Integrating macro and micro Hierarchical Task Analyses to embed new medical devices in complex systems

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ABSTRACT: The introduction of new medical devices (technologies) into complex systems usually includes usability evaluation (formative and summative) using Human Factors (Engineering) methods. This paper outlines the use of Hierarchical Task Analysis (HTA) to not only look at usability but also consider implementation in a complex system. Firstly, the macro system is mapped as a process model for a complex field exercise (simulation) for prehospital care following a chemical incident; and secondly the individual human-medical device interface is analyzed. This allows the two outputs to be integrated by combining the macro systems modelling and micro product interactions. It provides an example of using HTA to support implementation of new devices and technologies in complex healthcare systems.

Keywords: hierarchical task analysis, pre-hospital care, medical devices, emergency response

Presentation Preference: Oral

1. INTRODUCTION

Medical devices are used in a wide range of complex environments with pre-hospital care being one of the most unpredictable. There may be unknown and rapidly changing environments and patient presentations. For example when a Chemical, Biological, Radiological or Nuclear (CBRN) event occurs, the emergency services responders (Fire, Police and Ambulance) could be working '*with a very large number of components that function in a highly uncertain, dynamic, real-time environment'* (Humphrey and Adams, 2011). Before implementing new medical devices into these complex situations, an understanding of the system will help to predict where the medical device may benefit, but possibly also hinder, the response.

Sujana et al (2018) discuss the use of Human Factors/Ergonomics (HFE) methods within a large 5 year UK healthcare project which aimed to adopt and trial proactive safety management techniques from safety-critical industries, such as task analysis, human reliability analysis and safety cases. The approach was structured into five steps with Steps 1 (pathway definition and context) and 2 (system diagnosis) supported by a range of tools for system definition and risk analysis, including process mapping and Hierarchical Task Analysis (HTA); and Steps 3–5 (option appraisal, planning, system improvement) supported by rapid improvement cycles and statistical process control approaches. They reported that clinical teams found that the use of task analysis supported a better understanding of processes, and of variations.

This paper describes how HTA was used to model both a macro complex system and micro medical device interaction; it aims to explore the possibility of 'plug and play' implementation whereby new medical devices can be 'plugged' into an existing system.

2. METHOD

HTA is used to understand interactions among humans and other elements of a system with applications in a range of safety critical applications with example from medicines management (Allitt et al, 2017) and surgery (Demeril et al, 2016). The method identifies the highest-level task defined in terms of the overall goal *'a statement of what the system is required to achieve,* …[and operator] *actions which are consistent with the system's goals'* including pre-conditions. At each level of subtasks, a plan directs the sequence and possible variance of task steps as statements of the conditions necessary to undertake the operation(s) (Shepherd, 2001).

The macro HTA was developed using document analysis and interviews based on the script of a CBRN field exercise (simulation). It was iteratively reviewed to check for omissions, inaccuracies and usability (content and presentation) before the final version was agreed (signed off as complete and accurate).

The new potential in vitro diagnostic (IVD) medical device was a breath analyser (BreathSpec®) which was developed to increase rapidity of field diagnosis and thereby the speed at which treatment would be delivered for casualties (Toxi-TRIAGE, 2018). It was at Technology Readiness Level (TRL) 6: '*technology demonstrated in relevant environment (*Horizon, 2020). The user manual was analysed followed by interviews with the technology developer until a final version of the HTA was agreed.

3. RESULTS

The outputs were delivered as a HTA diagram for the field exercise (macro system, Figure 1) and IVD device (micro system, Figure 2). Additionally, a tabular HTA was produced to improve usability (content and presentation) of the Figure 2, as a standard operating procedure (Table 1) for training and evaluation.

4. DISCUSSION

Previous systems analyses of CBRN responses identified the difficulty of systems mapping for this *'dynamic domain that contains high levels of uncertainty'* (Humphrey and Adams, 2011).

The two outputs were integrated to consider usability of a new potential IVD device in the complex system of a field exercise following a chemical incident by combining the macro systems modelling and micro product interactions. This demonstrated the versatility of HTA as both a systems mapping method and for training (Sujana et al, 2018).

Table 1. Extract from HTA for BreathSpec®

2	Take breath sample
Plan 2	Do in Sequence
2.1	Set up device for breath analysis mode (do not click 'Start' yet)
2.2	Connect the mouthpiece to the reservoir tube
2.3	Connect the 5ml syringe to the reservoir tube
2.4	Ask casualty to exhale smoothly into the mouthpiece
2.5	Take a sample with the syringe (smoothly pull plunger) whilst the patient is exhaling
2.6	Disconnect syringe from reservoir tube
3	Label (Tag) the sample
Plan 3	Do 3.1 if needed Do 3.2.
3.1	Attach electronic Tag to casualty (if not already tagged)
3.2	Scan tag against device to link Tag ID and inject sample breath into device

5. CONCLUSION

Before implementing new medical devices into complex situations, a clear understanding of the macro and micro systems will support operational integration. This paper offers an example to support macro-micro systems integration in the introduction of new devices and technologies into complex healthcare systems.

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Toxi-TRIAGE (2018) BreathSpec® - Triage screening of human exposure to CBRN agents using breath analysis http://toxi-triage.eu/node/501

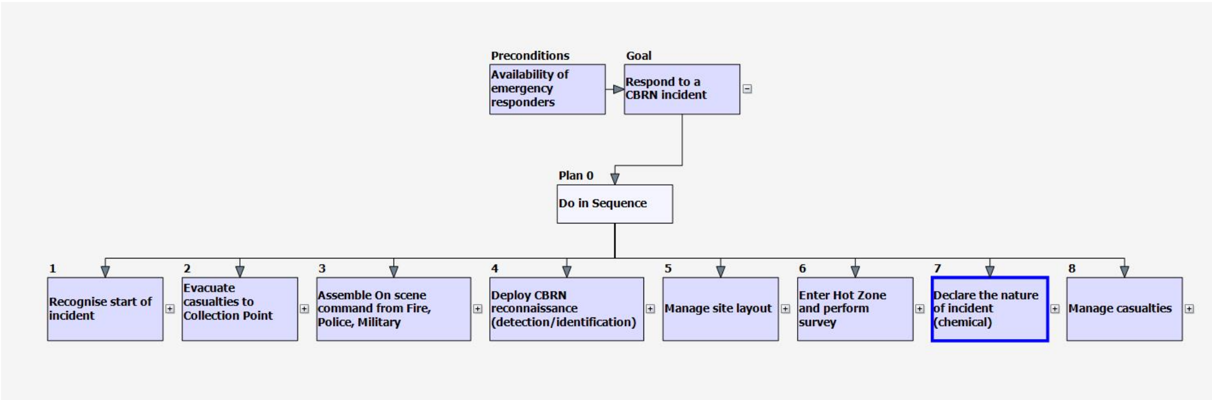

Figure 1 – HTA for macro system (CBRN Response)

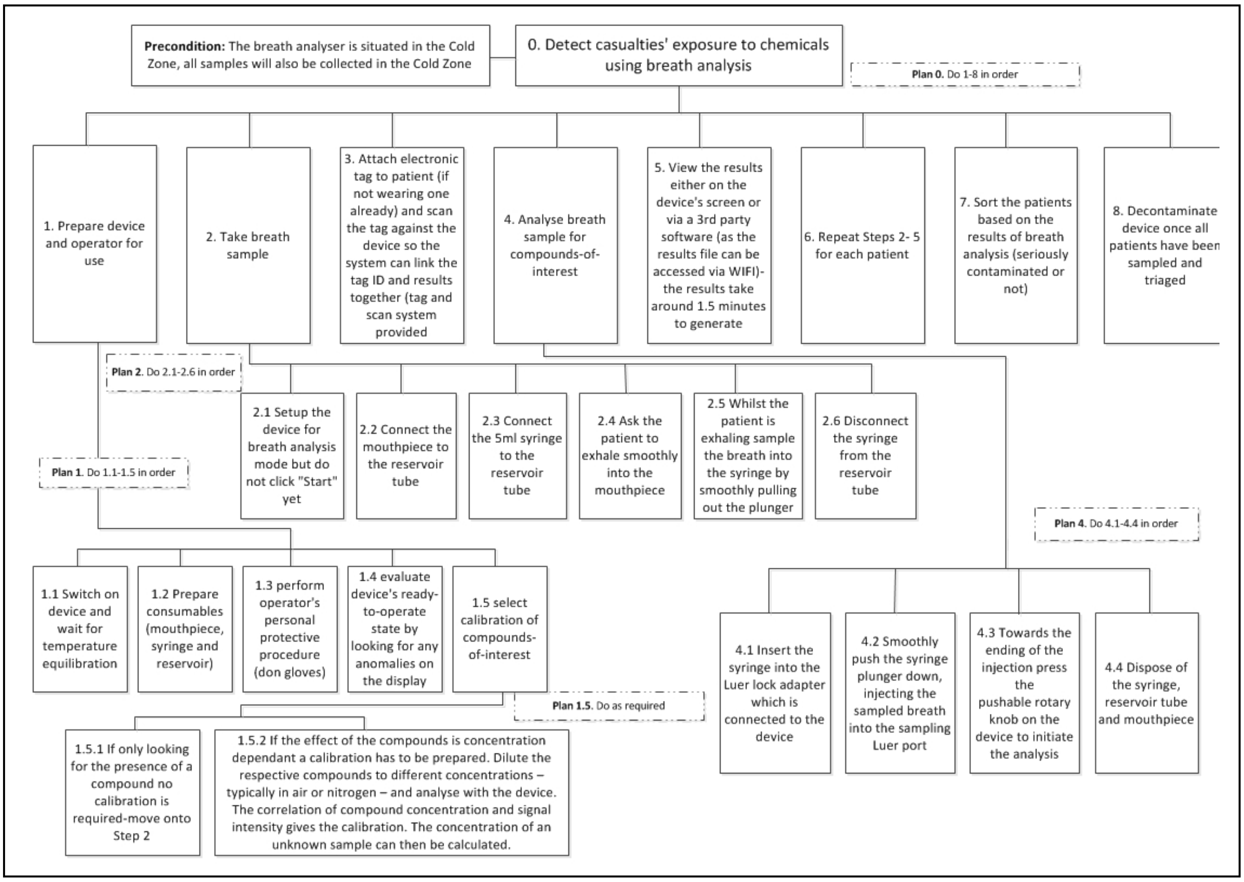

Figure 2 – HTA for BreathSpec® (http://toxi-triage.eu/node/501)