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Research Studies to Understand Risks

An Overview for Beginning PhD Students

HumanIC CBT1

27th Feb 2025

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HumanIC project has received funding from the European Union's Horizon Europe research and innovation program under the Marie Sklodowska-Curie (HORIZON-MSCA-2022-DN-01, project no 101119726

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Agenda

- Introduction to Risk in Research
- Types of Risks
- Research Designs for Studying Risk
- Data Collection and Analysis
- Ethical Considerations
- Case Studies
- Challenges and Emerging Trends
- Conclusion & Q&A

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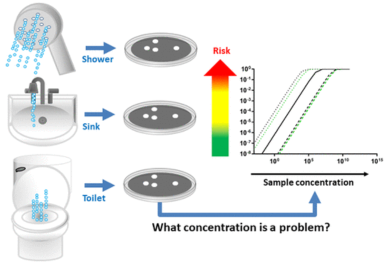
Introduction to Risk in Research

Definition of Risk:

- Risk in research refers to the uncertainty regarding outcomes. It encompasses not only the possibility of unexpected or adverse results but also the chance that these outcomes may impact the validity or ethical integrity of a study.



Uncertainty about Outcomes:

- In any research study, especially in fields like healthcare or environmental studies, outcomes are not guaranteed. Variability in data, unforeseen interactions, or external influences can all introduce uncertainty into your findings.

Potential Adverse Events:

- Risks include negative events—such as unintended side effects in clinical trials or data misinterpretation due to confounding factors—that could harm participants, affect the quality of the study, or have broader societal consequences.

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Why Does Risk Matter?

- **Designing Robust Studies:**
  Understanding risk helps researchers anticipate potential pitfalls. By identifying sources of uncertainty—whether methodological, operational, or ethical—you can design studies that are resilient, incorporate safeguards, and have built-in mechanisms to address these risks.
- **Ethical and Safety Considerations:**
  In healthcare research, for example, assessing risk is crucial for ensuring participant safety and obtaining informed consent. Evaluating the risk-benefit balance helps to protect those involved and adheres to ethical standards.
- **Informs Policy and Decision-Making:**
  When research outcomes have implications for public health or environmental policy, quantifying risk offers evidence-based guidance for resource allocation, intervention strategies, and regulatory decisions.
- **Resource Allocation:**
  A thorough risk assessment identifies where additional resources or safeguards are needed, ensuring that funding and effort are focused on mitigating the most significant uncertainties and adverse outcomes.

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Importance for PhD Researchers

- **Foundation for Methodological Rigour:**
  For emerging researchers, a deep understanding of risk is key to developing sound methodologies. This includes planning for data variability, anticipating challenges, and implementing appropriate control measures.
- **Enhancing Credibility and Impact:**
  When risks are clearly defined, measured, and managed, research findings become more credible. This transparency not only strengthens academic work but also enhances its relevance to policy and clinical practice.
- **Guiding Ethical and Practical Choices:**
  Awareness of risk informs ethical decision making, and helps balance scientific inquiry with participant protection. It is also essential when designing studies that might influence public health interventions or environmental management strategies.

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Types of Risks in Research

Inherent Risks in Research:

- Methodological Risks: Bias, confounding variables, measurement errors
- **Why It Matters:** These risks can lead to incorrect conclusions, compromising the study's validity.
- Ethical Risks: Participant safety, data privacy breaches, informed consent issues
- **Why It Matters:** Maintaining ethical integrity is essential for protecting study subjects and upholding public trust.

Context-Specific Risks:

- Clinical research: Health and safety risks for participants.
- Environmental research: Exposure to hazardous substances.
- Social science: Risks of misinterpretation or misapplication of findings.

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Operational Risks:

- Technical failures, insufficient sample sizes, unexpected disruptions.
- **Why It Matters:** These risks can derail a project’s timeline and affect the reliability of data.

Relevance for PhD Research:

- Identifying and managing various risk types ensures that the study design is robust and that results are credible.
- It informs how to build safeguards into research protocols—from pilot testing instruments to establishing clear ethical review procedures.

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Research Designs to Study Risk

Research design refers to the overall strategy for integrating various components of the study in a coherent and logical manner, allowing one to address research questions effectively.

Observational Studies: observing and measuring variables without intervention.

- Cross-sectional Studies: Snapshot of risk factors at one time.
- Cohort Studies: Following subjects over time to assess risk development.
- Case-Control Studies: Comparing those with and without an outcome.

Experimental Studies: manipulating one variable to determine its effect on another.

- Randomised Controlled Trials (RCTs): Gold standard for minimising bias and laboratory experiments
- They provide stronger evidence of causality by controlling confounding factors.

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Mixed-Methods Studies:

- Combining quantitative and qualitative approaches can yield both statistical rigor and contextual depth.
- **Relevance for PhD Research:**
- Choosing the right design is key to addressing your research questions and managing uncertainties.
- A well-considered design strengthens the interpretability of your results and their applicability to policy or practice.

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Research Design	Key Features	Strengths	Weaknesses
Cross-sectional Study	Snapshot of risk factors at one time	Quick and cost-effective; good for prevalence studies	Cannot establish causality; susceptible to bias
Cohort Study	Follows subjects over time to assess risk development	Can establish temporal relationships; good for studying multiple outcomes	Time-consuming and expensive; potential for loss to follow-up
Case-Control Study	Compares those with and without an outcome	Efficient for rare diseases; relatively quick and inexpensive	Prone to recall and selection bias; cannot directly measure incidence
Randomised Controlled Trial (RCT)	Manipulates one variable to determine its effect on another; participants randomly assigned	Gold standard for minimising bias; can establish causality	Expensive and time-consuming; ethical considerations
Laboratory Experiment	Controlled environment to test hypotheses	High level of control over variables; can establish causality	May lack external validity; results may not be generalisable to real-world settings

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Data Collection and Analysis/Interpretation

Quantitative Methods

- Statistical techniques: Regression analysis, survival analysis, hazard ratios.
- Measuring risk: Relative risk, odds ratios, absolute risk.
- **Why it matters**: Quantitative data provides measurable evidence that can support risk estimates and validate study hypotheses.

Qualitative Approaches

- Interviews and focus groups to understand perceptions of risk.
- Mixed-methods research: Combining qualitative insights with quantitative data.
- **Why it matters**: Qualitative data adds depth by capturing perceptions, experiences, and context that numbers alone might miss.

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Addressing Bias and Confounding: Strategies for design and analysis to mitigate risk-related biases.

- **Technique**: Sensitivity analyses, triangulation, data validation strategies.
- **Why it matters**: It improves the credibility of your findings by demonstrating robustness.
- **Relevance for PhD Research:**
- Mastery of data collection and analysis techniques is central to producing reliable and publishable research.
- It teaches you to critically assess data quality and the implications of methodological choices.

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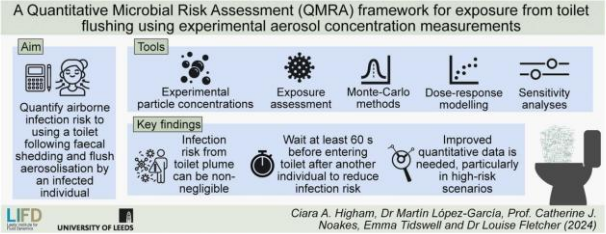
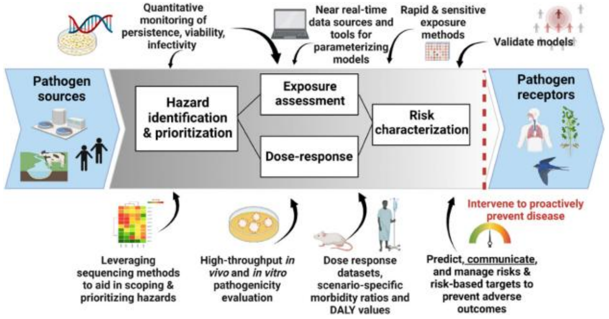
Quantitative Microbial Risk Assessment (QMRA)



- QMRA is a systematic approach used to estimate the risk of infection and illness from exposure to microorganisms in various environments, including healthcare settings.

QMRA involves four key steps:

- **Hazard Identification**: Identifying the microorganisms of concern and the diseases they cause.
- **Exposure Assessment**: Determining the pathways of exposure (e.g., air, surfaces) and measuring or modelling the levels of pathogens.
- **Dose-Response Assessment**: Establishing the relationship between the dose of the pathogen and the likelihood of infection or illness.
- **Risk Characterisation**: Combining the exposure and dose-response data to estimate the risk of infection or illness.



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QMRA relevance to Indoor Environment

- **In healthcare settings**, particularly operating rooms, QMRA can be used to:
- **Identify Pathogens**: Determine which microorganisms pose a risk in the operating room environment (e.g., bacteria, viruses).
- **Assess Exposure**: Measure or model the levels of pathogens in the air and on surfaces within the operating room.
- **Evaluate Infection Risk**: Estimate the probability of infection for healthcare workers and patients based on exposure levels and dose-response relationships.
- **Develop Control Measures**: Inform the design and implementation of infection control measures, such as air filtration systems, surface disinfection protocols, and personal protective equipment (PPE).

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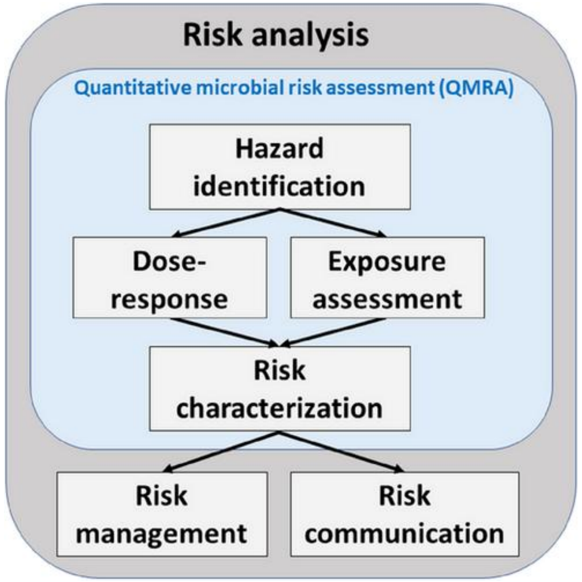
- Which step of QMRA involves determining the relationship between pathogen dose and infection probability?"
- A) Hazard Identification
- B) Exposure Assessment
- C) Dose-Response Assessment
- D) Risk Characterization



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- "Which data collection method do you think is most effective for assessing microbial risks in operating rooms?"
- A) Air sampling
- B) Surface swabbing
- C) Both

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Examples of QMRA studies

QMRA for Drinking Water Safety

Study: Boil Water Advisory

- **Context**: This study evaluated the effectiveness of boil water advisories in reducing the risk of infection from fecal contamination in drinking water.
- **Pathogens**: Campylobacter jejuni and Cryptosporidium were selected based on their prevalence in surface water and their role in waterborne outbreaks.
- **Approach**: The study modelled a hypothetical breakdown at a water treatment plant, leading to untreated surface water being supplied to a city of 100,000 people.
- **Findings**: The study assessed the risk reduction achieved by issuing a boil water advisory and highlighted factors affecting its effectiveness, such as public compliance and the duration of the contamination event.
- https://qmrawiki.org/index.php/case-studies/boil-water-advisory-assess.pdf

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QMRA for Recreational Water Quality

Study: US EPA's QMRA for Recreational Waters

- **Context**: This study aimed to estimate the health risks associated with exposure to pathogens in recreational waters impacted by wet weather events.
- **Pathogens**: Various pathogens, including bacteria, viruses, and protozoa, were considered.
- **Approach**: The study used QMRA to predict relative risks for future scenarios and evaluate the efficacy of alternative management actions, such as treatment and other mitigation measures.
- **Findings**: The study provided insights into the potential health risks from recreational water use and informed the development of water quality guidelines.
- https://archive.epa.gov/ow/ost/web/pdf/recreation-stakeholder-2008-risk-assess.pdf

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QMRA for Indoor Air Quality in Healthcare Settings

Study: QMRA for Airborne Pathogens in Operating Rooms

- **Context**: This study assessed the risk of infection from airborne pathogens in operating rooms.
- **Pathogens**: Pathogens such as Staphylococcus aureus and Mycobacterium tuberculosis.
- **Approach**: The study measured airborne pathogen concentrations, modelled exposure scenarios for healthcare workers and patients, and estimated the risk of infection using dose-response relationships.
- **Findings**: The study provided recommendations for improving air filtration systems, implementing disinfection protocols, and using personal protective equipment (PPE) to reduce infection risks in operating rooms.
- Quantitative microbial risk assessment (QMRA) | U.S. Geological Survey

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Ethical Considerations

Ethics in research addresses the moral obligations of researchers to protect participants and ensure integrity in study design and reporting.

Participant Safety

- Ensuring informed consent and minimising harm.
- **Why It Matters:** Protecting participants is fundamental to responsible research and maintaining public trust.

Data Integrity and Transparency

- Ethical handling of data, reporting negative results, avoid data manipulation.
- **Why It Matters:** Ensures that research findings are reproducible and reliable

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Ethical Considerations

Regulatory Oversight

- The role of Institutional Review Boards (IRB) and ethical committees.
- **Why It Matters:** Regulatory frameworks help enforce ethical standards and provide guidance during study design.
- **Relevance for PhD Research:**
- Ethical considerations are not just a regulatory hurdle but are central to the credibility and societal impact of your research.
- For early-career researchers, understanding ethics enhances the ability to design studies that are both safe and methodologically sound.

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Case Studies and Practical Examples

Case studies provide real-world examples of how risk research has been implemented, offering insights into both successes and challenges.

Examples in Healthcare:

- Studies on surgical site infections, indoor air quality in operating rooms, and infection control in hospitals.
- **Why It Matters:** They illustrate how theoretical risk assessments translate into practice.

Examples in Environmental Studies:

- Research on waterborne disease outbreaks, air pollution risk assessments, and risk management in climate change.
- **Why It Matters:** They demonstrate how risk analysis informs policy and operational decisions.

Relevance for PhD Research:

- Case studies offer tangible examples that can guide your own research design and risk management strategies.
- They help bridge the gap between theory and practice, showing how robust risk assessment can lead to improved outcomes.

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Challenges and Limitations in Risk Research

The inherent challenges researchers face when assessing risks, as well as the limitations of current methodologies.

Data Limitations:

- **Examples:** Incomplete data, small sample sizes, high variability.
- **Why It Matters:** Data gaps can lead to uncertainties that weaken risk estimates.

Methodological Challenges:

- **Examples:** Balancing model complexity with interpretability, handling confounding variables.
- **Why It Matters:** Overly complex models may not be practical, while oversimplified models can miss critical nuances.

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Challenges and Limitations in Risk Research

Interdisciplinary Hurdles:

- **Examples:** Integrating diverse types of data (quantitative and qualitative) communication across disciplines.
- **Why It Matters:** Effective risk research often requires collaboration, and interdisciplinary misalignment can compromise study outcomes.

Relevance for PhD Research:

- Recognising these challenges helps to plan contingencies and choose methods that are both rigorous and realistic.
- It also prepares to critically evaluate existing literature and identify areas for methodological improvement.

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Emerging Trends in Risk Research

Big Data and Machine Learning

- Using large datasets to predict and model risk.

Interdisciplinary Approaches

- Combining insights from statistics, computer science, and domain-specific expertise.

Innovative Methodologies

- Real-time data analysis and adaptive trial designs.

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Practical Tips

- **Pilot Studies**: Conduct pilot studies to identify potential risks and refine your methodology.
- **Consultation**: Seek advice from your institution's ethics board or experienced researchers.
- **Continuous Monitoring**: Regularly review and update your risk management strategies throughout the study

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Healthcare Context

Importance:

- High-stakes healthcare environments require precise risk assessment.
- Indoor air quality, thermal comfort, and strict infection control are critical for patient and staff safety.

Examples:

- Operating rooms where infection control is paramount.
- Hospital zones where thermal comfort affects both patient recovery and staff performance.

https://www.pexels.com/

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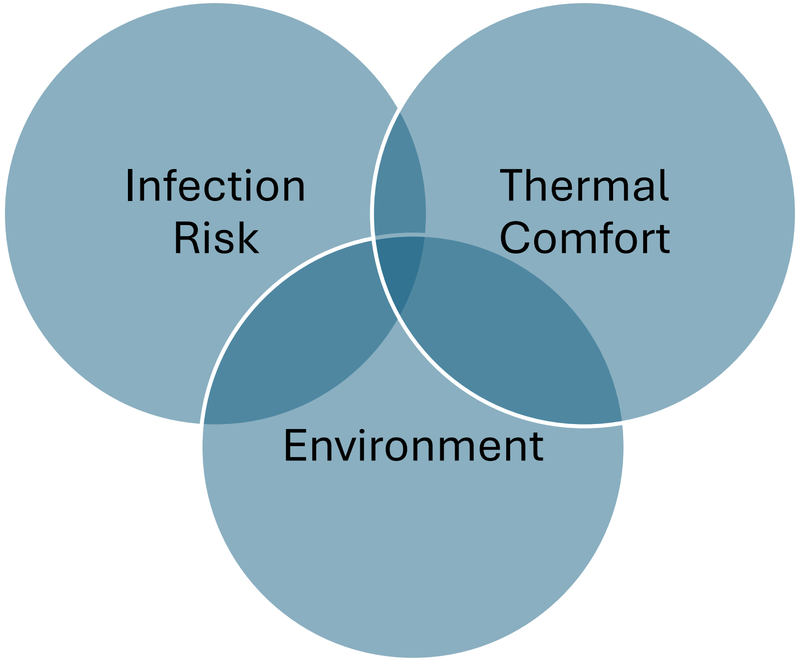
Risk in Healthcare Environments

Risk Definition:

- Uncertainty in outcomes that can lead to patient harm, operational inefficiencies, or compromised healthcare delivery.

Key Areas of Concern:

- Indoor infection: Airborne pathogens, surgical site infections.
- Thermal comfort: Impacts on human performance, patient outcomes.
- Operating room dynamics: Balancing sterile conditions, environmental control, and workflow efficiency.



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Types of Risks in Healthcare Environment

Methodological Risks:

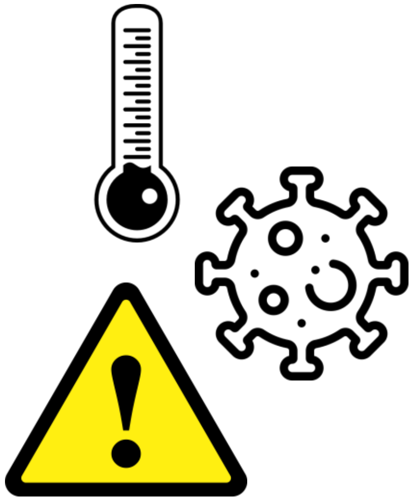
- Measurement errors in sensor data (e.g., temperature, humidity, particulate counts).
- Challenges in accurately tracking infection rates and correlating them with environmental factors.

Ethical Risks:

- Ensuring patient confidentiality and informed consent when using clinical data.
- Balancing intervention studies with patient safety.

Operational Risks:

- Disruptions in OR workflow during data collection.
- Inadequate ventilation or suboptimal thermal conditions impacting infection control.



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Emerging Trends & Future Directions Healthcare

- **Advanced Monitoring:**
- Adoption of IoT and smart sensors for continuous, real-time monitoring of environmental conditions.
- **Predictive Analytics**:
- Machine learning models that predict infection risk based on environmental and operational data.
- **Interdisciplinary Collaboration:**
- Joint efforts between engineers, epidemiologists, and healthcare professionals to design better ORs.

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Conclusion

Recap Key Points

- Understanding risk is essential to designing effective and ethical research. Particularly assessing indoor infection risk, thermal comfort, and operational efficiency in healthcare settings.

Implications for Future Research

- Encouraging critical thinking about methodology and risk mitigation. How robust research designs can lead to improved patient outcomes and safer operating environments.

Call to Action

- How beginning PhD students can integrate risk assessment into their research proposals. Integrate interdisciplinary approaches into future research projects.

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Activity 1: Risk Identification and Categorisation

Case Scenario Background:

- Based on the literature in healthcare risk assessment (e.g., Haas et al., 2014; Hamilton et al., 2018), imagine an operating room that has experienced a few sporadic infection incidents.
- The environment is monitored continuously, and key parameters include temperature, relative humidity, and air exchange rate.

Operating Room Layout:

- Size: 50 m^2
- Ventilation: 20-18 air changes per hour (ACH)
- Temperature: 21–23°C
- Relative Humidity: 45–55%

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Incident History:

- In the past month, 2–3 minor infection outbreaks were reported, with infection rates slightly above the hospital's benchmark.

Additional Observations:

- Some sensor data indicate occasional spikes in CO_2 and particle counts during peak operating times.

Group Task:

- Use these details to identify and categorise risks into methodological (e.g., sensor calibration issues, data variability), ethical (e.g., potential harm from infections), and operational (e.g., ventilation system performance) categories.

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Activity 1: Outcome

Methodological Risks:

- **Measurement Error:** Sensors might have calibration issues, leading to inaccurate readings (e.g., slight errors in temperature or humidity readings).
- **Data Gaps:** Occasional missing data due to sensor malfunction can affect risk estimates.

Ethical Risks:

- **Patient Safety:** The sporadic infection incidents, even if few, raise concerns about patient harm and the duty to ensure a safe environment.
- **Informed Consent/Data Privacy:** If data on patient outcomes is collected without clear consent or anonymisation, ethical issues may arise.

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Operational Risks:

- **Ventilation System Performance:** Variability in air exchange (e.g., a drop from 20 to 18 ACH) could increase airborne contamination.
- **System Overload During Peak Times:** Spikes in CO_2 and particle counts during high-occupancy periods indicate potential for system stress and increased infection risk.

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Activity 2: Data Analysis and Uncertainty Discussion

Date	Temperature (°C)	Relative Humidity (%)	Air Exchange Rate (ACH)	Particle Count (particles/m^3)	Documented Infection Cases
Day 1	22.0	50	20	1,800	0
Day 2	22.5	48	20	2,100	0
Day 3	21.8	52	20	1,950	1
Day 4	22.2	50	20	2,000	0
Day 5	23.0	47	18	2,400	1
Day 6	21.5	53	22	1,700	0
Day 7	22.0	50	20	2,050	0
Day 8	22.8	49	19	2,300	1
Day 9	22.1	51	20	1,900	0
Day 10	22.4	50	20	2,000	0

Synthetic Dataset for an Operating Room (10-Day Monitoring):

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Dose–Response Parameter Example:
Using a simplified exponential model, assume:

- **Dose–Response Coefficient (r):** 0.001

Exposure Calculation:

Dose (D) could be estimated as:

- D = (Particle Count) × (Exposure Duration in hours) × (Breathing Rate, e.g., 0.5 m^3/h)
- For instance, if on Day 3 the average particle count is 1,950 particles/m^3 and a typical exposure duration during surgery is 2 hours, then:
  D ≈ 1,950 × 2 × 0.5 = 1,950 particles

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Infection Probability:

- P(infection) = $1 - e^{(-r \times D)}$
  For Day 3:
  P(infection) ≈ 1 – exp(–0.001 × 1,950) ≈ 1 – exp(–1.95) ≈ 1 – 0.142 = 0.858 (or 85.8%)
  (Note: This is a highly simplified example. In practice, parameters would be derived from controlled studies.)

Task for Groups:

- Calculate the estimated infection probability for one of the days using the provided formula.
- Discuss how variability in parameters (e.g., fluctuations in particle counts or differences in exposure duration) can influence risk estimates.
- Propose one method (e.g., sensitivity analysis) to assess the uncertainty in your risk calculation.

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Outcome: Example Using the Synthetic Dataset:

Calculation Example (Day 3): Given Data:

- Particle Count: 1,900 particles/m^3
- Exposure Duration: 2 hours
- Breathing Rate: 0.5 m^3/hour

Dose Calculation:

- $D = 1900 \times 2 \times 0.5 = 1900$ particles
- **Infection Probability:**
  Using the exponential model with r=0.001:
  $P(\text{infection}) = 1 - \exp(-0.001 \times 1900) \approx 1 - \exp(-1.90)$
- $\approx 1 - 0.149 \approx 0.8504 \approx 0.85$ or 85%
- *Note:* This high probability is illustrative and suggests that the dose–response parameter or particle count may be conservatively estimated.

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Uncertainty Discussion:

- **Variability Factors:** Variations in particle counts (e.g., differences between 1,700 and 2,400 particles/m^3 on different days), exposure duration, and individual breathing rates can significantly alter risk estimates.
- **Sensitivity Analysis:** You might suggest using Monte Carlo simulations to assess how changes in each parameter affect the overall infection probability.
- For example, if the particle count decreases by 20%, what is the impact on P(infection)?
- *You might conclude that both the exposure measurements and dose–response parameters are critical drivers of risk and that understanding their variability is essential for accurate risk management.*

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Activity 3: Designing a Research Proposal with Integrated QMRA

- **Research Proposal Scenario:**
  You are tasked with designing a study to evaluate the impact of enhanced ventilation on reducing airborne infection risk and improving thermal comfort in operating rooms. Use the following background data from literature:
- **Baseline Environmental Data:**
  - Temperature: 22°C
  - Relative Humidity: 50%
  - Air Exchange Rate: 20 ACH
- **Observed Issues:**
  - Sporadic infection incidents (approximately 2–3 cases per month)
  - Occasional spikes in particle counts and CO_2 during peak operation hours

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- *Task for Groups:*
  Develop a mini research proposal that includes:
- **Research Question:** How does increasing the air exchange rate to 25 ACH affect the probability of airborne infections and thermal comfort levels?
- **Study Design:** Outline whether to use an observational study, a controlled experiment (e.g., a pilot intervention), or a mixed-methods approach.
- **Data Collection:** Specify which parameters will be measured (e.g., temperature, humidity, ACH, particle counts, infection rates) and how frequently.
- **QMRA Integration:** Briefly describe how you would use the QMRA framework to estimate risk changes.
- **Ethical Considerations:** Detail steps to ensure patient safety and data privacy.

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Activity 2: Designing a Research Proposal with Integrated QMRA (outcome)

Research Question:
"How does increasing the air exchange rate from 20 ACH to 25 ACH in an operating room affect the probability of airborne infection and thermal comfort?"

Study Design:

- **Type:** A quasi-experimental design comparing current conditions (20 ACH) to intervention conditions (25 ACH).
- **Phases:** Baseline monitoring for a set period (e.g., 1 month), followed by implementation of enhanced ventilation and subsequent monitoring.

Data Collection Plan:

- **Parameters to Measure:** Temperature, relative humidity, ACH, particle counts, CO_2 levels, and documented infection cases.
- **Frequency:** Continuous sensor monitoring with daily aggregation, plus weekly reviews of infection reports.

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QMRA Integration: Framework Steps:

- **Hazard Identification:** Airborne pathogens of concern in the operating room.
- **Exposure Assessment:** Use measured particle counts combined with breathing rates and duration of exposure to estimate the dose (e.g., using D = particle count × exposure duration × breathing rate).
- **Dose–Response:** Apply a simple exponential dose–response model (e.g., P(infection) = 1 – exp(–r·D) with r = 0.001).
- **Risk Characterization:** Compare estimated infection probabilities before and after the intervention.
- **Ethical Considerations:**
- **Patient Safety:** Ensure that any changes are communicated to clinical staff and that alternative measures (e.g., enhanced PPE) are in place during the study.
- **Data Confidentiality:** Protect the privacy of patient and staff data.

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Activity 2: Ethical Debate and Policy Implications

- **Debate Scenario:**
  Imagine that the QMRA-based study (from previous case) suggests that increasing ventilation to 25 ACH could reduce infection risk by 40%, but it also increases operational costs and causes brief periods of noise that might disturb surgical concentration.
- *Debate Question:*
  "Do the potential benefits of enhanced ventilation outweigh the costs and operational disruptions in an operating room setting?"

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Task for Groups:

- Divide into two teams: one representing healthcare administrators (focusing on cost, workflow disruption, and resource allocation) and the other representing clinical researchers (focusing on patient safety, risk reduction, and ethical imperatives).
- Prepare arguments based on ethical principles, risk data, and potential policy outcomes.
- Engage in a structured debate (few minutes total), then discuss as a full group how ethical, economic, and practical considerations must be balanced in healthcare decision-making.

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Clinical Researcher Perspective:

- **Argument:** The QMRA indicates that increasing ventilation to 25 ACH reduces the infection risk by about 40%.
- Given the high stakes in patient safety and the potential for preventing even a few infections (which can lead to severe complications), the benefits in terms of improved health outcomes justify the increased costs and temporary operational disruptions.
- **Supporting Points:**
- Reduced infection risk means lower morbidity and possibly shorter hospital stays.
- Improved thermal comfort can enhance both patient recovery and staff performance.

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Healthcare Administrator’s Perspective:

- **Argument:** While the potential reduction in infection risk is valuable, the increased cost, noise, and operational disruption must be weighed against budget constraints and overall hospital workflow.
- The administrators might argue for a pilot study or phased implementation to ensure that the benefits outweigh the trade-offs before committing significant resources.
- **Supporting Points:**
- Consider alternative strategies (e.g., noise mitigation, scheduling adjustments) to address operational challenges.
- A comprehensive cost–benefit analysis is necessary to evaluate long-term impacts on both safety and operational efficiency.

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Synthesis/Conclusion:

- **Joint Recommendation:** A balanced approach may be the best path forward. For instance, pilot testing the enhanced ventilation system in one operating room, while concurrently evaluating patient outcomes, operational costs, and staff feedback, could provide the evidence needed to justify broader implementation.
- **Ethical Implication:** Both perspectives stress that patient safety is paramount, but practical constraints must be managed through careful planning and stakeholder involvement.
- *Consensus? while enhanced ventilation is desirable from a health perspective, implementation should be carefully planned with additional measures to mitigate operational challenges.*

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