University of Nebraska Medical Center

GLOBAL CENTER FOR HEALTH SECURITY

Target Product Profile: Enclosure for patient care in transport in isolation

National Infection Control Strengthening Innovation Test Bed

Summary: This Target Product Profile (TPP) was generated at the request of an innovation team seeking to develop an enclosure appropriate for use while transporting a patient required to be placed in care while in isolation. The University of Nebraska Medical Center (UNMC) conducted a virtual exercise as part of Project FirstLine, a U.S. Centers for Disease Prevention and Control initiative. Test bed participants included both members of the standing Innovation Test Bed as well as other health emergency risk management responders from academia, civil society, and government. Both U.S. and persons from other countries participated. Some of the exercise participants have been involved in previous exercises for other infection prevention and control practice use cases. However, many of the participants had not, nor had they received any information on ISTARI. For the purpose of the exercise, instead of any particular device information, participants were provided a functional purpose of the innovation ("Purpose of the Black Box"), previously generated TPP for in and out of hospital patient care enclosures from similar exercises under this initiative, and then asked to discuss potential use cases; opportunities in their scope of practice and case management that might be afforded if using an innovation that meets this purpose; and, potential challenges or considerations in incorporating it into their work, including operational contexts. The innovation design team, CDC Project FirstLine team members, and other observers monitored the discussion separately. Injects were provided into the exercise by moderators with access to both discussions. This document is the product of the exercise participants and moderator. Observers (the innovation team, funding agencies, and other stakeholders) were afforded an opportunity to provide comment in parallel with the peer review process. This document does not necessarily reflect views of any agency.

Purpose of the Black Box: To provide an enclosure where care during transport of a patient suspected or confirmed to have a communicable disease where isolation is required (airborne, droplet, or contact) may be safely and effectively managed with both decreased risk to and less use of personal protective equipment by the healthcare team.

Requirements:

Aspect	Elements

Patient experience	• Suitable for accommodating a patient during staging, transport, and delivery for the travel time anticipated for the use case marketed by a given solution (e.g., 2 hours for close by use within a medical facility or neighboring facility; 8 hours for sub-regional movement; 12-24 hours for regional movement; 24-36 hours for international transport)
	  ○ Conducive to both patient and environmental hygiene
	  ○ Facilitates patient comfort
	  ▪ Supports both partially and fully reclined postures
	  ▪ Air exchange and quality akin to standard conditions in location of use (if not stipulated, in line with targets for accredited U.S. healthcare facilities)

	▪ Allows passage and adjustment of blankets and small items (including food and water) into patient space ○ Provides for safe physical restraint appropriate to the manner of movement, in general for waist, chest, shoulder, thighs, legs that can be cleaned, loosened or tightened, and released without violating isolation and regardless of state of attachment to a vehicle, specific setting and vehicle regulations may exist such as Federal Aviation Administration §135.128 ○ When designed for uses longer than 2 hours, ideally placing the patient in and out of prone position should be possible without breaking isolation • Has an internal mechanism or accommodates other solutions for ○ real-time patient-initiated communication with the healthcare team ○ real-time patient-initiated communication with support systems such as family and friends ○ temporary patient privacy ○ connectivity (internet, news, entertainment, appropriate to the usual level for the setting) • Facilitates detailed discussion between patient and visitors or healthcare workers, including interacting documentation such as informed consent • If a solution is intended for a large conveyance, the design intent regarding number of patients should be disclosed—such as, 1 patient, multiple patients, families
Healthcare worker experience	• Suitable for the management of patients that have or may have an infection from airborne, droplet, and contact transmitted threats • Decreases use of personal protective equipment while both increasing healthcare worker-patient contact time and decreasing lag time to contact • Allows for the rapid removal of a patients in exigent circumstances • Facilitates continuous audio and visual monitoring of and communication with the patient • Allows for the full employment of systems of care for the rating of the conveyance and team (e.g., advanced cardiac life support and a ventilated patient versus basic life support and bridging measures) up to the scope of practice and resources of the setting employing it • When appropriate to the scope of practice, allows for rapid escalation of care (initiation of resuscitation and increase in the applied system of care in a timeframe comparable to usual performance in that conveyance with that team) • Allows for the performance of basic patient and environmental hygiene, movement of limited supplies and equipment into the enclosure, and waste out of the enclosure (including potentially copious biological liquid, and solid waste) • Facilitates usual quality control and assurance practices (e.g., good clinical practice, direct hand-on-line or device nursing turnovers) • Facilitates or allows the usual turnover of medical consumables across the use period (e.g., lines and tubes, conduits)
Environment	• The isolation care enclosure should employ utilities customarily available at the setting of use (e.g., sending and receiving facilities) and in the conveyance (e.g., air and ground ambulances), and account for periods without utilities. The duration of loading, staging, transport, delivery, and exiting from the enclosure must be accounted in the travel time anticipated for the use case marketed by a given solution (e.g., 2 hours for close by use within a medical facility or neighboring facility; 8 hours for sub-regional movement; 12-24 hours for regional movement; 24-36 hours for international transport) • Habitable without utilities support for at least 15 min in order to allow for a deliberate change in setting • Can be fastened to the conveyance without violating isolation, and to a manner necessary for anticipated movement (some settings have specific requirements such as military transport and other aviation movement)

	• Barriers and ventilation perform fully in ambient temperatures ranging from 40 to 120 deg F, and any humidity and pressure usual for the locale
	• Isolation should remain possible at unpressurized altitude of up to 10,000 feet for the duration of transit; and, if used at greater than 10,000 feet, should accommodate patient safety in the event of de-pressurization
	• Intrinsic features, supporting assembly/ build instructions, and/ or accessory options in addition to preparation and maintenance procedures which address conditions where patients and healthcare workers must engage the enclosure and its equipment (e.g., beds) at a location in
	  ○ Direct sunlight
	  ○ Temperatures above ambient temperature in open air shade for hot environments
	  ○ Temperatures below 60 degF in cold environments
	  ○ Uneven, soft, and/ or wet ground
	  ○ Dusty or heavy rainfall environments (that also may have implications for intake air filters and adhesives/ zippers)
	• Has a shelf-life of 5 years; maintenance intervals for longer storage, after use in training, varying temperature and humidity settings, and resulting shelf-life changes should be fully delineated; if shelf life differs for different components that are amenable to maintenance or replacement, that, too, should be delineated
	• Facilitates unidirectional flow of waste and handling of other material which subsequently must undergo decontamination with or without intermediate storage
	• Space requirements or necessary footprint to employ the enclosure should be disclosed, and account for the need for healthcare teams to interact with an occupied enclosure. This includes clear labeling of dimensions in all configurations of employment, and disclosure of specific vehicles and airframes where the device employment has been assessed with those results.

Additional considerations	• Products should be accompanied by a manufacturer's compliance table delineating those aspects of this or derivative (more specific) target product profiles with which the product has been assessed, how, and the results • Non-strenuous receipt, storage, and set-up must be possible by 2 or fewer able persons (e.g., ideally should not weigh more than 40 kg), once familiarization training has been completed • The intended period of use when employed should be disclosed (e.g., isolation care of a patient or patients for a certain number of hours under various conditions) • Situations where duplicate equipment/ redundancy are required should be accounted in the design and disclosures; for instance, some jurisdictions require redundancy for life saving equipment • Individuals should be capable of setting up the enclosure for full use within 15 min, once familiarization training has been completed • Transport to a location of need should be able to be accomplished routinely by the conveyances for which it is designed to be employed • Cost should be appropriate to either a validated ability to re-use all or part of the enclosure or the need to replace the enclosure following each use; this may differ when the enclosure has been used by suspected but later confirmed negative (not infected) patients. A cost-price narrative should be provided that demonstrates the anticipated total landed cost of each complete deployment iteration in both a "contaminated" and "uncontaminated" scenario (e.g., awaiting use in suspect case scenarios). The total landed cost should be comprised of the following elements: set-up, employment, break-down, and replacement costs to return to original functionality, if re-use is anticipated • Consumable elements must be conducive to full destruction/ disposal in the field, ideally with degradable materials

	• Supply chain resiliency should be considered when selecting both durable component and potentially high failure rate parts including consideration for commonly on hand items, as well as readily available solutions to replacement or repair of consumable parts, when feasible • Accommodates hands-on training either through low cost or the ability to set up, train, and stow every 2-3 months prior to use with a confirmed communicable disease patient appropriate for isolation care • Considerations for familiarization and training that do not consume the product, reference operating procedures, as well as transparency regarding performance changes and assumptions in different operating conditions should be part of the packaging and distribution plan • Language agnostic visual cues for set up and use should be employed wherever practicable • Certain users may also seek solutions for non-individual patient enclosures or arrays of enclosures, that is cohorting of patients in a single space, either fully enclosed or through the use of adaptive room/ space partition solutions • For specific use cases, enclosure solutions may be designed to be compatible with particular personal protective equipment or unique laboratory capabilities, as well as enclosures at sending and receiving facilities; however, interoperability is a desired feature

Notes: Patient use cases discussed ranged from cosmopolitan (*C. difficile* colitis, *Norovirus*, tuberculosis, multi-drug resistant bacteria, etc.) to high consequence threats (SARS-CoV-2, *Y. pestis*, *Ebolavirus,* etc.).

Any design and build, validation, training should specifically account for transport process steps, and be matched with instructions and operating limits readily accessible to users. A template of process steps with representative considerations is provided in the following table. Please see the note below this table.

Step in process	**Considerations: Ground transport**	**Considerations: Air transport** (**all** ground transport considerations **AND** …)
Move enclosure into/ out of sending facility	Assessing corridors, steps, elevators, doorways, ramps—does the device fit and can it be passaged stably? Other ground traffic and pedestrians	Entry and turning enclosures as necessary for securing for use in an aircraft has limited space and angle breadth. Airstrip safety, foreign object and engine clearance, additional runway traffic
Place patient in enclosure	Whether the receiving vehicle(s) is (are) known and compatibility between the enclosure and both those transport mechanisms and their clinical support systems verified, to include specialized receiving facility systems; if specialized training is required to operate the enclosure with a patient, that such personnel are available and participating in patient care and movement through the entire process, and if not, whether patient transition planning has occurred; patient safety and comfort in movement from current location into the enclosure; body habitus; positioning relevant to space restrictions of vehicle (e.g. small vehicle versus a full-sized advanced care ambulance); in enclosure safety, comfort, and care adjustments that may not be possible to address once isolation	Additional positioning requirements for space (e.g., light lift helicopter versus a multi-engine passenger aircraft) to include ensuring that attachment points or devices to the airframe are unencumbered; additional physical restraint requirements; potential changes to ventilation or other support systems based upon atmospherics

	is established; vehicle entry access (space and manner)	
Conduct immediate healthcare interventions outside vehicle	Weighing anticipated transit time with scope of care to determine aggressiveness of procedures	Interventions to pre-empt escalation or other potential need to breach isolation in air, or that may be preferred to conduct with more people available
Move enclosure into vehicle	Space and safe movement constraints, especially measures required to avoid falls; adjustment to configuration or performance (e.g., ventilation motor settings); consequences of movement to clinical care equipment (e.g., infusion pump or ventilator outside of enclosure); transition of supporting services (e.g., power supply, oxygen); rehearsal to minimize time disconnected from appropriate support systems	Engine status during approach and entry (e.g., whether engine can be shut down or rotor disengaged); ramp/ step safety; need for specific equipment (e.g., K-loader)
Secure enclosure into vehicle	Access to enclosure and patient when secured in vehicle; resulting trip hazards; consequences of placement that cannot subsequently be remedied (e.g., supporting services, clinical equipment, patient orientation relevant to need to provide care such as reaching a line, tube, or wound)	Flight-specific regulatory requirements
Continue healthcare interventions in the vehicle	Supplies status and necessary equipment, e.g. transport vents, oxygen, with appropriate power supply while maintaining access to the patient	Clinical equipment and utilities needs' compatibility with airframe restrictions; whether current placement of lines and tubes is compatible with the spatial change from ground vehicle to airframe
Transport enclosure in vehicle	Speed and terrain elections relevant to safety attachments, patient safety and comfort, healthcare worker safety and effectiveness	Flight path elections relevant to storm/ turbulence avoidance, altitude and pressurization capabilities
Remove enclosure from vehicle	Space and safe movement constraints, especially measures required to avoid falls; adjustment to configuration or performance (e.g., ventilation motor settings); consequences of movement to clinical care equipment (e.g., infusion pump or ventilator outside of enclosure); transition of supporting services (e.g., power supply, oxygen); rehearsal to minimize time disconnected from appropriate support systems	Engine status during approach and entry (e.g., whether engine can be shut down or rotor disengaged); ramp/ step safety; need for specific equipment (e.g., K-loader)
Move enclosure to next location/ vehicle (repeat)	Revisit process steps to this point	Revisit process steps to this point
Move enclosure into/ out of receiving facility	Assessing corridors, steps, elevators, doorways, ramps—does the device fit and can it be passaged stably? Other ground traffic and pedestrians; rehearsal to minimize time disconnected from appropriate support systems	Airstrip safety, foreign object and engine clearance, additional runway traffic
Transfer patient from enclosure to bed/ chair/ room at receiving facility	Rehearsal for patient care continuity and safety in transfer, and maintenance of isolation	
Recycle enclosure (or part of) for use	Identification of appropriate staging area for recycle steps, if appropriate—value in minimizing number of locations so ideally capture of components to recycle should be able to occur without specialized equipment at the location of	

	either patient removal or disposal; if moving enclosure to a staging area, re-establishing isolation safely to include mindfulness of positive pressure generated when collapsing enclosure and conduct of exterior decontamination prior to movement	
Dispose of enclosure (or part of)	Inventory of parts appropriate for selection of disposal method (referral for commercial destruction, autoclave, incineration, other); order of operations of disassembly, as appropriate; coordinated staff infection prevention and control posture with each phase of disposal; international norms, nation and local level requirements for waste handling and disposal	
Other considerations/ steps	Configure the enclosure to optimize visibility in and out, access to the patient, and communication between patient and transport/ care teams; safety and quality assurance; verification of enclosure and supporting equipment lifecycle management; transport operations-coordination with health and emergency risk management authorities, as appropriate, to include breach reporting and potential listing as contacts	

Notes: Each process step must anchor on safe and effective care for both patient and care team, considering patient clinical needs coupled with continuous isolation. **Sea (or other water) conveyance** not specifically described in table. While most considerations are those of ground + air movement, additional hazards exist regarding safe transit from dock to vessel, negotiation of vessel hatches, corridors, and spaces, and rigging for sea and shielding from elements regardless of vessel size. This emphasizes the importance of pre-movement and just-in-time (immediately prior to executing each transport process step) rehearsal regardless of which conveyance(s) is(are) employed.

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