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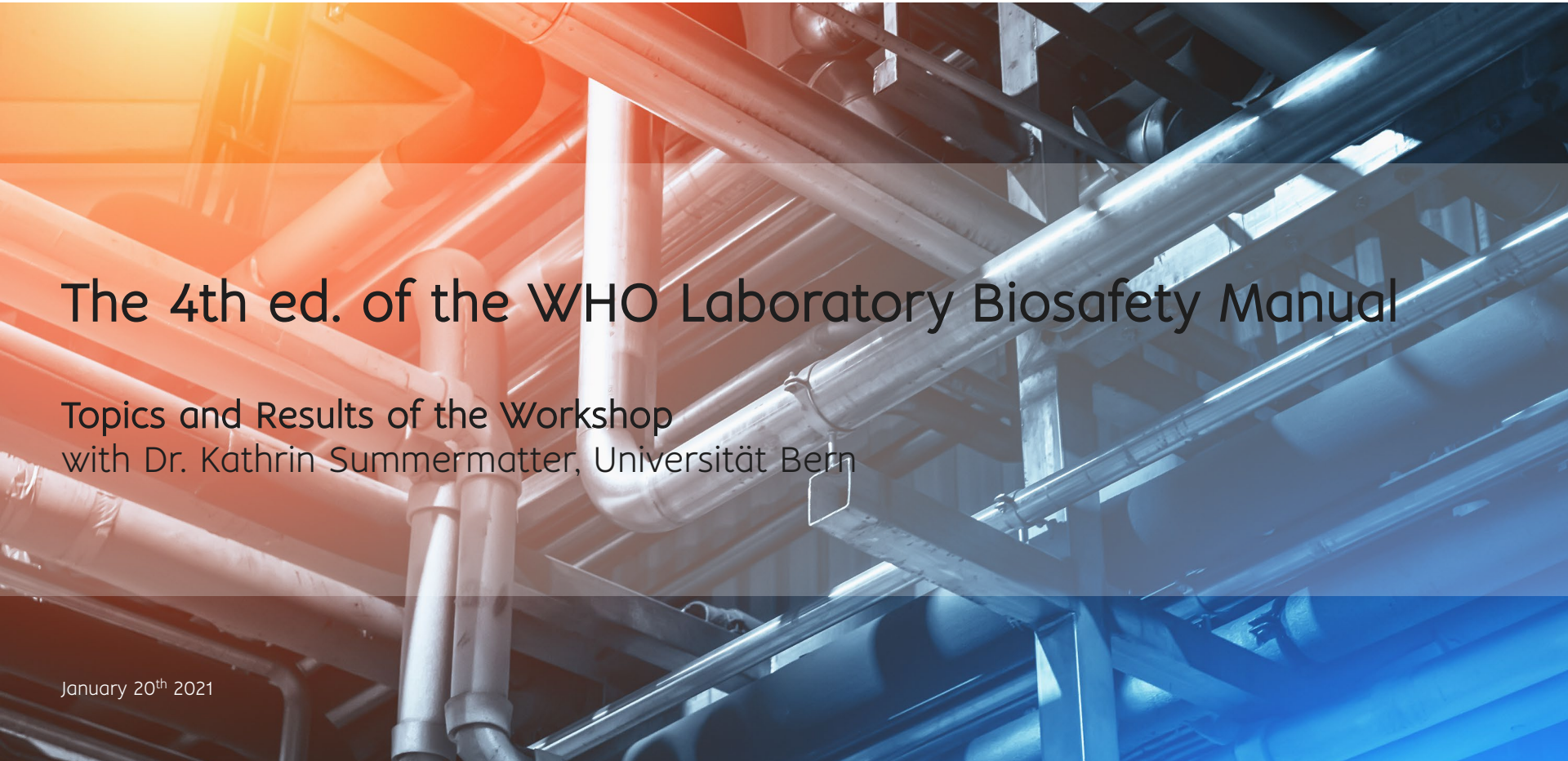

The 4th ed. of the WHO Laboratory Biosafety Manual

Topics and Results of the Workshop

with Dr. Kathrin Summermatter, Universität Bern

January 20th 2021

Overview

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1. Future Webinars on Biosafety
   - » In the Context of the 4th Edition of the WHO Laboratory Biosafety Manual
   - » Biosafety in Low-Resource Settings
   - » Lessons Learned in Biosafety Laboratories
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1. Future Webinars on Biosafety

1. Future Webinars on Biosafety

In the Context of the 4th Edition of the WHO Laboratory Biosafety Manual

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- We will send you an e-mail as soon as we have the date:
  - Improving on Core Requirements – How to Implement Continuous Improvement in a Biosafety Laboratory?
  - International Biosecurity Challenges – What to Learn from the 4th Edition of the WHO Laboratory Biosafety Manual?
  - Risk-based Decontamination and Waste Management: What to Learn from the 4th Edition of the WHO Laboratory Biosafety Manual?
  - Risk-based Selection and Use of PPE: What to Learn from the 4th Edition of the WHO Laboratory Biosafety Manual?
  - Risk-based Selection and Operation of Primary Containment Devices with Respect to Low-Resource Settings
  - How to Implement a Biosafety Committee: Lessons Learned
  - Application of a Risk-Based Approach to Animal Facilities: First Steps and Lessons Learned
  - How to Implement and Maintain a Risk Assessment Process: What to Learn from the 4th Edition of the WHO Laboratory Biosafety Manual?
- If you have suggestions on future topics, get in contact with Fabio Blaha (blaha.f@labconcert.de).

1. Future Webinars on Biosafety

Biosafety in Low-Resource Settings

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- We will send you an e-mail as soon as we have the date:
  - Evidence-based Design of a Cost-Effective and Sustainable Biosafety Laboratory
  - Biosafety Standards for Low-Resource Settings: What to Expect from the 4th Edition of the WHO Laboratory Biosafety Manual?
  - Sustainable Energy Supply for a Core Requirements Biosafety Laboratory
- If you have suggestions on future topics, get in contact with Fabio Blaha (blaha.f@labconcert.de).

1. Future Webinars on Biosafety

Lessons Learned in Biosafety Laboratories

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- The idea is to **share years of experience** in biosafety laboratories within the community.
- The format is a free of charge **open series of webinars**, where **everyone can contribute their lessons learned** or **unsolved problems** in biosafety laboratories.
- The webinars can include a workshop – especially if it is about unsolved problems.
- The goal is to **identify, develop and distribute best practices**: What does work fine in what context?
- The webinars will be hosted in unregular intervals, that means **whenever there is someone to contribute their lessons learned, or someone who would like to have a second opinion on their issue**.
- The time and date of the webinars can, of course, be adjusted to the time zone of the respective speakers.

- Just contact Fabio Blaha (blaha.f@labconcert.de) at LabConCert. We will organize everything!

2. Workshop Results

2. Workshop Results

Surveys

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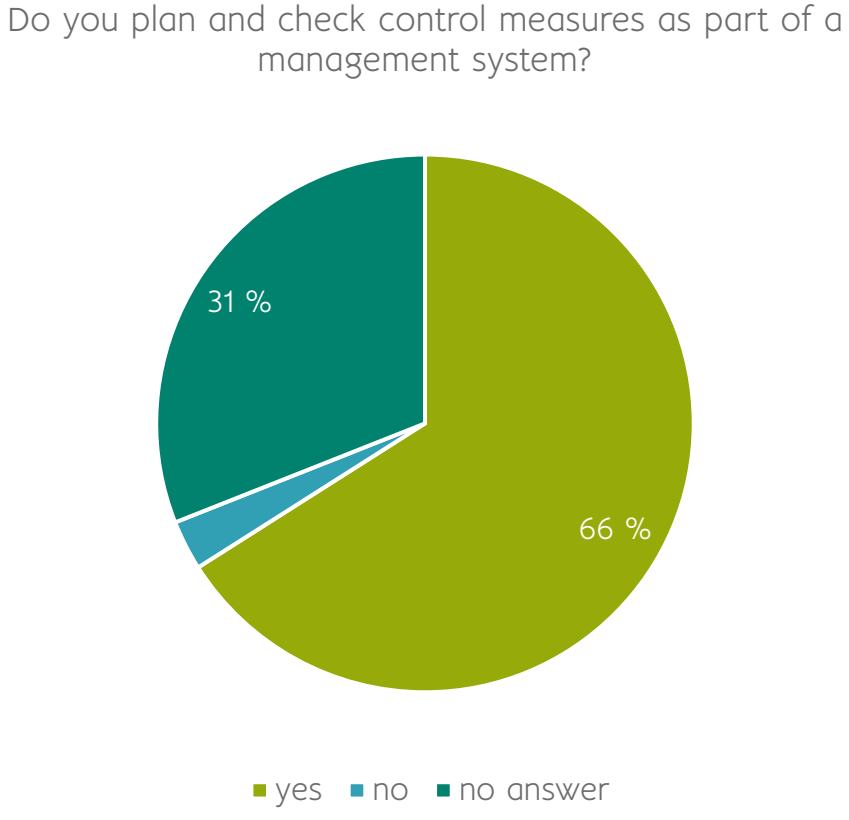

2. Workshop Results

Surveys

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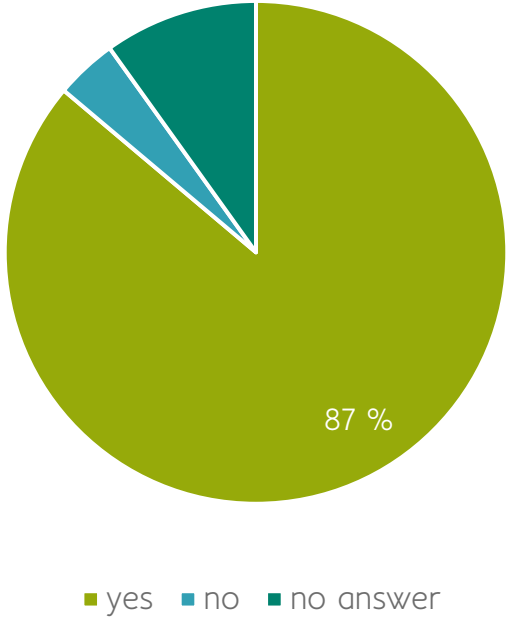
What is the status of the 4th edition of the WHO Laboratory Biosafety Manual in countries with established standards and guidelines? Can it still be useful?



2. Workshop Results

Surveys

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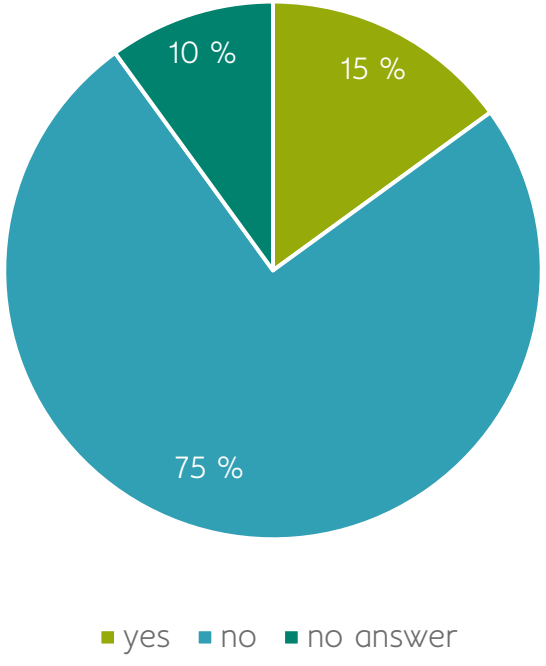
What do you think: Can we do without biosafety levels and risk groups?



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- Statements on **biosafety levels and risk groups**
  - » Reluctance to leave the security of biosafety levels and risk groups will be the biggest issue.
  - » People are used to think in biosafety levels and risk groups: retraining and learning a different approach may be difficult.
  - » A possible intermediate approach could be not to use risk groups, but to keep biosafety levels. This would make the necessity to assess the microorganism and how it will be handled to fit it in a specific biosafety level (maybe including BSL 2+ etc.).
  - » Risk groups are useful, but they are difficult for dealing with future threats.
  - » Risk groups and biosafety levels make the design easier, but risk assessment should be a mandatory step.
  - » With the new approach, there will be no more confusion between biosafety levels and BSC classes.

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- Statements on **risk assessment**
  - » Will the guidelines be more subjective because of the possibility of more subjective risk assessments?
  - » Will there be too much room for interpretation without biosafety levels and risk groups?
  - » Will we achieve the same quality of risk assessment, especially when there are no risk groups?
  - » Does the new WHO guideline give details on the makeup of the risk assessment committee? – The more diverse the risk assessment committee the more complete the risk assessment. Ideally, any risk assessment should be undertaken by a minimum of 3 people. Also, the hierarchy of controls places a much higher weighting on engineering and elimination, yet most of the in lab-based risk assessment would be working on the lowest hierarchy of controls (PPE and procedures) – which is potentially dangerous.
  - » The part on risk assessment is very useful, very comprehensive and applicable for many biosafety labs in many countries.

Topics

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- Statements on **present and future threats**
  - What happened to the precautionary approach?
  - What about future threats? How to conduct risk assessments on future threats?
  - The new approach is so focused on the risk you have in a specific moment, it may affect future changes in the work and new pathogens, especially in the research field.

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- Statements on the **paradigm shift**
  - » There is a need to break the paradigm of the classic biosafety model.
  - » We are facing an interesting era of biosafety regulations with the new edition of the WHO Laboratory Biosafety Manual and the ISO 35001 standard. We need to join efforts and align specific priorities.

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- Statements on the **global approach and low resource settings**
  - » Will there be biased perceptions from one country to the other? (especially regarding the risk assessment)
  - » Risk groups of organisms can be different, depending on the country and even within different regulations in one country. The WHO Manual differentiates between core/extended/high measures, so it may be useful to take this approach.
  - » On the importance of a global approach: now it is possible, because of the new WHO documents, to further global consistency.
  - » It is most practical for low-income countries: by providing a baseline standard for global implementation of biosafety regulations.
  - » What is the impact of a risk-based approach (that can be a little subjective) on getting the money to develop a new lab or maintaining an existing one, especially when the budget is not large?
  - » There could be difficulties with the national and regional regulations, which are not always as fast in modernizing as guidelines do.

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- Statements on the **(legal) responsibility and national regulations**
  - » Who takes the legal responsibility for a specific risk assessment? Do lab managements have the expertise?
  - » The head of the institute is legally responsible, but their position is built on the recommendations of experts – who conduct the actual risk assessment.

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- Statements on **diagnostic labs vs. research labs**
  - » Dilemma of diagnostic labs vs research labs when working with SARS-CoV-2 under different biosafety safety levels: will large diagnostic labs (with thousands of samples daily) require more safety in the future, and a small research project less (small volume culturing for example)?

- Q: Please explain what you mean by consequences. You use it in a way that it looks like a sort of likelihood. I would say it is almost always the same for a specific infectious disease. I suspect you mean something different in this case by consequences.
  - » Kathrin Summermatter: In the context of LBM4, it is defined as the consequences in relation to a laboratory accident. How severe is the disease if exposure occurs in a laboratory? What are the consequences of an organism released to the environment? What is the likelihood or probability of something going wrong in a laboratory when somebody is working with certain organisms. Am I working with it in a biosafety cabinet, or on an open bench where the likelihood is very high to get exposed, and then if I am exposed, what are the consequences for me or anybody in the lab? Do I get sick? Or if the infectious agent is not affecting people, the consequences for the worker will be low.

Discussion with Kathrin Summermatter

- Q: Thank you, but I am challenged by these principles. What happened to the precautionary approach – a principle being applied in the climate debate?
  - » Kathrin Summermatter: Probably I can answer that one. You are right. The precautionary approach is based on your risk assessment, and even if you have certain measures that you take in a certain environment or lab, and that may work in Switzerland, but it probably doesn't work in Germany. If there is not enough evidence, we may apply the precautionary approach. Risk awareness may change from one country to another, and what may be acceptable in one country or one institute, may not in another one. We may have to add an additional safety layer on top, because the risk needs to be minimized further. For example, a medium risk activity is performed and then additional safety measures are applied in order to go from a medium to a low risk.

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- Q: With the new approaches in categorizing the microorganisms or pathogens and the facilities (on the risk and the containment), do we anticipate that there might be some differing risk-based perceptions from one country to the other?
  - » Fabio Blaha: So, I would understand the question that we will differ from one country or culture to another regarding our perception of the specific risks that rise, and if we can make sure that with this new approach, that nevertheless biosafety is implemented in every country.
  - » Kathrin Summermatter: I think it depends on the whole setting. You know, we have on one side the facilities with certain engineering controls in place which we usually have to set in place before we start an activity. And then we have our own facility already in place where we have to deal with many different projects. And if something is working in a certain country – for example for many years in the UK, level 4 laboratories where not allowed as suit labs. They were using the glove box type BSL 4 (biosafety cabinet class III). And in other countries, it was completely different – there suit labs were used all the time. And that's the perspective of the country. That doesn't mean that they are less safe or safer.

Discussion with Kathrin Summermatter

- Q: The biggest challenge I see with this approach is deciding “what to build” in the absence or long before risk assessments can be carried out.
  - » Fabio Blaha: Yes, that’s true. Before the organization of the laboratory is in place, if you build a new laboratory, the question is how to make a thorough risk assessment.
  - » Kathrin Summermatter: Yes, this is the discussion that we always had. Independent of biosafety level and so forth. In the monograph on design, the process of planning of a facility is described, and what the user or those, who will using the facility, should provide as information. That is one of the most difficult parts. Ten years ago, we had a completely different situation, we had different technologies, we had different projects. And now we would have to plan for the next ten years. And it usually takes a few years until we get our lab ready. And one of the things is: how flexible can we build a facility? But we should know – at least approximately – what types of risks we will encounter in a certain facility. Otherwise, we will not be able to build a facility. That’s independent of biosafety level.

Discussion with Kathrin Summermatter

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- Q: As a facility designer, I am a bit worried that a risk assessment might initially show that a basic laboratory is required. However, at some point in the future (Sars-COV-2 as an example) it needs a better lab to handle this – perhaps still at BSL 2, however, the cost to retrofit will be dramatically higher than just building in a base requirement of good design practice. Similarly, the 2 regulators here in Australia are very hesitant to grant variations on base building requirements in case the science-based requirements on the facility change.
  - » Kathrin Summermatter: I won't be able to give you the solution here, because Tuberculosis is very specific, and if you build the facility according to this guideline, you still have to meet national regulations that are in place, no matter what the WHO Tuberculosis Manual says. And then, definitively, we had to face that problem, because we were planning a Tuberculosis facility and had to handle SARS inside the same facility. So, what we have then to decide is what are the mitigation measures that we have in place: are these enough to mitigate an aerosol risk from a virus which is transmittable by air, or do we have to put an additional layer on top. Do we have to use, for example, an isolator type laboratory? When do we have to decide on which measure?

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- Q: … continuation of the page before
  - » Kathrin Summermatter: … If we plan a laboratory, we have engineering controls, and we have the projects in this facility. As soon as we change the projects we have to reassess the activity, and have to decide if the risks can be mitigated with the measures already in place. I think, there is no answer to that question yet. But I think we have to live with it, and we have to start using it wherever we can, and at the same time complying with our national legislation. It is already difficult today, if a planned facility has to cope with future needs as well.

- Q: The question is, who takes, in the end of the day, the legal responsibility for each specific biorisk assessment? So, it is more open, more evidence-based and risk-based. But who is responsible afterwards?
  - » Kathrin Summermatter: For each facility, it is the facility manager, institutional head or similar. He or she is responsible that all the safety measures are in place to mitigate the risks in a facility. If, for example, we have a legal obligation to get a permission to perform activities in our facility. But if something goes wrong, it is not the authority that is guilty, because either I didn't train my people, I didn't provide appropriate equipment etc.

Discussion with Kathrin Summermatter

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- Q: Why was it important to make these changes in the update to the WHO manual? Risk assessments have always been important and have been a requirement to do. Does removing the international recommendations of risk groups and biosafety levels leave too much open to interpretation?
  - » Kathrin Summermatter: I don't think that. There is a lot of discussion about that. Because we have to know which type of organism we are using. And if I take the risk group, for example of influenza, there are so many different types of influenza. It is a risk group 2 for the seasonal flu, but H5N1 is risk group 3 in certain countries. There are more factors to consider and a risk group classification which is applicable for the whole world doesn't work. We have seen this over the past. If we talk about biosafety levels, we usually consider measures that mitigate a certain risk. For example, I build a facility where I will be working with an airborne pathogen of high consequence. So, one of the things that I would need is a facility with measures preventing dispersal through the air, and this is typically a HEPA filter. Over the past we were already be using this approach based on risk assessment. The WHO is a world organization which issues guidelines applicable all over the world. We all know that different BSL 3 cannot be compared so easily one to another. They have certain common principles, but the systems are, in general, different in different countries. And we have to think about sustainability. Do I really need a system from another country that is difficult to maintain? So, we have to think about what is sustainable in certain circumstances, and how we can maintain it on a long term, also.

Discussion with Kathrin Summermatter

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- Q: Does the WHO manual include recommendations of specific control measures for specific risks? – As the biosafety levels are not used anymore. That will help to design facilities, procedures, management systems, etc.
  - » Fabio Blaha: I would answer that: A very good publication about that would be WHO Tuberculosis Laboratory Biosafety Manual because they have written it especially for Tuberculosis measures, and it is very specific. Maybe such manuals for other pathogens come up as well. Kathrin Summermatter, the question is, if there are similar manuals planned for the future for other pathogens.
  - » Kathrin Summermatter: I think the Tuberculosis guideline is a very good document, as you mentioned it, and we have already a similar manual for SARS-CoV-2. And definitely there needs to be a lot of more information about which system works under which circumstances. But this is already the case now. When we are planning a facility, we always have a wide range of systems that we could place to mitigate risks. And sometimes we chose a system because it is cheaper, because the money is short and we have to cut down in certain equipment or engineering controls. That's what we do today already. But the problem is: this is not always risk-based or evidence-based. And when we have to think about a risk-based approach, it is the whole life span of a facility, particularly when it goes into the building-part: do we have a more expensive system and it lasts longer, or do we take a cheaper one without impeding safety, but after 5 years it needs replacement?

- Q: What are the benefits of the new WHO Laboratory Biosafety Manual for you and your field of application?
  - » Kathrin Summermatter: For me personally: I live in Switzerland and we have regulations with risk groups and biosafety levels in place. But I still miss a lot of guidance documents (example applied biosafety risk assessment). Particularly, I'm also involved in some building projects, and I will definitely use the templates (from the WHO manual and monographs) to train those people who are involved in building these laboratory facilities. I will use the risk assessment templates as well as the pathogen safety templates to use a more structured approach for our internal biosafety. One of the big advantages are all the templates that can be used to implement a biosafety program.

Discussion with Kathrin Summermatter

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- Q: What is the status of the 4th edition of the WHO Laboratory Biosafety Manual in countries with established standards and guidelines? Can it still be useful?
  - » Kathrin Summermatter: It is a very useful tool for every facility, even in countries with established standards. We are changing towards a more structured approach to biosafety management or biorisk management – which is not yet implemented all over the world. It is definitely a question of available resources. It will be a helpful document for all biosafety professionals. Biosafety is a profession and not just a need to have.

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- Q: Risk groups of organisms can be different, depending on the country and even within different regulations in one country. In the new WHO manual, there are certain requirements fixed in core/extended /high, so it may be useful to take this approach.
  - » Kathrin Summermatter: That's the case. So, core requirements include basic safety measures that should be implemented in every lab, independent what biosafety level. On top of these measures, additional measures may have to be selected depending on risk assessment. As an example: core requirements plus a biosafety cabinet, which is part of heightened control measures.

Discussion with Kathrin Summermatter

- Q: I am from Argentina. Here, we are worried about how a risk-based approach (that can be a little subjective) can impact getting the money to develop a new lab or maintaining an existing one when the budget is not large.
  - » Kathrin Summermatter: You know, you have a facility, and then you have certain systems in place. Let's say they require maintenance … A key element is the risk assessment which should also include the maintenance aspect. When we plan a laboratory, the maintenance must also be considered over the life span of a laboratory. As we all know, there are different systems and these should be selected in a way that all the risks are minimized to an acceptable level. In many cases we have to take organizational measures instead of engineering controls as they are less expensive. However it must always be ensured that the risks are acceptable. It is important to select measures that are proportionate to the risk.
  - » Fabio Blaha: There is a publication by Sharples on the topic of standards for low-resource settings for biosafety laboratories, very interesting to look into: https://www.ncbi.nlm.nih.gov/books/NBK542561/. Perhaps the new manual can provide a framework for all those new standards for low-resource settings, a framework to guide their implementation.

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- Q: … continuation of the page before
  - » Kathrin Summermatter: One important point is, that we start putting together information on systems that maybe more sustainable, probably also cheaper, but as safe, and they work. Do I really need – all the time – a highly sophisticated system that costs me 150,000 euros, or can the same result be achieved cheaper without impeding safety? As biosafety community we need to share lessons learned and what works. The documents published will definitely create a lot of discussion in the world. But my question is also to all of you: does it make sense if we apply the Australian standard in Switzerland? Is there something wrong with us? Why do we not apply similar products here in Switzerland? Or in other parts of the world? Or what about the Canadian one? Or the American one? I think, that is something that will be one of the challenges, for all of us.

Discussion with Kathrin Summermatter

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- Q: Having worked as a lab consultant in low resource countries for 17 years, the issue will be how to convince the funding authorities or the funding organization: which type of lab will be required, and how much it will cost.
  - » Kathrin Summermatter: Already now, we have to convince funding authorities. There is usually not only one solution but there are more. Therefore, we have to propose, as professionals, different types of measures / systems, a range of measures, that achieve the same goal. And usually, depending where you are in which country, it is very often a question of finances. The risk assessment will inform us which measures will mitigate which risk best. There is usually no black and white solution. There will always be the question which standard do we use to convince our government or our founder to get the money? Do we use the WHO standard and then provide a thorough risk assessment? That is, in any case, what we need to do, already now.

Discussion with Kathrin Summermatter

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- Q: In absence of national regulations, does a risk-based assessment turn researchers and biosafety officers into judge and jury?
  - » Kathrin Summermatter: Yes, that is true on one side. On the other side, a biosafety professional should have a certain background – and it is the same like someone driving a bus. If you are not trained as a bus driver, and if you provoke an accident, in the end it is clear: the driver is guilty because he did not have the permission to drive the bus. And it is the same for us (in biosafety): as biosafety professionals we have to know what we are doing. And if we are unsure, we have the biosafety community. We have colleagues or other team members to ask. The risk assessment is usually a team effort, and the relevant persons have to be included in the process. Our biosafety professional's judgement, as in every other profession, should be considered.

Discussion with Kathrin Summermatter

- Q: This pandemic (COVID-19) really pushes my country, Indonesia to a big dilemma. If we have to fulfil and implement all the biosafety and biosecurity requirements for COVID-19 diagnosis, and be very strict with it, then … It will reduce the capacity for COVID-19 diagnosis. Because many labs can't do it. What's your opinion about it?
  - » Kathrin Summermatter: Yes, you are absolutely right. We are all in the same boat. The WHO monograph for outbreak situations covers this important topic. We have to make trade-offs during outbreak situations and balance the risks against the benefits. The situation in each country must be considered individually. Sometimes we are forced to make compromises as we would no longer be able to ensure diagnostics in the present pandemic. What is the situation in our country, how can we best cope with the situation? How can we minimize risks for the lab people on one side? And on the other side, we have to balance it against the public health situation. But in the long term, if we consider all factors – it will help managing this pandemic in our own country. Probably, on the personnel view in the lab, we may be less safe, but, with regard to the whole country, we will be safer, faster, and we will cope much better with this pandemic.

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- Q: Do you have any experience about the ISO 35001 standard in your lab, and is it even relevant?
  - » Kathrin Summermatter: The new WHO manual and the ISO 35001 are complementing each other. The ISO standard is also based on a management system, and it is based on risk assessment. It can be certified against – which sometimes is very important for certain labs. In our case, we are ISO certified for diagnostics, but not the biorisk management. We use the standard to implement the principles in our facility. And I think it can be very well combined with the new WHO manual.

Discussion with Kathrin Summermatter

- Q: Maybe Ebola would also be a good example for this new risk-based approach. Because, I think it is risk group 4 (in Germany), but in the context where Ebola capacity in the laboratories is really needed, a level 4 facility cannot be provided.
  - » Kathrin Summermatter: Yes, that is really one of the things we have seen during the Ebola outbreak in West Africa: mobile labs were provided for the diagnostic and they were not equipped with all the sophisticated engineering control that we are used in other parts of the world for BSL 4 labs. People using these labs were safe, they were well trained and so far no laboratory associated infection happened. This is an excellent example that can be used to show how the risk-based approach could be used. In the outbreak monograph, there is more information on that topic.

Discussion with Kathrin Summermatter

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- Q: So, the Ebola experience has been considered for the new WHO manual?
  - » Kathrin Summermatter: Yes. And I see some colleagues here, who were part of the outbreak monograph.

Discussion with Kathrin Summermatter

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- Q: Is there any guideline (or magic formula) on how to prioritize a given improvement in a facility and its cost? Money is not infinite, and there is only a limited number of improvements that we can make. For example, is a shower needed for SARS-CoV-2? Or is it better to use that money for X improvement?
  - » Kathrin Summermatter: There is no magical formula. Considering SARS-CoV-2, I don't think you need a shower. The risk assessment would inform that a shower is not needed. One important element to consider is what we are going to protect from what hazard. This is nearly a daily question for biosafety professionals.

Discussion with Kathrin Summermatter

- Q: How can we make sure one institution and other has some quality of risk assessment, especially when there are no risk groups?
  - » Kathrin Summermatter: It will take some time to get used to this new approach, and to use the risk assessment in a more formal and structured way to decide on mitigation measures. The monograph biosafety programme management contains information about the composition of the biosafety committee and its responsibilities. The risk assessment monograph includes information on who should be involved in a risk assessment and which steps need to be considered. It depends on the facility – on the size, the structure and the people – but definitely those people involved in the risk assessment know what they do. They should be the experts. As biosafety professionals, we may take to role of the moderator of the risk assessment and ask the right question. We are the advisors and propose solutions, or we can advise on certain safety measures. A risk assessment is always a group exercise in which all the knowledge present in a facility should be used best.

Open Points

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- Consistency between the document and the monographs
  - » WHO LBM4, page 62, table 5.3.
    - This table nominates the following for an isolator laboratory:
      - Prevention of backflow of biological agents via supply duct (presumably could be backflow preventers or HEPA filters)
      - Class III isolator to have two HEPA filters in series
      - But – no mention of room exhaust requirements.
  - » WHO Laboratory Design and Maintenance Monograph, page 21, clause 4.3.1.
    - Title is for “cabinet line” laboratories – language is different to use of “isolators” in the main document. Is this intentional? Reason? Are any differences of interpretation or application intended?
    - “Must” have HEPA on supply and exhaust for laboratory ventilation, which is different to the main document. The main document is a risk-based statement to prevent reverse air flow via supply duct; room HEPA exhaust is not mentioned.
    - “Normally” has two HEPA filters in series for the cabinet line laboratory room ventilation, but this presumably can be risk-assessed.
  - » In these situations, and in order to provide a WHO compliant facility, how should designers advise people? I have looked through the documents to see if there is any priority of one document over another, but I cannot readily see this.
  - » How do you think we should be advising people, when in some cases it will be too early in a new project to perform specific task-orientated risk assessments?

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Thank you very much for your participation!

Contact:
Fabio Blaha (blaha.f@labconcert.de)

German LabConCert GmbH
Christoph-Sturm-Str. 25-29
91161 Hilpoltstein
Germany
info@labconcert.de
+49 (0) 9174 9765527

www.labconcert.de

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