Minimum product requirements for fit-for-purpose sample transportation packaging

Background

To enable equitable access to diagnostic services in low- and middle-income (LMIC) settings, a packaging solution is required for transporting patient specimens from remote locations to testing facilities that are often located at higher-level facilities in larger towns and cities. Protecting the safety of the carrier and the general public as well as maintaining the integrity of the specimens during the transportation process are key challenges. International regulations have been developed by organizations such as the International Air Transport Association (IATA)[1] and the United Nations, in particular the World Health Organization (WHO),[2] and have been adopted by many countries and logistics companies. Sample transport regulations specify that prior to transportation, all potentially biohazardous material require **triple packaging**, including a **primary receptacle** (specimen container), **secondary packaging** and **outer packaging**. However, a lack of availability of fit-for-purpose packaging results in use of improvised containers which are unsafe and compromise sample integrity. There is no comprehensive packaging supplier list that complies with regulations, although there are commercially available products. The outer and secondary packaging is usually not fit-for-purpose, is costly, non-environmentally friendly, and poses supply chain and disposal challenges. Investment in this area is limited, resulting in poor incentives to find a solution. As a result, FIND seeks to drive innovation and development of a fit-for-purpose sample transportation packaging solution that will be made freely available for local manufacture in LMICs.

Situation/context

Based on field experience in many countries across Africa and Asia, proper packaging for specimen transport is a significant challenge both due to limitations in training as well as availability of supplies. There have been efforts to train various cadres of staff including clinicians, phlebotomists, laboratorians and couriers in packaging and biosafety/biosecurity and there have been resources set aside for procurement of packaging, but the budgets are mainly organized around the primary receptacle. The secondary and outer packaging tend to be the most difficult layers to source and therefore tend to be the layers that are improvised. It is not uncommon to see readily available supplies, such as gloves and recycled reagent (cardboard) boxes used as the secondary and tertiary packaging, respectively. Using materials that are on hand in the health facility is laudable but minimum requirements to ensure safety and specimen integrity cannot be overlooked.

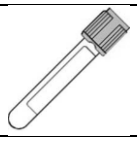
In some countries, the laboratory will use vaccine carriers or cold boxes from the immunization programme, but the challenge of reverse supply chain to return the boxes back to the facilities is sizeable, especially considering that there can be thousands of specimen collection points referring to a number of laboratories at various tiers within the health system. Availability of the secondary packaging can also be difficult due to supply chain bottlenecks, in part linked again to the thousands of re-supply points. Even if the secondary packaging is available, as it is only used once and then discarded, there is a considerable amount of waste generated, often in the form of single-use plastics.

There are many different shapes, sizes and volumes of primary receptacles used. Examples of the most common containers in the settings that this competition is focused on are listed in the table below,

[1] https://www.sujb.cz/fileadmin/sujb/docs/zakaz-zbrani/Infectious-Substances-Shipping-Guidelines.pdf
[2] http://www.un3373.com/info/regulations/

although even the primary receptacles listed are not standardized across countries and, as such, volume/sizes will vary.

Table 1: Examples of common primary receptacles

Disease relevance	Primary receptacle (material)	Pictorial example	Volume/size	Packaging requirements
TB	Falcon tube (plastic)		30x115 mm cylinder, 50 mL capacity	Potentially biohazardous, triple-packaging required
	Wide-mouthed jar with screw top (plastic)		Wide mouth at least 45mm in diameter, 50 mL minimum	Potentially biohazardous, triple-packaging required
HIV	Dried blood spot card (filter paper)		100–110x75 mm rectangle	Comes with own packaging materials and can be transported with other paper documents
	Blood-collection tube (plastic)		13x75 mm cylinder	Potentially biohazardous, triple-packaging required

After the specimens are collected in these primary receptacles, they are then placed in secondary packaging and although absorbent material is required (enough to absorb the full liquid contents if a spill were to occur), it is often missing. Depending on the specimen type, there also may be an ice pack included with the secondary packaging, all placed inside of the outer packaging, although not all specimens need to be/should be kept on ice. There are also paper documents that accompany the specimens, which at times go missing. These documents (test requisition forms, packing lists, etc.) should be kept separate from the secondary packaging (not inside of it) but ideally be somehow attached to the outer packaging so the documents are not lost.

Once the packages are prepared for shipment, the most common forms of transportation are motorcycles and public transport and the shipment may or may not be accompanied by a person carrier who could be a professional courier or a staff member from the referring facility. Therefore, packaging cannot be too bulky or heavy to carry by hand/back or affix to the back of a motorcycle.

Scope of this design competition

This competition will focus on specific pieces of the specimen referral packaging only:

- Secondary packaging
- Outer packaging (including a place for documents to be attached)

Each submission is required to create a design for **both of these packaging layers**. Absorbent materials and any layer beyond the outer packaging are not necessary to design but may be submitted. Primary receptacle designs are *not within scope* of this design competition.

Technical specifications

WHO and IATA regulations drive technical packaging requirements for specimen transport and for this competition, we have listed the relevant current triple-packaging requirements from the **2007 to 2008 WHO Guidance on Regulations for the Transport of Infectious Substances.**[3] In addition, there are other practical and desirable considerations on which this competition will be judged. Listed in the tables below are "Required" and "Desired" criteria for design. The tables are broken up by secondary (Table 2) and outer packaging (Table 3).

Table 2: Secondary packaging

Characteristic	Required	Desired	Explanations/limitations
Intended use			
Product to be designed	A second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s)		
Target user	Design to be developed with end-users in mind – health workers, couriers		
Setting (lowest level of implementation in the healthcare system)	Primary health facilities		Facilities are often in rural or difficult-to-access settings
Target specimen type	TB sputum specimens	Range of different types of specimens	
Operational characteristics			
Size/weight/volume	Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage.	Packaging materials should accommodate a range of different types of primary receptacles.	The most common types of primary receptacles are listed in Table 1
Shape	None		At the discretion of the designer provided other requirements are met
Biosafety	Primary receptacles and secondary packaging containing infectious substances shall not be consolidated with primary receptacles and secondary		This means that documents, for example, cannot be placed within the secondary packaging along with the primary receptacles

[3] http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2cc.pdf

	packaging containing unrelated types of goods		
Materials	Materials should be sustainably sourced and environmentally friendly.		
Training	Minimal training should be required to use		
Production and supply chain			
Production	Local production of design must be possible	Ease of producing locally with minimal investment and readily available materials	
Supply chain	None	Ease of supply chain, such as bundling all of the packaging materials necessary together	
Pricing			
Cost		If secondary packaging is one-time use, cost should be less than $1 per package	Estimated cost of the product will be very important to consider in design

Outer packaging:

Characteristic	Required	Desired	Explanations/limitations
Intended use			
Product to be designed	Outer packaging protects its contents from outside influences, such as physical damage, while in transit	Required documents should be attached to the outer packaging so they are not lost	Secondary packaging(s) are placed in outer packaging with suitable cushioning material.
Target user	Design to be developed with end-users in mind – health workers, couriers		Consider what other items these people might also carry with them
Setting (lowest level of implementation in the healthcare system)	Primary health facilities		Facilities are often in rural or difficult-to-access settings
Target specimen type	TB sputum specimens	Range of different types of specimens	
Operational characteristics			
Size/weight/volume	For surface transport there is no maximum quantity of primary receptacles to be carried per package Volume of the outer packaging should be at	Weight/size of the outer packaging and total contents should be easy to carry by hand/back or affix to the back of a motorcycle	Assume secondary packaging and primary receptacle weight is not significant in comparison with the tertiary packaging

	least 9L. If the volume of specimens that need to be transported exceeds this volume, more than one outer package could be used		
Shape	None		At the discretion of the designer provided other requirements are met
Orientation of specimens/secondary packaging	Any primary receptacle with a capacity of more than 50 mL shall be oriented in the outer packaging so that the closures are upwards. Orientation labels ("UP" arrows[4]) shall be affixed to two opposite sides of the outer packaging	A mechanism is incorporated to reduce shaking and vibration of specimens	Racking inside the outer packaging may be incorporated but is not required.
Biosafety	Outer packaging should have a biohazard label[5] in the form of a square set at an angle of 45° (diamond-shaped) when there are potentially biohazardous specimens inside		
Temperature during transport	Outer box should be somewhat insulated (ideally to maintain temperature for 4–8 hours) and have the ability to hold an ice pack, if necessary		Most specimens need to be kept at refrigerated (2–8°C) or ambient (20–25°C) temperatures. If the air temperature outside is much hotter or colder, insulation will be required or an ice pack should be put within the outer packaging
Materials	Outer packaging may or may not be reusable. Reusable packaging must be able to be disinfected between usages. Materials should be		

[4] https://www.iata.org/SiteCollectionImages/Images/smBlackArrows.gif (example only, not necessary to purchase)

[5] https://www.iata.org/SiteCollectionImages/Images/smN024Class6InfectiousSubstance62.gif (example only, not necessary to purchase)

	sustainably sourced and environmentally friendly.		
Labelling	Outer packaging should have space for identifying information that is clearly visible and not covered by any other label or marking		Identifying information includes: contents of the package, the nature of the hazard, and the packaging standards applied
Training	Minimal training should be required to use		
Production and supply chain			
Production	Local production of design must be possible	Ease of producing locally with minimal investment and readily-available materials. Proposals may consider re-purposing of materials provided the minimum requirements are fulfilled	
Supply chain	None	Ease of supply chain, such as bundling all of the packaging materials necessary together or flat-packed materials	
Pricing			
Cost	None	As a guide, a reusable outer box should be less than $5. A disposable solution should be <$1.	Cost of the product will be very important to consider in design