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Pharmaceutical Sector Group

Summer 2024

NEWSLETTER

The Pharmaceutical Sector Group has continued to make great progress across the multiple projects we have ongoing, thanks to our outstanding group of volunteers. This edition of the newsletter is an update on various group activities and a guest contribution to the MSc Pharmacovigilance course at the University of Hertfordshire.

Guest Contribution:

HF in Hospital Practice

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Chartered Institute of Ergonomics & Human Factors

A message from the Co-leader

We have taken time to rethink our strategy, regroup and choose our priorities we have established a new Sector Engagement Plan which is a document outlining our focus and activities. Julie Avery has continued to organise regular online sessions and presentations. An important step in choosing our strategy was a meeting CIEHF arranged in Birmingham last November where key opinion leaders in pharmaceuticals met to discuss a better system for pharmaceuticals and devices. Our thanks go to Ben Peachey for arranging and chairing this. In summary, the participants agreed that our Group's priorities should include bringing human factors techniques into drug and device development, improving information loops between healthcare professionals, the pharmaceutical sector and regulatory bodies and be conscious of the need to be consistent with building out shared definitions of key terms and product categories (such as might be found in the human factors toolbox). As a result, three specific projects are underway. The first is a collaboration with Safe Anaesthesia Liason Group (SALG) (https://www.salg.ac.uk/) and the Association of Anaesthetists to help validate the place of prefilled syringes with high-risk medicines in improving human performance and so enhancing safe use of these products. The second is to explore better ways of investigating the pharmaceutical system based on the success of Health Services Safety Investigations Body (HSSIB) and what we can learn from other sectors. Currently there is no investigative framework for the entire pharmaceutical or device system and poor organisational learning. Thirdly, we are still keen in moving forward with draft guiding principles for human performance based on what Julie and I have learnt from the manufacturing subgroup as well as incorporate wellness as part of the definition of quality. These principles could be applied across the system to help enable closer cooperation and communication focussed on improving human performance. Our Group wants to take a leadership role in coordinating collaboration with other organisations such as International Society of Pharmacovigilance (ISoP) (https://isoponline.org/) and International Ergonomics Association (IEA) with common aspirations and objectives to improve the systems for medicines and devices.

So, if you are a CIEHF member and want to know more and take part, please sign onto our community page where you will be invited to our regular meetings and other events. Finally, I would like to welcome to Dr Carlos Aceves-Gonzales as Senior Lecturer at the University of Derby who moved to the UK in February as he will be playing a key role in supporting our strategy.

Thanks to the contributors to this newsletter and Gary Guan and Colin Knight for putting the newsletter together and doggedly reminding me to contribute to it!

Written by: Brian Edwards
CIEHF Pharmaceutical Sector Group Co-Leader

Photo by Pixabay

Pharmaceutical Sector Training & Education

I would like to start this brief report by advising the group that one of the core team members has recently retired from her role in Pharmacovigilance.

Anne Lloyd who was one of our Core Members in the Pharmaceutical Sector Group has taken retirement. We would like to place on record our thanks to Anne for her valuable contribution to the life and activities of the group, and the connection she provided with Pharmacovigilance and Medical Information colleagues in the Pharmaceutical Information & Pharmacovilance Association (PIPA) organisation. We wish you a very happy retirement Anne.

We continue to maintain our links with the University of Hertfordshire (Hatfield campus) so that we can support their MSc Pharmacovigilance students with MSc HF projects that the students can take advantage of.

We are keen to maintain those good links that we have established as a group over the last 8 years, and they have always welcomed MSc projects that we can offer to their course students.

A similar course is now run at the University of Portsmouth, which is coordinated by our friends at the Drug Safety Research Unit (DSRU). I will also be discussing with them the HUF projects that we may be able to offer them as they arise.

Theme contributors:
Colin Knight (Theme Lead)
Gary Guan
Rosemary Lim
Andrew Parsons
Angela Carrington
Brian Edwards

Written by Colin Knight
Retired Pharmaceutical Scientist

Using HF to take a Whole System Approach to Medication Safety

Throughout my career I have developed and grown my knowledge and experience in patient safety. I always had an appreciation of Human Factors (HF) but through my Chartered Institute of Ergonomics and Human Factors (CIEHF) membership, I recognised that I had a knowledge gap as I became increasingly aware and exposed to application of HF principles and tools that were new to me.

I decided to embark on more formal training and the distance learning course at Staffordshire University suited my personal and learning needs. I was attracted to the curriculum content which is aligned to the CIEHF competencies and the course is also accredited by the CIEHF and led by experienced HF specialists. The flexibility of the course meant that as teaching sessions were recorded, I could catch up in my own time; fitting this around my work and busy home life and an added bonus is that it is assignment assessed; so no exams!

Undertaking the course was an enlightening experience. I've come to appreciate that HF is truly a scientific discipline that applies scientific rigor to understand better and improve work systems that impact on performance and well-being. Learning about the extent of application of HF in other high risk critical industries and the range of standards produced by the International Standards Organisation and British Standards Institute, that govern work system requirements was fascinating. I also developed an improved appreciation of people factors e.g. anthropometrics, biomechanics, psychological and sensory capacity, and the impact that these have on the design of work systems which also considers the physical environment, the tasks and equipment. For one course assignment I had to do an environmental Human Factors assessment, so as I was working from home, I assessed my home office. I learned about how light, temperature and room capacity impact on my performance, wellbeing and ability to do my job. In fact, I realised that my light bulb emitted too much warm light and I actually needed a high blue-content bulb to increase my alertness.

For another assignment I had to analyse an educational training video and website on how to use an inhaler safely. It was really fascinating learning about inclusive, user-centred design which considers people's physical, cognitive and social attributes. I'd certainly never encountered the term 'anthropometry' before—the scientific study of the measurements and proportions of the human body. As a mum of three children and with two elderly parents, I can really see how designing safer medication and information can't have a one-size-fits-all approach, and we need to move away from designing to suit the 'average' individual, as they don't actually exist.

Since completing the Postgraduate Diploma I am championing greater awareness and education of HF principles and methods within Northern Ireland.

This is paramount to the successful delivery of Transforming Medication Safety in Northern Ireland (TMSNI). This is the Northern Ireland Department of Health's (health-ni.gov.uk) response plan to the World Health Organization's third Global Patient Safety Challenge, Medication Without Harm (who.int). I assisted in developing this and am now responsible for leading its implementation.

TMSNI details specific aims and commitments that are aligned to the four domains of the Challenge: Patients and the Public, Healthcare Professionals, Systems and Practice and the Medicines themselves. HF is recognised as a key enabler of the strategy, along with collective leadership, quality improvement and ehealth technology. Key activity to date:

• Collaborating with HF/E specialists, Professor Paul Bowie and Dr Helen Vosper, to introduce HF to community pharmacy with a focus on insulin safety and application of SEIPS (Systems Engineering Initiative for Patient Safety), an HF tool developed specifically for application within healthcare.

• Supporting the trusts' medication safety pharmacists to develop their HF skills. This has enabled a redesign of the undergraduate interprofessional medication safety training at Queen's University using a hybrid of simulated recorded video and classroom based training. It focuses on the medication safety management of complex antimicrobials using SEIPS, to examine the interacting system elements and their outcomes on performance and well-being. Also in response to major changes to UG pharmacy curricula where pharmacists will graduate as prescribers, the introduction of systems thinking concepts is an incremental approach to help students build their own systems thinking mindset and equip them with these skills in the workplace.

• Introducing systems thinking concepts to regional learning Project ECHO session on serious adverse incident reporting focused on wrong route administration errors with oral morphine liquid.
• Awareness and application of HF to the regional opioid safety collaborative improvement programme and real-world application of SEIPS to support design of a patient information leaflet.

The TMSNI programme recognises that collective leadership and co-design is essential for its delivery. To support further design of the programme, we plan to offer stakeholders HF awareness and skills to enhance their capability and capacity and apply their learning to help develop current and future TMSNI work streams.

Ireland, led by Trinity College Dublin, has been awarded the host country for the next Healthcare Systems Ergonomics and Patient Safety (HEPS) conference 2025. This will provide an opportunity for policy and decision makers on the Island of Ireland to learn about the benefits of HF integration within healthcare and to consider how this can be achieved at scale. As medication is the most common cause of preventable harm in healthcare, this will also be a feature of the conference programme.

My links with the Pharma Sector Group supported an exploration of the patient safety issues where glucose solutions have been inadvertently and incorrectly used to flush arterial lines. This had led to inaccuracies in blood glucose measurements, resulting in unnecessary insulin administration and patients have suffered from severe or fatal hypoglycaemia. This is a known patient safety risk but despite awareness and national recommendations, still continues to occur. The labelling and packaging of intravenous fluids is a latent hazard that puts healthcare professionals at risk of selecting the wrong product because of indistinguishable appearance. They are presented in clear colourless packaging with similar naming design and layout.

At the same time this patient safety concern became the focus of a Health Services Safety Investigation Body (HSSIB) national investigation. I was able to represent the CIEHF Pharma Sector Group at their stakeholder engagement workshops and provided peer review to the final report.

HSSIB acknowledges the need for improved regulation to develop design guidance on labelling and packaging of fluids to reduce selection errors. Whilst this reference event was specific to arterial lines, wrong fluid selection has caused fatal harm in other situations. For example, hypotonic fluids incorrectly given for maintenance fluids for children undergoing routine surgery, incorrect fluids used in management of critical conditions such as diabetic ketoacidosis, water for injection used for bladder irrigation and solid organ perfusion fluids administered intravenously.


Photo by Pixabay

This is a global issue and more needs to be done in this area. Despite advances in automation with electronic prescribing, SMART drug cabinet storage and barcode administration, fluids continue to be mis-selected as these are not failsafe controls. The products are malleable and can be difficult to scan and sometimes don't present with a barcode. Staff inevitably develop workarounds in order to get the task done. Look alike, sound alike errors are a leading cause of all medication errors and if there could be a united international effort that applies HF principles to improve fluid packaging, we could make significant impact on achieving 'Medication Without Harm'.

Written by Angela Carrington
Lead Pharmacist for Medication Safety in Northern Ireland

Angela has 25 years' experience in the healthcare sector underpinned by 17 years in dedicated strategic and operational medication safety roles. She is nationally and internationally recognised as a medication safety lead and expert and has provided medication safety consultancy for the World Health Organisation. She plans to start a PhD later this year focusing on the development of an ePrescribing safety assesment framework.

The System Layers of Medication Safety

Everyone at **every** level is **responsible** for medication safety

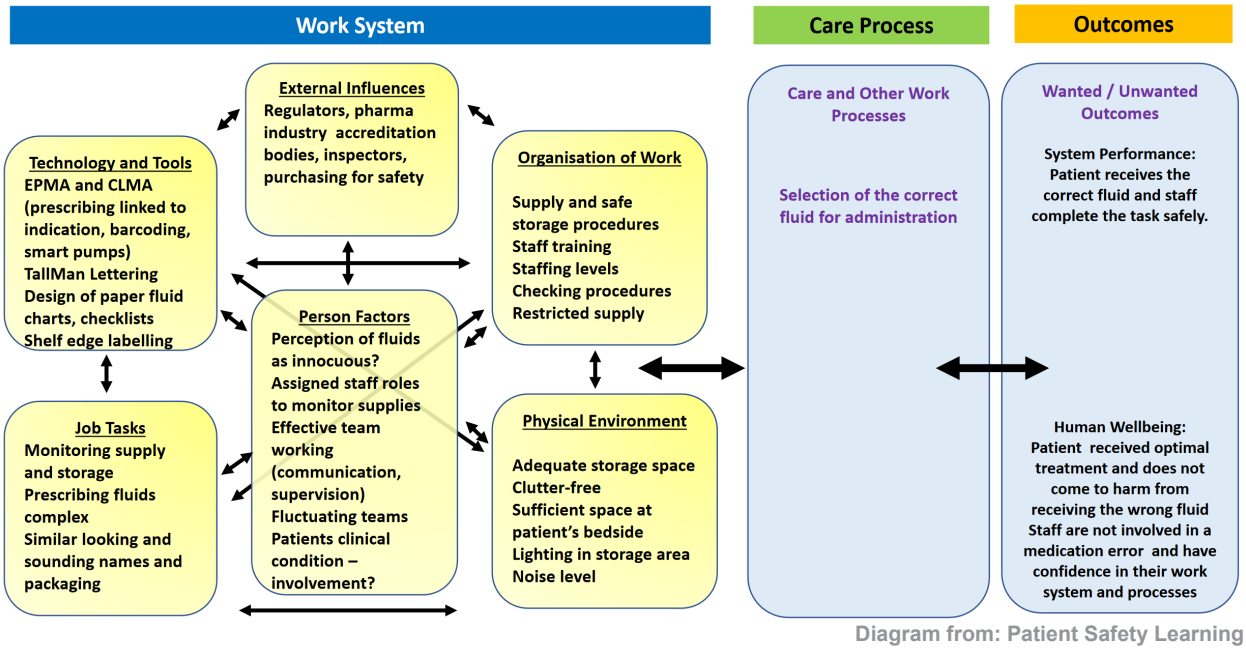


Diagram from: Patient Safety Learning

HF in Pharmaceutical Manufacturing

Overview

Our group works with the wider Pharmaceutical group to engage the Healthcare 'system' , regulators, healthcare providers, pharma industry from R&D, Clinical trials, Manufacturing and patient groups in how human performance can support their goals. Identifying opportunities where we can to engage.

We had a busy year and enjoyed the company of some expert speakers at our meetings to provoke discussion and permit exploration of the some of the common challenges we face as an industry. We are all advocates for human performance in our companies and networks and it's great to have a place to share stories and learn.

Our mission is to engage our stakeholders including industry and regulators to understand and explore how to integrate human factors into existing systems to support patient outcomes and business goals. We struggle whilst the industry cling on to what is, at times, out-dated thinking – single root cause, and causal tools of limited effectiveness e.g. 5-Whys and over-reliance on long, confusing standard operating procedures which are 'trained' out by 'Read and Understand'. There is a ground swell now to move toward a more integrated approach for compliance, education and organisational learning at system level.

One tangible example is the 2023 industry standard update ICH-Q9 which drives more risk-based approaches to pharmaceutical manufacturing. Human performance mental models tools are an effective way to achieve this.

Vision

Make it easier for people to do their work, and optimise human performance within the manufacturing pharmaceutical 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, CIEHF

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

Our meetings
It is great to hear from members about the opportunities they have created and developed to make work easier and improve quality and safety outcomes.

Practical examples of implementation, integration and associated change management and engagement provided us with unusual insights from Pharma and other sectors – we found all speakers wonderfully generous with their time and insight. Many follow up conversations are had after these events.

Highlights
"Helping business understand and manage variation" - Speakers from Astra Zeneca shared their effective integration of human factors with lean manufacturing principles and systems in the Safety and Quality space. Appreciating human error as a normal variation in process can be transformational in the mental model organisations hold and promotes learning.

"Do Quality Differently" – an excellent insight and chance to talk with joint authors Amy Wilson and Cliff Berry on their insightful playbook, sharing experiences and case studies of how to integrate human performance into your organisation for risk reduction and improved KPIs.

We heard from one of our members Mrs. Nilanjana Basu, about her experiences working in Indian Pharmaceutical companies when applying human factors strategically and tactically

Members from Merck shared how they focused on Integrating knowledge management into existing systems which helped us explore a common industry issue – how to maintain organisational learning when experienced people move to other roles or leave the business. I have not seen such a thorough and genuinely applied strategy in this area before.

We learned from The Human Diver Gareth Lock about his passion in campaigning for safer diving and developing capability in human factors – Gareth is a prolific author. Check him out on LinkedIn for examples and he is now sought by many sectors to inspire their leadership and teams. Our Christmas present was a session with the amazing Steve Shorrock who I personally cite and quote endlessly in my work "Whose work is it anyway" – really struck a chord with the group as we all find that despite our best organisational efforts we still don't always set people up for success.

Thanks to everyone for your support and input during the year – facilitating this group is really great fun for me and a wonderful chance to learn.

Written by Julie Avery
Director of Chatham Consulting

Human Performance Learning from the Best

Adopting the principles and practices of human performance has led to valuable business, quality and safety performance improvements in high-risk high-consequence industries including energy and aviation.

Eager to realise similar levels of improvement, companies in the pharmaceutical and biopharmaceutical manufacturing sector have begun the adoption of human performance principles.

However, our unique industry context and regulatory environment has proven the adoption of human performance principles and practices to be challenging and complex.

HF in Organisations - What needs to happen

In the aftermath of a headline-making industrial accident, how often do we hear the line that lessons will be learned? In such a situation, one I have heard described memorably as a “brutal audit”, it is only natural to question how lessons will be learned because if an organisation allows a serious event to happen, then it is hardly equipped to prevent a reoccurrence. Unless the organisation changes and improves and it is this which is the running theme of the CIEHF 2020 white paper on Learning from Adverse Events.

It is fast approaching five years since I reviewed what was the draft for the white paper. At the time of the review, I could not work out whether the paper was breaking new ground or in fact a timely reminder of widely understood principles. My brief though was to provide comments on the content as a source of guidance and support for organisations that wish to adopt good practice in HF but lack in-house professional skills and expertise in the discipline. I was reminded that the paper was not intended either as a review of the knowledge-base or a “how-to” guide. Rather, the objective was to identify and set out several principles that reflect what constitutes good practice in investigating and learning about the human contribution to adverse events.

In recent months I have returned to the published paper, but this time searching for pointers on how to operationalise learning from process safety incidents that have the potential to cause multiple fatalities as well as physical damage to commercial and community assets and the wider environment. In this new guise, as a user of the content, it is striking that the paper places organisational learning at its heart and then from there makes the case for how the investigation of adverse events supports and enables that learning. In effect, the paper focuses exclusively on learning investigations, a term coined by the paper, whose express purpose is system improvement. This is a novel approach because many texts on incident investigation start with the process of investigation and then as an afterthought bolt on some nebulous observations on learning from failure. The paper flips the convention and both the investigation and learning process are presented as a coherent whole primarily through the observation of explicit principles that incorporate human factors into learning investigations.

The stated principles, nine in total, set out what good looks like and will undoubtedly resonate differently with readers and users. For me, the first principle, be prepared to accept a broad range of types and standards of evidence, is perhaps the most radical. The received wisdom in incident investigation is to uncover the facts or hard evidence, often at the expense of informed judgment or opinion, which are then separately corroborated through interview, observation, and documentation. This can pose too high a bar for a truly learning investigation. A second principle, that works in tandem with the first, is centred around local rationality and consideration of both the situational and contextual factors associated with the adverse event. The paper makes a persuasive argument for consideration of those factors which are not necessarily observable but influence the way people behave when placed in certain situations. This requires the learning investigator to get into the hearts and minds of those involved in the build up to an incident and to understand the internal preoccupations and external distractions that can influence behaviour and decision making at critical junctures.

Later in the paper, two principles can be considered to represent sides of the same coin. The first is for organisations to accept that learning means change and the second is to understand that learning will only be enduring if change is embedded in a culture of learning and continuous improvement. An absence of the latter is often the reason why the actions from an investigation can be subsequently criticised and undermined especially if those actions require concerted effort to complete. It is not unheard of for such actions to remain incomplete some considerable time after the investigation. To avoid such a scenario, the paper places great emphasis on treating the intended changes as part of a formal change management programme as illustrated in the schematic.

There is much to admire and hopefully inspire in the white paper with several case studies, quotes and explainers peppered throughout the document which underpin the principles. The paper raises some key points for debate – for example is local adaptation simply a natural reaction to poor engineering design and end user training or is it a healthy sign that front -line staff are taking ownership of the asset and in effect, completing the design? That said, I have a couple of minor quibbles. The section on planning for investigating incidents is more of a justification for the use of structured incident analysis methods rather than on the planning itself and the paper concludes with a short section on knowledge management which opens another significant topic which would have been better left to a subsequent paper. I would also take issue with the intended audience of the paper which I feel would benefit organisations, and certainly those across the high hazards sector, irrespective of whether they have recourse to inhouse expertise or not.

In summary, the single take- away message from the white paper is that there should be no investigation without learning and no learning without change. Businesses would be wise to take note.

Download the white paper here: https://ergonomics.org.uk/resource/learning-from-adverse-events.html

Written by Lee Alford
Halcyon Safety

From Learning from Adverse Events, CIEHF

HF and the impact on Wellness


Photo by Inzmam Khan

The concept of salutogenesis was developed by medical sociologist Aaron Antonovsky in the 1970's and 1980's. He explored the resilience of individuals exposed to high levels of stress.

Instead of a binary classification of healthy or not, he proposed a continuum from healthy (salutogenic) to disease (pathogenic). Salutogenesis means the process of promoting and enabling health. It is complementary to approaches focused on treating disease.

It is a holistic approach that considers all aspects of the person, their communities and their workplaces.

Key factors that promote health are the ability of the individual to access and develop useful resources within themselves and identify and use those available to them. This ability can be predicted by a mindset termed a sense of coherence which involves engaging with useful beliefs regarding meaningfulness, an ability to manage and understanding how life is structured and how it impacts them and things they care about.

Over the last 40-50 years this approach has been validated across cultures and provides a robust approach to supporting mental wellbeing.

Mental health challenges are a significant source of morbidity. In the UK nearly half of people believe they have had a mental health problem in their lives. Many of these have not been diagnosed by a medical professional and therefore cannot access traditional support, leading to a potential large number of people experiencing significant challenge in their personal and professional lives without medical support [4].

Nearly 1 in 7 people experience mental health problems in work. The impact of this radiates to colleagues, families, communities and to the business. Improving mental health support has been projected to save UK businesses up to £8 billion per year [5]. Sickness rates and presenteeism are still high in many organisations [1].

These trends are also noticeable in the BioPharma industry. According to Great Place to Work (2023), 44% of UK employees in the BioPharma Industry feel excessive stress due to the demands of their job and 48% of respondents feel exhausted [3].

The Biopharma Workplace is one of high demands. In Biotech, the funding cycle for many companies is one of high uncertainty and high risk. There are high demands, tight deadlines and little margin for error or delays. With funding comes the need for rapid growth and the transition of scientists into managers and leaders. These create additional demands and potential sources of pressure for both the individual and the organisation.

Within larger Pharma organisations, there is an increasing role for Medical Affairs and R&D teams to be more heavily involved in marketing, business development and technology development.

Resilience and wellbeing management are therefore a key skills and practices in the modern BioPharma Industry and many companies have policies and ways of working in place to support health and wellbeing. CIPD (2023), the HR professional development organisation, report that over half of organisations have a formal policy [1].

If this is the case in the BioPharma sector, what is going wrong?

With nearly half of UK employees feeling exhausted and stressed there certainly seems to be an opportunity to improve engagement, performance and wellbeing within this sector.

A recent large-scale study may provide some insight. William Fleming recently (2023) reviewed the impact of wellbeing initiatives on over 46000 individuals in over 200 organisations. The interventions were individual based. There was limited, if any, benefit.

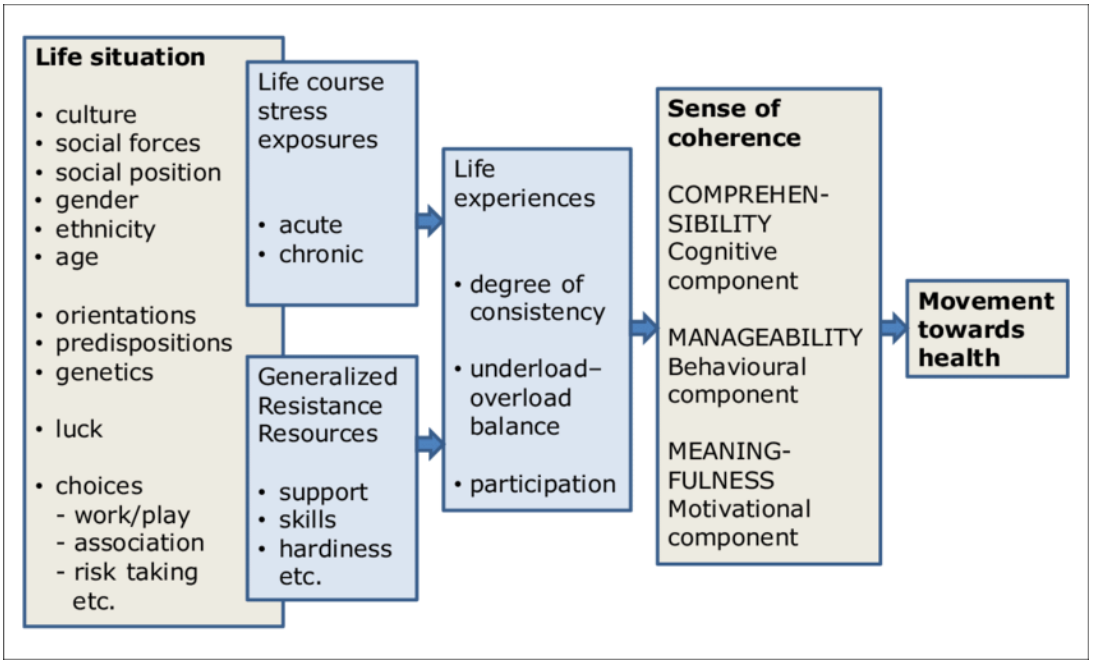
An overwhelming conclusion is that just focussing on the individual has little impact on overall mental wellbeing.

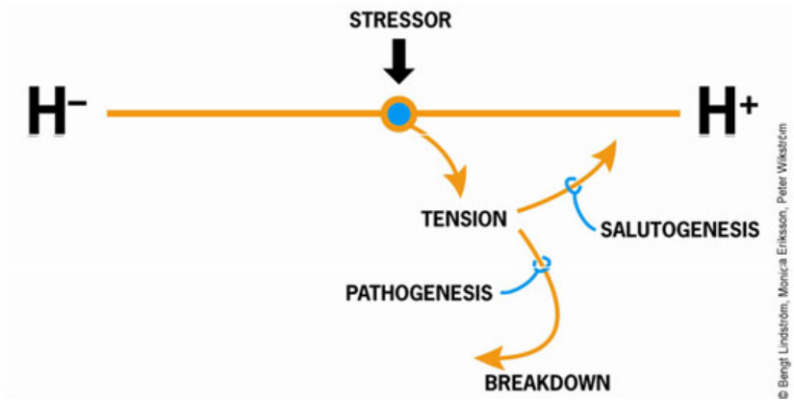
However, some consideration to the pathogenic or salutogenic orientation of the intervention many be warranted. A pathogenic orientation will focus on treatment and prevention and typically involve standardisation of processes to measure the effect of that intervention on a population of individuals.

In contrast, a salutogenic orientation will focus on the individual, their situation (eg the workplace) and their communities.

Mindfulness interventions provide a focus for highlighting the difference between these 2 orientations. In the broadest sense, Mindfulness is a way of being. Meditation can be seen as a practice that can bring a state of mindfulness.

Diagrams to show the Salutogenesis Model





Antonovsky explained that everyone is positioned on this horizontal line. Where H- is the total absence of health and H+ is total health, we encouter stressors on a daily basis and it shows that salu-togenesis takes us a step closer to total health.

From an outcome perspective, how can a state of being, be assessed from participation in a training programme? There will be a continuum of learning as with all training programmes which will impact the overall benefit, typically assessed as wellbeing or quality of life. There will be many individual environmental and community-based issues that will impact an individual's ability of attaining this state of being.

From a large study of mindfulness interventions in a school setting to improve mental wellbeing involved over 28000 students there was little or no benefit [6,8]. The Principal Investigator concluded "for any intervention to work, we must consider a range of factors from individual to societal" [8]. One size does certainly not fit all. Involving people in the design and use of such interventions was a key learning.

For Ergonomics and Human Factors Professionals, a salutogenic orientation may provide a useful approach for design, development and implementation of interventions to deal with the rise of mental health issues in the BioPharma Workplace. A salutogenic orientation provides a way to consider issues before embarking on any intervention. It provides an opportunity to tailor not only content, but also how it can be communicated to the different cultural and diverse groups in the population under investigation.

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Written by Andrew Parsons
Director of The Conscious Workplace

Photo by Marcel Strauss

Group Administration Contribution


Photo by Andrew Neel

November 2022. This was when we released our last newsletter, how quickly time has gone by. The group celebrates 8+ years since Brian and Colin set it up. However, I would like to thank our amazing members for their continued support of the group. This newsletter is a great example, as we have had a record number of contributions from members.

2023 got off to a slow start, with the trial for the new meeting structure not being as efficient as we anticipated and it did not increase the engagement. One of the factors is likely to be due to COVID as all members were extremely busy. We continued to review our engagement plan for the 2023, and managed to organise a face-to-face roundtable discussion on the topic “Designing a better system for medicines” in November of last year. People attended from various backgrounds from industry to academia and regulatory. There were interesting discussions throughout the day with some thought provoking points raised.

The meeting minutes for the discussion have been produced and if you would like a copy then please get in touch with me. Some of the next steps which we outlined included integrating human factors techniques into the development of medicines and drugs and looking at ways to improve the information loops between healthcare professionals and the regulatory bodies. We will be looking to progress this, and we are currently planning the next meeting. If you would like to participate then please let me know.

The CIEHF is also celebrating its 75th anniversary. Myself and Brian managed to attend the CIEHF Ergonomics & Human Factors conference in April. It was also great to see Pharma SG member Clare Crowley give a talk about her work around understanding the variability in acute hospital care of adults with a learning disability. Tracey Herlihey gave a talk about using a human factors approach to develop a learning toolkit for the NHS, and there were a whole host of other healthcare-related presentations. Brian also managed to network at the event so our group will be having some new members joining shortly.

The group will be looking to become more active during the remaining part of 2024 as we plan further activities and meetings. If you have any suggestions of what you would like to see us incorporate then please get in touch. I am also really excited to welcome Carlos Aceves-Gonzales. We worked with Carlos in previous years as he was leading the Latin America Human Factors Group called RELEASA.

Written by Gary Guan
Pharmaceutical Sector Group Administrator
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