Restricted and Uncontained: Health Care and Public Health Considerations in the Event of Loss of Containment During the Restricted Earth Return of Extraterrestrial Samples

Abstract
The normal scope of an adequate public health response to released biological material is framed by working with biological vectors with known pathogenicity and virulence. Defining the scope of a response to the release of biological material with unknown pathogenicity and virulence enters into a novel and yet to be framed domain. A current case, the case of returning samples from a location other than Earth, extraterrestrial samples from a location such as Mars, which may harbor life as we know it, requires framing a public health response. An unintentional release of biological material with unknown pathogenicity and virulence may occur when biological containment mechanisms in the Earth-returning transport method are lost. This paper raises initial public health and healthcare response questions during a return of extraterrestrial samples to Earth, in the event of its release from biological containment mechanisms: How does the public health community prepare for a response when there is release of samples that may contain potential extraterrestrial organisms from a planetary body or hardy terrestrial organisms surviving a round trip? If a mishap occurs during the return of these samples, what considerations need to be made to confine, decontaminate, and collect material in regions around the mishap? How will the public health community work with relevant government organizations to prepare the general public? The unknowns of exposure, potential extraterrestrial pathogenicity, and decontamination approaches, underscore gaps in biopreparedness for this novel case from the federal to local levels.

Introduction
The recent explosion in the scientific search for life in our solar system has exposed a novel low-probability, high-consequence avenue for exposure to biological threats—a sample (rock, soil, atmosphere) from another planet or moon in our solar system. The increased interest in

planetary exploration poses unique challenges for biological preparedness and response efforts. To introduce the topic, some background into current NASA policy and requirements is needed.

A NASA-funded spacecraft is currently required to have a method of containment when returning samples from a planetary body that may contain life.[i] In addition to requiring containment, NASA also currently requires that a mission consider the implications of the failure of sample containment.[ii] An example of a source of failure in containment is when an Earth--returning spacecraft has a breach in its containment due to a collision with the Earth's surface as a result of loss of deceleration mechanisms, such that the breach in containment is immediate and complete. For this discussion, a returning spacecraft would be able to maintain control of guidance and navigation, limiting the collision to occur in the intended landing region, a significant distance from a high-containment lab or near a populated area.[iii]

Use of biological containment for the return of extraterrestrial material to Earth is determined based on the possibility of life on the planetary body under investigation. If extraterrestrial material is collected from a solar system body that has been "deemed by scientific opinion to have no indigenous life forms" and returned to Earth, missions are not required to insure containment of samples. This is known as Unrestricted Earth Return. Examples of planetary bodies that have Unrestricted Earth Return include the planet Venus, Earth's Moon, most comets and asteroids.[iv,v] If extraterrestrial material is collected from locations "from solar system bodies that may harbor indigenous life," biological containment is required, as that material that may affect humans or the Earth's environment.[vi] This is known as Restricted Earth Return. Examples of bodies subject to Restricted Earth Return are bodies where there is clear evidence that there are regions containing liquid water and temperatures to support organismal replication: Mars, Europa and Enceladus.

Restricted Earth Return is considered to be a research activity in the U.S. Government that falls under the purview of the Presidential Directive/National Security Council, #25 (PD/NSC-25).[vii] PD/NSC-25 evaluates the potential for large-scale or protracted biological impact of a research activity on the environment[viii]. The National Environmental Protection Act (NEPA) is a process that is defined under 40 CFR Part 1508.18 and is invoked when a federal agency is taking a significant federal action that may have large-scale environmental impact of a biological or radiological nature. In the early stages, there is an assessment of local environmental impacts, including human inhabitants, local wildlife, and associated plant species subject to exposure to an unknown pathogen. A recent example is the Department of Homeland Security's Proposed Tracer Particle and Biological Releases for the Hazards of Dynamic Outdoor Release effort,[ix] which evaluated options for alternative methods and materials for the proposed action of conducting tests that release biological and inert particulate matter in order to simulate the protective factor of buildings in the event of a bioweapon attack using abandoned buildings on the Chilocco campus of the Indian Agricultural School in Oklahoma near a small town (Newkirk, OK; pop 2300). In the context of a Restricted Earth Return, this process would be invoked in the identification of the landing ellipse as well as for the new construction or modification of a facility for sample handling under BSL-4 conditions. Unrestricted Earth Returns do not carry a requirement for any risk analysis for the return of extraterrestrial material, though safety and hazard analyses for the local terrestrial landing environment are conducted. For Restricted Earth Returns, NASA requires an additional specific risk assessment associated with the return of extraterrestrial material, which is documented in the Earth Safety Analysis Plan[x,].

Analysis of Human Safety Hazard Variables for an Unrestricted Earth Return Scenario

For Unrestricted Earth Returns, the risk assessment takes on the form of an analysis of chemical and physical hazards, as the extraterrestrial material is assessed to carry no risk to the terrestrial biosphere. The specific hazards under analysis are the chemical and physical interaction between the spacecraft hardware and the landing site, including humans that interact with it upon its immediate return.

An example of the risk assessment that is conducted for an Unrestricted Earth Return with a mishap consistent with our assumptions is the Genesis mission. The Genesis mission was launched in 2001 to collect materials to investigate the chemical composition of the solar wind. During its return to Earth in 2004, a parachute, which was designed to slow the capsule during its flight through the Earth's atmosphere, did not deploy, [xi] and the capsule collided with the Earth's surface in the intended landing region, the Utah Test and Training Range, an uninhabited desert area. The debris field included fragmented pieces of the spacecraft which spanned a radius of 50 feet from the point of immediate collision, some of which penetrated as deep as 2 feet.[xii] NASA formally defined this event as a "mishap"- an unplanned event resulting in destruction of, or damage to property (NASA property, public or private property, including foreign property), caused by NASA operations or NASA-funded research and development projects[xiii]

After the collision, helicopters were deployed to scout the desert and locate the sample return capsule. Prior to sample recovery, the focus was to assure the explosive and chemical safety of the mishap site to allow the recovery team to enter. Safety was insured by defusing explosive bolts on the capsule and measuring toxic gas exposure levels (heatshield material, used to prevent the sample return capsule from burning up, generates toxic gases).[xiv] Exposure populations were fortunately limited to those arriving at the isolated desert mishap site. To give a

sense of the potential number of participants exposed -six people and three aircraft arrived at the Genesis mishap site to assure safety, a small number.

Analysis of Human Safety Hazard Variables for a Restricted Earth Return Scenario

For Restricted Earth Returns, the Earth Safety Analysis contains a risk assessment of the local chemical and physical hazard risks in the landing area as well as an assessment of the risk of returning extraterrestrial material to the Earth's biosphere. Given the additional component of a potential biological hazard risk, Restricted Earth Returns must also be consistent with NEPA and PD/NSC-25. NASA has published previous efforts to conduct basic analyses, though the consistency with NEPA and PD/NSC-25 have not been defined or formally vetted. As an example in recent history for an analysis of an unknown pathogen with unknown pathogenicity, the risk analyses requested by the U.S. Government's response to loss of containment in Gain-of-Function studies of Avian Influenza H5N1[xv, xvi,xvii] may offer a model for consistency.

Unlike the analyses conducted for H5N1, at the outset, the organization leading the Earth Safety Analysis may also assume responsibility for the handling of an unknown pathogen. This may affect the underlying assumptions that contribute to the overall approach, including any consideration to adhere to the precautionary principle, where steps are taken in handling a sample with unknown pathogenicity, until scientific investigation has been able to assess risk or assumption of the same level of care that exists in Federal Regulations for the handling, transportation, and packaging of select agents[xviii] until biohazard risk analyses and any measurements are completed.[xix]

Fully assessing the biological implications for the terrestrial biosphere may be unknown at the time of arrival and may take days, if not longer, to complete. Main modes for transmission—exposure routes—and their relationship to the landing location will be critical to

understand in order to fully grasp the risk of a loss of containment and methods to decontaminate the return capsule and surrounding areas affected by collision must be considered.

Exposure Routes

The Genesis mission example frames a minimal case for assessing safety hazards of the sample return capsule. Even without a mishap, chemical, physical and explosive hazards arising from the spacecraft and landing site require assessment prior to approaching the spacecraft. Explosive bolts or toxic gases on the spacecraft or pre-existing unexploded ordinance dispersed throughout the UTTR landing site location represented clear chemical, physical and explosive hazards that required protected and verifiable hazard assessments by direct measurement and test. Exposure was limited to the six personnel on site, who wore appropriate Personal Protective Equipment (PPE).

Expanding this to a Restricted Earth Return case expands the potential routes for exposure beyond on site personnel. If a spacecraft experienced a mishap similar to Genesis there may be a potential for dispersion of spacecraft materials and contents at a range comparable to Genesis, (entry velocity 11.04 km/s[xx]) or perhaps even farther, given the potential for higher entry velocities for a Mars sample return (> 11.56 km/s[xxi]). Direct contact and primary inhalation would be the likely immediate exposure routes for personnel on site, followed by secondary aerosolization, which may transfer into the atmosphere of a local inhabited region.

Studies from the U.S. Army in the Utah desert show persistence of *B. atrophaeus* in static release sites for up to 7 days and that re-aerosolization formed a plume that extended nearly 300 meters away from the deposition area.[xxii] The persistence and radius of re-aerosolization suggest mitigations for decontamination to minimize direct contact, inhalation and recontamination hazards for on-site personnel upon immediate arrival to the landing site and in the days that they

continue to work to conduct basic non-biological hazard analyses as well as any on-site hazard analyses. BSL-4 operations, including PPE, in the initial stages hazard analysis at the landing site[xxiii]. BSL-4 suits and hardware would also have to provide for safety from toxic liquids, gases, which may not exist in current commercially available suits.

Secondary aerosolization may expand the sphere of an unknown biological threat depending on a population's proximity to the mishap site and relative weather conditions.[xxiv] Secondary aerosolization of *Bacillus* in the Utah desert from movement of troops or trucks was observed as far as 10 kilometers. While existing models rely upon concentration levels, microbial diversity, and spatiotemporal viability, the exposure routes for a novel biological agent will inherently carry unknowns. Any mobile units pre-staged or carried to the landing site will need to be evaluated for risk of re-aerosolization upon departure, with appropriate decontamination steps taken. In the Apollo era, mobile units, including helicopters, were bagged, sealed, and decontaminated with formaldehyde.[xxv] smaller scale hardware and areas in contact with hardware (walkways and platforms) were decontaminated with bleach.

Conducting a Healthcare Response: Surveillance, Quarantine, and Disinfection

A loss of containment surrounding a Restricted Earth Return is a novel situation for public health and healthcare alike. In fact, an exposure to an unknown pathogen raises questions that are not addressed in existing infectious disease preparedness plans. Such an incident goes beyond dealing with a novel or emerging infectious disease, but rather places hospitals and public health into a situation where basic response and control measures may not be effective and reveals existing gaps in preparedness and response measures.

Normal infectious disease response mechanisms rely on knowledge surrounding incubation, exposure, and disinfection. A novel pathogen from extraterrestrial material is likely to be wholly unique and possibly fall outside of conventional microorganism taxonomy.

Hospitals have existing surveillance protocols within their infection prevention and control programs but will depend upon guidance given from federal agencies.[xxvi] This would include guidance on exposure definitions and infection control, which would include PPE, negative pressure requirements, disinfection/isolation practices, length of isolation). Direct relay of guidance from the Federal level to the local healthcare/hospital level has been utilized in the past for active surveillance during outbreaks, such as imported cases of Ebola during the 2014/2015 West Africa outbreak. The strength of this guidance in the context of surveillance was based upon established pathogen guidelines, which may not exist in a timely fashion for a potential extraterrestrial pathogen. Such information gaps could pose a challenge for willingness to work, as well as compliance to temporary isolation guidelines. If the highest levels of transmission-based precautions are used, hospitals within the exposure range or neighboring facilities should ensure their Airborne Infection Isolation Rooms (AIIR) are operational per CDC and OSHA guidelines.[xxvii]

Infection control practices that are dependent upon established incubation times, transmission, and disinfection methods may require advance development work. Healthcare facilities within the potential exposure range may be a priority region to focus efforts for training and education. Ultimately all hospitals within the United States should partake in surveillance efforts, if there is potential large-scale biological impact.

Until tested for biohazards, the period of quarantine and surveillance may follow the precautionary practice that encompasses the most aggressive of existing strategies, thus including margin for unique replication and dormancy.[xxviii] Apollo 11, 12, and 14 astronauts spent 21 days in quarantine. In parallel, lunar samples, underwent 30-day test periods under containment to look for evidence of replicating microbial life via a range of methods, including tests for viral

replication in vertebrate and invertebrate systems.[xxix] Advances in research since Apollo have uncovered a wealth of dormant species and slow metabolizers, which reveals a wide range for potential incubation periods and challenges older quarantine protocols. For example, prion diseases like Creutzfeldt-Jakob have an incubation period of 11-12 years, thus potential organisms may lie dormant during their return cruise to Earth and remain undetected.[xxx] Medical surveillance of Apollo astronauts continued for one calendar year after leaving quarantine, but response efforts to a larger exposure with novel organisms pose unique challenges for prolonged surveillance/quarantine that may be impractical to implement. It is important to note that the Apollo astronauts had no restriction on travel after release from quarantine. Since the Apollo era, the rise of globalization and increased frequency of airline travel may further influence the development of quarantine and surveillance timelines.

A novel space pathogen also challenges the ability to properly disinfect and sterilize equipment and surfaces in the healthcare environment. Current practices following the Spaulding classification method categorizing instruments and other patient care equipment as critical, semicritical, and noncritical based upon the degree of infection risk involve when the item is used.[xxxi] Will the Spaulding approach to disinfection and sterilization be applicable to critical medical equipment used to care for infected patients in this unique circumstance?[xxxii] The decision should be made as to what biosafety level should be followed for sterilization and disinfection practices. Following BSL-4 laboratory sterilization practices, a bioshield frame will be needed around the autoclave (a hermetic seal around the sterilizing machine that maintains sterility) and a thermal biohazard system to sterilize the air extracted from the autoclave chamber. Beyond sterilizing medical equipment, the environmental contamination of objects and surfaces requires disinfecting guidelines. The ability for existing disinfection practices and

products to be effective is unknown and a considerable knowledge deficit. There are currently known organisms that are environmentally hardy, like *Bacillus anthracis* and *Clostridium difficile* spores, which already challenge existing infection control efforts but could be a starting point for which disinfection and sterilization recommendations to be made for a space pathogen.[xxxiii,xxxiv] This equally applies to disposal of waste when disinfection or sterilization cannot be performed on items associated with extraterrestrial pathogen exposure.

Preparedness of healthcare facilities will be critical for early identification of illness and act as sentinels for disease following exposure to an extraterrestrial pathogen. Current hospital preparedness scenarios rely upon laboratory testing capabilities and medical management. An extraterrestrial pathogen lacks existing diagnostic testing and medical management protocols. Future health emergency response measures may need to incorporate knowledge deficits into plans and exercises and all those involved in responding, including healthcare workers and first responders, will need education and training in advance of the spacecraft's return.

Until guidelines can be established, federal and local response efforts may include preparation for lapses in infection control, worried well, and staff refusal to work. Like the hospital response during SARS-CoV outbreaks and the Texas Ebola virus disease cluster in 2014, protocols and recommendations will evolve with the strength of the correlation between exposure and disease.[xxxv] The relationships among all parties, from federal agencies to local hospitals, will be critical as guidelines and processes are developed in real-time.

Gaps in the Public Health Response

The public health system, ranging from local to national, includes entities that deliver essential public health services within a jurisdiction and respond to a wide range of public health threats.[xxxvi] The core mission of the public health system is to contribute to the health and well-being of the community or state. Such entities support the provisions of Emergency Support

Function-8 (ESF-8 Public Health and Medical Services) and the four Health Care Preparedness and Response Capabilities to support the healthcare delivery response.[xxxvii]

In the event of a breach in containment in a Restricted Earth Return spacecraft, the roles and operational control would likely differ from existing health emergency plans. Typically, local and state public health systems take operational control in most emergencies with external support provided by government agencies (FEMA, CDC), etc.). This event represents a substantial difference, where the federal government would play a larger operational role and level of control. This role change may not only take the form of increased roles by federal agencies in the response to the mishap, but also investigation into the mishap, with states requesting support from the federal entities. State and local response to exposure will likely warrant close collaboration and coordination between healthcare delivery systems and public health agencies. Development of response plans may cross multiple sectors/agencies and in the face of unknown events, require extensive collaboration and coordination.[xxxviii]

From the public health perspective, the response to this novel event may vary considerably based on the capabilities and resources required to detect, contain, and resolve any health threats to communities that may be posed. These include emergency public information, warning and education; enforcement of laws and regulations (quarantine and isolation); information sharing; emergency management; public health surveillance and epidemiology; public health laboratory testing; pharmaceutical and non-pharmaceutical interventions in coordination with healthcare delivery systems and consulting subject matter experts. Given the novelty of such an event and the potential for catastrophic impacts, key federal agencies may lead the response efforts across the different sectors, but the importance of risk communication can not be overstated.[xxxix]

Public communication during such an event is critically important and must be timely, clear, and concise to inform and educate the community, provide situational awareness, inform on any legal authority or enact laws and regulations, and share any actionable items such as preventative behaviors that may limit adverse events. Timely and relevant information will also be critical for the healthcare response measures, both internally (to healthcare workers) and externally (from the hospital to the public).

Summary

The renewed interest in space exploration creates potential for Restricted Earth Returns of extraterrestrial samples that may contain organisms, of which there is no protocol for public health and healthcare response. In the event of an exposure due to a loss of containment in a Restricted Earth Return spacecraft, existing public health and healthcare infection control protocols may be ineffective. The lack of knowledge surrounding extraterrestrial pathogens in regards from everything including disinfection to incubation periods, presents a novel situation that current public health/healthcare emergency preparedness efforts have not yet been developed. The spectrum of biological threats (natural outbreak, intentional attack, and laboratory accident) does not include a novel pathogen of unknown biological makeup. Continuous risk communication, collaboration, and coordination among healthcare delivery systems and public health agencies will be paramount to the response. Such coordination may include preparing providers and facilities mechanisms for identification and management of any public health threats, length of surveillance, infection control measures including appropriate personal protective equipment, educating frontline staff and the community at-large, and overall healthcare system preparedness. From a healthcare perspective, education will need to be provided for frontline staff to ensure patients are appropriately screened and isolated. The unknowns of an extraterrestrial pathogen underscore gaps in biopreparedness from the federal to

local levels. While such an event is low-probability, it also represents a high-consequence biological risk.

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