Medication Safety perspective from International Society of Pharmacovigilance

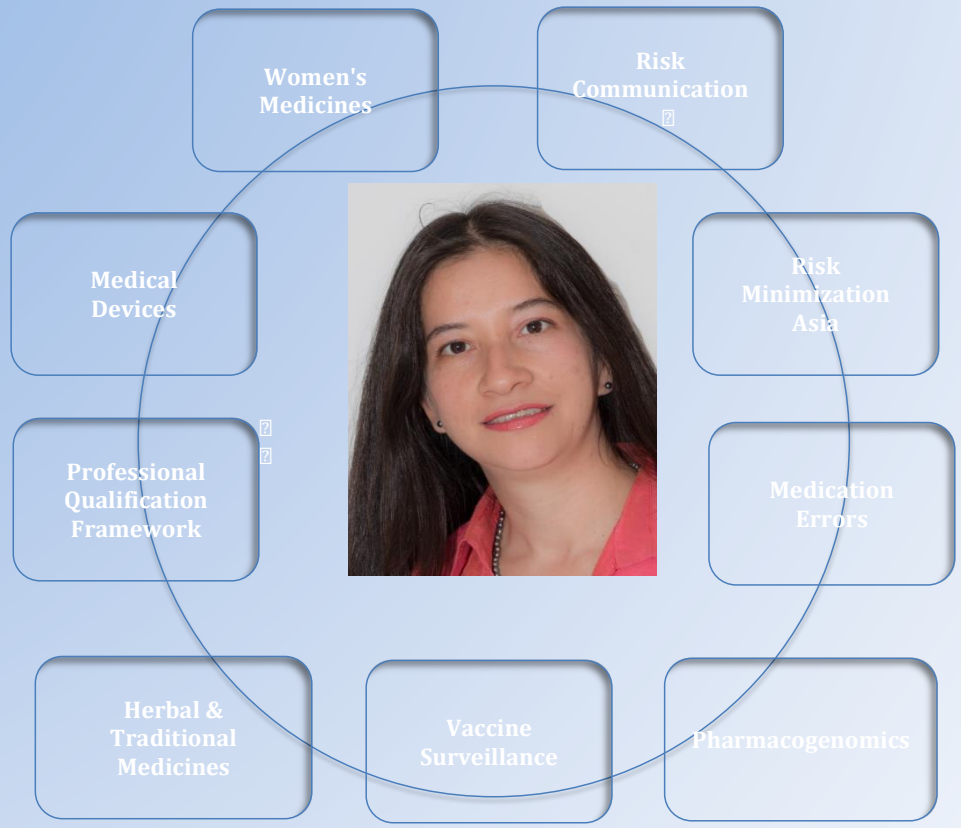
Monday November 8th, 2021

Dr Brian Edwards Chair Medication Errors SIG

https://isoponline.org/special-interest-groups/medication-errors/

International Society of Pharmacovigilance

Special Interest Group Coordination



Thanks to Angela Caro who has held this role since October 2019
.. And is also my co-chair and has orgnaised presentations for WHO Patient Safety Day 2020 and 2021

AGENDA

- Background to the SIG: history, who are we?
- What have we been up to?
- Coding medication errors is a challenge
- The importance of networking and raising awareness
- Developing systems science
- Breaking news: guiding safety principles

It is amazing what you can accomplish if you do not care who gets the credit.

Harry S Truman

Development of Medication Errors SIG

- Established May 2017 with Prof. Ian Wong
- Mission: To provide an opportunity for ISoP members and like-minded collaborators to network globally in a professional and neutral environment to share evidence and solutions to tackle medication errors thereby continuing systematic improvement in optimising the use of medicines in the interest of healthcare professionals, patients and their families.
- Dedicated project manager
- Web Call monthly with agenda and minutes all freely available to ISOP members
- Global team with representatives from all continents (except Antarctica)

What does the Medication Errors SIG offer?

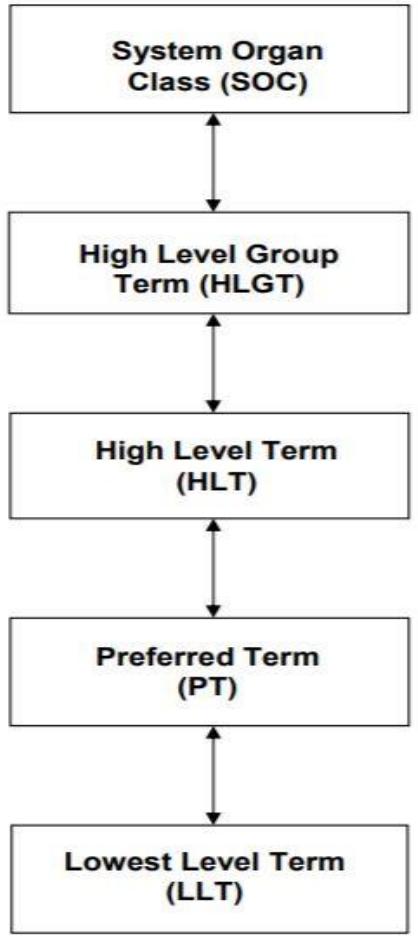
- Create opportunities for those researching and investigating medication errors to network in a friendly and mutually supportive environment and publish their research using good quality outlets.
- Support healthcare professionals with scientific evaluation of medication errors and how to prevent them.
- Help regulatory authorities with medication errors guidance and evaluation
- Organizing trainings and tutorials to provide effective support to pharmacovigilance centres to extend their role in detecting and preventing medication errors through Individual Case Safety Reports (ICSRs) by using specific methods and tools.
- Through social media and other forms of communication, build on current activities to provide a platform for discussion and generation of new research and ideas.
- Explore the need for meetings, education and affordable training such as encouraging abstracts for the Annual Meeting and imputing into ISoP and chapter training meetings.
- Provide a neutral and impartial forum for all stakeholders including patients to ask difficult questions and obtain answers within a reasonable timeline.

What does the Medication Errors SIG offer?

- Social media activities including infographics
- Prescribing Safety Assessment
- Coding and classification group (liaison with MSSO)
- Systems approach to labelling
- Activities locally: India, Morocco, Middle East, UK, Ireland, LATAM
- Developed pharmacogenomics SIG which is now its own SIG
- Exploring ecopharmacovigilance group; nurturing possibility of SIG for ‘the elderly’; ‘oncology products’
- Unique linkage with UK and LATAM Human Factors groups

ME coding: MedDRA (Katarina Kralova)

- The five-level structure of this terminology provides options for retrieving data by specific or broad groupings, according to the level of specificity required
- Each level in the hierarchy may reflect a variable degree of specificity or “granularity” from one SOC to another
- HLTs and HLGTs facilitate data retrieval and presentation by providing clinically relevant grouping of terms



ME: Practical experience, frequent examples and pitfalls

- Company database: for identical situations, different PTs and LLTs are used:

Scenarios reported	Encountered PTs	Encountered LLTs
Patient inadvertently took his dose one week earlier than the right schedule	Product use issue **Inappropriate schedule of product administration** Wrong schedule	Drug use for unapproved schedule **Inappropriate schedule of drug administration** Wrong schedule
Patient with an unexplained gap between two doses	Product use issue **Inappropriate schedule of product administration**	Drug use for unapproved schedule **Inappropriate schedule of drug administration**

ME: Practical experience, frequent examples and pitfalls

- Sometimes cases of « **off label use** » or « **misuse** » are miscoded/confounded with situations:

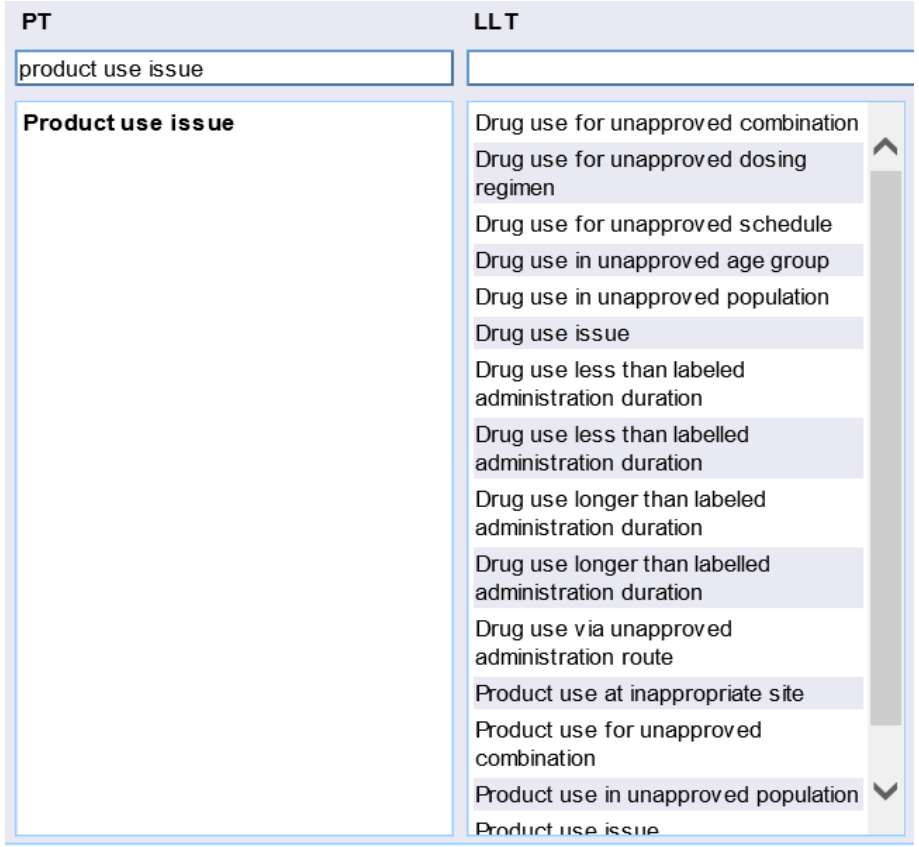
Scenarios reported	Encountered PTs	Encountered LLTs
Patient using the drug every 3 weeks, by order of the physician, whereas the label mentions every 2 weeks	Product use issue **Off label use**	Drug use for unapproved schedule **Off label dosing frequency**
Patient taking the drug on the 1st and 15th of every month (instead of every 14 days)	**Inappropriate schedule of product administration*** Wrong schedule **Intentional product misuse**** Intentional product use issue	**Inappropriate schedule of drug administration** Wrong schedule **Intentional misuse in dosing frequency** Intentional product misuse Intentional product use issue

* / ** recommended coding; depends on intent **

PT Product use issue

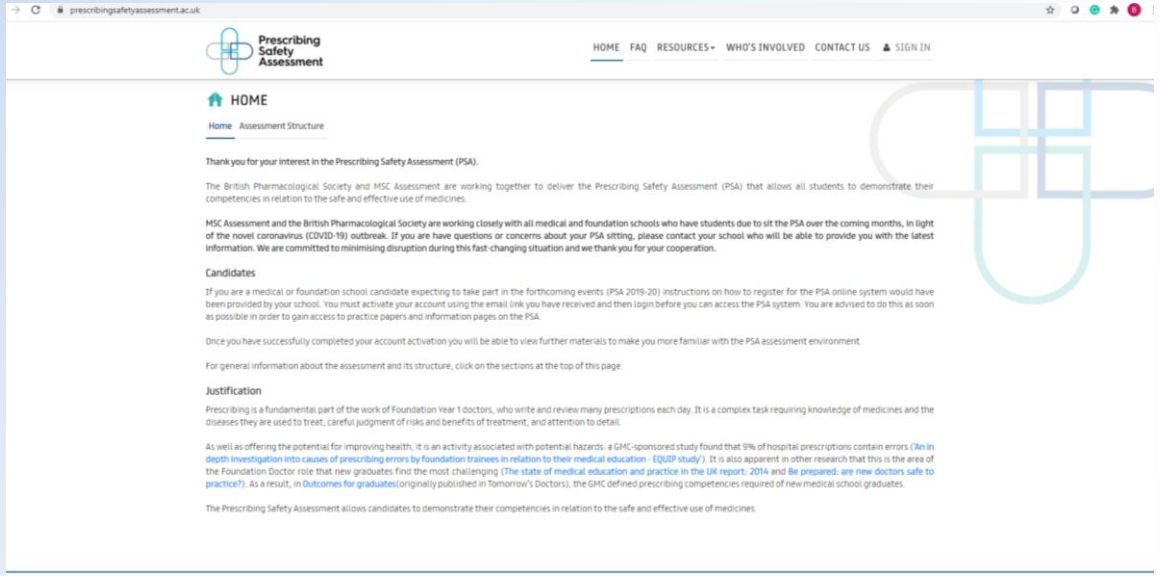
- As seen in the examples provided before, PT « **Product use issue** » (as well as PT « **Intentional product use issue** ») are vague terms which are covering **various different scenarios** (age group, population, administration duration), which may lead to **inconsistency** when creating a **PT query**.

- LLT « **Drug use for unapproved schedule** » (PT « Product use issue ») and LLT « **Inappropriate schedule of drug administration** » (Under PT « Inappropriate schedule of product administration ») are quite alike which leads to the following question:
  - Should this LLT, classed under a more precise PT than Product use issue, be used to obtain more clarity ?



Promoting Prescribing Safety Assessment

- British Pharmacological Society has collaborated with the UK Medical Schools Council to develop the Prescribing Safety Assessment (PSA), an online training and assessment package to promote better prescribing skills in healthcare.
- The PSA is a validated assessment that allows final year medical students to demonstrate that they have the necessary knowledge, skills and judgement (in relation to the safe and effective use of medicines) to begin their work as independent junior prescribers in UK hospitals.
- The PSA presents learners with realistic clinical cases where they are scored on their performance and receive targeted feedback to improve their future performance.



Promoting Prescribing Safety Assessment

prescribingsafetyassessment.ac.uk

Prescribing Safety Assessment

HOME FAQ RESOURCES WHO'S INVOLVED CONTACT US SIGN IN

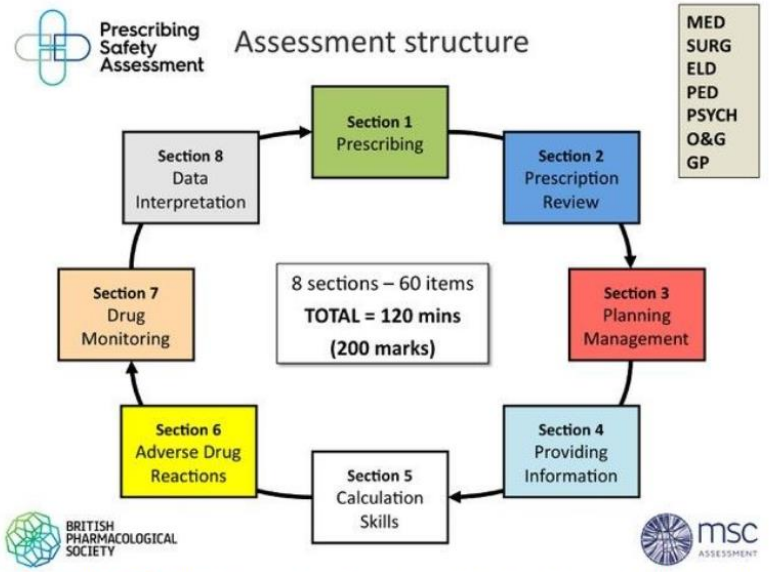
HOME

Home Assessment Structure

The Prescribing Safety Assessment (PSA) is a pass/fail assessment of the skills, judgment and supporting knowledge related to prescribing medicines in the NHS. The PSA assesses the prescribing skills of final-year medical students and is based on the competencies identified by the General Medical Council outlined in *Outcomes for graduates* (originally published in *Tomorrow's Doctors*). These competencies include writing new prescriptions, reviewing existing prescriptions, calculating drug doses, identifying and avoiding both adverse drug reactions and medication errors and amending prescribing to suit individual patient circumstances. The content of each item is relevant to the prescribing tasks expected of an F1 doctor, i.e. the questions refer to ailments and drugs that graduates are likely to be dealing with in year one of the Foundation Programme.

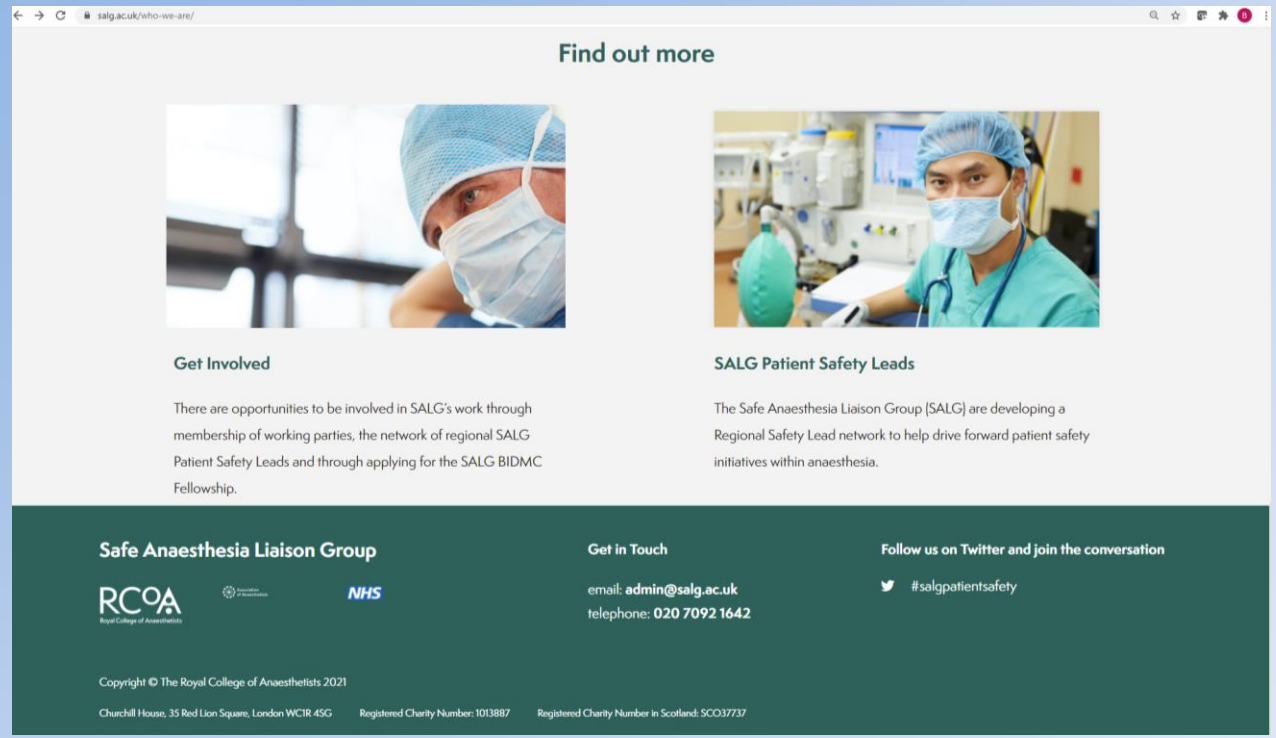
The Prescribing Safety Assessment Blueprint identifies eight different question types, each of which may be set in seven different domains of clinical activity:

Question types	Domains
Prescribing	Medicine
Prescription Review	Surgery
Planning Management	Elderly Care
Communicating Information	Paediatrics
Calculation Skills	Psychiatry
Adverse Drug Reactions	Obstetrics & Gynaecology
Drug Monitoring	General Practice
Data Interpretation	

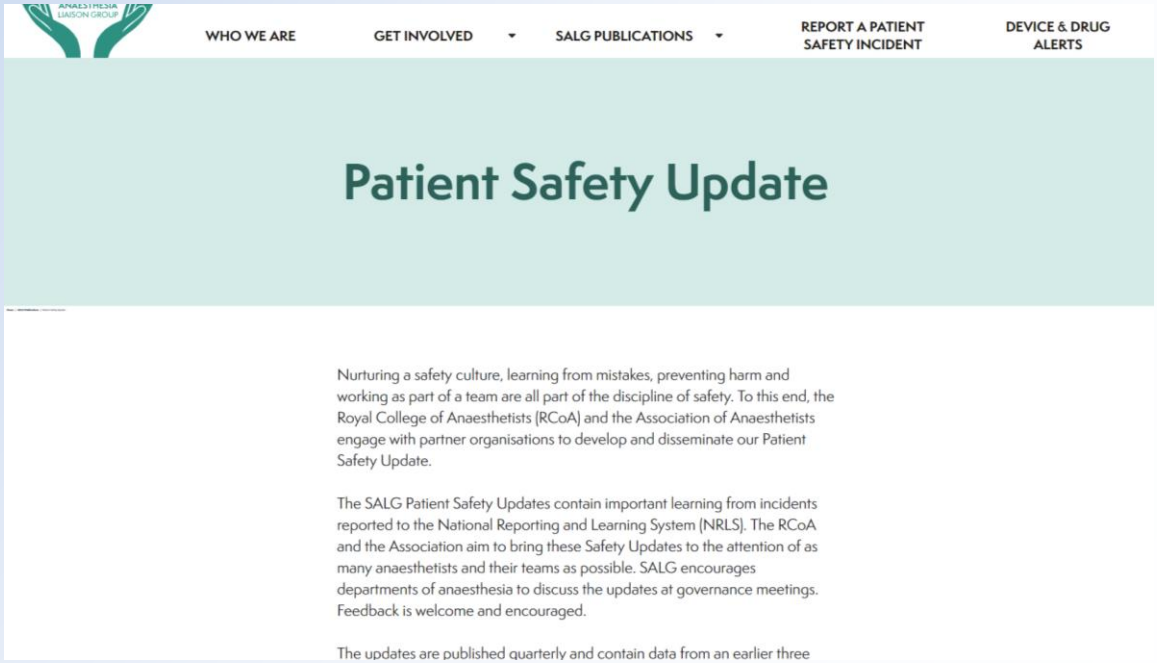


For a better idea of what assessment items look like please see the Example Question Items in the Resources section. Users who are registered by their school to take the final-year PSA gain access to interactive practice papers, which provide examples of what the assessment questions look like.

Reach out to the Safe Anaesthesia Liaison Group



https://www.salg.ac.uk/



Promote Healthcare Safety Investigation Branch

HSIB HEALTHCARE SAFETY INVESTIGATION BRANCH

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About us

We conduct independent investigations of patient safety concerns in NHS-funded care across England.

In this section

- About us
- What we do
- Our purpose and values
- Reports and publications
- Our team
- Our Advisory Panel
- Who we work with
- Partnerships
- Equality and diversity
- Jobs

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England.

Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. The recommendations we make aim to improve healthcare systems and processes in order to reduce risk and improve safety.

Our organisation values independence, transparency, objectivity, expertise and learning for improvement.

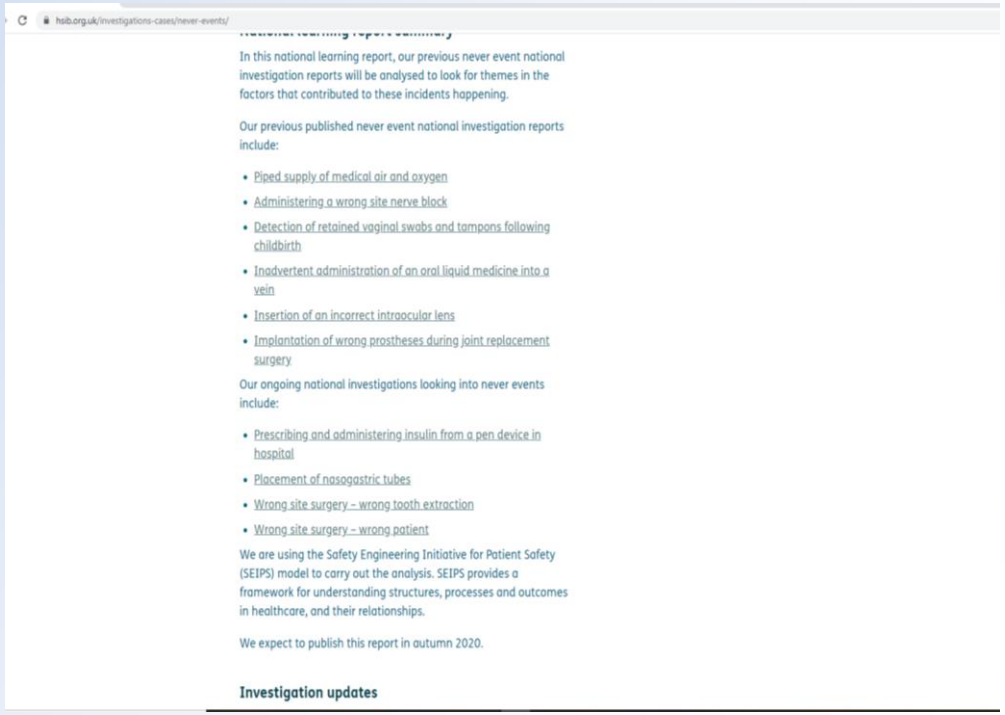
We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

Our investigations

Our team of investigators and analysts have diverse experience working in healthcare and other safety critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes.

National investigations



In this national learning report, our previous never event national investigation reports will be analysed to look for themes in the factors that contributed to these incidents happening.

Our previous published never event national investigation reports include:

- Piped supply of medical air and oxygen
- Administering a wrong site nerve block
- Detection of retained vaginal swabs and tampons following childbirth
- Inadvertent administration of an oral liquid medicine into a vein
- Insertion of an incorrect intraocular lens
- Implantation of wrong prostheses during joint replacement surgery

Our ongoing national investigations looking into never events include:

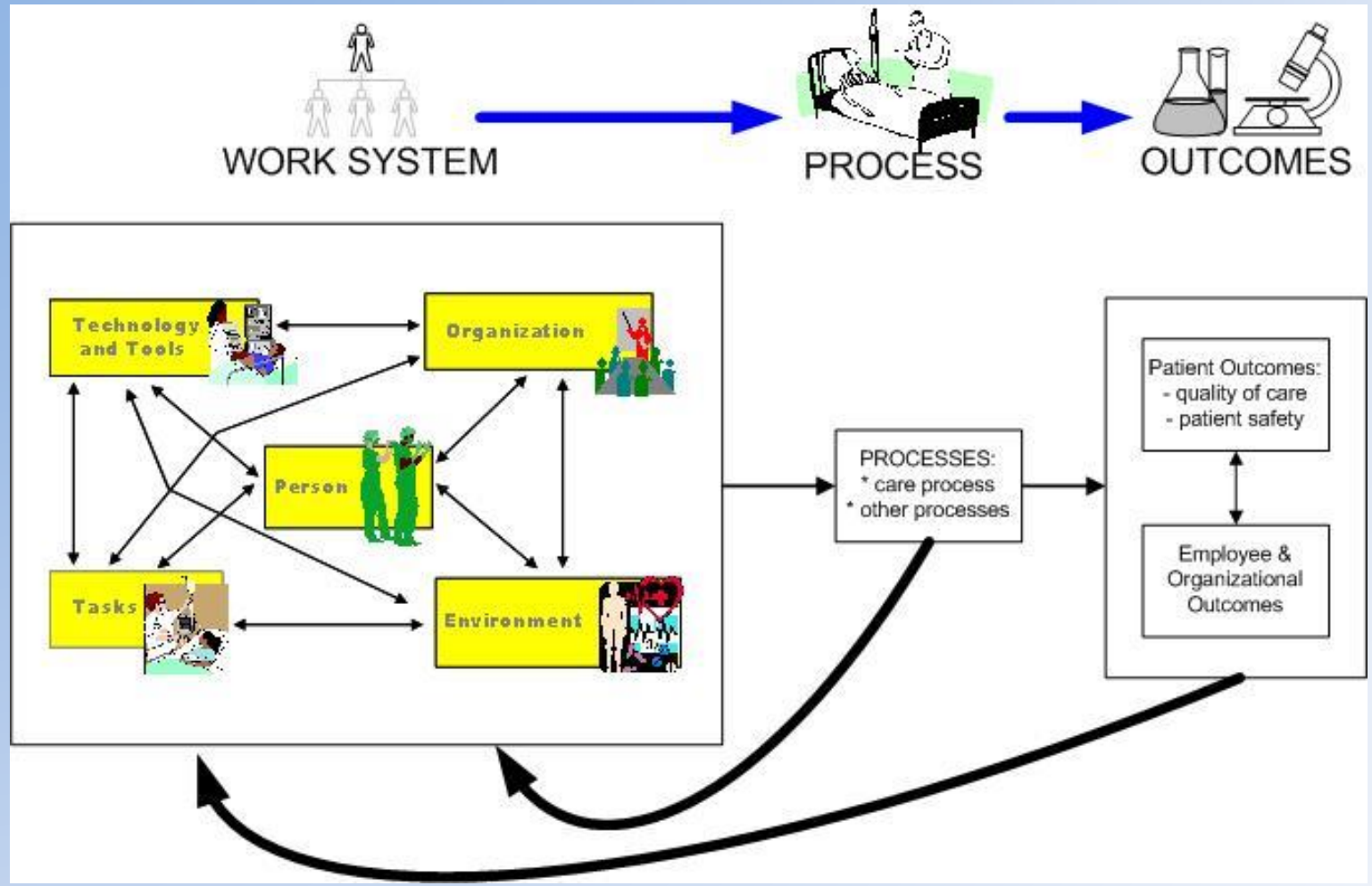
- Prescribing and administering insulin from a pen device in hospital
- Placement of nasogastric tubes
- Wrong site surgery – wrong tooth extraction
- Wrong site surgery – wrong patient

We are using the Safety Engineering Initiative for Patient Safety (SEIPS) model to carry out the analysis. SEIPS provides a framework for understanding structures, processes and outcomes in healthcare, and their relationships.

We expect to publish this report in autumn 2020.

Investigation updates

System Engineering Initiative for Patient Safety (SEIPS) Model



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Carayon et al., Qual Saf Health Care. 2006 Dec; 15 (Suppl 1): i50–i58.

Human factors assessment of labelling: user support programme

- May refer to all or some of the labelling of an individual product
- Priority topic area is risk minimisation of medication error.
- USP can be targeted specifically at one user group or more broadly to all users involved.
- Define a persona of interest which typically reflects the user group under evaluation (such as patients, pharmacists, doctors)
- USP can be conducted face to face or remotely using web-based conferencing

Supporting MSc projects such as EU2P

Creation of a process and questionnaire to assess video-based training materials for adrenaline auto-injectors

Ornella Fauconnot[1], Brian Edwards[2], Dominic Furniss[3]

Objectives

This qualitative study aimed at:

- Evaluating how well Marketing Authorisation Holders (MAHs) of Adrenaline Auto Injectors (AAIs) have communicated about **risks** and **instructions for use** in their training materials
- Determining **what** can be improved in these videos and **how**
- Creating a preliminary process to evaluate training materials in the future

☛ The ultimate goal of this study is to **implement a systematic process** that both regulatory agencies and MAHs can use to assess and validate video-based training material.

Introduction

More and more people are being prescribed **adrenaline auto-injectors** to manage potentially life-threatening anaphylaxis events. These devices now come **with instructional online-based videos**. However, there are not agreed standards for testing the quality and effectiveness of these videos.

How can we make sure that **risks** and **instructions for use** are communicated effectively through these videos?

We sought a systematic approach, using the SHERPA Human Factor analysis.

Training materials of AAIs are available online. To watch, please visit the link: https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-updated-advice-after-european-review.

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Methodology

Creation of a **preliminary process** in **4 steps:**

1. Choice of an evaluation tool
2. Design of a questionnaire using a Human Factors approach
3. Feedback and improvement of the tool
4. Data collection

1. Choice of a questionnaire, Why?

Cost effective, provides fast results from many people, ease of interpretation, flexibility in the design and number of questions.

2. Design of the questions, How?

We performed a literature review on the use of AAIs and the most commonly reported mistakes, to better understand the potential risks related to the use of these devices. Blending this information with results of a form of hierarchical task analysis, called Systematic Human Error Reduction Prediction Analysis (SHERPA), helped us design relevant questions.

SHERPA method in brief

SHERPA is a set of tools to document and risk assess **safety critical tasks.**
The main objective of this method is to understand *how a task is performed in practice,* in order to better identify **vulnerabilities.**
There are **3 main steps**:

- ✓ **Hierarchical Task Analysis**: Instructions for use broken down into different subtasks -> graphical representation interaction user / device.
- ✓ **Failure identification:** Importance and likelihood of failure for each task. *What could possibly go wrong?*
- ✓ **Performance Influencing Factors:** Factors driving likelihood of errors.

Is it task related, device related, or due to context of use?

Fig. 1. Hierarchical Task Analysis of Epipen

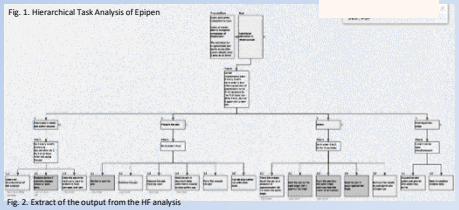


Fig. 2. Extract of the output from the HF analysis

ID	Description	Agent/Person	Warnings	Comments	Activity Type	Failure Mode	Error Description	Observable Outcome	Clinical Consequence	Consequence Type / Severity
1.1	Check for discolouration of the solution.	User/carer/family members		Use the viewing window	Checking	CH1 Check omitted	The solution has not been checked for discolouration	Delay in medical care of anaphylaxis	Lack of efficacity of the active product	5. Catastrophic - Patie death
					Checking	CH5 Check too late/early	The solution is dark when the user needs to use the pen.			
1.2	Replace device if solution changes colour or goes dark.	User or carer, GP		Go to see your GP for a new prescription of the pen. The solution turns dark or changes colour if the date expired or if the pen has been used already.	Actions	AC19 Action omitted	Device has not been replaced by a new one	Delay in medical care of anaphylaxis	Pen not available when needed.	5. Catastrophic - Patie death
1.3	Keep the pen in its hard carry case to protect it from damages and light	User/carer	adrenaline light sensitivity		Supervision	SUP2 Supervision inadequate	Pen not stored in its case, exposed to light or damages	anaphylaxis untreated	Loss of adrenaline efficacity	5. Catastrophic - Patie death

3. Feedback and improvement of the tool

The questionnaire was assessed and reviewed by **4 regulators, 4 Human Fa specialists and 1 pharmacology student**. Feedback helped us to improve not onl quality of the questionnaire including the design of the questions, the logical flow, b also the vocabulary used and the relevance of the questions.

4. Data collection

Respondents of the questionnaire were self-elected volunteers from Allergy UK, a British medical charity supporting adults and children with their allergies.

Criteria for the inclusion in the survey were: to be aged 18 years or over and be a current or former user of adrenaline auto injectors. Volunteers were sent an online questionnaire by email.

Results

7 volunteers — 6 Females — 1 Male

All **had already experienced anaphylaxis** and were aware of the existence of training materials.

Among the various answers collected, it was mostly reported that:

- Communication on risk is **lacking** for the three videos
- Information is not always clear and should be **adapted to younger populations**
- More emphasize should be placed on key points, including the **importance of carrying two AAIs at all times**, and the situations in which these devices should be used (i.e. how to recognize the symptoms of anaphylaxis)
- The design of the videos should be improved to make them more attractive and retain attention of the audience.

Conclusion

- **Lack of transparency** on how training materials are designed and assessed.
- **Poor communication** on risks and usability in the three videos assessed,
- Such videos need further improvements, both in **design** and **contents**.
- The collaboration between Human Factors science and Pharmacovigilance is valuable to **improve communication on risks and usability**
- The implementation of a systematic process in the future will enable to **better validate training materials, improve communication and transparency.**

References
1.(PDF) SHERPA: A systematic human error reduction and prediction approach [Internet]. ResearchGate. [cited 2019 Mar 29]. Available from: https://www.researchgate.net/publication/289067701_SHERPA_A_systematic_human_e rror_reduction_and_prediction_approach
2.Latest data from NHS digital show allergy hospital admissions have increased by 33% in five years [Internet]. Anaphylaxis Campaign. 2016 [cited 2019 May 3]. Available from: https://www.anaphylaxis.org.uk/2016/10/11/latest-data-hscic-shows-notable-increasenumber-hospital-admissions-allergies-anaphylaxis-across-englan/
3. Human Factors for Health Technology Safety | IFMBE Clinical Engineering Division [Internet]. [cited 2019 Mar 29]. Available from: http://cedglobal.org/human-factors-forhealth-technology-safety/
4. Anaphylaxis in children and adolescents: The European Anaphylaxis Registry - ScienceDirect [Internet]. [cited 2019 Mar 29]. Available from: https://www-sciencedirectcom.docelec.u-bordeaux.fr/science/article/pii/S0091674915029917

Conclusions

- We provide a neutral and impartial forum for all stakeholders including patients: we were represented on CIOMS group
- We have created opportunities for researchers and professionals to share their work and publicise it.
- Promoting prescribing safety assessment is an effective way for supporting prescribers.
- By looking at case coding and investigating new approaches such as SEIPS this will help find new solutions
- We have been involved in arranging past training medication errors and will continue to do so
- We have an active and thriving infographic strategy with a growing You Tube library (https://www.youtube.com/channel/UCo-jtROXZbiDk_1GLxzThzQ)
- None of this possible without enthusiastic and energetic support of SIG members and project management support (Peishan Liu/Alem Zekarias). I cannot thank them enough.
- But now looking to the future…..

Vision

Make it easier for people to do their work, and optimise human performance within the global healthcare product sector and systems to support patient outcomes

Goals

Collaborate as an experienced community of practice. Share meaningfully how human performance capability delivers value for all

Connect and engage key stakeholders including patients, manufacturers, suppliers and regulators to include human performance in strategies and approaches.

Values

Create a diverse learning group across sectors and disciplines including Industry, Academia, Consulting experts, Professional Associations, Regulatory authorities

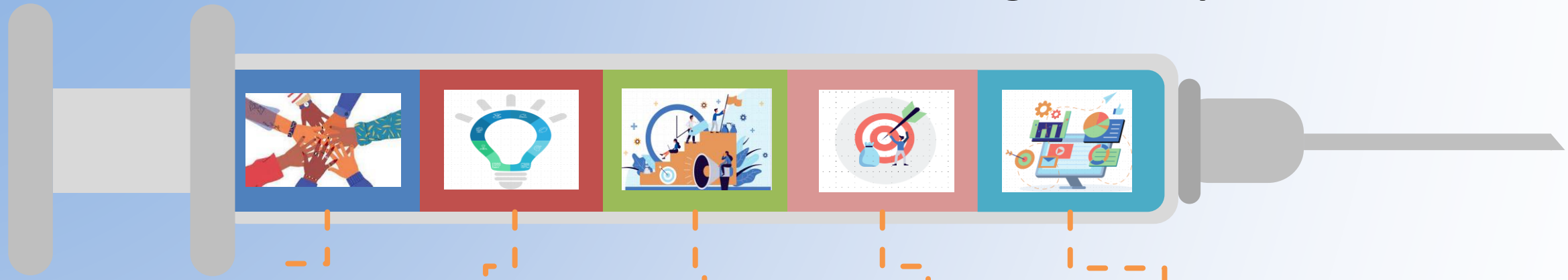
Engage to make concepts and language more accessible and inclusive to promote application in existing systems for everyone

Pharmaceutical Human Performance Sub-group

VISION, GOALS & VALUES

Inject practical help into the system

Draft Healthcare Product Guiding Principles



Inclusion

Help *everyone* have a voice to share ideas & concerns safely and constructively

Values

Human Factors as an imperative for Leaders focus on improvement

Our response matters

Set people up for success

Examples of successful application of human factor methodologies e.g., Pre & post job reviews

Focus on Important

Focus on improvement

Our response matters

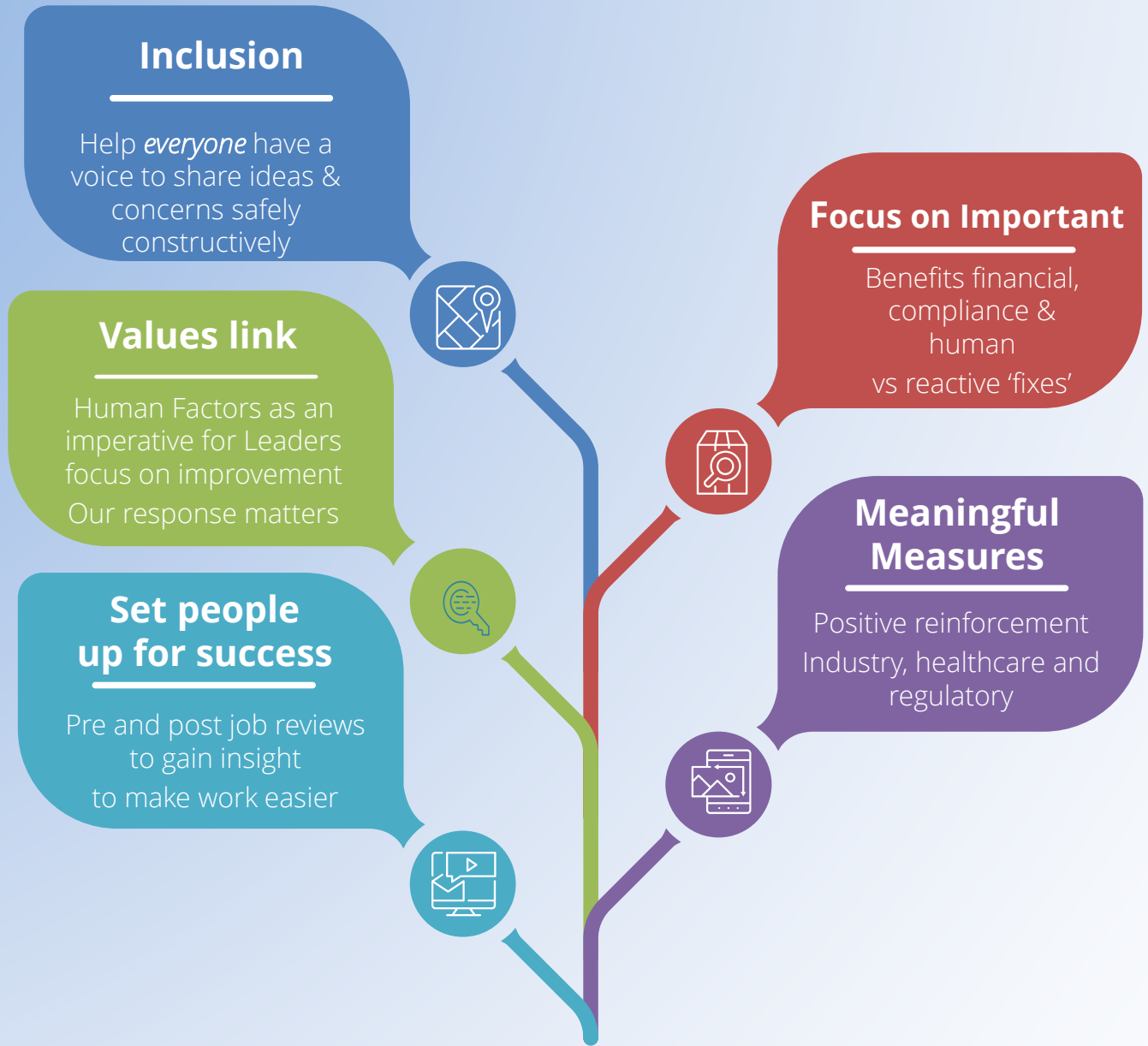
Financial, compliance & human benefits

Meaningful Measures

Positive reinforcement

Industry and regulatory

Healthcare Product Guiding Principles



Suggestions for collaboration IMSN and ISOP

- Joint working group to collate evidence and develop education and training using systems techniques such as SEIPS in investigating and preventing medication errors

- Develop an international community of practice focussed on human performance and prevention of medication errors underpinned by guiding principles

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