



Outbreak Readiness & Response

Obtaining human samples in austere environments for infectious disease countermeasures

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Speaker Disclosures

- Disclosures:
 - Current Position: VP for Research Strategy, Integrum Scientific
 - Research activities conducted by Integrum will be mentioned
 - Integrum does not produce, market, sell, re-sell, or distribute healthcare products used by or on patients
 - Scientific Advisory Boards: Integrum (Chair)
 - ASTMH (unpaid), Geneva Foundation (unpaid)
 - Equity investments:
 - Pfizer, United Therapeutics, Eli Lilly, Clorox, Immunity Bio
 - No commercial products are mentioned or related to this presentation

Coauthor Disclosures

- Mark Cashin
- Rita Corrales
- Jen Zimmerer
- Wendy Boone
- Joe Sgherza
- All associated with Integrum as employees or shareholders. No other potential COIs noted.

Learning Objectives

- Describe potential pitfalls when obtaining human samples in austere settings.
- Discuss the logistics considerations to move samples inside and between countries.
- Develop a risk assessment for planning a collection protocol in an austere setting.

Introduction

- Gaps exist for countermeasures to diagnose, treat, or prevent Warfighter infections from viral hemorrhagic fevers
- Developing countermeasures for VHFs relies on first understanding the immune response to the disease in question
- Animal and *in vitro* models are useful, but development and validation of countermeasures relies on obtaining human samples from acutely infected or convalesced patients
- Outbreaks often occur in remote regions that may present risk to Warfighters directly or threaten operations
 - Obtaining such samples presents significant challenges
 - Understanding them allows for preparation required for success.



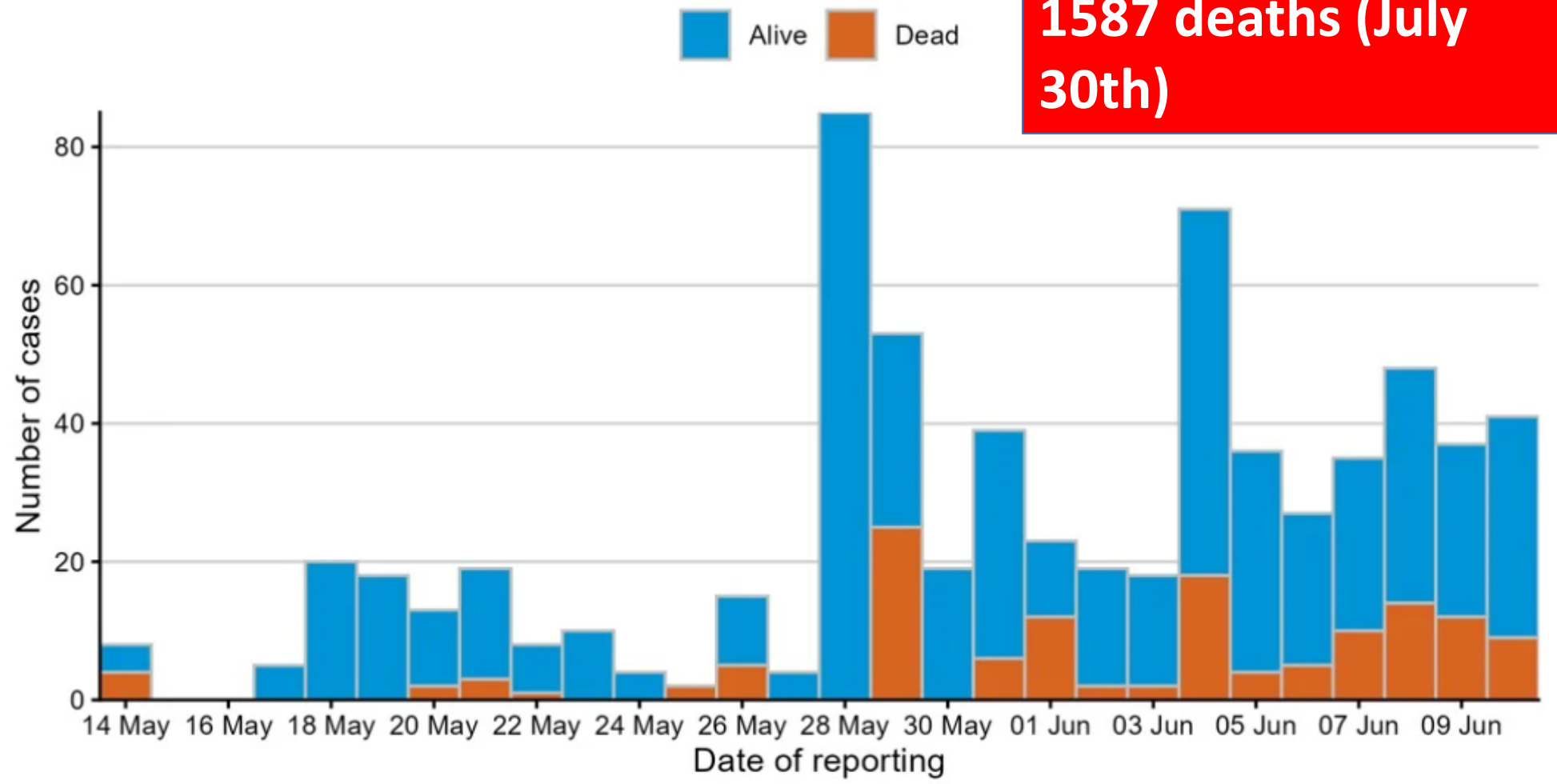
MV Hondius

- As of May 28, 2026, WHO has reported 13 cases (11 confirmed and two suspected), including three deaths. Investigations are ongoing.

WHO



Figure 2: Number of confirmed cases (n = 676) in the Democratic Republic of the Congo, by date of reporting as of 10 June 2026



**Now over 2605 cases,
1587 deaths (July
30th)**

Source = Centre des Opérations d'Urgence de Santé Publique (COUSP) situation reports

<https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON607>

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Viral Hemorrhagic Fever



● Filoviruses

● Flaviviruses

● Bunyaviruses

● Arenaviruses

Scientific Value of Human Specimens

- Convalescent Samples
 - Disease confirmation
 - Diagnostic assay validation (positive controls)
 - Diagnostic standards for vaccine development
 - Understanding adaptive immune response timeframe and duration
 - Surveillance for disease prevalence
- PBMCs
 - Understand innate immune response
 - In vitro vaccine effectiveness
 - Monoclonal antibody development
- Validate *in silico* modeling

*Developed as a direct response to the lessons learned
responding to real pandemic outbreaks*



Developed in response to lessons we learned when responding to critical infectious disease outbreaks

OUR VISION

To *reduce the impact* of infectious disease threats, especially in the *most vulnerable regions of the world*

OUR MISSION

To *improve the effectiveness* of global and local clinical research initiatives by promoting *prevention, preparation, and awareness*

Infectious Disease Scientific Advisory Board

World leaders in infectious disease field responsive research, specialty vehicle design and manufacturing, and international logistics



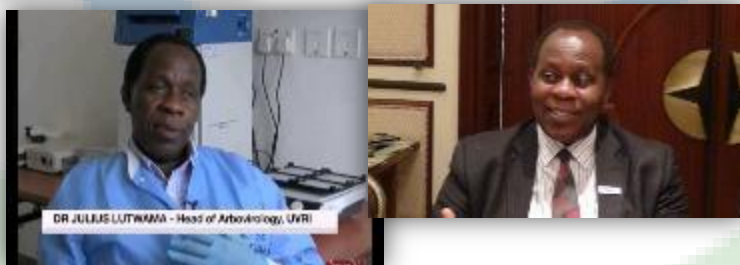
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Headquarters and
IDSAB (USA)

Additional IDSAB Members:
UK, Liberia, Uganda



MAP KEY

- ★ Headquarters, N.C.
- IDSAB Members
- Areas of Operations

Results

- We have partnered successfully in five countries to obtain serum, plasma, and PBMCs for diagnostic, therapeutic, and vaccine development on 10 different infections

Integrum Scientific Collection Projects

<u>Country</u>	<u>Virus</u>	<u>Number of Projects</u>
Uganda	Marburg	2
	Sudan	2
	Rift Valley Fever	2
	Crimean Congo Hemmorhagic Fever	1
Georgia	Old World Hantavirus	1
	Crimean Congo Hemmorhagic Fever	1
Sierra Leone	Lassa Fever	1
Bolivia	Machupo	2
	Chapare	1
Panama	Venezuelan equine encephalitis	1

Challenges to consider

- Partnership development
- Regulatory/ethical aspects
- Logistics:
 - Travel
 - Sample collection and processing
 - Cold chain storage and transportation
 - Force majeure



Partnerships

- No partner = forget about it
- Respect the locals
- Understand the local constraints, timelines
- Work toward something that is mutually beneficial
- Ensure the sponsors have realistic expectations of what can be achieved and what it takes to meet the expectations
 - Can the team increase flexibility to mitigate potential risk?



Photo Credit: Kortepeter



Photo Credit: Kortepeter collection

Regulatory/Ethical

- Be aware of the local regulatory framework and pathways/IRBs
- Can ICH/GCP guidelines be met?
- Paper vs electronic records?
- Are there unique human use issues and standards?
- How are local decisions being made?
- Avoid potential pitfalls – have eyes and ears on the ground
- Plan for unexpected timelines and delays

Logistics

- Travel
- Sample collection
- Processing
- Cold chain storage and transportation
- Force majeure





Photo Credit: Kortepeter
collection



Photo Credit: Kortepeter

Logistics

- Travel
- Sample collection and processing
 - Assess the site in advance
 - Adequate waiting area for volunteers?
 - Space for confidential informed consent?
 - Adequate space for blood draws?
 - Onsite lab or transport to a central lab?
 - Need for Integrum or non-local staff to complete sample processing to ensure sample quality and appropriate processes followed?
- Cold chain storage and transportation
- Force majeure



Photo Credit: Kortepeter



Photo Credit: Kortepeter



Photo Credit: Sgherza

Logistics

- Travel
- Sample collection
- Processing
- **Cold chain storage and transportation**
- Force majeure

Power

- Long or short-term storage?
- Power sources
- Power compatibility?
- Battery/generator Backup?
- Empty freezers?
- Availability of dry ice?
 - LN2 generators?



Photo Credit: Kortepeter



Photo Credit: Kortepeter

- Timeline for trans
- Method of trans
- Cold chain neede



Logistics

- Travel
- Sample collection
- Processing
- Cold chain storage and transportation
- **Force majeure**



Bolivia declares state of emergency, deploys military to quell protests

Story by Agence France-Presse • 5h •  2 min read



WELL-PREPARED Bolivian soldiers patrol the Cochabamba-La Paz highway near Parotani, department of Cochabamba, on June 20, 2026.

Burundi Highway
2018



Photo Credit: Kortepeter



Bolivia floods,
2025

Photo Credit: UNITAU
Foundation



Bolivia floods,
2025

Photo Credit: UNITAU
Foundation



Step-by-Step Assessment

- Assessment of risks and potential pitfalls prior to launching an operation
- Finding a reliable in-country partner
- Understanding the local regulatory/ethical framework
- Language barriers
- Determine availability of power
- Feasibility of maintaining a cold chain
- Assess laboratory resources or the need to build capacity
- Determine transportation modes to move samples to/from field sites
- Awareness of the diplomatic relations with the U.S.
- Assess risks for force majeure (floods, earthquakes, armed conflict).



Pre-Operational Risk Assessment for International Survivor Sample Collection Activities

Assessment of risks and potential pitfalls prior to launching an operation

RISK CATEGORIES		RISK MATRIX – INITIAL (INHERENT) RISK						
1	Finding a reliable in-country partner	LIKELIHOOD	Almost Certain (5)	IMPACT / CONSEQUENCE				
2	Understanding the local regulatory /ethical framework			Low (1)	Moderate (2)	High (3)	Critical (4)	Catastrophic (5)
3	Language barriers							
4	Determine availability of power					6	5	
5	Feasibility of maintaining a cold chain				3	4	2	7
6	Assess laboratory resources or the need to build capacity				8	1	9	
7	Determine transportation modes to move samples to/from field sites	Possible (3)						
8	Awareness of the diplomatic relations with the U.S.	Unlikely (2)						
9	Assess risks for force majeure (floods, earthquakes, armed conflict)	Rare (1)						

RISK REGISTER (DETAILS)		LIKELIHOOD (1–5)	IMPACT (1–5)	INITIAL RISK SCORE (LxI)	INITIAL RISK LEVEL	MITIGATION / CONTROLS (Examples)	RESIDUAL RISK (AFTER MITIGATION)			
							LIKELIHOOD (1–5)	IMPACT (1–5)	RESIDUAL RISK SCORE (LxI)	RESIDUAL RISK LEVEL
1	Finding a reliable in-country partner	2	4	8	HIGH	Due diligence, references, site visits, MOUs, pilot activities	1	4	4	MEDIUM
2	Understanding the local regulatory/ ethical framework	3	4	12	HIGH	Early engagement with ethics committees and regulators, documentation, local guidance	2	4	8	MEDIUM
3	Language barriers	3	2	6	MEDIUM	Hire local/bilingual staff, translators, standardized tools	2	2	4	LOW
4	Determine availability of power	3	4	12	HIGH	Assess power reliability, backup generators, UPS, power monitoring	2	4	8	MEDIUM
5	Feasibility of maintaining a cold chain	4	5	20	CRITICAL	Redundant refrigeration, temperature monitoring, contingency plans, trained staff	2	5	10	HIGH
6	Assess laboratory resources or the need to build capacity	4	4	16	HIGH	Capacity assessment, training, equipment procurement, SOPs, QA/QC	2	4	8	MEDIUM
7	Determine transportation modes to move samples to/from field sites	3	4	12	HIGH	Multiple transport options, validated carriers, contingency routes, tracking	2	4	8	MEDIUM
8	Awareness of the diplomatic relations with the U.S.	2	4	8	HIGH	Monitor political climate, engage local partners, comply with regulations	1	4	4	MEDIUM
9	Assess risks for force majeure (floods, earthquakes, armed conflict)	2	5	10	HIGH	Risk monitoring, contingency planning, insurance, schedule flexibility	1	5	5	MEDIUM

LOW (1–4) MEDIUM (5–9) HIGH (10–16) CRITICAL (17–25)

Note: Risks and scores should be reviewed and updated regularly throughout the project lifecycle.

Generated thru AI assistance

Conclusions

- Obtaining human samples in remote settings is achievable
- Requires an understanding of the potential pitfalls of operating in austere environments
- Integrum Scientific has “battle-tested” its methods in five countries on 10 infectious diseases of importance to the military
- Step-by-step preparation can help researchers meet success
 - Ultimately obtain and use samples as a foundation to develop innovative countermeasures for the Warfighter



Photo Credit: Kortepeter



EBOLA N'INGWARA Y'IKIZA YANDUKIRA KANDI YICA NINGOGA.

Ni inkeneziya ku ingenzi
buzisuzuma ibimenyetso
vy'ingwara ya Ebola zishitse ku
mabibe z'igihugu.

Ibimenyetso vyibonekeza k'umunwanyi wa Ebola

akurikira akurikira igihe cose
wibonywe ibimenyetso
kimwe muri byose.

Ingwara ya Ebola kuryamwo gute?

- Kubwira gusa mu mubiri
- Kuryamwo umuho umuho
- Kuryamwo umuho umuho

Organisme
mubiri ya Ebola

Photo Credit: Kortepeter collection

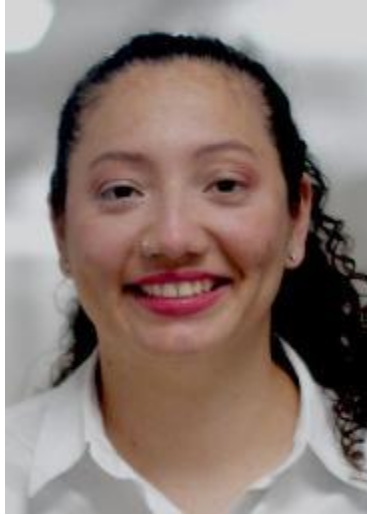
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- USAMRIID





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QUESTIONS?