University of Maryland Project Management Symposium



Team Resilience in Action: Risk Management in Clinical Research Projects During Ebola Outbreak in West Africa

Jiwan Giri

Project Manager III (PMIII), Clinical Monitoring Research Program Directorate (CMRPD)



Project Management Symposium

Team Resilience in Action: Risk Management in Clinical Research Projects During the 2014 Ebola Outbreak in West Africa

Jiwan Giri, MS, MIS, PMP

Clinical Monitoring Research Program Directorate, Frederick

National Laboratory for Cancer Research

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Presentation Outline

- Describe clinical research projects from PM perspective
- Define team resilience and its core characteristics
- Identify key strategies for building team resilience
- Describe a resilient team's role in promoting risk management
- Explain how a resilient team can apply tailored risk mitigation strategies to lead a clinical research project

Clinical Monitoring Research

Program Directorate

(CMRPD) Suppo

Teams

Clinical

Safety

Oversight

Services Supported over

600 clinical

research

projects

Reference: CMRPD, Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc., Frederick, Maryland 21702



Coordination

Administrative

Management

Need to establish resilient teams

∠024 Project Management Symposium

Ebola project

Project Management



Clinical Research Project from PM Perspective: Definitions

What is clinical research?

Clinical research is a component of medical and health research intended to produce knowledge that is valuable for understanding human disease, preventing and treating illness, and promoting health.

Reference: Institute of Medicine, 2002

What is a clinical trial?

A type of research study that tests how well new medical approaches work in people.

Reference: National Institute of Health (NIH)



Impacted three countries, communities and societies:

- Guinea,
- Liberia, and
- Sierra Leone

Reference: Fallah et al, 2023; Dixon, M. G., & Schafer, I. J. (2014).

Clinical Research Project from PM Perspective: Background for 2014 Ebola Outbreak in West Africa



As of June 10, 2016: 28,616 cases; 11,310 deaths; and over **10,000** survivors of Ebola virus disease.





The 2014 Ebola Virus Outbreak

- Ebola virus disease (EVD): a severe, often fatal, hemorrhagic disease
- EVD research was still in the early stage
- No licensed products available at the time
- No safe and effective Ebola therapy at the time
- Researchers had no potential vaccine efficacy in hand
- EVD outbreak: provided research opportunities



Challenges

Current State of the 2014 Ebola Emergency in West Africa



Ebola Emergency





Project Context/Operational Challenges

- No known clinical research infrastructure: workforce (HR), IT/research infrastructure, weak healthcare system
- In-country logistics: travel, food, accommodation, safety, security, procurement, supply chain infrastructure
- Community barriers: rumors, false perceptions, fear, and misinformation
- Environment: epidemiological, regulatory, political, geopolitical, ecological, and socioeconomic complexity





Not Enough People



Balancing stakeholders' interests

Former State of Clinical Research Infrastructure





Redemption Hospital: Before







Renovated Clinical Research Infrastructure

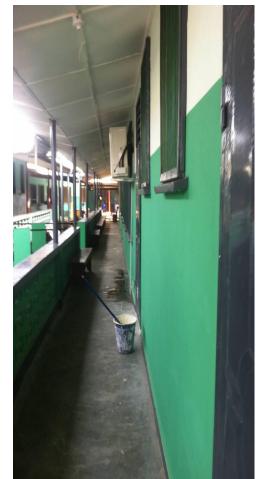




Redemption Hospital: After







Team Resilience and Risk Management in Support of Clinical Research Project

Topic # 1

Define resilience, team resilience, and their core characteristics

Team

Resilience

Topic #3

Describe a resilient team's role in promoting risk management

Key **Strategies**

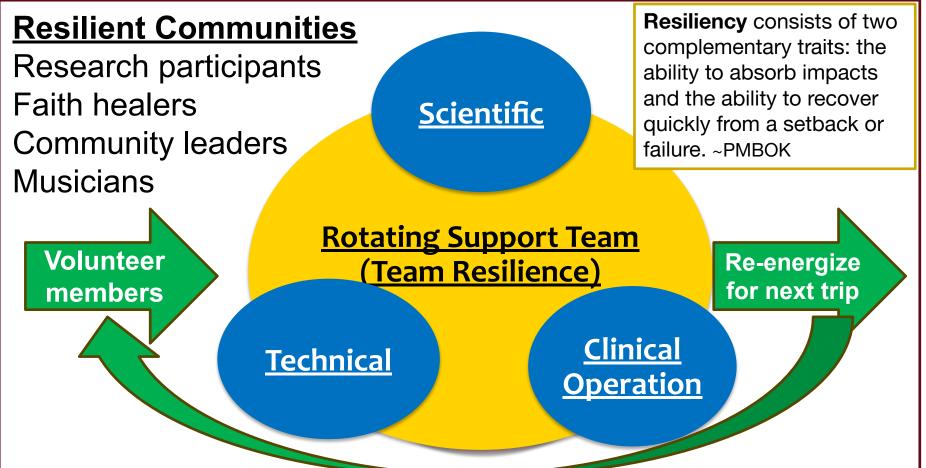
> Risk Management (MGT) **Framework**

In the context of the 2014 **Ebola Outbreak** in West Africa

Topic #2

Identify key strategies to build team resilience

Defining Team Resilience in Clinical Research Context



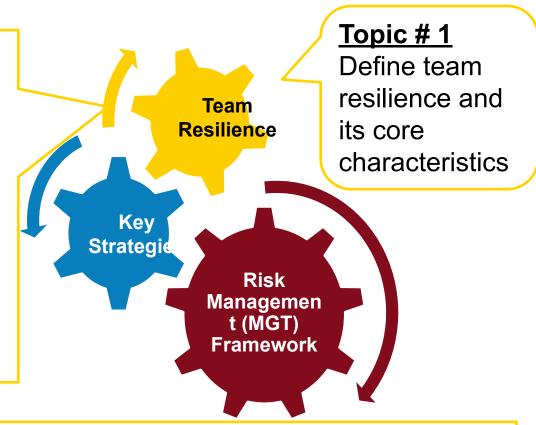


Definition of Resilience and Team Resilience

- Resilience is defined as "the capacity to rebound or bounce back from adversity, conflict, failure or even positive events, progress and increased responsibility" (Luthans 2002b, p. 702).
- **Team Resilience** is the capacity of a group of people to respond:
 - to change and disruption in a flexible and innovative manner.
 - to effectively confront and navigate challenges, overcome obstacles, and withstand the pressure of adverse situations.

Core Characteristics of Team Resilience

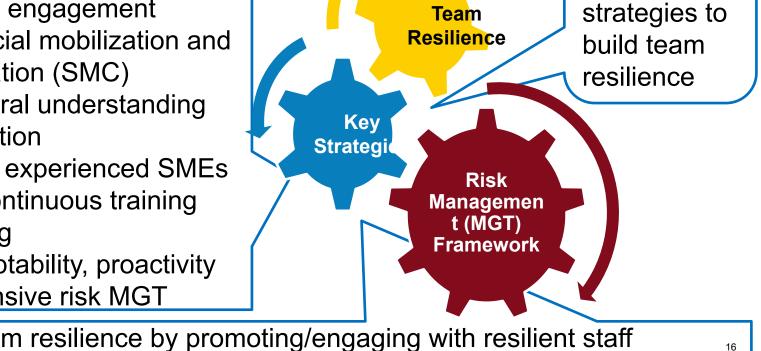
- Promoting open and transparent communication/collaboration
- Fostering adaptability and flexibility
- Prioritizing well-being and support
- Integrating risk management across all functions
- Embracing continuous learning and innovation



• Positive mindset, problem solving, survival mentality, self-awareness, and compassion

Key Strategies to Build Team Resilience

- Engaged leadership agreed upon how it governs
- Community engagement through social mobilization and communication (SMC)
- Cross-cultural understanding and integration
- Leveraging experienced SMEs
- Promote continuous training and learning
- Foster adaptability, proactivity
- Comprehensive risk MGT



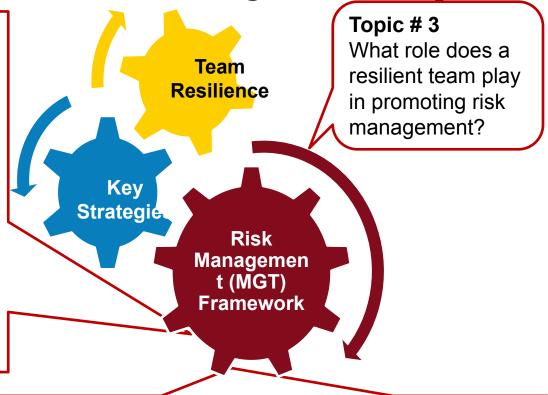
• Enhance team resilience by promoting/engaging with resilient staff members and community leaders through SMC strategies.

Topic #2

Identify key

The Role of Team Resilience in Promoting Risk Management

- Promotes effective communication
- Adapts to proactive risk MGT
- Maintains the well-being of support team
- Ensures the safety of research participants and integrity of the research data
- Enhances the quality of research outcomes
- Expedites the approval of treatments



- Place communication/collaboration first and empower resilient people
- Leverage tailored and integrated risk management approach



CMRPD's Tailored Risk MGT Framework:

Risk Case Example

Request: Support a high-priority clinical research project

Summary: International Four sites n = 500

Identify **Analyze Risks Risks** Risk Register (Tracker) Communicate **Mitigate Risks Risks Monitor Risks**



CMRPD's Tailored Risk MGT Framework:

Risk Case Example

Identify aspects that could impact the project

Request: Support a high-priority clinical research project

Summary:

International Four sites n = 500

Identify Analyze Risks Risks Risk Register (Tracker) Communicate Mitigate Risks **Risks**

Monitor

Risks

- Analyze the importance of a risk in comparison to the project
 - Consider the probability of the risk occurring
- Determine the seriousness of the risk



CMRPD's Tailored Risk MGT Framework:

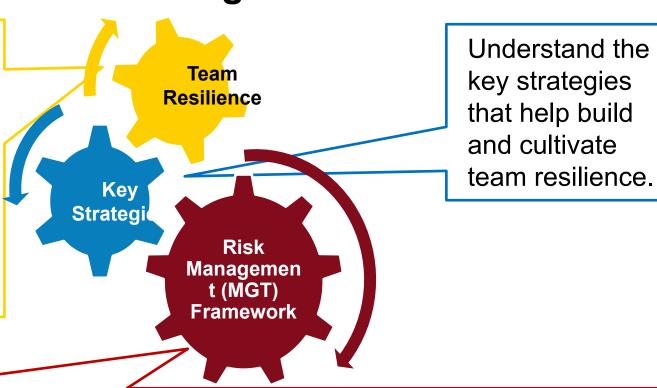
Risk Case Example

Decide what Identify **Analyze** should be done Risks Risks Determine who about the risk the risk gets reported to Risk Register (Tracker) Evaluate whether Communicate **Mitigate** Request: Support a the implemented **Risks Risks** high-priority response clinical research project strategies are Summary: working **Monitor** International Four sites **Risks**

n = 500

Messages

- Be resilient and support resilient team members in a team
- Recognize the core characteristics and core value of team resilience



- Prioritize communication/collaboration first and empower resilient people
- Leverage tailored and integrated risk management approaches



Summary

It takes a village to conduct clinical research.

Insights from working with resilient teams on the ground:

- All projects are risky not all risks are bad
- Risk identification is an iterative process
- Have tailored risk mitigation strategies across all functions
- Promote and build team resilience throughout the project lifecycle
- All hands on deck approach: empower the research team
- Team resilience and risk management = project success





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Contact Jiwan Giri giriji@mail.nih.gov 240-586-0134





Evaluate Session

