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Organization of a pediatric/congenital cardiac catheterization laboratory

Introduction

The recommended equipment and the arrangement and organization of the space and equipment for the pediatric/congenital cardiac catheterization laboratories which are discussed in this chapter are a culmination of my own experience in cardiac catheterization laboratories over the past 40+ years. During that time I have had the privilege/opportunity of performing catheterizations in some 180 different catheterization laboratories in 120 different institutions throughout the US and much of the rest of the world. During that time I also had the experience of directing several catheterization laboratories for more than 25 years and of having a significant role in, and part of the responsibility for, building 14 different cardiac catheterization laboratories in several different hospitals over those years. The equipment, space and personnel requirements described in this chapter meet *or* exceed all published standards for pediatric/congenital cardiac catheterization laboratories^{1,2}. The cardiac catheterization rooms/suite described in this chapter are in operation at Texas Children's Hospital.

The total space requirement for a twenty-first century pediatric and congenital cardiac catheterization room (laboratory) and the accompanying support area or "suite" is significantly greater than for the catheterization laboratory of even one decade ago. The increased requirement for space is a consequence of the physical dimensions of the modern, biplane X-ray equipment, which is capable of compound angulation of both X-ray tubes, the sophisticated ancillary electronic equipment which is required and the increased complexity of the procedures which are now performed in these laboratories. Many of the therapeutic catheterization procedures require additional, large pieces of ancillary equipment (anesthesia machines, transesophageal and intracardiac echo, equipment for partial or total cardiac support, etc.), which not only must be in the catheterization laboratory,

but often must be positioned immediately adjacent to the catheterization table. Significant *additional* space also is required to "park" each of these pieces of equipment in the immediate vicinity of the laboratory, if not actually within the catheterization room, when they are not actually in use.

With the longer, more complex procedures and particularly with the frequent use of implants in the catheterization laboratory the cardiac catheterization *room* should be considered a "sterile" environment similar to an operating room. The catheterization room should operate with the doors to adjacent areas (except the control room) closed and it should have a separate, filtered air input which maintains a "positive pressure" circulation within it³. At the same time, because of frequent equipment maintenance and other outside support, the entire catheterization *area* or *suite* adjacent to, but outside of the actual catheterization room, is considered a "clean", rather than sterile, area.

The exact location of the catheterization area in relation to other hospital facilities often is dependent upon overall space availability and requires considerable pre-planning. Optimally, pediatric/congenital cardiac catheterization laboratories are located immediately adjacent to, and have easy access to the pediatric/congenital cardiac operating rooms and cardiac intensive care areas. Although the need for surgical intervention during a cardiac catheterization is still very rare, when surgical support is needed, it is needed immediately. "Open chest", operative intervention is preferably performed in the operating room, not in the catheterization room. Having the surgical suite immediately adjacent to the catheterization laboratory and accessed through a sterile corridor allows a patient to be transported very rapidly and expediently from the catheterization laboratory to an operating room even when the patient is on external support or his chest is opened.

The requirements for, and the optimal arrangement of, the modern catheterization laboratory space are detailed in the following section.

The cardiac catheterization room itself

A current cardiac catheterization laboratory ideally should be at least 32 feet long by 24 feet wide. In addition to the large length and width requirements of the catheterization room, the ceiling height must be at least 14 feet in order to accommodate the suspension system of the X-ray tubes and intensifiers from any manufacturer. The *only* “fixed” equipment in the actual catheterization room should be the catheterization table and the suspension systems for the X-ray systems along with the X-ray and physiologic monitors, with no fixed cabinets and none of the X-ray generating equipment included within the actual catheterization room. The arrangement of the catheterization table in the room and the “connections” or “communications” to the room from adjacent areas depend upon the “real estate” which is available immediately adjacent to the catheterization room. The control room for the physiologic and X-ray systems must be adjacent to the catheterization room and have at least a doorway access to the laboratory. The control room can be positioned at the end or at the side of the catheterization room, but in either location the operators in the control room should have a clear view of the patient on the catheterization table. The storage for the majority of the expendable catheterization equipment should be immediately adjacent to the catheterization room with a readily accessible doorway. The catheterization room should have a one-and-a-half or even a double-width doorway for patient access. Even though the patient may arrive on a narrow hospital stretcher, there must be the capability of leaving the room easily with “attached” equipment and personnel adjacent to or alongside of the bed/stretcher during a resuscitation or emergency transfer to an operating room.

The scrub sink(s) for the catheterization laboratories should be located *outside* of the actual catheterization room in an adjacent “clean” corridor or room. It is essential that all personnel in the laboratory scrub before working in the room and that the physicians scrub between each case. At the same time, scrubbing, which is a relatively short task, is performed before the catheterization procedure. It has nothing to do with the procedure itself, it actually can have “dirty” fluids splashing away from the sink and, as a consequence, there is no justification, nor logic for having the scrub sink occupy valuable space within the catheterization room.

During the course of an interventional catheterization procedure the catheterization room can become very crowded with equipment and personnel. The location and arrangement of each piece of *fixed equipment* become critical for the most efficient and safe completion of the procedure.

X-ray equipment

The basic equipment in a catheterization laboratory for pediatric and congenital heart patients includes a biplane X-ray system with compound angulation capabilities, an extra-long catheterization table and dual (quadruple!) CRT or flat panel monitor screens. This basic equipment requires a very large “footprint” of floor space in the room for just the catheterization table and the suspension systems for the X-ray tubes/intensifiers. The catheterization table needs to be “extra long” or have a long extension at the foot end in order to prevent the contamination of the very long catheters, delivery systems and exchange length wires which are introduced and undergo multiple exchanges through the femoral vessels. The footprint of the catheterization table and the suspension system for the X-ray tubes/intensifiers should include enough width to allow unimpeded rotation of the X-ray tubes and support arms without bumping into or having to move other equipment. There must be significant space towards the head of the table to allow clear cephalad–caudal movement of the suspension system, space for physicians working from the head-end of the table, adequate space for relatively large anesthesia/respiratory equipment adjacent to the head *and* room to have a transesophageal echo console adjacent to the patient’s head. It is often necessary to have all of this space occupied at the same time! Additional floor space cephalad to, and away from the working areas is required to “park” the lateral X-ray suspension gantry a distance away from the head of the catheterization table in order to allow room for transferring the patient to and from the table.

The catheterization table

The spacial orientation of the catheterization table within the room helps to optimize the usable space. When the catheterization table is placed at an angle, somewhat diagonally across the room, this opens up a large area on one side of the table at the head of the table and an equally large area on the opposite side at the foot of the table. When the larger space at the head of the table is on the side of the access doorway for the patient, this allows a more convenient access to the table for a patient on a stretcher. As an added bonus, the extra space in this area opens up an area for a transesophageal echo machine working from the head of the table. The larger open area at the foot and on the opposite side of the table allows more working space for the physicians on that side of the table. A straight alignment of the table along the long axis in a slightly narrow room compromises the space on both sides of the table and for its entire length.

Work space for the physician/operators

In addition to the large space requirement for the X-ray equipment and the catheterization table, there must be liberal space adjacent to, and all around, the catheterization table/X-ray equipment to allow access to the table for other large pieces of support equipment. This space should allow unrestricted movement of the X-ray tubes and intensifiers as well as the free movement of the personnel within the laboratory around all of this equipment regardless of the positions of the X-ray tubes. The monitor screens are grouped together as a bank of monitors on a large ceiling mounted support, which is on tracks and is movable about the table. The operating physician must have a clear view of all of the monitors while looking *forward* (not over his shoulder or behind him), regardless of the site of catheter introduction into the patient. A very satisfactory arrangement is to have the bank of monitors mounted on a *long* swivel arm which, in turn, is on ceiling tracks aligned *across* the catheterization table at the foot of the table. With this configuration, the monitors can be moved directly over the foot of the table when vascular access is from either side of the neck or even the arm, and completely across the table when vascular access is totally from the left side of the patient. A *long* support arm on a swivel base for the bank of monitors allows sufficient movement of the monitors along either side of the table. With the multiple locations which are possible for the monitors, the operator can always be located across the table and facing the monitors with an unobstructed view of them without any body contortions or having to look round structures or behind him/herself.

The exact configuration of the catheterization table varies from laboratory to laboratory. Most catheterization tables are orientated for a right handed operator—i.e. with any extra space for the scrubbed physician(s) predominately on the right side of the patient's trunk. The person who operates the controls for the movement of the table and X-ray tubes and the person who operates the pressure/flush manifolds and the flush lines, all vary from laboratory to laboratory and affect how the catheterization table is configured. There must be adequate space for two, or possibly three, *scrubbed* operators on either side of the catheterization table particularly during complex therapeutic interventional procedures, when as many as four individuals may be scrubbed with several personnel on both sides of the table when the vascular access is from both sides. It also should be possible for at least two operators to work together from either side of the head and neck area while other operators are working from the femoral areas.

In the catheterization laboratories at Texas Children's Hospital, the table position/movements, the movement

of the C-arms suspending the X-ray tubes, the collimation of the X-ray tubes and the control and replay functions of the angiograms all are controlled by the catheterizing physician(s). As a consequence these controls are all maintained sterile with sterile covers/drapes and are positioned on the same (right) side of the patient as the operator, but nearer the foot of the table. In some laboratories these table/cine controls are operated by a separate technician or even a radiologist, in which case the controls are at the foot of the table or even physically away from the table on a separate stand.

In addition to the space for the table controls, an additional length of the table "real estate" along one side or the end of the catheterization table is required for the pressure transducers, pressure/flush manifolds and the flush/pressure lines. The manifold is a series of three or more, three-way stopcocks to which each transducer and the tubing to both the fluid reservoirs and to the patient are connected. In addition, the transducers are attached to electrical cables which run from the transducers to an electrical connection on the table and eventually to the physiologic recorders. When three or four transducers are used simultaneously during a case, the manifolds holding the transducers occupy a meter, or more along one edge of the table. Three-way stopcocks on the manifold allow "opening" the transducer to environmental pressure for balancing, as well as additional connections for the flush tubing to the transducers and separate tubing for flush/pressure lines to the patient from each transducer. In some catheterization laboratories where multichannel pressure recording is not used routinely, the manifold and even the transducers themselves are positioned on the catheterization "field" and operated by the catheterizing physician. Specifically arranged manifolds including the stopcocks, transducers and tubing are available commercially (Merit Medical Systems, Salt Lake City, UT). The exact positioning of the manifold on the surface or along the side of the table will depend upon which personnel operate the manifold during the case.

During the catheterization procedure, the manifold with the transducers ideally is fixed to the catheterization tabletop at a specific height on a stand which allows an initial adjustment in the height of the manifold to compensate for the "height" of the heart within the patient's chest above the tabletop. The exact level (height) for the pressure transducers varies and is determined for each individual patient according to the anterior-posterior (AP) diameter of the chest. The height for the transducer is the measured distance from the tabletop to the mid level of the posterior-anterior chest diameter, or the exact location of the heart is determined on the lateral fluoroscope. The height from the tabletop to the heart should be measured accurately with a ruler and then this exact measurement is

transferred to the transducer stand to determine the height of the transducers on the stand. When the transducers are attached to the table at the correct level on a stand, the transducers then move up and down *with the patient* when the table is raised or lowered and, in doing so, the reference height to the heart for *accurate* pressure measurements always remains exactly the same.

In the catheterization laboratories at Texas Children's Hospital, there are usually four transducers with as many as six to eight color-coded flush/pressure lines passing to the patient from pressure/flush manifolds. Each color-coded pressure line corresponds to a similar colored pressure curve which is displayed on the monitors. The entire manifold is operated by a designated nurse/technician who has no other *assigned* duty during the procedure. In this circumstance, the optimal position for the transducers is on the opposite side of the catheterization table as far as possible toward the foot of the table away from the operating physicians, but still within the sight of the catheterizing physician. Since the majority of catheter manipulations by the catheterizing physicians are performed through the femoral vessels and from the right side of the patient, regardless of whether the catheter is introduced from the right or left femoral vessels, the transducers optimally are fixed, semi-permanently, on the left (opposite) side of the table and as far as possible toward the foot of the table.

In some laboratories where one, or at most two transducers are used, the catheterizing physician operates the manifolds including the transducers, the stopcocks, and all of the fluid/pressure lines. In this circumstance, the manifold is fixed on the catheterizing physician's side of the table or actually laid on the patient's legs on the catheterization field. This arrangement is more suited when the catheterization laboratories are used predominantly for adult (coronary) catheterizations where less sophisticated hemodynamics usually are necessary.

Regardless of which vascular access site is used, there must be space located immediately behind the catheterizing cardiologist for at least one 30" × 60" work table to hold flush solutions, a container of contrast solution, needles, catheters, wires, instruments and other expendable equipment. The work table should have enough room around it to allow the "circulating" personnel and the operators to have access to and around the table without bumping into, or contaminating, it. *Two* large (30" × 60") work tables placed end to end behind the operators are optimal for interventional procedures where multiple long balloon catheters or very long delivery systems for device implants are utilized. The additional length of the two tables positioned end to end allows sufficient workspace for the preparation of the long balloon dilation catheters and device delivery catheters. The very long table prevents these long items from hanging over the

ends of the table and from being contaminated when they are stretched out lengthwise during their preparation or loading procedures.

Anesthesia space requirements

The anesthesiologist, along with the space for the anesthesia machine, requires access to the patient's head from either the right or left side of the patient. The anesthesia access is *cephalad* to the lateral X-ray support ("C") arm and must allow a convenient connection of the anesthesia machine/tubing to the patient's airway. Connections for oxygen, gas and suction lines usually come through the anesthesia machine from a separate ceiling- or wall-mounted console near the head of the catheterization table. It is essential that the oxygen, gas, suction console also is somewhat mobile and can be moved close to the patient's head for situations where general anesthesia and an anesthesia machine are not being used.

When general anesthesia is being used, the anesthesiologist controls the patient's airway while simultaneously operating the anesthesia machine. This requires a close proximity of the anesthesia machine to the head of the catheterization table. Anesthesiologists usually prefer the right side of the patient's head; however, when vascular access for the catheterization is available only from the right neck, it is preferable that the endotracheal tube connections to the anesthesia machine approach from the patient's left side. In rare circumstances, where vascular access and a complex procedure are to be from the right side of the patient's neck, it is desirable to have the anesthesia machine on the patient's left, as well.

A mobile, floor anesthesia machine provides more flexibility than a ceiling-mounted anesthesia machine when changes in the orientation of the room may be necessary to adjust for different access sites to the patient. At the same time, the floor anesthesia console does occupy considerable floor space.

This same need for sufficient room for access from a particular side of the head holds true for the patient who is on ventilator support without general anesthesia where the ventilator and the connecting tubing need a specific area and room for access. With or without a ventilator, a suction line/apparatus must always be adjacent to the patient's mouth and airway and must be immediately accessible.

Transesophageal echo

Although the transesophageal echo (TEE) console may not be "parked" permanently in the catheterization laboratory, the increasing frequency of use of TEE during congenital cardiac catheterizations has created an additional semi-permanent space requirement very close to the head

of the catheterization table. The connecting cable between the TEE probe and the echo console is relatively short, and the person manipulating the TEE probe frequently operates the console while manipulating the probe. As a consequence, the large TEE console is positioned very close to the head of the table. It must be possible to have access to the patient with the TEE probe and the TEE machine from either right or left side of the head of the table. The location of the TEE depends upon whether vascular access for the catheterization is from either the arm or neck and, in addition, on which side of the head the anesthesia access is located. The current TEE consoles also have a large footprint and necessitate a large amount of space cephalad to the head of the catheterization table, regardless of which vascular access to the patient is used.

The TEE machine is usually operated with the echo console positioned cephalad to the support arm for the lateral X-ray tube and intensifier and to the left of the patient's head. This places the echo console with its monitor and the operator cephalad to (and behind) the lateral image intensifier and out of the view of the catheterizing physicians. An additional mobile "slave" monitor away from the TEE machine will then be necessary in order for the operating cardiologist to see the TEE image. The remote monitor can be positioned away from the TEE console and directly in front of the catheterizing physicians, in order to allow the TEE image to be visualized continuously, no matter where the catheterizing physicians are positioned around the table relative to the TEE console. Ideally the slave TEE monitor is mounted with the other ceiling suspended (X-ray and physiologic) monitors. Another alternative is to have the slave monitor of the TEE mounted on a mobile floor cart, which can easily be moved to any open, viewable position around the table. Some X-ray systems allow a "picture in picture" positioning of the TEE image within the image of one of the X-ray monitors. This is not as satisfactory as may be perceived. If it is large enough to be usable the superimposed TEE image occupies approximately one-fourth of the X-ray image and always extends into, and compromises, the critical, *central area* of the X-ray image.

Whenever either X-ray tube is in an LAO-cranial position, the TEE console and the TEE operator physically compete with the location of the image intensifier. This requires good communication and, usually, some displacement of the TEE operator and the console when the X-ray tube/intensifier are rotated into, and remain in that position.

Adjunctive equipment required within the catheterization room

There is a considerable amount of additional, essential, but at the same time, usually mobile equipment in the

modern catheterization laboratory. This equipment, although mobile, remains in the catheterization room and takes up a finite, and often a significant amount of additional floor space there. This equipment includes the emergency medication/defibrillator cart, often a separate medication cart, the apparatus for blood oxygen saturation determinations, a patient-warming system, a cardiac output computer, and space for the mobile storage of very frequently used, consumable supplies. In some laboratories the angiographic injector, radiographic protective equipment, suction equipment and adjustable "operating field" lights are on floor-mounted, mobile stands, in which case they require additional floor space.

Emergency cart/defibrillator

Each cardiac catheterization room must have a mobile cardiac defibrillator and an "emergency cart" containing medications and resuscitative equipment. The defibrillator should have a rechargeable battery source of power in addition to a fixed source of (wall) electrical power. Often the emergency cart and defibrillator are combined into one mobile cart. The emergency cart contains items to establish an oral or nasal airway, equipment for endotracheal intubation, equipment to start intravenous or intra-arterial lines, suction catheters and the accessories for the defibrillator. Whenever a patient is in the room, the items on the emergency cart and the defibrillator must be available immediately and conveniently to the personnel in the room and to the patient. This, however, does not require that the emergency cart and defibrillator always be *immediately* adjacent the patient. However, the supplies on the emergency cart are organized in such a way that the location of each item on the cart is known instinctively and each item is available immediately to *all personnel* in the room. The defibrillator is turned on with the appropriate paddles for the patient attached to it and the paste for the paddles readily available. The correct voltage according to the size of the patient is set and the defibrillator is placed in a location from which there is immediate and unobstructed access to the patient during the procedure.

Medication tray/cabinet

In addition to the emergency and defibrillator cart(s), each catheterization room has a separate, readily accessible, medication tray or cart. The medication cart contains all of the emergency drugs, sedatives, and other medications used both in emergencies and more routinely in the cardiac catheterization laboratory as well as a variety of intravenous fluids. The details of the medications which are maintained in the medication cart are discussed in Chapter 2. This medication tray is located in close proximity to the manifold containing the transducers

and flush lines. When a nurse is operating the manifold, this nurse has immediate access to the medication cart and usually is responsible for administering medications from the cart.

Operating lights for the catheterization table

Movable or widely adjustable, focused lights over the operating field are essential in the catheterization laboratory. Free-standing floor lights, mounted on a mobile stand and with a long neck that extends over the catheterization table, were the standard for years and are still used in some institutions. These floor lights take up additional floor space immediately adjacent to the catheterization table, they often do not permit the light source to shine from the correct direction on the specific field, creating shadows rather than light over the working areas, and they are a constant potential for contamination of the sterile field. Ceiling-mounted operating room lights on long movable arms are the standard in most catheterization laboratories at the present time. Ceiling-mounted lights conserve floor space and allow the light to be directed more appropriately, but, when there are other ceiling-mounted accessories (angiographic contrast injectors and radiation protection screens), the ceiling-mounted lights add to the congestion in the area immediately above the catheterization table due to the multiple suspension arms. This congestion of the arms creates a problem in the optimal use of the other accessories.

The ideal lights for the catheterization laboratory are a set or group of recessed, high-intensity, focused, ceiling lights, which can be directed toward a specific spot on the catheterization table with a remote apparatus. The lights are adjusted by a small hand-held strobe light or "light wand", which is positioned immediately over the catheter introduction site. The strobe light positioned over the puncture site, in turn, directs each individual ceiling light to that specific spot on the catheterization table. With one, or several, of the lights mounted in the ceiling cephalad to the image intensifier (and the lateral tube X-ray suspension arm) and with the remainder of the lights mounted caudal to the image intensifier, excellent lighting is available to any area of the head, neck or arms as well as to the inguinal areas. These recessed lights do not interfere with other ceiling-mounted equipment and take up "no real estate", but do represent a very expensive initial investment.

Blood oxygen saturation analyzer

The oximeter apparatus for the analysis of blood samples for the immediate determination of oxygen saturations is situated in the catheterization room and in very close proximity to the catheterization table. Most oxygen

analyzers are located on a very small, mobile table or cart. The physician should be able to hand the syringe with the blood specimens for analysis directly to the technician/nurse for insertion into the analyzer and, at the same time, the technician should not have to take more than one or two steps between receiving the sample and inserting it into the analyzer. The results from most oxygen analyzers are displayed digitally on a very small screen on the analyzer. A read-out of the saturation results also should be clearly visible to the operator immediately, conveniently and on a large display in the catheterization laboratory. A large, immediately available display of the digital read-out of the oxygen saturation, the time of the sample and the location of the sample can be accomplished with some "hard wiring" from an A-Vox™ Oxygen Analyzer (A-VOX Systems, Inc., San Antonio, TX) to a "slave" computer with a large CRT or flat panel display, which utilizes special computer software which is now available from Scientific Software Solutions (Scientific Software Solutions, Inc., Charlottesville, VA). This provides a large, timed, instantaneous display of each oxygen saturation and its location as it is analyzed. The developed table of saturations, their time and location can be printed and used to verify the data that have been verbally transmitted to the computerized catheterization record.

Ideally, these same data could also be transmitted directly from the oxygen analyzer to the electronic record on the catheterization laboratory computer and be logged into the timed computer record without any verbal (shouted!), hand-written or manually typed transmission of the information. Unfortunately the small pediatric/congenital market has not been enough of an economic stimulus for any of the large manufacturers of physiologic equipment for the catheterization laboratory for them to provide the communication necessary to incorporate this already available, digital information into their physiologic monitoring/recording equipment.

Patient-warming equipment

Equipment for warming the patient is mandatory. Most cardiac catheterization laboratories operate in a very "cool" ambient environment. When the drapes on the patient become wet and room temperature (cold) flush solutions are continually running into the patient, most patients require supplemental support of their body temperature. The most effective means of maintaining the body temperature of the patient is to increase the environmental temperature of the catheterization room. For infants or debilitated patients, this requires an environmental temperature of up to 80° Fahrenheit. Such a high temperature is uncomfortable for most personnel within the room, but at the same time is absolutely necessary for

very small or debilitated patients regardless of the use of other supplemental warming systems. High environmental temperatures also interfere with the cooling of any X-ray generating equipment which happens to be positioned within the room and provide another strong argument for a separate equipment bay for this machinery.

There are several separate patient-warming systems commercially available for the catheterization laboratory. Separate, supplemental warming systems for the patient are attached directly to the table or the warming component is actually positioned on the catheterization table. The Bear Hugger™ hot-air warmers currently appear to be the most suitable system for cardiac catheterization procedures and they require a relatively fixed amount of floor space immediately adjacent to the catheterization table. The heating mechanism with its blower is usually positioned at the foot of the catheterization table. A connecting tube from the blower attaches to a very long U-shaped, sterile and disposable “paper tube”, the arms of which run, unobtrusively, under the sterile drape and along each side of the length of the patient. The warmed air is blown through these tubes around the patient under the drapes. The tubes do not interfere with access to the patient nor do they show up on fluoroscopy or angiograms.

Several other patient-warming systems are available which take up less fixed space around the table, but in general, are less satisfactory for use in the catheterization laboratory. The K-Pad™ heating system utilizes a plastic pad through which warm water is circulated. The pad, which is positioned under the trunk of the patient, is attached by tubing to a small heater/pump, which is placed on the catheterization table, under the drapes at the foot of the table. The K-Pad™ is not available nor suitable for patients of all sizes and the tubing within the pad is slightly radio opaque and, in turn, shows up on the fluoroscopy and angiographic images, particularly in smaller infants.

Another, even less satisfactory alternative for warming a patient is a floor-mounted “heating lamp”. These take up less space on the table and are very mobile, but they must be positioned immediately adjacent to, and over, the trunk of the patient, which always positions the lamp in the working area of either the operator or the fluoroscopy. Like the lights on a floor-mounted stand, the heating lamp extending over the trunk of the patient represents a constant potential for contamination of the sterile field. Of even greater concern is it that, in order to warm a patient through a very focused heat source from above, the heating lamp must generate a relatively high heat and must be positioned fairly close to the patient’s skin, the combination of which creates a real potential for actually burning the latter. The use of this type of lamp must be monitored very closely to prevent this occurrence.

Angiographic injector

The angiographic injector should be capable of being attached to the angiographic catheter from either side of the catheterization table, from the top or bottom end of the table and from any catheter introduction site. The injector syringe must always be angled *downward* when it is connected to the hub of a catheter or connecting tubing for an injection. The downward angle forces any air which might be trapped in the injector tubing or injector syringe to rise to the back end of the injector syringe. When the injector syringe is attached directly to the catheter hub, the injector head is *always* positioned above the level of the hub of the catheter in order to assure that the *tip* of the injector syringe is pointing downward.

Fortunately, the “injector head” of the modern MedRad (MedRad, Inc., Indianola, PA) and Liebel-Flarsheim (Mallinckrodt Inc., Hazelwood, MO) angiographic injectors can be separated from the large, bulkier, control apparatus of the injector. This allows the injector head to be mounted separately and away from the control unit. Mounting the injector on a long, movable, ceiling-mounted arm positions the injector head well above the surface of the catheterization table and allows it to be moved to any location about the table. A ceiling-mounted injector does not occupy any floor space and there is less danger of the sterile field or the operator being contaminated when the injector is being attached to, or while it is attached to, the catheter. The separate control unit can be positioned across the catheterization room away from the catheterization table or, preferably, even in a separate, but adjacent control room.

A less satisfactory arrangement is to have the separate injector head mounted on a mobile floor stand. However, the floor stand occupies valuable floor space wherever it is positioned and it must also be moved about the room and positioned immediately adjacent to the catheterization table for injections. This positions the stand very close to the side of the patient and necessitates that the injector extends over, and very close to, the sterile field. With a rigid attachment to the floor stand, the injector head cannot be raised much above the level of the catheter hub in order to keep the tip pointing downward. Some of these disadvantages can be obviated by the use of very long connecting tubes between the injector syringe and the catheter.

Adjustable radiation protection screens

In addition to the regular use of lead aprons and optimal X-ray techniques, supplemental X-ray protection screens should be used during every catheterization procedure. Most of the radiation to the operating physician originates from the scatter, which emanates out of the patient’s body *above* the catheterization table. The most effective way of

minimizing this radiation to the operator is by the use of a leaded glass screen placed between the patient's body and the operating physician. The preferred screen for the protection of the operating physician is suspended on a long articulated arm from the ceiling above the catheterization table. In this way the screen, covered with a sterile, transparent drape, is moved between the patient and the operator without occupying any "real estate" on the floor of the room and without contaminating the field.

Similar protective leaded glass screens are available on floor mounted stands, which move on casters; however, the floor screens occupy valuable floor space and when used near the catheterization table, interfere with angulation of the X-ray tubes. Large, free standing, transparent, leaded glass X-ray screens, mounted on casters, are useful for the protection of personnel not working directly at the table. The additional personnel who benefit the most from these screens include the anesthesiologist, the circulating nurse/technicians and respiratory therapists.

Cardiac output computer

Determination of the cardiac output is often required during the catheterization of pediatric and congenital heart patients. Although a precise cardiac output is not necessary for calculating *relative* shunts and obvious gradients, when the calculations of absolute flow and resistances are necessary, an accurate cardiac output becomes mandatory. Our cardiac catheterization laboratories now use a thermodilution technique with a small, dedicated, Dualtherm™ Cardiac Output Computer (B. Braun Medical Inc., Bethlehem, PA) designed specifically for calculating thermodilution cardiac outputs. The thermodilution apparatus is relatively small and is mounted on a small mobile cart. When a cardiac output is to be determined, the computer is connected to the specific thermodilution catheter (B. Braun Medical Inc., Bethlehem, PA) on the catheterization table with a sterile, reusable cable, which extends directly from the computer to the catheter. This small cart is moved close to the table for cardiac output determination and is parked well away from the catheterization table when not in use.

"In-room" consumable equipment storage

The great bulk of the consumable equipment, including the back-up supply of the most frequently used items, is stored in a *separate*, dedicated storage room, which is situated immediately adjacent to the actual catheterization room. At the same time, a limited supply of multiple sizes of very frequently and repeatedly used sterile consumable items including percutaneous needles, a variety of guide wires, sheath/dilator sets, syringes, the most frequently used catheters and even gloves are stored directly in the

catheterization room, but in mobile carts. While all of the consumable equipment could be stored in the adjacent storage room, the repeated retrieval of very frequently used items from a separate, even though adjacent room, during the case, reduces the functional efficiency of the laboratory very significantly.

Storage of the "high use" expendable materials actually within the room maximizes the efficiency for the frequent retrievals. Specifically configured, mobile storage carts provide the most effective vehicle for this in-lab storage of the frequently used consumables. These can be moved in and out of the room for cleaning, for restocking with new supplies or when the particular items on that cart are not being used at all. These carts can also be moved easily to accommodate a reconfiguration of the arrangement of the room according to the various introductory sites for the catheters or according to the type of procedure being performed.

The mobile storage carts maximize the usable space of the room as opposed to the traditional, fixed cabinets along the walls of the room. Any fixed, built-in cabinets for storage within the catheterization room represent "wasted" floor space, which is lost permanently and cannot be "adjusted". Each row of fixed cabinets or counters reduces the functional width or depth of the catheterization room by at least three feet and reduces the total floor space of the catheterization room by this width times the length of the wall(s) covered with cabinets! Built in cabinets do not allow even minor reconfiguration of the room for different procedures.

"Mobile" equipment stored outside of the catheterization room

There are other pieces of mobile equipment that are shared between several catheterization rooms and stored within the general area of the catheterization laboratory, but preferably just outside of the actual catheterization room. Each piece of this equipment requires space for storage outside of, but adjacent to, the actual catheterization room and, when the equipment is in use, additional space must be provided for it in the catheterization room itself. Among this ancillary equipment are included a separate, but constantly available, 2-D echo machine, a radio frequency generator, an oxygen consumption apparatus with its constant air withdrawal system and several "hoods", an echo console for intravascular ultrasound (IVUS), transesophageal echo (TEE) and/or intravascular echo (ICE), a Laser™ generator and possibly a cardiac "mechanical assist" device. When used, most of these pieces of equipment must be positioned immediately adjacent to the catheterization table. At the same time, the location of this equipment while it is being used should not interfere with the catheterizing physician's access to

the patient or the overall mobility within the room. This requires a greater overall planned width or depth to the room in order to prevent severe side-by-side crowding at the table side.

2-D Echo machine

A 2-D echo machine capable of transthoracic scanning of the pericardial space should be available in the catheterization laboratory immediately for emergency situations. This does not have to be the latest nor the most sophisticated echo machine available but it must be functional. This echo machine is required in addition to, and separate from, the TEE/ICE console, which usually is a special console utilized specifically for TEE and/or ICE and is brought to the catheterization laboratory only when TEE and/or ICE is/are used. Much of the time, the TEE/ICE machine may be needed elsewhere in the hospital and, in turn, may not be available for some time or be physically far from the vicinity of the catheterization laboratory. The separate, always available 2-D echo machine is primarily for screening patients who deteriorate either acutely or unexpectedly. This is particularly important when screening for suspected cardiac tamponade. The added time needed to transport an echo machine to the catheterization laboratory from an area outside of, and remote from, the immediate catheterization area represents a delay in confirming a diagnosis, which could easily represent the difference between a successful and an unsuccessful resuscitation.

Radio frequency generator

Pediatric cardiac catheterization laboratories now require a dedicated radio frequency (RF) generator, which is designed specifically for the perforation of tissues. Although this unit may be used only 6–12 times per year, the infants in whom an RF generator is used are not “scheduled” and often have a critical time window for their treatment. The BMC Radio Frequency Generator (Baylis Medical Co. Inc., Montreal, Canada), specifically for perforation, is quite small and can be stored outside of the actual catheterization room when not being used. When used in any particular procedure it is placed on a small, temporary cart adjacent to the catheterization table and connected to the RF catheter (Baylis Medical Co. Inc., Montreal, Canada) with a sterile reusable cable.

Oxygen consumption apparatus

The MRM-2 Oxygen Consumption Monitor (Waters Instruments Inc., Rochester, MN) for measurement of oxygen consumption is a gas analyzer in conjunction with several different hoods and a vacuum pump/blower used

to draw air through the hoods. In most laboratories, the apparatus is used infrequently and, as a consequence, is (should be) stored in an adjacent area, out of the catheterization room. The apparatus is cumbersome; it covers the patient’s head, neck and upper thorax and is fairly disruptive to the usual catheterization procedure. When an oxygen consumption determination is to be performed on a patient during a catheterization procedure it is planned ahead of time and the specific arrangements are made for the oxygen consumption measurement when the patient is being placed on the catheterization table. The patient’s head and neck are positioned on a flat surface on the catheterization table with no pillow beneath their head. There can be no catheter lines entering the neck and the patient cannot be intubated or receiving oxygen or general anesthesia while oxygen consumption is being measured.

Intravascular ultrasound and intracardiac echo equipment

Currently intravascular ultrasound (IVUS) and intracardiac echo (ICE) imaging are used frequently in many pediatric and congenital catheterization laboratories. The particular consoles from Acuson, Mountain View, CA or Boston Scientific, Natick, MA, which are used for this imaging are quite large. The consoles are usually stored out of the actual catheterization room and brought into the laboratory only when needed for a specific case. The catheter for ICE is a 10–11-gauge French catheter and usually is introduced from a femoral vein, while the catheters for IVUS are smaller and can be introduced into a vein or artery from a femoral or jugular access site and can be introduced from either arm. The catheters are usually attached to their respective console with a long connecting cable within a long sterile sleeve. The physician operating the console is not necessarily the catheterizing physician who is maneuvering the catheter. As a consequence, the machines (consoles) for these procedures usually do not have to be immediately adjacent to the catheter introduction site, but do require a relatively large space, relatively close to the catheterization table in the general area where the imaging catheter is introduced. Like the TEE, a remote or slave monitor is usually necessary in order for the catheterizing physician to visualize the intravascular echo images conveniently.

Laser™ generator

A Laser™ generator (Spectranetics, Colorado Springs, CO) is used for lead extractions and some purposeful perforations. It is another very large piece of equipment, which is used in a pediatric/congenital cardiac catheterization laboratory only occasionally and, when moved into the room, requires significant additional space adjacent to

the catheterization table. The Laser™ generator is stored outside of the catheterization room or even away from the laboratory as a shared piece of equipment between several services or even institutions. The use of the Laser™ is scheduled well ahead of time and the generator is moved into the laboratory for the specific procedure. Special precautions for eye protection are required for all personnel who are, or might be, in the room for the procedure. Considerable rearranging of the equipment in the room is required during these isolated and rare circumstances.

Extra cardiac membrane oxygenator (ECMO) or other left ventricular assist device (LVAD)

An even more rarely used piece of very large and cumbersome adjunctive equipment which may become more common and even essential in the future catheterization laboratory is one of the cardiac assist devices including an ECMO apparatus, an intra-aortic balloon pump or even an LVAD. When an assist device is necessary, it likely would be as an emergency. Although the equipment for these procedures would have to be moved from the operating room or intensive care area, it would not be expedient to have to move other equipment which is being used in the catheterization laboratory out of the laboratory, or to have to rearrange the catheterization laboratory very significantly in order to bring these large pieces of emergency equipment to the patient rapidly during such an emergency. A potential physical “corridor” to the table, and place for this equipment, should be considered ahead of time when a catheterization is planned on a patient who might be a potential candidate for such therapy.

Electrophysiology equipment

The pediatric/congenital electrophysiologic (EP) laboratory contains additional very large pieces of equipment which, unlike the catheterization table itself, are not fixed structures in the room, but, at the same time, are not particularly mobile and take up considerable additional fixed space. This equipment varies with each EP laboratory, but at a minimum includes a separate computer and monitor, a separate recorder, a stimulator, a radio frequency generator for ablations, multiple additional CRT monitors and additional mobile storage cabinets for the frequently used, special EP consumables. The Laser™ generator for lead extractions is more likely to be used and stored in the EP laboratory. The extra EP “capital” equipment often has a space requirement equivalent to the space of a separate control room. Usually this equipment is housed in, and used directly within the catheterization room. This extra space should be included in the basic design of the catheterization room which is to be used for electrophysiologic procedures.

Support areas for the catheterization room(s)

The actual cardiac catheterization room is not a “free standing”, independent or isolated room, which can be placed randomly at the convenience of any available space. Each catheterization room requires a significant amount of space which must be immediately adjacent to the catheterization room, for the logistical, mechanical and personnel support for the operation of the actual catheterization room. This support space plus the catheterization room(s) make up the catheterization suite. The support space occupies more square footage than the catheterization room(s). The support space ideally includes a separate control room for each catheterization room, a large room for the storage of the majority of the consumable equipment, a separate electrical equipment room or “bay” for the X-ray generators, controls and high-tension switches, a patient holding/preparation area, an administrative support area, a record/angio review/work area, an on-site storage area for “active” patient records and angiograms, a biomedical service/supply area and a separate procedure room for procedures other than X-ray which require monitoring (e.g. phlebotomies, thoracentesis, transesophageal echocardiograms).

Control room

The control room houses the physiologic monitoring equipment, computer recorder and the controls for the X-ray system for each specific catheterization room. In addition, each control room contains remote monitors of the CRT screens which are in the catheterization room, the controls for the angiographic injector, the computer(s) which is/are connected to the hospital system, the digital X-ray recording system, a digital disk copier, printers for physiologic records, the computer log of the procedure, and hard-copy printers for X-ray images, all with adequate space for at least two nurses/technicians to function comfortably. An area 10 to 11 feet wide and as long as the width of the catheterization room (e.g. 10 × 24 feet) provides a reasonable sized control room with room for some fixed counters and cabinet space in addition to the monitoring equipment. In addition to a good view of the entire catheterization room, including the entire catheterization table, and clear voice communication between the catheterization room and the control room, the personnel in the control room should have direct and easy physical access into the catheterization room.

The control area preferably is *not* situated *within* the actual catheterization room. The control/monitoring/recording equipment takes up a large amount of valuable floor space, which should not be taken from the actual

catheterization room. The control room equipment generates noise, accumulates dust and is operated more effectively in a clean, but non-sterile, environment. In addition, when the control room equipment is located within the catheterization room, it exposes the nurses/technicians who operate it to extra and unnecessary radiation. At the same time, the control room must be *immediately* adjacent to the catheterization room. The orientation of the catheterization table diagonally across the catheterization room facilitates a view of the entire length of the patient on the table whether the control room is directly at the end or along the side of the catheterization room. The control room usually is *not* a sterile area and can have additional space in it, which serves as an observation area for consultants/visitors.

A shared central control room between two or more catheterization rooms is seen occasionally, but is not an optimal arrangement. Except for a questionable economy of space, there is no justification for a combined or shared control room. None of the actual electronic control equipment in the control room is shared between separate catheterization rooms. Much of the communication between the separate catheterization rooms and the control room and within the control room is verbal. When the control equipment and personnel from two or more laboratories are grouped together in one room, there are continual distractions, the communication becomes confused and the working environment becomes very congested and noisy.

Consumable equipment storage room

The *majority* of the consumable equipment (catheters, introducers, wires, dilation balloons, special devices, etc.) is stored outside, but immediately adjacent to, the actual catheterization room. For a laboratory performing therapeutic catheterizations on pediatric and adult congenital heart patients, this requires a huge amount and variety of consumable equipment which, in turn, requires a very large storage space, which is equal in size to the optimal sized catheterization room (roughly 32 × 24 feet). Fortunately two, or even three, separate catheterization rooms do not require significantly more consumable equipment and additional storage space for the consumable equipment than a single laboratory. If there is more than one catheterization room, it is most efficient to have a single storage room for the consumables adjacent to, and connected to, all of the separate catheterization laboratories (rooms) with convenient access to each of the laboratories. Because of the large amount of very expensive consumable material required for a pediatric/congenital catheterization laboratory, the storage area must be absolutely secure.

The storage room requires an organizational plan or arrangement for inventory control which (1) keeps track

of each item used to facilitate the expedient reordering of used items and, (2) obligates the use of the older items before newer, more recently acquired items in order to avoid the problem of having to discard new and unused items because of material or sterility expiry dates. This organization of the inventory is even more critical when several or more catheterization rooms are drawing supplies from the same storage source.

A catheterization laboratory should have both a blood gas analyzer such as an ABL 700 Radiometer (Radiometer, Copenhagen, Denmark) and an activated clotting time (ACT) machine (Hemo Tec, Inc., Englewood, CA). Both of these machines can be shared between several or more catheterization rooms. These machines are fixed in location and when shared, they are housed conveniently in a central consumable storage area, which is adjacent to all of the actual catheterization rooms. This equipment must be in close proximity to each catheterization room but, preferably, must not be within the catheterization room itself. Under usual circumstances this equipment is used only two or three times during an entire catheterization procedure. Both the blood gas and ACT machines require regular maintenance and calibration by biomedical personnel who normally function more proficiently in a non-sterile environment. When these machines are not in the actual catheterization room, any maintenance/calibration can be performed on them while a catheterization is in progress. Rarely, blood gas machines are used to calculate all of the blood oxygen saturation determinations. In that situation, the blood gas machine should be physically in the catheterization laboratory.

A separate, X-ray equipment room or "bay"

It is now *essential* that modern X-ray generators and X-ray power supplies are housed in a dedicated equipment room, which is completely separate from the catheterization room. There no longer is a place for the cabinets for the X-ray generators, controllers and high-tension "switches" to be located within the actual catheterization room. In addition to the physical space occupied by the high-tension generators and other X-ray electronic equipment, this equipment requires a separate and efficient refrigeration/air conditioning unit to allow continuous, extra and extreme cooling of the X-ray and other electrical components in order to counteract the excessive heat generated by it. The cool environment is essential for the day-to-day stability and operation of the sensitive equipment and in order to maintain the durability of the very expensive electrical equipment. When the electrical equipment is situated in the catheterization room, an environmental temperature which is cool enough to keep the equipment adequately cooled is far too cold to maintain the body temperature of a patient.

Although the “equipment bay” is a separate room, because of the limitations of the maximal lengths of the high-tension cables connecting the X-ray tubes to the generators, it must also be in close proximity to the actual catheterization laboratory. Assuming the “geometry” can be solved for situating more than one catheterization room adjacent to the equipment bay, a single equipment bay can house the generators and power supplies of two or more catheterization rooms while using the same additional cooling system. The equipment bay needs a lot of wall space for the modern digital electronics so that a relatively long but narrow room, for example 10 × 32 feet, will suffice to hold the heavy electronic equipment for two biplane catheterization rooms (Siemens Medical Systems, Inc., Iselin, NJ) as well as the extra cooling equipment.

In addition to the cooling requirements, even the latest digital and computerized catheterization laboratory X-ray generating equipment still takes up a large amount of space and, if positioned within the actual catheterization room, would reduce its functional width by at least two feet in depth along one entire, long wall. When the generation equipment is within the sterile catheterization room, access to the equipment for maintenance or even minor resetting of circuits is restricted to times when the room is not in operation. Like the electronic equipment in the control room, the X-ray generating equipment has huge areas for attracting and collecting dust, which is not acceptable in a “sterile” working catheterization room.

Preparation, holding and recovery area(s) for patients

Patients do not enter directly into the cardiac catheterization laboratory from “outside”, nor do they go directly home after a catheterization. With many pediatric and congenital heart cardiac catheterizations now being performed as outpatient or “day-surgery” procedures, an area is required for the admission of the patients for the catheterization procedure, their preparation for catheterization and the administration of premedications. When the catheterization laboratories operate adjacent to, or in conjunction with, the cardiovascular operating rooms, the same preparation/holding area can be used to admit the patients for both the catheterization laboratories and the operating rooms. The total size of the “holding area” depends upon the number of procedure rooms (catheterization labs or operating rooms), which are being supported.

Each bed space in a “holding/admitting” area should be capable of monitoring and recording several leads of an electrocardiogram, a pulse oximetry display, a display of the patient’s body temperature and the capability of displaying at least one pressure monitoring line. The physical space of each “holding bed” must comply with

standards for recovery room beds. Each bed requires piped in oxygen, compressed air and suction. The holding area must have a separate “crash cart” including emergency cardiac medications, intubation and temporary ventilation equipment as well as a cardiac defibrillator. All of the facilities and equipment for drawing blood samples as well as starting and maintaining intravenous lines must be available in the holding area. All of the beds can be in one open area, but must be separated from each other by at least curtains or screens. Since some patients may remain in the area for a relatively long period of time awaiting their catheterization or surgery, a television or “play station” is made available for at least half of the beds.

The number of beds and the size of this area, obviously, depend upon the number of catheterization rooms (and operating rooms if the area is shared), any function of the area besides admitting and holding, and the total number of patients expected through the area per day. For patient preparation and premedication, one bed per catheterization procedural room *and* one bed for each operating room are sufficient. This allows for the simultaneous preparation at the beginning of the day of all of the “first” patients for each of the procedural rooms and allows each procedural room to start at approximately the same time when desired. Patients who are scheduled for catheterization (or surgery) as second, third or later cases are scheduled to arrive at the holding area later according to a staggered schedule. This allows a bed for each patient, time to admit each patient comfortably, prepare them for the procedure and to have them totally prepared and sedated by the time the procedure room is ready to start.

A four to six hour recovery/observation period is mandatory immediately post-catheterization for cardiac catheterization patients. The patient should have close monitoring by experienced nurses during that time immediately after a cardiac catheterization. Ideally, this monitoring is accomplished in a cardiac recovery area or cardiac intensive care unit. However, if the cardiac catheterization laboratory is in a location remote from the cardiac recovery/intensive care units, the holding area can be adapted to serve as an observation/recovery area for the patients post-catheterization. With an adequate number of beds and the space and monitoring equipment to be used for patient recovery post-catheterization already established, the same area used for the patients’ admission can be expanded to a recovery area. In that circumstance, because of the overlap of the patients arriving for their procedures with the patients who are recovering, the “recovery” beds in the area should be separated from the “admission” beds more solidly than with just curtains. A recovering patient who is uncomfortable, vomiting or having more serious problems, is extremely upsetting and frightening to a patient who is about to undergo “the

same" procedure! When the holding area is used for post-catheterization recovery, the nursing staff is larger, the nurses need additional training and experience in the recovery of catheterization patients and the functioning "hours" of the holding area must be extended and very flexible according to the anticipated procedures for the day.

Administrative and general support areas

A liberal amount of additional space is required *within the general catheterization area* for the general administrative support of the catheterization laboratory. This support area includes the working areas for the catheterization laboratory manager and secretarial/administrative assistants. They should be located in close proximity to the actual laboratory in order to support the minute-to-minute activities of the laboratory including the changes in scheduling and assignments during each day. The administrative support area also provides a work area for the nurses, technicians and physicians to review and compile the catheterization records and angiograms, space and the equipment for copying these materials and space for the temporary storage of, at least, the most current and "active" catheterization records and angiograms. For the support of two or more laboratories, this requires working space for two or more personnel. This area can be relatively long and narrow in order to be positioned immediately adjacent to the catheterization laboratories, for example 10 to 11 feet by 32 feet in length.

The catheterization laboratory area must have adequate and convenient toilet facilities, which include sinks and a shower along with secure lockers and changing space for all of the personnel working in the catheterization area. The personnel should not have to leave the general area of the catheterization laboratories to use the toilet or changing facilities. Easy access to a supply of "scrubs" in a convenient changing/locker area within the catheterization suite encourages the personnel to change into scrubs while in the catheterization laboratories, but, at the same time, encourages them *not* to wear the scrubs out of the hospital.

The overall cardiac catheterization area needs a separate break or relaxation area for all of the personnel who work there. The personnel in the catheterization laboratory work in a continually stressful atmosphere and, frequently, at a continual and frantic pace. At least a short intermittent break out of the catheterization room improves the working atmosphere in the room. When this "break room" is still within the area of the catheterization suite, it allows the personnel to have time out of the actual rooms without losing "transit" time to and from a break area and without the personnel having to change out of their laboratory scrubs.

Cine/angio/data review area

Each catheterization suite requires an area for the physicians to review and analyze the data and the angiograms from the current catheterizations. The review area should have space to accommodate up to four or five physicians at a time as well as a large counter space for the review and measurement of the paper tracings of the recorded pressures, which when stretched out extend for several meters. The review area requires at least one computer, which is in communication with the catheterization laboratory as well as the information systems of the hospital including the hospital X-ray and echo systems. This (or these) computer(s) also should be in communication with the on-line, digital storage system for the digital angiograms from the catheterization laboratory.

The review room requires specific and usually separate equipment for the review of "outside" angiograms as well as those generated in the catheterization laboratory itself. The common transferable, digital media at the present time is the DICOM encoded compact disk (CD). This requires a digital viewer/review station, which can read all medically encoded DICOM digital data. Although all major medical manufacturers supposedly comply with a single DICOM standard, occasionally separate software is required in the CD reader or a completely separate computer/review station is necessary to read CDs from different systems/manufacturers. Since many of the previous, older, angiographic studies on the current patients were recorded on cine film and some existing cardiac catheterization laboratories are still recording on cine film, the reviewing area requires a functioning cine film viewer (Tagarno of America, Inc., Dover, DE).

The review area must have some space designated for the storage of the catheterization reports and angiogram of patients who are currently hospitalized, or who will be hospitalized in the near future. A copying machine for records, catheterization diagrams and digital angiograms improves the efficiency of the area and helps to keep permanent records intact.

Biomedical support area

With the total dependence in a modern catheterization laboratory upon the large variety of both simple and very complex electro-mechanical equipment, all cardiac catheterization laboratories are equally and totally dependent upon biomedical support being readily available in order to operate the cardiac catheterization laboratories daily and continuously. Ideally the biomedical personnel for the cardiac catheterization laboratory are a part of the catheterization laboratory personnel, and their primary responsibility is to the catheterization laboratory. There should be adequate space in the vicinity of, or actually in,

the catheterization laboratory suite for the biomedical personnel to work on the mobile equipment. The biomedical area must include space to store the testing and repair equipment as well as pieces of frequently needed and essential "spare" equipment. When there is more than one catheterization laboratory or other "high-intensity electrical areas" (operating rooms, intensive care areas) in close geographical proximity, there is adequate justification for specific biomedical engineers who are knowledgeable in that particular equipment to be assigned to the catheterization laboratories.

Any delay in the investigation and repair of an equipment malfunction, no matter how minor, results in an equivalent "down", or "inactive time" for the room, which includes three or more salaried nurses/technicians and one or more physicians who would be working in that room. A malfunction of a piece of equipment often requires a "repair" which is as simple as resetting a relay or switch and actually takes only seconds for a knowledgeable person to correct. At the same time, the relay may be located in a "high-tension" cabinet containing very complex electronics and, as a consequence, should be manipulated only by experienced biomedical personnel. An otherwise short delay is prolonged unnecessarily when the biomedical support who is capable of the simple "repair" or "resetting" is located any distance (and time) from the catheterization area. An active, fully scheduled, cardiac catheterization laboratory cannot afford any significant "down time". Any equipment failure during operating hours results in the rescheduling of the patients with a frequent "domino" effect on other patients and services throughout the hospital, in addition to the obvious costs in personnel "down time".

A separate "minor procedure" room

Depending upon the size of the cardiology service, there are a variable number of procedures which require monitoring, sedation and, occasionally, even general anesthesia. These procedures include phlebotomies with colloidal volume replacement, "tilt table" and other vaso-motor electrophysiologic testing, transesophageal echocardiography under general anesthesia, pleural taps and drainage with or without chest tube insertion, some pericardial taps and even some difficult intravenous or intra-arterial lines. The "interventional", "intensivist" or "catheterizing" physicians frequently perform these procedures. Although these procedures have been, and can be, performed in catheterization laboratories, they generally do not require *all* of the elaborate equipment and personnel of a catheterization laboratory.

Ideally, a separate "procedure room" is available in the immediate area of the catheterization laboratories/holding area. This room needs to be large enough to

accommodate the procedure table, a sterile work table for the physician, any ancillary large equipment (e.g. a TEE machine, an anesthesia machine) and area for personnel to function in the room. The procedure room should have monitoring available with the capability of permanent recording of the ECG, pulse oximetry, a periodic recycling cuff blood pressure apparatus and at least one pressure transducer and recording channel for an indwelling line when desired. Piped in oxygen, compressed air and suction are essential. The procedure table in this room is an operating type of table, capable of tilting or there is a separate "tilt table" which can be moved into the room. The procedure table is lit with a high-intensity, ceiling-mounted, mobile "operating room" light. This room should have a mobile equipment cart to hold the consumables for any procedure being performed. The procedure room must have immediate access to a separate "crash cart" with intubation equipment, resuscitative drugs and fluids and a defibrillator. If the procedure room is *immediately* adjacent to the "holding" area, the emergency cart is shared with the holding area. Patients who are treated in this procedure room need admitting and frequently a recovery time similar to a catheterization patient.

Film processing room

A film processing room (area) is no longer necessary in a cardiac catheterization laboratory with digital X-ray equipment. A film processing room is still necessary in laboratories with older X-ray equipment which are using cine film as the recording medium. Although the image is produced by X-ray energy, cine-angiography film is a photographic film and is processed in a separate processor and with completely different techniques from the processing of X-ray film. Cine film processing is complex, time consuming, space occupying and environmentally polluting, all of which justifies upgrading cine film X-ray equipment to a digital system.

A film processing area includes not only a room for the film processor, but also a dark-room and a separate room to store the processing chemicals. The film processors are fairly compact but very complicated and require plumbing attachments from the chemical tanks and separate attachment to a special drainage system for the highly acidic and toxic developing chemicals. The processor requires constant maintenance in order to obtain the optimal processing of each roll of film. The daily maintenance includes adjusting the composition and temperature of the chemicals, assurance that all of the pumps and drives are functioning properly, and the cleaning of the multiple separate tanks and rollers in the processor. In addition to being consumed by the processor, the processing chemicals deteriorate with time and must be changed regularly regardless of the use of the processor. Possibly by the time

this book is published, film processing in the catheterization laboratory will be delegated to the historical annals!

Catheterization laboratory personnel

Physicians

The medical director of the pediatric/congenital cardiac catheterization laboratory should be a pediatric cardiologist who regularly performs procedures in the catheterization laboratory. The ultimate responsibility for the proper equipment and the necessary personnel in the laboratory and, in turn, the smooth operation of the laboratory, is that of the medical director of the laboratory. The physician director must have the full support of the hospital. The number of cardiologists who perform catheterizations and their qualifications depend upon the number and type of procedures being performed in the catheterization laboratory.

A "simple" diagnostic catheterization procedure in a congenital heart patient can be performed by a single pediatric/congenital cardiologist with well trained and experienced support staff. The physicians and staff, for a diagnostic catheterization, do not have to have special training in *therapeutic/interventional* catheterization procedures, but should be experts in the anatomy and hemodynamics of congenital heart disease.

Most complex interventional (therapeutic) catheterization procedures performed on congenital heart patients should be performed by pediatric cardiologists with extra training in interventional catheterizations or with extensive experience in the catheterization laboratory and particularly with these procedures. New devices/procedures being introduced require even experienced interventional cardiologists to have some special individualized mentoring by a physician experienced in the procedure before beginning to use the new device/procedure. Most pediatric cardiologists who are entering the field of interventional/therapeutic catheterizations should and do take at least a year of additional and specific training in interventional catheterization procedures².

The more complex the catheterization procedure which is to be performed is, the more highly trained the physician(s) and catheterization laboratory staff must be for performing that procedure. Also the more complex the procedure is, the more experienced physicians and highly trained support nurse/technicians are required to be scrubbed and circulating during each procedure. For example, to perform complex catheter manipulations or even a "simple" balloon dilation procedure, there are multiple exchanges of catheters and wires with long lengths of guide wire extending out of the catheters which must be controlled to prevent their falling off the table. During the

single balloon inflation a knowledgeable individual controls the position of the catheter/wire while a second knowledgeable individual inflates and deflates the balloon. The implant of two stents simultaneously represents an extreme of additional staffing needs for skilled staff. Two knowledgeable physicians maintain the stent/balloons precisely in place while two additional, trained individuals simultaneously control the inflation of the two balloons—i.e. four skilled individuals *scrubbed* for one procedure. Working with insufficient numbers of personnel or inadequately trained personnel prolongs a procedure significantly and increases the likelihood of adverse events or serious complications. The same procedure *can* be accomplished with fewer and less well-trained personnel scrubbed, but only with the substitution of a great deal of luck for skill and with an increase in the likelihood of an unsuccessful procedure or a procedure which results in serious complications! The problems encountered are in inverse proportion to the skill of the personnel and the number of skilled personnel involved with the procedure.

Non-physician catheterization laboratory personnel

Most pediatric/congenital cardiac catheterization laboratories require three, if not four, professional nurses or catheterization laboratory technicians to operate a catheterization room *efficiently*. The total number of nurses/technicians for an entire catheterization service must include not only the precise number of skilled individuals to operate each catheterization room, but enough extra personnel to account for illness, vacation, educational and compensatory time of the regular staff. Because of the extensive extra training each individual requires to function effectively as a catheterization nurse/technician in a pediatric/congenital cardiac catheterization laboratory, extra personnel cannot be pulled from other areas or from a general "pool" of personnel in the absence of one of the regular catheterization laboratory nurses/technicians. The laboratory itself must have its own pool of trained nurses/technicians to pull from. This is easier to accomplish when two or more catheterization rooms are operating in the overall pediatric/congenital cardiac catheterization unit.

The nurses/technicians who work in the cardiac catheterization laboratory have a background of registered nurses, practical nurses, radiographic or pulmonary technologists or have graduated from specialized cardiac catheterization or cardiopulmonary technician schools. Regardless of their background, almost all nurses/technicians starting in a pediatric/congenital cardiac catheterization laboratory require *at least six months* of orientation (on the job training) working in the catheterization laboratory under the supervision of the already experienced personnel in the laboratory. To work in a pediatric/

congenital cardiac catheterization laboratory further, extensive training/orientation is necessary, even for a nurse/technician who has extensive catheterization laboratory experience in an adult catheterization laboratory.

All of the nursing/technician personnel in the pediatric catheterization laboratory should be "cross trained" to perform all of the nursing/technician functions within the catheterization laboratory. In that way, any combination from all of the individuals in the laboratory pool can be on call together and in the unexpected absence of any one individual, any other nurse/technician is trained in, and can assume, the missing person's functions. This requires additional in-house training of new personnel in order to make them experts in areas and procedures which were not included at all in their pre-pediatric catheterization laboratory, background training.

Because of all of the extra training, the complex and potentially dangerous procedures performed daily on very sick patients and, in turn, the very high degree of responsibility and stress imposed on each individual, the cardiac catheterization laboratory personnel represent an elite, special group. The efficient completion of every procedure depends upon each nurse's/technician's skills, on their cooperation with each other and the physicians and on their willingness to work together as a team.

The minimum number of nurses/technicians required for each cardiac catheterization room is determined by the physical layout of the laboratory, the organization of the personnel, and the amount of nurse's or technician's work which the physicians themselves perform. Reducing the required or even optimal number of nurses/technicians available during a case represents a false *economy of bodies* at the increased expense of an *inefficiency of function*. When one nurse/technician is missing in a catheterization laboratory, that individual's particular jobs are performed by one of the remaining personnel in the room who, however, already has their own, assigned jobs and functions. The two or three nurses/technicians and the one to three physicians still in the room performing a procedure when one of the support personnel is missing, must wait several or more minutes for a particular procedure to be performed or for an item to be procured while the individual who normally performs that procedure or function is now performing the job of the missing person. Each delay of two minutes as a result of the absence of one individual results in a minimum of 12 minutes of total personnel time lost during the operation of the catheterization laboratory!

For example, in the absence of a circulating nurse, the nurse who operates the manifold must leave the manifold to retrieve an item of consumable equipment in the adjacent storage room. During the time the manifold nurse is out of the room, the operator cannot flush the catheter if he draws a sample, cannot switch to or from the pressure/flush line or balance the transducer to record a pressure

and cannot administer medications until the manifold nurse returns. These lost segments of time for all of the personnel performing the case are multiplied many fold during every case when one essential person is missing. The repeated waiting time of the multiple individuals adds up to much more than enough time to account for the salary of the "extra" individual who is missing!

Emergency and off-hour cardiac catheterizations still occur quite frequently in a busy pediatric or congenital cardiac catheterization laboratory. A full complement of nurses/technicians for one catheterization room must be available on call. Although most emergency catheterizations are not as extensive or as prolonged as the usual scheduled procedures, emergency cases are performed on the very sickest and most precarious patients. These patients require the most intensive medical and most *timely* management. As a consequence, the emergency cases should not be undertaken short handed with less than a full complement of nursing/technician personnel in the room during the emergency procedures.

The "on-call" personnel may need to stay late in the laboratory for a prolonged or delayed scheduled case or have to return to the catheterization laboratory in the case of an emergency at any time, twenty-four hours a day and seven days a week. The on-call nurses/technicians are compensated financially for their time on call. In addition, they receive overtime salaries when actually called into the laboratory. In spite of this compensation, the on-call status requires a definite sacrifice for the personnel. They must have a commitment to either no other activities when on call or being able to interrupt *any activity* at *any time* when called. With a fully cross-trained staff of nurses/technicians, this allows the rotation of individuals within the "on-call teams" and allows some distribution of the call to suit the schedules of each of the individuals working in the catheterization laboratory.

The extra on-call duty is not the only sacrifice a pediatric catheterization laboratory nurse/technician makes. In a dedicated, busy, pediatric/congenital cardiac catheterization laboratory, a "normal", *scheduled* day does not exist. Cases frequently extend beyond their scheduled duration as well as beyond the normal working day. The individual cases frequently are longer than scheduled, the pediatric patients often need stabilization by the catheterizing physician between the catheterization procedures, which delays the start of the next case, and there are frequent "add on", urgent cases which appear regularly in the busy pediatric cardiovascular service. All of these factors very regularly extend the hours of the pediatric/congenital catheterization laboratory beyond the "8-hour day".

Rare or occasional extra time added to the regular work day is satisfactorily solved by merely having the involved personnel remain beyond the hours of their work day

while receiving overtime compensation in the form of extra overtime salary or compensatory time off. However, in a busy pediatric/congenital catheterization laboratory where the extra hours are a regular occurrence, having each employee working extra hours *regularly* is not a solution. The cost of regular, repeated overtime pay becomes prohibitive to the hospital and there is never time available for the individuals to have compensatory time off. Of even greater importance, the strain on the employees of never having a fixed or dependable finish time to the working day results in employee dissatisfaction and a high employee turn-over. Besides the inconvenience of hiring and retraining new nurses/technicians, the retraining of new personnel is very expensive and time consuming.

As a consequence, in a busy pediatric/congenital catheterization laboratory it is necessary to provide a flexible working schedule for the nurses and technicians. There must be a sufficient total number of nurses/technicians to allow for staggered working hours and to allow additional scheduled time (or days) off to compensate for hours worked overtime. When the catheterization laboratories do finish the scheduled cases early, the personnel are allowed to leave without penalty. In a busy laboratory they still will work their minimal hours! The physicians working in the laboratory must also use some consideration when adding extra or "urgent" cases which could possibly be worked into the regular schedule.

The multiple duties of the nurses/technicians in a pediatric/congenital cardiac catheterization laboratory are divided into three or four different "job descriptions" during the catheterization:

Recording nurse/technician

One or two nurses or technicians operate the monitor/recording and the X-ray equipment in the control room (or area) of the catheterization room. The recording nurse or technician enters the time of the patient's entry into the laboratory, all of the patient's demographics, and the patient's vital signs and overall status upon arrival in the laboratory into the data system of the catheterization laboratory. In the integrated laboratory these data are distributed electronically to the physiologic recorder, the data recorder and the X-ray system, otherwise they must be entered into each of these systems separately. When the data have been entered, the nurse/technician begins a running, timed and detailed record of every event during the catheterization procedure. These detailed records document every event of the procedure with enough detail to become the critical information for a defense in a court of law!

The recording nurse/technician "balances" the pressure transducers electronically and numbers and identifies each recording. At the request of the operating physician

the recording nurse/technician sets the scale or "gain" of each of the pressure tracings or changes the gain of all, or individual, channels. When requested, the recording nurse/technician creates a paper recording of the pressure tracings and events occurring on the monitor screen. Most current physiologic recorders also time the events and recordings automatically in the computer record and on any paper recordings. The recording nurse/technician starts the paper recorder at the onset of a major or unusual event occurring to the patient in the catheterization laboratory. A well trained, experienced and attentive recording nurse/technician will begin this recording automatically, without specific instructions and before joining in any emergency efforts.

The data recording person places notations or comments on the *timed record* in the computer record of any changes in the patient's status and for all events occurring during catheterization. The values of the saturations obtained from the oximeter in the laboratory are entered into the running, timed record. In most laboratories these data are transmitted verbally from the nurse/technician in the actual catheterization room to the recording nurse/technician in the control room, who then enters the numbers manually into the computerized, timed record. The timed record also includes all medications and the dose and route of their administration. The introduction, exchanges, and specific manipulations of catheters, wires, sheath/dilators and special devices are all recorded. These recorded data include the type, size, and entry vessel through which the item is introduced.

The recording nurse or technician keeps the operating physician in the catheterization room constantly apprised of the patient's hemodynamic status during the procedure. The recording nurse/technician keeps track of, and records changes in pressures and the electrocardiogram throughout the entire case and watches particularly for any significant changes or *trends* in the patient's vital signs. Although the catheterizing physician can see the physiologic tracings on the monitors in the catheterization room, he or she usually is concentrating on the catheter manipulations directly on the table or on the fluoroscopic screen and cannot watch the physiologic tracings constantly.

When angiograms are obtained, the time, the site of the injection, the type and the amount of contrast, the pressure and rate of injection and the angles of the X-ray tubes are recorded on the continuous flow sheet. In the electronically integrated laboratory the X-ray settings are automatically inserted into the timed record of events, otherwise these values are inserted manually. In addition to recording all of the angiographic related information, a nurse/technician in the control room also adjusts the major settings for exposure rate on the X-ray equipment, the settings for amount of contrast, pressure of injection, flow rate and delay or "rise" time on the injector, "arms"

the injector and then initiates the injection during the angiogram. In some laboratories the nurse/technician in the control area also operates the start–stop of the angiographic equipment.

At the conclusion of the procedure, the time the various catheter lines are removed, the time hemostasis is achieved, the type of pressure bandages applied, the vital signs and overall status of the patient, the time the patient leaves the catheterization laboratory and who is accompanying the patient out of the room, are all recorded.

After the patient is removed from the catheterization room, the control room nurse/technician makes printed copies of the catheterization laboratory recorded data for the patient's chart and for a hard copy "catheterization folder" for each patient. When the catheterizing physicians have finished all measurements of the images on a digital system, the images are transferred onto the central storage computer for archiving and a copy onto a back-up storage system is performed by the control-room personnel.

Whenever possible it is desirable, if not absolutely necessary, to have at least two recording/operating nurses/technicians in the control area. During a complicated, difficult case and even with many pre-entered abbreviations and "pre-entered comments" in the recorded data of the catheterization laboratory computer program, the responsibilities in the control room exceed the capabilities of a single person.

Circulating nurse/technician

The third essential person in the catheterization laboratory is the circulating nurse/technician, who performs his/her activities predominantly within the catheterization room. This nurse/technician, along with the "manifold nurse/technician", sets up the catheterization room for the particular patient. This includes opening and arranging the sterile "catheterization pack", which includes the table drape, sterile protective drapes for adjacent equipment, towels, "operating gowns", flush bowls, specific monitoring lines, and, for each particular patient, the needles, wires, and introducers. Any other special or particular catheters or other consumable items specified by the catheterizing physician are added to the tray by the circulating nurse/technician. The circulating nurse/technician sets up any other special or unique equipment necessary for the particular patient including the patient-warming system, intravenous perfusion pumps, cardiac output computers, etc. The circulating nurse/technician may assist the manifold nurse/technician in setting up the manifold and in his/her duties when the manifold person is tied up with other duties.

When the patient arrives in the catheterization room, the circulating nurse/technician helps to position the patient on the catheterization table and secures them in a

comfortable position with tape or straps. This same nurse/technician connects the ECG leads, the pulse oximeter, and a cuff blood pressure cuff to the monitor. If the patient requires a Foley™ urinary catheter, this is inserted at this time by the circulating nurse/technician. When there is an intravenous (IV) line, the fluid connection to the line is secured. If there is no IV line and the procedure is being performed under deep sedation without an anesthesiologist, the circulating nurse usually starts a separate IV line once the patient is secure on the table. In such a circumstance, if the patient requires additional sedation, the circulating nurse administers it, either through the IV line or, when no IV is available, intramuscularly.

After the physician has infiltrated each potential vessel entry area with local anesthesia, each area is "scrubbed" thoroughly and widely by the circulating nurse/technician. The circulating nurse assists the physician in draping the patient to isolate all of the sterile fields with the drape and in draping all adjacent equipment which might come in contact with the operator or catheters and wires.

Once the catheterization procedure begins, the circulating nurse/technician takes the syringes with the blood samples for oxygen saturation determination from the physician, verbally notifies the recording nurse/technician in the control room of the location where the blood sample was obtained, injects the blood sample into an oximeter cuvette, places the cuvette in the oximeter device, reads the digital read-out to the physician/operator and to the recording nurse/technician, and makes a record of the result from the oximeter. The results from the oximeter are transmitted verbally to the operating physician and the recording nurse/technician in most laboratories.

There now is the capability of the digital read-out from an A-Vox™ oximeter to be transmitted electronically to a separate computer for a large display and a site-specific, timed, permanent record. This "communication" between the oximeter and the computer requires a special software program from Scientific Software Inc™ (Scientific Software Solutions, Charlottesville, VA). The site where the sample was obtained is selected in the program in either the oximeter or the computer directly by the circulating nurse/technician while the time of the reading and the oxygen saturation of the sample are recorded and displayed automatically on a computer screen. A timed, accurate record of the oxygen saturations and their specific sites from the entire catheterization can be printed at the end of the procedure. Eventually, with a small amount of additional effort on the part of the major manufacturers, these data should go directly to the recording computer in the control room without the current verbal/manual transmission!

In addition to running the oximeter samples, the circulating nurse/technician runs the blood gas analysis or

ACT tests on samples received from the physicians and assures that the operating physician, the anesthesiologist and the recording nurse/technician have the results of these tests. The same circulating nurse/technician is responsible for retrieving additional catheters, wires and devices as needed during procedure from the "in-room" or adjacent room storage. The circulating nurse/technician also has the responsibility for periodically loosening the restraints on the patient's arms and "exercising" the arms by putting them through a full range of motion to prevent brachial plexus injury. If the catheterization laboratory does not have a separate "runner" to retrieve supplies, blood, etc., from sites remote from the catheterization laboratory, the circulating nurse/technician performs that function.

This nurse/technician checks the crash cart for its stock of expendable supplies and drugs before the procedure begins and the defibrillator is pre-set according to the patient's weight and then checked for function. The circulating nurse/technician may be called on to introduce a nasogastric tube or a nasopharyngeal airway into the patient electively during the procedure. During the procedure, in the event of an emergency, the circulating nurse/technician is responsible for bringing the defibrillator to the bedside, "arming" the defibrillator and giving the paddles to the physician. The nurse/technician, however, should be capable of confidently applying the paddles and administering the current him/herself.

At the end of the procedure, the circulating nurse/technician assists the physicians in removing the table drapes and then applies the pressure dressings to the various puncture sites after hemostasis has been achieved. In a laboratory still using cine film, the circulator removes the film cassettes and makes sure the film gets to the person responsible for processing.

"Manifold nurse/technician"

The fourth essential person in the catheterization room is the "manifold nurse/technician". As the name implies, the manifold nurse/technician controls the "manifold"—i.e. the stopcocks, transducers and flushing of the pressure/flush lines connected to the patient. The manifold nurse/technician prepares and sets up the plastic pressure bags of flush solution, sets up and balances the pressure transducers on the manifold, and connects the pressure bags/flush system to the "manifolds". The pressure transducers are mounted on a stand attached to the side of the catheterization table, which is adjustable vertically to allow for the "mid-heart" position according to the patient's size. The manifold nurse/technician physically measures the patient's anterior-posterior chest diameter with a ruler/caliper and then adjusts the height of the transducer stand so that the transducers are *exactly*

at the level of the *mid* chest. The exact site of the "mid-heart" height can be determined by a brief look at the lateral fluoroscopy while measuring the chest with a ruler. The accuracy of *all* of the subsequent pressure measurements during the catheterization is dependent on this height measurement and the positioning of the manifolds/transducers!

The pressure bags of flush solution are "spiked" with the bags upside down so that the vent/connecting tubes are positioned upward. Once spiked through the vent/connecting tubes, the bags are squeezed until *every last bit* of air is evacuated from the bag as well as out of the "spiking" tube. Once the bag and tubing are emptied *completely* of air, three units of Heparin/cc of flush solution are injected into the injection port of the bag and mixed with the flush solution. Once the Heparin is added, the pressure/flush bag is turned right side up with the vents and tubing now at the bottom of the bag. The bag is rechecked for *any* residual air in it. When the pressure bag containing the flush fluid unequivocally is empty of air, the bag of fluid is inserted into a pressure cuff, pressure is applied to the cuff and the *tubing* is flushed of any remaining air. Once this bag and tubing system are emptied *completely* of all air, there is no possible way for air to enter that part of the system even when the fluid bag is squeezed totally empty or turned upside down again! The pressure bags are maintained with enough pressure to flush any or all parts of the manifold system and against any intravascular pressures (including systemic arterial pressures) with a good, steady flow of fluid.

Once the pressure flush lines are cleared, they are attached to the manifolds and the entire system including the manifolds, the stopcocks on the manifolds and the transducers are flushed while "tapping" each plastic joint/connection sufficiently to dislodge any micro bubbles, which invariably are trapped on the poorly "wetable" plastics. This assures that the system is completely free of even micro air bubbles and that quality pressure curves are obtained through this part of the system.

Once the patient is prepped and draped, the manifold nurse/technician takes one end of each sterile pressure/flush line from the physician and attaches it to the manifold of the appropriate pressure transducer. Each line is placed on a pressure flush to the table while the physician "taps" that end of the line and the in-line stopcock until it is free of air and any "micro cavitation". Each pressure curve displayed on the physiologic monitor is color-coded to match a specific transducer. Each pressure/flush line on the table is also color-coded and is attached to the transducer with the corresponding colored pressure tracings on the screen. The colors on the monitor screen can be switched or changed completely in the recording computer so that the colors of the flush tubing attached to the transducer and the monitor tracing always

correspond. This synchronization of the colors between the flush/pressure tubing and the monitor tracings easily and precisely identifies each pressure/flush line with a specific pressure transducer and tracing on the monitor, and greatly simplifies and increases the accuracy of the communication between the operating physician, the manifold nurse/technician, and the recording technician when requesting flushing, balancing or changing "gains" of any particular pressure curve.

The manifold nurse/technician flushes and "zeros" strain gauges at the beginning and as necessary during the procedure. During the catheterization procedure, the manifold nurse/technician turns the pressures lines on and off *at the manifold* and flushes the system and the catheters from the manifold as directed by the catheterizing physician. The catheterizing physician draws blood samples from a stopcock close to the catheter/line in the patient and, when sure that there is no air in the system, returns the stopcock to the flush/pressure position and requests the manifold nurse/technician to flush the line. The manifold nurse/technician should anticipate and be ready for the physician's next move or request whenever a sample is drawn or a line is disconnected. For example, when a catheter is disconnected from the pressure line in order to withdraw a blood sample, it *always* will need flushing when the line is reconnected to the catheter. At the same time it cannot be flushed until the physician is sure it is clear of air or clot. As the line *is being reattached* to the flush system, the manifold nurse/technician should have his/her hand on the flush stopcock/device awaiting the request for a flush. The physician should never have to request the flush a second time!

The manifold nurse/technician is trained to recognize poor and artifactual pressure curves and should be aware of what causes particular abnormalities in the curves. Any abnormalities noted in the pressure curves should be pointed out to the catheterizing physician if he/she has not noticed the problem. The most common problems with the pressure curves are a result of "micro-cavitation" in the fluid with the creation of micro bubbles as the fluid warms. The almost "non-wettable" nature of the plastics in the manifold, transducers, stopcocks and tubing allows for the progressive accumulation of these micro bubbles until they create an artifactual "over shoot" in the tracing. These artifacts in the pressure curves are eliminated by the meticulous "tapping" and flushing of all of the plastic areas of the tubing and connectors as the system is flushed with the stopcock open and away from the patient.

The other major responsibility of the manifold nurse/technician is the administration of intravenous drugs and solutions during the procedure, particularly when it is performed under sedation without an anesthesiologist. Supplemental sedation is the most frequent medication administered. At the time of very critical maneuvers,

often the manifold nurse/technician will have the specific amount of the additional sedation for the particular patient drawn into a syringe in advance and will already have the syringe attached to the manifold in anticipation of the necessary dose. In that situation, the additional sedation can be administered within seconds of when it is needed and requested. The manifold nurse/technician also administers other medications/solutions through the catheters, including supplemental narcotics, heparin, electrolyte and glucose solutions and supplemental fluids as ordered by the operating physician.

The manifold nurse/technician also assists the circulating nurse/technician in setting up the catheterization laboratory and securing the patient on the catheterization table. The manifold nurse/technician may assist the circulating nurse/technician in his/her duties during the procedure; however, the manifold nurse's/technician's primary responsibility is the manifold and he/she should not be away from the manifold for any significant length of time.

Extra "float nurse/technician"

During a very complicated case in the catheterization laboratory, particularly when multiple samples are obtained or where many different wires, catheters and devices are used, a minimum of three nurses/technicians is not sufficient to keep up with the pace of the case, much less operate the room efficiently. This is even truer when a complex therapeutic intervention is performed. When a complicated case is anticipated, the full complement of four nurses/technicians is assigned to the room. The fourth person helps with retrieving the multiple pieces of consumable equipment, may perform the blood saturation, blood gas or ACT determinations, and assists with the data recording in the control room. During a very long case, the "extra" nurse/technician trades duties temporarily with one, or more, of the other personnel in the room to allow them a transient break. The time saved by utilizing this fourth person easily justifies the additional salary.

In cardiac catheterization laboratories which still use cine film, the nurse/technician in the "float position" frequently is the person responsible for processing the cine film. In a cine film laboratory either this person, the technical director or the biomedical engineer turns on the film processor each morning. Turning on the processor includes running a quality control, test filmstrip through the processor at the start of each day.

At the end of each procedure the cine film cassettes are collected from the cine cameras in the catheterization laboratory. In the processing room of the catheterization laboratory, the film is threaded from the cassettes into the photographic film processor and the processor started.

After the film is processed, it is transferred by the nurse/technician from the processing reels to spools for viewing on cine viewing machines.

Technical director

One nurse/technician of the “catheterization team” functions as the technical leader/director of the catheterization laboratories. The technical director is responsible for maintaining the inventory of consumable items, arranging for the preventive and emergency maintenance of all of the equipment, and the scheduling of all of the catheterization laboratory personnel. With one laboratory, the time commitment for the technical director for just these administrative obligations is approximately half of the working time of one of the other catheterization laboratory nurses/technicians. With two or more catheterization laboratories, the technical director’s position is a full time job and represents an *additional* full-time employee equivalent (FTEE) for the catheterization laboratories.

In addition to the technical director, one nurse/technician is designated as the leader in each room, at least during each case. The “room” leader for the particular case is responsible for assigning the specific duties to each of the personnel in the room during the case and supervising their activities during the particular case, in addition to his/her assigned duties.

Catheterization laboratory support personnel

Each catheterization laboratory is dependent upon considerable additional support outside of the actual catheterization room. This includes a nurse for admitting and preparing the patient for the catheterization, administrative/secretarial support, environmental services/custodial support, biomedical support and “out of lab” engineering support.

Admitting/holding area nurse/technician

The primary responsibility of the catheterization holding area nurse is to facilitate getting the patient safely into the catheterization laboratory in the most timely manner possible so that there is no delay in the function of the catheterization laboratory. Most cardiac catheterization procedures are performed as an outpatient or “day case”, followed by an extended period of close observation. The patients are admitted directly to an admissions/holding area in the cardiac catheterization suite where the patient’s demographics and eligibility are verified, the administrative admission to the catheterization laboratory is performed, and the patient is prepared for catheterization. The catheterization admissions area may be exclusively for admissions to the cardiac catheterization laboratory,

but it is often shared with admissions for the cardiac operating rooms. When sharing is possible, considerable duplication of equipment and personnel can be avoided.

The admission procedure is relatively extensive. This includes administratively documenting the patient’s pre-admission eligibility for the procedure, assigning or verifying the patient’s medical record number, placing the patient’s identity bracelets on them, and the preparation and organization of the patient’s chart. Medically, the pre-admission history and physical examination are verified or obtained, the previous laboratory work is checked for its results and its completeness, and samples for any necessary additional laboratory work are obtained. When the use of blood during the procedure is considered a possibility, a blood sample is obtained for type and cross match or the availability of blood from a previous cross match is verified. Finally, it is assured that the procedure is understood by the patient/their family and that the “operating permit” is understood and signed by the appropriate person(s).

Even patients already admitted to the hospital, but coming from other areas of the hospital, are “admitted” to the catheterization laboratory through the catheterization laboratory admitting/holding area. This assures that the patients are completely ready for the procedure both physically and mentally and that they are physically in close proximity to the catheterization laboratory as soon as the catheterization room is ready for them. Having the patients prepared by the catheterization laboratory personnel and close to the laboratory facilitates a rapid “turn around” time in the catheterization room between patients.

The patient is dressed in a hospital gown and is encouraged to void before being placed on a stretcher/bed. The potential introduction sites for catheters are scrubbed (and shaved if necessary), a peripheral intravenous line is started and the patient is given their pre-medication at the appropriate time. If the patient is to receive general anesthesia, the anesthesiologist is informed of the patient’s presence and consults with the patient and family if they have not seen them earlier.

A nurse who is very familiar with the catheterization procedures performs the admission procedures and the preparations of the patient. This nurse is usually one of the catheterization laboratory nurses/technicians or, at least, is assigned to the catheterization laboratory and is *responsible* to the catheterization laboratory. The “holding area” nurse is responsible for the efficient and timely movement of the patients to the catheterization laboratory. The logistics of moving several patients through the holding area when there are two or more catheterization rooms with both rooms starting at the same time requires some assistance, temporarily, from one or more of the “in-room” nurses/technicians.

Ideally the patient is ready to enter the catheterization room as soon as it is ready for the patient. The holding area nurse/technician keeps the physicians in the catheterization room notified of the status of the patients in the holding area, keeps the patient/family informed of their potential starting time and, in doing so, helps to explain any delays from the originally scheduled time. When there are significant delays, the holding area nurse can arrange for a change in the patient's "nothing by mouth" status.

Administrative/secretarial support

In addition to the nursing/technician staff actually operating the catheterization rooms, each catheterization room requires significant administrative and secretarial support.

The extended schedule of the catheterization laboratory, the daily schedule of the patients, the schedules and the assignments for each of the laboratory personnel within each room as well as the schedules for the time off, holidays and "on call" for each of the personnel, all have to be created, maintained and "published". The time sheets for each of the personnel are maintained on a daily basis. Purchase orders for all of the consumable materials are completed and submitted expeditiously. As all consumable items are received, the original orders are compared with the items received and verified. The catheterization laboratory director is informed of any delays/discrepancies in the orders received. The administrative secretary prepares the billing sheet for the procedure, which includes each procedure performed and each piece of consumable equipment that is used in the catheterization laboratory during a procedure. This is submitted to the hospital billing office for the hospital charges.

A new cardiac catheterization record and folder are created for each patient, and for each time they undergo a procedure in the catheterization laboratory. This patient catheterization laboratory folder contains copies of the pressure tracings, a printout and tabulation of all of the hemodynamic data from the procedure, the diagram(s) of the particular heart, a descriptive summary of the important maneuvers and procedures performed during the catheterization procedure, a description of the angiographic technique during each angiogram along with a description of the findings from the angiograms, and a summary of the diagnoses and recommendations as a result of the procedure. Ideally, the catheterization summaries are transcribed by a transcriptionist, who is assigned to the catheterization area and who, in turn, understands the terminology and information in the summaries. When the transcriptionist is a member of the catheterization team, any questions about, or peculiarities of the catheterization summary can be clarified directly

and in a timely manner by the physicians or personnel in the catheterization laboratory. The more detailed and specific the catheterization report, the more necessary is this close working association. In laboratories where the complex anatomy is transferred to an individualized diagram, this close cooperation is even more essential. Copies of the finalized catheterization report are included in the patient's hospital record and sent to the referring physicians by the catheterization laboratory secretary.

The catheterization folders are stored in, or in the immediate area of, the catheterization laboratory, separate from the central hospital records, and are maintained by the catheterization laboratory administrative personnel. The catheterization records must be available for rapid retrieval whenever old information on the particular patient becomes necessary for subsequent catheterizations in the future. As many of the most recent catheterization records as possible are stored in the immediate catheterization laboratory area and the remaining (the majority) of the folders must be stored in "off-site" storage. When it is possible to reproduce a hard copy conveniently and *reliably* from an entirely electronic record, the catheterization records are maintained entirely in a computer storage system with a separate electronic backup.

In addition to the hemodynamic data, all angiograms are cataloged with permanent copies stored so they can be retrieved easily and expeditiously. This requires a monumental amount of organization and filing space. With a completely digital laboratory, a digital copy of the angiogram is stored on readily accessible, large "Raid" disks in the cardiac catheterization laboratory/hospital computer system. A separate hard copy of the digital angiogram is maintained as a separate archive. This separate archive copy is stored on either a digital tape, an optical disk or separate compact disks. In any case, these copies are cataloged and physically stored so that they can be retrieved readily or copied back into the electronic system.

Cardiac catheterization laboratories which still use cine angiography have the additional logistical and space problems of a cine-angiogram storage system which is useable yet conserves as much space as possible. Large "rolling files" of the cataloged cine films, which are maintained by the administrative personnel of the catheterization laboratory, are very efficient, but at the same time occupy large amounts of space in the catheterization area.

Biomedical support

The "in-house" biomedical engineer(s) for the catheterization laboratories is/are committed full time to the catheterization laboratories or, at least, they have their time prioritized for the catheterization laboratories. The complexity of the equipment in the modern cardiac

catheterization laboratory no longer allows for the laboratory to be dependent only on outside or manufacturers' engineers for the minute-to-minute support of the catheterization laboratory. Each minute of down time in an operating catheterization laboratory adds up to hours of extra, uncompensated expense to the hospital. The in-house biomedical engineers must be intimately familiar with all of the catheterization laboratory equipment, capable of repairing most of the electrical/mechanical equipment, and at least "resetting" major X-ray computer "lock-ups". The in-house biomedical personnel should be able to change common "boards" on the X-ray equipment and of equal, or more, importance, expediently identify major problems with the equipment which do require out of hospital manufacturers' support.

The in-house biomedical engineers must also have a good working relationship with the engineers from the manufacturers/distributors of all of the catheterization laboratory equipment in order to have good "out of hospital" and in-depth support. No in-house biomedical personnel are expected to be experts in each of the infinite types or the continual upgrades of the varieties of capital equipment in a catheterization laboratory. Similarly, no catheterization laboratory, no matter how large or how many catheterization rooms, can maintain a complete inventory of spare parts for all of the electronic, X-ray and mechanical equipment in the laboratory.

The catheterization laboratory equipment usually is extremely dependable; however, when it does fail, rapid *quality* service is indispensable. When service cannot be accomplished expediently by the in-house engineers, manufacturers' support that is immediately available and reliable is essential for the repair of malfunctioning equipment or replacement of defective equipment in the catheterization laboratory. A busy cardiac catheterization laboratory relies upon the manufacturers' local representatives to maintain an inventory of repair/replacement parts within a reasonable access to each laboratory. The availability of this manufacturers' support should play an essential part in the decision as to which type of equipment to purchase.

In 2005, no piece of equipment, no matter how large or where it is manufactured, is more than 24 hours away from a major city! Entire catheterization laboratories routinely are shipped around the world *and assembled* within a day for a *sales display!* The care of patients should receive at least as much priority as a sales exhibit!

A "down" catheterization laboratory is not just an idle piece of "real estate". Inoperable equipment interferes with the timeliness of the remainder of the medical therapy for the particular patient—for example the cancelation of surgery which is already scheduled for that patient following the catheterization. In addition to the huge inconvenience and disappointment, the patient or their

family incur extra expenses for their travel, the associated costs for lodging and feeding the remainder of the family, the lost work time for the "provider" or lost school time for the patient plus the additional hospital expenses of an extra stay.

A "down" catheterization laboratory also incurs significant ongoing expense for the hospital while the laboratory is out of function. The personnel on the catheterization laboratory staff still receive a salary, but are idle. There is a necessary rescheduling of any other patients in the catheterization laboratory (and possibly in the operating rooms and other hospital schedules to accommodate the canceled patient(s)). The physicians involved are not optimally productive and require urgent rescheduling of their own, as do many other persons'/patients' activities.

Housekeeping/environmental services

A cardiac catheterization laboratory is considered a sterile environment like an operating room. In order to maintain this environment, the walls of the room and each piece of equipment in the room require frequent scrubbing or wiping down to prevent dust from accumulating. The entire floor requires a thorough antiseptic mop scrub at least once a day as well as localized scrubbing between each case.

In order for a catheterization laboratory to have a rapid turn around for multiple patients during the day, the catheterization room must have a very rapid but thorough cleaning between cases. This includes scrubbing down the catheterization table with a disinfectant and actually scrubbing the floor of the room with a mop. All biologically contaminated materials must be gathered and disposed of properly in "bio-hazard" containers before a new patient can be brought into the room. Usually these custodial services are performed by individuals from an "environmental services" department. When the environmental services personnel are not part of the catheterization laboratory team, but are assigned from other areas of the hospital to help occasionally in the catheterization laboratory, there is frequently a significant delay in getting them back to the catheterization area at the critical times.

The nurses/technicians can (and often do) perform the between-case cleaning. However, these same nurses/technicians have numerous other absolutely necessary duties at the end of one case and just before the next case, but that incurs an obligatory delay while the nurses/technicians perform the extra custodial duties instead of their nursing duties. A catheterization laboratory service with two or more active laboratories justifies a separate employee from environmental services who is assigned to the catheterization laboratories. The environmental services person then becomes very familiar with the operation of the laboratories, is always available in the laboratory area and, as a consequence, is able to anticipate the

end of cases and facilitate the cleanup between cases. The employee from environmental services who is assigned to the catheterization area and becomes part of the functioning team also takes more pride in their individual area and tends to perform better.

Catheterization laboratory nurse clinician

Although often not included as part of the catheterization laboratory support personnel provided by the hospital, one, or more, nurse clinician(s) working with the physician(s) is/are an indispensable part of a catheterization laboratory team. The nurse clinician provides continuous contact/communication with the family or patient before, during and after the catheterization. This ongoing communication is invaluable in maintaining a solid rapport with the patient and their family.

The nurse clinician answers questions pertaining to the catheterization and checks on the patients when the physician is occupied in the catheterization laboratory or elsewhere and is not available. The nurse clinician can arrange for and schedule the necessary laboratory work pre- and post-catheterization. The nurse clinician actually performs the patient scheduling for the catheterization laboratory and coordinates support from anesthesia,

echocardiography, respiratory therapy and other specialty services. The nurse clinician prepares the patient for discharge and arranges for their follow-up care following the catheterization. When the patients are on “protocol” studies with follow-up visits required at specific times and with specific tests, the nurse clinician arranges these and assures compliance with the protocol. All of these activities *could* be performed by the cardiologist; however, the catheterizing physician is far more productive as a patient care provider and for “income generation” while actually performing catheterizations.

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