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Proposal of a decision tree for the classification of road transport in biocontainment regimen using an isolator

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Proposta di uno schema decisionale per la classificazione del trasporto su strada in biocontenimento mediante l'impiego di un isolatore

Abstract

Introduction: ground biocontainment transport is essential for managing highly transmissible diseases, yet standardized decision-making tools for road-based transfers are lacking in civilian literature. This study aimed to develop an operational model to support clinical and logistical decisions during such transports.
Materials and Methods: a decision tree was developed through retrospective analysis of 1.994 biocontainment transfers performed in Sicily between December 2020 and March 2022. Key variables included patient condition, use of life-support equipment, and transfer characteristics. The model was refined through structured post-mission briefings and categorized transfers into three complexity levels (C1–C3) based on clinical and logistical criteria.
Results: patients were stratified by walking ability, need for monitoring or life support, and infectious risk. A total of 590 high-complexity transfers used isolators, while 1.403 lower-complexity cases were managed with a biocontainment minibus. No critical equipment failures were recorded. The decision tree supported consistent planning and improved safety.
Discussion: comparison with literature-based recommendations confirmed the model's validity and highlighted operational issues such as miscommunication and equipment integration. Integration with NEWS2 is proposed to enhance risk stratification.
Conclusions: the proposed decision tree provides a reproducible framework for classifying biocontainment transport complexity. Prospective validation is needed to support its application in broader healthcare contexts.

Key words: biocontainment; infection control; bioisolator; medical evacuation; decision-making tree.

Riassunto

Introduzione: il trasporto su strada in biocontenimento è essenziale per la gestione di pazienti affetti da patologie altamente trasmissibili, tuttavia nella letteratura civile mancano strumenti decisionali standardizzati a supporto dei trasferimenti su strada. Questo studio si propone di sviluppare un modello operativo per supportare le decisioni cliniche e logistiche in tali trasporti.
Materiali e Metodi: è stato elaborato uno schema decisionale attraverso un'analisi retrospettiva di 1.994 trasferimenti effettuati in regime di biocontenimento in Sicilia tra dicembre 2020 e marzo 2022. Le variabili principali includevano le condizioni del paziente, l'impiego di dispositivi di supporto vitale e le caratteristiche logistiche del trasferimento. Il modello è stato perfezionato attraverso briefing strutturati post-missione, arrivando a classificare i trasferimenti in tre livelli di complessità (C1-C3) in base a criteri clinici e logistici.
Risultati: i pazienti sono stati classificati in funzione della capacità di camminare, della necessità di monitoraggio o supporto vitale e del rischio infettivo. Sono stati identificati 590 trasferimenti ad alta complessità eseguiti mediante l'utilizzo di isolatori, mentre 1.403 casi a bassa complessità sono stati gestiti con un minibus di biocontenimento. Non sono stati registrati guasti alle apparecchiature critiche. Lo schema decisionale ha supportato una pianificazione coerente e ha migliorato la sicurezza operativa.
Discussione: Il confronto con le principali raccomandazioni presenti in letteratura ha confermato la validità del modello e ha messo in evidenza criticità operative come la comunicazione inefficace e l'integrazione delle apparecchiature. Si propone l'integrazione dell'indice NEWS2 per migliorare la classificazione del rischio clinico.
Conclusioni: lo schema decisionale proposto fornisce uno strumento riproducibile per classificare la complessità del trasporto sanitario in biocontenimento. È necessaria una validazione prospettica del modello al fine di garantirne l'applicabilità in contesti sanitari più ampi.

Key words: biocontenimento; controllo delle infezioni; bioisolatore; evacuazione medica; schema decisionale.

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Introduction

During the COVID-19 pandemic, the need to simultaneously transfer multiple patients under a biocontainment regimen by road across diverse distances,[1,2] became evident in order to alleviate the pressure on hospital facilities.

In 2006, the Italian Red Cross, in collaboration with the General Directorate of Health Prevention of the Ministry of Health, established a biocontainment team (Reparto di Sanità Pubblica) to provide healthcare support during emergencies at both national and international levels. This team has since become a key resource in epidemic response efforts, assisting other agencies in the evacuation of infectious patients.

In support of these missions, effective and adaptable biocontainment technology was critical to ensuring safe patient handling and transport logistics. In the context of transporting patients with Highly Transmissible Diseases (HTDs), Biocontainment Isolators (BCIs) became an essential safety measure. BCIs consist of a transparent PVC structure mounted on a metal frame. They use negative pressure, generated by electric motors, and HEPA filtration ensuring high biological safety. However, similar systems such as the Aircraft Transport Isolator (ATI) or Stretcher Transport Isolator (STI), although described in the literature,[3-5] are not fully compatible with ground vehicles of small to medium size, highlighting the need for more adaptable ground-based biocontainment solutions.

These technical aspects are further compounded by logistical factors, among which transfer duration plays a critical role, increasing the risk of potential complications. These time-related variables, combined with the confined environment of biocontainment isolators, require accurate pre-transfer planning to mitigate clinical deterioration or logistical delays.

In addition to these temporal and spatial constraints, the limited interior space of ambulances used for biocontainment transports requires careful team composition. It is essential to balance the patient's clinical needs with the inclusion of adequately trained personnel for the management of the isolator, thereby ensuring both operational safety and treatment continuity during transfer (Table 1).

Based on transport duration, transfers can be broadly classified as short (*e.g.*, within the same hospital), medium (e.g., inter-hospital within the same or neighboring cities), or long-distance (travel exceeding one hour). In specific cases, air transport using fixed or rotary-wing aircraft may be required.

The experience accumulated by the Italian Red Cross team during the COVID-19 pandemic period, combined with the lack of adequate civil-oriented scientific literature on road transfers, led to the development of a decision tree that utilizes objective data to classify transport complexity. This tool has been developed to guide healthcare staff in selecting the appropriate biocontainment equipment to protect both the staff and the community while ensuring the highest level of patient care.[3]

The model is designed to classify transport complexity by considering not only the patient's clinical condition but also the use and management of life-support and monitoring devices.

Materials and Methods

The decision-making algorithm for biocontainment transport was developed directly in the field, based on the experience gained during patient transfer operations conducted between December 2020 and March 2022. The algorithm, developed during the COVID-19 pandemic, was initially designed to manage diseases primarily causing respiratory failure. During the missions, it became evident that assessing only the patient's condition was insufficient to determine the most appropriate transport approach. The use of advanced medical devices, such as mechanical ventilators, multiparametric monitors, and infusion pumps, required detailed planning, as their integration with biocontainment isolators imposed significant operational constraints. Consequently, the algorithm had to take into account two fundamental factors: on one hand, the challenges related to the patient's clinical status and the potential evolution of their condition; on the other, the logistical and technical difficulties posed by the management of life-support equipment that needed to be operated throughout the transport.[6] To structure the decision-making model, a retrospective analysis of completed transports was conducted, examining patients' clinical parameters, transfer durations, the use of medical equipment, and operational challenges encountered. The development and refinement of the decision-making algorithm were strongly influenced by operational feedback gathered through post-transport briefings conducted after each biocontainment transfer.

The briefing represented a moment of critical analysis of the clinical, logistical, and communicative aspects related to the recently completed biocontainment transport. It was conducted within the first hour after the end of the intervention,[7] with an average duration of approximately 10 minutes, and involved all members of the operational team, including the team leader, biocontainment technicians, the coordinator (who also acted as moderator of

Table 1. Team composition.

	Isolator	Minibus
Low Complexity (C1)	Min 2, Max 3 units. (Biocontainment Technicians, including one driver.) Optimal: 3 Units (1 Dedicated Driver, 2 Biocontainment Technicians)	2 Biocontainment Technicians (Including one Driver)
Intermediate Complexity (C2)	Min 3 Units (1 Driver, 1 Biocontainment Technician, 1 Nurse)1, Max 4 Units (1 Driver, 2 Biocontainment Technicians, 1 Nurse) or (1 Driver, 1 Biocontainment Technician, 1 Nurse, 1 Doctor) Optimal: 4 Units (1 Driver, 1 Biocontainment Technician, 1 Doctor, 1 Nurse)	
High Complexity (C3)	Min 3 Units (1 Driver, 1 Biocontainment Technician, 1 Doctor)1, Max 4 Units (1 Driver, 1 Biocontainment Technician, 1 anesthesiologist/intensive care Doctor, 1 Nurse) or (1 Driver, 1 Nurse, 1 Doctor) Optimal 4 Units (1 Driver, 1 Biocontainment Technician, 1 anesthesiologist/intensive care Doctor, 1 Nurse)	

the discussion), and, if present, the Medical Doctor (MD) and the Registered Nurse (RN).[8] The discussion was structured around five main thematic areas.[9] The correspondence between the clinical information provided by the referring facility and the patient's actual condition was assessed; any discrepancies were analyzed in relation to the team's management strategies, and possible corrective actions were identified to prevent the recurrence of similar situations. The transport preparation was then explored, examining the adequacy of human resources employed, the completeness of the equipment provided, and the clarity in the distribution of roles. Specific attention was given to logistical challenges encountered, including difficulties in accessing facilities, travel times, and the overall organization of the route. Patient management was examined with respect to the operational difficulties related to the use of monitoring and ventilation devices within the isolators, as well as the effectiveness of transport planning in anticipating potential clinical deterioration. Finally, the consistency between the planned complexity level and the one observed in the field was evaluated, with the aim of verifying the appropriateness of the operational decisions made during the initial assessment phase. The observations emerging during the briefings serve as a basis for subsequent discussions and coordination among team members.[7-9]

By incorporating real-world feedback into the algorithm's iterative refinement process, the decision tree was optimized to better reflect practical constraints, enhance safety measures, and streamline transport procedures in future biocontainment missions. To ensure maximum protection for both personnel and patients from the risk of contamination, the use of BCIs with adequate negative pressure was deemed necessary.[6,10,11] The selected devices were already available within the Public Health Department and complied with the Ministry of Health's requirements for the safe transport of patients with infectious diseases. For the transport of non-ambulatory infectious patients or in cases of high-complexity transfers, characterized by patients in critical condition, a high risk of airborne transmission, or the need for airway management and monitoring, the IsoArk N36-4 isolator, manufactured by Beth-El Zikhron Yaaqov Ind. Lt., was employed. Mounted directly on an ambulance stretcher, this device ensured a high safety standard while allowing the use of life-support devices during transport (*e.g.,* mechanical ventilators, multiparametric monitors, and infusion pumps). For low-complexity transfers, involving patients in good health conditions, a biocontainment minibus was used an IVECO vehicle equipped with an IsoArk isolation chamber, which enabled the simultaneous transport of up to seven patients. This system optimized operational efficiency, facilitating multiple transfers while maintaining adequate levels of protection.

The integration of life-support devices within BCIs required meticulous operational planning due to spatial limitations, power autonomy constraints, and the need for compatibility with the sealed environment.

Ground biocontainment transfers need to be systematically oriented in patient care and transport choices. In order to achieve this, it is mandatory to adopt a common line to guide operators,[12] to orient them on the type of isolator to be used[13] and to determine the possible need of MDs or RNs on board,[11] depending on the complexity of the transfer.[3,10] To meet these needs, we created a decision tree scaffold that integrates clinical and logistic variables. One fundamental aspect is the pathogen classification, as defined in the WHO's Laboratory Biosafety Manual, 4th edition, which ranks pathogens from Class I to IV.[1]

This classification helps identify the required level of biocontainment and support planning tailored to the specific risks of each scenario.[11,14,15] Another key factor in transport planning is the patient's walking capability. The ability of a patient to move independently determines the level of assistance required when transitioning between the bed and the isolator,[16] as well as the feasibility of alternative transport positions such as a sanitary chair. Patients who can walk independently without assistance are classified as W1, while those who require help moving are identified as W2. W3 patients are non-walking and require life support measures, thus representing the highest level of care dependency.

Careful patient preparation is therefore mandatory, including the anticipation and mitigation of possible adverse events.[17] It is advisable to overestimate potential issues, given the limited space within the isolator, which may restrict emergency interventions.[18]

Additionally, the type of route must be taken into consideration. The transport pathway, defined from the starting point to the final destination, is directly linked to travel time and logistical challenges.

A final critical element in transport classification is the need for life support and invasive or continuous monitoring.[18,19] Patients requiring intensive care and continuous monitoring necessitate meticulous planning of both logistical and medical needs. These transports may require the presence of a Medical Doctor (MD) or a Registered Nurse (RN) who is trained and experienced in operating BCI-related equipment and procedures.

Considering the parameters mentioned above, we propose three levels of transport complexity. Low-complexity (C1) transports involve W1 patients who do not require any form of life support. Intermediate-complexity (C2) transports apply to patients requiring sub-intensive care, including continuous monitoring, non-invasive ventilation (NIV) such as high-flow nasal cannula (HFNC), or infusion pumps. High-complexity (C3) transports involve critically ill patients who require multiple life support measures, continuous and invasive monitoring, or management of severe infectious diseases. Patients affected by Class IV pathogen-related conditions are included in this category, regardless of their clinical status.[20]

The decision tree proposed (Figure 1) utilizes these parameters to facilitate rapid assessment of transport complexity. This allows operators to make informed choices regarding the appropriate transport methods, routes, and personnel required for each mission.[18]

The biocontainment transport team is typically composed of several key professionals, each with a specific role in ensuring the success and safety of the operation. An essential figure is the Biocontainment Technician, trained in the use of isolators and responsible for managing the practical logistics of the transfer, a role that may also be performed by a healthcare professional with adequate technical expertise. The Team Leader, usually the most competent and technically experienced member, oversees operations from within the vehicle to ensure smooth and efficient execution. The Coordinator operates externally, supervising and verifying each phase of the transfer to ensure adherence to protocol. The MD is the clinical lead performing pre-transport assessment, preparing resources, and coordinating with the team leader to align medical and logistical needs. The RN is responsible for patient care during the transfer. In the absence of an MD, they assume full clinical responsibility, while in their presence, provides critical support and ensures continuity of care.

The assignment of tasks and resource management for biocontainment transport are entrusted to individual operational structures. These structures may vary in terms of healthcare team composition and the vehicle availability, depending on specific needs and logistical capabilities.

Results

Between December 2020 and March 2022, a total of 1.994 patients positive for COVID-19, or suspected of being affected yet not already confirmed, were transported from and to several destinations around Sicily for a total of 188.305 km traveled with a maximum continuous distance of about 315 km from Catania's Airport to Trapani city (Table 2).

Of these, 590 patients were transferred by road using two Isoark N36-4 isolators and 1.403 patients were transferred using a biocontainment minibus.

The IsoArk N36-4 isolator was used for patients requiring higher biocontainment levels, particularly for those with confirmed highly transmissible infectious diseases, as well as for patients awaiting diagnostic results but with strong clinical suspicion of such conditions. The biocontainment minibus was employed primarily for group transfers of patients with lower transport complexity, optimizing efficiency for medium-distance missions. Operational experience underscored the importance of well-equipped ground transport units capable of ensuring safety over long distances. The longest recorded transport (315 km) underscores the necessity of careful pre-transfer planning, particularly in terms of oxygen supply, medical staffing, and patient stabilization.

No critical failures in biocontainment equipment were reported, confirming the operational reliability of the devices used.

Discussion

To adapt the algorithm to a broader range of pathogens, including Class IV diseases that pose additional risks such as hemorrhagic complications,[20] further evaluations are required. Integrating quantitative assessment tools would enable a more comprehensive and objective analysis of the patient's clinical condition. In particular, the National Early Warning Score 2 (NEWS 2),[21] based on key physiological parameters such as respiratory rate, oxygen saturation, and blood pressure, would be useful in refining risk classification (Figure 2). Its dual oxygen saturation scale makes it particularly suitable for patients with chronic respiratory failure or

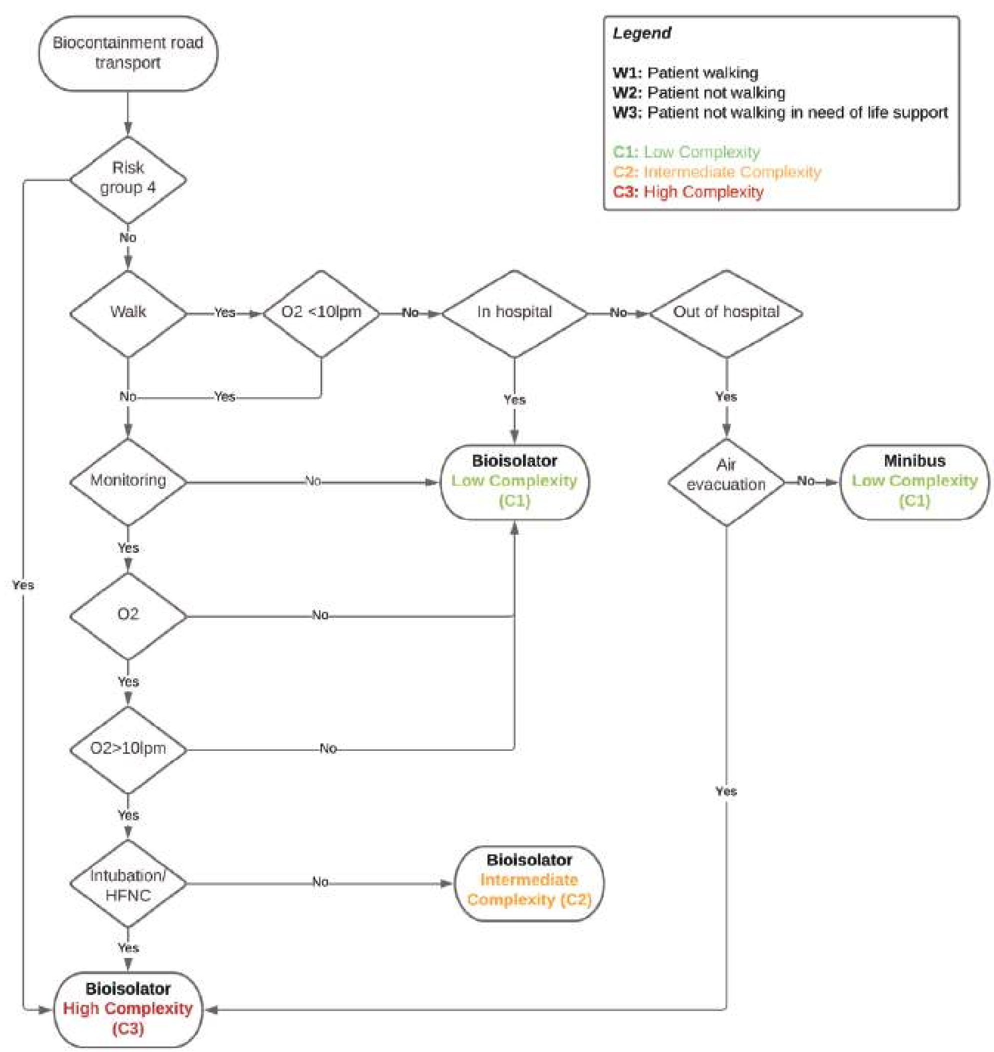

Figure 1. Decision tree of road transport in biocontainment.

those undergoing oxygen therapy. Additionally, its increased sensitivity to sepsis makes it an effective tool for the early identification of patients with respiratory and hemodynamic impairment, a common condition in systemic infections.[22,23]

A patient with a high NEWS2 score, indicating a severe clinical deterioration, would likely require a high-complexity (C3) transport, where advanced monitoring and intensive care support are necessary. Conversely, a patient with a low score, who is stable and does not require intensive interventions, may be classified as a low-complexity (C1) transport case. However, it is essential to recognize that transport complexity is not solely determined by the patient's health status but also by logistical constraints related to medical equipment. The combination of NEWS2 with the decision tree could provide a more structured and reproducible approach, reducing subjectivity in risk assessment and improving the allocation of resources. Its implementation within the decision-making model would improve risk stratification, allowing for a more precise distinction between patients requiring minimal intervention and those in need of advanced monitoring, increased healthcare personnel, and medical interventions during transport. Furthermore, it would make the decision tree more adaptable to a wide range of infectious diseases, particularly those affecting the

Table 2. Summary of biocontainment transport operations and characteristics.

Transport Mode	Total patients transported	Biocontainment device used	Primary use case
Road – Single patient	590	IsoArk N36-4	High-risk patients requiring intensive care and mechanical ventilation
Road – Multiple patients	1403	Biocontainment Minibus	Group transport of lower complexity patients

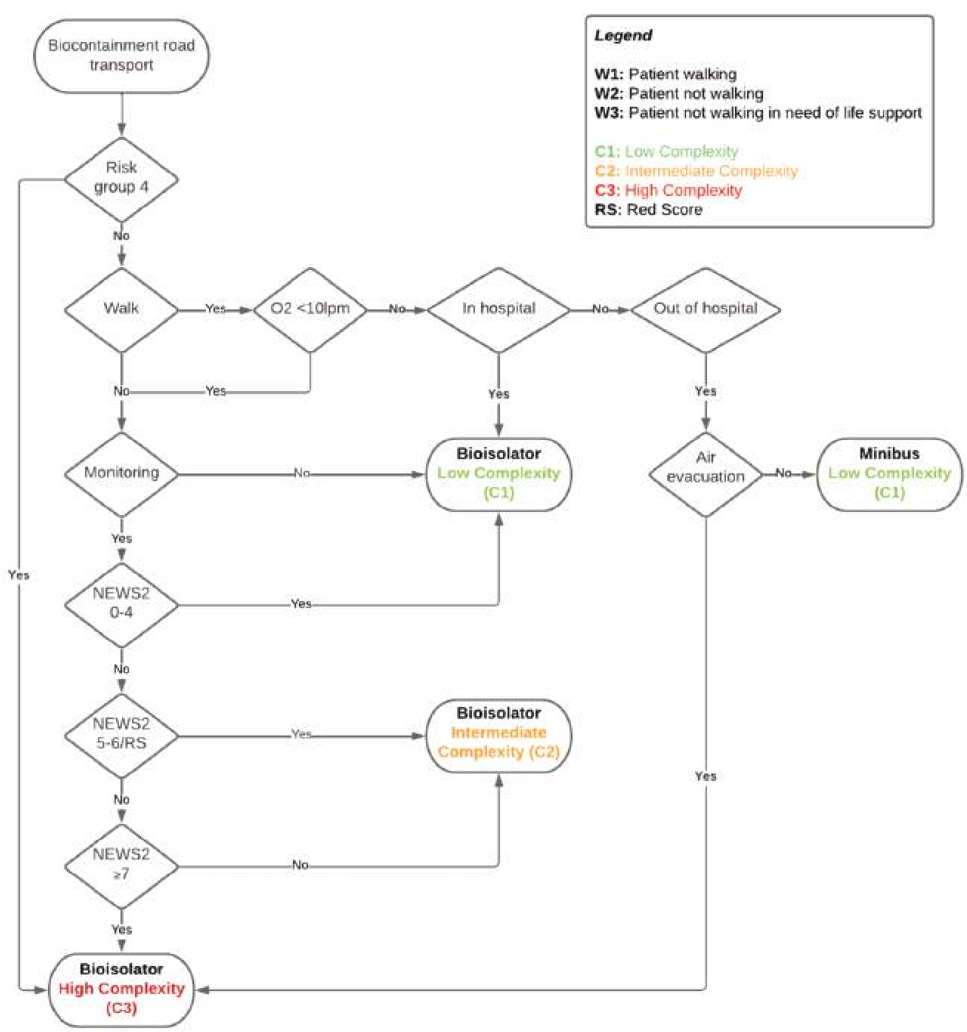

Figure 2. Decision tree of road transport in biocontainment integrated with NEWS2.

respiratory and cardiovascular systems, enhancing its effectiveness as a tool for biocontainment transport. This tree would facilitate better coordination between transport teams and receiving facilities, optimizing pre-alert systems and the management of critically ill patients.[24]

In addition to its theoretical structure, the decision tree was refined by comparing retrospective data with operational decisions made in the field, aiming to verify its applicability and consistency with real-world practices.

This process allowed the identification of recurring patterns, enabling their systematization into a decision tree aligned with current scientific recommendations. Corradi *et al.*[14] and Lowe *et al.*[15] stress the significance of an initial classification of transport complexity based on objective parameters, consistent with the approach adopted in this study. Isakov *et al.*[20] highlight the critical role of early risk assessment in determining the appropriate level of clinical support required, a concept reflected in the integration of the NEWS2 score into the proposed model. The comparison also revealed several critical issues. In multiple cases, discrepancies between the clinical information transmitted by the referring facility and the patient's actual condition necessitated adjustments during transport, resulting in delays and increased operational stress for the team. This contrasts with the recommendations of Herstein *et al.*,[5] who underscore the importance of structured systems for the early sharing of clinical and logistical information, between transfer team and start and receiving facilities. Furthermore, in certain scenarios, the simultaneous management of patients requiring life support within isolators exposed notable logistical challenges, similar to those described by Dang *et al.*[17] regarding the integration of medical devices within containment systems.

Among the negative outcomes, we primarily observed delays related to transport organization, communication between starting and destination facilities, and the need to reassess team composition based on the actual complexity encountered. These aspects underscore the importance, already emphasized by Garibaldi *et al.*[11] and Hilbert-Carius *et al.,*[18] of adopting flexible decision-making models that can be updated in real time according to operational conditions.

The main limitations of this article are that the decision tree was developed and tested within a specific context (Sicily, Italy) and may require adaptations for implementation in other healthcare systems with different resources and protocols. Additionally, the lack of direct comparison with other decision-making models limits the ability to assess its comparative effectiveness, highlighting the need for prospective validation with future data.

The missions carried out have highlighted the importance of adopting a structured decision tree to support choices related to biocontainment transport. However, to validate the proposed model, further verification through real-time case studies is required.

Conclusions

Ground biocontainment transport is a complex challenge that requires balancing patient safety, operator protection, and logistical management.[14,20,24] The experience gained during the COVID-19 pandemic has highlighted the need for standardized protocols to guide operational decisions and optimize resource utilization.[24] The decision tree developed in this study provides a structured approach to classifying transport complexity by integrating both clinical and logistical factors. Its implementation could improve risk assessment, enhance communication among healthcare teams, and ensure safer and more efficient decision-making. However, prospective validation is needed to adapt it to different healthcare systems and extend its applicability to a broader range of infectious diseases, including those caused by Class IV pathogens. The integration of standardized assessment tools, such as NEWS2, could refine transport classification, but operational constraints, including the availability of vehicles and life-support devices, must also be considered. Comparative studies with other decision-making models could further clarify its effectiveness and potential areas for improvement.[1] In conclusion, this study represents a step forward in standardizing biocontainment transport; however, further research and validation are necessary to tailor it to diverse healthcare settings and enhance the global response to infectious disease emergencies.

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Contributions: FD conceptualized and designed the study, led the data acquisition, analysis and interpretation, and was primarily responsible for drafting and critically revising the manuscript; UA contributed to the study design, interpretation of the results, and critical revision of the manuscript, providing significant intellectual input; MGB and EF supported the study design and data collection, contributing to the critical revision of the manuscript; SM provided essential technical input thanks to his extensive expertise in various biocontainment devices, contributing to the evaluation of operational solutions and the manuscript revision; VC provided a fundamental contribution to the initial design of the study and the definition of its methodological framework. Thanks to his expertise and strategic vision, he significantly shaped the structure of the decision-making algorithm and the organization of the operational model. Although he passed away before the finalization of the manuscript, his work served as a constant reference throughout all phases of the study. The authors wish to remember him with deep gratitude and respect, acknowledging the substantial and lasting value of his scientific and human contribution. All authors approved the final version of the manuscript for submission and agree to be accountable for all aspects of the work.

Ethics approval and consent to participate: All data collected, analyzed, and presented in this study were handled in full compliance with ethical principles, ensuring respect for patient confidentiality and adherence to the applicable standards of research integrity.

Availability of data and materials: the data used in this study derive from a retrospective analysis of biocontainment transports conducted between December 2020 and March 2022 in Sicily. All relevant data are included in the article and supporting tables. Additional details can be provided upon request to the authors, in compliance with data protection regulations.

Conflict of interest: the authors have no conflict of interest to declare.

Funding: this study did not receive funding. The research and manuscript preparation were carried out voluntarily as part of the institutional activities of the authors' respective affiliations.

Acknowledgments: the authors would like to express their sincere gratitude to all healthcare and technical professionals who, during the pandemic period, ensured the safe transfer of patients affected by highly transmissible infectious diseases. Their commitment, dedication, and expertise not only protected the health of patients and personnel involved but also played a crucial role in refining the decision-making tool presented in this study. We extend our heartfelt thanks to them.

Received: 4 November 2024. Accepted: 28 June 2025.

Scenario 2025; 42:612
doi:10.4081/scenario.2025.612