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Renovation and creation of a Biocontainment Unit: the experience of Azienda Ospedaliero-Universitaria Pisana (Pisa, Italy).

Angelo Baggiani[1,2], Francesca Di Serafino[1], Michele Totaro[1], Sara Civitelli[1], Giulia Geminale[1], Alessandro Daole[1], Federico Vannini[1], David Rocchi[1], Nunzio Zotti[1], Alessia Civitelli[2], Monica Scateni[2], Stefano Gaffi[2], Stefano Colombini[2], Michele Cristofano[2], Grazia. Luchini[2], Silvia Briani[2]

[1]*Department of Translational Research and New Technologies in Medicine and Surgery, University of Pisa, Italy.*
[2]*The Azienda Ospedaliera Universitaria Pisana (AOUP), Italy*

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Abstract

Infectious diseases are a major public health concern. In recent decades, there has been a succession of bacterial and viral diseases, which when added to the endemic diseases found in certain areas of the world, can become a global health problem.

In emergency medicine we talk a lot about Mass Casualty Incident (MCI) preparedness, but the main focus today is bio-preparedness. Therefore, especially after the Ebola experience, much investment has been made in the development of Biocontainment Units (BCUs).

At present, in Italy there are no national realities that have experimented the construction of a completely new biocontainment units detached from the Emergency Department (ED) RNPP-funded. Given this, the project of the Azienda Ospedaliero-Universitaria Pisana (AOUP) is to make renovations on existing ED structure and build an entire new facility for biocontainment.

1. Introduction

Emergency Departments (EDs) are high-risk areas for disease transmission in hospital settings since they are often overcrowded, and potentially infectious or susceptible patients may wait nearby for several hours.[1]

Since Covid-19 caused an overload on healthcare systems, huge improvements in surge capacity are required. Moreover, hospital capacity and capability to the response must be reviewed.[2]

In compliance with the provisions of the Italian "Organizational guidelines for the strengthening of the Covid-19 emergency hospital network" [3,4], to cope with possible sudden increases in the epidemic curve, AOUP intends to rearrange the ED, providing separation of the pathways of infected or suspected infected patients and isolation areas for their stay in visit, observation or waiting for diagnosis/result of nasopharyngeal swab or admission.

Preparedness and training lead to the success of a high-level isolation unit. Staff must be familiar with infection prevention practices, personal protective equipment (PPE), and

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clinical care protocols for high-consequence pathogens. [5]

According to Sauer et al., high-level isolation units must be activated promptly to receive patients, within 8 hours or less, and may benefit from implementing an Incident Command System (ICS) to manage patients with highly infectious diseases. [6]

Ebola Virus Disease (EVD) demonstrated that well-defined processes may guide the evaluation and management of the Person Under Investigation (PUI) combining the expertise of both ED and BCU teams to address highly infectious diseases that may enter the health system through the ED. [7]

Since Mass Casualty Incidents (MCI) occurred (mainly 9/11 and the anthrax mailings of 2001), the U.S. planned efforts on bio-preparedness. In this way, bioterrorism was the drive for preparedness planning, but hospitals are more likely to face infectious diseases, such as SARS, Monkeypox Virus and multidrug-resistant organisms, socio-preparedness measures help to prepare for naturally occurring infections as well. [8]

The Centre for Research on the Epidemiology of Disasters (CRED) of Université Catholique de Louvain (UCL) set up The International Disaster Database (EM-DAT) [9]. From 2002 to 2022, excluding the CoViD-19 pandemic, 696 biological events were reported, for an overall amount of 10,5 mln people affected. Reported diseases were mostly cholera, dengue, measles, meningococcal disease and Severe Acute Respiratory Syndrome (SARS). The major affected continent was Africa (66% of reports), followed by Asia (18%).

Since the European Union has approved the Next Generation EU, Italy with the National Recovery and Resilience Plan (NRRP) guarantees 15.6 bln € in funds for health care, to which 2.9 bln € can be added from the Complementary Plan. Given this, many works will be done for innovation and progress in Italian healthcare. The AOUP project falls under these, aiming to create the first case in Italy of a completely new and separated Biocontainment Unit, even connected to the ED of the hospital. In particular, this project is expected to serve as an example of bio-preparedness in the fight against SARS-CoV-2 and other infectious diseases that may arise in the future.

2. Design Process

By meeting the need for a strengthened emergency network and bio-preparedness, the following project is being implemented:

1. Renovation of the area of the building in front of the ED positioned to the west of Building 31 and parallel to the ambulance entrance, through the construction of:
    a. Waiting areas dedicated to pediatric/adult patients;
    b. Connections and support rooms to the adjacent biocontainment area.
2. Construction of a new facility consisting of biocontainment rooms for patients accessing the ED. This new facility will have separate pathways and will contain triage rooms, examination/observation/waiting boxes for patients waiting for swab results and consequent admission to minimize overcrowding and the risk of contagion within the ED, ensuring examination rooms suitable for ED management of patients, including critically ill patients with Sars-CoV-2 (or suspected Sars-CoV-2) or other infectious and diffusive diseases, according to future epidemiological developments, with separate pathways from the remaining part of the ER.

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The project will be implemented in two phases:

1. Realization of the structural adjustment works of the area mentioned in point 1;
2. Realization of the new building.

3. Design Features

3.1 Structural adjustments

Structural adjustments are required for the facility existing in front of the ED. Intervention areas are designed for the waiting room and connections and support rooms to the new facility, for an overall area of 196 m2 (Figure 1).

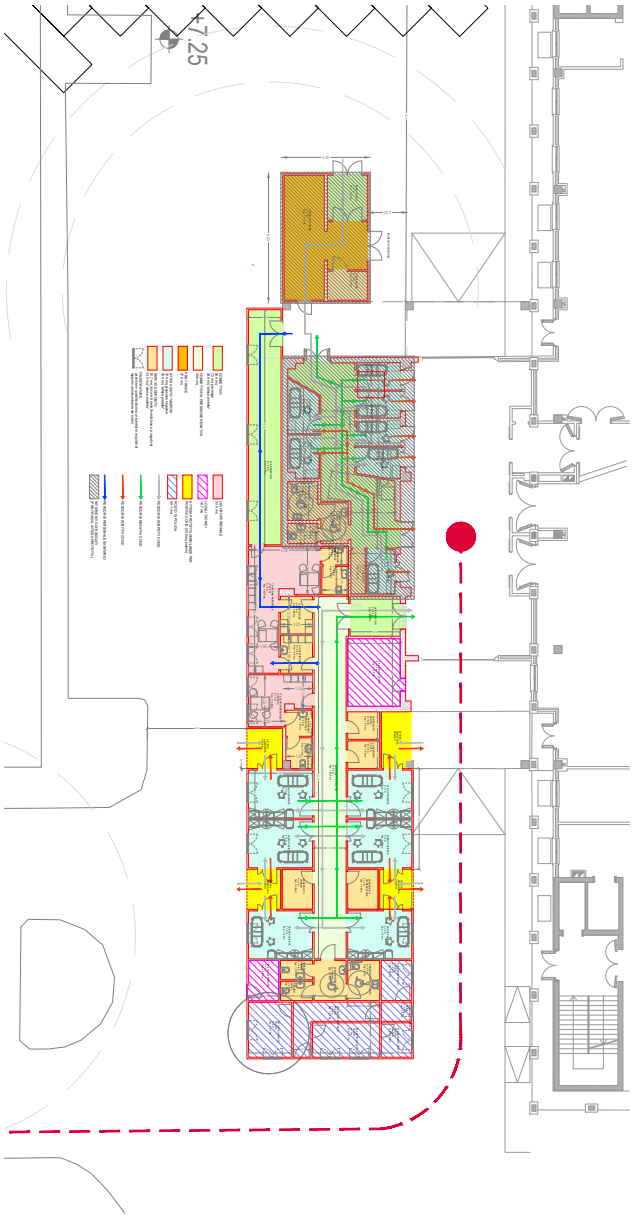

Figure 1: Structural map of the Biocontainment Unit in Azienda Ospedaliero-Universitaria Pisana (AOUP)

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At the regimen phase, there will be a waiting room for pediatric and/or adult patients destined for admission and/or awaiting swab results.

The area will have the function of relieving the ED of stable, self-sufficient patients, who do not require treatment, awaiting admission and/or discharge, for whom a short stay is planned.

It will include 7 boxes, equipped with a call bell (in pre-triage), capable of accommodating one stretcher each, or chair and changing table (in case of pediatric use); the area will be equipped with an emergency trolley and toilets for patients and a nursing station. Moreover, the doors of the boxes are intended to allow the patient to be seen by personnel and should be provided with adequate air changes and a sink for operator use.

Regarding the waiting area, there will be the following areas:

- 7 boxes (rooms PD01-PD07) of the protected waiting area of 4.5m2 to 5.8m2 (h. 3m), equipped with a chair or stretcher and changing table;
- 1 aisle (room PD08) with 1 nurses workstation;
- 1 anteroom (room PD09);
- 1 disabled toilet with changing table (room PD10);
- 1 toilet with changing table (room PD11);
- 1 storage room (room PD12).

Connective and support rooms serving the new facility are:

- aisles leading to the biocontainment area (rooms 07 and 08);
- portion of health personnel work room (room 10);
- dressing room (room 11);
- operators' toilets (room 13 anteroom and room 14 operators' toilet);
- cleaning storage (room 15);
- clean material storage (room 16);
- technical room (room 23);
- positive patient ambulance waiting area serving box 01.

The iter of the patient will begin from the entrance of the aisle (room PD08), on which the entrances of the waiting boxes open.

In boxes from PD01 to PD05, patient exit will occur directly into the ambulance entrance; in the remaining 2 boxes (rooms PD06 and PD07) patients exit will occur in the aisle within the area (room PD08) to reach a dedicated exit facing the ambulance entrance.

3.2 New facility

The construction intervention area will be adjacent to the adjusted building, for an overall area of 296,1 m2 with two functional areas:

- pre-triage for adult and pediatric patient
- Biocontainment area for examiation/observation/waiting patients, who come to the ED with suspected COVID-19 symptoms. This will minimize overcrowding and the risk of contagion within the ED.

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There will be also 2 technical rooms, both with outside access (room 26, with an area of 13.9 m2 and a height of 2.4 m; room 27 with an area of 4.8 m2 and a height of 3 m).

The pre-triage area will include:

- 1 Filter area (room PTR01)
- 1 Pre-triage area (room PTR02)
- 1 toilet for operators (room PTR03)

Patients will enter the pre-triage area through room PTR01; subsequently, they will go to the ED to undertake the diagnostic/therapeutic procedures. The patient, following the initial assessment, will be either directed to the ED or the examination/observation area or the waiting area.

The examination/observation area will be equipped with 6 biocontainment boxes, also suitable to manage critically ill patients, with related service rooms, separate routes for staff and patients, and demarcation of "dirty" and "clean" areas. Outside the biocontainment area there will be:

- connective access for sanitary personnel and clean material (room 07)
- patient connective access (room 08), which through a door, gives access to the biocontainment area, in the filter (room 09)
- clean room for staff work (room 10), of 22.6 m2, height 3m, equipped with anteroom and bathroom (rooms 14 and 15), from which the personnel can access the dressing filter room (room 12) leading into the biocontainment area (in the filter room 09); through the dressing filter (room 13), equipped with a sink, it is possible to rekindle from the filter to the clean working room. The clean working room complies with the minimum luminance ratio of 1/8 following current regulations.

The biocontainment area will consist of:

- filter (room 09), equipped with negative pressure (-5 Pa); sinks are placed for staff use, since the sink inside the box is intended for use in bedridden patient hygiene.
- 6 examination/observation boxes (rooms 01, 02, 03, 04, 05, 06), with negative pressure (-10 Pa), air extraction filtration system, airtight doors and windows; doors to the inner corridor must be sliding and visible. Each box should be suitable for the management of one patient each and have direct access to vehicle parking areas for transporting patients positive for Sars-CoV-2 (patients who have tested negative can alternatively exit the boxes via the filter room 09 and then the connective room 08). Boxes have an area of 12 m2 and a height of 3 m, which can be equipped with a stretcher or technical bed. All boxes are equipped with medical gases and alarm system for medical gas exhaustion.

The following rooms will also be supporting the examination/observation boxes:

- 1 staff work area (room 11) of 10.9 m2, height 3 m, equipped with ante-bathroom and toilet (rooms 16 and 17), separated from the filter by a door. The room complies with the minimum luminance ratio of 1/8 following current regulations;
- 1 cleaning service storage room (room 18);
- 1 clean storage room (room 19);
- 1 equipment storage room (room 20);
- 1 dirty storage room (room 21);

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- 1 patient anteroom (room 23), 1 toilet for disabled patients (room 22), and 2 patient toilets (rooms 24 and 25); the area related to toilets is all placed under negative pressure (-10 Pa).

In each box are guaranteed:

- 3 oxygen supply outlets capable of ensuring a flow rate of 45 l/min;
- 2 compressed air outlets with a flow rate of 35 l/min;
- 2 suction (vacuum) outlets;
- at least 12 electrical outlets;
- facility for connection of vital parameter monitors to the control unit located in the medical staff workroom;
- sink;
- doorbell (with external warning light) and intercom.

Boxes will comply with the minimum luminance ratio of 1/8 following current regulations.

The boxes will have monitors for vital parameters, respiratory support (NIV, C-PAP, up to the possibility of invasive ventilation) and hemodynamic support.

The biocontainment area will be equipped with an emergency cart with a defibrillator.

The entire area will have HEPA filters, air conditioning system and air changes above 6 changes per hour (in the boxes, it is necessary to get to 12 changes per hour in case of TB). The area will be equipped with a control unit/monitor and a class 2 electrical system.

Wastewater from the entire area will be subjected to chemical treatment in chlorination before being discharged into the public sewer.

On the outside, on the ambulance entrance side the existing canopy will be extended to include the patient outlet on this side, as well as on the street side.

Patients access the examination/observation box directly from the adjacent SARS-CoV-2 positive patient transport vehicle stop area. The exit of SARS-CoV-2 positive patients is through the covered aisles where vehicles transporting patients positive to Sars-CoV-2 stop.

The exit of patients negative for SARS-CoV-2 will be done in the same way or through the filter room 09 and then the connective room 08.

Staff will enter the area through the sanitary personnel and clean material access connective room 07, the clean staff workroom (room 10), and then the dressing filter room 12; personnel will exit the biocontainment area through the dressing filter room 13, and then the clean staff workroom.

Dirty material will be brought outside directly from the boxes via the positive patient transport vehicle parking areas or collected in the dirty storage area (room 21), brought out through the filter connective room 09 and then through the connective room 08.

4. Conclusion

Current international health emergencies have shown that preparedness requires an

interdisciplinary approach, from planning to decision and action. In addition, pandemic occurrences poses a threat to general population health. In this scenario, a biocontainment system as here described assumes a critical and effective role in biohazard management to confine an infectious organism to reduce potential contagion.

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Corresponding author
Prof. Angelo Baggiani
Department of Translational Research
and New Technologies
in Medicine and Surgery,
University of Pisa, Italy.
Tel. 050 2213583;
Fax. 050 2213588;
E-mail: angelo.baggiani@med.unipi.it