FACILITATOR’S NOTES
Practical Training Exercise: Analyzing and Managing Risks in Life Sciences Research

Based on the article by Ali, A et al. “Prevalence of HBV infection in suspected population of conflict-affected area of war against terrorism in North Waziristan FATA Pakistan”

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Case Study Reference Article Citation
Case Study Summary:

The purpose of this case study is to use a high-quality life sciences research article from the broader Middle East or North Africa to explore and analyze potential risks and risk management strategies in life sciences research.

Participants will learn how to identify, assess, manage, and communicate a wide range of risks during the design, conduct, and communication of research. By the end of this exercise, they should be able to apply what they learn to their own research activities, the laboratory work of their staff and students, or research they review. The current case study is based on actual research conducted in the region in order to help teach the risk analysis framework in a realistic and appropriate manner, as well as to facilitate its application to participants' scientific activities.

Note that the purpose of this is not to critique the case study article or the authors' choices.

This case study is based on an article that analyzes the prevalence of HBV infection in Waziristan, a war-torn region of Pakistan. The case study has been designed to train participants in doing research risk analysis and promote dialogue on the biosafety risks associated with human samples and human pathogens; risk management strategies and ethical dilemmas in carrying out research in violence-prone settings; and human safety and security risks, including risks to researchers in high-conflict areas and risks to human subjects who are infected with a disease that has negative social stigmas.

The primary risk areas that this case study addresses are:

- Human subject protection
- Personnel security
- Biosafety and biosecurity
- Information and data security
- Blood borne pathogen safety

You, as a facilitator, should choose this case study if you are interested in focusing your training on these above-listed topics and risk areas. This case study is designed to be accessible to a life sciences-educated, but non-specialist audience; however, some facilitators may want to select case studies where the audience is familiar with the basic scientific concepts addressed by the research article.
Introduction

This case study exercise is designed to engage scientists in interactive discussion about research related risks and should take approximately 90 to 120 minutes.

The goals of this case study are to enable participants to:

- Develop the skills to think critically about risks and risk mitigation strategies needed in their own scientific environment;
- Enhance their ability to identify strategies and approaches that minimize identified risk while continuing to maintain the high-quality and utility of the scientific activity; and
- Apply the risk analysis framework to their own or their peers’ scientific activities.

This exercise is intended to be interactive and to allow students to think about possible risks on their own and through group discussion. The first part of the case study summarizes the research article; the second part asks participants to consider and discuss risk identification, assessment, management, and communication in the research article; and the third encourages participants to apply what they have learned about risk analysis to their own research.

Facilitator’s Role

Your role as the facilitator of this practical exercise is to ensure that students understand the research article upon which the case study is based, to instruct participants on the format of the case study and expectations for their participation, and to guide and facilitate group discussions so that participants are challenged to think about diverse research risks and appropriate risk management approaches.

You, as the facilitator, are fully responsible for engaging students in discussion, clarifying any confusing concepts or experiments, and encouraging participants to think about safety, security, environmental, and ethical risks in new ways. Use the guidance and prompts from these facilitator’s notes and your own knowledge of the subject and the article to prompt discussion. As the facilitator is the case study expert, you must have read and understood the full case study article provided in the Participant Packet; you should be familiar with the potential risks associated with this case study; and you must understand the concepts of different biological risks and the 4-step risk analysis framework this exercise uses (identification, assessment, management, and communication). As you are preparing for the session, think about ways to guide the discussion so that participants consider the diverse range of risks in this research and appropriate approaches to managing and communicating risk that participants may not have used before. Please stress the importance of maintaining the high quality of science needed to answer a particular scientific question; risk management measures that reduce the quality of the science call into question the utility of the research activity. You may want to include additional examples and cases, ask probing questions, or use your own knowledge and experience to help guide participants in discussion.
The facilitator is also responsible for making sure that the key responses and themes are written down on an easel or visible board for all participants to see. You can either write down responses yourself or assign a co-facilitator or assistant to write down important responses and discussion points.

You may choose to invite experts in laboratory biosafety, biosecurity, and bioethics to help answer any questions or provide additional expertise in these areas.

How to facilitate this practical exercise:

The following contains guidance and instructions on how to facilitate this practical exercise.

At least one week before:

1. Send participants the case study research article and the Risk Glossary.
2. Read through all the facilitator instructions and notes, as well as the article. As the case study “expert”, you should be comfortable explaining the basic scientific concepts, methodologies and procedures, as well as the possible risks to a life sciences-literate audience. If you are unclear about any of these concepts or methodologies, read some or all of the materials recommended in “Appendix: Biorisk and Responsible Research References” or contact the case study developers for more information.
3. Decide if you want to do this exercise over one or two days. Especially for student participants, you may want to do this exercise in two, one-hour sessions. In the first session you will cover the risk analysis definitions, concepts, and framework in Slides 1-9. In the second session you will go through the case study, the discussion, and the final exercise of applying the case study to the participants’ own research.

At least one day before:

1. Print out one Participant Packet for each participant in your session. This Packet contains the Risk Glossary, which you have already sent participants, the risk analysis framework, all discussion questions, and the final exercise. You may also want to print out a copy of the case study article for all participants.

On the day of:

1. If you are doing the Participant Pre-Test to assess the baseline level of knowledge, give the pre-test in the morning before beginning the practical training exercise.
2. Make sure the room you are in has a projector and screen to show the case study slides, and a chalkboard, blackboard, or large post-it notes to write down participant answers to the discussion questions.
3. Give one Participant Handout to each participant to use as a reference and for note taking throughout the case study exercise.

4. If there are more than 20 participants, divide participants into small groups of 5-8 individuals and hand out one case study worksheet to each individual. Ask each small group to select one person to be the group reporter/rapporteur—the person responsible for reporting their discussion to the whole group. Each person should take their own notes on the worksheet provided to help the group rapporteur in accurately reporting the group’s responses.

5. Ask participants if they have read the materials sent in advance. If not, you may want to give ~10 minutes for participants to read an article before going through the research article case study. Participants should come prepared to the session; they should be instructed to read the pre-session materials for every case study included in the session.

6. Open the case study file. Throughout this exercise, advance by clicking on the slide.

**After the practical training exercise:**

1. Either directly after the final exercise or within a week after this practical training exercise, give participants the Participant Post-Test if you will be doing pre and post-testing.

2. Six months after the practical training exercise, you may want to do an Implementation Assessment to determine if your participants have implemented any of the information in this case study into their own research or at their institution. We would be very interested to hear feedback from all facilitators, including recommended improvements, how you used these case studies, and the results of your Participant Post-Tests and Implementation Assessments. Please send any information to Kavita Berger, PhD at kberger@aaas.org and we will use your feedback and results to improve these exercises and facilitators notes.

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**IF YOU ARE DOING MULTIPLE CASE STUDIES WITH A SINGLE GROUP, ONLY USE SLIDES 1-9 BEFORE THE FIRST CASE STUDY. FOR ALL SUBSEQUENT CASE STUDIES, ADVANCE IMMEDIATELY TO SLIDE 10: THE CASE STUDY INTRODUCTION SLIDE.**

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**Slide 1: Title and disclaimer**

1. Read the title and author of the case study.

2. Summarize the Disclaimer (located below) to participants.

3. Inform participants of what your role is as the facilitator. Your primary role, as stated in the Introduction to these notes, is: to guide the discussion about risk identification, assessment,
management, and communication in scientific research. This role may include clarifying the background, research purpose, experimental approach, results, or conclusions; asking probing, and even controversial, questions about how participants understand and evaluate potential risks and risk mitigation strategies; maintaining the objectives and ground rules of the exercise; and encouraging participants to translate what they have learned to their own research.

Disclaimer

This case study is based on a scientific article published in a peer reviewed journal by scientists from one of the following seven countries: Pakistan, Jordan, Yemen, Lebanon, Tunisia, Algeria, or Egypt. The background information is accurate (as of December 31, 2013) and summarized from published literature and authoritative organizations, such as the World Health Organization or the U.S. Centers for Disease Control and Prevention. The research statement, experimental approach, results, and conclusions are taken directly from the scientific article on which the case study is based. You must stress the case studies and questions are not intended as a critique of any specific research activity or scientist, but instead to elicit discussion and consideration of the risks biological and biomedical research and appropriate risk mitigation approaches.

4. Explain the basic format for the case study:

Part 1. An overview of the case study exercise, including:
1. Goals,
2. Ground rules for participation, and
3. Risk Glossary definitions
4. Risk Analysis categories and chart
   1. Risk identification asks the question, 'what are the possible risks associated with the research?'
   2. Risk assessment asks the questions, 'how likely are the risks to occur?'; 'what are the potential consequences if the risks occur?'; and 'do the risks outweigh the benefits?'
   3. Risk management asks the questions, 'what risk management strategies, including physical barriers, personnel training or vetting, regulations and laws, and/or alternative experiments - could minimize the likelihood that the risk will occur or the consequences if the risks occurred?'
   4. Risk communication asks the question, 'what risks, if any, might come from sharing research data or results?'

Part 2. The Case Study:
1. Summary of the main themes of the case study article
2. Discussion and analysis of risk in the case study article
3. Final discussion on how these risks might apply to participants’ own research

Advance to the next slide.
Slide 2: Copyright information

1. Inform participants that the case studies were developed by the American Association for the Advancement of Science and that if they have any questions, they can email or call the case study authors at the email address and phone number provided.

Advance to the next slide.

Slide 3: Learning Objectives

1. This exercise has 3 broad learning objectives for all audiences, as well as specific goals for certain audiences. Read through or summarize the case study goals and objectives for the broader audience, which are listed on the slide. Answer any participant questions about the exercise objectives.

2. Next, read the appropriate specific objectives for your audience (i.e. students, junior faculty, IRB committee members). You may want to write or print out these specific goals and objectives for all participants to see. Answer any participant questions about the exercise objectives.

Learning Objectives:

The three overarching learning objectives that apply to any audience are to:

- Develop the skills to think critically about risks and risk mitigation strategies needed in their own scientific environment;
- Enhance the ability to identify strategies and approaches that minimize identified risk while continuing to maintain the high-quality and utility of the scientific activity; and
- Apply the risk analysis framework to their own or their peers’ scientific activities.

The following are specific learning objectives for the case study exercise for different audiences.
Students: The objectives are to:
- educate students about the risks they might encounter during the course of a research project; and
- provide them with the critical thinking skills needed to identify, assess, manage, and communicate risks.

Junior faculty: The objectives are to:
- train junior faculty in identifying, assessing, managing, and communicating risks of their own and their students’ research; and
- provide them with the skills and knowledge to train their staff and students in analyzing and mitigating risks associated with their research.

Senior faculty: The objectives are to:
- train senior faculty in identifying, assessing, managing, and communicating risks of their own, their peers’, and their students’ research; and
- provide them with the skills and knowledge to train their staff, junior colleagues, and students in analyzing and mitigating risks associated with their research.

Clinicians and Public Health Scientists: The objectives are to:
- train public health scientists in identifying, assessing, managing, and communicating risks of the epidemiologic and diagnostic work conducted in their laboratories or in the field; and
- provide them with the skills and knowledge to train their staff, junior colleagues, and students in analyzing and mitigating risks associated with laboratory and field studies.

Veterinarians: The objectives are to:
- train veterinarians in identifying, assessing, managing, and communicating risks of the epidemiologic and diagnostic work conducted in their laboratories or in the field; and
- provide them with the skills and knowledge to train their staff, junior colleagues, and students in analyzing and mitigating risks associated with laboratory and field studies.

Ethics Committee or other Research Reviewer: The objectives are to:
- train members of ethics committees or other reviewers of research in identifying, assessing, managing, and communicating risks of research or diagnostic analysis which they must review; and
- provide them with the skills and knowledge to train their colleagues in analyzing and suggesting risk management approaches to the scientist wishing to conduct the research.

Institutional Administrators: The objectives are to:
- train institutional officials in identifying, assessing, managing, and communicating risks of research or diagnostic analysis which they might oversee; and
- provide them with the skills and knowledge to train their staff, faculty, and students in analyzing and suggesting risk management approaches to the scientist wishing to conduct the research.

Advance to the Participant Expectations.
Slide 4: Participant Expectations

1. The purpose of this slide is to provide participants with an overview of what they can be expected to learn during this exercise. Read aloud or summarize the expectations, making sure that all participants understand what these expectations.

Participant Expectations:

By the end of the exercise, participants should have familiarity with:

1. The definitions of different types of risks associated with laboratory, field, and public health research.

2. The process of risk analysis—risk identification, assessment, management, and communication—including:
   - How to identify and assess risks by considering the possible likelihood and consequences of risks, and the risks versus benefits of a research activity,
   - Strategies for managing risks, and
   - Who, when, and how to communicate risks.

3. How to apply the risk analysis framework to your own scientific activities.

Advance to the Ground Rules.

Slide 5: Ground Rules

1. Summarize the Ground Rules. Answer any participant questions.

A summary of the ground rules:

- Participants should have read the case study article.
- Participants should ask the facilitator (you) for any clarification needed.
- You, the facilitator, should stress that the focus of the case is to understand and analyze research risks. The focus is NOT to conduct a critical peer review of the article.
• You, the facilitator, should stress that this is an interactive, educational exercise. Participants should listen to the views and ideas of other participants in their small groups and in the large group. They are welcome to disagree with another’s opinion, but please be respectful.

• Participants should take notes on the risk identification, assessment, management, and communication worksheets that you have provided them in order to aid in their own learning.

Advance to the Biorisk Glossary.

Slide 6: Biorisk Glossary

1. Inform participants that the purpose of this glossary is to introduce participants to the concepts and definitions that are important to risk analysis and risk management in life sciences research.

This glossary includes definitions, risks that the participant is might encounter during the conduct and communication of research.

These selected definitions focus on risks that are commonly associated with field and laboratory research and diagnostic analyses.

As you read through the definitions, please illustrate the definitions with examples from your own experience. For example, mention certain biosafety measures you use in your laboratory while explaining the concept of biosafety. Although the definitions are listed in English, you are welcome to define the terms, describe the concepts, and provide the examples in French, Arabic, or other language as appropriate. This could enhance understanding of the risks and how they might apply in practice.

The range of biorisks and important responsible research concepts are explained on the continuum below.

Subset of Definitions from WHO

“Bioethics: The study of the ethical and moral implications of biological discoveries, biomedical advances and their applications, as in the fields of genetic engineering and drug research.”

“Biorisk: The risk (risk is a function of likelihood and consequences) that a particular biological event (in the context of this document: naturally occurring diseases, accidents, unexpected discovery, or deliberate misuse of biological agents and toxins), which may affect adversely the health of human populations, may occur. An assessment of these risks can be both quantitative and qualitative.”

“Biorisk reduction: The reduction of the occurrence of risks associated with exposure to biological agents and toxins, whatever their origin or source, encompassing the full spectrum of biorisks.”

“Laboratory biosafety: The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release.”

“Laboratory biosecurity: The protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.”

“Dual-use life sciences research: Knowledge and technologies generated by legitimate life sciences research that may be appropriated for illegitimate intentions and applications.”

“Research excellence: Research that is of high quality, ethical, rigorous, original and innovative.”

Additional Definitions


Research Misconduct: “Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.”

Falsification: “Manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record.”

Fabrication: “making up data or results”

Plagiarism: the use “of another person’s ideas, processes, results, or works with our giving appropriate credit.”

Protection of Human Subjects: “Protect the interest of research Subjects” by ensuring “that risks to human participants are minimized; that risks are reasonable given the expected benefits; that the participants or their authorized representatives provide informed consent; that
the investigator has informed participants of key elements of the study protocol; and that the privacy of participants and confidentiality of data are maintained.”

**Animal Subject Care and Use:** “to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing.” Researchers should consider “reduction in the numbers of animals used, refinement of techniques and procedures to reduce pain and distress, and replacement of conscious living higher animals with insentient material.”

**Negligence:** “Haste, carelessness, inattention – any of a number of faults can lead to work that does not meet scientific standards or the practices of a discipline.”

The definitions below are from the *U.S. National Academy of Sciences (1992) Responsible Science, Volume I: Ensuring the Integrity of the Research Process.*

**Research Integrity:** “the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities.

**Research Process:** “the construction of hypotheses; the development of experimental and theoretical paradigms; the collection, analysis, and handling of data; the generation of new ideas, findings, and theories through experimentation and analysis; timely communication and publication; refinement of results through replication and extension of the original work; peer review; and the training and supervision of associates and students.

Advance to the next slide.

**Slide 7-9: Risk Analysis Framework**

Advance to the next slide, titled “Risk Analysis Framework.” This slide outlines the framework that this exercise will use for risk analysis. This framework has 4 risk categories: risk identification, risk assessment, risk management, and risk communication. This process is iterative, meaning as the research progress, you continue to identify, assess, manage, and communicate potential risks. This exercise is designed to educate scientists about the broad range of risks they might encounter during research design, conduct, and communication and to equip scientists in analyzing and managing risks in practice and on an ongoing basis.

1. Read or summarize the four stages aloud (see Risk Analysis Stages below). Please add additional information and details based on your own experience and from your own research.
2. To test whether participants understand the four stages, you may want to ask a participant to give a sample answer to each question. For example, ask participants “What are some of the possible risks associated with research on XXX topic (for example, epidemiological studies of pathogen infection?)” An answer for this question might be “accidental exposure or release of pathogen, access to infected samples, misuse of results, no protection of human subjects, and other.” Answer any questions participants have.

## Risk Analysis Categories

**Risk Identification:** the process by which researchers consider all possible internal, external, and organizational risks.

This step asks the question:  
**What are the possible risks associated with the research?**

**Risk Assessment:** the process by which researchers identify needed resources and consider biosafety/biosecurity recommendations.

**Risk Assessment** (OHSAS 18001:2007): process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable. This definition comes from the CWA15793. (See Appendix 1 for the full citation.)

This step asks the questions:  
**How likely are the risks to occur?**  
**What are the potential consequences if the risks occur?**  
**Do the risks outweigh the benefits?**

**Risk Management:** the process by which researchers consider regulations/guidelines, training, and SOP compliance issues.

This step asks the question:  
**What risk management strategies could minimize the likelihood that the risk will occur or the consequences if the risks occurred?**

Possible strategies for managing risks include: physical barriers, personnel training or vetting, regulations and laws, and/or alternative experiments. This is by no means
a comprehensive list, but is a starting point for thinking about the available range of risk management options.

**Risk Communication:** process by which researchers consider communication strategies, non-compliance issues and approval/modification processes.

Asks the questions:
- What risks should be communicated with ethics or other research review committees prior to project initiation?
- What risks should be communicated to research participants or fellow researchers during the research project?
- What risks, if any, might come from sharing research data or results?
- What strategies could be used to minimize the risks?

Advance to Next Slide.

**Slide 10: Risk Analysis Chart**

1. The chart on this slide is intended as a visual aid to assist participants in understanding how the concepts and definitions they have learned fit into the risk analysis framework in this exercise. The chart shows the types of possible research risks that feed into the risk analysis process, the 4 risk analysis stages, and suggestions on how to think about each stage of the risk analysis process. Before you move on in this exercise, all participants should understand these three components and how they fit together: types of potential risks, risk analysis stages, and how to think about each stage.

2. Read and explain the chart to participant or ask a participant to do so. You might consider asking participants to give examples of a potential risk and how it fits into the risk analysis framework to help you determine whether more instruction is needed to clarify risk analysis framework.
The reference section at the end of these facilitator’s notes (Appendix 1) lists several useful documents that provide more advanced and detailed information on research-related risks of biological research and diagnostic activities. You may want participants to read parts of these documents either before or after the practical exercise to improve their understanding of possible risks and risk analysis.

If you are planning to split the practical exercise into 2 days, you may want to assign participants to read parts of these documents after doing Slides 1-7 on day 1.

**IF YOU ARE DOING THIS EXERCISE OVER 2 SESSION, STOP HERE AT THE END OF THE FIRST SESSION.**

If you are doing this exercise in one session, advance to the next slide.

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**Slide 11: Case Study Introduction Slide**

1. Inform participants that it is now time to begin the case study.
2. Inform participants that the case study is based on a real, published research or epidemiological study. The research purpose, experimental approach, results, and conclusions are taken from the referenced scientific article.
3. Remind participants that this exercise is not to conduct a critical peer review of the article. Remind participants that the goal of the exercise is to impart the skills to identify, assess, manage, and communicate risks in scientific studies.

Advance to the next slide.

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**Slide 12: Case Study Outline**

1. Briefly outline the 5 parts of the case study to participants. Inform participants that this case study has been organized to most closely reflect the how the risk analysis framework would apply in practice.
   - Part 1: The Article Summary, which includes:

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• 1 slide about the Research Statement,
• 2 or more slides with necessary background information from the article and other authoritative resources
• 1 or more slides on the research methodology/experimental approach

Part 2: Interactive Risk Analysis Discussion, with 1 slide each on Risk Identification, Assessment, and Management.

Part 3: Summary of research results and conclusions.

Part 4: Interactive Risk Communication Discussion

Part 5: Applying this Risk Analysis Framework and Strategies from this case study to your own research.

Advance to the next slide.

**Slide 13: Research Question/Hypothesis**

1. Read the research question slide or ask a participant to read the slide.
2. We recommend ask a participant to summarize the research question to assess whether participants understand the key elements of the research question.

Advance to the first Background Information slide.

**Slides 14-16: Background Information Overview**

1. Read the background information slides aloud to participants. Feel free to add information or data from your own experience in order to aid participants in fully understanding the research context of this case study. At the end of the Background Information slides, you may want to ask a participant to summarize key background information to assess their understanding of important background information.
2. Try to answer any questions participants might have, referring to the article and to your own knowledge.
Background Information Overview
Hepatitis B Virus (HBV) Infection

- Hepatitis B virus is a blood borne pathogen that affects 2 billion people worldwide. Approximately 400 million people are chronic hepatitis B carriers.
- Hepatitis B virus infects the liver and can cause acute and chronic disease.
  - Acute symptoms of infection include jaundice, dark urine, extreme fatigue, nausea, vomiting, and abdominal pain.
  - Chronic disease includes liver disease, cirrhosis, and liver cancer.
- Hepatitis B virus is most commonly spread from mother to child at birth, or from person to person in early childhood. Other transmission routes include through sexual transmission and sharing of contaminated needles. (WHO, HBV, 2013)
- Hepatitis B virus can survive outside the body for 7 days.
- More than 250 million people have chronic liver infections.
- About 700,000 people die every year due to the consequences of hepatitis B. (WHO, 2013)
- The hepatitis B vaccine is 95% effective in preventing infection and its chronic consequences. (WHO, HBV, 2013)

Background Information Overview
Health Landscape in North Waziristan

- In FATA region as a whole and in North Waziristan in particular, health services have deteriorated significantly since 2001.
- Vaccination programs have deteriorated due to attacks on medical personnel and facilities.
- Limited healthcare is currently provided by:
  - Government-funded hospitals, rural health and community health centers
  - Insurgent-funded hospitals and clinics
  - The international aid community

Advance to Research Methodology slide.

**Slide 17: Research Methodology**

1. Briefly describe the experimental approach used to address the research statement. Specific details, such as research reagents, kits, or equipment are not necessary to identify and assess the risks. Please focus on the concepts and experiments used. Remember, these experiments were actually conducted in the published research; the goal is to analyze risks as they were conducted, not to critique the research team’s chosen methodology.

2. Answer any questions participants might have.

**Research Methodology**

- **Participant identification.** A total of 790 suspected hepatitis B infected individuals were enrolled in the study. Research scholars asked participants to provide their name, gender, age, socioeconomic status, educational level, and several health questions using a questionnaire.
- **Sample collection and serum preparation.** Research scholars obtain 5ml whole blood from study participants. Serum was separated within 48h of collection, transported to the University, and stored in the freezer until further processing.
- **Serological investigation.** The presence of cross-reacting antibodies to hepatitis B virus in participant sera was analyzed using enzyme-linked immunosorbent assays (ELISAs).
- **HBV DNA extraction and amplification.** Hepatitis B DNA from sera of ELISA positive participants was extracted using a commercially available kit. Real time polymerase chain reaction was carried out to confirm viral DNA and quantify the level of viral DNA in the samples.
- **Statistical analysis.** The data was analyzed using commercially available software.
3. You might need to revisit this slide while participants identify the risks.

Advance to the Risk Analysis slide.

Slide 18: Risk Analysis in this Research Article

1. This slide is designed to help you transition from the research statement and methodology to the interactive risk identification, assessment, and management worksheets.

2. Remind participants to refer to the risk analysis framework chart and definitions in their Participant Handbook as they begin the discussion.

3. Remind participants that the goal of the discussion is not to critique the choices of the authors, but to apply the risk analysis framework to this case study article and its experimental procedures as they were conducted. Participants should consider a wide range of risks relevant to the research article, including biosafety, biosecurity, and ethical risks that are capable of causing harm to persons, facilities, institutions, governments, the environment, human subjects, animal subjects, and society.

4. Make sure you have a flip chart, dry erase board, chalk board, or other large writing space available to record the key discussion points for all participants to read. Designate a person who will write down participant responses; this person could be you, a co-facilitator, or participant.

Involve all participants in identifying possible risks and discussing risks that other participants have identified. Please remember that the discussion should remain respectful of participant views and suggestions; having said this, interactive discussions often include disagreement and are essential to building critical thinking skills about possible risks.

Note for facilitator: Throughout this case study exercise, you are encouraged to ask questions and/or provide scenarios to help participants consider possible risks, their potential consequences, and approaches to manage, mitigate, and communicate the identified risks. Suggested prompts or scenarios are included in the facilitator's notes for many of the questions found on the risk identification, assessment, management, and communication slides.

Advance to the Risk Identification Slide.
Slide 19: Risk Identification

This slide has questions to encourage and guide participants to identify possible risks that might be associated with the research statement and experimental approach.

1. Ask participants to spend 5 minutes thinking about and writing down answers to the Risk Identification questions asked on this slide. Participants should be asked to draw on the possible risks described at the beginning of the exercise; the background, research statement, and experimental approach; and their own personal experience.

2. Ask participants to spend another 5-10 minutes discussing the Risk Identification questions and their answers with other participants in their small groups. One individual from each group should be recording the group’s discussion; this person is the rapporteur.

2. At the conclusion of the small group discussions, ask group rapporteurs to report risks their group discussed. Write the identified risks on the flip charts/chalkboard/dry erase board, noting which have been identified by more than one group.

3. Discuss the risks as a whole group for 10 minutes before moving onto the Risk Assessment slide.

Risk Identification Questions:

1. What, if any, are the potential safety and security risks to research scholars and laboratory scientists involved in this experiment?

2. What, if any, safety, security, or ethical considerations are associated with identifying and taking samples from HBV positive individuals in conflict-affected areas?

Prompt: Encourage the participants to especially consider the ethical risks and security risks to the research subjects in this research project.
Prompt: If participants do not address the fact that HBV positive is a disease that faces stigma and discrimination in many countries, prompt them to consider the potential risks to the social standing, job prospects, and even safety of human subjects if their positive status or background information was made public. Examples that could support this line of questioning include:

- in many Middle Eastern countries (including the UAE) non-citizens found HBV positive can legally be deported;
- injecting drug workers — group specifically identified in the background questionnaire—face systematic discrimination in Pakistan, including from police: [http://r4d.dfid.gov.uk/PDF/Outputs/ReproHealthHIV_RPC/PolicyBrief2_Pakistan.pdf](http://r4d.dfid.gov.uk/PDF/Outputs/ReproHealthHIV_RPC/PolicyBrief2_Pakistan.pdf)

3. What, if any, additional risks or concerns are associated with obtaining samples from disadvantaged and a poorly literate population?

Advance to the Risk Assessment Slide.

**Slide 20: Risk Assessment**

This slide has questions designed to aid participants in assessing the level or degree of risk from the potential risks identified in the previous Risk Identification Slide. This slide includes questions on the type of information needed to accurately assess this risk (which may or may not be included in the research article), the likelihood of the risk occurring, and the risk burden of various stakeholders (i.e. the researcher, laboratory head, or responsible government agency). This category also requires participants to consider the potential consequences of the potentially risky research, and evaluate and weigh the potential risks and benefits of the research. These are critical in research practice. Remind participants of the purpose of this category.

1. Ask participants to spend 5 minutes thinking about and writing down answers to the Risk Assessment questions asked on this slide. Participants should be asked to draw on the risks identified on the previous slide; the background, research statement, and experimental approach; and their own personal experience.

2. Ask participants to spend another 5-10 minutes discussing the Risk Assessment questions and their answers with other participants in their small groups. One individual
from each group should be recording the group’s discussion; this person is the rapporteur.

3. At the conclusion of the small group discussions, ask group rapporteurs to report their assessments and answers to the entire group. Write the identified risks on the flip charts/chalkboard/dry erase board, noting which have been identified by more than one group.

4. Discuss the risk assessments and information needed to conduct the assessments as a whole group for 10 minutes before moving onto the Risk Management slide.

At the conclusion of the 5 minutes, ask group rapporteurs to report the results of their discussion. Record unique findings where all participants can see.

As a whole group, discuss how each group assessed and ranked the risks they previously identified. Spend 5-10 minutes in whole group discussion before moving onto the next risk category.

**Risk Assessment Questions:**

1. What, if any, are the potential consequences of the biosafety risks associated with the research project?

2. What, if any, are the potential consequences of the biosecurity risks associated with the research project?
   - Which risk is likely to be higher: theft of human sera containing HBV or misuse of research materials and/or results?

3. What, if any, are the potential consequences of the ethical risks associated with the research project?

4. What are the resources, expertise, training, and tools that could be useful in assessing the risks identified for this research project?

Advance to the Risk Management Slide.

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**Slide 21: Risk Management**

This slide asks questions guide participants in thinking about, discussing, and deciding upon possible and appropriate risk management/mitigation strategies for the risks previously identified. Risk mitigation strategies could be implementation of physical controls, personnel
controls and training, use of alternative experiments, or a range of other appropriate strategies. Participants should consider the role of the many scientific stakeholders capable of managing risk, including: scientists, laboratory heads, institutions, governments, and legal structures. Remind participants that the goal is to maintain the quality and utility of the scientific study while also minimizing or eliminating research-related risks.

1. Ask participants to spend 5 minutes thinking about and writing down answers to the Risk Management questions asked on this slide. Participants should be asked to draw on their knowledge of approaches to mitigate risk and their own personal experience.
2. Ask participants to spend another 5-10 minutes discussing the Risk Management questions and their answers with other participants in their small groups. One individual from each group should be recording the group’s discussion; this person is the rapporteur.
3. At the conclusion of the small group discussions, ask group rapporteurs to report the risk mitigation strategies their small groups discussed. Write the identified risks on the flip charts/chalkboard/dry erase board, noting which have been identified by more than one group.
4. Discuss the identified risk mitigation strategies as a whole group for 10 minutes before moving onto the Results and Conclusions slide.

**Risk Management Questions**

1. What risk mitigation strategies could researchers use to mitigate the ethical risks to the HBV-positive human subjects in this research project?
   
   **Prompt:** Encourage participants to consider that there is inadequate healthcare available to help manage the disease that the research team is potentially diagnosing. To what degree might the research team be responsible for future healthcare or for aiding the research subject? How could such an obligation be built into the risk management plan.
   
   If participants do not consider any ethical management strategies, consider asking them a provocative ethical question such as “Imagine that a research subject is diagnosed as being HIV positive, in addition to having HBV. Assuming that there is no adequate HIV treatment available in North Waziristan, who do you have an ethical obligation to inform about the HIV positive status? What obligation does the research team have to mitigate any security and safety risks to the patient from a positive diagnosis?”

2. What risk mitigation strategies could researchers use to mitigate the laboratory biosafety and potential biosecurity risks of the research project?
   
   **Prompt:** Give a more specific question, if there is minimal or no conversation. For example, what standard operating procedures (SOPs) or best practices should be employed to reduce the likelihood that laboratory staff become infected by HBV or an unknown virus in whole blood samples?

3. What approaches, if any, could be taken to reduce the risks to research scholars?
4. What, if any, are specialized competencies, skills, and training needed to successfully enroll, interview, and collect blood samples from participants, and separate and transport sera in conflict-ridden areas?

5. Are there any international, domestic, or institutional laws and regulations that could help manage risks from this research project?

Advance to the Results and Conclusions slide.

**Slide 22: Results and Conclusions**

1. Read through the results and conclusions. Remind participants that the results and conclusions were taken from the scientific article and not hypothetical.

2. Answer any questions that participants might ask.

Advance to the Risk Communication slide.

**Slide 23: Risk Communication**

The objective of these questions is to guide participants in thinking about strategies to communicate risk responsibly to all involved stakeholders, including other investigators, those helping with the research, research subjects, reviewers, the institution and institutional ethics boards, government or intergovernmental organizations, and the broader scientific community.

To help facilitate this discussion, you might want to describe the 2012 experience with the H5N1 influenza papers, which raised national (in the U.S. and Netherlands) and international dialogue about the risk of communicating: 1) the mutations (or viral sequence) that might confer increased mammal-to-mammal transmissibility; and 2) the methods of the experiments conducted. These were raised as security, safety, and ethical concerns at the time of publication. The complicating factor in this situation was that the research and/or results had been communicated widely to funding agencies, scientific conference attendees, institutional review bodies and administrators, and peers.
1. Ask participants to spend 5 minutes thinking about and writing down answers to the Risk Identification questions asked on this slide. Participants should be asked to draw on the possible risks described at the beginning of the exercise; the background, research statement, and experimental approach; and their own personal experience.

2. Ask participants to spend another 5-10 minutes discussing the Risk Communication questions and their answers with other participants in their small groups. One individual from each group should be recording the groups discussion; this person is the rapporteur.

3. At the conclusion of the small group discussions, ask group rapporteurs to report risks and mitigation strategies their group discussed. Write the identified risks on the flip charts/chalkboard/dry erase board, noting which have been identified by more than one group.

4. Discuss the risks as a whole group for 10 minutes before moving onto the Final Discussion slide.

**Risk Communication Questions**

1. What are the risks that should be communicated during this research? To whom?

2. How would you communicate the risks from being involved in the research to a potential research participant that: Is illiterate? Is a child? Lives in a high-conflict area?

3. What data and information protection measures should be implemented to protect the safety and anonymity of research participants?

   **Prompt:** Make sure that the discussion covers the following types of information and data protection: data aggregation, (where subjects are grouped together before publishing), de-identification of data (including coding the data, taking out names, specific locations, and ages) before it is shared or published, and software or computer encryption that hides information such as email and IP addresses. The US has a “minimum de-identification standard” for health-related research. An overview of this standard can be found here: [http://policy.umn.edu/Policies/Operations/Health/HIPAARESEARCH_PROC04.html](http://policy.umn.edu/Policies/Operations/Health/HIPAARESEARCH_PROC04.html).


4. What social and cultural sensitivities are associated with the research project?

5. What, if any, safety and security risks are associated with communication of the study area, research methods, and research results?

6. What, if any, strategies would you use to minimize identified risks during communication of the research project and results to other researchers, individuals in the conflict areas, and the broader public?
The purpose of the final discussion is for participants to apply the risk analysis framework to their own research. An extremely important goal of this case study exercise is to equip participants with the skills to identify, assess, manage, and communicate risks associated with their own research or the scientific activities of their peers and/or students. The guidance you provide during this final discussion should focus on helping participants translate what they have learned during the exercise into practice and to their own scientific environment.

1. Inform participants that their task is to now think about how the risks, mitigation strategies, and risk analysis framework apply to their own research.
2. Spend 10-15 minutes involving participants in discussing the questions listed on the slide.
3. Ask participant to spend another 10-15 minutes conducting the risk analysis on their own research or scientific activities. You should help answer questions, ask thought-provoking questions, and guide participants as they go through the analysis.

Remind students that in practice, risk analysis is an iterative process where researchers make risk-benefit decisions that require developing new and/or revising existing risk management approaches during the design, conduct, and communication of research.

The next slide has a schematic of the biorisk management framework from the CEN Workshop 31 on Laboratory biosafety and biosecurity (see below). While this schematic uses a different flow than the framework used in this case study, the core concepts and elements of risk identification, assessment, and management are similar.

You may want to ask participants to look at the framework as they develop their own research risk analysis. Some participants may find it useful to see this second
framework as an example of how risk analysis can be done in the laboratory. This framework is the last page in the Participant Packet.

**Slide 25: Example Risk Analysis Framework**

The flow chart below is one example of how biorisk identification, assessment, and management can be practiced in a laboratory context. Part of a European agreement document on Laboratory biorisk management, this flow chart may be useful for some participants to see, because the flow shows the “yes/no” component of determining whether or not a risk is acceptable, and shows options for managing or eliminating risks that are assessed as not acceptable.

**Citation:**
Appendix 1. Biorisk and Responsible Research References

General Biosecurity and Biosafety References


University of Bradford, [http://www.brad.ac.uk/bioethics/nationalseries/](http://www.brad.ac.uk/bioethics/nationalseries/)


Laboratory Biorisk Management


A highly technical document that is developed primarily as a standard for well-equipped laboratories, this contains useful definitions and context about how life scientists globally are thinking about and implementing biorisk management.

Responsible Conduct of Research—Ethics and Misuse

World Health Organization. “Section 5.2: Monitoring the risks as a responsibility of individuals and scientists.” Life science research: opportunities and risks for public health. pp. 18-20. Available at: http://www.who.int/ethics/Life%20Science%20Research.pdf. This section of the report contains an excellent overview of the misuse risks of and research responsibility in life sciences research.

Steneck, Nicholas H. Introduction to the Responsible Conduct of Research. Office of Research Integrity (ORI). August 2007. Available at: http://ori.hhs.gov/sites/default/files/rcrintro.pdf. While focused on U.S. definitions and policy, Chapters 1 and 2 provide a good overview of research responsibility and misconduct concepts, terms, and applications.