LABORATORY PREPARATION AND THE EBOLA SPATIAL CARE PATH™—ACCELERATING DIAGNOSIS AT THE POINT OF NEED

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Research results may be preliminary. Final conclusions may differ. Please consult published papers. Device use must comply with regulatory and legal requirements.

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Please email questions to Dr. Kost at gjkost@ucdavis.edu. Thank you.
Principle: If it is not feasible to eradicate the primary sources, we must be prepared to detect the disease.
Principle: Isolation is fundamental to control of spread.

Principle: We must diagnose early before it is too late.
To study case examples of hospitals that have admitted patients with Ebola Virus Disease ("Ebola")—Emory University Hospital ("Emory"), which has an isolation unit for highly infectious disease patients set up by the Centers for Disease Control 12 years ago, the University of Nebraska Medical Center ("Omaha"), and Madrid, Spain.

To review molecular diagnostics and new tests for Ebola—Several tests received “Emergency Use Authorizations” (EUAs) from the FDA, and others are in development outside the U.S.

To be able to implement a Spatial Care Path™ (SCP)—A Spatial Care Path™ starts with the patient, positions POC testing optimally, accelerates decision making, and enhances community resilience.

To understand how to improve community resilience—POC testing is the modality of choice, so industry must respond with flexible test clusters, and governments, with national policy and guidelines.
The clinical course is protracted, elusive, tricky, quick, and highly dangerous.
• Ebola proved unequivocally the need for POC testing at initial points of contact and in patient isolation units.

• Basic test clusters must cover whole-blood analysis for critical care, detection of coagulopathy and DIC, molecular diagnostics, and the ability to rule out confounding infections.

• POC devices must be simplified, integrated, harmonized, and implemented in a culturally acceptable manner to optimize their usefulness and value at the point of care.
Move POC testing upstream in the Spatial Care Path.™
Detect the disease before the patient spreads it!

World Health Organization

“Target Product Profile for Zaire Ebola virus rapid, simple test to be used in the control of the Ebola outbreak in West Africa”

Source: http://www.who.int/medicines/publications/target-product-profile.pdf?ua=1

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### Key Features

<table>
<thead>
<tr>
<th>PRIORITY FEATURES</th>
<th>DESIRED</th>
<th>ACCEPTABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population</td>
<td>Patients presenting with fever to health care facilities for assessment.</td>
<td>Decentralized health care facilities with minimum laboratory infrastructures available</td>
</tr>
<tr>
<td>Target use setting</td>
<td>Decentralized health care facilities with no laboratories infrastructure available</td>
<td>In Ebola outbreak setting, distinguish between symptomatic patients with acute Ebola virus infection and non-Ebola virus infection without the need for confirmatory testing</td>
</tr>
<tr>
<td>Intended Use</td>
<td>In Ebola outbreak setting, distinguish between symptomatic patients with acute Ebola virus infection and non-Ebola virus infection with the need for confirmatory testing</td>
<td></td>
</tr>
<tr>
<td>Clinical sensitivity a, b</td>
<td>&gt; 98%</td>
<td>&gt;95%</td>
</tr>
<tr>
<td>Analytical specificity</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Type of analysis</td>
<td>Qualitative or Quantitative</td>
<td>Qualitative</td>
</tr>
<tr>
<td>Sample type</td>
<td>Capillary whole blood from finger stick once/ if the use of this type of samples has been validated. Other less invasive sample types (e.g., saliva, buccal) once/ if their use has also been validated</td>
<td>Whole blood from phlebotomy, in particular if collection is simple and automated to reduce biosafety requirements</td>
</tr>
</tbody>
</table>

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### Test Procedure

<table>
<thead>
<tr>
<th>Number of steps to be performed by operator (use of different reagents/incubation steps)</th>
<th>&lt; 3 timed steps</th>
<th>&lt;10 timed steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biosafety c</td>
<td>No additional biosafety in addition to Personal Protective Equipment c</td>
<td>No additional biosafety in addition to Personal Protective Equipment c</td>
</tr>
<tr>
<td>Need for operator to transfer a precise volume of sample</td>
<td>No</td>
<td>Acceptable if adequate disposable blood transfer device is provided</td>
</tr>
<tr>
<td>Time to result</td>
<td>&lt; 30 minutes</td>
<td>&lt; 3 hours</td>
</tr>
<tr>
<td>Internal control</td>
<td>included</td>
<td>included</td>
</tr>
</tbody>
</table>
Multi-organ pathogenesis requires flexible multiplex testing.
Global Point of Care
Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by
Gerald J. Kost & Corbin M. Curtis

AACCPress

THE CURRENT AND FUTURE DESIGN OF POINT OF CARE IN NATIONAL DISASTER CACHES
CORBIN M. CURTIS, RICHARD F. LOUIE, AND GERALD J. KOST

OVERVIEW

The objective of this chapter is to describe, innovate, recommend, and foster the implementation of point-of-care testing (POCT) in disaster caches in order to enhance crisis standards of care and improve triage, diagnosis, monitoring, treatment, and management of victims and volunteers in complex emergencies and disasters. The authors compared point-of-care (POC) technologies in US disaster caches to commercially available POC technologies to enhance the caches and reflect current state-of-the-art diagnostic capabilities. They also provided recommendations based on literature review and knowledge from newly developed POC technologies from the University of California, Davis Point-of-Care Technologies Center on designing POC caches applicable to most global needs.

US POC testing devices comprise chemistry/electrolytes, pregnancy, hemoglobin, cardiac biomarkers, hematology, fecal occult blood, drugs of abuse, liver function, blood gases, and limited infectious disease tests. Deficiencies with existing POCs for cardiac biomarkers, hematology, and infectious diseases should be eliminated. POC resources can be customized for pandemics, complex emergencies, or disasters based on geographic location and the potential for pandemics. Additionally, new thermally stabilized containers can help alleviate environmental stresses that reduce test quality. Innovations in POC technologies can improve response preparedness with enhanced diagnostic capabilities. Several innovations, such as the i-STAT® Wireless (Abbott Point of Care, Princeton, NJ, USA), OraQuick ADVANCE® HIV-1/2 (OraSure Technologies, Inc., OraSure Technologies, Inc., OraSure Technologies, Inc.), and VeriChip™ Lab-on-a-Chip (VeriChip Laboratories, Singapore), and new compact hematology analyzers will improve test clusters that facilitate evidence-based decision making and crisis standards of care during national disaster responses. Additionally, strategic resources and operator training should be globally harmonized to improve the efficiency of international responses.

Our goal is to describe, innovate, recommend, and accelerate the implementation of POCT in disaster caches in order to (a) enhance crisis standards of care; (b) improve diagnosis, triage, and monitoring in complex emergencies and disasters; and (c) harmonize evidence-based decision making during responses globally. The Office of the Assistant Secretary for Preparedness and Response (ASPR) under the US Department of Health and Human Services (DHHS) maintains three Mission Support Centers (MSCs) located in the western, central, and eastern United States. The eastern region and largest cache warehouse (200,000 ft²) serves as a training facility, home base for cache management, and national headquarters. Disaster response supplies deploy by trucks from any of the three locations to reach a disaster site in the contiguous United States or by airplane to sites outside the landlocked states such as Hawaii, Alaska, and the Republic of the Marshall Islands, within 12 h.

The caches within each facility hold supplies that Disaster Medical Assistance Teams (DMATs) use to triage, diagnose, and monitor victims following catastrophic events. Each facility has an inventory of pharmaceuticals, DMAT response packages, Basic Load Resupply packages to replenish 3 days of supplies for 175 patients per day, temporary portable housing, electricity generators, communication supplies, and vehicles to deliver resources to disaster sites where they converge with DMATs. The packages load straight onto trucks or airplanes without needing further organization. POC devices

This study was supported by the Point-of-Care Testing Center for Teaching and Research (POCT-CTR) at the National Institute for Biomedical Imaging and Bioengineering (NIBIB) Point-of-Care Technologies Center grant (Dr. Kost, PI, NIH U54 EB007939). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIBIB or the National Institutes of Health.
Disaster Point of Care

**COMING ORASURE EBOOLA POC TEST**

- **i-STAT® 1 Wireless** with G3+ (blood gases), Chem 8+ (electrolytes), BNP, and cTnI Cartridges
- **Oraquick ADVANCE® HIV 1/2**
- **Sure-Vue® Urine hCG Cartridge**
- **Onyx® II 9560 Fingertip Pulse Oximeter**
- **QuickVue® Influenza Test**
- **Rapid tests for Strep Throat, Mono and D-dimer**
- **Multistix® 10 SG Urinalysis Strips** Bilirubin, Blood, Glucose, Ketone, Leukocyte Esterase, Nitrite, pH, Protein, Specific Gravity, Urobilinogen
- **ABORhCard® Blood Typing Test Card**
- **CoaguChek® XS Plus System for PT/INR**
- **Hemoccult®-Immunochromatographic Fecal Occult Blood Test**
- **Min-Max Temp**
- **Triage® Drugs of Abuse Test Card**
- **StatStrip Glucose, Lactate, β-hydroxybutyrate and Creatinine**
- **Masimo Rad-57™ Oxygen Saturation and Hemoglobin plus pediatric probes**

**EVOLVING POC HEMATOLOGY ANALYZERS**
WBC & 5-PART DIFFERENTIAL ENVIRONMENTAL STRESS VALIDATION IN PROGRESS

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1. Fill microcuvette.
2. Place microcuvette into analyzer.
3. View results.

The microcuvette cavity is analyzed in separate layers to enable detection of cells at different depths. The camera lens moves in small steps taking several images through the cavity of the microcuvette.

All cells in all images will be cut out.

Identification when each cell is in focus.

Mount the focused cells into one image.

Total WBC and differential counting as final step.

Neutrophils
Lymphocytes
Monocytes
Eosinophils
Basophils

Transferring characteristics into mathematical algorithms. WBC DIFF uses over 30 features and state-of-the-art image analysis technology.
Source: Preparing for Ebola: What U.S. Hospitals Can Learn From Emory Healthcare and Nebraska Medical Center. Planning to Treat Patients with Ebola Virus Infection by Dr. Ribner, Emory Serious Communicable Disease Unit. CDC Webinar. 2014.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Instrument</th>
<th>Test(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abaxis</td>
<td>Piccolo</td>
<td>Chemistry profiles, Magnesium, Phosphate, liver enzyme assays, others available&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Express</td>
<td></td>
</tr>
<tr>
<td>Instrumentation Laboratory</td>
<td>GEM Premier 4000</td>
<td>pH, pCO₂, pO₂, Na⁺, K⁺, Ca&lt;sup&gt;++&lt;/sup&gt;, Cl⁻, Glu, Lac, Hct, THb, CO-Oximetry, TBil</td>
</tr>
<tr>
<td>Siemens</td>
<td>CLINITEK Status</td>
<td>Albumin, Bilirubin, Cr, Glu, Ketone, Leukocytes, Nitrite, pH, Protein, Specific Gravity, urinalysis Urobinogen, others available&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>automated urinalysis</td>
<td></td>
</tr>
<tr>
<td>Hoffman-La Roche</td>
<td>CoaguChek</td>
<td>PT/INR&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sysmex</td>
<td>pocH-100i</td>
<td>CBC: WBC (3-part differential), RBC, Hb, Hct, MCV, MCH, MCHC, Platelets&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Alere</td>
<td>BinaxNOW</td>
<td>Malaria</td>
</tr>
<tr>
<td>BioFire Diagnostics</td>
<td>FilmArray</td>
<td>Infectious diseases including Ebola&lt;sup&gt;e&lt;/sup&gt; (see Table 1)</td>
</tr>
</tbody>
</table>

Conclusions: Isolate suspected and confirmed patients, protect healthcare workers.

Belen Fernandez-Puntero*, Ruben Gomez-Rioja, Maria Jose Alcaide, Paloma Oliver, Pilar Fernandez-Calle, Jose Manuel Iturzaeta and Antonio Buno

The Laboratory Medicine and the care of patients infected by the Ebola virus. Experience in a reference hospital of Madrid, Spain

Abstract

The ongoing Ebola virus outbreak in several countries in West Africa was considered by the World Health Organisation (WHO) as a public health emergency of international concern. Healthcare providers must be prepared by organising specific procedures in our hospitals based on recommendations from national and international healthcare organisations. Two aims should be considered: appropriate medical care for patients with suspected or confirmed disease must be ensured, as must measures to prevent transmission to healthcare workers. The clinical laboratory plays an important role and must define and establish its own procedures in accordance with clinicians and integrated into those of the institution, starting with the definition of the organisation model in the laboratory to achieve those goals. In this review we present our experience based on the care of three patients with confirmed cases. We hope it will help other colleagues to plan for Ebola.
Significant hematology changes!

Late changes explained by hemoconcentration. Must identify initial trends.

Treatment should target hypovolemia, electrolytes, and acute renal failure.

• The sensitivity and specificity of pathogen detection must be improved to minimize false negatives when patients are asymptomatic.

• Instruments must have flexible multiplex test clusters and must address novel new threats.

• Simple and cost-effective approaches (FAST•POC™ and POCT•POD™) are needed so that patients, public health practitioners, and primary healthcare staff can perform testing quickly and easily.
Fact: Personal protective equipment saves lives of the medical workforce.

Fact: Deadly and fast!

WHAT MAKES EBOLA SO DEADLY

Ebola is a viral illness which infects through direct contact with blood or bodily fluids of a sick person or animal, or with contaminated objects. It leads to haemorrhage and organ failure and kills up to 90% of victims.

INFECTION: Ebola genome contains four genes which together prevent dendritic cells - in skin, nose, lungs and digestive system - from sending messages to trigger immune system.

UNCHECKED VIRAL GROWTH:
Virus spreads to cell types throughout body by binding glycprotein to receptors on cell surfaces.

Fact: Lack of rapid pathogen detection is a critical deficiency.

1. SYMPTOMS: Onset of illness is abrupt and is characterized by fever, headache, joint and muscle aches, sore throat, red eyes, and weakness.

2. CYTOKINE STORM:
Immune cells get caught in endless loop, releasing extreme levels of cytokines - proteins within cells which cause inflammation - and attracting yet more immune cells.

3. SEPTIC SHOCK:
Infected cells detach from blood vessels, causing massive haemorrhage. Loss of blood leads to kidney and liver failure.

Source: University of Texas Medical Branch, Picture: Public Library of Science, GRAPHIC NEWS
Molecular detection and point-of-care testing in Ebola virus disease and other threats: a new global public health framework to stop outbreaks


Gerald J Kost*, William Ferguson, Anh-Thu Truong, Jackie Hoe, Daisy Prom, Arirat Banpavichit and Surin Kongpila
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Ultrahigh sensitivity and specificity assays that detect Ebola virus disease or other highly contagious and deadly diseases quickly and successfully upstream in Spatial Care Paths™ can stop outbreaks from escalating into devastating epidemics ravaging communities locally and countries globally. Even had the WHO and CDC responded more quickly and not misjudged the dissemination of Ebola in West Africa and other world regions, mobile rapid diagnostics were, and still are, not readily available for immediate and definitive diagnosis, a stunning strategic flaw that needs correcting worldwide. This article strategizes point-of-care testing for diagnosis, triage, monitoring, recovery and stopping outbreaks in the USA and other countries; reviews Ebola molecular diagnostics, summarizes USA. FDA emergency use authorizations and documents why they should not be stop-gaps; and reduces community risk from internal and external infectious disease threats by enabling public health at points of need.

Free access during the meeting! Please try this link—

http://www.tandfonline.com/doi/full/10.1586/14737159.2015.1079776
Ebola tests are also emerging from other countries, such as China.
COMPACT PCR-BASED MOLECULAR DIAGNOSTICS

Influenza A & B CLIA Waived

Sensitivity  A 99.3%  B 98.1%
Specificity  A 98.9%  B 99.6%
MERS CoV—Saudi Arabia 2012, recently So. Korea, now 26 nations, touch surfaces, & 30-40% mortality.

Camels vs. Humans
Update Fall, 2015
37 dead/186 cases with case fatality rate of 20% in South Korea [579 dead/1,618 cases with 36% CFR in Saudi Arabia]
Influenza A & B
Sensitivity A 100%  B 100%
Specificity A 96.8% B 94.1%
(CLIA Waived)

Strep A
Sensitivity 98.3%
Specificity 94.2%
(CLIA Waived)

20 min PCR assay
Invest in POC technologies, stop outbreaks, and improve community resilience!

THE NEW FLEXIBLE MOLECULAR PARADIGM

1. TARGET HIGHEST PRIORITY DIAGNOSES
2. MAKE DECISIONS IN 20 MINUTES
3. TREAT IMMEDIATELY
Principles for Optimizing Strategic Planning

• Comprehensive planning for community resilience in small-world networks is deficient and must be improved.

• FAST•POC™ moves decision making upstream on the Spatial Care Path™ and can help stop outbreaks. Use POCT•PODs™ for isolation of testing in primary care and ERs along the SCP.

• International mobility, spread of epidemics, and huge national and regional economic losses warrant significant financial investment in POC testing.
THE SPATIAL CARE PATH™ (SCP™)

- **Definition**: The most effective route taken by the patient when receiving definitive care in a small-world network.

- **Hypothesis**: Common purpose in public health integrates prevention and intervention to shift focus upstream to the patient site in order to save resources, time, and lives.

- **Features**: Starts with the patient rather than the institution, empowers primary care, establishes critical access using geographic information systems (GISs), positions POCT, and optimizes decision-making, including unexpected crises.

Reference: Kost GJ, Ferguson WJ, Kost LE. Principles of point of care culture, the spatial care path™, and enabling community and global resilience. e-JIFCC. 2014;25(2):4-23.
Drawing Kalasin and Maha Sarakham Province SWN ambulance routes

Kalasin: above to her right

Maha Sarakham: below to her left

Critical paths (bold) of Kalasin Province SWN extracted from the ER RN’s highlights (orange)

Legend:
- Ambulance transport
- Main road
- Community hospital (CH)
- CH surveyed
- Regional hospital
- Dam and reservoir
- Sawoel Cliff

Map showing routes and distances between different locations in Kalasin Province.
Principles of point of care culture, the spatial care path™, and enabling community and global resilience

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Running title
Enabling Community and Global Resilience

Key words
Care path, customs, decision-making, empowerment, geographic information systems (GIS), geography, intervention, lifestyle, medical poverty, needs assessment, point-of-care (POC) technologies, POC testing, prevention, public health jurisdictions, small-world network, survey, and value

ABSTRACT

Goals: This article a) defines point of care (POC) culture; b) presents seven underlying fundamental principles; c) describes the importance of needs assessment; d) introduces a new innovation, the spatial care path™; and e) illustrates how POC testing that properly fulfills needs and spatial care paths™ enable community and global resilience.

Observations: Often, POC testing supplants the conventional clinical laboratory, which may be too distant, prohibitively expensive, or simply not available in limited-resource settings. New POC technologies “fit” future medical problem solving. Screening and testing directly in the home or primary care facilitate rapid diagnosis, monitoring, and treatment. In contrast to the past where attention has been placed on emergency departments, hospitals, and referral centers, the spatial care path™ starts with the patient and guides him or her through an efficient strategy of care in small-world networks (SWNs) defined by local geography and topology, long-standing customs, public health jurisdictions, and geographic information systems (GIS).

Conclusions: POC testing needs in limited-resource settings are striking. Fulfillment is best guided by thorough understanding of POC culture. Quick feedback and fast decision-making
Transforming the Physical Domain to the Temporal Domain in Small-World Network Spatial Care Paths™

Shortcut to Heart Center if cTn is Elevated

In this study, ~50% reported direct contact. Hence, prevent spread. Early detection can help stop outbreaks!

Reference: Clin Inf Dis 7 Aug 15 DOI: 10.1093/cid/civ568
Stop the spread of disease!

Develop POC strategies and invest in matching POC technologies that will improve community resilience!

Highly contagious

Vulnerable children
The patient obtains his or her own sample with an automatic retractable lancet or simple sampling device.

The device is self-aspirating, self-contained, and built into a microcassette, microcuvette, or cartridge, which then seals for automated processing by the POC instrument.

Another person, the “facilitator,” instructs and guides hands off, so there is extremely limited or no exposure to infectious agents.
Compact disposable POC test

FAST POCT™

Facilitator instructions

Next Step
Insert the FAST strip with your sample into the reagent cassette.
Principles Related to Enhancing Resilience

- International mobility of people distributes responsibility for preparedness to all nations, all of which should invest in POC technologies.

- Public health must focus on early detection of Ebola and other threats before patients spread disease, plus emergency room staff must re-educate, re-tool, and refresh to avoid missing the diagnosis and discharging sick patients.

- Point-of-care testing can help stop outbreaks, and therefore, limit epidemics.
Doctors Without Borders/ Médecins Sans Frontières (MSF) Ebola Clinic

MSF has set up a specialized Ebola clinic in a hospital in Conakry, Guinea. The virus is contagious and so dangerous that patients must be quarantined. Access to the isolation area is thus strictly controlled.

Inside an MSF Ebola treatment centre

1. Low-risk infected
   Patients are kept apart from the high-risk group while they wait for their blood test results.

2. High-risk of infection
   Those showing symptoms are kept apart from zone 1. Sent to zone 3 if they test positive.

3. Infected patients
   There is no cure for Ebola, but good supportive care increases chances of survival.

4. Visiting area
   No direct contact between patients and visitors to eliminate the risk of infection.

Source: Médicins Sans Frontières (Doctors Without Borders)

3-D reconstruction from an MSF graphic

MSF’s largest treatment centre (in Liberia) holds 200 patients
Sad but true in the patient’s view—people avoid what they believe are treatment center “death traps”!
Integration requires national POCT policy and guidelines!

CDC REQUIREMENTS FOR EBOLA CENTERS

- Accept patients within eight hours of being notified,
- Have the capacity to treat at least two Ebola patients at the same time,
- Have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients,
- Conduct quarterly trainings and exercises,
- Receive an annual readiness assessment from the soon-to-be-established National Ebola Training and Education Center, composed of experts from health care facilities that have safely and successfully cared for patients with Ebola in the U.S., and funded by ASPR and the Centers for Disease Control and Prevention, to ensure clinical staff is adequately prepared and trained to safely treat patients with Ebola and other infectious diseases,
- Be able to treat pediatric patients with Ebola or other infectious diseases or partner with a neighboring facility to do so, and,
- Be able to safely handle Ebola-contaminated or other highly contaminated infectious waste.

Does not require POC resources or strategies. 
No harmonized POC testing, molecular diagnostics, or early detection. Neglects integrated community resilience and optimized geospatial care (no SCP).

Source: ASPR Press Office. HHS selects nine regional Ebola and other special pathogen treatment centers. June 12, 2015. HSS.gov or http://www.hhs.gov/news
• **Disaster caches** should be redesigned and **harmonized** for **collaborative use** throughout the world in the event of public health crises, especially highly infectious diseases.

• **Spatial Care Paths™** start with the **patient**, position POCT optimally, and will **accelerate Ebola care**.

• **National POCT policy and guidelines** with appropriate fiscal planning and financial investment in POC testing will **enhance community resilience**.

• **Vision for a New POC Culture!** POC testing absolutely is needed for the detection and care of patients with Ebola, MERS CoV, and other novel threats—what will be next???


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