

Target Product Profile: Just-in-time isolation care enclosure
(outside of a healthcare facility)
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 isolation care enclosure appropriate to field use. 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 academic, civil society, and government. Both U.S. and persons from other countries participated. Some of the exercise participants have been involved in a previous event for a healthcare facility-based version triggered by development of ISTARI. 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”), 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. 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 moderators, and does not necessarily reflect views of any agency.

Purpose of the Black Box: To provide an enclosure (appropriate for use outside of a healthcare facility) where care for 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	<ul style="list-style-type: none"> • Suitable for at least 72-hours of isolation care in order to case management until presence of the communicable disease is confirmed, or until the patient is collected for transport to a higher echelon of care; solutions may seek to enable care through an acute illness or convalescence during continued communicability <ul style="list-style-type: none"> ○ Conducive to both patient and environmental hygiene ○ Facilitates patient comfort <ul style="list-style-type: none"> ▪ Supports fully reclined, fully seated, and fully standing patient positions each for extended periods of time ▪ Supports at least a few steps of ambulation, pacing ▪ 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) • Has an internal mechanism or accommodates other solutions for <ul style="list-style-type: none"> ○ real-time patient-initiated communication with the healthcare team

	<ul style="list-style-type: none"> ○ 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) ● Allows for in-person visitation and facilitates detailed discussion between patient and visitors or healthcare workers ● The design intent regarding number of patients should be disclosed—such as, 1 patient, multiple patients, families
Healthcare worker experience	<ul style="list-style-type: none"> ● 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 entry and exit of patients and staff (if that is intended) in a way that adheres to the required isolation level and respects decontamination and doffing requirements; this includes any necessary patient transport into and out of the enclosure ● Facilitates continuous audio and visual monitoring of and communication with the patient ● Allows for the full employment of advanced systems of critical care in case management (e.g., mechanical ventilation, advanced vascular access such as renal replacement therapy and ECMO, procedural intervention including obstetrics) up to the scope of practice and resources of the setting employing it ● Allows for rapid escalation of care (initiation of resuscitation and increase in the applied system of care in a timeframe comparable to that facility's usual performance) ● Allows for the performance of patient and environmental hygiene, movement of 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	<ul style="list-style-type: none"> ● The isolation care enclosure should employ utilities customarily available at the setting of use (e.g., in the U.S. 120V at 60Hz, low pressure potable water), preferably at a power load suitable for field solutions such as combinations of small generators, packable solar kits, and batteries. The power and other utilities requirements of medical equipment relevant to the level of care anticipated (e.g., ventilation, pumps, laboratory equipment, additional lighting) should be considered in planning tandem requirements and interfaces ● Habitable without utilities support for at least 30 min in order to allow for a deliberate change in setting ● Barriers and ventilation perform fully in ambient temperatures ranging from 40 to 120 deg F, and any humidity and pressure usual for the locale ● 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 <ul style="list-style-type: none"> ○ 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)

	<ul style="list-style-type: none"> • Has a shelf-life of at least 1 year in dry storage at 50 to 85 deg F; without maintenance requirements while in storage • Can be employed singly or in an array when multiple patient management must be considered • 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
Additional considerations	<ul style="list-style-type: none"> • Non-strenuous receipt, storage, and set-up must be possible by 4 or fewer able persons (e.g., ideally should not weigh more than 70 kg) • The exercise team recognized the range of use cases from transient holding with initial resuscitative measures prior to evacuation to longer term management. Consequently, the intended period of use when employed should be disclosed (e.g., isolation care of a patient or patients for a certain number of days under various conditions) • Trained individuals should be capable of setting up the enclosure for full use within 30 min • Transport to a location of need should be able to be accomplished with a pick-up truck size vehicle, though ideally a personal sized vehicle • 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, 1-week operations (recurring or average), 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 durable component 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 • The exercise team recognized the varied definitions of "field" among stakeholders—e.g., outside versus in a warehouse or parking structure versus in a co-opted or erected structure now acting as a healthcare facility • For specific use cases, solutions may be designed to be compatible with particular personal protective equipment or unique laboratory capabilities; however, interoperability is a desired feature

For questions on this document, contact Professor David Brett-Major (UNMC; david.brettmajor@unmc.edu).

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