

Is the SEIPS model a suitable tool for the investigation of non-conformances in an NHS Production Manufacturing Unit?

Author: Jody Varley. Project Supervisors: Rebecca Cohen (Leeds Teaching Hospitals), Sue Renn (University of Manchester)

1. Introduction

- Investigations are a mechanism to protect patient safety and improve the efficiency of operations by an organisation
- As part of an investigation, contributing factors will be determined. The ideal outcome is a true root cause is discovered, but this is not always the case.
- The strength of investigations is an ongoing area of concern with the MHRA⁽¹⁾
- Therefore, the quality of investigations needs to be improved to aid continuous improvement in departments
- NHS England have adapted the already established System Engineering Initiative for Patient Safety (SEIPS) tool and are encouraging the use of it to investigate patient safety incidents.⁽²⁾
- So can it be adopted and used in the world of Pharmacy Technical Services?

2. Objectives

To test the usability of the SEIPS model within a Licensed PMU to assess if this new method is suitable in non-patient facing incidents.

This data can be used to inform other departments (licensed and unlicensed) in using an alternative method to investigate non-conformances.

3. Methods

The SEIPS method was used to blindly investigate 20 non-conformances raised in the licensed PMU. The outcomes of these investigations were then compared to the investigations performed by another member of staff using alternative methods/tools, to assess whether SEIPS provided similar outcomes. This provided an insight on whether the SEIPS model was useful or not.

4. Results

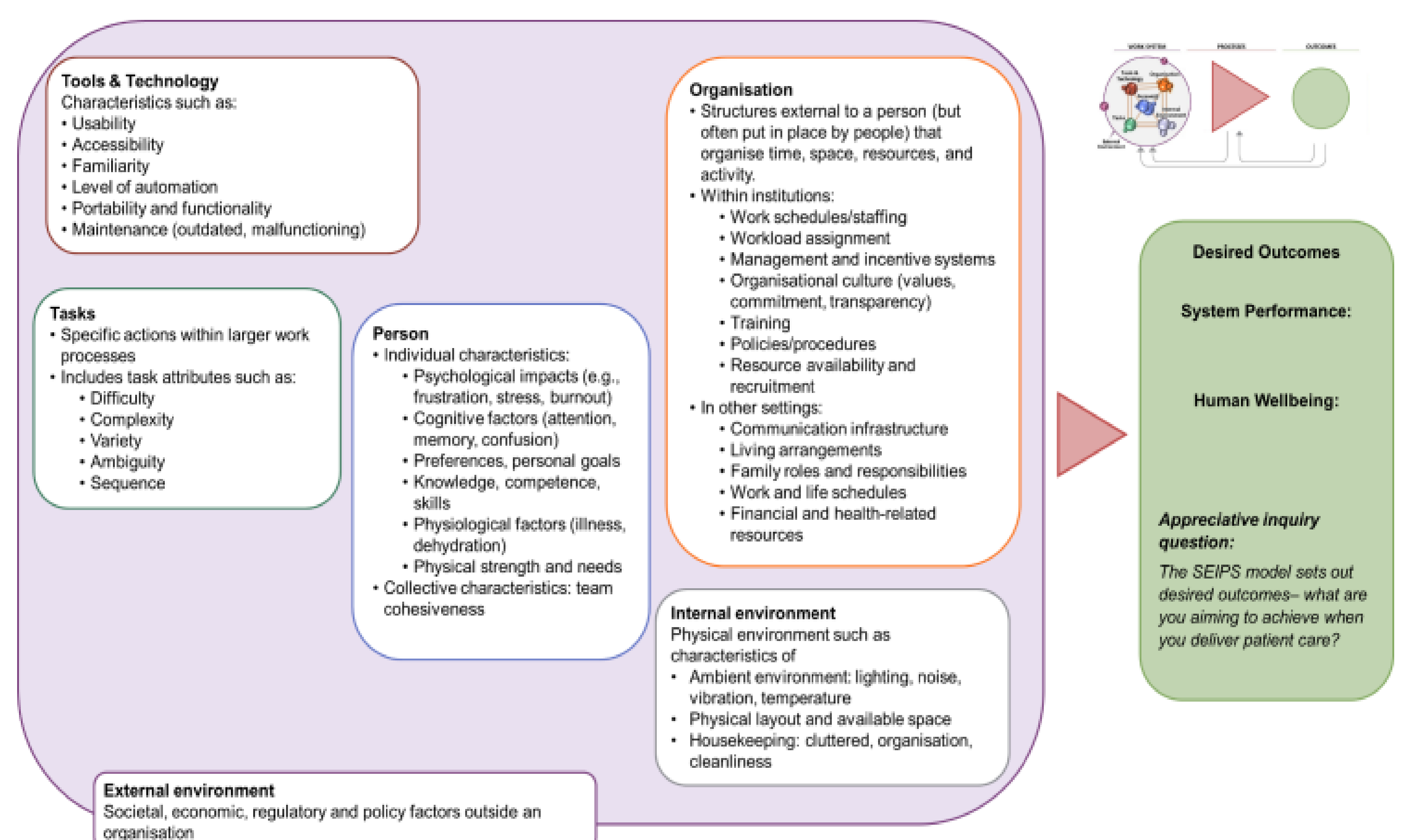
The results showed that the SEIPS tool was largely successful in attaining similar investigations to other tools and prompted the investigator to ask relevant questions to gather information required to assign a root cause.

The use of the SEIPS tool seemed, at times, too in depth for a 'minor' investigation but was more appropriate for events requiring a more in depth investigation.

The SEIPS tool was effective in prompting information collection, and on some occasions prompted certain aspects of the work system to be considered that were not considered in the original investigation.

The SEIPS tool was useful as a data collection tool, however it proved not as useful as a root cause analysis tool. Therefore the SEIPS tool would be most useful when used in conjunction with a root cause analysis tool such as the 'five why's'. The tool did not include any prompts for CAPAs and this would need to be considered separately.

The SEIPS tool provides an easy to follow layout which results in a structured investigation.



Non-conformance ID	Risk Classification	Did the SEIPS investigation include any extra information than the original investigation did?	Was there any information in the original investigation that the SEIPS tool didn't include?	Comments
782	Minor	No, same information included.	No, all information included in the original was included using the SEIPS tool.	Original investigation was uploaded as a bulk of text on a word document with no headings or structure making it difficult to follow. SEIPS tool provides more structure and an easier to follow layout.

5. Conclusions & Future Work

The SEIPS tool is certainly a possible tool for the investigation of non-conformances and was successful in attaining information needed for a structured investigation. However, it would be of most benefit when used in conjunction with a root cause analysis tool. More work is needed to assess its use in an unlicensed unit/Radiopharmacy units, as well as assessing how useful other investigators find this tool.

6. References

1. McLoughlin C. A fresh look at an old topic: Investigations in the GMDP environment. 2020 Sep 14 [cited 2024 Jan 08]. In: MHRA Inspectorate. BLOG [Internet]. Available from: <https://mhrainspectorate.blog.gov.uk/2020/09/14/a-fresh-look-at-an-old-topic-investigations-in-the-gmdp-environment/>
2. NHS England. SEIPS quick reference guide and work system explorer. [Internet] 2022 [cited 2024 Jan 22]. Available from: <https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-SEIPS-quickreference-and-work-system-explorer-v1-FINAL-1.pdf>