

# Organization and Management of IVF Units

A Practical Guide  
for the Clinician

Steven D. Fleming  
Alex C. Varghese  
*Editors*



Springer

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# Preface

A number of books have been published on the scientific aspects of assisted reproduction. However, they have been mainly aimed at the experienced practitioner alone, with limited benefit to those working in ancillary areas relevant to the IVF unit in its entirety. In contrast, the primary objective of this book is to provide an easy to read, comprehensive guide to establishing and managing an IVF unit from its very inception, with an emphasis on quality control. Therefore, an attempt has been made to direct the material at a broad readership, including those in the clinic, the laboratory, marketing, and IT.

While every effort has been made to ensure that the information contained in this book is as up to date as possible, it should be noted that manufacturers and distributors reserve the right to change product specifications and discontinue product lines without prior notice. New products will invariably be introduced in the future, and it is hoped that future editions of this book will address such innovations. The editors welcome feedback and further discussion regarding any of this book's content.

Sydney, NSW, Australia  
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**Part I**  
**IVF Unit Establishment**  
**and Organization**

# Chapter 1

## IVF Unit Location, Design, and Construction

Jason Spittle

### Primary Considerations During Planning

#### *Purpose of Clinic*

Firstly define what work will be conducted in the clinic. Will it be a full-service clinic offering everything from diagnostic services to IUI, IVF, and PGD? Will it be a boutique clinic offering personalized treatment by a small team or a large clinic offering efficient service to a large patient population? A clear vision of what services are intended will help define the space required and lead to effective planning.

It is also important to consider how the clinic will grow and expand over the next decade and beyond. Try to create some flexibility in the design to allow for changing the room configuration. Assisted reproduction is rapidly evolving and is quick to adopt new technologies. Space requirements will change as the science of IVF evolves. It is very challenging to renovate in an operational clinic. Similarly, it is hard to shut down a busy clinic, so time spent now on planning for the future will save a lot of problems later.

#### *Patient Pathway Review: What Will Be Done in the Clinic?*

Viewed simplistically, the process of diagnosing the cause of infertility followed by appropriate treatment represents the basis of care for patients and is universal. How this is implemented in practice varies widely around the world based on factors such as private versus public clinic operations, government and private insurance

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reimbursement, local legislative directives as to what techniques can be performed, relative affordability of treatment in a country, location, proximity of associated medical services, and the vision of the clinicians/owners/managers.

Careful consideration of the patient treatment pathway (Fig. 1.1) will indicate possible services the clinic can provide.

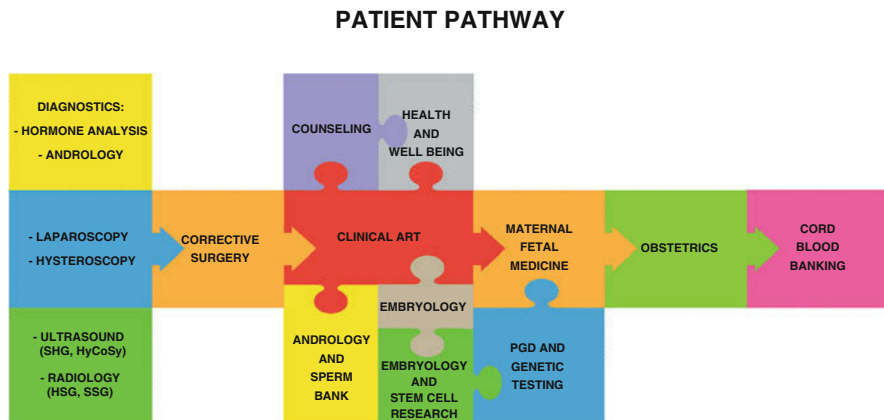
Many clinics, particularly those competing in a crowded marketplace, look to differentiate themselves by expanding their range of services and taking a more holistic approach to patient care.

Such ancilliary services includes: diagnostic services such as pelvic ultrasound examinations eg., sonohysterography (SHG) or hysterocontrastsonography (HyCoSy), hysterosalpingography (HSG), or testicular ultrasound (increasingly used to assist in diagnosis of male infertility); hormone analysis; andrology; and gamete cryo-banking.

With improvements to the size of instrumentation, hysteroscopy can now be performed in-office with minimal anesthesia requirements. This reduces the cost to the patient of performing hysteroscopy and might assist in improving patient outcomes [1].

Given the proven benefits to reproductive performance of weight reduction [2] and improving patient health prior to undergoing IVF treatment, many clinics now offer dietary advice and management, stress management classes that cover modalities such as meditation, tai chi, and yoga. Psychological counseling is also mandatory in some countries, such as Australia, and routinely offered in many others.

Pre-implantation genetic diagnosis (PGD) is an area of ART that has undergone rapid technological change over the last decade. The advent of next generation sequencing (NGS) of the entire genome promises to simplify the process of PGD, making it more cost effective, easier and faster to perform and more accurate in



**Fig 1.1** Patient treatment pathway

detecting a wider range of genetic abnormalities [3]. Accordingly, provision for performing embryo biopsy and NGS testing and accompanying genetic counseling for the patients may be warranted.

Following successful treatment, pregnancy management including high-risk pregnancies, maternal fetal medicine procedures such as fetal karyotyping from maternal blood, chorion villus biopsy, amniocentesis, and ultrasound might also be offered alongside obstetric services. Finally clinics might also wish to offer cord blood banking to parents.

Although private research is diminishing as ART treatment protocols and outcomes are optimized, some clinics may wish to pursue research. This can be entirely self-funded or performed in conjunction with universities or commercial partners. Depending on the local tax laws in each country, clinics might be able to claim a tax rebate on medical research or attract grant funding from bodies such as the National Health and Medical Research Council or similar.

Determining what will be done in the clinic both now and with a view to future expansion is vital. This vision will be used to create a description of space needed, services required and ultimately the business model to describe how the clinic will be funded. It might not be possible to offer all services initially; however, these can be added later as the clinic expands if allowance (and space) is made during planning.

## **Outsourcing Versus Insourcing**

Determining what services can be offered within your clinic coupled with financial modeling and possibly space restrictions are likely to determine what services might need to be outsourced. This in turn gives indications as to potential locations for basing the clinic; as for patient efficiency, having facilities nearby that can offer the needed services is important. If they are within easy walking distance or have readily accessible parking, so much the better.

## **Location**

### ***Patient Population Demographics***

Establishing a new clinic requires significant financial input, so careful estimation of expected cycle numbers is necessary to determine the size and scope of what the clinic can offer. As revenue is driven by patient throughput, if available, population demographics may assist to identify areas within a city or region populated by people of childbearing age (20s to early 40s). Identification of areas populated by

potential patients and not well serviced by existing clinics may provide a better opportunity to found a successful clinic rather than opening up across the road from a well-established clinic.

## ***Zoning***

Having identified potential locations for the clinic, check the relevant zoning requirements for that location along with any building restrictions likely to impact on the design and construction of the building. It is essential to first clarify what permits/permissions, etc., the local council or government requires as these might restrict what can be done on any chosen site. Always obtain permissions in writing before commencement.

## ***Patient Access***

In today's society everyone, it seems, is time-conscious and patients are no different; they are keen to minimize the inconvenience of infertility treatment in their lives. If they have a choice they may opt for clinics that offer the simplest access and most rapid turnaround. It is therefore important to consider how easy it is for patients to access the clinic. Is it close to public transport such as train stations and bus stops? Is there sufficient car parking available for patients—and staff? Are there bicycle racks where nearby residents wishing to ride can secure their bicycles? If in a multistory building, are the lifts efficient so that waiting time is minimal? These might seem like small issues, but to patients attending regularly for injections, ultrasound, and blood tests they can be a major annoyance and add to the stress they experience.

Another consideration is wheelchair access for patients with mobility restrictions as well as for emergency access for ambulance services, should any patient require this.

## ***External Pollution***

It is well established that volatile organic compounds (VOCs) are commonly found inside IVF laboratories [4] and can significantly affect the performance of an IVF lab. It is possible to remove these from the lab environment, but it is better to try to minimize those entering the lab if possible. For this reason when choosing a site for a new lab be aware of what VOCs might be emitted upwind of your clinic from local industry, particularly in heavily industrialized cities where environmental controls

on emissions might not be rigidly enforced. On a more local level also take note of major roads, as they can be a large source of VOCs, particularly from diesel vehicles and particulates. This necessitates finding a balance between providing easy access for patients and sufficient distance to minimize external pollution. Obviously it may not be possible to avoid exposure to external VOCs in which case focus can be put into removing these from the internal air inside the clinic and this is discussed below.

Another good reason for maintaining a sufficient distance from major roads is that the exposure to traffic pollution has been well studied and linked to respiratory disease and generally poor health of individuals exposed. External pollution tends to concentrate inside buildings, particularly in winter, and combined with seasonal viruses can contribute to health issues in those working in the building. As no clinic can afford to have staff absent a case can be made to consider using HEPA and carbon filters to purify all the internal air fed into the clinic.

External vibration and ICSI do not mix. Anti-vibration tables will assist; however, if external sources of noise and vibration such as trains, subways, and roads carrying heavy vehicles, plant and equipment can be avoided, do so. ICSI is stressful enough to perform without being challenged by vibrating pipettes!

### *Electromagnetic Fields*

The question, do electromagnetic fields (EMFs) have the potential to negatively impact embryos in culture is one that has not been adequately answered and it could be said that research in this area is still in its infancy. Luo et al. found that EMFs could cause DNA damage in pre-implantation embryos in vitro; however, the electromagnetic field was directly applied close to the culture dishes inside an incubator [5]. It is possible that the metal walls of an incubator could act as a Faraday cage to insulate the contents from EMFs thereby protecting embryos in culture. At the moment this is a topic with more questions than answers, however as laboratories have significant electrical wiring and electronic equipment, and we move to greater use of computers communicating wirelessly to equipment via wireless routers, it is apparent that we work in a “sea” of electromagnetic radiation. Electrical equipment particularly that accredited for use in operating theaters is required to meet regulatory standards for EMFs to avoid interference with other electronic equipment. Nonetheless, it may be advisable to consider what has the potential to emit radiation and to consider its location relevant to where embryos are cultured. The health of staff working in the laboratory should also be considered from this perspective, as there is increasing evidence that some individuals can be sensitive to electromagnetic radiation [6].

## **Design**

The principles discussed apply to both building a new clinic from the ground up and adapting an existing building or space. If renovating an existing space, it is worthwhile considering stripping back the space provided to an empty “shell” as then you can identify what materials and piping are in that space and have complete control over what you then place into that space. This also aids the design process as it is then constrained only by the floor area available, ceiling height and any load bearing walls or piers.

### ***The Planning Process***

Starting with a blank sheet of paper can be a daunting task, so the following may assist to provide a starting point and aid logical decision making as part of the planning process.

### ***How Much Space Is Required?***

Create a list of the functions that will be performed in the clinic and assign a room or rooms to each. Nominate who will work in that room and assign a floor area to it. Equipment and furnishings can also be listed, and this will help determine floor area.

### ***Spheres of Influence***

The heart of an IVF lab is the embryo culture area. Consider viewing this as the central point in a series of concentric circles comprising the other areas of the clinic. These will impact what happens in the embryo culture lab to a greater or lesser extent, so mapping the areas of influence may help provide a visual map of interacting functions and factors. Locating related areas close to one another creates efficiency, while separating high traffic areas such as waiting rooms from vibration sensitive areas such as the intracytoplasmic sperm injection (ICSI) workstation just makes sense. The same applies to separating areas sensitive to VOCs such as the culture laboratory from the more dirty areas in the clinic such as the cleaner’s room. Using this method and the rooms listed in the section above, create a layout for the clinic. Common sense dictates that areas with similar functions will be grouped together. For example, the egg collection room/operating theater and culture lab will be side by side. The patient reception, waiting room, consulting and accounting areas will similarly be located in close proximity, etc. (Fig. 1.2).

### Process Mapping

This is an old concept that can be incredibly useful when designing a clinic. Basically it involves mapping on paper (or using one of many available computer programs) the processes that will occur in the clinic. Maps provide direction. They indicate dangerous ground as well as safe paths, highways versus tracks. Committing ideas to paper allows the design team to break down processes into critical steps, to objectively examine these and identify issues. This allows potential difficulties to be avoided early in the design process. The clarity that comes with process maps should aid in creating efficient systems and reduce risk.

Process mapping can be used to map patient flow through the clinic, and include who comes into contact with the patient, what interactions occur, what resources are required, what time who spends where, what risks are involved, where bottlenecks are likely to occur, etc. Similar maps can be undertaken for almost every activity or procedure. Examples for consideration include, sample

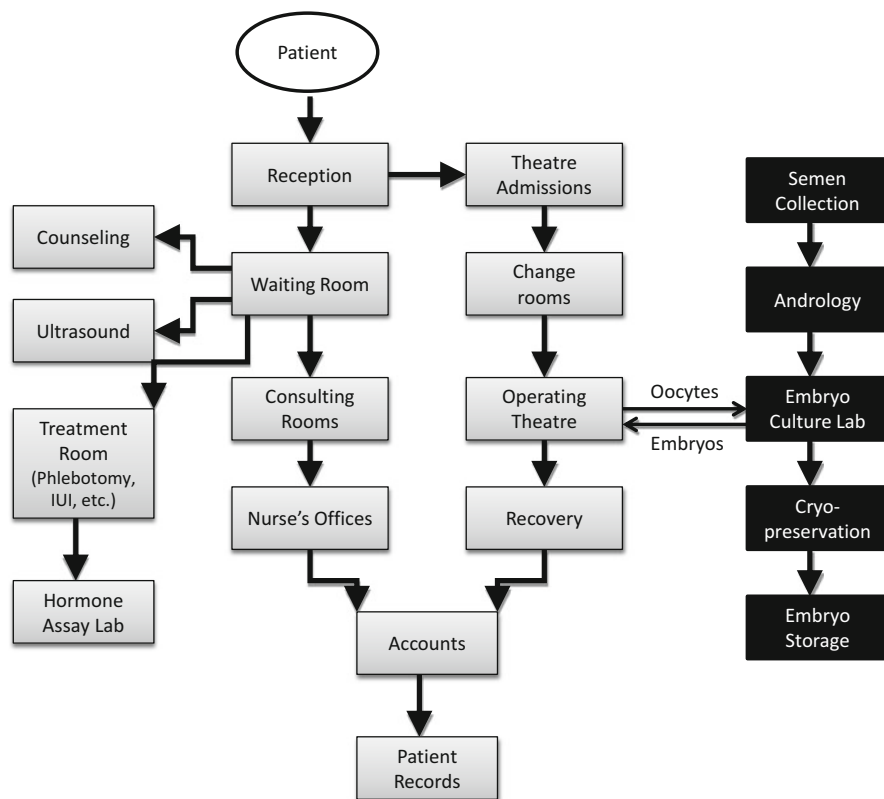
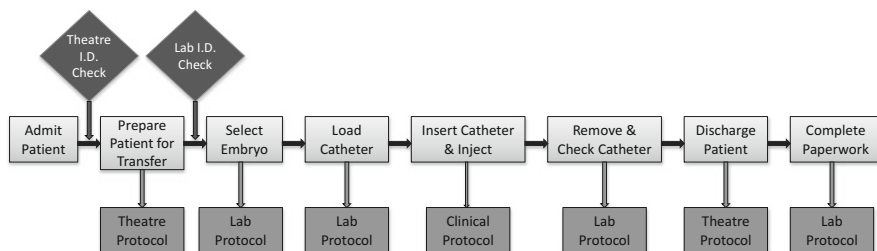


Fig 1.2 Patient and sample flow through the clinic guides proximity of functional areas



**Fig 1.3** Example of a flowchart for an embryo transfer procedure. Each process will have a separate, more detailed protocol assigned to it

collection (e.g., blood or semen), the ovum aspiration process, handling of oocytes, ICSI, embryo culture, IUI, cryopreservation, embryo transfer (Fig. 1.3), data entry, billing, and giving patients disappointing news.

If you are new to process mapping, it is easier to start with the big picture processes and keep them simple. Each of the steps mapped can be the basis of another layer of process mapping and these can be built up until all the key processes in the clinic are described. Once the basics have been outlined they can then be used as the basis for more detailed examination, particularly those related to risk management, creation of standard operating procedures (SOPs), designing training requirements, and a myriad of other uses.

## Essential Services

### *Power*

All the critical functions of an IVF theater and lab are dependent upon electricity. Not only is failure of supply a major issue, the quality of electricity supplied to a clinic is also important. Spikes and surges otherwise known as brown outs and white-outs and other fluctuations of supply can cause problems for sensitive electronic equipment. These can occur in the short term resulting in shorts or failure, or over the long term having a cumulative effect, gradually weakening the equipment until failure occurs. This commonly occurs in many developing countries, where the power supply is inconsistent.

Backup in case of power failures is essential and options can include generators and uninterruptable power supply (UPS) systems. Many backup systems also provide power filtering to remove the problems associated with spikes and surges. It is worthwhile in any country to consider the benefits of additional power filtration. It can assist protecting vital lab systems, computers, databases, and the increasing number of electronic devices being employed in medicine.

Generators are usually located external to the building in a secure room, which is readily accessible for servicing, often near to the car park. Generators usually run on diesel or petrol, which is stored in a tank near the generator. Fuel is a potential source of VOCs so should be placed as far away from the air-conditioning air intake as possible.

## *Gas*

The IVF lab requires special mix gas or N<sub>2</sub> and CO<sub>2</sub> for its incubators and clinics with an operating theater will require anesthetic gasses. Gas cylinders are both heavy and dirty and are difficult to move around. The ideal location for cylinders is next to the car park or in a location where fresh cylinders can be collected and empties removed without the need to transport cylinders far from the delivery vehicle. If the clinic is located within a multistory building, ensure that access is available to a service elevator to separate deliveries of gas, liquid nitrogen, and supplies from patient access elevators.

Assigning a small room or caged area to store cylinders and the regulators for each of the gasses used is the ideal solution. Keep gas cylinders out of the culture lab wherever possible. Appropriate storage racks for securing the cylinders from accidentally falling over will reduce the risk to property and staff. Appropriate fittings can be obtained from a local gas supply company.

Any gasses supplied to the laboratory or operating theater should be connected via an automatic changeover regulator system, to ensure that the gas supply does not run out. These are usually supplied and installed by an anesthetic gas supply company. Investigate the quality of the regulators used in the changeover units as these can vary in quality. Some can contain neoprene diaphragms, which have the potential to release VOCs into the gas stream. Regulators with stainless steel diaphragms avoid this issue.

During installation of the gas supply system plumbing will be installed to supply gas into the laboratory. Gas piping is usually made from copper or stainless steel and much debate has occurred over what is the best material for use in an IVF setting.

Another option is to use polytetrafluoroethylene (PTFE) tubing for plumbing gas. This is an inert, non-embryo-toxic material that is ideal for special mix gases as it is not permeable to CO<sub>2</sub>. Of the many types of plastic available, even those recommended as food or medical grade, PTFE is the most inert and has less extractable elements such as plasticizers (e.g., phthalate) that can cause embryo toxicity. Silicone is another inert plastic but is permeable to CO<sub>2</sub>, so not suitable for pre-mixed gases as the CO<sub>2</sub> concentration will drop proportionately with the length of the tubing, leading to wrong gas concentrations entering the incubator. PTFE tubing has the added advantage that being flexible it can be easily rerouted in the event that the lab requires reconfiguration. It can be purchased as plain tubing or covered in braided stainless steel for protection. It is available from companies like Swagelok®. The addition of Swagelok® fittings allow it to be readily attached to regulators, gas taps and other gas supply fittings.

## ***Liquid Nitrogen (LN<sub>2</sub>)***

Liquid nitrogen is an important consumable used in cryopreservation and storage of gametes and embryos. It is also hazardous and requires care in handling. If cryo-storage will be performed in the lab a regular supply of LN<sub>2</sub> will be required. The volume of cryopreservation performed and quantity of samples stored will determine delivery and storage methodology. Small and startup units usually use standard dewars containing from 6 to 10 canisters; larger units may choose to use liquid or vapor phase storage vats. Large cryobanks are better served by having a large on-site storage vessel, preferably sited directly outside the lab and in a room that can be easily accessed by delivery personnel. Piping can then deliver LN<sub>2</sub> to the cryolab where it can be used to top up dewars, feed directly to storage vats via an automated top-up system, and provide a source of LN<sub>2</sub> for filling vitrification vessels. Keep piping as short as possible and insulate to minimize loss of LN<sub>2</sub> during delivery. Depending on the volumes used, LN<sub>2</sub> is either delivered in the form of several small tanks or for high volume users the external tank of LN<sub>2</sub> is filled from a delivery truck. In either event external access by delivery vehicles and a transport path needs to be planned.

The cryolab or room where LN<sub>2</sub> will be dispensed and used requires careful design. Some spillage of LN<sub>2</sub> from dewars is inevitable, so floor coverings need to be able to resist the sudden change in temperature and contraction that accompanies this without cracking. Proper ventilation is critical to ensure that LN<sub>2</sub> vapor is rapidly removed and replaced with fresh air, and an oxygen meter installed to warn staff if nitrogen gas has displaced all the oxygen in the room. As this can cause staff to fall unconscious and asphyxiate the investment is warranted.

## ***Air-Conditioning and Air Quality***

The relationship between air quality and environmental health is a global issue, although worse in some cities than others. IVF laboratories require pure air to ensure that culture systems remain uncontaminated with pollutants such as VOCs, particulates, and infectious agents such as bacteria and fungi. After ensuring the stability and rapid recovery of temperature and pH of the embryo culture system, VOCs present the next major risk factor to be controlled. As VOCs are ubiquitous it is safe to assume that they will be present in and around any building, although those close to heavy industry and freeways are likely to be more challenged by high concentrations. The first need is to understand where the air is sourced from and potentially what is in it that will need to be removed. VOC meters are available for hire or purchase and can be very useful in this respect, although they do vary in sensitivity. Parts per billion (PPB) meters are by far the better choice as many VOCs can be deleterious to embryos at a PPB level and will of course not be detected by a parts per million (PPM) meter. If VOCs are detected, having the air analyzed to determine what

chemicals are present can assist in determining what is the potential risk of toxicity, as not all VOCs are embryo toxic.

Apart from the general quality of air in the environment around your chosen site, consider where the air inlets will be placed to feed air into the air-conditioning and supply system. Conventional wisdom dictates that the air-conditioning system be placed next to the car park to make it easy for the service agent to drive their vehicle close to the machinery for easy servicing. Unfortunately this results in car exhaust fumes being routinely sucked into the air-conditioning and fed into the lab, particularly if the car park is enclosed. Ideally the air intake should be on the top of the building or as far away from car exhaust fumes as possible.

The second consideration is design of air recirculation pathways within the building. It is common for internal air to be recirculated to reduce the expense of heating or cooling external air. Air exhaust vents carry the room air back into the conditioning system where it is mixed with a percentage of external air and then fed back into the building, the key point being that air from “dirty” areas that may contain VOCs might be piped back into the lab. As VOCs are concentrated inside buildings and many are emitted from furnishings, finishes and construction materials, it is wise to view internal air as potentially toxic. One solution is to keep the culture lab’s air-conditioning on a completely separate circuit, to more closely control the air quality entering.

While it is possible to remove VOCs from within a lab by use of Coda® Towers or similar filtration systems, it is preferable to remove the contaminants before they enter the lab in the first instance. While HEPA filters will remove particulates, they will not remove VOCs so consideration should be given to installing appropriate filtration systems designed specifically to remove VOCs. They usually comprise filtration systems consisting of activated carbon and an activated alumina substrate impregnated with potassium permanganate. More recently photocatalytic systems that work with titanium oxide have become available. These are designed to fit industry standard air-conditioning ducts and can be retrofitted into existing buildings. Polarized media filtration devices that function using electrostatic attraction may also be useful to filter submicron particles.

Clinics that operate in particularly humid environments should also consider means of controlling the relative humidity in a laboratory. This is due to the correlation between relative humidity and the growth of molds. The presence of mold in an incubator can be disastrous to the embryos in culture and once colonized an incubator can be very difficult to completely sterilize. In addition, high humidity levels can saturate the carbon being used in carbon filters to remove VOCs rendering them ineffective and releasing the VOCs trapped by the carbon.

The ambient temperature in both the theater used for oocyte pickups and transfers and the culture lab is best run as warm as bearable, preferably above 24 °C, to reduce thermal shock to oocytes and embryos exposed to room air, unless environmental chambers are used for all embryo handling, ICSI, and manipulation procedures. It is therefore preferable to have these rooms on a separate circuit whereby their temperature can be controlled without affecting other areas in the building.

## ***Lifts***

Lifts are a source of vibration and VOCs so while they may be essential to assist patient access, consideration should be given to the siting of the lift in relation to the culture and ICSI laboratory. Ideally there should be separate lifts for patients and for moving deliveries of consumables such as gas and liquid nitrogen.

## ***Emergency Access***

Consideration should be given in the planning phase to emergency access for services such as the ambulance and fire brigade.

Paramedics may require access to the operating theater or collection room in the event that a patient suffers a mishap that is not treatable with the facilities available in the clinic. Passages and doorways should be wide enough to permit easy passage of a gurney to remove patients.

Similar thought should be given to the access that may be required for fire brigade personnel to enter the building in case of fire. This will accompany thought on how to rapidly remove tanks of stored embryos and patient records should the integrity of the building be in jeopardy.

## **The Floor Plan and Room Design**

### ***Clinic: The Doctor, Nurse, and Patient Interface***

#### **Ambiance and Stress Reduction**

As attending an infertility clinic brings attendant stress for patients, the creation of a welcoming, relaxed ambiance can do much to help put patients at ease. This can be achieved in many ways, limited only by imagination. Plants, fish tanks, external views of a natural environment, paintings, music, lighting, and specific wall colors can all assist in relaxing patients. Other examples (that have been tried) extend to having a grand piano in the foyer playing relaxing music to patients attending for morning blood tests, having four or five small separate waiting rooms, so that patients have complete privacy and rarely see other patients, having tea, coffee, and refreshments on hand, a library of relevant books on infertility for patients to read, Internet stations, TVs for entertainment, etc.

Depending on cultural background, patients often like to mix with other patients and share the highs and lows of the journey. This can be beneficial as a means of mutual support. In this instance creating a space where patients can socialize with



**Fig 1.4** A relaxing waiting room where patients can socialize

each other before or after treatment can help create a supportive environment. Figure 1.4 shows a relaxing waiting room where patients can socialize over coffee.

Patients are often in a rush to return to their regular employment, so efficiency in checking in patients in and then seeing them for blood tests, ultrasound, and consultations is appreciated and can help mitigate stress.

A clinic does not need to be “clinical” in appearance, particularly the patient consultation areas. With appropriate design clinics can operate in old, renovated homes, with antique furniture, that feel more like visiting a friend’s house than attending a medical practice. There is no right or wrong in styling, only efficiency in how the patient flow works and what suits the cultural temperament of the patients. Advice from a qualified interior designer can be beneficial and as they are used to working with architects, and they can be a useful part of the design team.

### **Privacy and Confidentiality**

Maintaining patient confidentiality, if not a law, is a significant expectation in most countries. In an infertility clinic, this is hard to maintain as patients usually see one another while attending for appointments or tests. Patient files can be left on desks, or patient lists posted where patients can see. Some of this is

unavoidable, however beyond seeing a face in the waiting room, it is imperative that patient data and treatment records are kept strictly confidential and access is controlled to those who have a legitimate need to work with it. Commonsense is the cornerstone of building processes that maintain confidentiality. Methods for controlling access to different sections of the clinic should be decided during the planning phase. Numerical keypads or key cards that electronically open doors to admit staff can help control who can access particular areas such as the lab or record storage/filing rooms. Patient files should be kept in a locked room, or locked filing cabinet. Files should not be left unattended on desks; they should be secured when not being worked on.

As many clinics are becoming paperless or at least moving to patient management software and databases, regulations and training for staff on how maintain confidentiality in terms of what can be accidentally viewed on a screen, can assist to maintain what is becoming an important issue for clinics. Similarly, maintaining login passwords and changing them regularly is also key to maintaining the integrity of patient data, as is restricting access to areas where computers are kept.

Many countries now have strict privacy laws and take a dim view if patient data is stolen so systems need to be put into place to secure any data put into laptops and taken outside the clinic, as well as access protocols to virtual private networks (VPN'S) used to allow external access to the clinic's data.

When designing the consulting rooms consider the use of soundproofing materials so that the people in the next room cannot hear what is being said. Plasterboard used for building walls comes in a soundproof grade and insulation installed inside wall cavities can also assist.

### **Semen Collection Rooms**

Providing a semen sample is a part of undergoing infertility treatment, but this can be embarrassing for men. While the option of producing at home is one possibility each clinic usually has one or more rooms for semen collection. Discreet placement of these rooms so that they can be accessed without walking in front of a waiting room full of other patients is desirable. So too is having a system that clearly indicates which room is occupied as this can save much embarrassment and additional stress to the patient. Consideration should also be given to using soundproofing materials to reduce extraneous noise entering these rooms.

### **Treatment Rooms**

As most patient examinations and treatments involve at least a partial disrobing, give attention to ensuring privacy for patients in treatment rooms. Pay particular attention to possible lines of sight through open doors, to avoid inadvertently exposing patients when clinic staff enter and leave rooms.

## **Counseling Rooms**

As psychological counseling is mandatory in many countries and commonly offered to assist patients cope with their treatment these rooms should be soundproofed and designed to present a comfortable and safe environment. Even in clinics with high pregnancy rates, many patients do not become pregnant, so both patients and staff appreciate having a private space to deliver disappointing news.

## **Patient Traffic and Ergonomics**

Creating an efficient environment to receive and see patients can make a huge difference to how a clinic functions, especially at the busiest times. Think about the most common patient pathway within the clinic and consider how the clinic layout can best facilitate this. For example patients tend to flow from the main entrance, to reception, the waiting room, Doctor's office, nurses' office, back to reception and out the main entrance again. Designing a floor plan to allow patients to move through the clinic with minimal crossing of paths or backtracking, can make the clinic function much more efficiently and avoid bottlenecks, confusion, and patient mix-ups. Spending time with a good architect and discussing patient flow and the different services offered will be of great assistance in finalizing a design that works well.

## **Information Technology**

IVF clinics run on data, much of it based around patient records. A paper-free record system is a possibility that can add efficiency to a clinic's operation. The advent of tablet computers means that data collection can be portable and adaptable to a clinic's needs. Whether designing a new system or purchasing a commercial system consideration needs to be given as to how the computer system that runs the clinic will operate. The reason for this is that a computerized clinic will require considerable wiring of consulting and examination rooms, the accounting department, nursing and reception, and each workstation in the IVF lab. Even if wireless is used, wiring of routers is also a consideration. In addition, the scope of computerization required to run the clinics of the future will require a central server to operate the system and this will require a temperature controlled room with secure access and a UPS, so this needs to be added to the floor plan.

In addition, as clinics become more computer-dependent and as clinical and patient data is mined for information, office space for information technology (IT) personnel will also be required.

## Laboratory

The IVF laboratory forms the heart of an IVF clinic and has a major role to play in creating pregnancies. Given its importance, significant planning time should be allocated to optimizing the design of this space.

Modern assisted reproduction requires several functional areas such as the andrology lab, embryology/culture lab, cryopreservation area, and perhaps a research lab. While it may be tempting to place all these into one big lab for efficiency the negatives outweigh the benefits and it is better to keep these as separate, though closely related rooms.

Planning should be done with risk management principles in mind. These principles form the cornerstone of thought processes, design and operation of the lab and are intended to manage and reduce the risk of adverse events happening to patients, staff and the gametes and embryos in the lab. There are a number of good texts published on the subject, for example Mortimer and Mortimer [7], and an understanding of the principles of quality assurance and risk management will be a great help in designing any new clinic.

### *Security: Stored Embryos, Patient Data, and Staff*

#### **Controlled Access**

Given the irreplaceable value of gametes and embryos, both stored and in culture, the embryo lab and environs is not a place for through traffic or persons who do not have a legitimate reason for being there. For this reason securing access to this part of the facility is a simple measure that can help avoid many problems. This can be achieved through the use of security doors operated with key cards or keypads with a numeric access code. The benefit of key cards is that the door locks can be connected to a central computer and staff movements traced if required. This can be particularly useful as units commonly operate seven days a week and after-hours access by staff is both common and necessary.

### *Ergonomics and Efficiency*

IVF laboratories can be extremely busy places with a lot of traffic through the lab. This creates the risk of embryologists bumping into each other and the possibility of dropped dishes containing patient's embryos. Planning the layout giving consideration to the movement of gametes and embryos through the culture processes will help avoid excessive and unneeded staff movement and crossing of pathways. Manufacturing companies aim to have a one-way flow of the product during manufacturing with no crossing or backtracking of this pathway. This minimizes the risk of mixing batches or raw materials. The same considerations apply to IVF

labs. Consider that the journey begins in the operating theater or room used for egg pickups. From there the follicular aspirates go to a workstation for oocyte identification. The oocytes are then placed in an incubator waiting insemination. If ICSI is being performed the oocytes will then move to the ICSI stations and then back to incubators for culture. From there embryos are then graded and prepared for transfer and finally excess embryos are moved to a cryopreservation area where they are frozen or vitrified.

Aim to keep this path unidirectional with zones defined by the work performed in them. ICSI is a task that requires intense concentration, so aim to keep the ICSI area segregated from the rest of the lab to avoid the distractions caused by staff moving behind the ICSI embryologist. Accidental bumping and the added vibration caused by movement make performing ICSI harder, so if these risks can be removed it makes the process more efficient. For example consider having an alcove off the main area of the lab set aside for ICSI, or place the ICSI area at the end of a room where there is no through traffic.

Most embryology involves moving eggs or embryos from an incubator to a microscope and back again. The closer that incubators are to the microscope the less movement involved, which reduces the risk of accidents, reduces the time out of the incubator and increases efficiency. The advent of small benchtop incubators means that these can be easily sited next to microscopes and workstations, reducing the need to stand up and move embryos across a lab to a bank of large “box style” incubators. As it is well known that temperature and pH fluctuation is undesirable for embryo culture, another advantage of having benchtop incubators close to the microscopes is that it helps to minimize the duration of exposure of the embryos to ambient conditions and the faster recovery times of benchtop incubators return the culture conditions to the desired state quicker, thereby reducing stress [8].

## *Airflow*

Hospital theater complexes operate as a series of cleanrooms, where the most critical area, usually the operating theater, is the cleanest and kept at a higher pressure than surrounding rooms to ensure air flows out from this room and in doing so prevent contaminants entering the room.

If the embryology lab is adjacent to the operating theater, consideration should be given to running the lab on a separate circuit and trying to minimize the ingress of air from the theater into the lab. The reason for this is that anesthetic gases, sterilizing and cleaning solutions used between cases, and disinfecting solutions are all potentially embryo toxic compounds and should be excluded from the lab environment. This is particularly true if the theater is used for purposes other than ovum aspiration and embryo transfer as a wider range of chemical substances may be used.

Careful consideration also needs to be given to the location of air-conditioning outlets with respect to placement of incubators. As the physical mass of benchtop style incubators is smaller than that of conventional big box incubators, they are

more sensitive to being cooled by drafts of cold air exiting the air-conditioning vents. Transient cooling can sometimes trigger their alarm systems, which is an annoyance, particularly after hours. Therefore ensure that cool air does not blow directly onto the benches where incubators will be sited.

### ***Windows and Sunlight***

A similar problem to that caused by cool air from air-conditioning vents can be caused by direct exposure to sunlight. If there are windows in the lab, sunlight shining directly onto incubators can cause transient heating and alarming. In general most labs aim for a low level of light to minimize light exposure to embryos while out of the incubator, so would usually shade windows to reduce the amount of ambient light entering the lab.

### ***Andrology and Diagnostic Labs***

These labs commonly work with a wide range of potentially toxic chemicals (e.g., PAP stains) as well as pathogens. These areas should be separated physically and be served by separate air-conditioning systems to ensure no crossover of toxins from the diagnostic lab into the culture areas. The use of biosafety cabinets should be considered.

### ***Computerization and Wiring for Quality Management***

Modern IVF laboratories should run a comprehensive quality assurance program to ensure consistent outcomes and rapid identification of nonconformance. To this end most items of lab equipment should be independently monitored to ensure they are functioning correctly. Examples are remote temperature and CO<sub>2</sub> monitoring of incubators, fridge and freezer temperatures, liquid nitrogen levels in dewars, ambient temperature sensors, etc. Monitoring devices can be hard wired to a central monitoring database, so plan to incorporate wiring channels for monitoring equipment to the planned location for all capital equipment in the lab.

As some level of computerization is required within any lab, space needs to be allowed for computer access for data entry and review. Depending on the type of patient management system used, the lab could be paperless in which case touch screens for data entry may be located next to each work station and connected by hardwiring or wireless communication to the central server.

The growth of wireless technology means that hardwiring may be replaced by wireless in the near future, so this will require consideration particularly around “future