Understanding work-as-planned and work-as-done in biomedical laboratories

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SUMMARY

An important concept in Safety II is distinction between Work-as-Imagined (WAI) and Work-as-Done (WAD). As in all industries, there are gaps between WAI and WAD in the biomedical laboratories, these concepts are poorly studied and understood. This study interviewed 15 biomedical lab workers to understand the gaps between WAI and WAD and how they were addressed.

KEYWORDS

Biomedical laboratories, workplace trade-offs, work-as-planned vs work-as-done.

Introduction

Gaps between work-as-imagined (WAI) and work-as-done (WAD) have been studied in many industries, but such concepts have not been applied to work in biomedical laboratories. WAI takes the form of Standard Operating Procedures (SOPs) and work instructions, developed with a mental image of how work should be done. WAD is the way in which work is really done. Safety in biomedical laboratories is managed through a Biorisk Management System (BMS) that addresses biosafety and biosecurity in an integrated manner. A fundamental purpose of BMS is to contain the risk posed by biological material where the work necessitates the presence of such material. Depending on the local work situations workers will not follow the written procedures exactly and will make adjustments based on experience and know-how. This study aims at understanding the gaps between WAI and WAD, the rationale of why the workers made the deviation and how the deviation is handled in biomedical laboratories.

Materials and Methods

Biocontainment is a combination of primary and secondary barriers, design of facility infrastructure and air handling units, facility practices and procedures, and safety equipment, including personal protective equipment (PPE). Biocontainment is described as biosafety levels (BSL) 1-4, with 1 being the lowest and 4 the highest level of containment. SOPs and work instructions are a key part of ensuring safety and productivity are maintained as part of the containment principles to ensure that workers and the environment are protected. BSL-2 is the most common type of biomedical laboratories. This study used convenience sampling method was used to invite 15 BSL-2 laboratory workers from different regions of the world to participate in the study. This study used the one-on-one semi-structured virtual interview method using key questions and topics (Table 1) to understand and explore the participants' opinions and experiences. This allowed the discovery of information which may be important to the participant but was not known to the interviewer prior to the interview thus allowing the interviewer to explore other dimensions of the research question.

Table 1: Interview questions

1. Demographic information
2. Are there safety SOPs/regulations in your lab?
3. Were you part of the team that established the safety SOP for your lab?
4. Do you deviate from safety SOPs/regulations
    i. Which is a common deviation?
    ii. What is the common reason for you to deviate from the safety SOP?
5. Do you know what Dynamic Mental Risk assessment is? *.
    i. Do you do Dynamic Mental Risk assessment
6. Do you think that the safety SOPs provides room for flexibility to accommodate diverse circumstances or varied conditions?
7. How to you communicate lessons learned or improvement in work instructions among your team:
8. How do you learn the lab work and the safety aspects

* Dynamic Mental risk assessment is the continuous process of identifying hazards, assessing risk, taking action to eliminate or reduce risk, in the rapidly changing work environment. The participants did not know the term and needed explanation by the interviewer.

Results

Standard Operating Procedures (SOP)

Clinical diagnostic laboratories provide diagnosis for patient care while research laboratories engage in research and development. Biomedical laboratories, both diagnostic and research have written step-by-step work instructions on how to perform the procedure for diagnosis or research. This ensures that the output is standardized and is of acceptable quality. In research laboratories reproducibility and replicability are very important to corroborate the results of the experiments. In clinical diagnostic laboratories, quality control ensures that the diagnostic results are reliable and consistent for patient care (Bayot, 2024; Diaba-Nuhoho, 2021).

As opposed to work instructions, Safety SOPs are developed by the organization, departments or laboratory heads as part of the biorisk management system. Safety SOPs address safety issues like: safe work practices, good microbiological practices and procedures, PPE requirements, waste management, establishing oversight committee(s) and many others. As this study is aimed at understanding the gaps between WAI and WAD solely for safety SOPs, the interviews did not focus on the gaps between WAI and WAD for the experimental/analytical work instructions. 14 of the 15 participants said that safety SOPs were not integrated into the work instructions. The one participant in whose laboratory safety SOPs and work instructions were integrated, said that the work instructions had references to the safety SOPs so that they would know at each step if any additional safety practices were required. Five participants said that the laboratory workers were consulted when developing the safety SOPs. The rest said that it was developed by the safety department or supervisor without consultation with the laboratory workers. The 15 participants each had very different understanding of how to integrate safety SOPs into the experimental/diagnostic work processes. One diagnostic laboratory had only a few written instructions for performing their work and no safety SOPs. Staff in this laboratory relied on word of mouth conveyed through the senior staff and the instructions were committed to memory.

Gaps between WAI and WAD

All participants did a mental risk assessment on the spot and made deviations to the SOP which resulted in gaps between WAI and WAD; these were never written down. All participants followed the SOP for certain steps like 1) using the biosafety cabinet (BSC), which is a crucial primary containment equipment, for work with live virus or samples containing a live virus; 2) Stock virus handling; 3) Virus Inventory Maintenance; 4) Waste Management; 5) Disposal of Sharps; and 6) Use of Personal Protective Equipment.

Among the participants interviewed there was a wide array of practices with one participant saying that very few rules were followed in their laboratories, and three saying that the workers followed the rules very strictly. The rest were somewhere in between, where the participants used mental risk assessment to make decisions. It is also worthy to note that the three laboratories where the workers followed the rules strictly had consulted the workers in preparing the SOP.

Examples of gaps between WAI and WAD

Use of PPE:

The core PPE requirements consist of laboratory coats, gloves and covered shoes. In a few laboratories additional PPE consisting of safety glasses and N95 or surgical masks were included in the SOP. All the participants wore the core PPE when working in the laboratories with no deviations. They wore a mask and safety glasses based on their individual mental assessment. The reason for this was cited as discomfort and they were not convinced that it was needed.

Sample transport:

The safety SOP contains an overall statement that all virus containing material must be transported within or between laboratories in double containment i.e. a primary container, usually a test tube to hold the biological agent and a leak-proof secondary container to contain the primary container. The SOP further stated that for transportation outside of the institution, double or triple packaging must be used based on the route of movement and the material being transported. Participants explained that within the laboratory they would carry infectious material in test tubes placed in an ice box which was not leak-proof. However, no one omitted the ice box because they wanted to keep the temperature of the material stable for the success of their work. All participants also used the correct packaging if they transported the material outside the laboratory or institution.

Use of fume cupboard for working with volatile chemicals:

Participants had access to a fume hood (device with exhaust ventilation that is designed for working volatile chemicals) which was usually placed in a central location for all laboratories to access. All participants did a mental risk assessment to decide whether to use the fume hood as stated in the SOP, based on the chemical, the quantity and the distance they needed to travel with the chemical bottle.

Incident reporting:

Incident reporting had a wide range of practice. In three laboratories where workers were consulted in preparing the safety SOPs, worker feedback as well as incident reporting was encouraged. Two participants from these laboratories, who held supervisory positions, said they had a system that at least 10 incidents should be reported every month, and each one was addressed with a strictly no-blame culture. The remaining 12 participants said that they would report only serious incidents. Seven of them said that reporting resulted in blame, and they would not report. The one laboratory with no written SOP also did not have any system to report incidents.

Reasons for gaps between WAI and WAD:

The most common reason for deviating from the SOPs is work pressure and time constraint (Figure 1). Participants had to ensure that the experiment was not jeopardized, especially in time-sensitive experiments with precious samples and reagents. In addition, participants chose convenience and the path of least effort, and if this worked and nothing untoward happened, they were likely to do it again. As they gained more experience, they would also omit steps that they thought were unnecessary and were not commensurate with the risk. This indicates that they relied a lot on their own mental risk assessment.

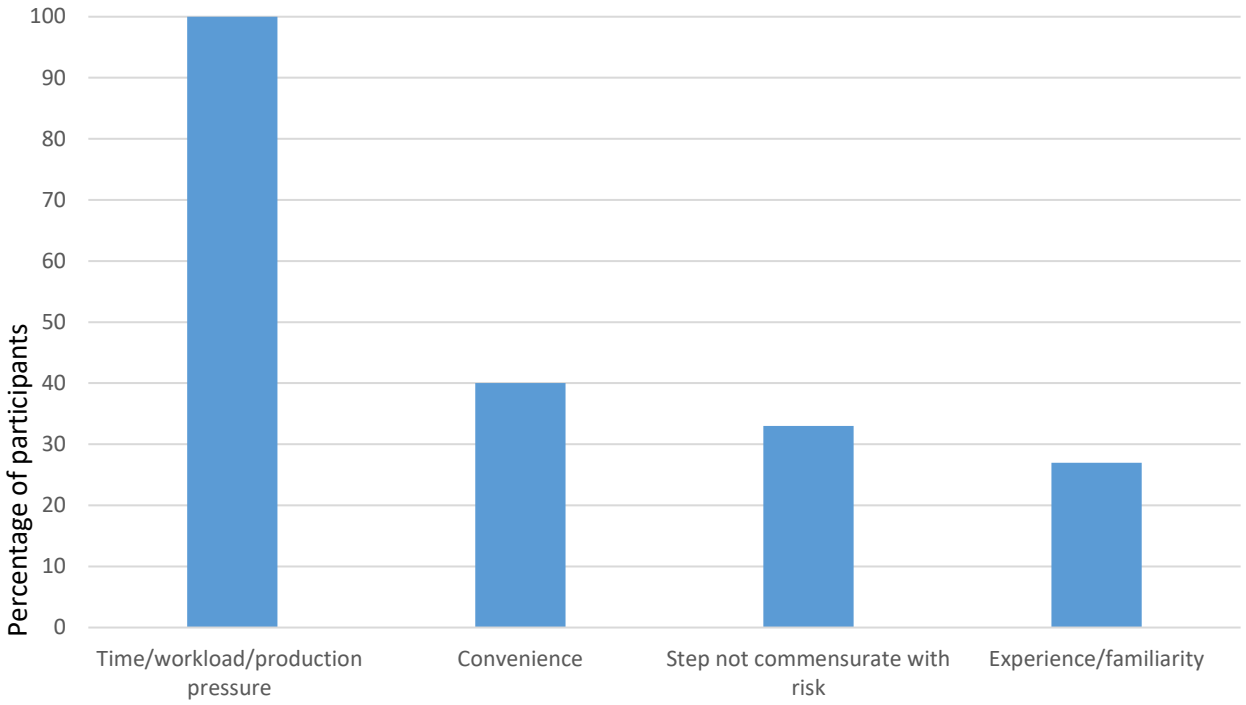

Figure 1: Reasons for gaps between WAI and WAD

Skills acquisition

Learning from their seniors was the most important method of skills acquisition. Only three said they learned from safety SOPs, and one from safety training. 47% of participants said they learned from information about accidents and incidents that happened to others and 20% said that they learned from others pointing out their mistakes. Regarding mistakes, 83% of participants said they learned from their mistakes and 13% said that if they got away with the mistake, they would do it again. When probed further about learning from incidents and accidents, the main reluctance appeared to be the assigning of blame that came with incident reporting and communication about incidents. One participant who is a supervisor said:

"When I was a junior the system in our institution is a blame system. I grew up in that kind of system where they blame you instead of correcting you or mitigating the problem so that's why in the course of my career here, I advocate the blame-free system, and we encourage incident reporting not to blame them but to mitigate the situation and to learn"

Discussion

This study shows that the laboratory workers do not always read the safety SOPs because they do not find it useful to do so. They said that the SOPs are repetitive and contain information that is not relevant to them. Based on published literature, this is not unique to biomedical laboratories (Eisner, 2022; Hammond Mobilio, 2022). Perhaps the SOPs are too prescriptive, for example, the use of a leak-proof secondary container to move infective samples a short distance within the laboratory and additional PPE that is not the normal practice in BSL2 laboratories. All the participants used mental risk assessment to assess the need for a leak-proof secondary container during transport of infectious material. They took into consideration the type of virus, the route and distance of the movement. This type of mental risk assessment is termed "Dynamic Risk Assessment" and has been used in industries with complex and dynamic work conditions (Jamshidi, 2018; Li, 2018; Paltrinieri, 2015).

All participants understood the need to use a BSC, which is the single most important primary equipment in biomedical laboratories. Class II A1 or A2 is the most used BSC, which not only protects the worker from aerosols generated when working with samples or cultures but also protects the samples and material from contamination (Jagtap, 2023; Pawar, 2021). One participant said that if they were working with an infective agent that was not aerosol transmitted but perhaps transmitted by a vector like mosquito, they would still use the BSC, but the reason would be to protect their samples from cross contamination rather than themselves. Such arguments and explanations of their work process show clearly that participants do understand the risks and use their on-the-spot mental assessment to decide whether to deviate from the written safety SOP.

Majority of the participants in this study said that they would not report or talk about any incidents or mistakes because they are associated with blame. Here, it can be useful to consider the idea of "just culture" where incident reporting and learning from incidents do not include assigning blame, unless the act was intentional with a malicious intent (van Baarle, 2022; Siebericchs, 2021; Amalia, 2019; Ale, 2020). The laboratories where the workers were consulted in developing the SOPs were also the ones where incident reporting without blame was encouraged. Learning from their mentors is the most critical knowledge transfer and skills acquisition method that is used. This highlights the need to pay attention to training senior workers to be good and effective mentors. Mentors need to teach both work and safety, remaining approachable and supportive (Hill, 2022; Roussakis, 2022).

Tresfon *et al* used the Functional Analysis Resonance Method to understand WAI and WAD in a hospital ward. The authors report that the use of this methodology gave the workers opportunities to reflect on the deviations and workarounds collectively as part of the study. One notable finding in this study was that the gaps between WAI and WAD were used to rewrite the SOPs, reduce the number of pages in the SOPs and change the narrative to a more friendly and helpful tone instead of a prescriptive tone of voice. Since the birth of the Safety II concept there have been many new ideas like safety differently, behaviour-based safety, safety culture among others. There is also heated debate on their usefulness and application. None of these are mutually exclusive and can be used in the same laboratory for different situations. In fact, there is no need to fixate on the nomenclature of these concepts as long as they are used to address safety and productivity at the same time. It is the workers who need to accept and deploy these concepts. We should think of the workers as a source of resilience instead of a problem to be controlled. Based on this very small and preliminary study, the first step is to encourage regular open discussion without assigning blame, include the workers in developing SOPs, accept that not all rules will be followed and study how to address the gap between WAI and WAD. More research is needed to understand WAI and WAD in biomedical laboratories, but in my extensive experience as a biorisk and human factors professional I am convinced that it is time to change and adopt newer concepts of safety to ensure that the gaps

between WAI and WAD are addressed and minimised so that these deviations do not become normalised.

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