

Guidelines

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Recommendations for the configuration of a cardiac catheterisation laboratory for the treatment of children with CHD

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Abstract

A modern catheter laboratory for the treatment of children with CHD should be in close proximity to the paediatric ICU, operating theatres, and imaging facilities. Space requirements and equipment for an up-to-date catheter laboratory are discussed. The document was endorsed by the council of the Association of European Paediatric and Congenital Cardiologists.

Rationale for this document

A cardiac catheterisation laboratory has a limited life span. Heavily used machinery wears out, but even more importantly radiation doses used to achieve adequate imaging quality increase over time, on an average of 6–10% per year.¹ This means that after 10 years the doses needed for adequate imaging will have almost doubled. In addition, advances in the treatment of children and improvements in the technology available to achieve this – for example hybrid working between surgeons and cardiologists – mean that within a matter of a number of years current technology can be almost obsolete. For these reasons all catheter laboratories require cyclical replacement.

Refurbishment/replacement of a catheter laboratory is an important and expensive process. Compromises made during planning and the configuration will lead to compromises in the treatment of potentially vulnerable patients.

This document was written following consideration within the interventional workgroup of the Association of European Paediatric and Congenital Cardiologists to inform those planning or replacing a cardiac catheter laboratory. The recommendations are in concordance with currently available literature and national guidelines.

Location

A catheterisation laboratory should be in close proximity to the paediatric cardiac ICU, located within the same building, as critically ill patients from paediatric cardiac ICU may require diagnostic or interventional catheterisation, or untoward events may occur in the catheterisation laboratory leading to admission to paediatric cardiac ICU. Rapid transport is necessary in both directions. Clearly, moving critically ill patients is dangerous and distances should be as short as possible.^{2,3}

The same physical considerations are necessary for the operating theatre, which also should be adjacent to the laboratory. Bailout surgery may be required after complex catheter interventions. Conversely, immediate catheter evaluation of operative results may be needed in some situations – for example, exit angiography for neonates after Norwood surgery to visualise the branch pulmonary arteries. Collaboration in terms of hybrid procedures will be discussed later in this document. These patients are very difficult to transfer and there are major risks that must be minimised. A C-arm in theatre compromises image quality, compared with a fixed imaging system, and radiation doses may be higher.^{2,4}

For these reasons, in many units if constructions are planned they have focussed on bringing paediatric cardiac ICU, cardiac theatres, and catheter facilities as close as possible, ideally immediately adjacent within the same building.

Should, for whatever reasons, co-location not be possible, then the time for transport should be short enough to enable prompt surgical or paediatric cardiac ICU support, as even during short transport complications can occur.^{2,3}

The German “gemeinsamer Bundesausschuss”, the highest decision-making body for the joint self-administration of doctors, dentists, psychotherapists, hospitals, and health insurance funds in Germany, which is responsible for commissioning of services, has clearly stated that co-location at least within the same building is essential,⁵ and commissioning of services has ceased for some services for the reason that these requirements were not fulfilled. The British

Congenital Cardiac Association in their recommendations regarding therapeutic cardiac catheterisation for children state that facilities for cardiopulmonary bypass should either be provided in catheterisation laboratory or in a “close by” theatre.⁶ A further recommendation from the European Association for Pediatric and Congenital Cardiology interventional working group highlights the need for location of cardiac theatres close to the catheterisation laboratory.⁷

Space requirements

As early as 1999, lack of space was identified as a major problem for the optimal function of cardiac catheterisation laboratories.⁸ With increasing procedural complexity requiring larger teams, the need for space is even more important.⁹

Catheterisation laboratory

A catheterisation laboratory for the treatment of paediatric patients requires a minimum space of 80 m²; ideally 100 m² is recommended (i.e. 8 × 10 or 10 × 10 m). This does not include the space for the X-ray generator, stocking room, and the control room, but the catheterisation laboratory room itself. The X-ray system – ideally biplane – should be ceiling-mounted to occupy as little of the floor space as possible. Angulations of the X-ray system require space, as do radiation protection screen. These should also be ceiling-mounted on long support arms.

Supplemental screens to project the X-ray images and physiologic measurements are necessary to allow staff to follow the procedure. Typically, these should be ceiling-mounted and adjustable.

The anaesthetic team should be involved from the early stages of planning a new catheter laboratory or a major re-fit. The anaesthetic equipment is typically located at the head of the patient, and adequate room for the anaesthetic team to access the patient at any time should be provided. Besides the anaesthetic machine and ventilator, typically a patient warming system such as a forced air system should be available for patients of all sizes. Approximately 8–10 m² should be calculated for anaesthetic space within the catheterisation laboratory. For patients under sedation, the same space allows for staff to monitor the patient, administer medication as necessary, and perform emergency intubation and ventilation as needed. A separate anaesthetic room is not mandatory; many anaesthetic teams prefer to anaesthetise patients on the catheter laboratory table, but this is an issue that should be planned and agreed locally.

As many interventions are performed with more than one imaging modality, space for an echocardiography machine (and operator) for transoesophageal or transthoracic echocardiography should be planned. This needs to take into account situations in which the X-ray system is angulated or when larger teams are working – for example, during hybrid. In particular, X-ray exposure of the echocardiographer needs to be considered and mitigated as far as possible. Usually, ca. 3 m² is adequate for echo machine and staff, although 5 m² may be necessary when procedures from the head and neck are planned.

The catheterisation table itself should be extra long, to accommodate catheterisation equipment – catheters, wires, and delivery equipment for devices. The table needs to be accessible from both the right and the left hand side, even if most interventionalists work routinely from the right side of the patient. Anatomical considerations and the need for multiple operators

for complex procedures make it necessary to provide the same space on both sides of the table.

High-quality operating lights are essential both for vascular access and in case of any emergency or hybrid surgical approach. These need to be highly adjustable and should be ceiling-mounted on long support arms. This allows free movement of the light, so that the area of interest can be illuminated without being disturbed by the shadows of the operator or any equipment.

Essential equipment

A large preparation table, accessible both from the team at the catheterisation table itself and from the support staff, is necessary. Such a table should ideally be at least 150 cm (better 200 cm) long to accommodate long pieces of equipment. If necessary, a second table of similar size can be added – that is, for interventional valve replacement. A second table may provide greater flexibility to make best use of the space.

Should cardiopulmonary bypass become necessary for an emergency operation or for a planned hybrid procedure, the bypass machine and the perfusionist need space additional to the interventional team and equipment.

An oxygen analysis machine should be in close proximity to the catheterisation table, as well as blood glucose analysis facilities and facilities for testing the activated clotting time.

Frequently used equipment can be accommodated within the catheterisation laboratory, to avoid unnecessary opening of the doors from the radiation area to the storage facilities. This equipment can be stored in mobile carts, so that in case of planned or emergency surgery the space can be freed for the surgical team and their equipment. Beside catheters of different types and sizes, this equipment will contain of guidewires, puncture needles, and sheaths, and medications frequently applied by either the anaesthetic team or the interventional team. In addition, a defibrillator needs to be easily accessible within the catheterisation laboratory.

Anaesthetic room

If interventions are carried out under general anaesthesia, the induction can either be performed within the catheterisation laboratory itself or in an adjacent room. If the latter is chosen, there should be a room equipped with an anaesthesia machine and the necessary equipment for monitoring vital parameters, consumables needed for anaesthesia, and cupboards for medications. It should be connected to the catheterisation laboratory by a wide enough door to allow a full-size hospital bed to pass through. Such an anaesthetic or multi-purpose room requires ca. 20–25 m².

Scrub space

This should be located outside the actual catheterisation laboratory in a “clean” area, but with direct access to the catheterisation laboratory. This room typically contains a sink and shelves for surgical hats and masks, sterile gowns, and gloves. To allow more than one person to scrub at the same time, this room should be 5–8 m². The scrub facilities can also be located in the multi-purpose room mentioned above.

Storage space

A storage room must be directly adjacent to the catheterisation laboratory. Depending on the size of the interventional programme, the area needs to be able to accommodate equipment

including devices, stents, balloons and catheters, snares, and specific sheaths. Even if equipment is ordered specifically for a procedure and not permanently in stock, space must be provided to avoid unpacking in the catheterisation laboratory itself. Ideally, only equipment needed for the procedure should be taken to the catheterisation laboratory. This is specifically important because when patients with infections such as methicillin resistant *Staphylococcus aureus* are treated, opening doors of stocking cabinets within the catheterisation laboratory could lead to contamination. With a separate storage room, such problems are avoided.

Less frequent, but still inevitable, equipment such as a radio-frequency generator and a pacemaker for temporary pacing and a small cart to accommodate these if in use in the catheterisation laboratory will be stored here too.

If there is a dedicated echo machine for the catheterisation laboratory, this will not be in use for every procedure. Rather than taking up valuable space in the catheterisation laboratory when not in use, it can be stored in the storage room. It needs to be immediately accessible for potential emergency echocardiographical assessment. In centres where ultrasound-guided vascular access is performed, this is frequently done with portable machines requiring less space.

All in all, storage space of ca. 50 m² has shown to be adequate.

Control room

The control room contains the monitoring equipment for physiologic parameters and remote monitors displaying the angiographic images. The digital storage facilities are typically also located here. If the angiographic injections are performed by the physician himself, and not by a radiographer within the catheterisation laboratory, the injector controls may also be in the control room. If rotational angiography is available, a workspace for the segmentation is typically located here. Further equipment is needed depending on the interventions carried out: if electrophysiological studies and ablations are performed, then the generators, pacing equipment, and so on will be housed in the control room.

Space for reporting and the necessary IT equipment, such as offline imaging viewer and computers for dictation/writing, must be outside the catheterisation laboratory and these are typically located within the control room.

As communication between the catheterisation laboratory and the control room is essential, this can be achieved either by remote controlled headsets or by ceiling-mounted microphones within the catheterisation laboratory and control room, and wall-mounted loudspeakers on both ends.

From the control room there should be an unimpeded view of the whole catheterisation laboratory, including the patient on the table. Typically, this is achieved by a large lead glass panel on the longer side of the room, which is adjacent to the catheterisation laboratory. In addition, ceiling-mounted cameras can be helpful.

From the control room, the catheterisation laboratory must be directly accessible.

Although every single piece of equipment does not take up too much space, the space requirement for a modern control room adds up to ca. 25–30 m².

Space for the X-ray generators

These produce heat and need permanent cooling to maintain the equipment's workability. They should not be located within the catheterisation laboratory, as there is a need to have a comfortable temperature for the patients and staff. As they are bulky pieces of

equipment, they should be located in a separate room, which does not necessarily need to be accessible from the catheterisation laboratory itself.

Radiation equipment

For catheterisations to treat CHD, a biplane X-ray system is currently standard to allow optimum viewing of the areas of interest, to save contrast agent, and to achieve lower radiation doses. Monoplane with rotational capabilities may be another possible option. Anyhow, any angulation must be reachable unimpeded.⁹

Nowadays, ceiling-mounted flat panel screens on long support arms can be moved in any position so that the operator can have an optimum view even if the intervention is performed from the patient's left or head.

As patients of several sizes and ages are treated in a catheterisation laboratory for CHD, the X-ray equipment needs to be adjustable in terms of frame rate for fluoroscopy and angiography, and energy used. Ideally, several presets are available, but the different parameters can be adjusted if the need arises. This lowers the burden of radiation significantly.^{10,11}

Flat panel detectors of different sizes allow to adjust for patient size. Filters for radiation protection must be adjustable. Many interventionalists prefer the same magnification on both planes, and others consider different scales superior.

Radiation protection

Radiation protection is paramount both for the patient and the staff.^{1,11,12} Apart from the actual operating of the system according to the ALARA principle, as low as reasonable achievable,¹ to minimise the doses used, radiation protection needs to be provided. In addition to X-ray protection aprons, thyroid shields, and hats, this includes ceiling-mounted lead-glass shields to decrease scatter radiation exposure of the staff. For the aprons, storage space needs to be considered ideally outside the catheterisation laboratory directly adjacent to the scrub area. The X-ray equipment itself needs to be adjustable according to the patient size and image quality needed – that is, for electrophysiological studies a low quality is adequate to position the catheters.^{11,12}

Echocardiography

Many interventions require more than one image modality. Echocardiography can supplement or even replace fluoroscopy in certain cases.¹³ An up-to-date echocardiography machine with full two-dimensional and Doppler capabilities with adequate transthoracic probes for different-sized patients and transoesophageal probes is the minimum requirement. Ideally, three-dimensional live guidance can be provided too. Smaller, portable machines are typically used for ultrasound-guided access.

As echocardiography is not required for all interventions, the machine should be stored outside the actual catheterisation laboratory when not in use. In many centres, the catheterisation laboratory has no dedicated echo machine, as this is shared with the adjacent paediatric cardiac ICU. It needs to be ensured that echo-support can be provided in minutes in case of emergencies, as echo-support is crucial especially in emergency situations.

Connections for cardiopulmonary bypass

It is clear that for any hybrid theatre connections for oxygen and air, as well as suction, are necessary to enable a cardiopulmonary

bypass machine to work. The same connections are obligatory for any catheterisation laboratory for the treatment of CHD for management of untoward events, and as more and more complex procedures with the need for occasional or emergent surgical access are carried out.¹⁴

Space for a bypass machine must be considered. As this is necessary, a perfusionist needs to be accommodated too. All the necessary wall connections must be planned in such a way that in case of emergencies the space is not crowded with other equipment and can be occupied by the bypass machine and staff in very short time.

Patients who are on extracorporeal membrane oxygenation may need catheterisation.⁴ For the extracorporeal membrane oxygenation, space and connections need to be planned too.

Airflow

The airflow system should ideally meet the same requirements as for any operating theatre.¹⁴

Recovery area

This needs to be in close proximity to the catheterisation laboratory, but can be shared with recovery from surgical theatres. Should there be the need for urgent re-intervention within the early post-interventional time, long distances should be avoided.

The actual size will be dependent on the number of patients treated per day/session, and on the co-location to other surgical/interventional theatres. Thus, in this document no space recommendations are given.

The recovery area needs to be equipped with full monitoring for the vital parameters, suction, oxygen and air supply, defibrillator, and emergency cart.

Summary

Many concurrent catheterisation laboratories are perfectly functional without meeting the presented recommendations, but several aspects of a paediatric cardiac catheter laboratory need to be well considered during planning of replacement or refurbishment. To allow an optimum workflow for even complex procedures, apart from the equipment adequate floor space must be provided. The location of the catheterisation laboratory close to intensive care and surgical theatres is a basic requirement. Collaboration with other specialties can be beneficial within the paediatric hospital.

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