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Equipment for Germ-free Caesarean Section and Baby Care

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ABSTRACT. A germ-free isolator system was designed and constructed, It permits a sterile caesarean section and rearing of an infant under germ-free conditions. The system includes a plastic surgical and rearing isolator and two supply isolators; one of the supply isolators served as a transport mobile unit for the transfer of the newborn from the operation room to the neonatal intensive care unit. All members of staff participating in the sterile caesarean section and in the postnatal care of the germ-free newborn underwent to a special training and all of them were able to meet the high requirements of this work. The surgery itself was without complications. the newborn was absolutely sterile up to the age of 1 month; afterwards the infant was gradually colonized with selected strains of bacteria and thus prepared for conventialization. In the course of this work further possibilities of application of gnotobiological techniques in pediatrics were proposed (*e.g.* care of premature, high-risk neonates).

Gnotobiological methods and technology made it possible in the past years to obtain a number of laboratory and farm animals for various experimental purposes. Germ-free technology and equipment have been also employed in human medicine; the plastic isolators permit to perform absolutely sterile surgical procedures including caesarean section. An infant born under sterile conditions can be transferred into the rearing unit and kept further in a sterile environment. Such a system can be used primarily for protection of newborns suffering from congenital immunodeficiencies. A suitable isolator system permits appropriate pediatric care and therapy of immunodeficiency including transplantation of needed cell elements.

Barnes *et al.* (1968, 1969) reported a caesarean section using a plastic surgical isolator. Dutch authors (Mackenzie *et al.*, 1969; Dooren, 1971) used similar technique for treatment of a presumptive congenital agammaglobulinaemia. Flad *et al.* (1971) and Dietrich *et al.* (1972, 1973) used a method of decontamination of an infant after birth for the therapy of immunodeficiency; this method was previously tested on laboratory animals (van der Waaij, 1967). In non-identical twins, suffering from combined immunodeficiency, decontamination was performed and at the age of four weeks the infants were placed into special isolators. A similar system was employed in 1970 in Birmingham and in 1972 in Houston. In infants previously born to these mothers, immunodeficiency was established and early death recorded. In these cases subsequent delivery was performed by normal caesarean section and newborns were immediately placed into the plastic isolator (Wilson *et al.*, 1973, 1975, 1977). After a microbiological control, decontamination was performed with antibiotics. As in the case of the newborn from Birmingham, no immunodeficiency was found and the baby was released from the isolator. The child from Houston has been maintained in the isolator for 4 years now; a detailed report concerning its development under germ-free conditions was published recently (Pediatric Res. *11*, 65, 1977). Lauvergeon *et al.* (1975) and Saint-Martin *et al.* (1975) obtained newborns by normal delivery, performed under strict aseptic conditions followed by decontamination. The French isolator system for germ-free infants was described by Griscelli and Ghnassia (1975).

Since 1957, when first experiments with germ-free piglets were performed in the Laboratory of Gnotobiology (Czechoslovak Academy of Sciences), several types of germ-free isolators have been designed and constructed and a complex germ-free technology has been devised. The long-term experience permitted us to apply the know-how in the field of the care of human neonates with presumed immunodeficiency.

In three previous pregnancies of mother B., the newborns died of septicaemia immediately after birth. Therefore, it was proposed to perform germ-free delivery of the fourth expected child, using the germ-free isolator system developed here. It was decided to perform a sterile caesarean section within the plastic surgical isolator. Such system has already been routinely used for germ-free caesarean sections in sows (Trávníček *et al.*, 1972, 1975). A new type of this isolator, adapted for use in human medicine was designed and constructed (Plate 1). The plastic bag is equipped with rubber gloves, an outlet air filter and with a connection part, joining the isolator with the sterile transport unit. In order to make the manipulation with the isolator simpler, it is suspended on a frame, which is fixed to the rigid transport isolator. The bottom of the isolator has a built-in special surgical foil (Vi-Drape Surgical Film, Parke-Davis) which is fine and flexible. Before operation, all equipment and materials (*i.e.* surgical instruments, injection solutions, diapers *etc.*) were sealed in polyethylene bags and sterilized by gamma rays (^{60}Co). The bags were then placed into the transport isolator which is connected to the surgical isolator and the whole unit was then sterilized by aerosol of 2% peracetic acid (Persteril). After sterilization the unit was thoroughly ventilated with sterile air and sterility was controlled microbiologically. The three outlet filters which permit to control the air pressure within the isolator, are equipped with the same type of filtration material.

Before caesarean section the operation field was treated in the usual way, the final step being the application of a special sterile glue (Vi-Drape Adhesive, Parke-Davis) on the skin and on the bottom (surgical foil) of the isolator. The isolator is thus sealed to the abdomen of the mother. Following the section, the newborn is taken out into the absolutely sterile environment of the surgical isolator and can be transferred into the transport isolator for further treatment. The transport isolator is then locked and the surgical unit can be removed. Detailed description of the surgical procedure will be published elsewhere.

The transport isolator is in fact an adapted isolator which has been used routinely for rearing germ-free piglets (Trávníček *et al.*, 1966). It is a rigid, fiberglas box equipped with two pairs of rubber gloves, two plexiglas windows, ventilator, inlet and outlet filters and a sterile lock which permits to transport materials into and out of the isolator. The isolator and all accesories are placed on a metal cart. This isolator was used to transport the newborn from the operation room to the premature neonate ward (Plate 2).

For the care of the neonate a new special isolator was designed and constructed which permits to meet the following requirements: routine handling of the neonate (feeding, changing of diapers, weighing), and performing various diagnostic and therapeutical procedures (*e.g.* taking various biological samples, ausculation, taking X-ray, measurement of body temperature *etc.*). The isolator is made of transparent polyvinylchloride foil and is equipped with two pairs of rubber gloves (Plate 3). The measurement of body temperature and of temperature of the internal environment of the isolator is ptrformed by a thermo-couple, and the digital monitor, placed outside the isolator, registers continuously the temperature and signals its changes. The long side of the isolator carries a blind plastic bag; underneath the bag is a balance for routine control of body weight, examination of the newborn and X-ray controls. The short side of the isolator carries a stainless-steel sterile lock. The bottom of the isolator contains a sealed-in polyurethane mat. The isolator is placed on a metal frame. In a special room, the plastic isolator with the infant and two rigid supply isolators were continuously present. Manipulation was performed according to the following scheme: all instruments, food and other materials necessary for one week were placed into the supply isolator and the isolator was sterilized inside with an aerosol of peracetic acid for 12 h followed by thorough ventilation with sterile air. The air was conducted from the room by polyethylene tubing to prevent accumulation of fumes of peracetic acid in the room. The supply isolator was connected by a PVC sleeve with the plastic rearing isolator. Once a week the supply isolators were changed (each isolator has inner and outer doors of the sterile lock which permit to connect and disconnect the isolators without disturbance of the sterile barrier). Before disconnection of the isolator, all materials as well as blood, urine and stool samples were transferred into the supply isolator. A new supply isolator containing fresh sterile material was then connected to the rearing unit. Thus, only the infant and most necessary material (bottles with milk formula and diapers) were inside the plastic isolator. Other material was stored in the supply isolator and transferred to the rearing isolator according to immediate need.

The results of clinical, immunological and biochemical follow-up studies of the sterile infant will be published elsewhere.

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The plates will be found at the end of the issue.

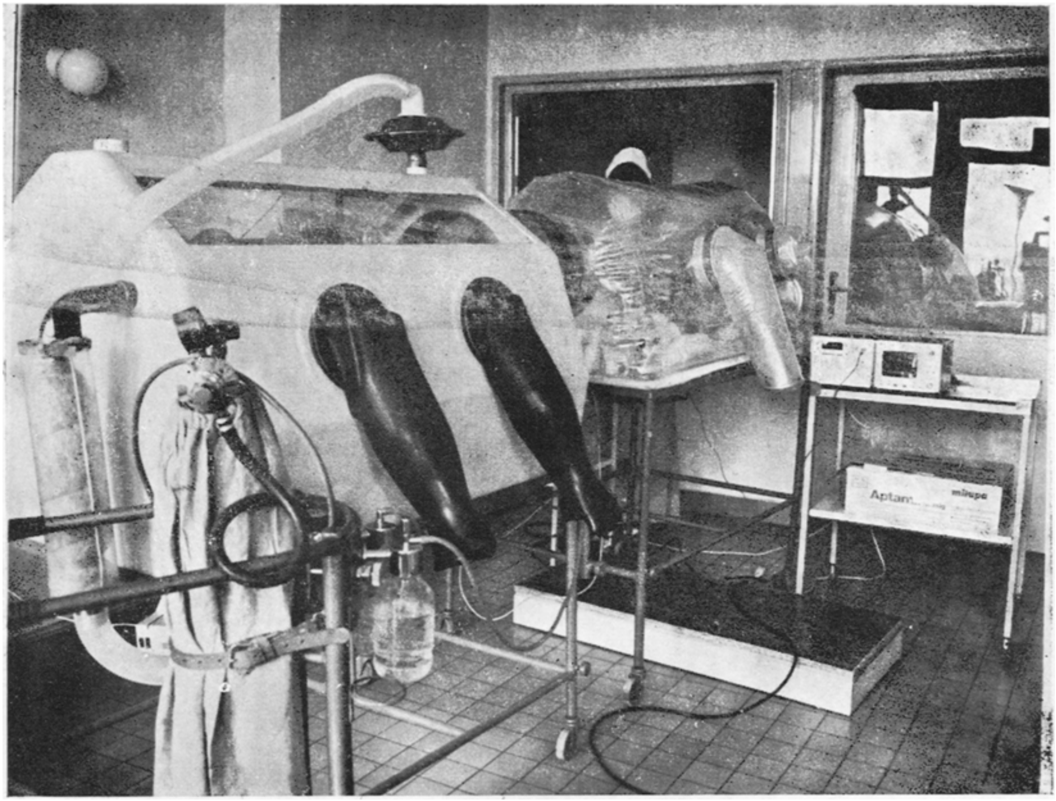

PLATE 2. Transport isolator, connected with isolator for handling the neonate.

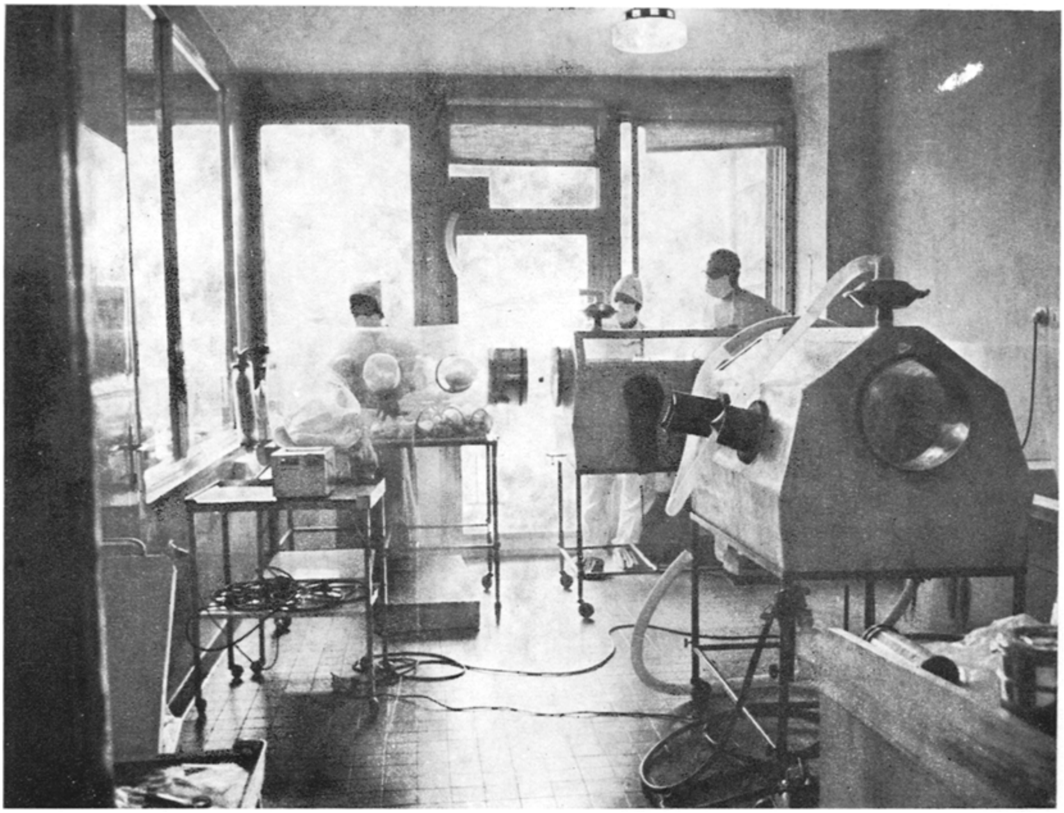

PLATE 3. View into the premature-neonate ward with transport and neonate isolators.

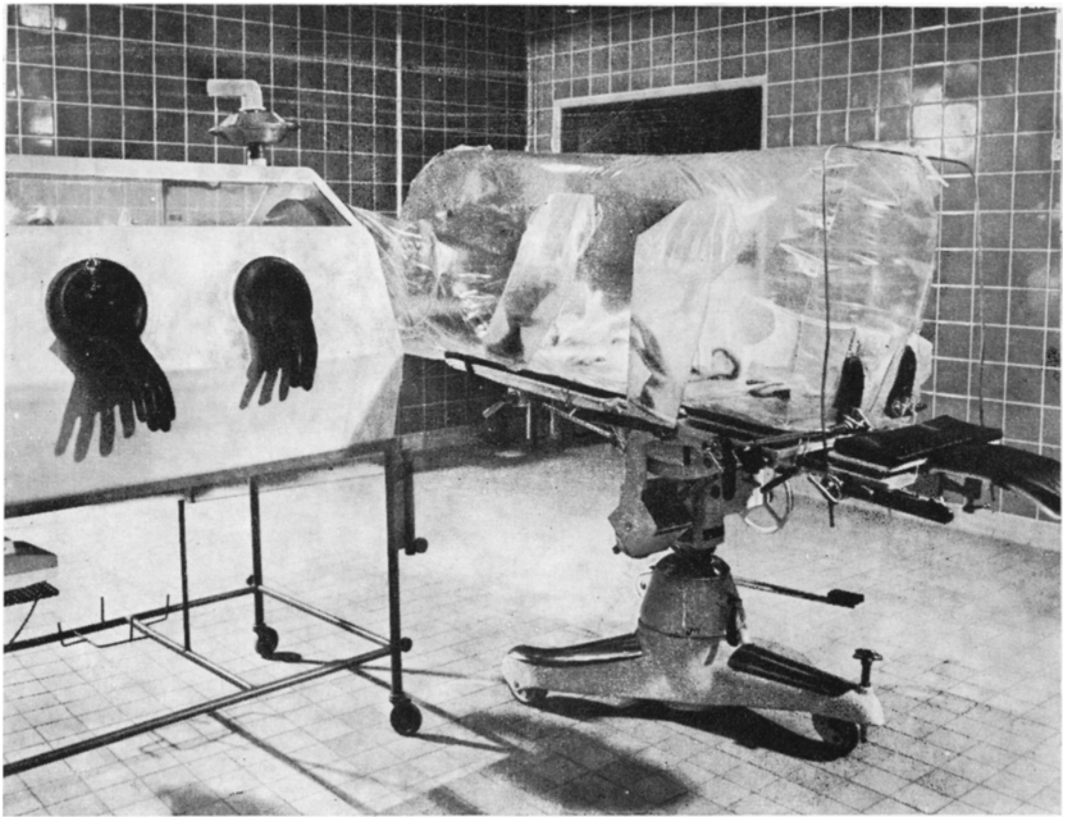

PLATE 1. Plastic surgical isolator, joined with the sterile transport unit.