generic sociotechnical system and the pharmacovigilance system across multiple levels of analysis, in an attempt to better understand how taking a sociotechnical systems perspective can lead to improved design and implementation of HITs which are more acceptable by, and provide better value to, all stakeholders of the system.

The aim of this paper is to set the scope for further research on incorporating HITs to address some of the more prominent challenges in the PV landscape; as well as providing an argument for the value added by taking a sociotechnical systems approach to standardising some elements of the PV system.

## LEVEL OF ANALYSIS

The activities relating to pharmacovigilance can be associated with different levels of a health system. The functions of a PV system are carried out by different people, in different physical environments, working under different organisational structures, with different responsibilities, across these different levels of the healthcare system. The need to describe the level of analysis stems from the

tendency of people to describe the same system in different ways, according to how they experience the system. People draw the system boundaries in different places based on their role in the system (Eason, 2001). The scope of this research revolves around the first stage of the PV system, that is, the reporting of ADRs, and the subsequent propagation of the generated signal to the VigiBase monitoring system of the World Health Organisation. With this in mind, the four levels in Figure 1 will be explained briefly below:

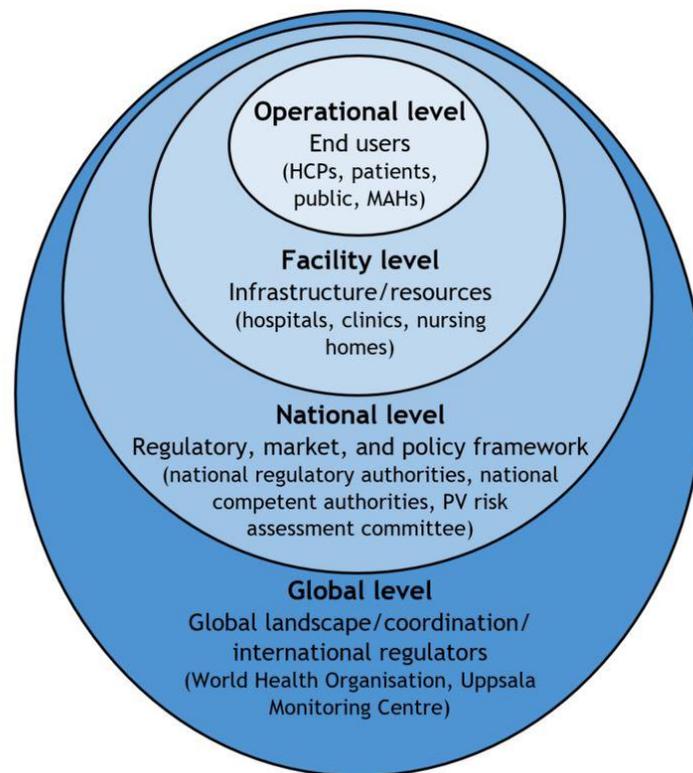


Figure 1: A conceptual diagram of a four-level health system. (Adapted from: Ferlie *et al.*, 2001)

- i. **Operational Level:** From an engineering perspective, the operational level of a system is the level at which decisions relating to the day to day activities of an organisation are made. Spontaneous reporting of suspected ADRs is the cornerstone of pharmacovigilance in that it generates the largest amount of data. It is at the operational level where the HCPs and patients have a direct interaction with the HIT system. At this level the nature of healthcare work and the individual characteristics of the HCPs, such as the knowledge base, skill level, training and education, attitudes, beliefs, and physical capabilities have the largest influence on the success or failure of the system.
- ii. **Facility Level:** The facility level encompasses the operational level. The facility within which the HCP works will have a number of intrinsic characteristics, such as the physical environment and layout, the organisational structure, embedded human-system interfaces, communication and coordination practices, as well as local work procedures.
- iii. **National Level:** All facility level activities are governed and coordinated at the national level. Each country conducting PV activities will do so according to different healthcare policies, laws and regulations. Decisions made at this level have a trickle-down effect on the facility and operational levels, affecting the overall safety, quality, and efficiency of these parts of the

larger system. The PV data generated at the preceding levels is collated and analysed internally by National Competent Authorities before transmitting the signals to the VigiBase system.

- iv. **Global Level:** At a global level there are a number of external environmental forces influencing the system, such as technological innovations, economic pressures, political climate, and public awareness. The global level is unique in the context of a PV system in that participatory countries submit their domestic PV data to the World Health Organisation for the benefit of the entire world's population.

Based on these descriptions of the levels of the healthcare system, it becomes clear that the outcome of patient care is produced through the interaction of multiple intricate and fragmented subsystems. This view of a health system highlights the need to educate healthcare providers across all levels and make them aware of their functioning in the greater system that is the healthcare system (Hartman *et al.*, 2017). The successful design and implementation of HITs would therefore be of demonstrable value in terms of improving the delivery of patient care and, in the context of PV, improving patient safety.

## INTRODUCTION TO SYSTEMS ENGINEERING AND SOCIOTECHNICAL SYSTEMS

A system is a purposeful collection of inter-related components that work together to achieve a common objective. A system may include software, mechanical, electrical and electronic hardware (Sommerville, 2004). People, and the respective organisations to which they belong, are responsible for the system's entire development life cycle, including its operation and ownership. The properties of these systems are most often inextricably inter-mingled, which can lead to high degrees of complexity. The behaviour of complex systems is often very difficult to predict. This represents the largest challenge that is faced by organisations which seek to develop, leverage, and control complex systems to improve their operations and activities.

Systems Engineering is an interdisciplinary field of engineering which comprises the body of knowledge concerned with the design and management of complex systems throughout a system's life cycle. In the early years of systems engineering, the general consensus was to take a technocentric<sup>1</sup> approach to systems development, this approach has been challenged by the introduction of a relatively new body of knowledge known as Sociotechnical Systems Engineering (STSE). A sociotechnical system (STS) is one which includes technical systems but also operational processes and people who use and interact with the technical system.

STSE places more importance on a user-centred approach; one which focusses more so on job satisfaction and the needs of the end user. The use and value of sociotechnical systems design methods is discussed in more detail in the sociotechnical systems design section of this paper. As with systems engineering and its focus on the end user, the activities related to PV are patient centred. It can be argued that every actor involved in the pharmacovigilance system is an end user in that every actor extracts value from, and interacts with the system in a different way. A sociotechnical approach to studying systems places special attention on the interactions and interdependencies of the system components, not only on the components themselves.

---

<sup>1</sup> Technocentrism is a value system rooted in classical science, technology, conventional economic thinking, and in the human control over nature.

A typical sociotechnical system comprises the following components:

- Operators: the people who use the system.
- Procedures and processes: ways of working that use the IT system.
- Policies: rules and regulations that govern work and the way that it is done.
- Standards: definitions of how work should be done across the organisation.
- Culture: the ways in which work is done in a local, professional and national setting.

### **The sociotechnical nature of healthcare work**

Healthcare information technologies (HITs) such as EHRs, CPOEs, and CDSSs are those which leverage computer systems to improve safety and quality of care, while assisting in cost reduction and improved efficiencies. Difficulties faced by those using these HITs have been widely described as being “organisational issues” (Berg, 1999). When designing information technology solutions for health systems, it is important to acknowledge that health care work has an inherent ‘ad hoc’ and ‘Byzantine’<sup>2</sup> nature; and that many attempts to use IT initiatives in a health care context have failed due to incompatibility between organisational issues and the structured, standardised and rational nature of IT systems.

A common challenge in implementing HITs is to move from the drawing board to successful implementation. HITs are too often bound to the specific context within which they have been developed (Berg, 1999). When designing a new HIT system, it is clear that a sociotechnical design approach can hold significant value, the nature of healthcare work is inherently irregular and the goal of protecting the health of a patient is often realized through a collaborative effort between many HCPs across multiple healthcare disciplines. With the introduction of a new technical system, one must be sensitive to the fact that the system will become intertwined with the work environment in which it exists, and that each change in IT will have widespread consequences for that work practice (Berg, 1998).

Sociotechnical approaches focus on the nature of health care work and working with information technologies as a social process. Patients have varying needs and present various problems to the healthcare professionals seeking to care for them. Standard organisational solutions never wholly fit a patients’ individual problem. A patients’ needs are typically met through the collaborative decision-making efforts of multiple healthcare professionals, each with unique knowledge bases, across multiple healthcare disciplines (Harrison *et al.*, 2007).

Studies in cognition show that what we traditionally conceive as ‘individual’ thinking processes are in fact heavily influenced by the social and physical contexts within which these ‘thinking’ processes take place (Hutchins, 1995). With new technologies enabling new forms of communication between health care workers, the relations between those communicating are invariably affected. When communication between health care workers becomes more efficient, the delivery and quality of patient care is improved (Mehta *et al.*, 2014).

---

<sup>2</sup>(of a system or situation) excessively complicated, and typically involving a great deal of administrative detail.

## Sociotechnical Systems Design

STS design is an approach to systems design which considers human, social, and organisational factors with equal importance to that of technical factors (Baxter and Sommerville, 2011). Adopting a sociotechnical approach to systems development results in systems which are more acceptable to end users and deliver better value in the organisations within which they exist. A sociotechnical approach to organisational change, such as in the case of implementing new ICTs in healthcare systems, focusses on two key activities, namely, sensitisation and awareness, as well as active engagement of all relevant stakeholders (Hugman, 2006).

The aim of taking a sociotechnical approach to system design and the implementation of new technologies in a healthcare environment should be to improve the traditional way of carrying out the primary care process. The largest challenge and simultaneously the largest opportunity with regard to this is to find a synergy between the formal tools of information technology and the sociotechnical nature of healthcare work.

Technological innovation can be seen as a social process in which organisations are deeply affected (Berg *et al.*, 2003). Insights from the social sciences are becoming increasingly recognised within the field of health informatics and information systems in general. Information systems require human interaction and input, resulting in both elements of the system affecting each other. To understand these effects, the interrelation between technology and the social context of its use must be studied. Taking a sociotechnical approach to systems design aims to accomplish exactly that. Sociotechnical approaches seek to understand the way in which information technologies are developed and implemented, as well as how these systems become a part of social practices. In the simplest way, sociotechnical approaches seek to strike a balance between the social, environmental, and technical elements of a system so as to develop users' skills and to improve job satisfaction and working relationships (Berg *et al.*, 2003).

Technological development cannot be seen as a merely 'technical' linear process. Upon uncovering how the introduction of new technologies impact the work setting in which they have been implemented, one can investigate the feasibility of the social 'roles' that are inscribed in the system for the working environment (Berg *et al.*, 2003).

The process of developing the technology is of paramount importance. A sociotechnical approach to the development process favours the central role of the user, however, involving the user is often not as easy as it might seem. The design approach should embrace the non-linear nature of technology development and allow for iterative and incremental improvements to be made in the system. Instead of aiming to design the perfect system before implementation, the design approach must allow for a more flexible approach involving the stitching together of partially integrated systems which would better satisfy the information needs of a complex organisation (Monteiro *et al.*, 2003). Sociotechnical systems exhibit emergent properties, in that some of the properties of the system only emerge after it has gone into use and cannot be predicted in advance (Adesina *et al.*, 2017). This is true of all systems, but it is particularly prominent in sociotechnical systems because of the complexity of the interactions between parts of the system.

From a sociotechnical perspective, design is about finding the synergy between specific characteristics of healthcare work, and the potential benefits of ICT. It is about designing interactions not from the perspective of the technology but from the perspective of the users that work with that technology,

and the practices in which it will become embedded (Berg *et al.*, 2003). The emphasis should be on guiding and nurturing the natural properties of sociotechnical systems rather than imposing top-down instructions and hierarchical structures from people who do not actually work at the operational level (Braithwaite *et al.*, 2009).

As stated previously, the activities relating to pharmacovigilance occur at different organisational levels throughout the health system. Systems engineering approaches to improve pharmacovigilance fall short of their goals when these merely focus on the lower levels of the of the system. Although it is clearly important to focus on the point of patient care, one must not forget to consider the multitude of other influential factors at higher organisational levels. The STS design approach allows for more cognisance of failures originating from different levels of the system (Henriksen *et al.*, 2008). Active failures are characterised as being those resulting from the decision of an individual, in the context of pharmacovigilance this could be an incorrect dosage delivery, choice of drug, or route of administration. These types of failures are typically found in and constrained within the lower levels, such as the operational level. Latent failures are those which manifest as a culmination of small inefficiencies and flaws in the higher levels of the system, and which have a trickle-down effect on the lower levels (Henriksen *et al.*, 2008). In terms of PV this could be the effects of national policies and the way in which these policies are implemented on an operational level. Another example of a latent failure is the inadequate education and training of HCPs with regard to pharmacovigilance activities.



Figure 2: Layers of a sociotechnical system stack. (Reproduced from: Sommerville, 2004)

Figure 2 shows the layers that make up a typical sociotechnical system. When comparing this figure with the discussion on the levels of analysis in the preceding section, one can see how the operational level encompasses the majority of the lower levels of the sociotechnical system stack. Furthermore, Figure 2 shows that by considering the system from the more traditional perspectives of systems engineering or software engineering, the process of standardisation would be the seemingly obvious approach to improve the system. This is because the lower levels of the sociotechnical stack are primarily hardware and software related.

## PHARMACOVIGILANCE AS A SOCIOTECHNICAL SYSTEM

Considering the sociotechnical nature of healthcare work as discussed in this article, one can classify pharmacovigilance as a sociotechnical system. Sociotechnical systems include IT systems and the social and organisational environment in which these systems are used.

Badham *et al.* (2000) defines five characteristics of open sociotechnical systems:

- i. Systems have interdependent parts.
- ii. Systems adapt to and pursue goals in external environments.
- iii. Systems have an internal environment comprising separate but interdependent technical and social subsystems.
- iv. Systems have equifinality. In other words, system goals can be achieved by more than one means. This implies that there are design choices to be made during system development.
- v. System performance relies on the joint optimisation of the technical and social subsystems.

Pharmacovigilance can be classified as an open sociotechnical system according to the five characteristics defined by Badham *et al.* (2000). Healthcare professionals interact with hardware and software infrastructure, recording, storing, and sharing data through the use of a human computer interface. These actions coupled with the multidisciplinary nature of communication and workflows in healthcare, influence internal organisational policies and culture, while adapting to ever changing external environments such as rules and regulations (Sittig and Singh, 2010).

The aim of this paper is to provide an argument for the adoption of sociotechnical systems design approaches to improve the design, implementation, and adoption of health information systems which seek to assist in promoting safer, better healthcare. The need to incorporate the social sciences in the improvement of health information systems has been widely acknowledged in literature (Braithwaite *et al.*, 2009)., however, it has not yet been realised through the application of conventional system design methods in the context of pharmacovigilance.

Individual users from different small work groups (general practitioners, nurses, pharmacists, etc.) will inevitably interact with the system in different ways. Certain features of the system will be appropriated by some but rejected by others, this relates to the common uncertainty between HCPs regarding where their individual responsibilities begin and end within the system.

To understand how technology changes the work practices of HCPs we need to investigate what HCPs understand about the technology and how they use technology in their daily work practices. An important consideration that is often overlooked is to study not only the adoption of new technology but also its rejection. This must be carried out with the use of qualitative research methods during the implementation and evaluation stages of the project lifecycle. When designing a system to support the work of HCPs, one cannot only rely on what the users say they do, instead detailed ethnographic studies must be carried out to understand how they perform their work functions *in situ* (Petrakaki *et al.*, 2010).

Research by Cho *et al.* (2008) shows how the adoption of a health information system in a hospital resulted in a redistribution of professional responsibility as well as a redistribution of labour as people tried to inscribe their interests into the technology. The research further showed that physicians were reluctant to adopt the new paperless information system as they believed it would project extra

administrative duties onto themselves, which they had previously informally displaced to nurses. Nurses on the other hand embraced the technological change process as they felt they would have increased control over the monitoring of their patients. This is an example of how different users experience the adoption process differently and how this can have varying influence on the design, development and use of the systems.

Studies on human factors and ergonomics relating to patient safety carried out by Safren & Chapanis (1960) found that the majority of medication errors could be categorised as: (1) wrong patient; (2) wrong dosage; (3) extra unordered medication; (4) omitted medication administration; (5) wrong medication; (6) wrong timing of medication administration; and (7) incorrect route of administration. The study found that the medication errors were largely due to work system factors such as a failure to follow the required protocols and procedures, as well as verbal or written communication problems.

Appelbaum (1997) proposed that clinicians work more efficiently when allowed to perform work in an autonomous manner, rather than being directed, micromanaged and controlled through a hierarchical structure. In view of this recommendation a bottom-up strategy is urgently needed to counter the traditionally top-down approaches which only result in modest improvements that are typically difficult to sustain. Healthcare reformation must be championed by HCPs themselves, too often politicians and bureaucrats seek to effect change by decree, when in reality clinical practice is shaped by social and behavioural aspects of clinicians (Braithwaite *et al.*, 2009). The collective values and behaviours of the individuals which make up a complex system comprise the culture of the system. Supporting the natural processes by which these individuals interact and cooperate, rather than constantly trying to reorganise them, is the key to changing the culture of the system.

Activities relating to PV can be considered a natural hub in the network of healthcare practices which pervasively negatively influences the practices and attitudes of clinicians who regard this work as being out of their scope of responsibilities. This negative association by a few opinion leaders in the network can have a disproportional influence on the attitudes of other colleagues with regard to patient safety.

### **Failures in sociotechnical systems**

Large complex systems fail not because of technical inadequacy, but rather because they do not recognise the social and organisational complexity of the environment in which they are implemented (Whitney and Daniels, 2013). Baxter and Sommerville (2011) describes common reasons behind the failure of sociotechnical systems including inconsistent terminology, levels of abstraction, conflicting value systems, lack of agreed success criteria, and multidisciplinary work environments.

Changing contexts of use mean that the judgement on what constitutes a failure changes as the effectiveness of the system in supporting work changes. Different stakeholders will interpret the same behaviour in different ways because of different interpretations of “the problem”. Therefore, the successful operation of a system for one set of stakeholders will inevitably mean “failure” for another set of stakeholders. This results in a conflict inevitability, as it can become increasingly difficult to establish a set of requirements where stakeholder conflicts are all resolved. Another contributing factor to the conflict inevitability is that groups of stakeholders in organisations are often in perennial conflict (e.g. managers and clinicians in a hospital).

Decision making within a system depends on the power held at some time by a stakeholder group (Markard *et al.*, 2016). There exists a plethora of intricate power relations within a sociotechnical system due to the large number of stakeholders and the overlapping nature of system boundaries.

### **Challenges in PV related to failures of STSs**

Healthcare outcomes are produced through the collaborative interactions between people, equipment, tools, documents, and organisational routines (Berg, 1999). Managers and HCPs too often blame the failure of newly implemented technologies on the technical properties (Poon *et al.*, 2017) (Miller & Sim, 2017). While technical flaws can certainly result in many problems, it is often the sociotechnical interactions between the new HIT and the existing social and technical systems that lead to undesirable outcomes of HIT implementation. A common misbelief is that computerisation inherently improves reliability, but what is often overlooked are the contributions of HCPs clinical judgement, communication within small work groups, and teamwork to patient safety (Baker *et al.*, 2006).

The most common reasons behind system failure in medical informatics are not attributed to hardware or software problems; but rather that systems are built upon incorrect assumptions (Hysalo *et al.*, 2003), or that they incorporate inaccurate characterisation of medical work, or failure to see the implementation process as an organisational change process (Van der Meijden *et al.*, 2003).

The chances of system failure can be significantly reduced if evaluation studies are performed throughout the system development. By making use of qualitative research methods to gain an understanding of user experiences, complaints and changes in working relations; organisational learning can be increased, facilitating the organisational change process (Kaplan, 1997).

The notion of aiming to design a failure-free technical system has been discussed in the sociotechnical systems design section. Instead of aiming for a perfect system, the design process must be flexible enough to account for small errors to be addressed through incremental improvements. By taking the sociotechnical system perspective and using higher levels of the sociotechnical stack to identify and trap failures, one limits adverse consequences. The goal should be to contain failures within technical systems and not allow the failure to propagate across the sociotechnical system.

### **THE PROBLEM WITH STANDARDISATION IN SOCIOTECHNICAL SYSTEMS**

When considering the process of standardisation in sociotechnical systems it is crucial to understand the balance between system adaptability to local work practices on a low level of abstraction against the interoperability of the system on a higher level of abstraction (Harrison *et al.*, 2007).

As discussed, healthcare systems are made up of complex interactions between people and technology, and the work found within these systems is inherently irregular and typically involves coming up with pragmatic solutions to problems. Decision making in healthcare work is distributed and relies on a collaborative agreement of diagnosis from multiple viewpoints and an always evolving and inconsistent knowledge base (Berg, 1999).

Different countries have, for multiple reasons such as economic or cultural factors, different approaches to work organisation. This is why traditional systems development methods have not been fruitful in providing a global solution to the management of healthcare information. Countries typically adapt these methods to suit their particular needs (Baxter and Sommerville, 2011).

It would, however, be nonsensical to ignore those elements of the system which lend themselves to standardisation. The primary care processes which are employed by healthcare practitioners are not subject to standardisation because every patient requires a unique combination of care approaches. The extent to which the standardisation of these elements is value adding is an important consideration and will result in a system which can alleviate the HCPs of some of their duties and ease their cognitive load, thus allowing them to perform the primary care processes more efficiently (Berg, 1998).

## **ROADMAP FOR THE FUTURE**

Sociotechnical systems are influenced by the organisation's culture, rules and objectives. They are inextricably bound to the organisation using these systems, how it thinks of itself and how it works. The implementation of new technology in an organisation is in essence a process of organisational change. For this process to be successful, a number of criteria must be met, including a high level of commitment and focus from the users as well as the management of the organisation.

There is a definite need to transition away from the static pre-and post-implementation impacts or notions of discrete change which currently dominate studies in healthcare (Hendy *et al.*, 2005; Hendy *et al.*, 2007).

Previous attempts to change healthcare practices involving education, persuasion and mandating through hierarchical structure have largely failed due to strong opposing forces such as clinical autonomy and an inability to overcome individual and regional variations in practice. Systems designers should embrace the natural properties of complex systems and empower, engage, and support clinicians in their efforts to promote better and safer patient care. By involving clinicians in the development of a structured data and information reporting system, organisational learning is increased.

User participation must be at the heart of HIT design and implementation, with users being an integral part throughout the entire development life cycle. Sensitisation and awareness of stakeholders across the system to the value of a sociotechnical approach is essential; as is constructive engagement in terms of involving a multidisciplinary team of developers, engineers and healthcare practitioners throughout the entire SDLC and integrating STS design approaches into the change management processes in the organisation (Baxter and Sommerville, 2011).

### **STS transition theory and the Reconfiguration pathway**

Geels & Schot (2007) are thought leaders in the field of sociotechnical transition pathways. They developed a typology of four sociotechnical transition pathways: *transformation*, *reconfiguration*, *technological substitution*, and *de-alignment and re-alignment*. The four transition pathways clarify the relationship between three structural levels (the multi-level perspective (MLP)) and the role of agency<sup>3</sup>.

---

<sup>3</sup> In social science, agency is the capacity of individuals to act independently and to make their own free choices. By contrast, structure is those factors of influence (such as social class, religion, gender, ethnicity, ability, customs, etc.) that determine or limit an agent and his or her decisions (Barker, 2003).

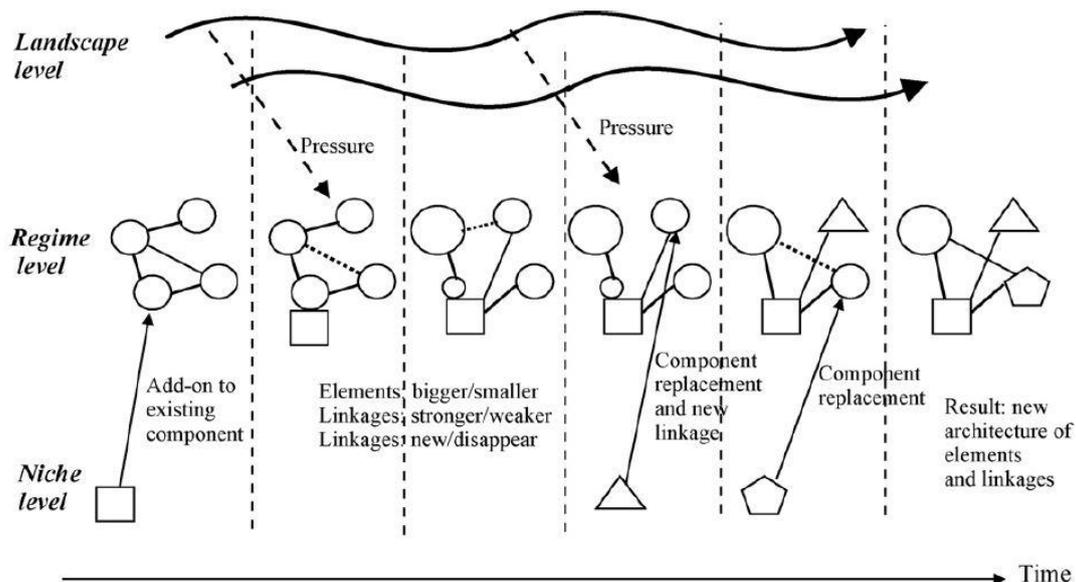


Figure 3: Reconfiguration pathway. (Reproduced from: Geels & Schot, 2007)

The *reconfiguration pathway* seen in Figure 3 has been identified as the most appropriate of the four pathways to aid in the understanding of the sociotechnical transition that is brought about through the design and implementation of HITs in the context of PV. The landscape level exerts pressure onto the regime level in an exogenous manner, here the regime level is the PV system within a health system. There are political, regulatory, technological, and social forces which are external to the inner-workings of the PV system that create pressure at the regime level. In addition to pressure from the landscape level, the niche level is the micro-level where new technological innovations emerge. These niche-level innovations, whether technological or social, accumulate and can destabilise the system, resulting in the origination of a sociotechnical transition. It is important to understand that these change process are influenced by complex interactions between various system components, and across all levels of the sociotechnical system (Geels, 2007).

Sociotechnical transition invariably results in a shift in work roles and responsibilities, more often than not from those who inherited extra work tasks from people who considered themselves to be in a position of power in the organisational hierarchy, back to the appropriate people. For example, general practitioners (GPs) often delegate the administrative duties of their work practices to the nurses, when in fact, the responsibility to perform those administrative duties is that of the GPs themselves.

This literature is valuable to those seeking to design and implement HITs in that it highlights the need to embrace the non-linear nature of technology development and allow for iterative and incremental improvements to be made in the system (Monteiro *et al.*, 2003).

### Understanding change in a sociotechnical system

An adaptation of Potter & Brough's (2004) capacity building pyramid can be seen in Figure 4. HIT interventions that embed pre-fixed sequences of steps in a care process, or that only allow for certain modes of data input would fail amidst the contingencies and pragmatic needs that characterise healthcare work (Berg, 1999). Additionally, new HIT initiatives must be developed according to sociotechnical systems design methods.

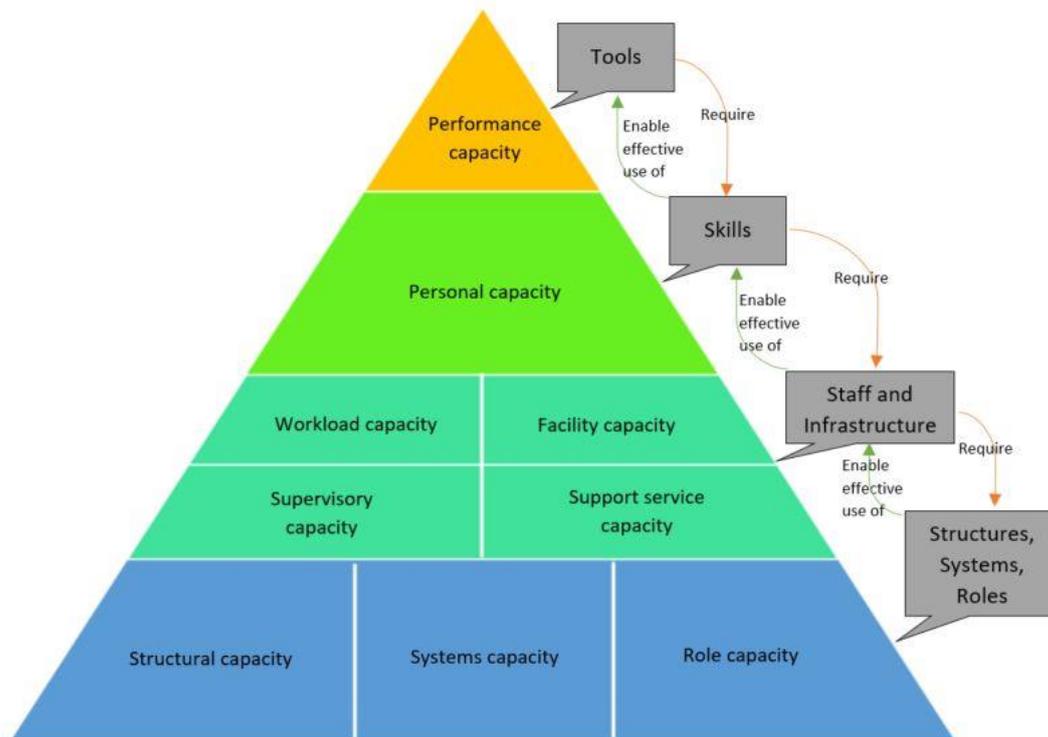


Figure 4: Capacity building pyramid. (Adapted from: Potter & Brough, 2004)

Tools and skills are more technical and are easier to change over shorter periods of time, when compared to staff and infrastructure; and structures, systems, and roles; this is partly attributed to the fact that these elements of the system lend themselves to the process of standardisation. Performance capacity is, to a large extent, governed by the tools which HCPs are afforded to make use of. These tools in the context of PV can be understood as being the hardware and software elements of the system. Personal capacity is governed by the skills that the HCPs are equipped with. New competencies for healthcare workers must be established so that higher levels of complexity in work tasks can be established. In other words, the doctors of the future will need to be trained to use emerging technologies whilst understanding the sociotechnical dynamics which undermine their work. The bottom two levels of the capacity pyramid are more socio-cultural and are more resistant to change, requiring more effort and more time to change.

## CONCLUSION

PV systems involve complex interactions between healthcare professionals, computer hardware and software, as well as the physical work environment within which they operate, all the while being exposed to external pressures from ever changing political, technological, cultural and social factors.

From the findings presented in this research we show that HIT innovations can never be fully achieved with technological advances alone. Problems regarding HIT implementations cannot be solved simply with more or better HIT, improved training of HCPs and better technical support.

To assist with the successful design and implementation of HITs, the notion of a sociotechnical transition must be considered. One must delve into the operational level of the system and consider relationships amongst and between technology and its users across multiple system boundaries. The change process must consider how people work *in situ* rather than merely accept what they 'say they

do', as well as how these people translate their beliefs into actions in the workplace and how they make choices in the workplace when executing their power (Petракaki *et al.*, 2010).

## REFERENCES

- Adesina, A.A., Hussain, Q., Pandit, S., Rejzek, M. and Hochberg, A.M., 2017. Assessing the Value of System Theoretic Process Analysis in a Pharmacovigilance Process: An Example Using Signal Management. *Pharmaceutical Medicine*, 31(4), pp.267-278.
- Appelbaum, S.H., 1997. Socio-technical systems theory: an intervention strategy for organizational development. *Management decision*, 35(6), pp.452-463.
- Badham, R., Clegg, C. and Wall, T., 2000. Socio-technical theory. *Handbook of Ergonomics*. New York, NY: John Wiley.
- Baker, D.P., Day, R. and Salas, E., 2006. Teamwork as an essential component of high-reliability organizations. *Health services research*, 41(4p2), pp.1576-1598.
- Barker, C., 2003. *Cultural studies: Theory and practice*. Sage.
- Baxter, G. and Sommerville, I., 2011. Socio-technical systems: From design methods to systems engineering. *Interacting with computers*, 23(1), pp.4-17.
- Berg, M., 1999. Patient care information systems and health care work: a sociotechnical approach. *International journal of medical informatics*, 55(2), pp.87-101.
- Berg, M., Aarts, J. and van der Lei, J., 2003. ICT in health care: sociotechnical approaches. *Methods Archive*, 42(4), pp.297-301.
- Berg, M., Langenberg, C., vd Berg, I. and Kwakkernaat, J., 1998. Considerations for sociotechnical design: experiences with an electronic patient record in a clinical context. *International journal of medical informatics*, 52(1), pp.243-251.
- Braithwaite, J., Runciman, W.B. and Merry, A.F., 2009. Towards safer, better healthcare: harnessing the natural properties of complex sociotechnical systems. *Quality and Safety in Health Care*, 18(1), pp.37-41.
- Checkland, P. and Poulter, J., 2006. *Learning for action: a short definitive account of soft systems methodology and its use, for practitioners, teachers and students*. John Wiley and Sons Ltd.
- Cho, S., Mathiassen, L. and Nilsson, A., 2008. Contextual dynamics during health information systems implementation: an event-based actor-network approach. *European Journal of Information Systems*, 17(6), pp.614-630.
- Corrigan, J.M., 2005. *Crossing the quality chasm. Building a Better Delivery System*. Institute of Medicine.
- Eason, K., 2001. Changing perspectives on the organizational consequences of information technology. *Behaviour & information technology*, 20(5), pp.323-328.
- Ferlie, E.B. and Shortell, S.M., 2001. Improving the quality of health care in the United Kingdom and the United States: a framework for change. *The Milbank Quarterly*, 79(2), pp.281-315.
- Geels, F.W. and Schot, J., 2007. Typology of sociotechnical transition pathways. *Research policy*, 36(3), pp.399-417.
- Harrison, M.I., Koppel, R. and Bar-Lev, S., 2007. Unintended consequences of information technologies in health care—an interactive sociotechnical analysis. *Journal of the American*

- medical informatics Association, 14(5), pp.542-549.
- Hartman, J., Härmark, L. and van Puijenbroek, E., 2017. A global view of undergraduate education in pharmacovigilance. *European Journal of Clinical Pharmacology*, pp.1-9.
- Hazell, L. and Shakir, S.A., 2006. Under-reporting of adverse drug reactions. *Drug safety*, 29(5), pp.385-396.
- Hendy, J., Fulop, N., Reeves, B.C., Hutchings, A. and Collin, S., 2007. Implementing the NHS information technology programme: qualitative study of progress in acute trusts. *Bmj*, 334(7608), p.1360.
- Hendy, J., Reeves, B.C., Fulop, N., Hutchings, A. and Masseria, C., 2005. Challenges to implementing the national programme for information technology (NPfIT): a qualitative study. *Bmj*, 331(7512), pp.331-336.
- Henriksen, K., Dayton, E., Keyes, M.A., Carayon, P. and Hughes, R., 2008. Understanding adverse events: a human factors framework.
- Hugman, B., 2006. The Erice Declaration. *Drug safety*, 29(1), pp.91-93.
- Hutchins, E., 1995. *Cognition in the Wild*. MIT press.
- Hyysalo, S. and Lehenkari, J., 2003. An activity-theoretical method for studying user participation in IS design. *Methods Archive*, 42(4), pp.398-404.
- Kaplan, B., 1997. Addressing organizational issues into the evaluation of medical systems. *Journal of the American Medical Informatics Association*, 4(2), pp.94-101.
- Markard, J., Suter, M. and Ingold, K., 2016. Socio-technical transitions and policy change—Advocacy coalitions in Swiss energy policy. *Environmental Innovation and Societal Transitions*, 18, pp.215-237.
- Mehta, U., Dheda, M., Steel, G., Blockman, M., Ntilivamunda, A., Maartens, G., Pillay, Y. and Cohen, K., 2014. Strengthening pharmacovigilance in South Africa. *SAMJ: South African Medical Journal*, 104(2), pp.104-106.
- Miller, R.H. and Sim, I., 2004. Physicians' use of electronic medical records: barriers and solutions. *Health affairs*, 23(2), pp.116-126.
- Monteiro, E., 2003. Integrating health information systems: a critical appraisal. *Methods of information in medicine*, 42(4), pp.428-432.
- Petrakaki, D., Cornford, T. and Klecun, E., 2010. Sociotechnical changing in healthcare. *Stud Health Technol Inform*, 157, pp.25-30.
- Pirmohamed, M., Breckenridge, A.M., Kitteringham, N.R. and Park, B.K., 1998. Fortnightly review: adverse drug reactions. *BMJ: British Medical Journal*, 316(7140), p.1295.
- Poon, E.G., Blumenthal, D., Jaggi, T., Honour, M.M., Bates, D.W. and Kaushal, R., 2004. Overcoming barriers to adopting and implementing computerized physician order entry systems in US hospitals. *Health Affairs*, 23(4), pp.184-190.
- Potter, C. and Brough, R., 2004. Systemic capacity building: a hierarchy of needs. *Health policy and planning*, 19(5), pp.336-345.
- Safren, M.A. and Chapanis, A., 1960. A critical incident study of hospital medication errors. *Nursing Research*, 9(4), p.223.
- Santoro, A., Genov, G., Spooner, A., Raine, J. and Arlett, P., 2017. Promoting and Protecting Public Health: How the European Union Pharmacovigilance System Works. *Drug Safety*, 40(10), pp.855-869.

- Schurer, M.J., Bam, L. and De Kock, I., 2017. An investigation into the value of a standardised global pharmacovigilance reporting system. *The South African Journal of Industrial Engineering*, 28(3), pp.78-88.
- Sittig, D.F. and Singh, H., 2010. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. *Quality and Safety in Health Care*, 19(Suppl 3), pp.i68-i74.
- Sommerville, I., 2004. *Software Engineering*. International computer science series. ed: Addison Wesley.
- Van der Meijden, M.J., Solen, I., Hasman, A., Troost, J. and Tange, H.J., 2003. Two patient care information systems in the same hospital: beyond technical aspects. *Methods Archive*, 42(4), pp.423-427.
- Vicente, K.J., 1999. *Cognitive work analysis: Toward safe, productive, and healthy computer-based work*. CRC Press.
- Viller, S. and Sommerville, I., 2000. Ethnographically informed analysis for software engineers. *International Journal of Human-Computer Studies*, 53(1), pp.169-196.
- Whitney, K.M. and Daniels, C.B., 2013. The root cause of failure in complex IT projects: complexity itself. *Procedia Computer Science*, 20, pp.325-330.