Target Product Profile: Just-in-time isolation care enclosure
(healthcare setting/ healthcare facility)
National Infection Control Strengthening Innovation Test Bed

Summary: This Target Product Profile (TPP) was generated as part of an intake exercise for an infection prevention and control innovation, iSTARI (version for a healthcare setting/ healthcare facility, i.e., not necessarily for a field setting), hosted by the University of Nebraska Medical Center (UNMC) as part of Project FirstLine, a U.S. Centers for Disease Prevention and Control initiative. Test bed participants included healthcare workers from UNMC, the University of Washington, and two critical access hospitals in Nebraska, Columbus Hospital and Morrill Hospital. Exercise participants were not provided specific information on iSTARI, though some individuals were familiar with the device. Instead, they were given 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. In addition to providing immediate feedback to the innovation team and other stakeholders, it informs approaches to subsequent proof of concept and validation exercises within the Innovation Test Bed.

Purpose of the Black Box: To provide an enclosure 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	• Suitable for at least 72-hours of isolation care in order to accommodate confirmation of a condition or transport to a higher echelon of care
	  ○ Conducive to patient and environmental hygiene
	  ○ 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
	  ○ Climate control and air exchange 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
	  ○ 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) • Allows for in-person visitation
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 entry and exit of patients (and staff if that is intended) in a way that adheres to the required isolation level • Facilitates continuous audio and visual monitoring of the patient • Allows for the full employment of advanced systems of critical care in case management (e.g., mechanical ventilation, renal replacement, ECMO) up to the scope of practice 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	• Employs utilities customarily available at the setting of use (e.g., in the U.S. 120V at 60Hz, low pressure potable water) • Habitable without utilities support for at least 30 min in order to allow for a deliberate change in setting • Performs fully and may be stored long term in ambient temperatures of 50 to 85 deg F, and any humidity and pressure usual for the locale • Performs fully in a single patient space (e.g., as small as or smaller than a single U.S. emergency department bay)
Additional considerations	• Non-strenuous receipt, storage, and set-up must be possible by 4 or fewer able persons • Trained individuals should be capable of setting up the enclosure for full use within 30 min • Ideally, storage will be possible within the healthcare facility (e.g., packaged, the enclosure should be easy to place within a closet or clinical storage room), and transport between facilities possible with personal sized vehicle • Cost should be appropriate to either a validated ability to re-use 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 • 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 in different operating conditions should be part of the packaging and distribution plan

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