MOBILE MEDICAL DIAGNOSTIC AND TREATMENT UNIT WITH BIOSAFETY LEVEL 3 (BSL-3)

History & Background

Treatment and diagnostics of HIV/tuberculosis/malaria and other infectious diseases require Biosafety Level 3 (BSL-3) laboratories. They in turn require a staggered vacuum from one room to the other, a personnel and sample lock as well as complete sterilization of all expendable materials. Already for conventional stationary laboratories the required installations and operator directives are restrictive and extensive. For decades, attempts have been made to construct a mobile treatment and diagnostic unit licensed for field and public road operation. In 2008 the Fraunhofer Institute for Biomedical Engineering (IBMT), as a member of the Fraunhofer Gesellschaft für die Angewandte Forschung with its more than 16,000 scientists, was tasked to resolve this problem. After only 18 months of development, construction and testing the vehicle has been accepted under the strict German regulations. Thus, for the first time a mobile, self-sufficient BSL-3 unit fully licensed by German authorities is available for operation on paved roads.

Specifications

The semi-trailer is built on a highly stable basis and has the maximum permitted length (18.5 m) and construction height (4 m) and is equipped with a comfortable interior facilitating complete decontamination. The vehicle is authorized for public roads through technical inspections by the German Technical Inspection Agency (TÜV) and has the corresponding operating permit necessary for the handling of biological material of Biosafety Level 3. The semi-trailer with its motor tractor is suitable for left- or right-hand traffic. Remote control via satellite and a network link is possible. The vehicle is equipped with its own 65 kW self-sufficient electrical power supply with a 1,000 liter diesel fuel tank enabling stand-alone operation of the vehicle without the motor tractor for weeks. Cable and hose connection to local supply units is possible.

Room layout

- treatment room (7.5 m²),
- personnel lock (1.5 m², up to -60 hPa vacuum level 1),
- first diagnostics room (7 m², up to -150 hPa vacuum level 2, HIV diagnostics),
- second diagnostics room (9 m², up to -150 hPa vacuum level 2, TB diagnostics and cryostorage of infectious material),
- large autoclave (1.5 m³),

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• storage room for liquid nitrogen (1 m², 200 l),
• technical room accessible from outside (1.5 m²),
• air conditioning and virus filter in the ceiling,
• additional space for medical treatment in a segmented porch tent (75 m²),
• entire vehicle laboratory technology is integrated into the floor on service friendly pullouts (20 m², height 0.6 m).

Crew & Personnel

A minimum of three to four persons (driver/security guard, physician, nurse/medical technician) is required to operate the mobile diagnostic laboratory. Additional study nurses, medical technicians and dedicated security guards can complete the crew to a maximum of six persons on demand.

Approvals & Permissions

The vehicle has the following official approvals:

- Permission for mobile use under Biosafety Level (BSL-3) according to Biological Agents Regulation, the Infection Protection Act (IfSG) and the Technical Rules for Biological Agents (TRBA 100) of the Federal Institute for Occupational Safety and Health (BAuA)
- Permission for the transport of infectious material (HIV, tuberculosis, malaria)
- Permission for the operation as a cryolaboratory
- Permission for the operation in traffic (TÜV)

Characteristics

- The first licensed vehicle of its kind
- Intuitive use of laboratory control system with touch-screen and computer link via satellite
- Pass-through autoclave equipped with vacuum steam sterilization (121°C/134°C) for secure germ disposal and self-sufficient water circulation
- Highly secure filter cascades for air supply and air exhaust with easy and secure exchange
- Absolutely contamination free during stationary and mobile use
- State-of-the-art modified diagnostic and sample preparation equipment (sterile workbenches, etc.) especially designed for vehicle use
- Special robust diagnostics equipment for mobile use: flowcytometer, hemoanalyzer, automation for serological and PCR-diagnostics, incubator with gimballed stabilization
- Transportation permission for infectious material (HIV, tuberculosis, malaria) because all patient samples are deep-frozen and stored at a temperature of -196°C of liquid nitrogen in shock-proof double-walled steel containers
- Fully equipped damage safe mobile cryobank on board guaranteeing utmost sample quality and security
- Entire equipment for an emergency physician, therapy tent attachable to the body of the vehicle

HIV/TB problems. The aim of this project which is supported by the Consul General of the Federal Republic of Germany in Cape Town, Mr. Hans-Werner Bussmann, is geared to the field testing of a newly developed robust BSL-3-capable diagnostic vehicle. The project comprises three strategic goals:

a) Alternative strategies for VCT as development and medical aid in remote rural areas (e.g., Eastern Cape) with a high HIV-1 and/or TB incidence.
b) Technology development in Germany with field testing of a new generation of rugged mobile diagnostic laboratory and/or treatment units and their technology transfer to developing countries.
c) Distinct improvements of diagnosis and treatment for HIV-1 and TB in underdeveloped regions.

Pilot Voluntary Counselling and Testing

To reach groups at risk of HIV-1 infection and tuberculosis (or other infectious diseases such as malaria) in rural areas of developing countries represents an enormous problem in view of the lack of medical support infrastructure in most of those areas. Basic medical care, medical consultations or medical diagnostic care for HIV-1 and tuberculosis exist only minimally or not at all. In South Africa HIV-tuberculosis co-infections or medical diagnostic care for HIV-1 and tuberculosis exist only minimally or not at all. In Eastern Cape) with a high HIV-1 and/or TB incidence.

The main idea of the suggested Voluntary Counseling and Testing (VCT) project under the umbrella of the Public Private Partnership (PPP) of the National DoH International Health Relations, HOPE Cape Town Association, National Health Laboratory Service (NHLS), the Division of Medical Virology at Stellenbosch University, and the Fraunhofer-Institut für Biomedizinische Technik is the testing of the new type of diagnostic vehicle for medical care of underdeveloped areas with...