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Possible care protocols for patients undergoing road transfer on a biocontainment stretcher model N 36 (36 m$^3$ air $>$ 60 ACH)

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Abstract
The practice of transporting a patient affected by a Highly Transmissible Disease (HTD) with a high risk of fatal evolution using biocontainment isolators requires careful planning and preparation. To date, there is only limited literature regarding aeromedical transport, most of which is military-derived, and it does not address patient transfer by road vehicles. To standardize these practices, or at least some of their most critical aspects, we tried to schematize a few of the improvements each author implemented during their practices as a scaffold, which could eventually be based on operative.
protocols. In particular, we focused on the series of actions that needed to be performed and planned to guarantee the safety of both the patient and operators during the entire duration of the operations.

Introduction

At the time of our writing, we all live in a very different world than just a few years ago. The COVID-19 pandemic has led the entire medical community to the edge of collapse, exposing structural and personnel deficiencies. The need to transport patients affected by a Highly Transmissible Disease (HTD), who pose a serious threat to those who stood in their immediate surroundings and who also needed intensive measures to be kept alive, grudgingly found the extensive daily application of devices that, before 2019, served a very restricted population of people.

Biocontainment Isolators (BCIs) are particular transport devices intended for isolating a patient with HTD, or supposedly so, from the external environment. Physical isolation is achieved using three layers of security: i) a specifically designed plastic housing the patient is enclosed within, ii) a High-Efficiency Particulate Air (HEPA) filter and iii) a blower motor, which creates a sufficient pressure gradient adequate to guarantee a dynamic airflow barrier.

Whenever dealing with the transportation of a patient suspected of being affected by an HTD, the use of BCIs is mandatory, especially if burdened by a biological agent with high mortality risk or effective treatment or preventive measures are not usually available. According to the World Health Organization (WHO) biosafety classification the agents responsible for such conditions are included in class IV (classes I-III referring to agents of minor clinical and epidemiological impact), serving a high individual and community risk. A few examples of such agents include the Filoviridae family and the Arenaviridae (including Rift Valley Fever Virus and Crimean Congo Fever Virus) and, theoretically, the Smallpox virus and their derivates (smallpox virus infection was officially declared extinct in 1979 thanks to extensive vaccination and other preventive methods). Also, other zoonotic viral agents including Nipah virus, Hendra virus, and Hantavirus, could enter this risk class.
All these pathologies involve human-to-human transmission, with varying degrees of potential harm, through contact with the patient's body fluids. The physical barrier constituted by the isolator represents the most effective protection when associated with Personal Protective Equipment (PPE) for the surroundings and, obviously, for the personnel. Although airborne transmission cannot be completely excluded, it can be effectively prevented by using BCIs and PPE.

In hemorrhagic fevers, the event that gives the syndrome its name is often a terminal manifestation, which generally occurs after days of illness. The onset of these manifestations is usually non-specific and similar to many other viruses, including fever, headache, and arthromyalgia, when the transmission by contact can already occur. When respiratory distress does occur, it usually happens later.

Even though the patient must be provided the best medical care and logistical support available, including intensive care if required, biocontainment and the safety of involved personnel are the priorities.

**Patient complexity**

To better understand the complexity of the operations, we tried to examine and schematize a few of the more crucial aspects involved.

The patient’s ability to walk: i) W1 is an independent patient; ii) W2 is a patient who is unable to walk independently; iii) W3 is a patient who cannot walk independently and needs advanced care.

Transfer distance is a crucial topic that influences several important choices regarding the preparation of patients involved: i) short range: transfers within the same hospital; ii) medium range: transfers between hospitals with travel times of less than an hour; iii) long range: transfers lasting more than an hour.

Monitoring or supporting equipment needed.

From the synthesis of these parameters one can derive the general complexity of the transfer, categorized as follows: i) low complexity (C1), transports of W1 patients without the need for life
support; ii) intermediate complexity (C2), transports of monitored patients with sub-intensive care measures (*i.e.* Non-Invasive Ventilation, NIV; High-Flow Nasal Cannula, HFNC; infusion pumps); iii) high complexity (C3), transport of patients in critical conditions who require multiple life supports and continuous and invasive monitoring.

**Used materials and cases**

The team involved carried out some tests conducted with a Gaumard HAL S5301 simulation dummy in a biocontainment stretcher, IsoArk N 36 (Beth-El Ind. Ltd., Zikhron Yaaqov, Israel), while equipped with full PPE garments and simulated different real-life scenarios during a live experiment held at Simula Hub (Parma, Italy) supported by highly realistic advanced technologies.

The actions and procedures here proposed for a bioisolated patient are based on two simulated cases with different complexity: i) Case 1, low complexity (C1); ii) Case 2, high complexity (C3);

For each case, the team carried out a complete scenario of a road transfer on a biocontainment chamber, from the patient's bed to the final destination point, including the patient's preparation and positioning maneuvers inside the isolator.

Both cases simulated patients with Ebola Virus Disease (EDV), the C1 case being paucisymptomatic.

The findings reported below synthesize a few recommendations (Supplementary Materials, Table 1) that we consider appropriate for the scope of this paper.

The two scenarios simulate two different patients: i) a C1 case involving a patient showing early signs and symptoms of a hemorrhagic fever syndrome (hyperthermia, lightly altered hemodynamics); ii) a C3 case involving a patient suspected to suffer from the same syndrome but in an advanced and evolving presentation.

**Discussion**

Aside from the complexity of the case here follows a short list of minimum equipment you should consider and predispose for the transport: i) oxygen, portable and fixed cylinders; ii) multi-parameter
monitor (Saturation of Peripheral Oxygen, \(\text{SpO}_2\); Electrocardiogram, ECG; Non-Invasive Blood Pressure, NIBP; Respiratory Rate, RR; End Tidal CO\(_2\), EtCO\(_2\)) with integrated defibrillator (AED); iii) electric or pneumatic ventilator (if necessary); iv) infusion pumps (if necessary); v) fixed and portable aspirator; vi) the isolator (>100 ACH).

In the two cases simulated cases (Table 1), the vital parameters were defined as a variable interval during the transfer, and conditions not reported were not subject to evaluation.

The success of a road transfer on a BCI depends on meticulous planning of all aspects and possibilities,\(^6,10\) relying on flexible execution and conclusion phases. Coordination between the sending structure, the transfer team, and the destination structure is essential.\(^{11}\)

The preparation of the ambulance or vehicle used is fundamental and goes strictly along with the correct preparation of the patient, especially in those cases in which the patient needs some support for vital functions. The availability and proper positioning of medical equipment will avoid interference with the operations during all phases of the road transfer.

If the patient is conscious, his psychological preparation is of particular importance. This includes explaining where and how they will be transported and what the transfer phases will be.

Explaining to the patient what is about to happen and what could be expected during medical procedures and transfers is proven to reduce periprocedural patient stress.\(^{12-14}\)

Preventive sedation should be considered for long-range transfers and for patients with anxious traits.\(^{10,15}\)

Given the peculiarities and risks of biocontainment transport, it is advisable to plan and act by overestimating the situation. If a patient is at risk for rapid clinical progression, it is advisable to stabilize their vital functions (monitoring, airway stabilization, vascular access, defibrillation pads) beforehand, since maneuvers on a patient inside a BCI are complicated and at high risk for complications.\(^{11,16}\)

After many tests on the previously listed simulated table, we created a scheme (Table 2) of basic procedures to consider when planning operations.
Further studies are necessary to the limits of this paper are related to the cases tested that cannot be considered as a model to create a procedure, but can provide a first point to open the discussion about the aim of this paper.

It is important to note that different BCIs may have different characteristics, and practical adjustments may be required to be planned (i.e. impossibility of placing an axillary or IJ-inserted central catheter because of securing straps).

Based on the specific needs, we suggest that anyone involved in a biocontainment transport should create beforehand a short list of equipment that may need to be placed inside the isolator, as transferring objects into it during the transfer phase may be difficult or even risky.\cite{10,17}

Here is a short example list of equipment that could be put into the BCI in case of need: i) Laryngeal Mask Airways (LMA) devices in proper sizes; ii) Artificial Manual Breathing Unit (AMBU) bag with a reservoir; iii) oropharyngeal/nasopharyngeal airways; iv) at least 2,5/5/10 ml Luer-lock syringes; v) pulse oximeter; vi) medical tape; vii) catheter mount and proper filters; viii) IV extension tubing.

**Conclusions**

The success of a road transfer of an HTD patient depends on interconnected factors requiring proper planning,\cite{6,10} and an attitude prone to overestimate any problem that may arise is recommended, as is never ignoring: careful preparation of the ambulance or vehicle, team training,\cite{7} the complexity of the situation and the patient, and full knowledge of what maneuvers are possible and what needs to be avoided.\cite{17}

Since more studies are needed, the actions proposed are meant to support what can be considered a new area of scientific interest within epidemiological emergencies, which needs to define new ways of carrying out life-saving maneuvers on critical and non-critical patients during road transfer in a biocontainment isolator.

The availability of standardized and internationally validated protocols and procedures might help in forging a new set of skills into today’s and tomorrow’s professionals, implementing patient and
community safety.

References


Table 1. Case parameters.

<table>
<thead>
<tr>
<th>Case name</th>
<th>Case 1</th>
<th>Case 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complexity</td>
<td>Low (C1)</td>
<td>High (C3)</td>
</tr>
<tr>
<td>Walking ability</td>
<td>Autonomous (W1)</td>
<td>Non-deambulatory (W3)</td>
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<tr>
<td><strong>Vital parameters</strong></td>
<td>HR (80-100) sinus, SpO₂ (97%-98% in FiO₂ 0.21), Body temp. 38°C, RR (12-16 breaths/min), BP 120/60 mmHg</td>
<td>HR (100-120 sinus), SpO₂ (97%-98% in FiO₂ 0.5), Body temp. 38.5°C, RR (12-14 breaths/min), BP 100/60 mmHg</td>
</tr>
<tr>
<td><strong>Case description</strong></td>
<td>Good health conditions, need to be transferred to another facility for hospitalization in a dedicated department.</td>
<td>Monitored (SpO₂, ECG, IBP, EtCO₂), sedated, intubated and ventilated, multi-lumen Central Venous Access (CVC), urethral catheter, temporary fecal diversion and containment system for hemorrhagic diarrhea. Needs to be centralized to an adequate intensive care facility.</td>
</tr>
</tbody>
</table>

HR, Heart Rate; SpO₂, Saturation of Peripheral Oxygen; FiO₂, Fraction of Inspired Oxygen; RR, Respiratory Rate; BP, Blood Pressure; ECG, Electrocardiogram; IBP, Intraperitoneal Bleeding; EtCO₂, End Tidal CO₂
Table 2. Patient preparation based on complexity.

<table>
<thead>
<tr>
<th>Complexity</th>
<th>Distance</th>
<th>Patient preparation</th>
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<tbody>
<tr>
<td><strong>Low complexity</strong>&lt;br&gt;(C1)</td>
<td>Short range</td>
<td>• Placement of a two-way cannula needle (16G or 18G), with an infusion line connected to appropriate fluids in a bag squeezer  &lt;br&gt;• Assess the need and possibility of sedation</td>
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<td></td>
<td>Medium/Long range</td>
<td>• Placement of a two-way cannula needle (16G or 18G), with an infusion line connected to appropriate fluids in a bag squeezer, and a second line outside the isolator  &lt;br&gt;• It is advisable to sedate the patient  &lt;br&gt;• Adequate monitoring  &lt;br&gt;• Assess the need and possibility of sedation  &lt;br&gt;• It is advisable to place a urethral catheter (uro-condom if intolerant to foley)</td>
</tr>
<tr>
<td><strong>Intermediate complexity</strong>&lt;br&gt;(C2)</td>
<td>Short range</td>
<td>• Placement of a two-way cannula needle (16G or 18G), with an infusion line connected to appropriate fluids in a bag squeezer, and a second line outside the isolator  &lt;br&gt;• It is advisable to sedate the patient  &lt;br&gt;• Adequate monitoring  &lt;br&gt;• It is advisable to place a urethral catheter (uro-condom if intolerant to foley)</td>
</tr>
<tr>
<td></td>
<td>Medium range</td>
<td>• Placement of a two-way cannula needle (16G or 18G), with an infusion line connected to ringer acetate in a bag squeezer and a second line outside the isolator  &lt;br&gt;• It is advisable to sedate the patient</td>
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<tr>
<td><strong>High complexity (C3)</strong></td>
<td><strong>Long range</strong></td>
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<tr>
<td></td>
<td>• Adequate monitoring</td>
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<td></td>
<td>• If necessary, provide preventive endotracheal intubation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Urethral catheter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Placement of a two-way cannula needle (16G or 18G), with an infusion line connected to ringer acetate in a bag squeezer and a second line outside the isolator</td>
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</tr>
<tr>
<td></td>
<td>• It is advisable to sedate the patient</td>
<td></td>
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<tr>
<td></td>
<td>• Adequate monitoring, assess need for defibrillator pads application</td>
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<tr>
<td></td>
<td>• If necessary, provide preventive endotracheal intubation</td>
<td></td>
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<tr>
<td></td>
<td>• Evaluate the need for Fecal Management System (FMS)</td>
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<td></td>
<td>• Urethral catheter</td>
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<th><strong>Short/ Medium/ Long range</strong></th>
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Online Supplementary Materials

**Table 1.** Possible maneuvers.

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