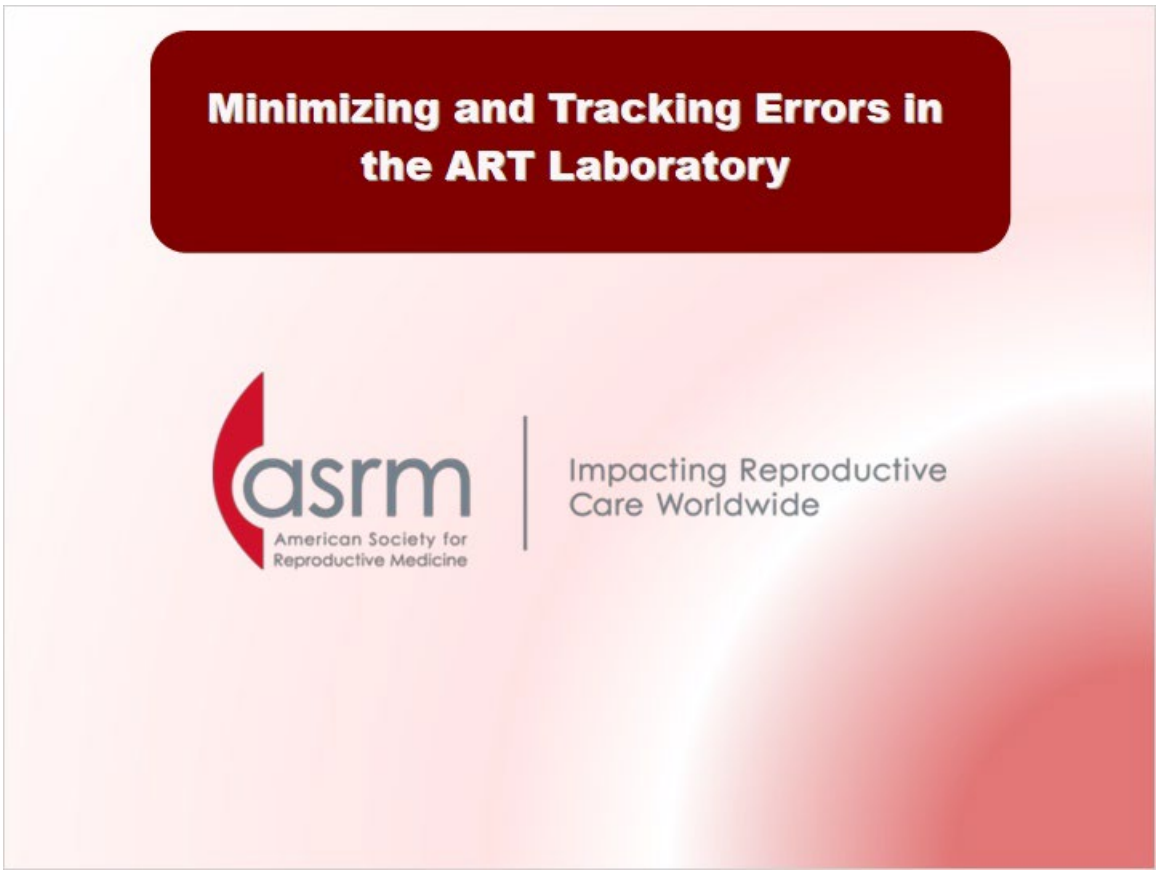
LABCC100 Lesson 37

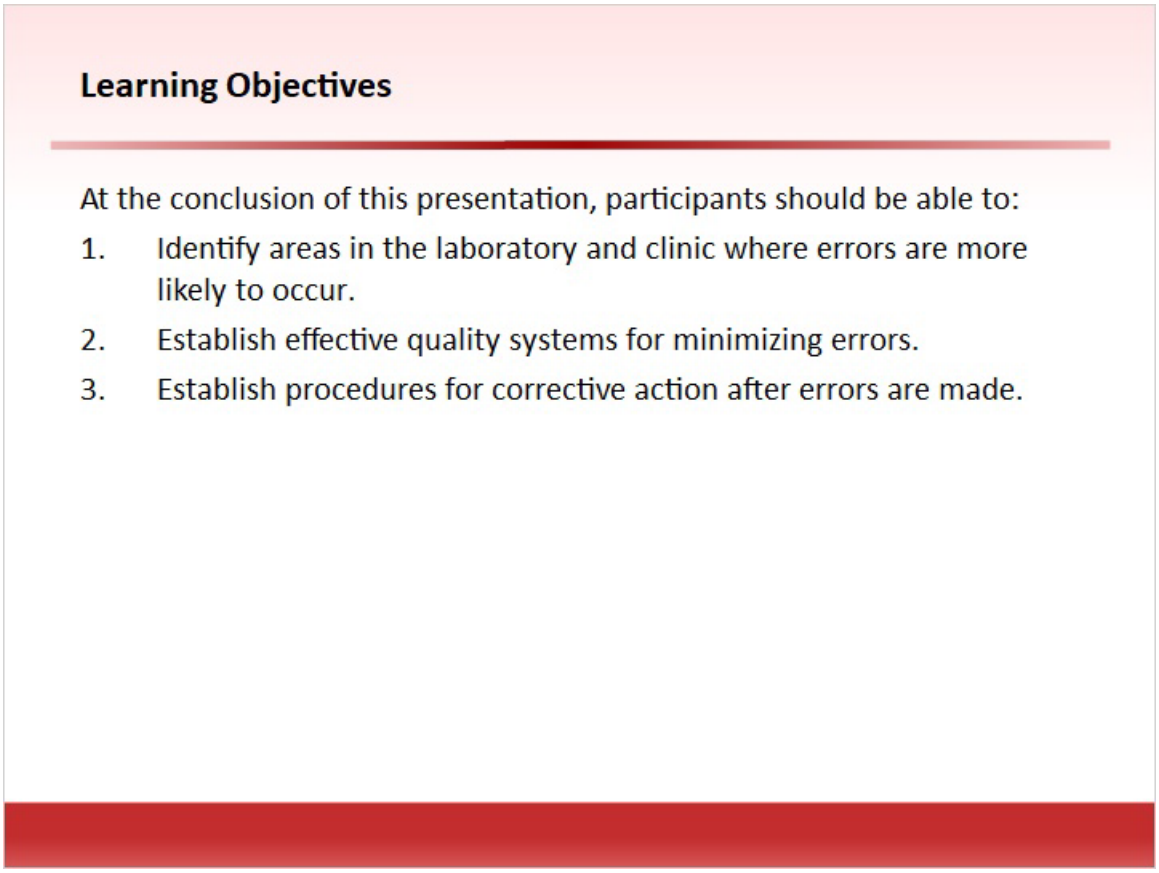
1.1 Minimizing and Tracking Errors in the ART Laboratory



Notes:

Welcome to the American Society for Reproductive Medicine's eLearning modules and the Embryology Certificate Course. The subject of this presentation is Minimizing and Tracking Errors in the ART Laboratory.

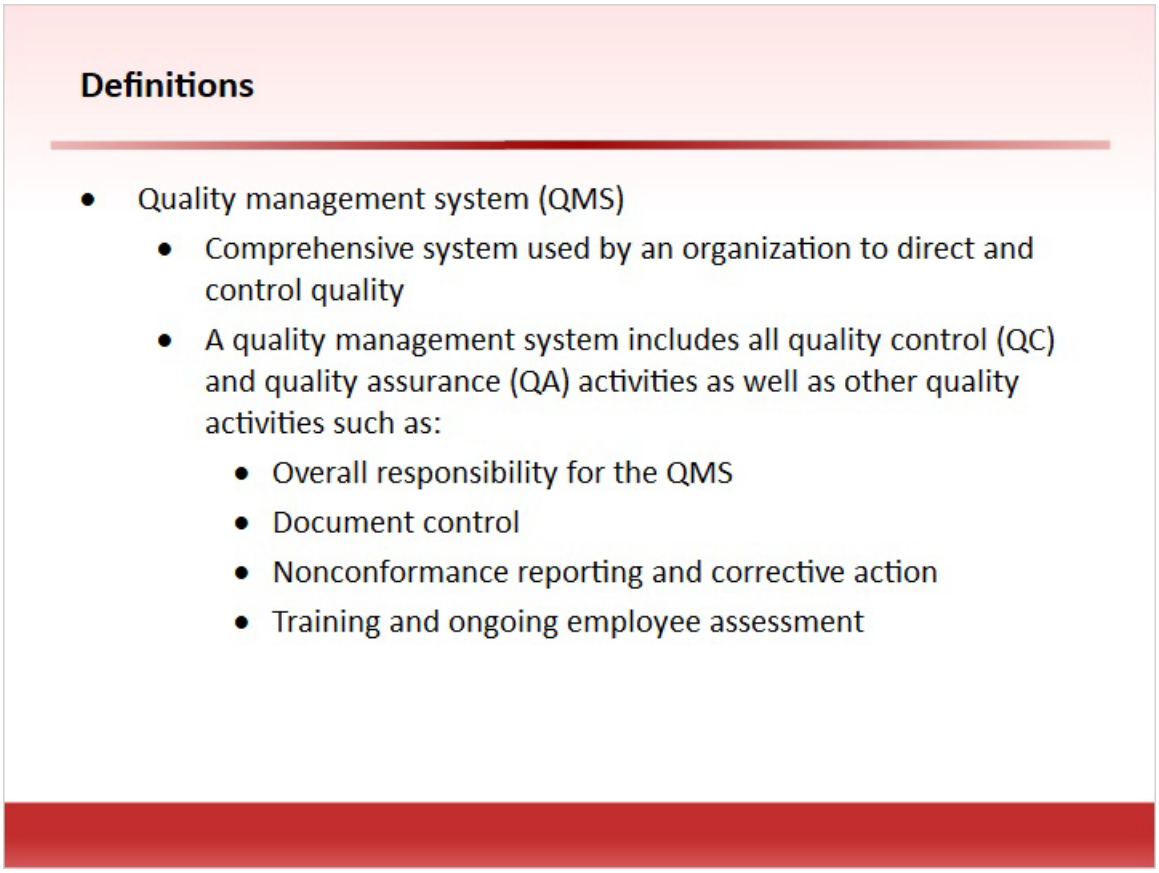
1.2 Learning Objectives



Notes:

At the conclusion of this presentation, participants should be able to:
1.Identify areas in the laboratory and clinic where errors are more likely to occur.
2.Establish effective quality systems for minimizing errors.
3.Establish procedures for corrective action after errors are made.

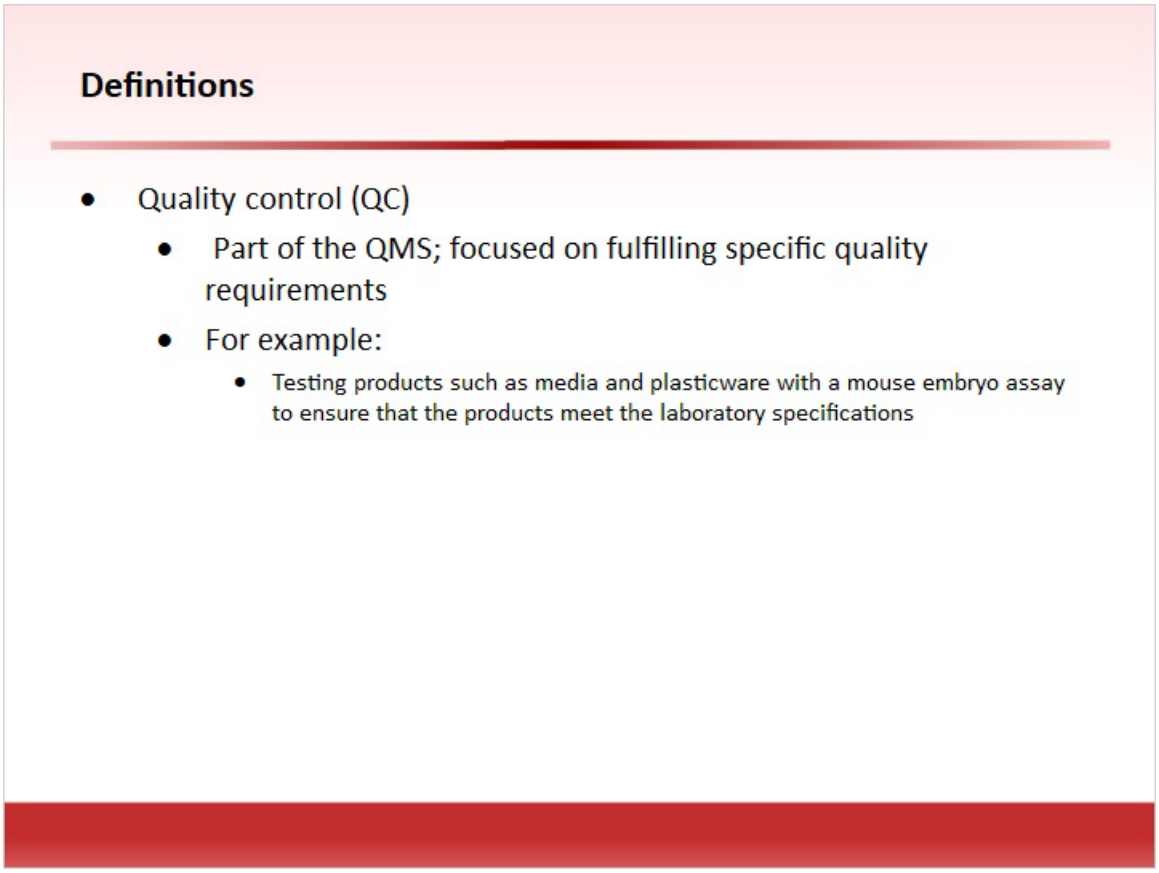
1.3 Definitions



Notes:

This module begins with the definitions of three critical terms. First, a quality management system is the comprehensive system used by an organization to direct and control quality. This includes all quality control (QC) and quality assurance (QA) activities as well as other quality activities such as overall responsibility for the quality management system, document control, nonconformance reporting and corrective action, and training and ongoing employee assessment.

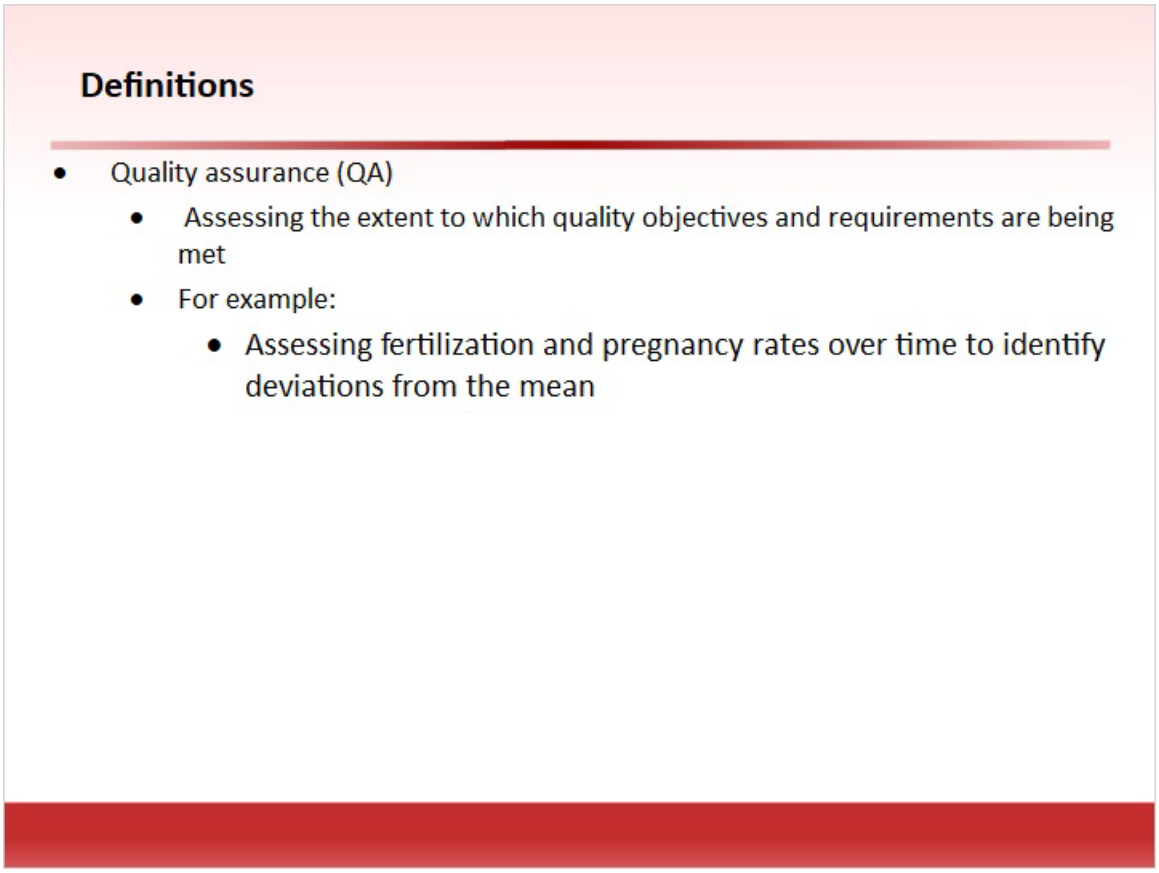
1.4 Definitions



Notes:

Quality control is part of the quality management system, which is focused on fulfilling specific quality requirements. This includes activities such as testing products used in the lab with a mouse embryo or human sperm assay to ensure that the products meet the laboratory specifications. For example, for a mouse embryo assay, the lab specification may be that 80% of 1-cell mouse zygotes develop to the expanded blastocyst stage within 4 days.

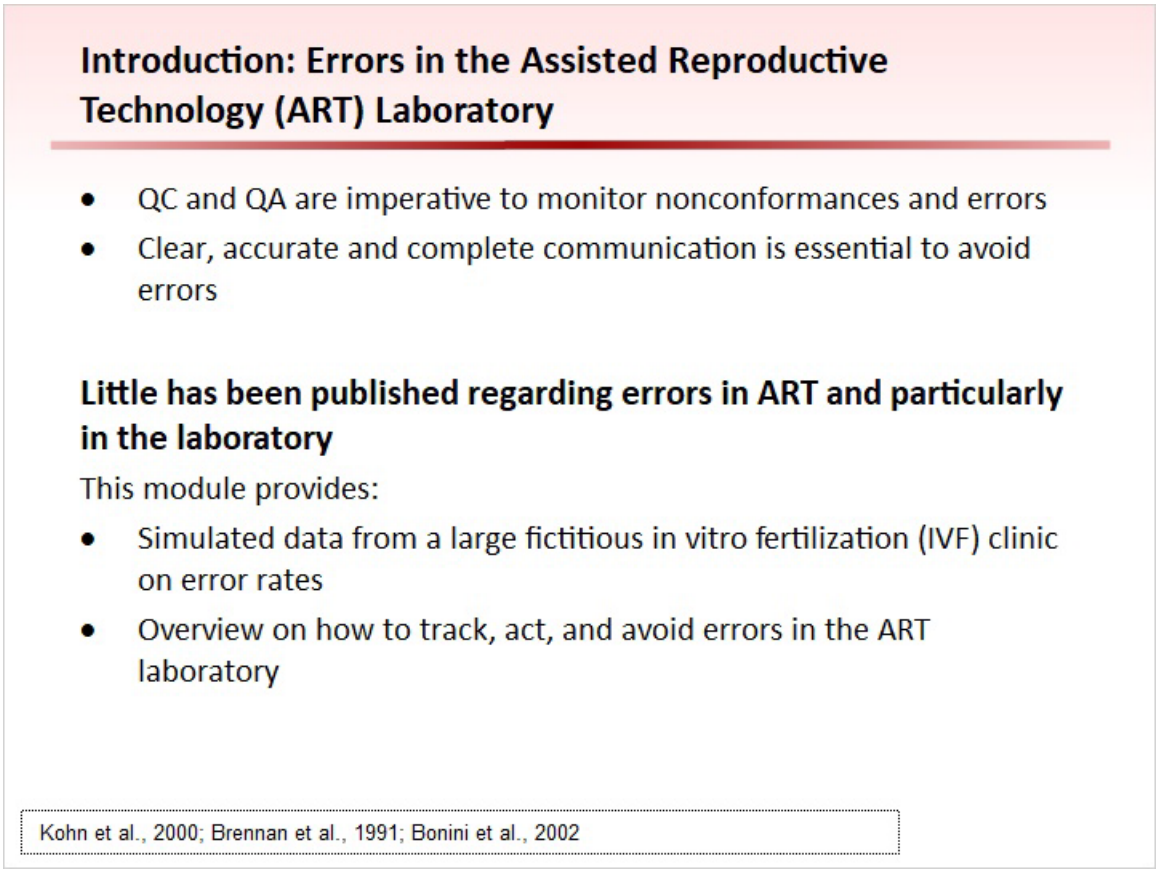
1.5 Definitions



Notes:

Quality assurance involves assessing the extent to which quality objectives and requirements are being met. For example, fertilization and pregnancy rates should be tracked to assess fertilization and pregnancy rates over time to identify deviations from the mean.

1.6 Introduction: Errors in the Assisted Reproductive Technology (ART) Laboratory

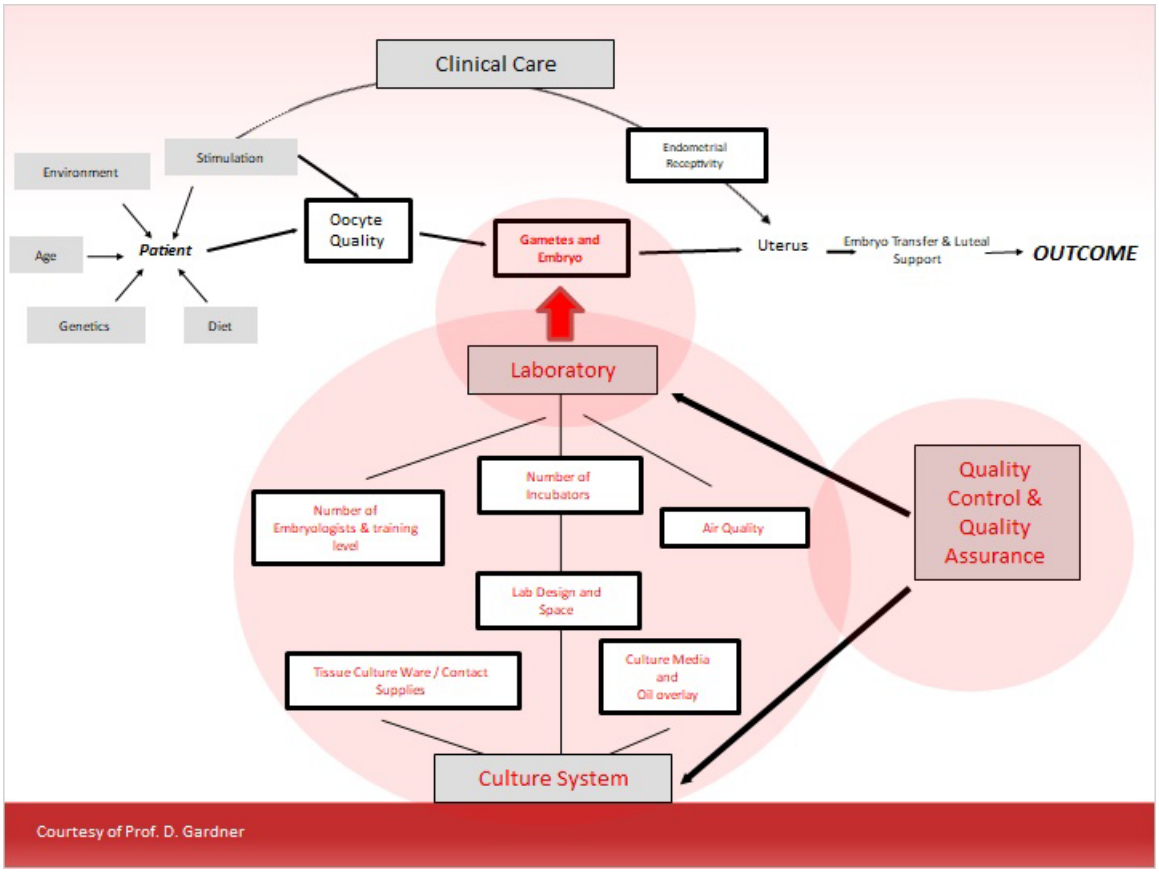


Notes:

This module will cover one of the critical areas of laboratory organization: quality control and quality assurance. In particular, it will focus on how communication at all levels throughout the laboratory and clinic is important and aid in creating an efficient laboratory. More importantly it will discuss an area that has been somewhat underreported, i.e., how to monitor nonconformances and errors in the laboratory and how to learn from and minimize them.

Clear, accurate and complete communication is essential in an ART laboratory in order to avoid errors. Errors in medicine have been identified as a serious problem in the United States and elsewhere. There have been numerous publications regarding error rates in hospitals and clinical labs; however, very little has been published regarding errors in ART and particularly in the lab. This module will provide simulated data on error rates from a fictitious, large IVF clinic and an overview on how to track, act, and hopefully avoid errors in the ART laboratory.

1.7 Untitled Slide



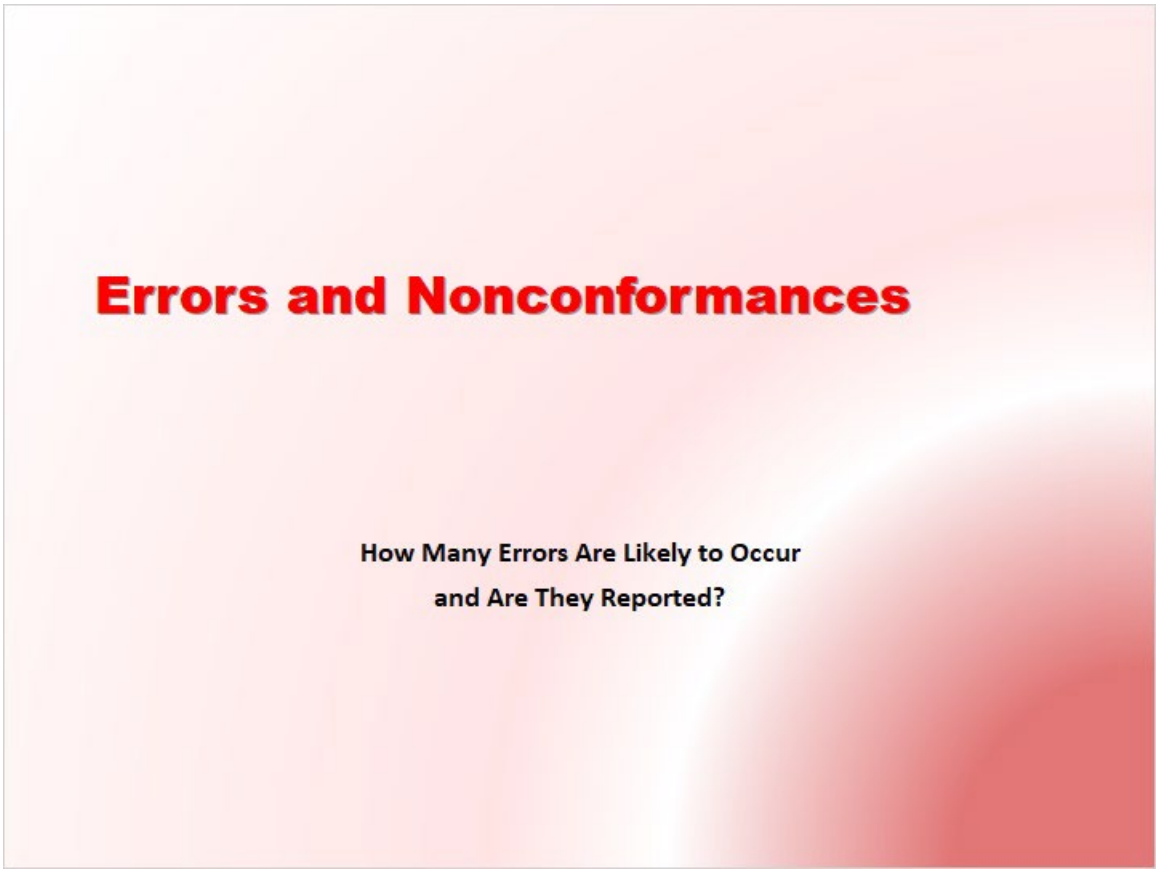
Notes:

The ART laboratory is tasked with the care of gametes, creation and care of embryos, and is a critical factor in the maintenance of pregnancy outcomes. In performing this role the ART laboratory:

- Is affected by the types of patients it is treating
- Must interact with other areas of the clinic
- Must have efficient QC and QA systems in place to enable itself to function efficiently

The ART laboratory within itself also has many areas where this control is needed. A lack of control in any of these areas can not only harm the laboratory's performance but more importantly can affect the entire clinic.

1.8 Errors and Nonconformances



Notes:

The process of IVF has grown extremely complex in relation to the adoption of highly technological laboratory procedures. Likewise, the patient population has moved from the traditional couple and can now include donation of gametes, surrogacy, single parents, and same-sex parents. As in other fields of medicine, these complexities have led the field to adopt stringent control measures during both surgical and laboratory procedures to reduce the risk of errors. Although it is assumed that these measures have been routinely adopted and are effective, there is little published in the literature outlining error rates in ART.

1.9 1999 Institute of Medicine Report

Notes:

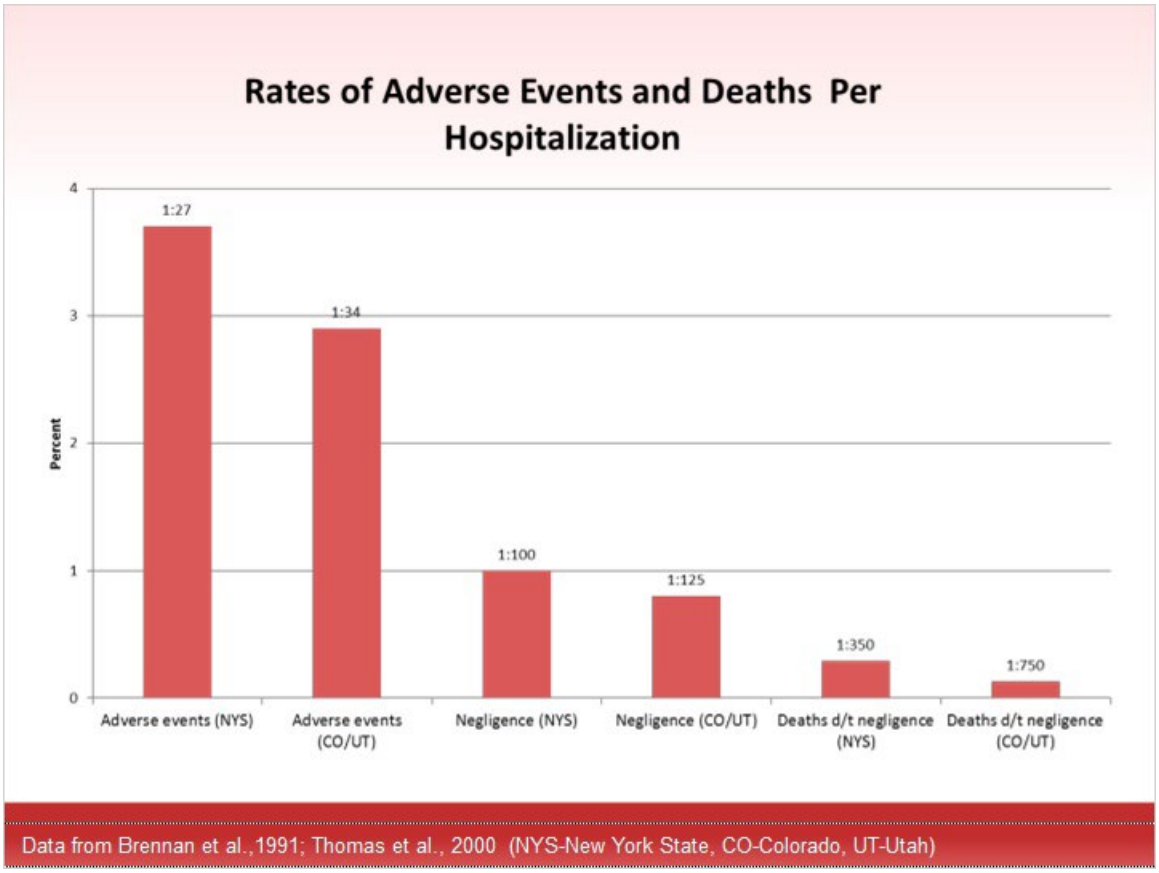
A 1999 Institute of Medicine Report showed that the stark reality is that errors do happen in medicine and the outcomes can range from a minimal inconvenience to extreme harm. These errors should not and cannot be ignored.
"The title of this report encapsulates its purpose. Human beings, in *all* lines of work, make errors."

1.10 To Err Is Human

Notes:

The Institute of Medicine Report and a subsequent article by Kohn and colleagues highlighted what is thought by many a taboo subject.
The statement highlights one of the major problems with reporting errors: "This report describes a serious concern in health care that, if discussed at all, is discussed only behind closed doors."

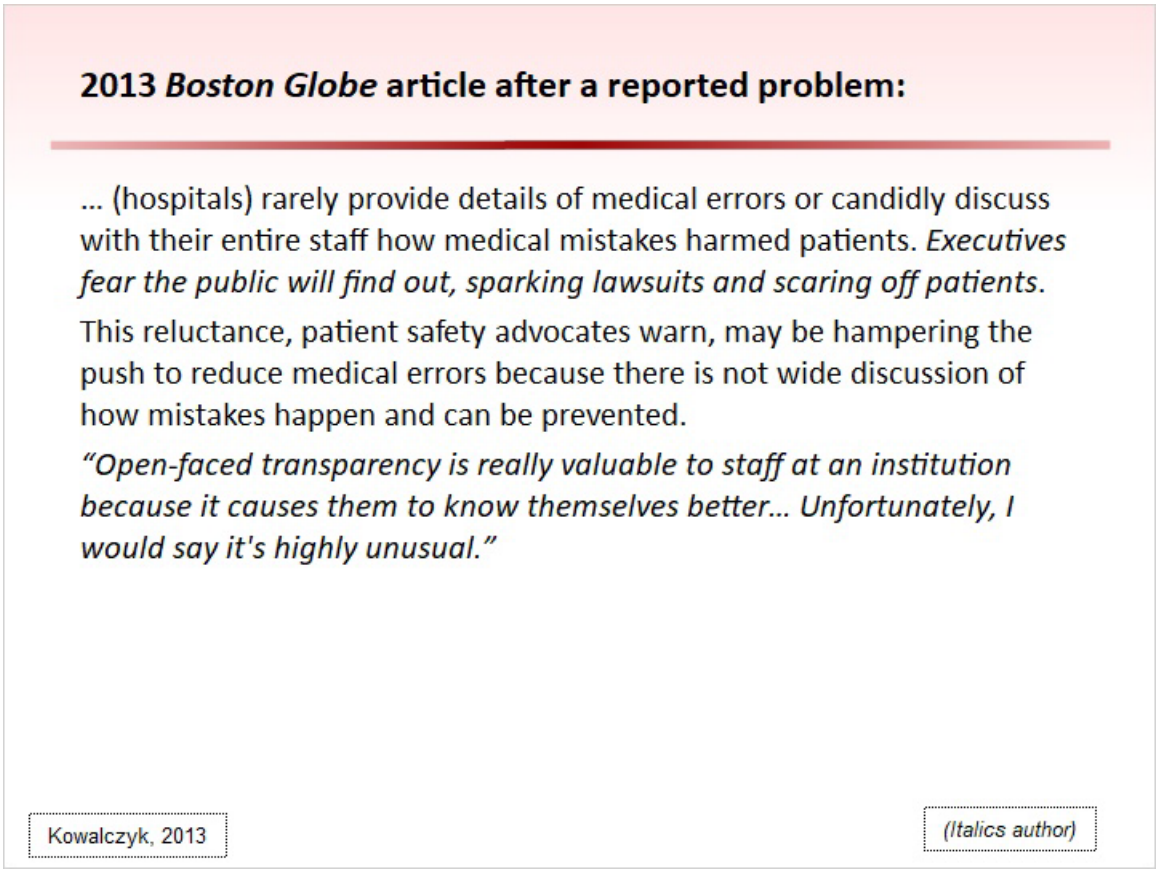
1.11 Rates of Adverse Events and Deaths Per Hospitalization



Notes:

Errors do occur in all fields of medicine. The landmark paper in the *New England Journal of Medicine* reported that the occurrence of these events may not be minimal. They found that adverse events occurred in 3.7% of the hospitalizations and that 27.6% of the adverse events were due to negligence. Although 70.5% of the adverse events gave rise to disability lasting less than 6 months, 2.6% caused permanently disabling injuries and 13.6% led to death.

1.12 2013 Boston Globe article after a reported problem:



Notes:

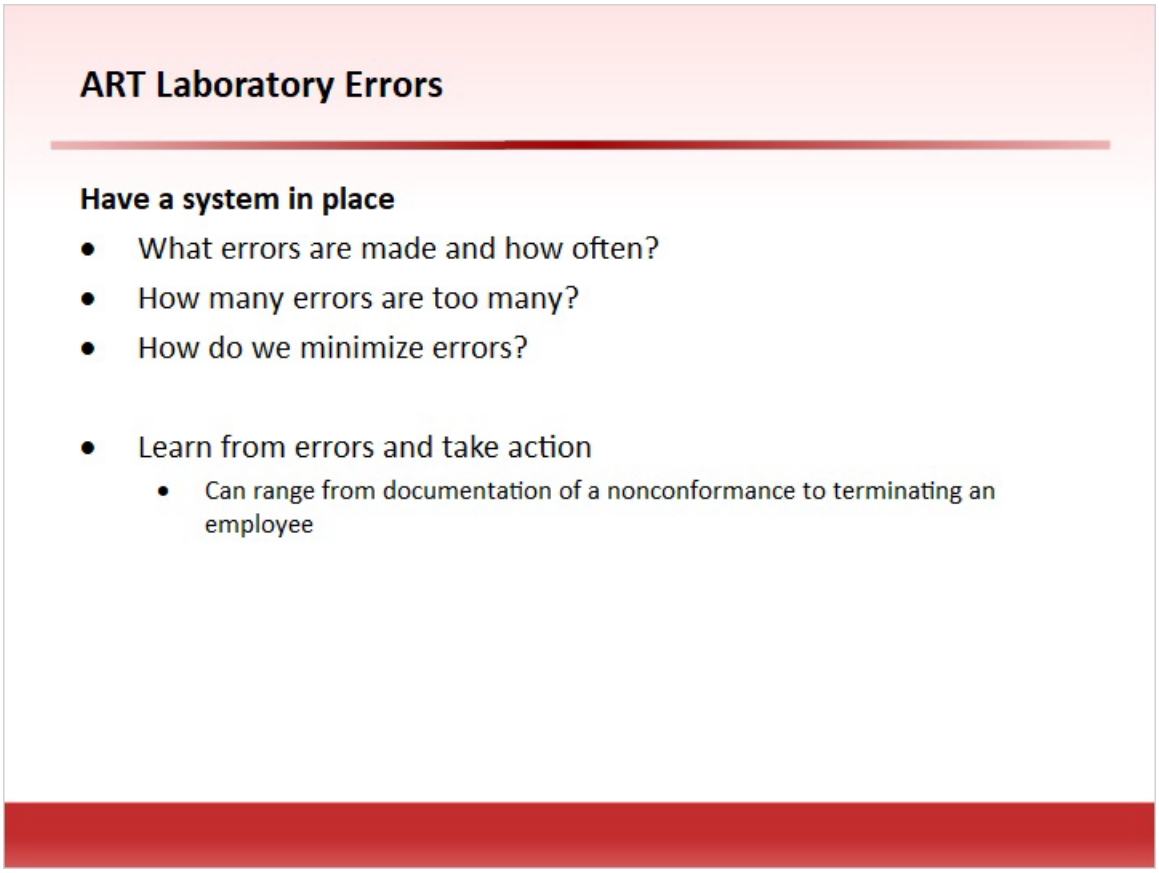
The reporting of errors is understandably guarded. This *Boston Globe* report sums up the stigma associated with reporting.

1.13 “My lab never makes mistakes…”

Notes:

The greatest error is to bury one's head in the sand and think that your laboratory never makes mistakes.

1.14 ART Laboratory Errors



Notes:

To run an efficient clinic and laboratory, a system must be put in place to learn from and act on the nonconformances and errors that occur.
This system should aim to understand:
What errors are made and how often?
How many errors are too many?
How do we minimize errors?

Once in place it is easier to both learn from the errors and also to take action. These actions can range from documentation of a nonconformance so that a protocol is amended, to the more critical action of terminating an employee if repeated nonconformances are made.

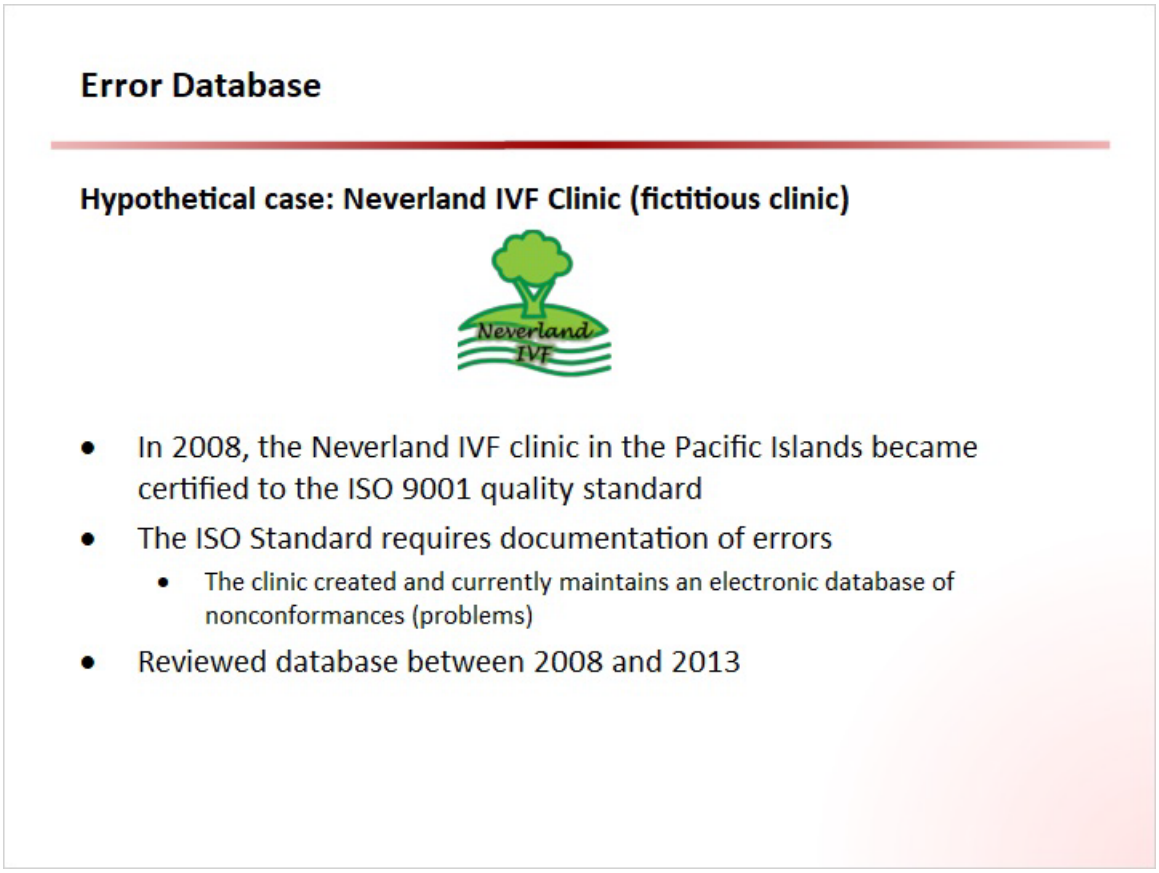
1.15 International Organization for Standardization (ISO)

Notes:

The International Organization for Standardization (ISO) standards ensure that products and services are safe, reliable and of good quality. ISO 9001:2008 specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

Organizations that implement this quality management system reduce costs by minimizing waste and errors and increase productivity. It also helps companies to access new markets, level the playing field for developing countries, and facilitate free and fair global trade.

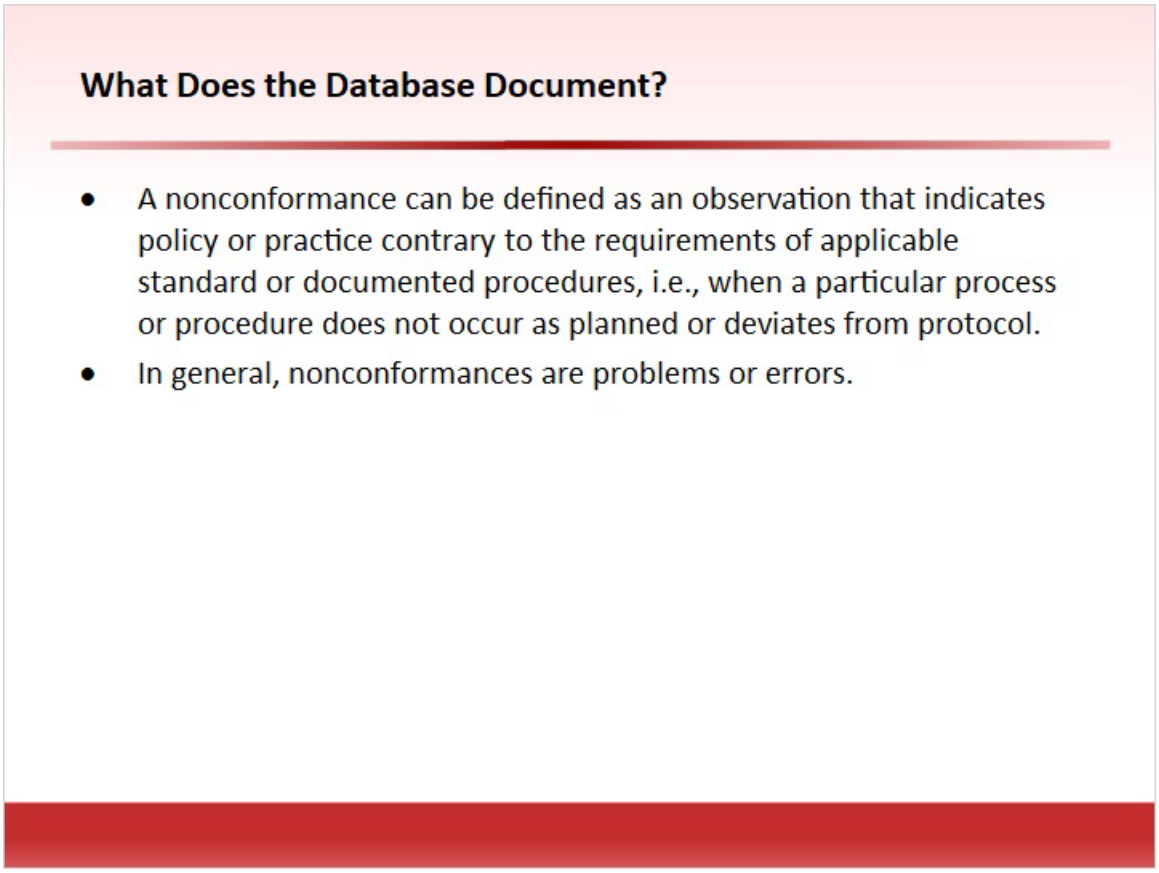
1.16 Error Database



Notes:

For illustration purposes, this module uses simulated data from the Neverland IVF clinic, which is a fictitious clinic located in the Pacific Islands. In 2008, the Neverland IVF clinic became certified to the ISO 9001 quality standard. An integral part of this quality management system was establishing a system for the documentation of nonconformances.

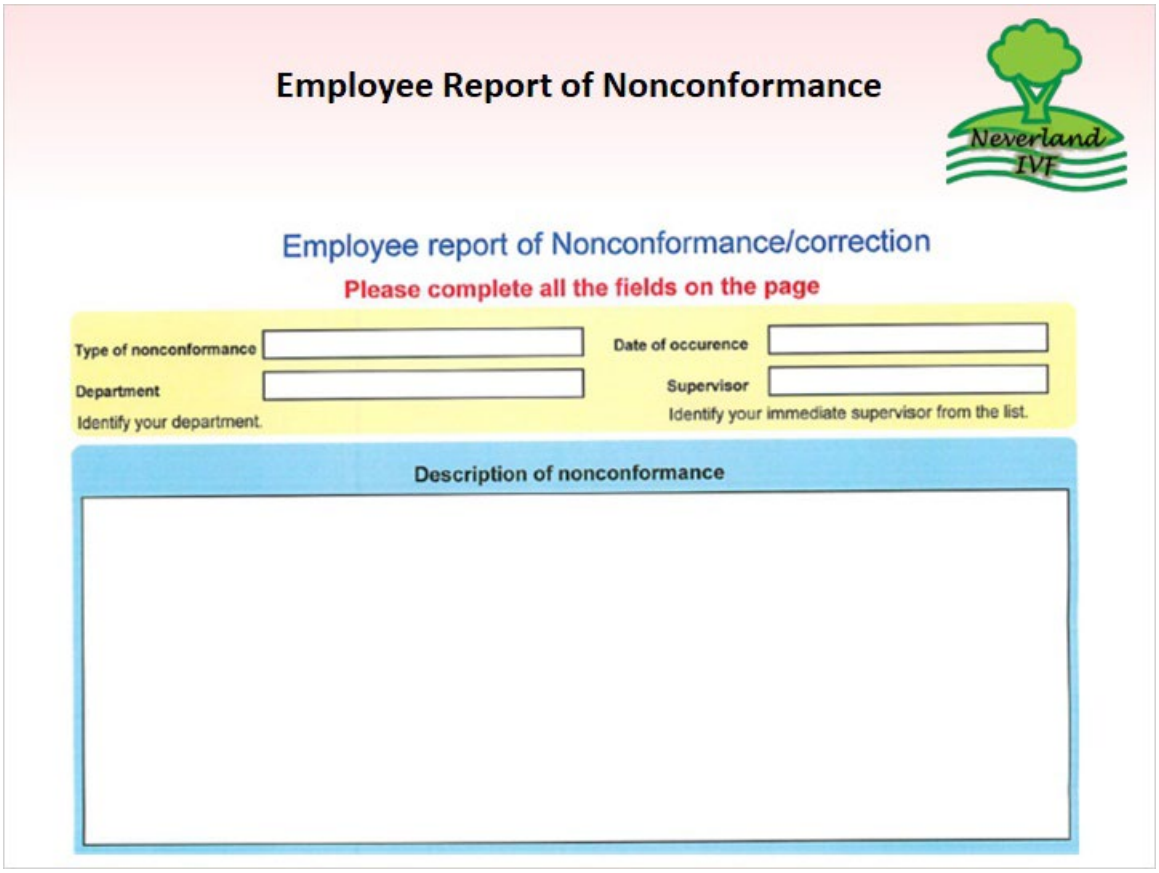
1.17 What Does the Database Document?



Notes:

The database largely documents any deviation from standard protocol. A nonconformance can be defined as an observation that indicates policy or practice contrary to the requirements of applicable standard or documented procedures, i.e., when a particular process or procedure does not occur as planned or deviates from protocol.
In general, nonconformances are problems or errors.

1.18 Employee Report of Nonconformance



Employee Report of Nonconformance

Neverland IVF

Employee report of Nonconformance/correction

Please complete all the fields on the page

Type of nonconformance

Date of occurence

Department

Supervisor

Identify your department.

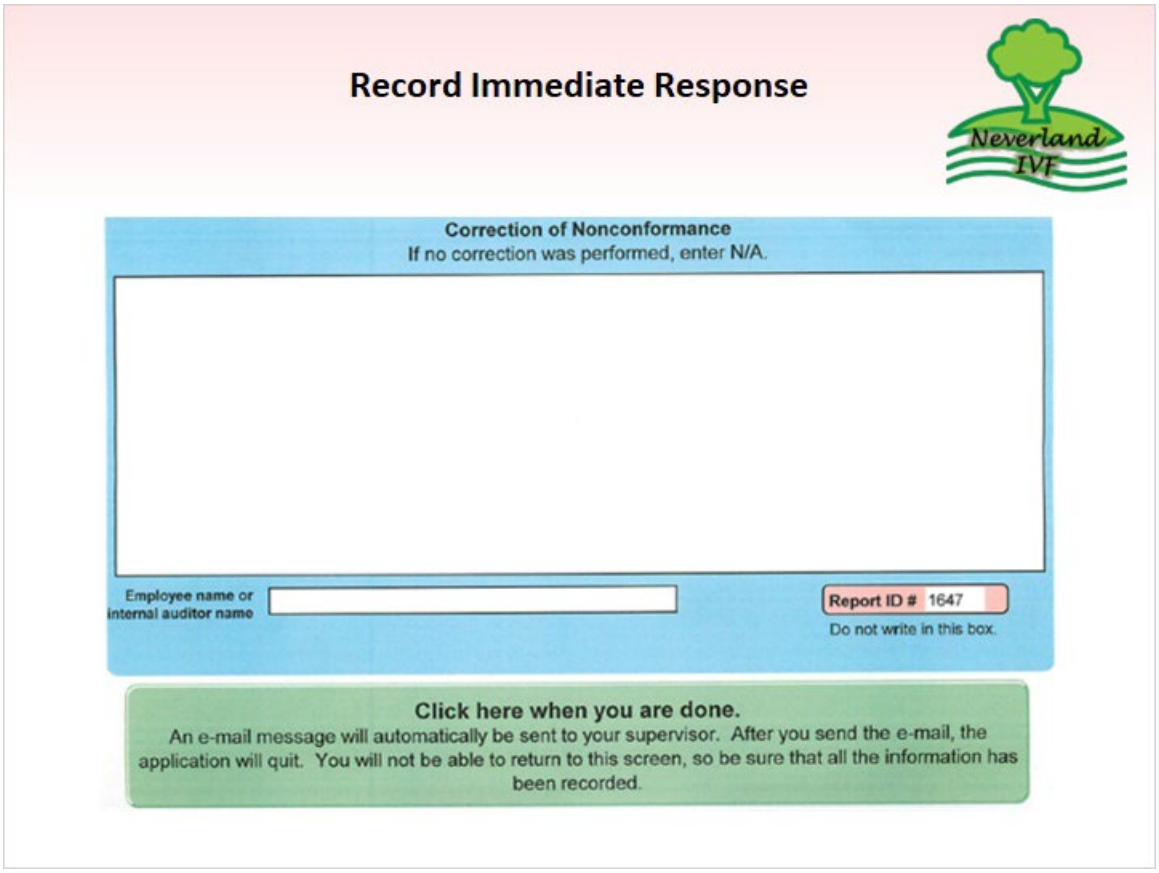
Identify your immediate supervisor from the list.

Description of nonconformance

Notes:

Documentation is all electronically recorded and all reports in the nonconformance database have 3 steps. First, the error or problem is entered into the database, generally by the employee who committed or discovered the error or problem. A full description of the nonconformance is recorded, including all relevant information.

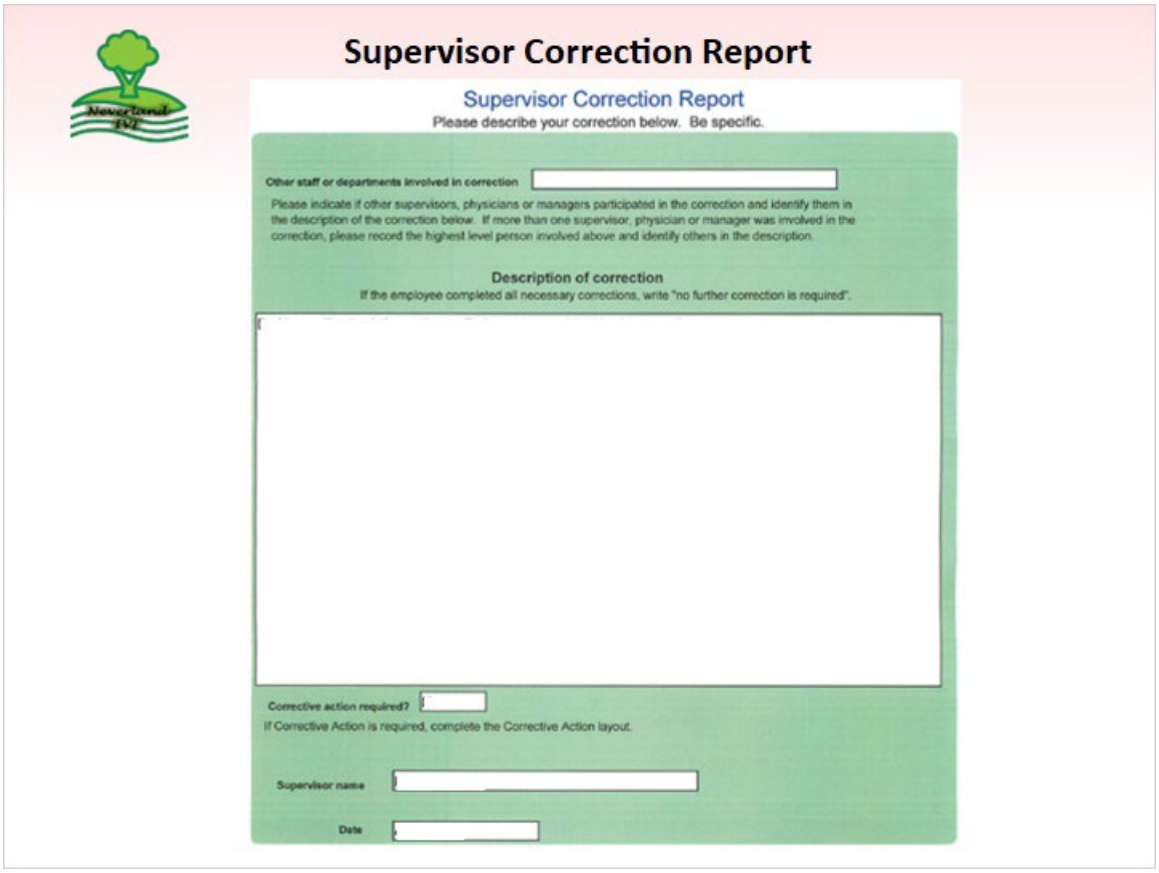
1.19 Record Immediate Response



Notes:

Next, the immediate response to the problem is recorded either by the employee involved or a supervisor called in to respond to the nonconformance. Once this documentation is completed, the report is locked and further access to the report is limited to supervisory personnel. An email is automatically generated and sent to the appropriate departmental supervisor or director.

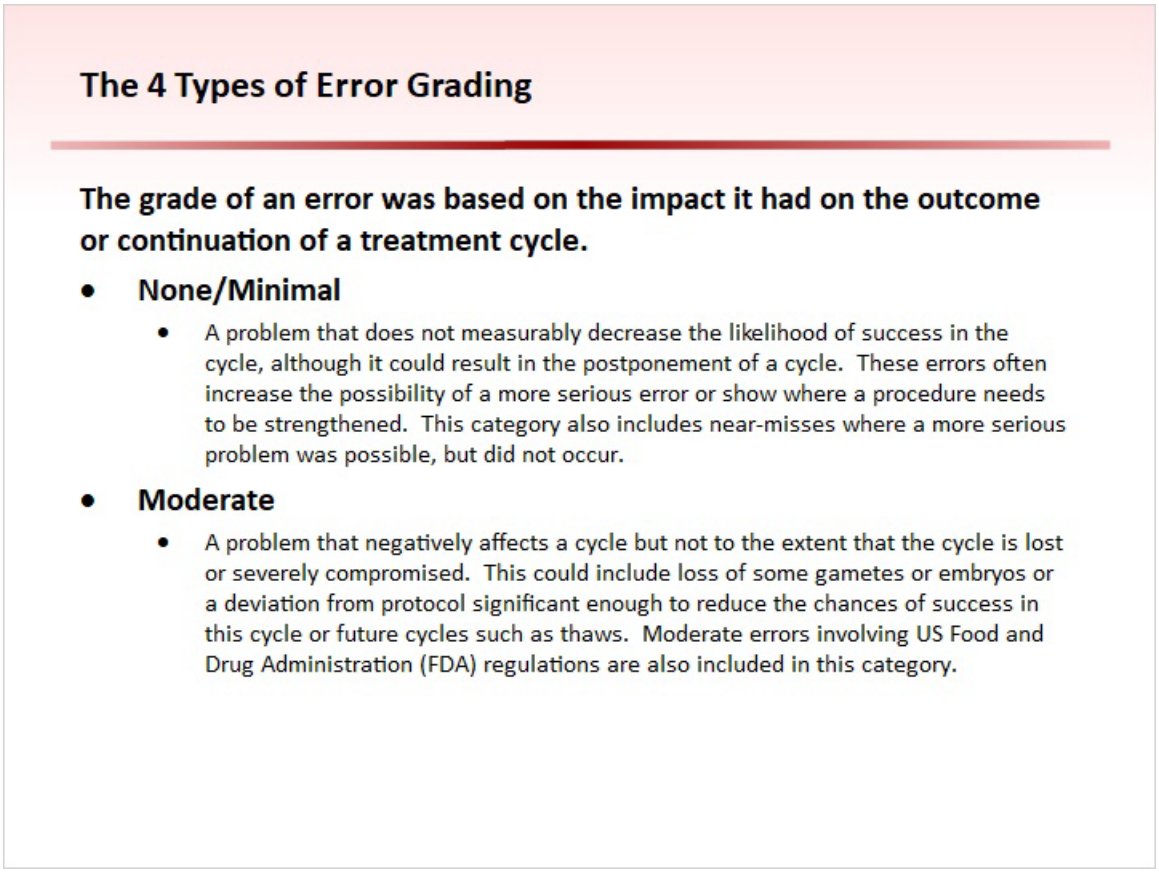
1.20 Supervisor Correction Report



Notes:

The supervisor or director then documents any further investigation into the problem, any changes in procedures as a result of the problem, any personnel who were apprised of the problem and/or procedure changes, and the final resolution of the nonconformance. Reports are audited annually to ensure no records are incomplete.

1.21 The 4 Types of Error Grading

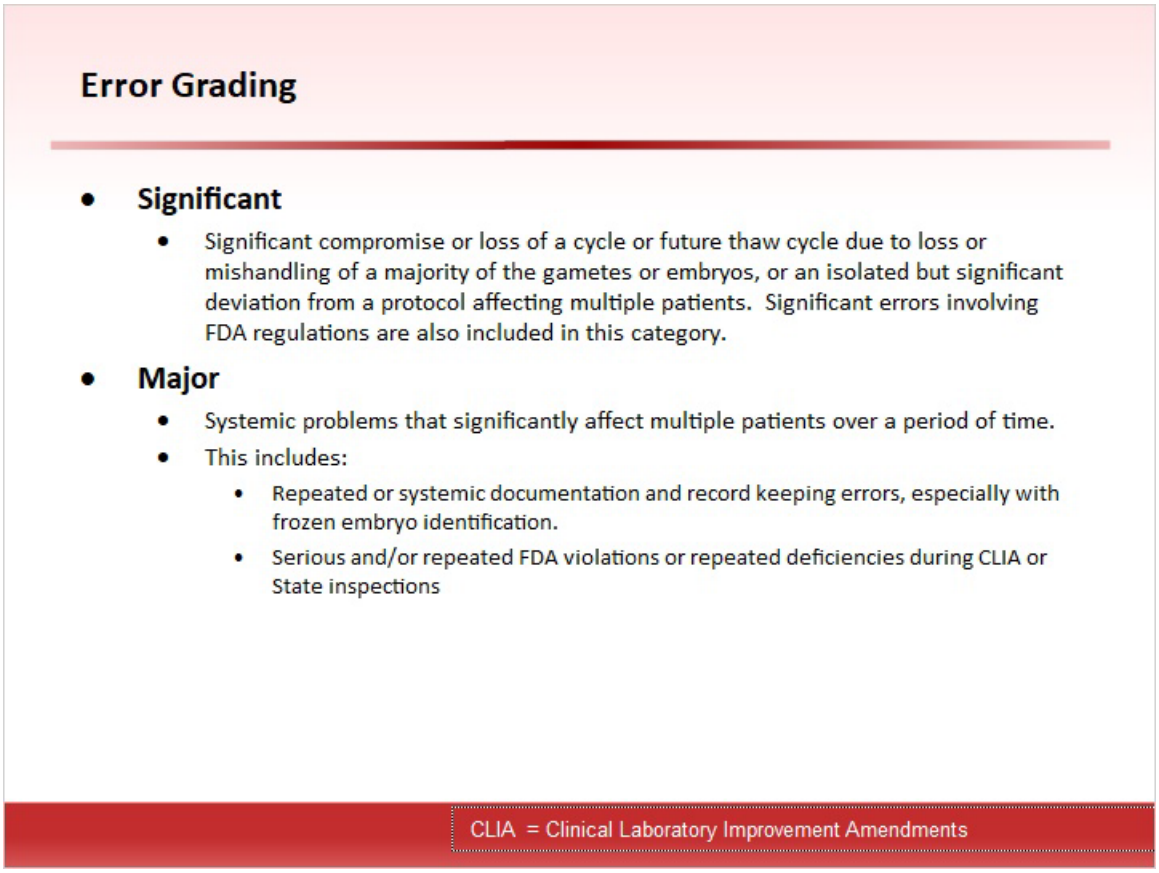


Notes:

The errors were categorized into 4 types specifically in relation to IVF. The grade of an error was based on the impact it had on the outcome or continuation of an IVF treatment cycle. Briefly, the criteria were as follows:
None/minimal refers to a problem that does not measurably decrease the likelihood of success in the cycle, although it could result in the postponement of a cycle. These errors often increase the possibility of a more serious error or show where a procedure needs to be strengthened, but do not, in and of themselves, result in a more serious problem. This category also includes near misses where a more serious problem was possible, but did not occur.

Moderate problems are those that negatively affect a cycle but not to the extent that the cycle is lost or severely compromised. This could include loss of some gametes or embryos or a deviation from protocol significant enough to reduce the chances of success in this cycle or future cycles such as thaws. Moderate errors involving US Food and Drug Administration (FDA) regulations are also included in this category.

1.22 Error Grading



Notes:

A significant error is defined as a significant compromise or loss of a cycle or future thaw cycle due to loss or mishandling of a majority of the gametes or embryos, or an isolated but significant deviation from a protocol affecting multiple patients. Significant errors involving FDA regulations are also included in this category.

Major errors are systemic problems that significantly affect multiple patients over a period of time. These include: repeated or systemic documentation and record-keeping errors, especially with frozen embryo identification and serious and/or repeated FDA violations or serious and repeated deficiencies during Clinical Laboratory Improvement Amendments (CLIA) or State laboratory inspections.

1.23 Examples of Andrology/Embryology Nonconformances Reported by Staff:

Examples of Andrology/Embryology Nonconformances Reported by Staff:
Relative Severity and Assignment to the Area Affected

AREA	SEVERITY	DESCRIPTION
Human	None/ Minimal	The paperwork for patient XX had stated that 21 eggs were retrieved, and there were actually 19 eggs in the dish.
Cryopreservation	Moderate	While freezing 4 patients I "paused" the Instrument for seeding. After seeding I left the laboratory. I returned after 15 minutes and observed that the instrument was still in the Pause mode and the temperature was at -7C.
Equipment	Significant	While stripping cumulus cells off eggs for intracytoplasmic sperm injection (ICSI) all 5 eggs were destroyed by a foreign object in the tip of the stripper.

Notes:

Selected examples of Andrology/Embryology nonconformances reported by Neverland staff and their relative severity and assignment to the area affected are shown here. The reports are fictitious. Reports are logged according to the area of the ART laboratory in which they occurred, their severity, and also a description of what occurred.

1.24 Nonconformances and Errors from the Neverland Andrology/Embryology Laboratory from 2008–2013

Nonconformances and Errors from the Neverland Andrology/Embryology Laboratory from 2008-2013

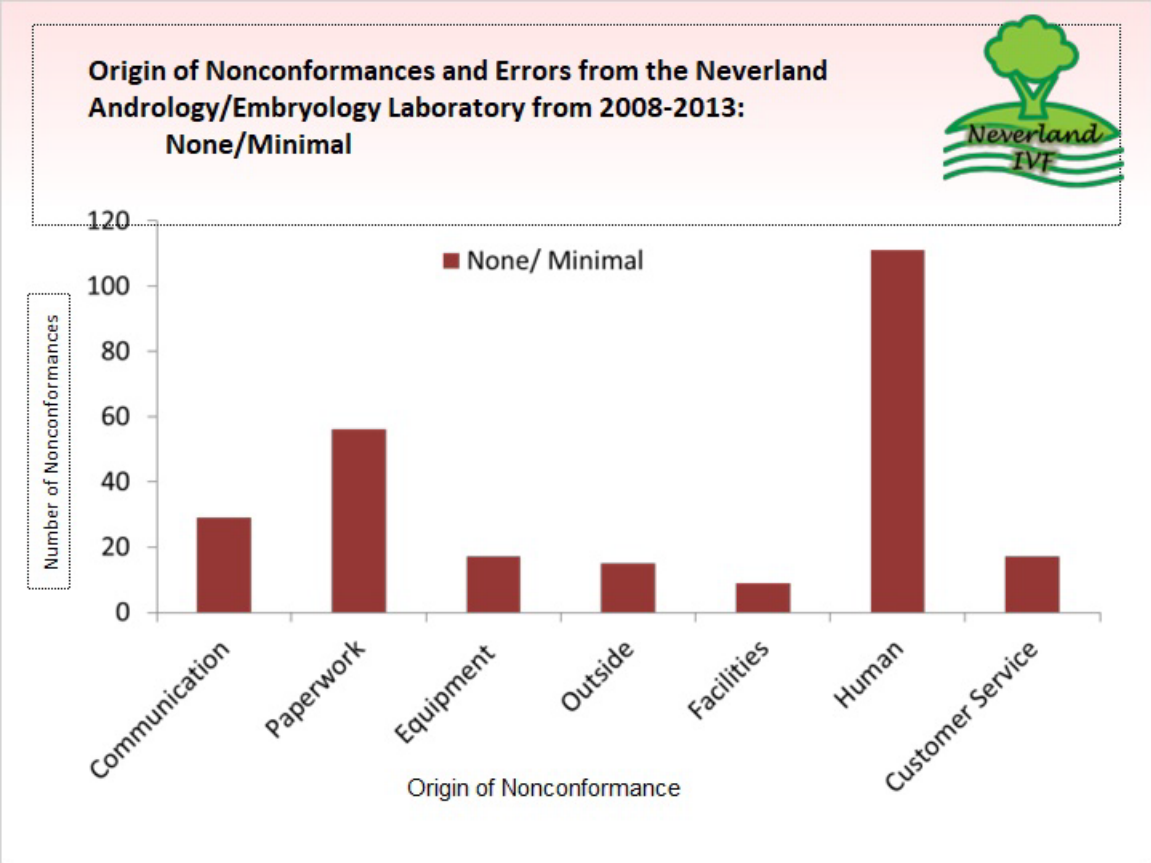
ANDROLOGY / EMBRYOLOGY	% (N=334)
None/Minimal	75.4
Moderate	20.2
Significant	4.2
Major	0.3

The number and percentage of nonconformances and errors from the Neverland Andrology / Embryology Laboratory from 2008 to 2013. >30,000 cycles performed.

Notes:

The occurrence of nonconformances and errors from the andrology/embryology laboratory from 2008 to 2013 are shown here. The number of cycles performed in this period was >30,000. In the andrology/embryology laboratory, most nonconformances were graded as minimal while both moderate and significant cases were reported at lower percentages. One case was classified as major.

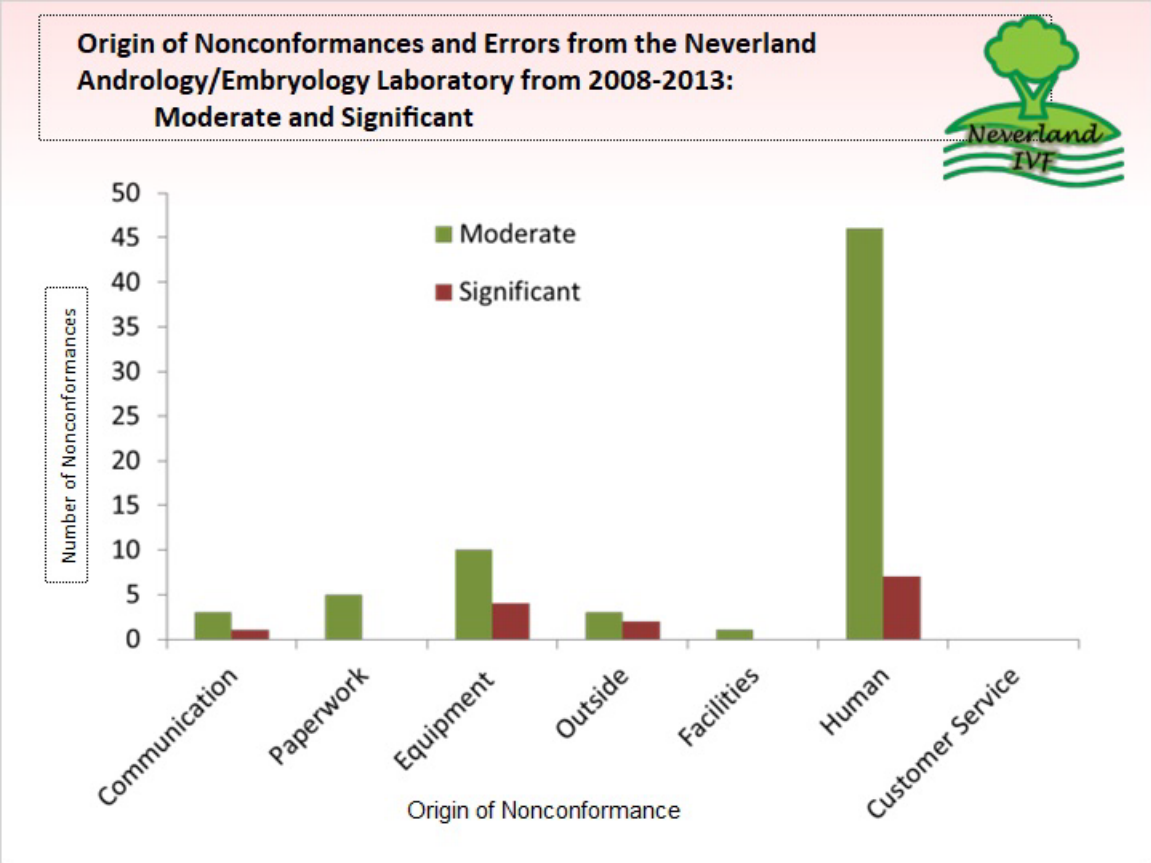
1.25 Origin of Nonconformances and Errors from the Neverland Andrology/Embryology Laboratory from 2008–2013: None/Minimal



Notes:

Here is the breakdown of nonconformances and errors from the andrology/embryology laboratory in relation to their origin. The number of minimal nonconformances and errors are shown indicating that the majority are related to human errors.

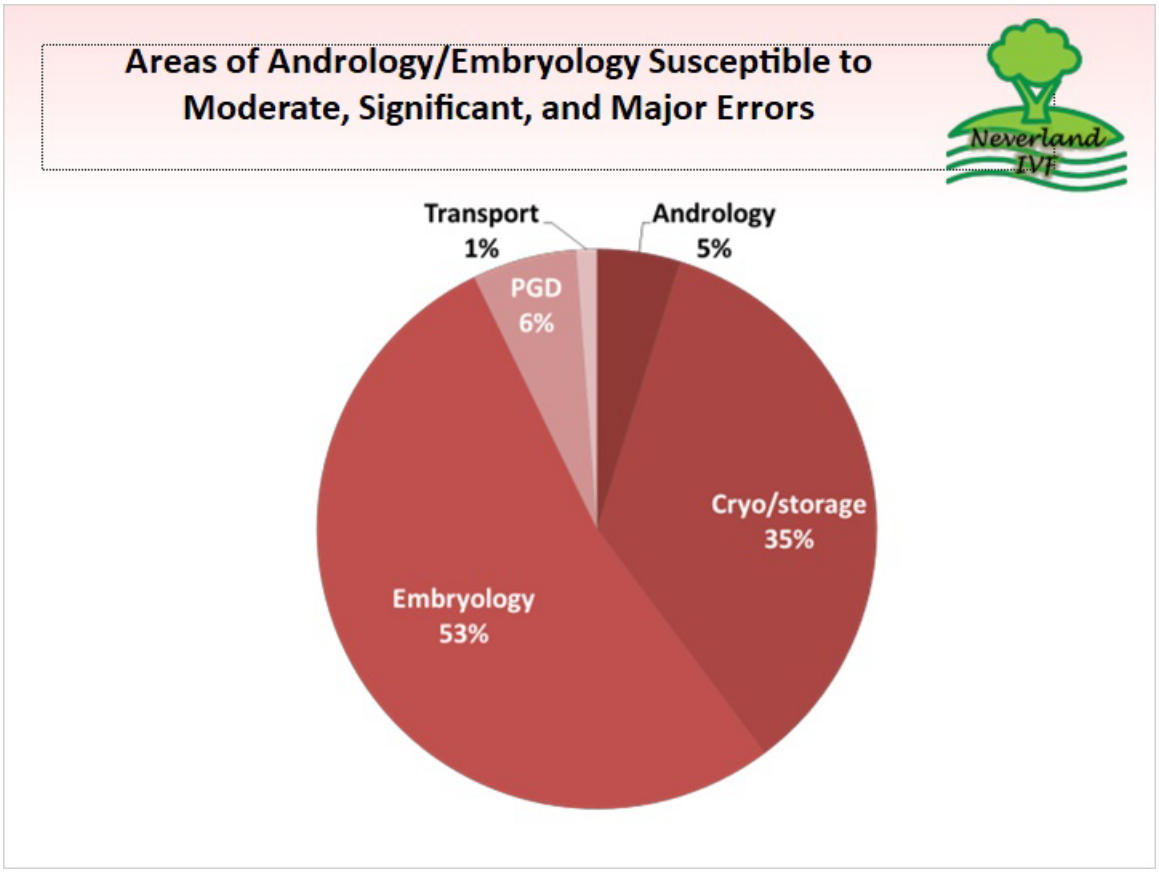
1.26 Origin of Nonconformances and Errors from the Neverland Andrology/Embryology Laboratory from 2008–2013: Moderate and Significant



Notes:

The number of moderate and significant nonconformances and errors are shown indicating that the majority are related to human errors. The numbers of significant errors are equally related to human and equipment problems.

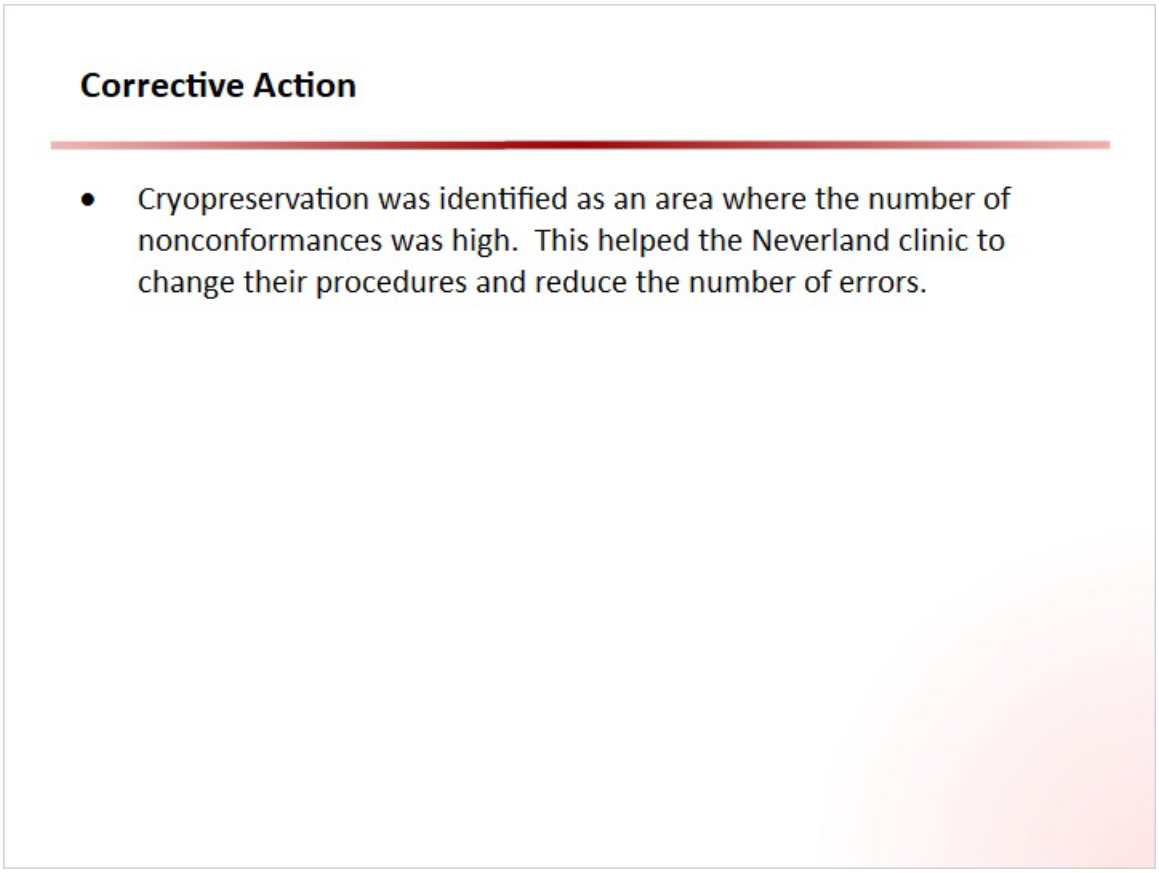
1.27 Areas of Andrology/Embryology Susceptible to Moderate, Significant, and Major Errors



Notes:

Embryology procedures made up the greatest percentage of moderate and significant errors. The procedure most prone to errors was cryopreservation, which represented 35% of the moderate and higher errors. Some of the embryology errors were related to pipette handling and sample handling.

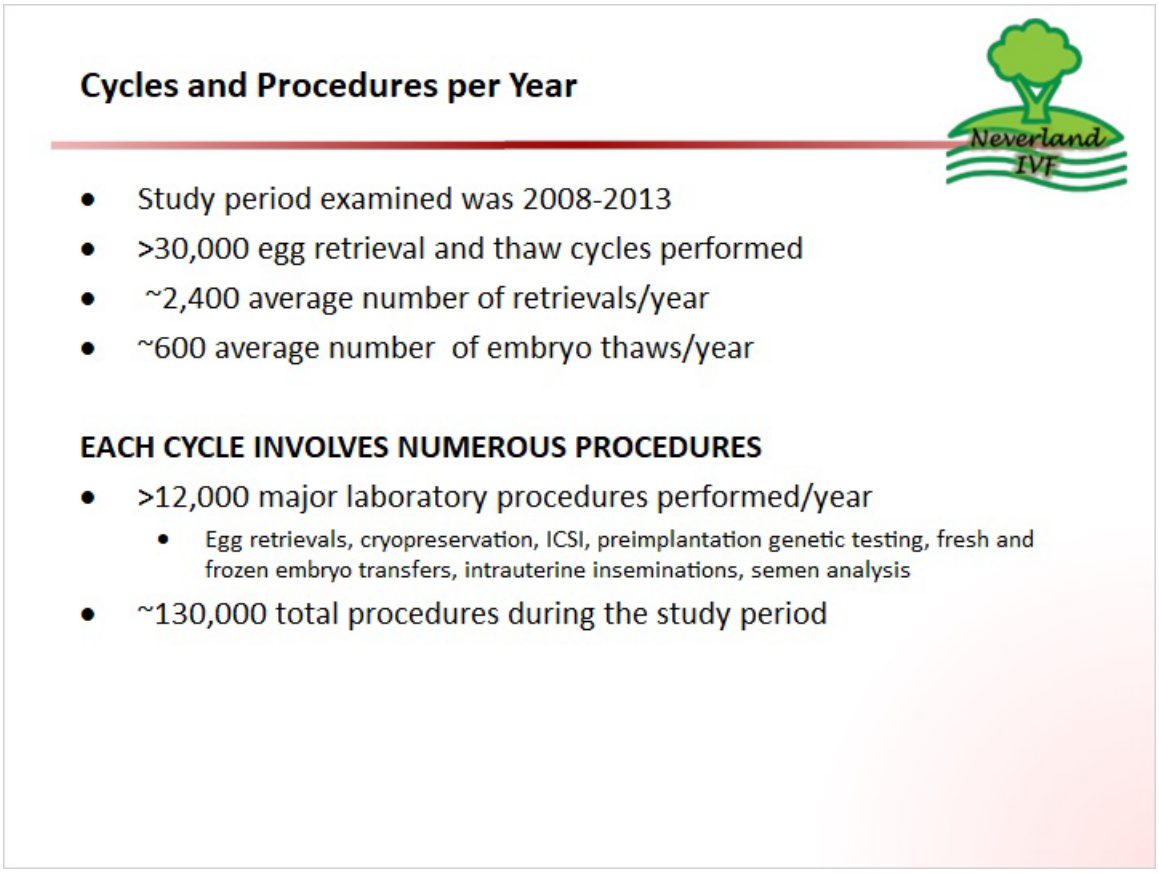
1.28 Corrective Action



Notes:

Identifying areas that appear problematic can provide forewarning of where major errors may occur. As noted, the data indicated that cryopreservation was a key area to investigate. Adoption of more control in this area has been implemented in the Neverland clinic.

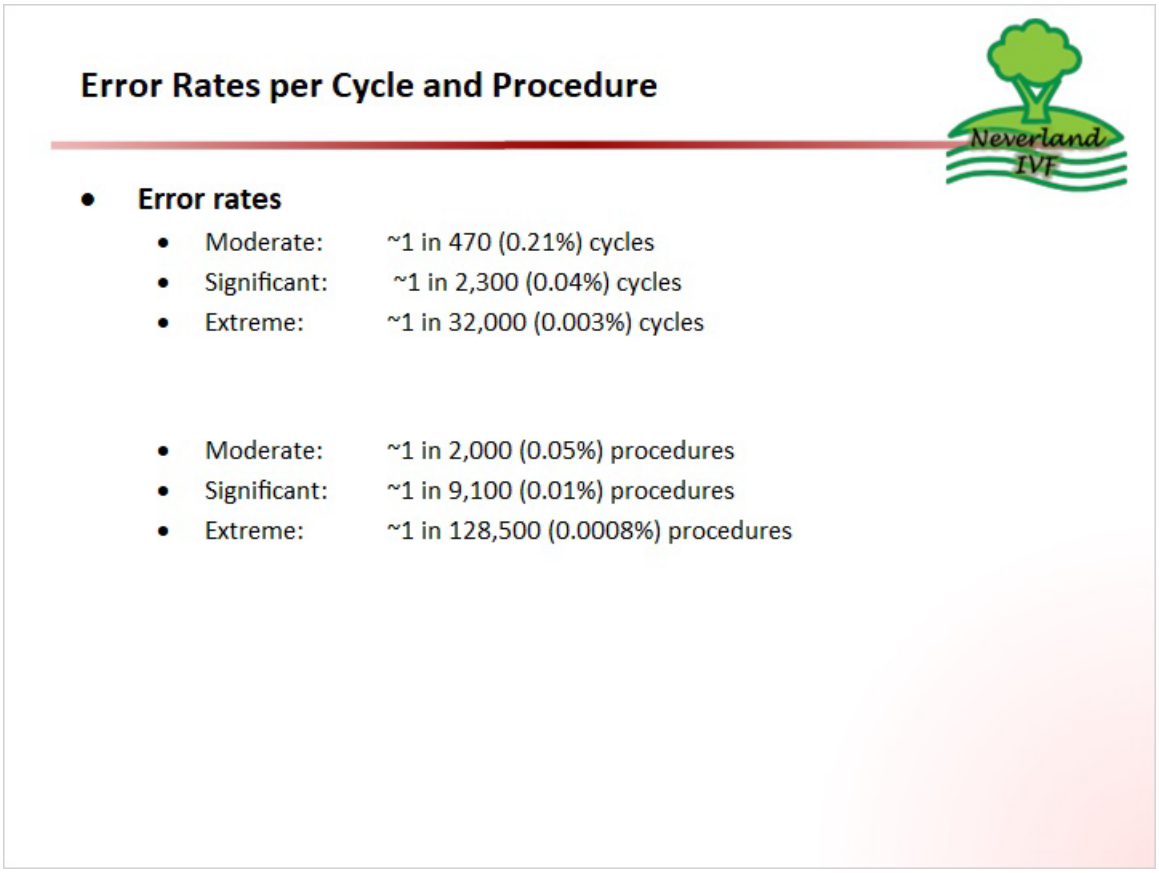
1.29 Cycles and Procedures per Year



Notes:

During the period of 2008 to 2013 a total of more than 30,000 egg retrieval and thaw cycles were performed. The average number of retrievals and embryo thaws per year was approximately 2,400 and 600, respectively. More than 12,000 major procedures within all cycles included egg retrievals, cryopreservation, ICSI, preimplantation genetic testing, fresh and frozen embryo transfers, intrauterine inseminations, and semen analysis. In all, there were approximately 130,000 procedures during the study period.

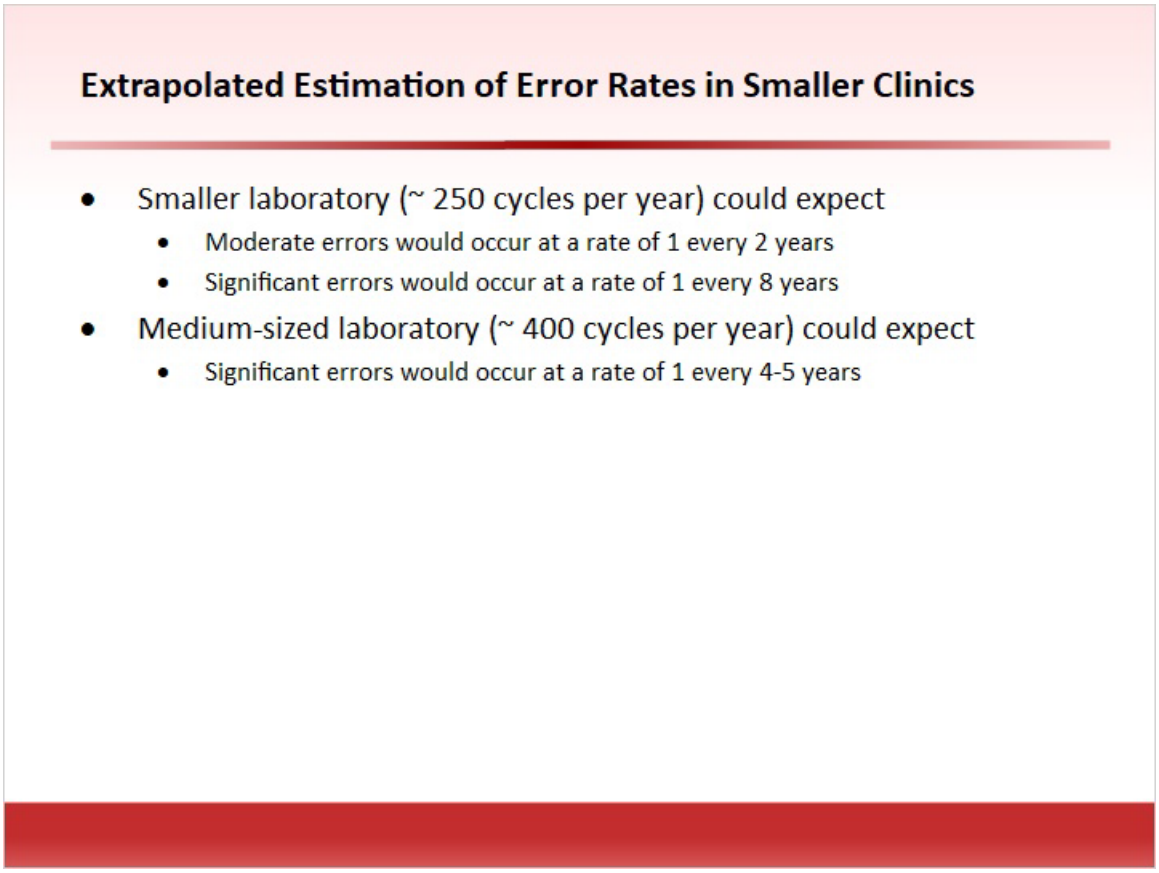
1.30 Error Rates per Cycle and Procedure



Notes:

The overall error rates of Extreme, Moderate, and Significant errors combined per procedure and per cycle were approximately 0.06% and 0.25%, respectively, during the more than 30,000 cycles. Of the Extreme and Significant errors only, the rates were approximately 1 per 9,000 procedures and 1 per 1,900 cycles.

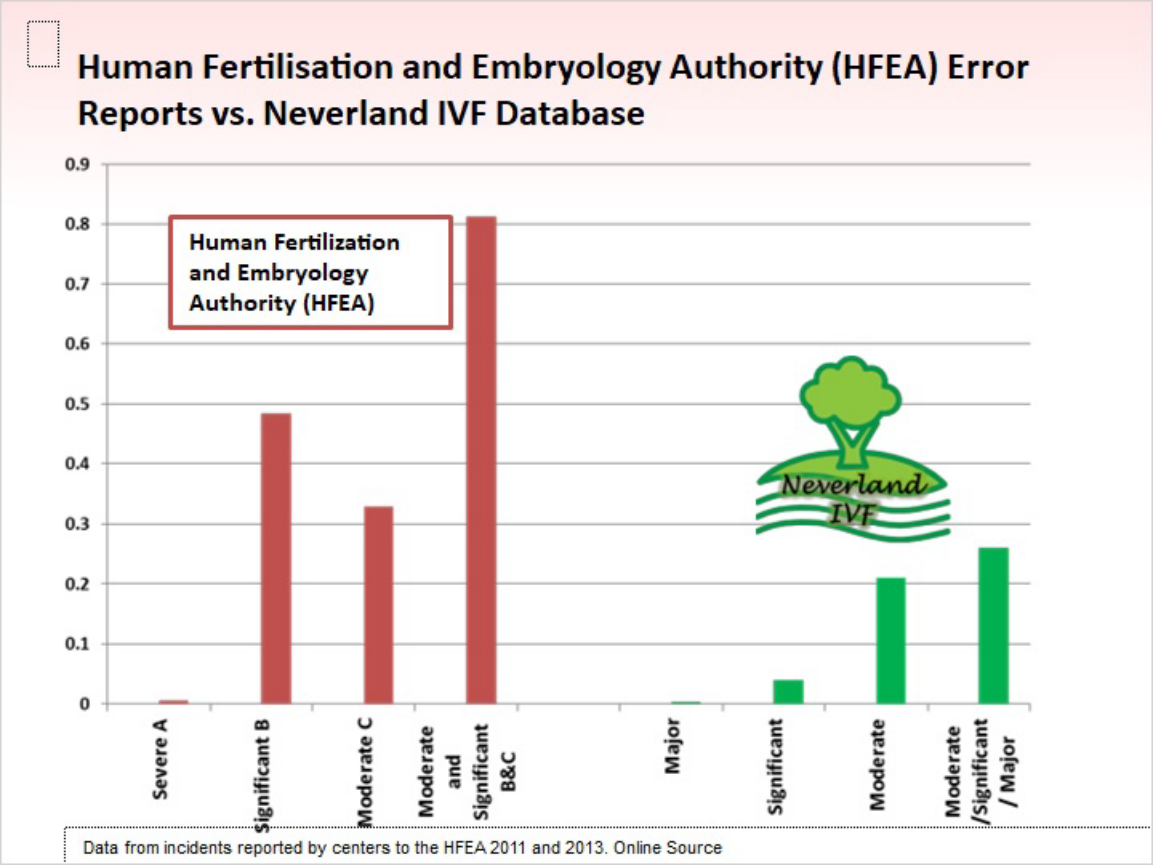
1.31 Extrapolated Estimation of Error Rates in Smaller Clinics



Notes:

The frequency of these occurrences could be extrapolated to smaller and medium-sized clinics, such as those performing approximately 250 or 400 cycles per year and allow estimation of the annual number of moderate/significant errors. A smaller-sized clinic would therefore expect a moderate and significant error once every 2 and 8 years, respectively. Using the same logic, a medium-sized clinic would expect a significant error once every 4 to 5 years.

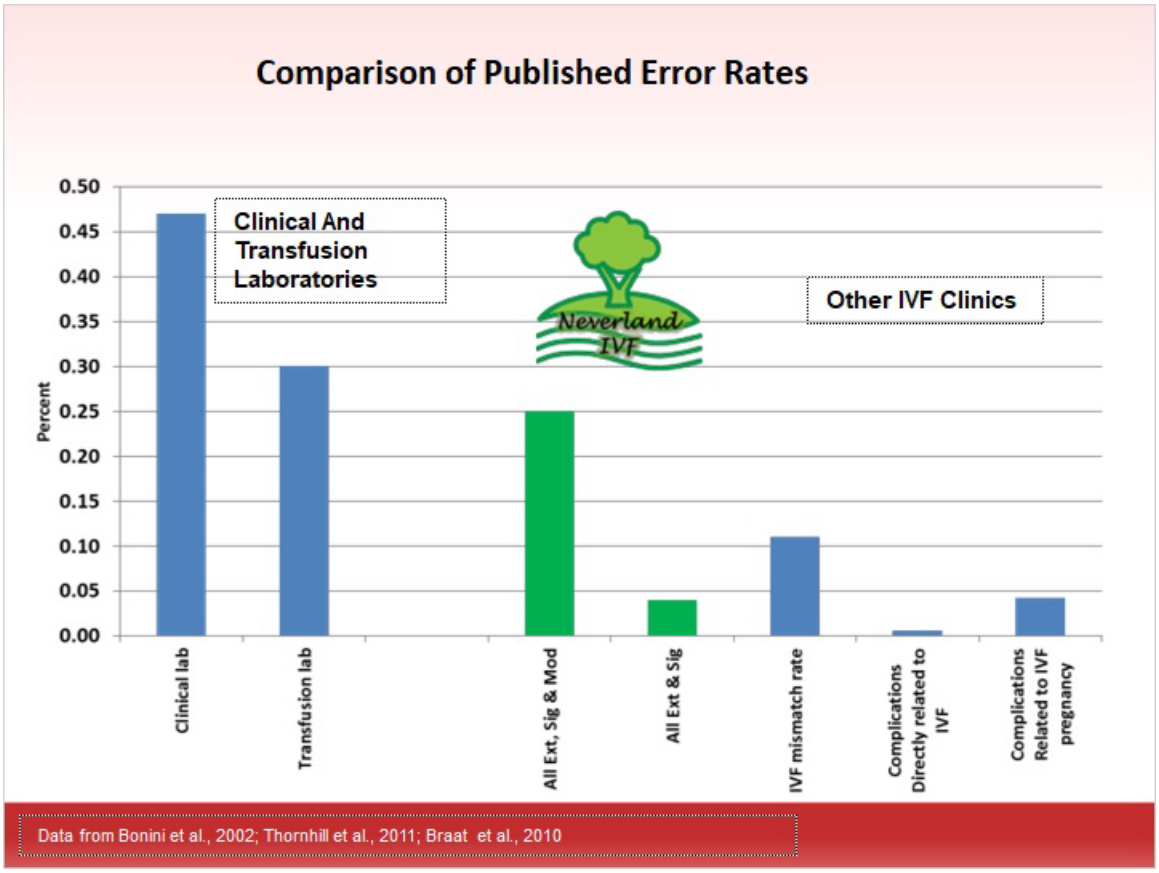
1.32 Human Fertilisation and Embryology Authority (HFEA) Error Reports vs. Neverland IVF Database



Notes:

This chart shows a comparison of the Human Fertilisation and Embryology Authority (HFEA) error reports on the number of incidents involving IVF clinics in the United Kingdom in relation to the Neverland IVF database of nonconformances and errors. Data are presented as the percentage of nonconformances/errors per all cycles in the time frame reported. The HFEA data are based on 120,000 cycles and the Neverland IVF Clinic data on over 30,000 cycles. A comparison of errors between centers is difficult because of different classifications; for example, cases of ovarian hyperstimulation syndrome (OHSS) were not included in the present analysis, whereas they were included in the HFEA data. The HFEA data may better compare with the Neverland clinic's moderate and significant classification.

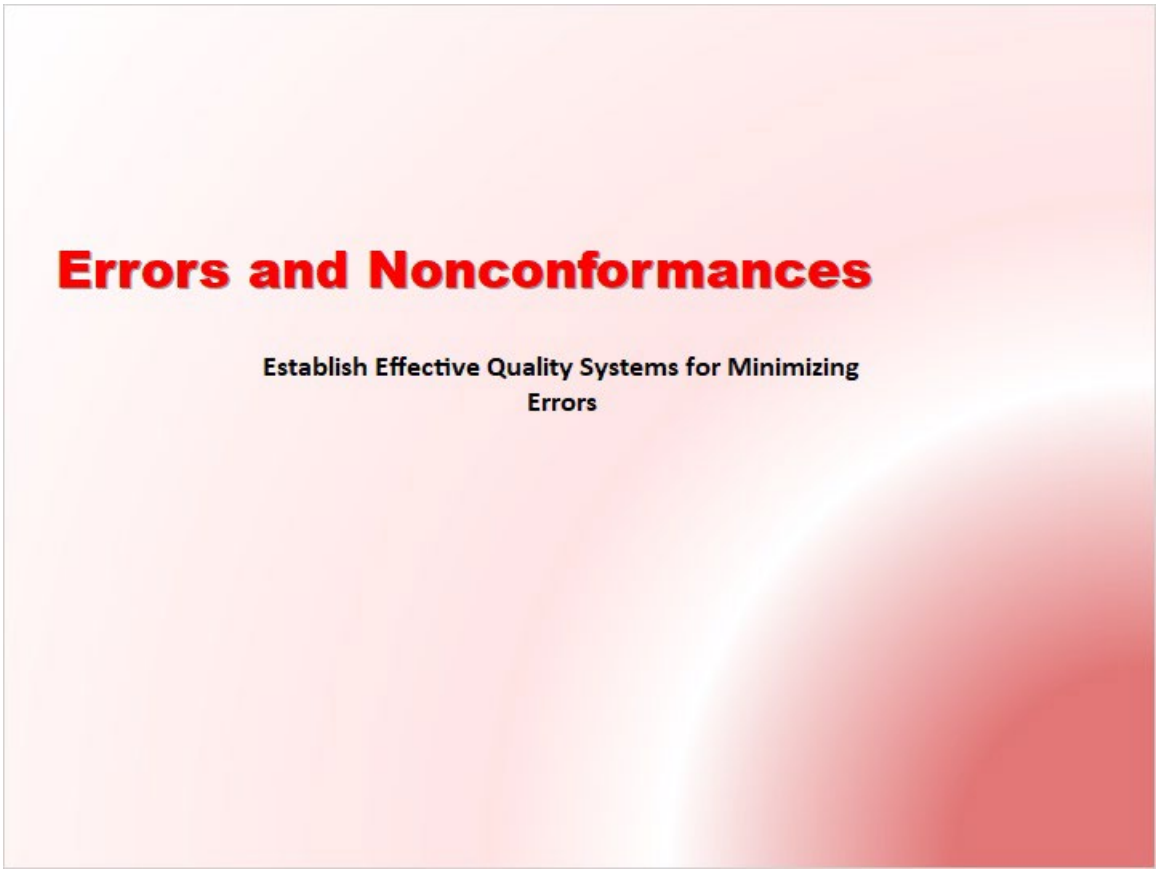
1.33 Untitled Slide



Notes:

When examining clinical lab and transfusion errors it has been reported that the percentage of errors is approximately 0.48% and 0.3%, respectively. The mismatch rate of samples in an IVF laboratory was examined in some studies related to electronic witnessing samples. These systems act by electronically matching label codes from dishes, tubes, vials, or straws and identifying a correct or incorrect match before any procedure or transfer of material takes place. One study showed that the total human mismatch rates were 0.11% (4/3,694) and 0.12% (5/4,105) during a comparison whereby both double manual and electronic readings were performed and then the electronic system was used as a witness.
When complications related to IVF were investigated, the complications directly related to IVF and those related to pregnancy were both below 0.05%.

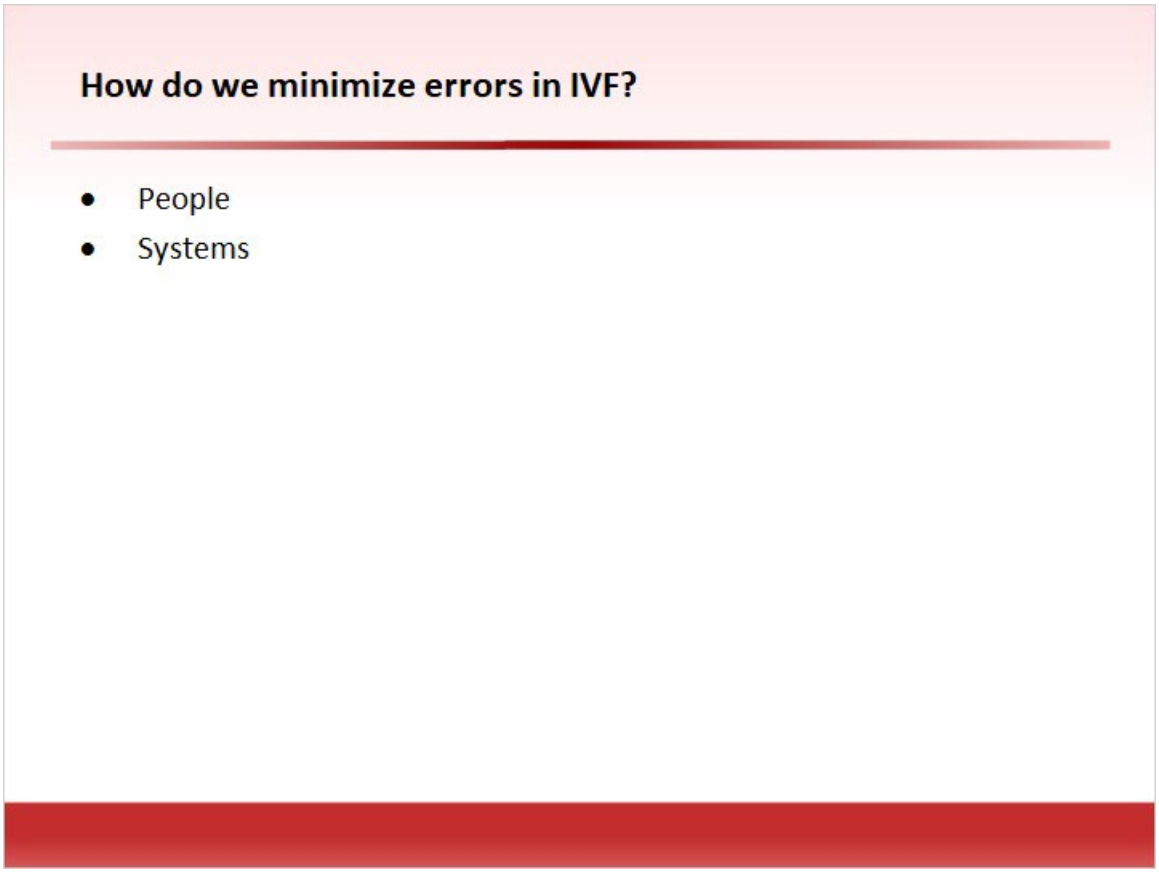
1.34 Errors and Nonconformances



Notes:

The previous data indicate that nonconformances or errors will occur. However, the frequency of occurrence may differ in the various aspects of medicine or laboratory practice. IVF is obviously not immune from these events and therefore establishing effective systems is crucial to minimize the occurrence of any errors.

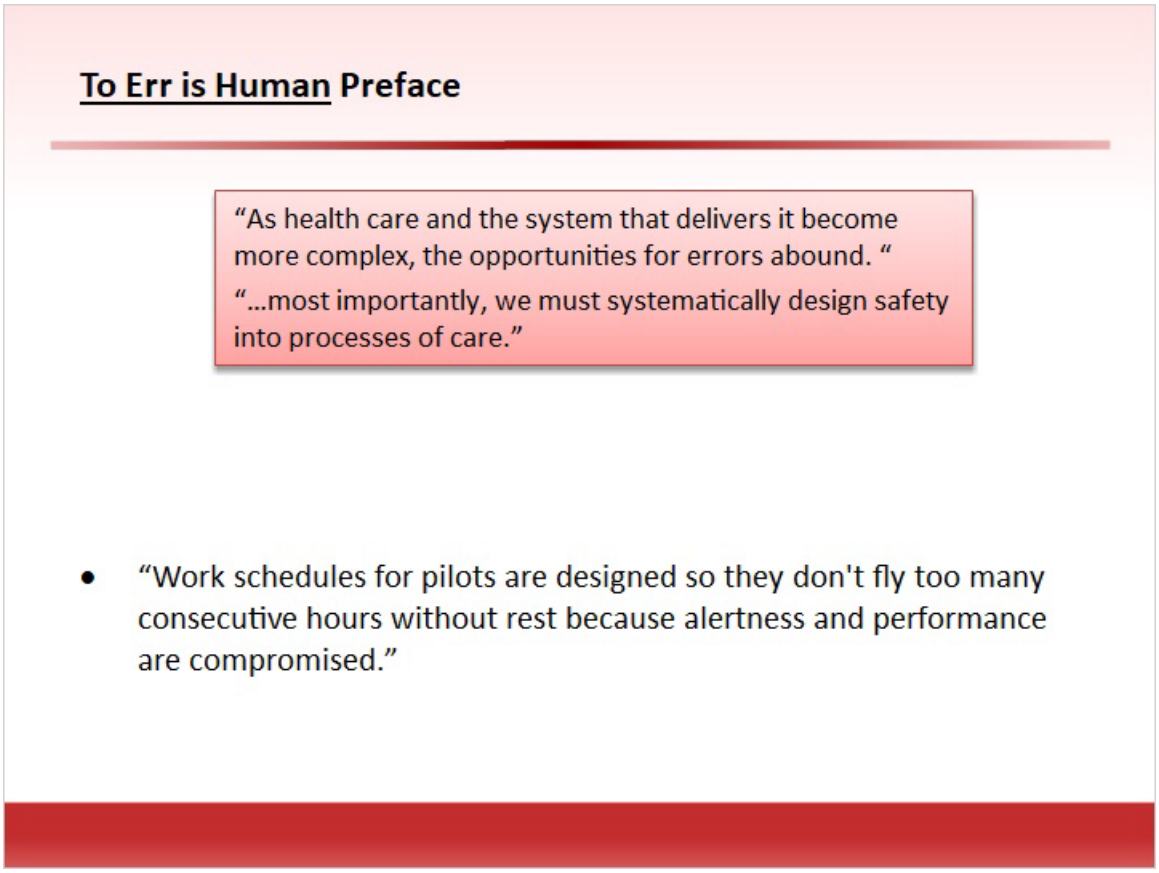
1.35 How do we minimize errors in IVF?



Notes:

Two key aspects of minimizing errors in IVF is having the correct amount of trained personnel and also having systems in place that will both allow people to work effectively but to also identify problem areas

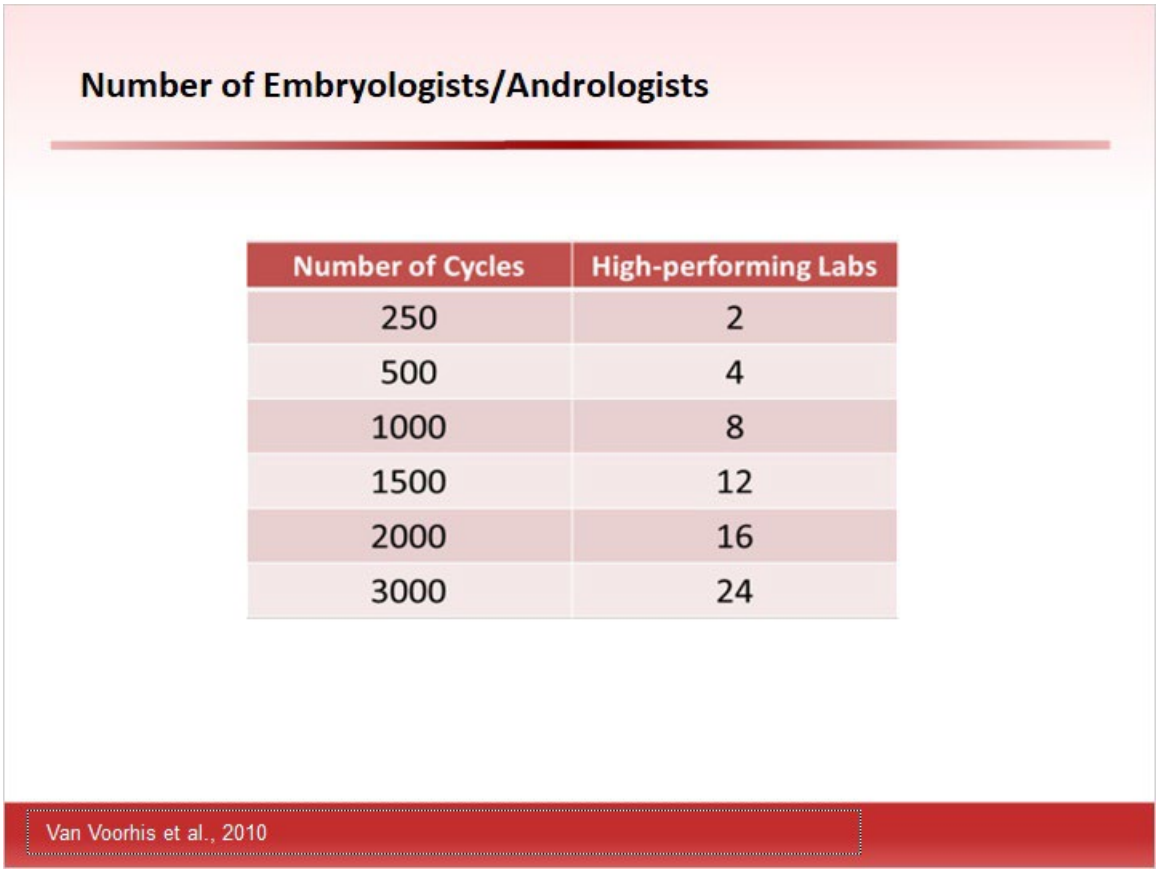
1.36 To Err is Human Preface



Notes:

The documentation and transparency of errors is routine in a number of fields, not just the health care industry. In particular, aviation has a defined system for reporting errors so that data regarding the types and frequency of errors can be appreciated. The Federal Aviation Agency has instituted the "Aviation Safety Reporting System (ASRS)" that allows pilots to anonymously report errors that they have committed to a third party and by so doing protect them from fines and enforcement if they have entered a report.

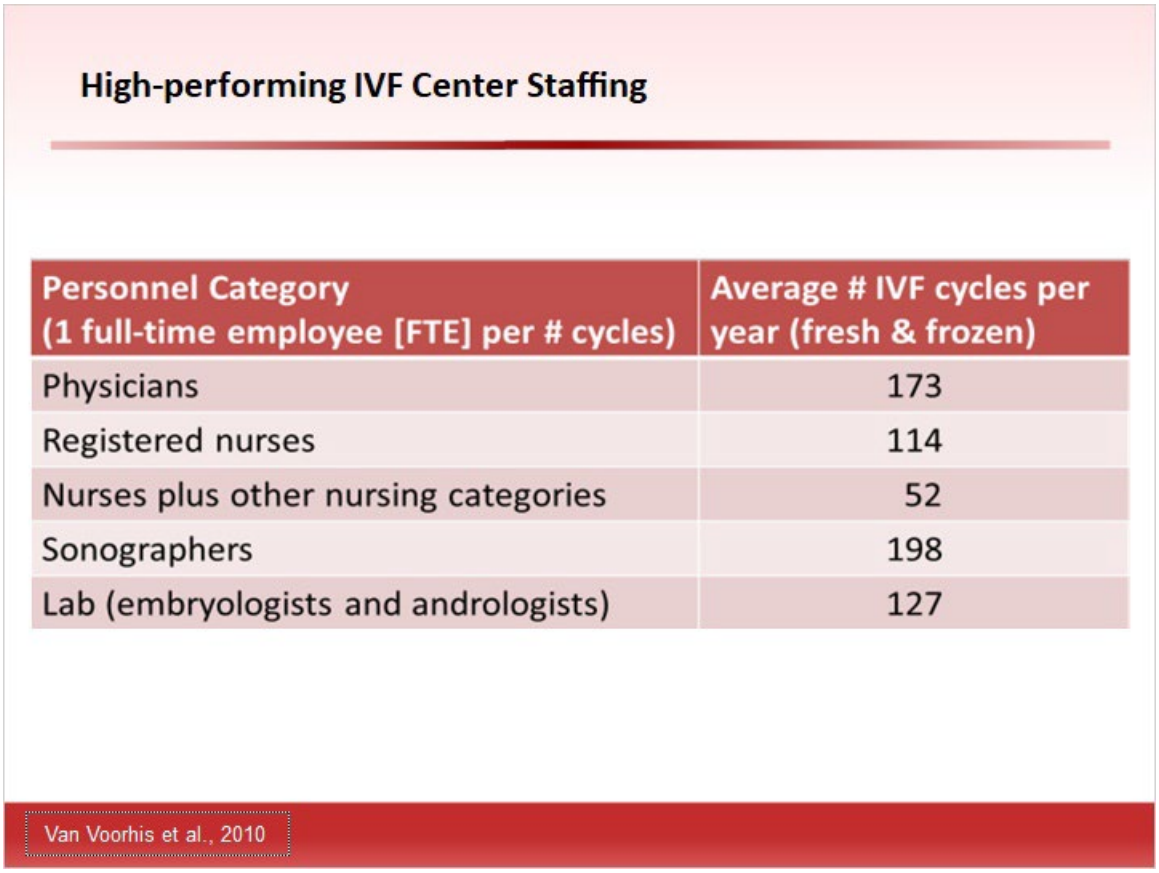
1.37 Number of Embryologists/Andrologists



Notes:

The complexity of an IVF laboratory must be taken into account when looking at nonconformances. In the past 10 years the complexity of the procedures, documentation, and record keeping needed during a routine IVF cycle has increased. The number of personnel in relation to how busy a clinic is becomes critical in dealing with the workload in a manner that does not create an environment prone to errors. This study by Van Voorhis et al. provides data on the average number of embryologists/andrologists needed per cycle in IVF laboratories with high pregnancy rates.

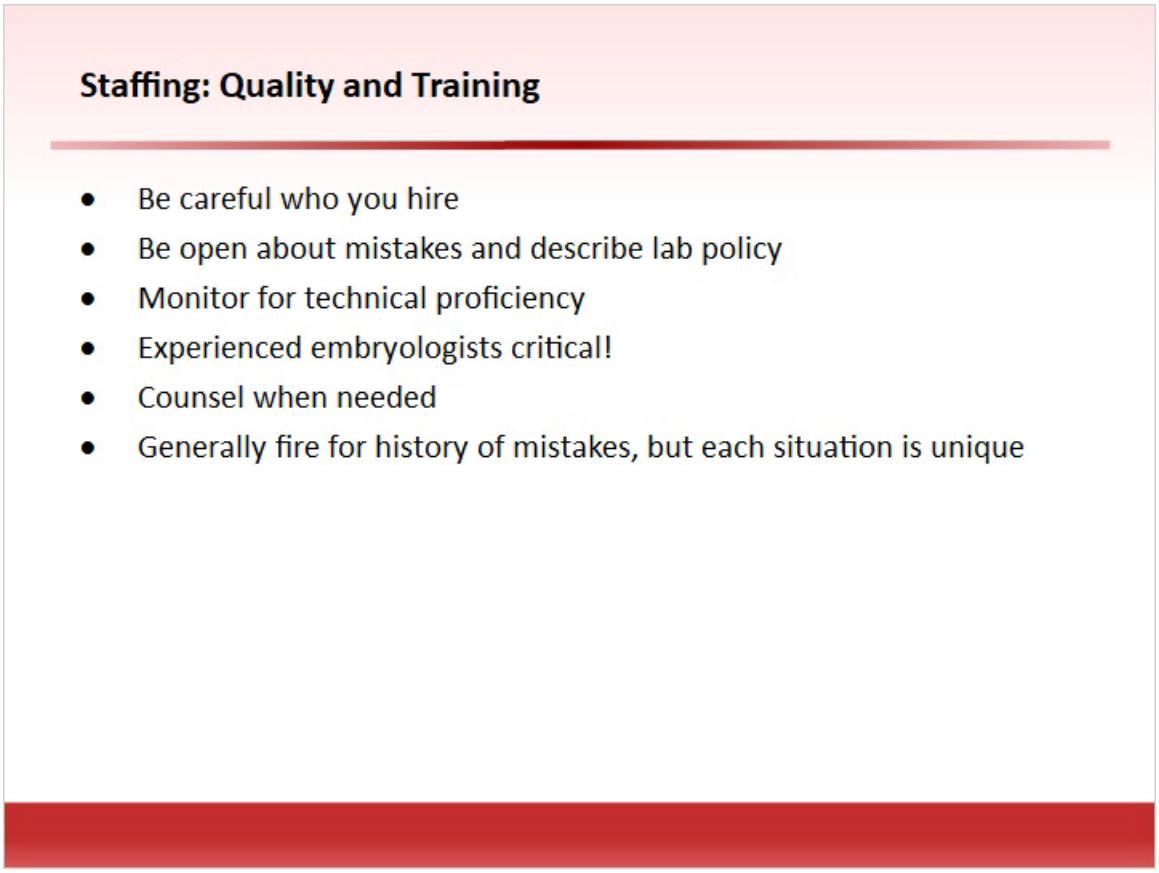
1.38 High-performing IVF Center Staffing



Notes:

Staffing does not relate only to the number of embryologists needed. As previously shown, IVF is a complex procedure bringing together different disciplines and parts of the whole ART clinic. Therefore the ratios of clinicians, nurses, and other support staff relative to the workload (number of cycles) are all crucial to having an IVF center perform at a high level and minimize any risks of errors.

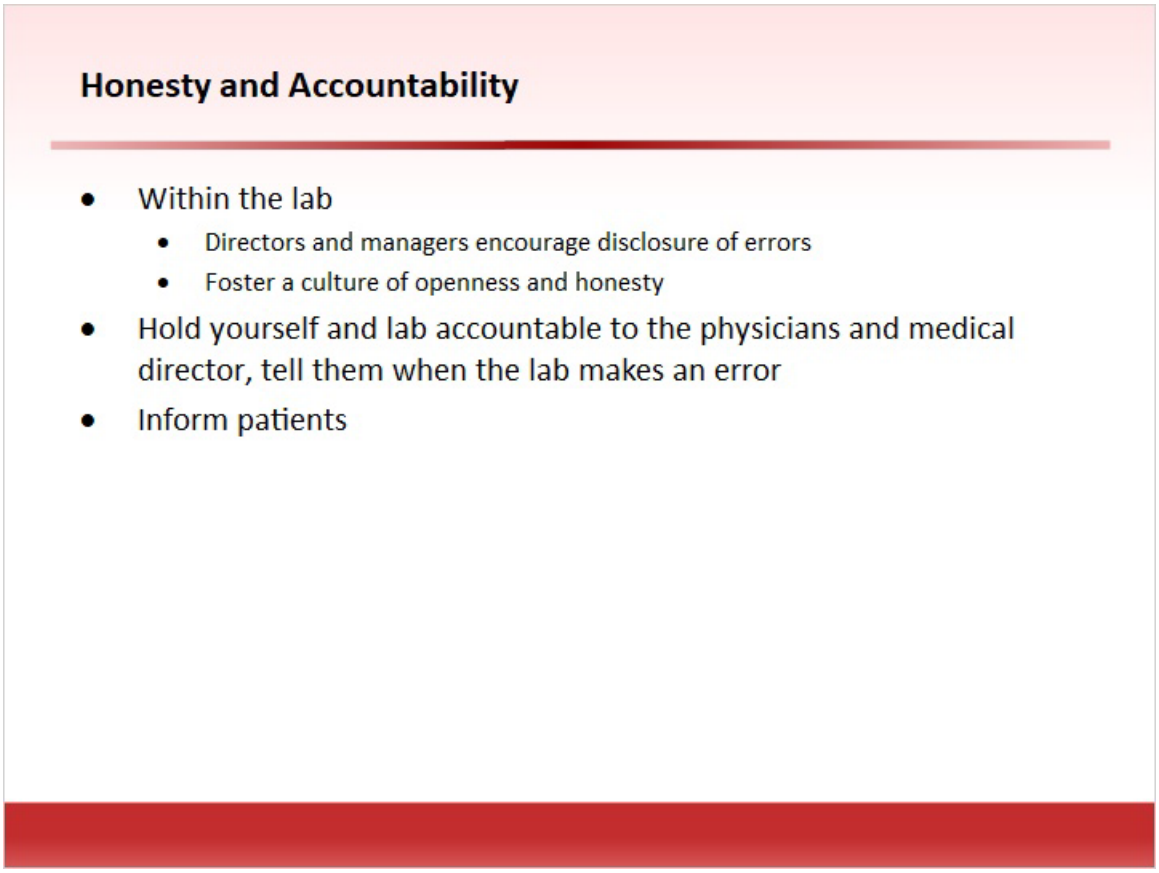
1.39 Staffing: Quality and Training



Notes:

The quality of staff is even more critical as is experience and ongoing training of all staff. Having staff adequately trained and signed off for their proficiency in each and every technique is paramount. The “see one, do one, teach one” mentality is not an appropriate approach in the IVF lab. Routine assessment of staff to make sure they have not drifted from protocol and monitoring of their performance is also needed. Monitoring staff on proficiency should not be construed as a negative, but as a way of maintaining high levels of results. In addition, if an employee consistently performs a technique at a higher level they can be used for training of new staff. Finally, if a staff member is unable to perform after all avenues of training have been attempted or there is a history of nonconformances to protocols it is prudent to consider removing that person from certain tasks.

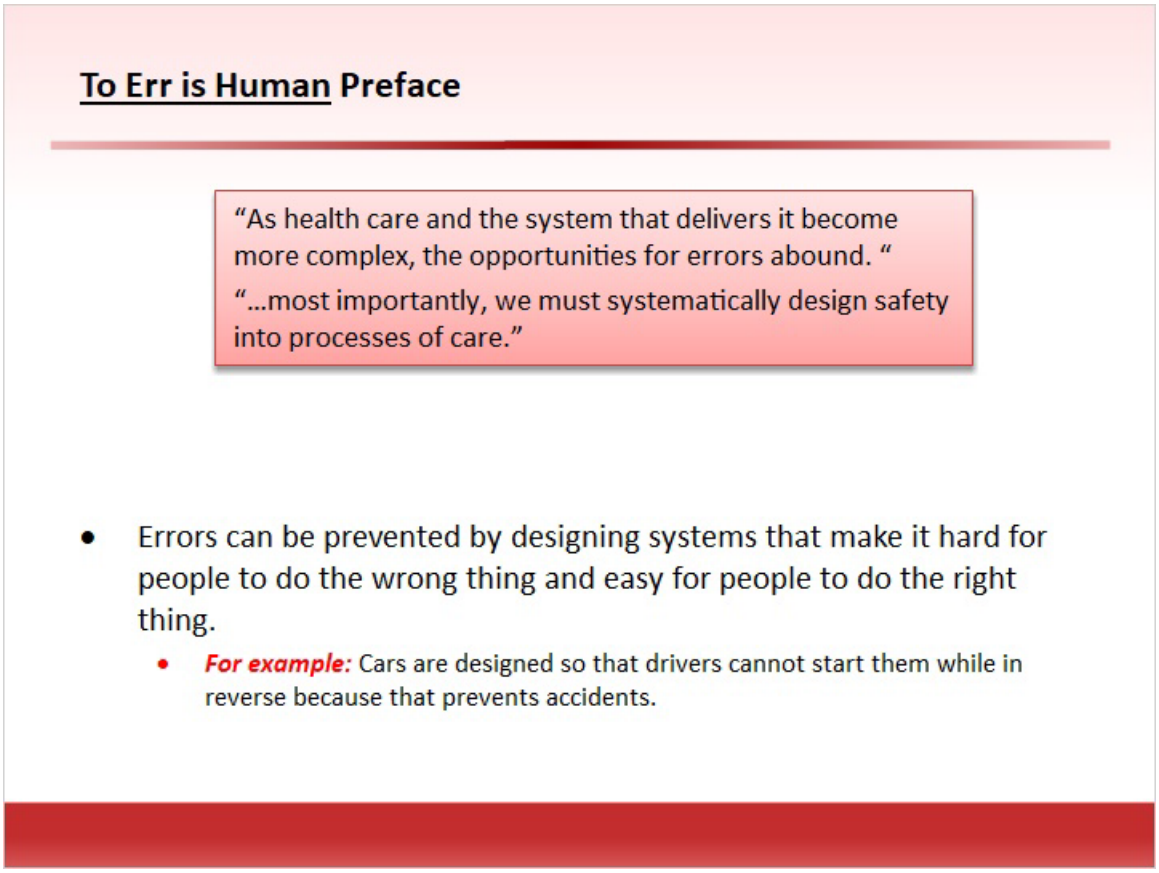
1.40 Honesty and Accountability



Notes:

Establishing the ethos of “To err is human…” is an important cornerstone in creating and maintaining high quality in an IVF lab. In this respect communication will only occur if there is honesty and accountability in the clinic. The last thing employees want to feel is that they are unable to speak to someone about an error and believe that they can hide it.

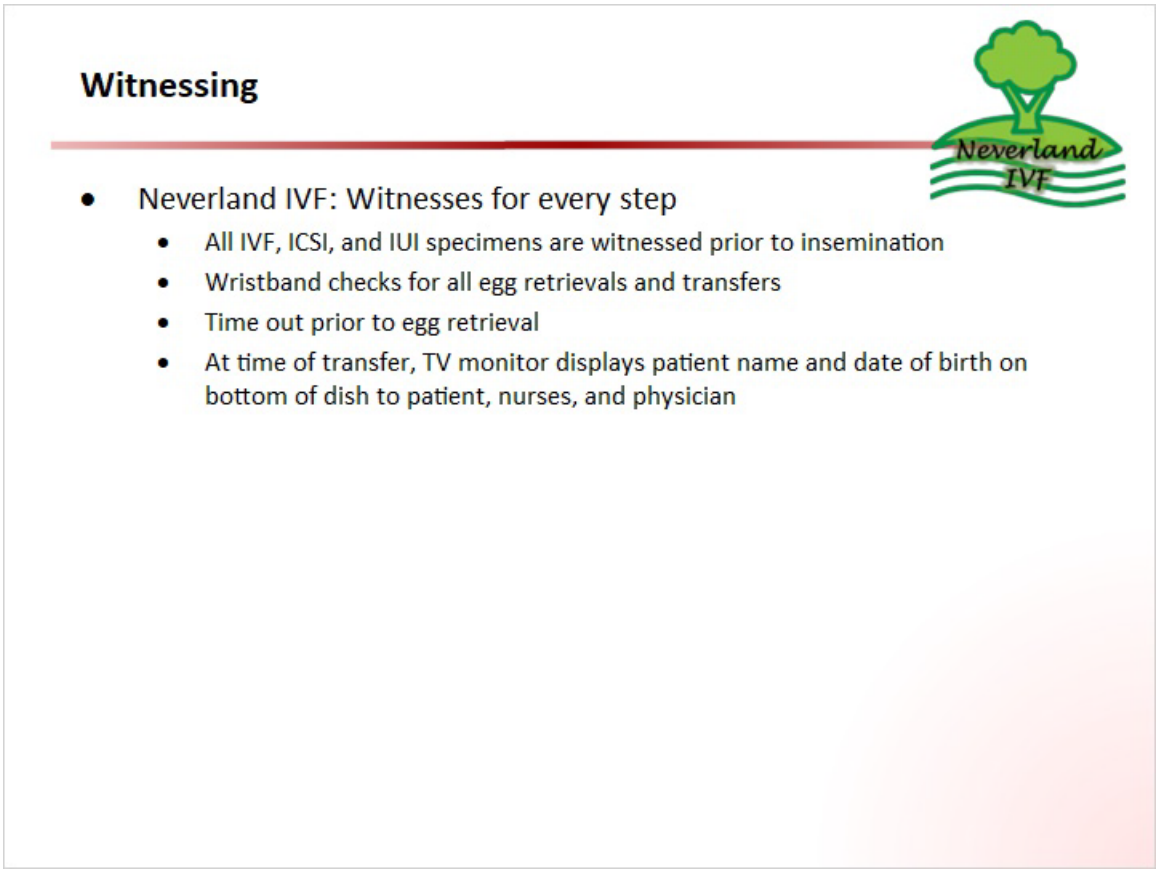
1.41 To Err is Human Preface



Notes:

The concept a clinic should develop is that systems are put in place to try and avoid any errors. Building tight and systematic protocols will protect a clinic from drift in procedures that increases the chance of error. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. For example, cars are designed so that drivers cannot start them while in reverse because that prevents accidents.

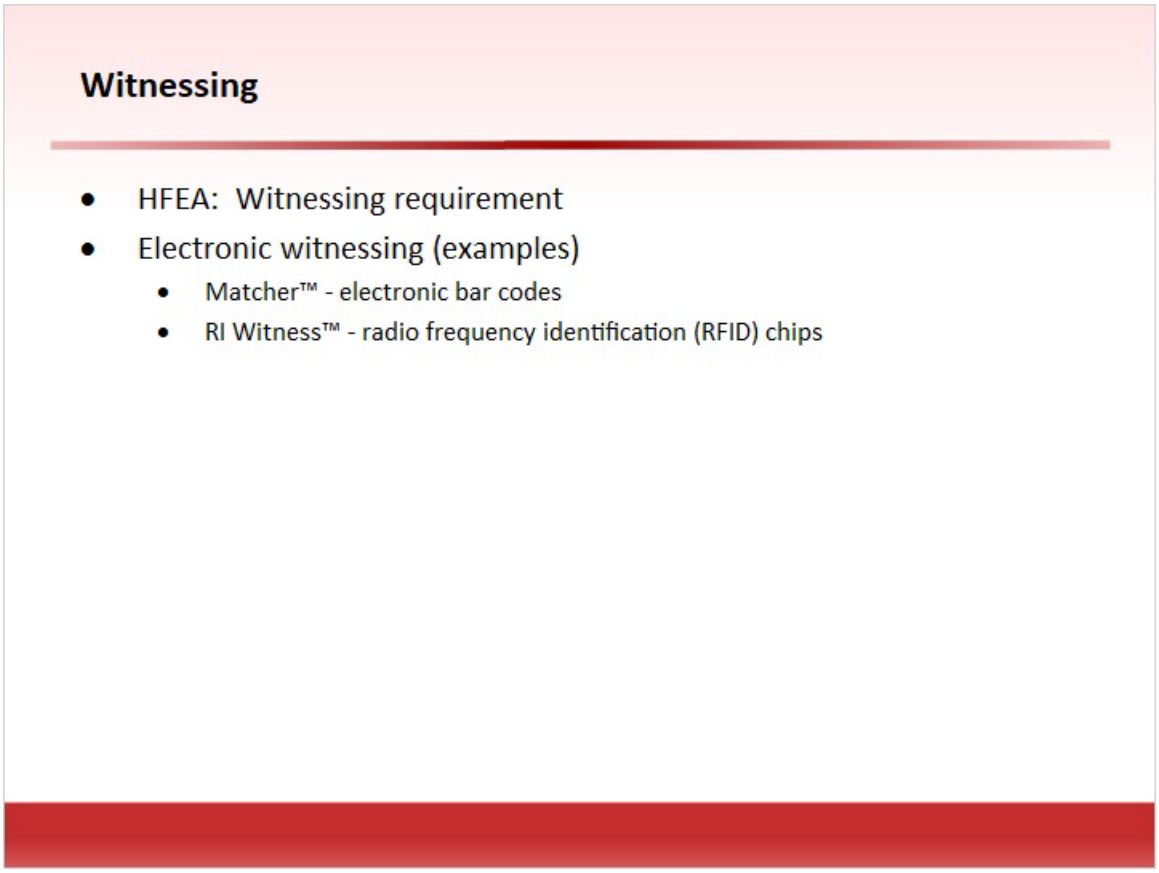
1.42 Witnessing



Notes:

One of the most dramatic errors that can occur in an IVF clinic is the mix-up of gametes or embryos between patients. Several years ago, the HFEA mandated that witnessing is needed in all UK-based IVF clinics. Neverland IVF witnesses all crucial steps, including any gamete preparations, retrievals, and transfers. Timeouts are also utilized to allow staff the correct amount of time to identify patients.

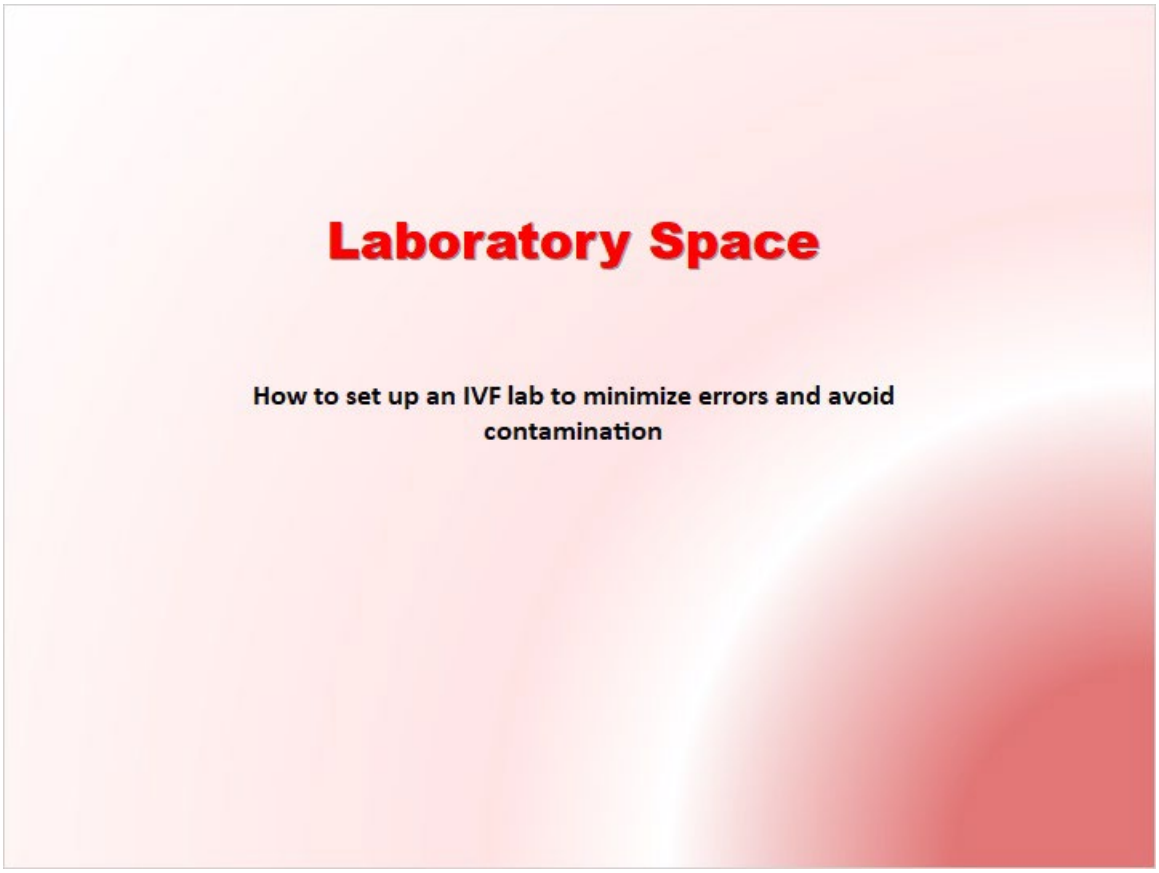
1.43 Witnessing



Notes:

Witnessing can be performed either manually or using electronic systems. In the United Kingdom there are companies that now offer electronic witnessing. These systems match tubes, dishes, and any other materials used to treat a couple and create an alarm whenever a match is not identified.

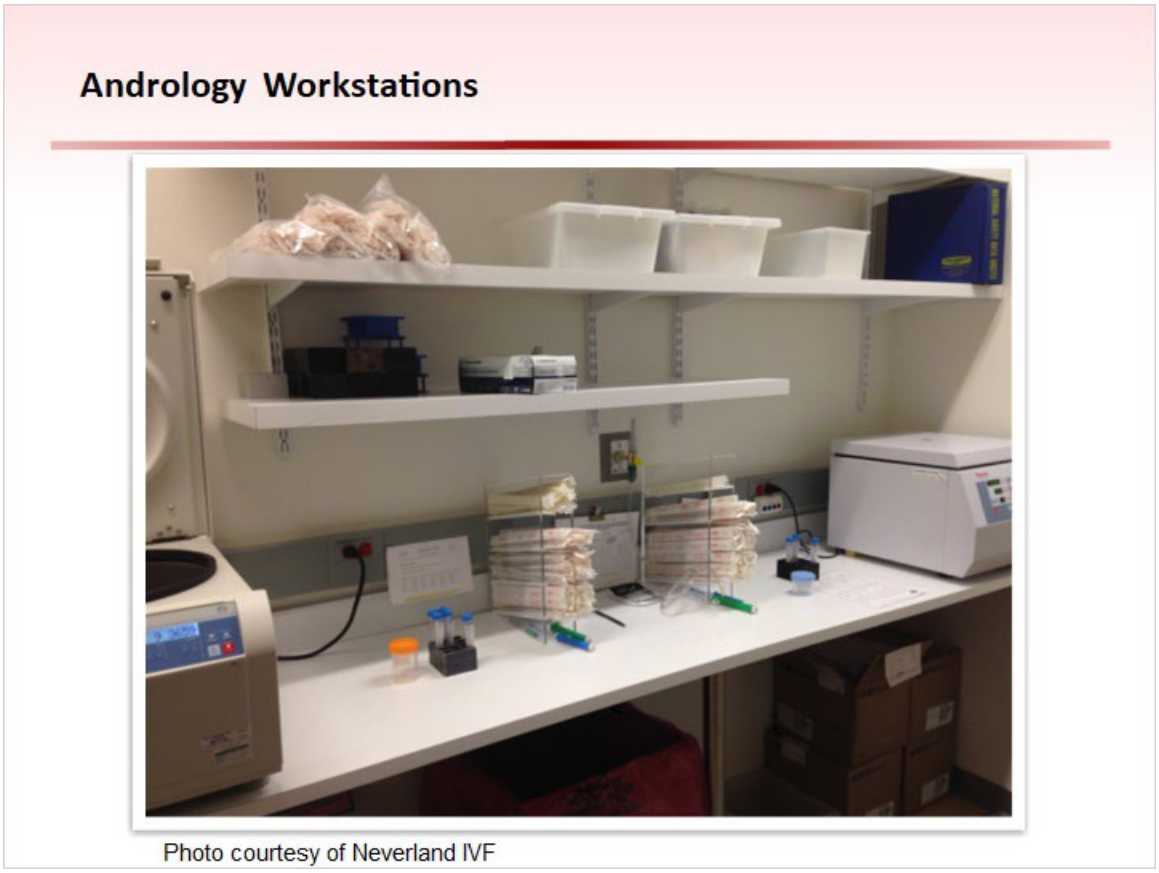
1.44 Laboratory Space



Notes:

Allocating sufficient space for different procedures in an IVF lab is also critical to minimize errors. Although many labs are constrained by the physical space they occupy, it is important to arrange the space in such a way as to create a safe yet efficient flow of work.

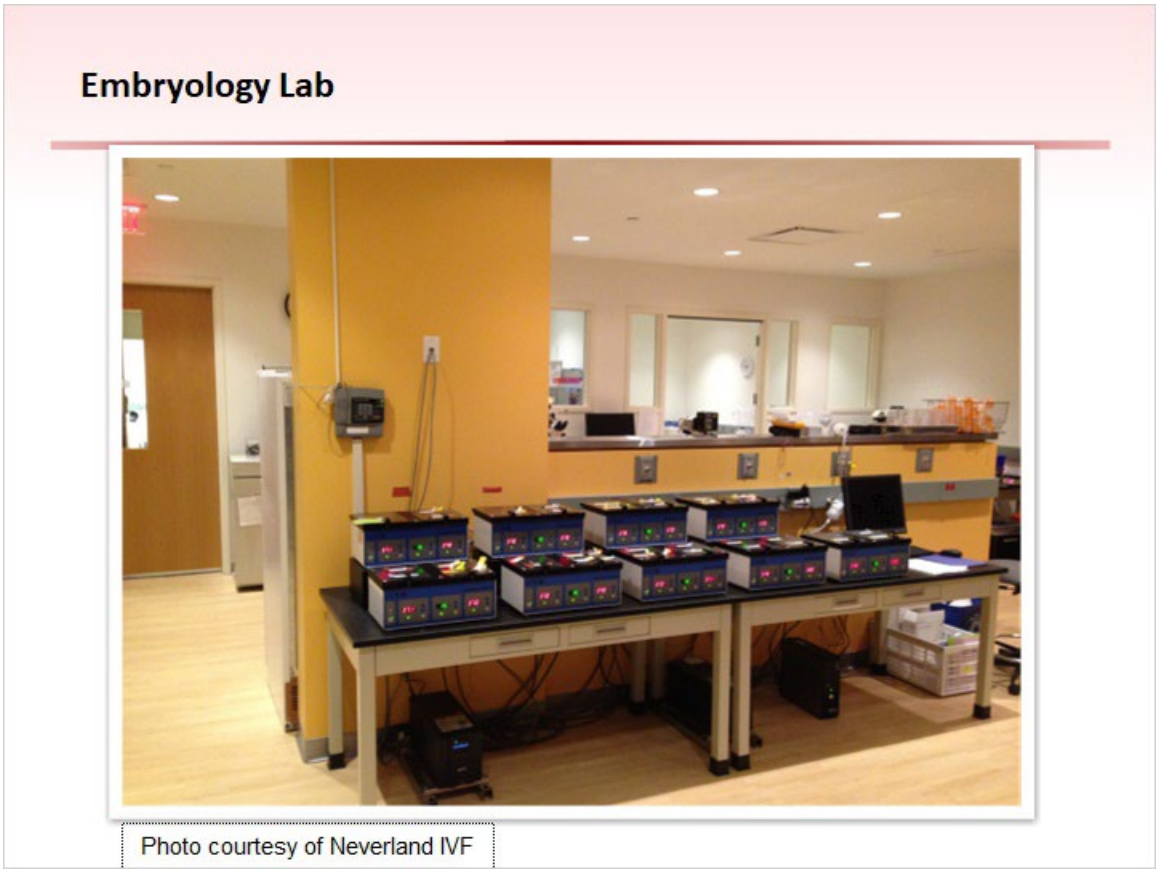
1.45 Andrology Workstations



Notes:

In order to avoid any errors in processing sperm, samples should be processed separately in time or space. This image shows a physical separation between sperm samples; each sample is processed on a different part of the bench and in a separate centrifuge. The sample container, tubes and processing documents are all labeled with the patient's name and date of birth and all of these are checked by two different andrologists. Other ways of minimizing the risk of cross-contamination include: processing sperm one sample at a time (this can work for smaller labs) or processing samples in different hoods.

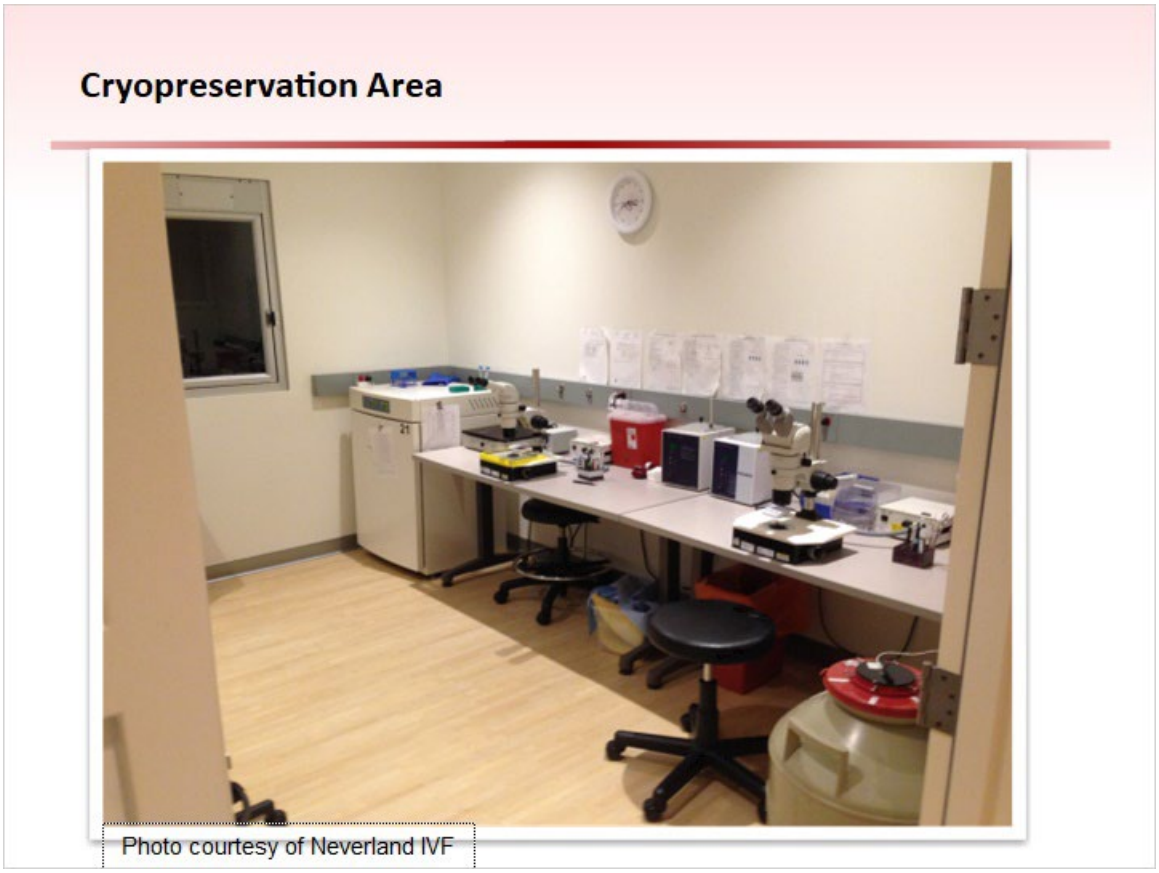
1.46 Embryology Lab



Notes:

Incubators should be easily accessible and at an appropriate height. They must be alarmed and generally an uninterruptible power supply (UPS) device and/or backup generator should be present in the event of loss of power. This lab has a high-efficiency particulate absorption (HEPA) and carbon-filtered air supply in order to minimize the risk of contamination from dust and decrease the amount of volatile organic compounds (VOCs) in the air.

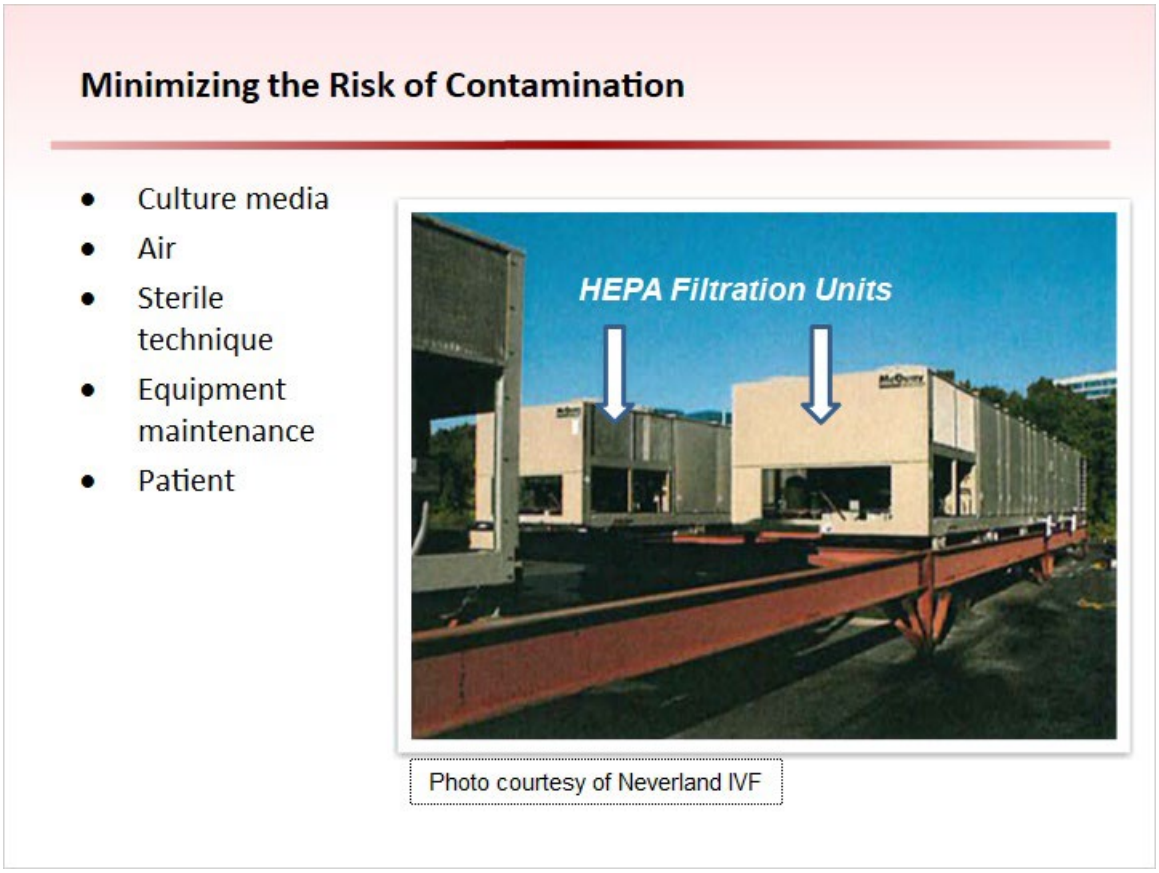
1.47 Cryopreservation Area



Notes:

Pictured here is the area used for freezing and thawing embryos. It is in a separate area of the embryology lab in order to minimize activity and allow the embryologists to be focused on their work. Separate workstations are used by each embryologist for each patient.

1.48 Minimizing the Risk of Contamination



Notes:

Culture medium can be contaminated by numerous routes, including poor air quality, nonsterile technique, poor equipment maintenance, and from the semen sample.
Minimizing the particle count in the air in an IVF lab is critical in order to minimize the possibility of contamination from airborne particles. All IVF labs use one of the following to reduce particulate counts: laminar flow hoods, stand-alone HEPA filtration units, or an HVAC system equipped with a HEPA filter, as shown on the image here. Air should be tested periodically for particle counts to ensure that the filtration system is functioning.
Whenever medium is prepared or pipetted into dishes, sterile technique is essential. Working under oil minimizes the risk of contamination.
Incubators must be kept clean and water for humidification must be changed regularly.
All equipment should be inspected by qualified technicians to ensure that it is in proper working order.
On rare occasions, a semen sample will contain bacteria resistant to antibiotics that will grow in the culture medium. Testing should be performed to identify the type of bacteria.

1.49 Errors and Nonconformances

Notes:

Organizations and companies often want to get certified to International Organization for Standardization (ISO) management system standards. The best reason for wanting to implement these standards is to improve efficiency and effectiveness.

An organization may decide to seek certification for many reasons, as certification may:
-be a contractual or regulatory requirement
-be necessary to meet customer preferences
-fall within the context of a risk management program, and
-help motivate staff by setting a clear goal for the development of its management system.

1.50 Systems and Procedures

Notes:

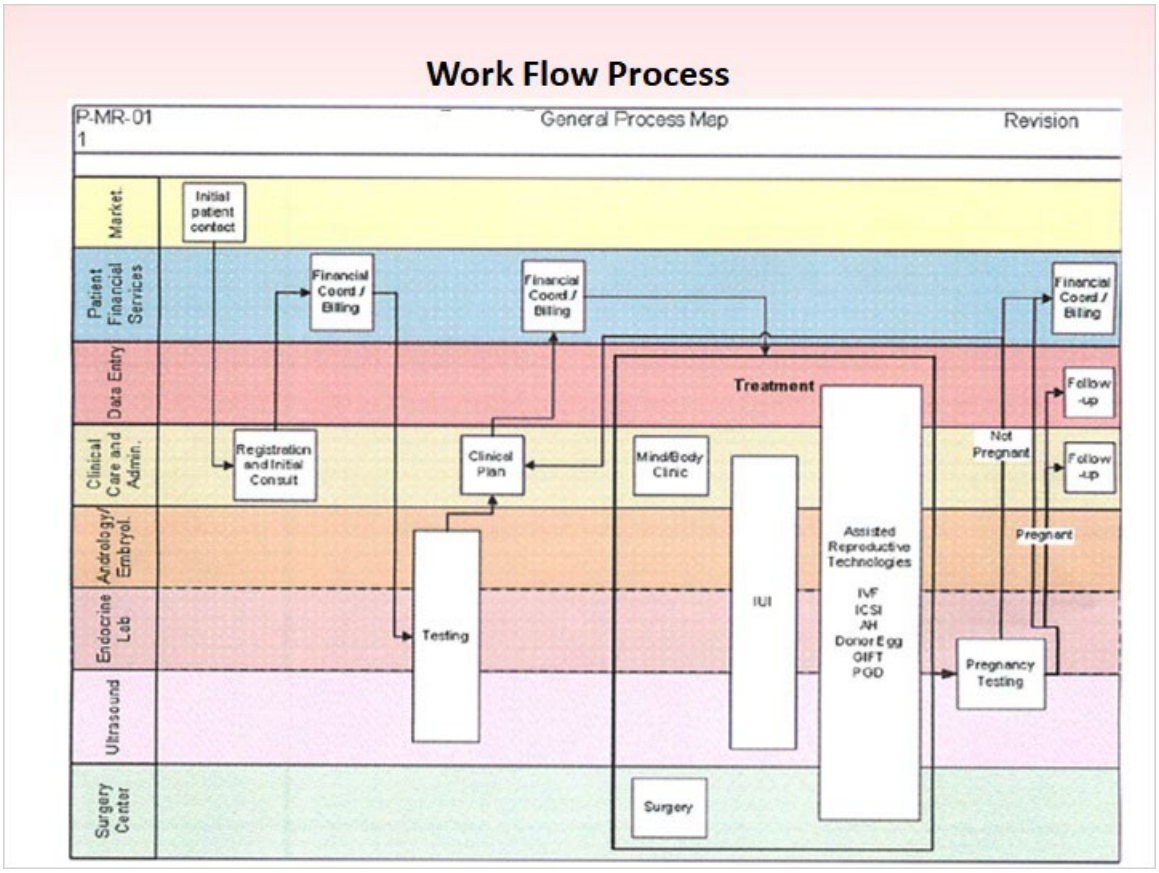
The ISO 9001:2008 is an international quality management system to which thousands of companies worldwide are certified. The system consists of numerous standards that must be fulfilled, although it is generally left up to the organization how best to do that. In contrast to other accreditation systems that sometimes only involve part of a clinic (e.g. CAP/CLIA for the lab), compliance to ISO 9001 involves the entire organization and is comprehensive.

1.51 Management Involvement

Notes:

No quality management system will function effectively without the active consent and involvement of the upper management in the clinic. The ISO quality standard requires this involvement as well as the identification of one person who is the Quality Manager for the entire company. In many, if not most clinics, quality is an afterthought and is, if present at all, confined to only parts of the clinic. Different areas will have different standards for quality and this results in inefficiencies and overall loss of quality even in areas that have higher quality.

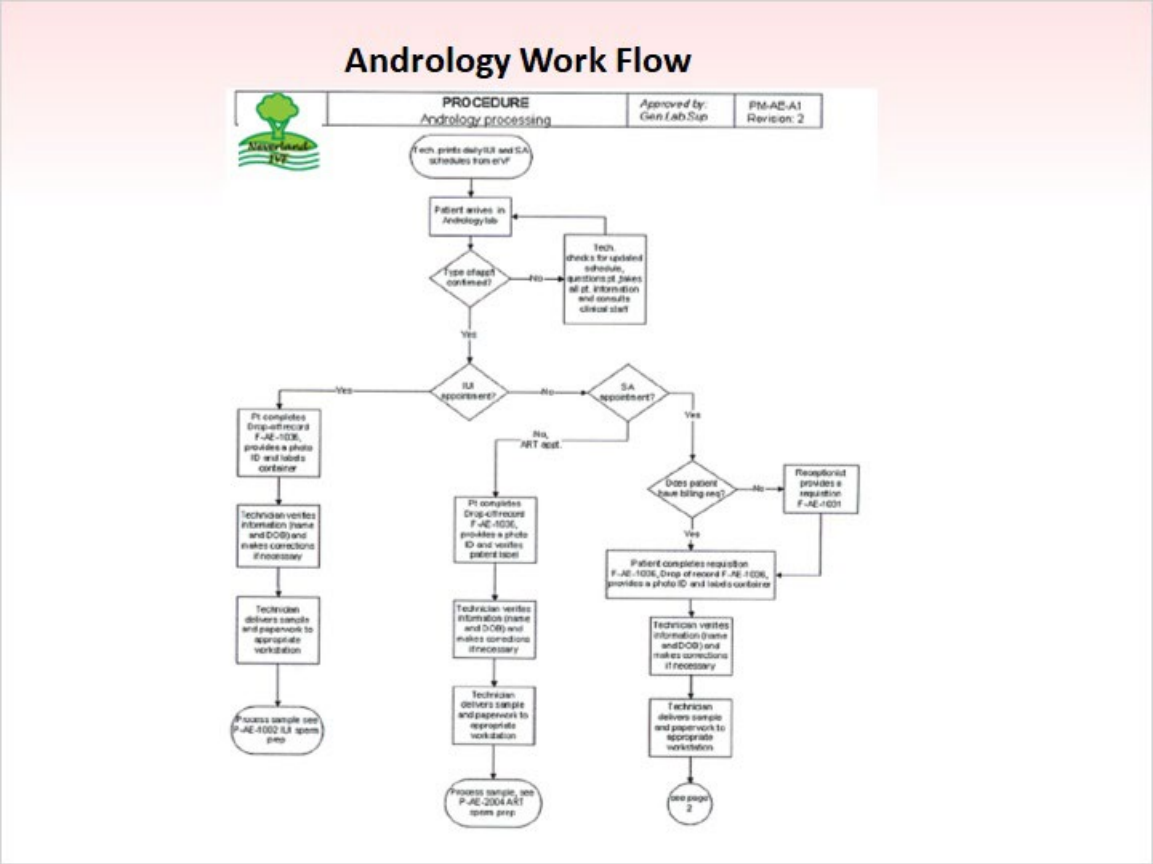
1.52 Work Flow Process



Notes:

One of the first steps in establishing a quality management system is to understand the flow of work in the clinic and how the different departments relate to each other. This flow chart is a high level view of the work flow for Neverland IVF. The different departments are listed along the left side and the points at which a patient will interact with the different departments are shown in the flow chart from left to right.

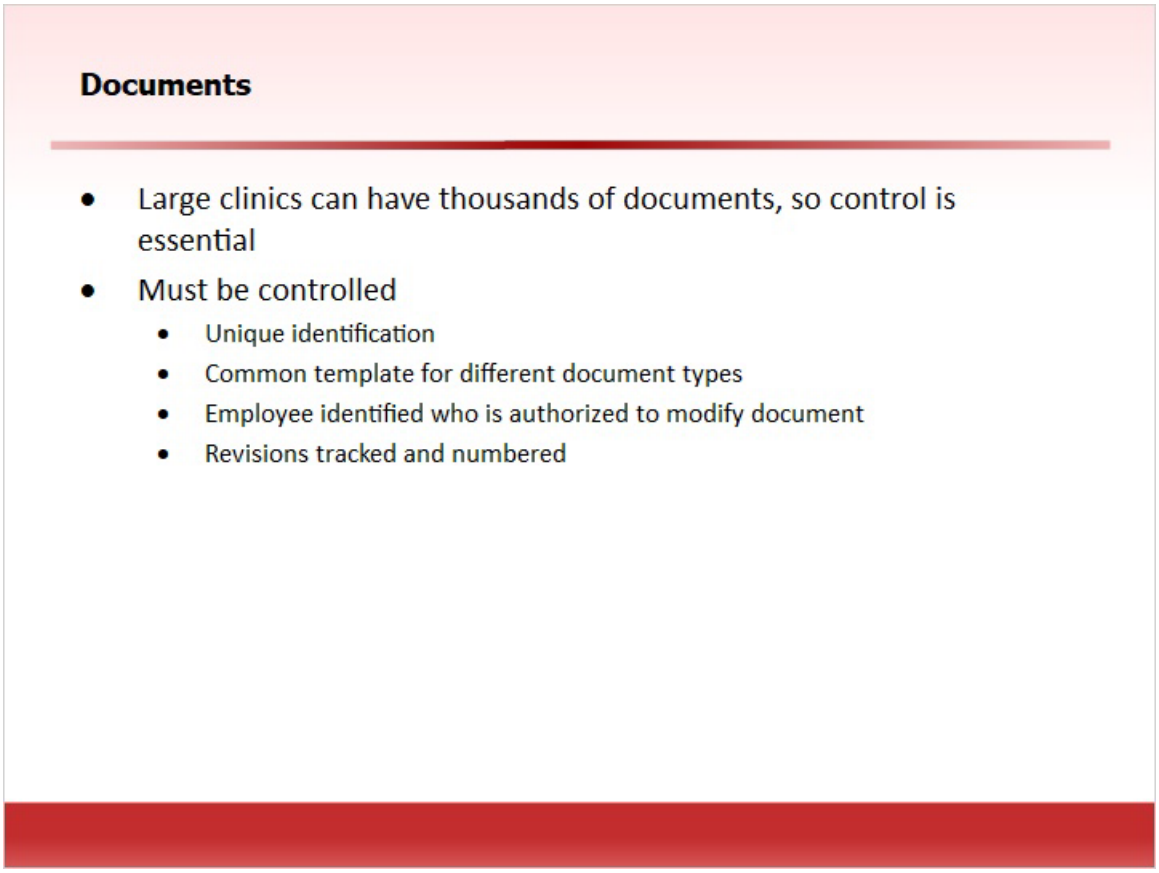
1.53 Andrology Work Flow



Notes:

Each department has its own work flow and the chart above shows part of this flow for the Neverland andrology lab. The process of writing down the work flow is critical to understanding how a particular procedure involves staff, equipment, and other departments. Performing an analysis of the flow of work allows for identification of inefficiencies and areas where errors can occur.

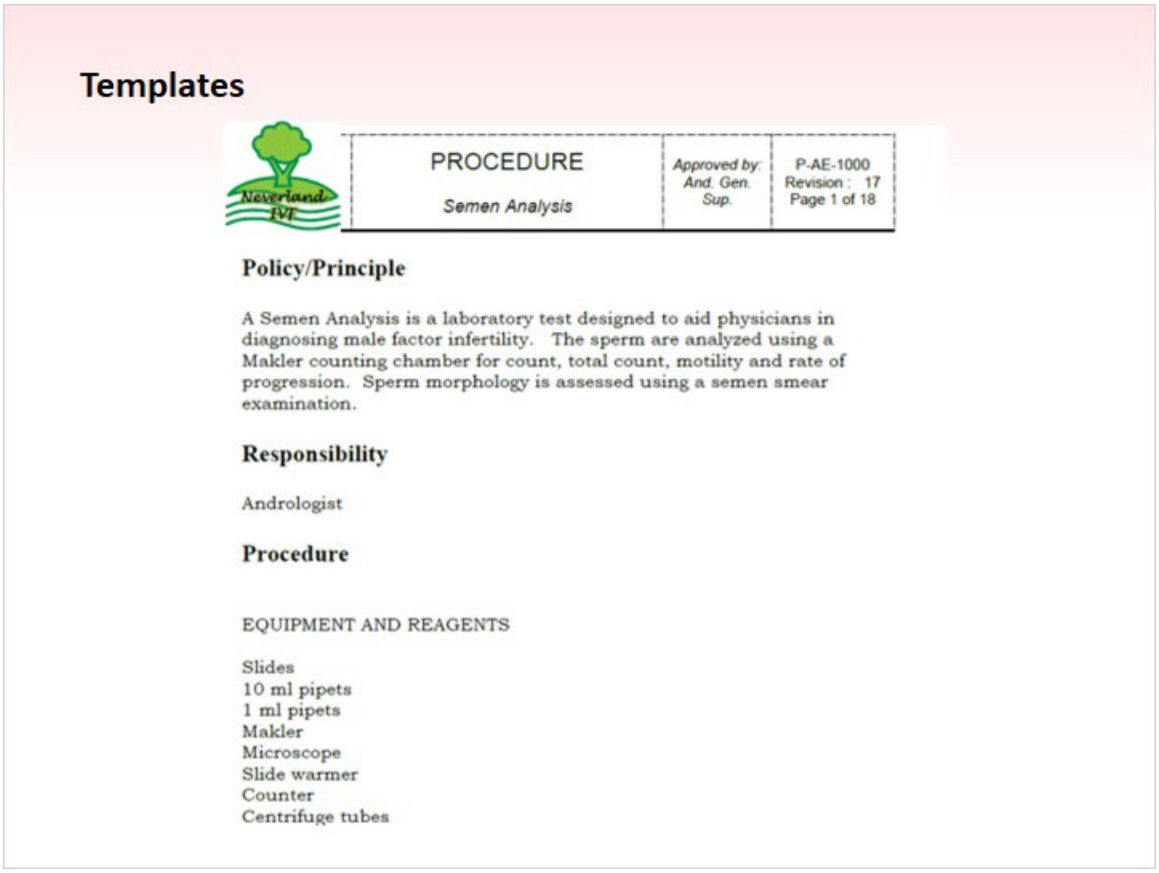
1.54 Documents



Notes:

As noted, ART is a complex field and involves many different types of documents. It is not unusual for a large clinic to have thousands of different documents that are used throughout the company. This can include hundreds of procedures and work instructions (shorter, 1-page documents that detail how to perform a specific function), as well as forms. Document control is critical and this involves identification of each document, a uniform format for naming and identifying documents, a record of when documents are changed, and identification of the individual(s) who has authority to change a document.

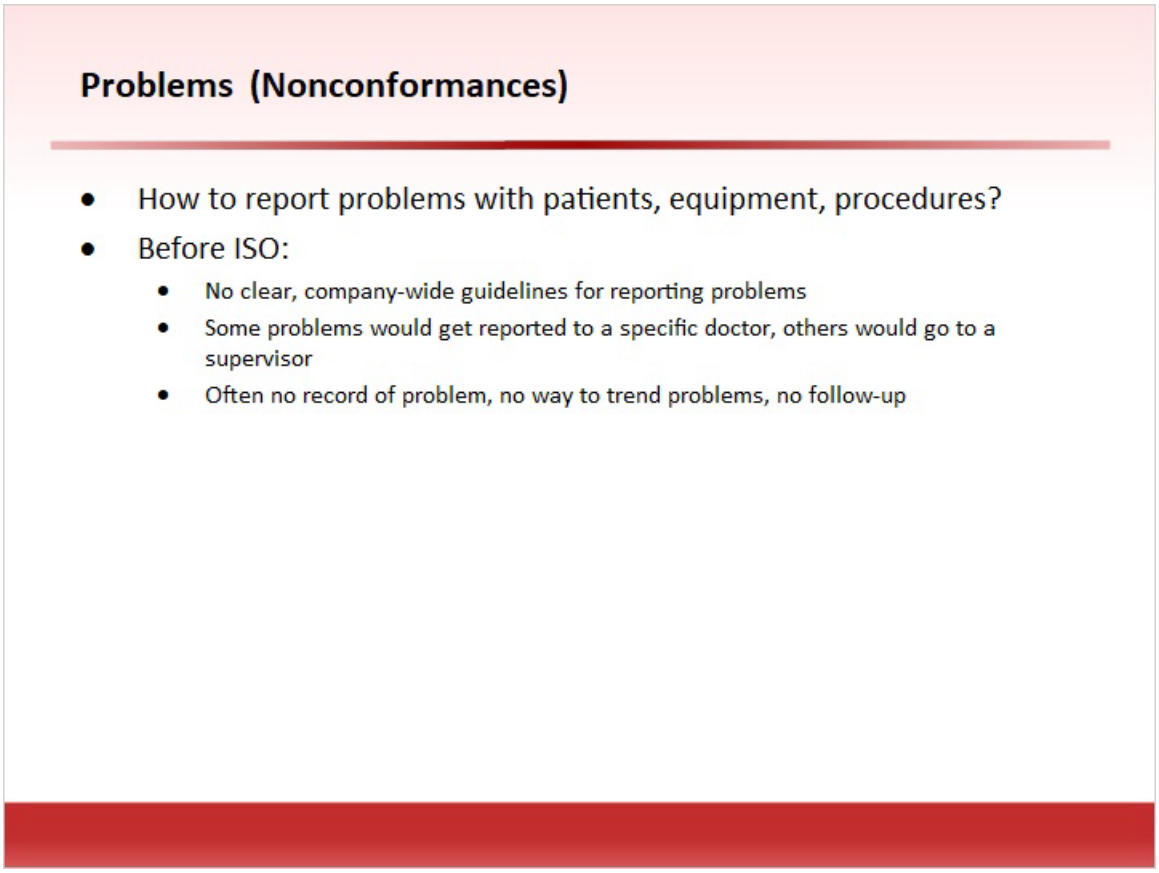
1.55 Templates



Notes:

Generally, templates are created to identify each type of document and this template is used throughout the company. The document shown above is a semen analysis procedure and indicates who has control of the document and the revision number.

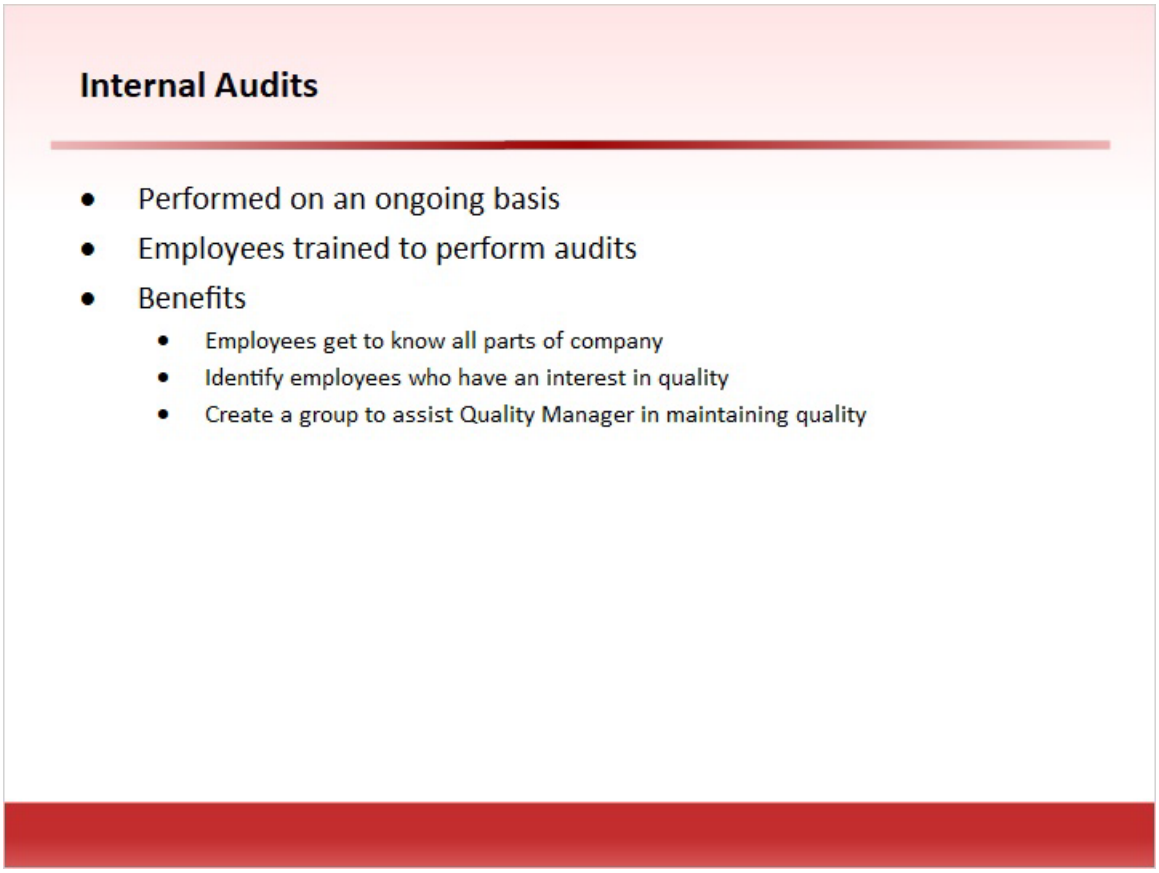
1.56 Problems (Nonconformances)



Notes:

The ISO 9001 quality standard requires that a system be established to report and document nonconformances that occur. At Neverland, before ISO, there were no clear, company-wide guidelines for reporting problems, some problems would get reported to a specific doctor, others would go to a supervisor, and often there would be no record of problem, no way to trend problems, and no follow-up.

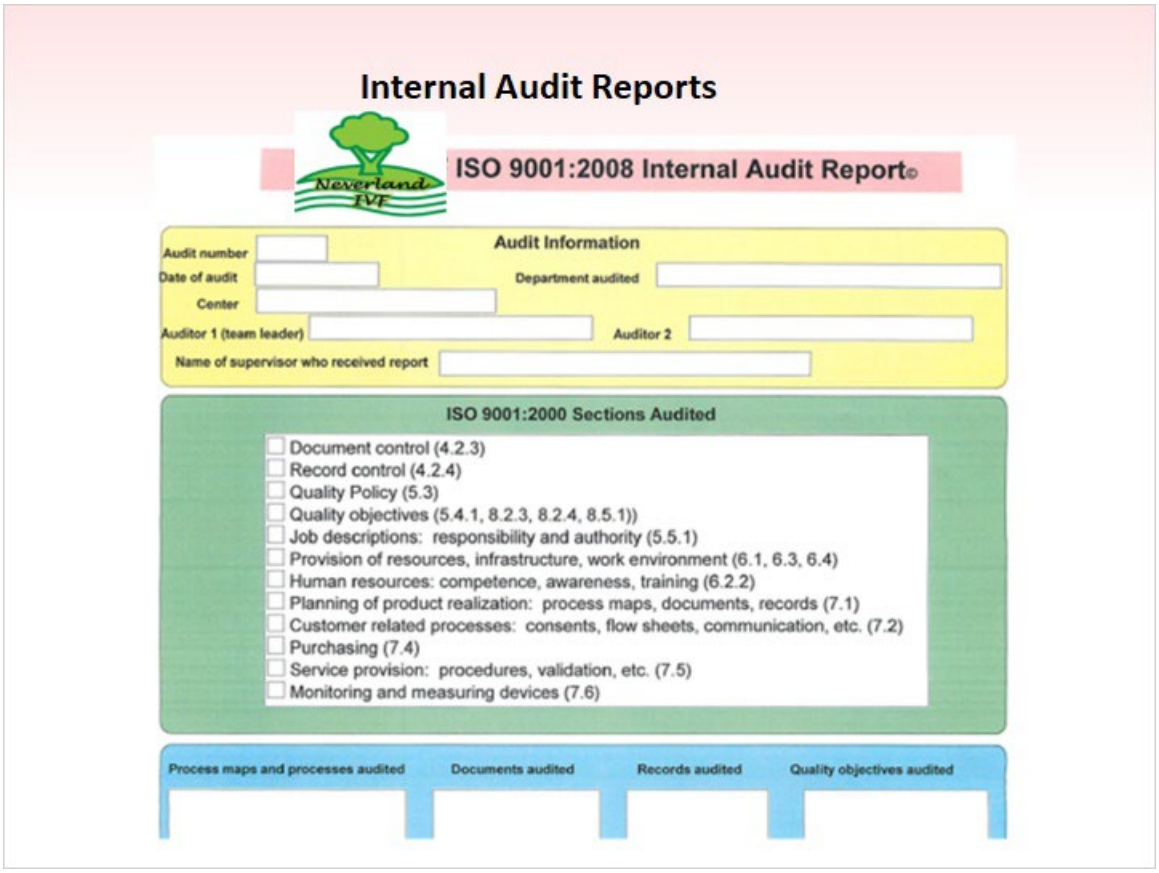
1.57 Internal Audits



Notes:

A Quality Management System must be monitored for compliance or it will quickly become unused and a nuisance that no one wants to use. The ISO 9001 standard mandates that audits be performed at regular intervals to ensure that the system is functioning correctly. These audits are performed by employees who have volunteered to be part of the ISO committee.

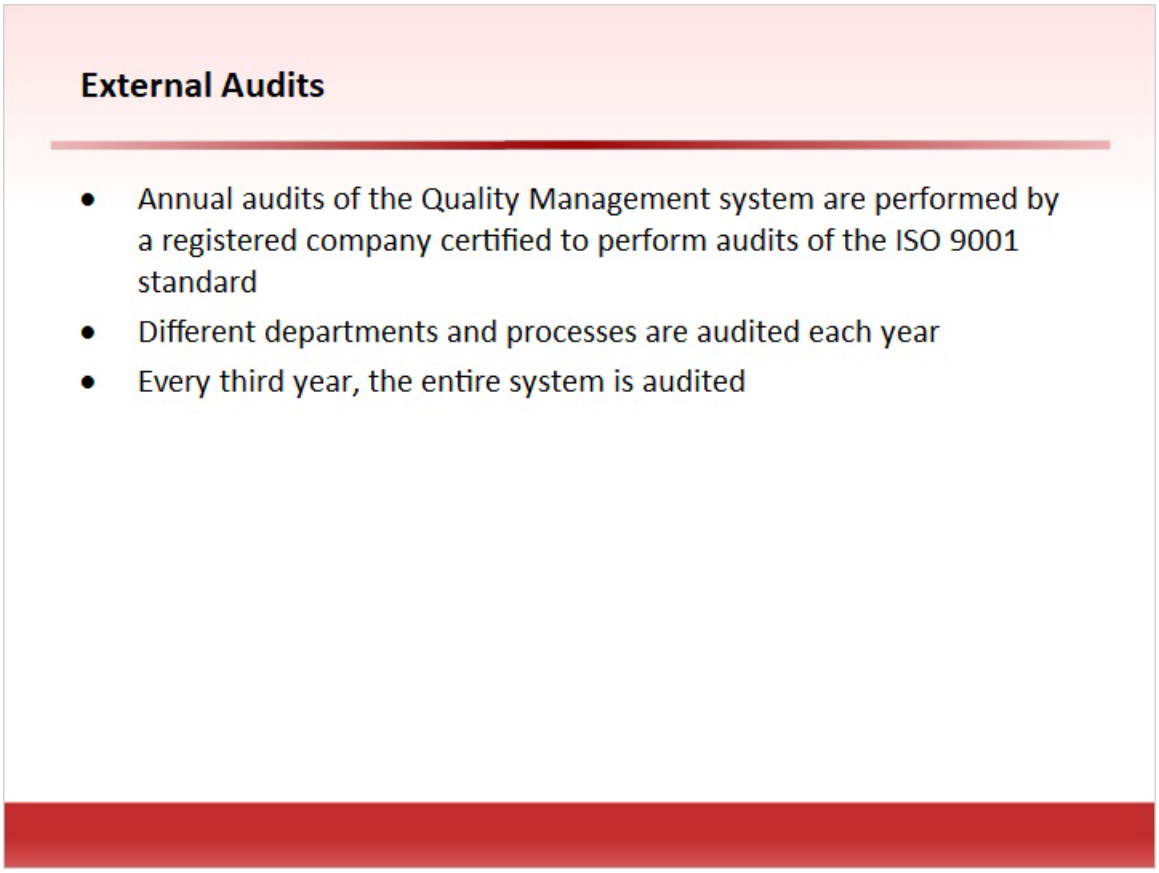
1.58 Internal Audit Reports



Notes:

Internal audits include reviews of all the sections listed here. Problems are identified, documented in an electronic database, and reported to the departmental supervisor for correction. More serious problems are also documented in the nonconformance database.

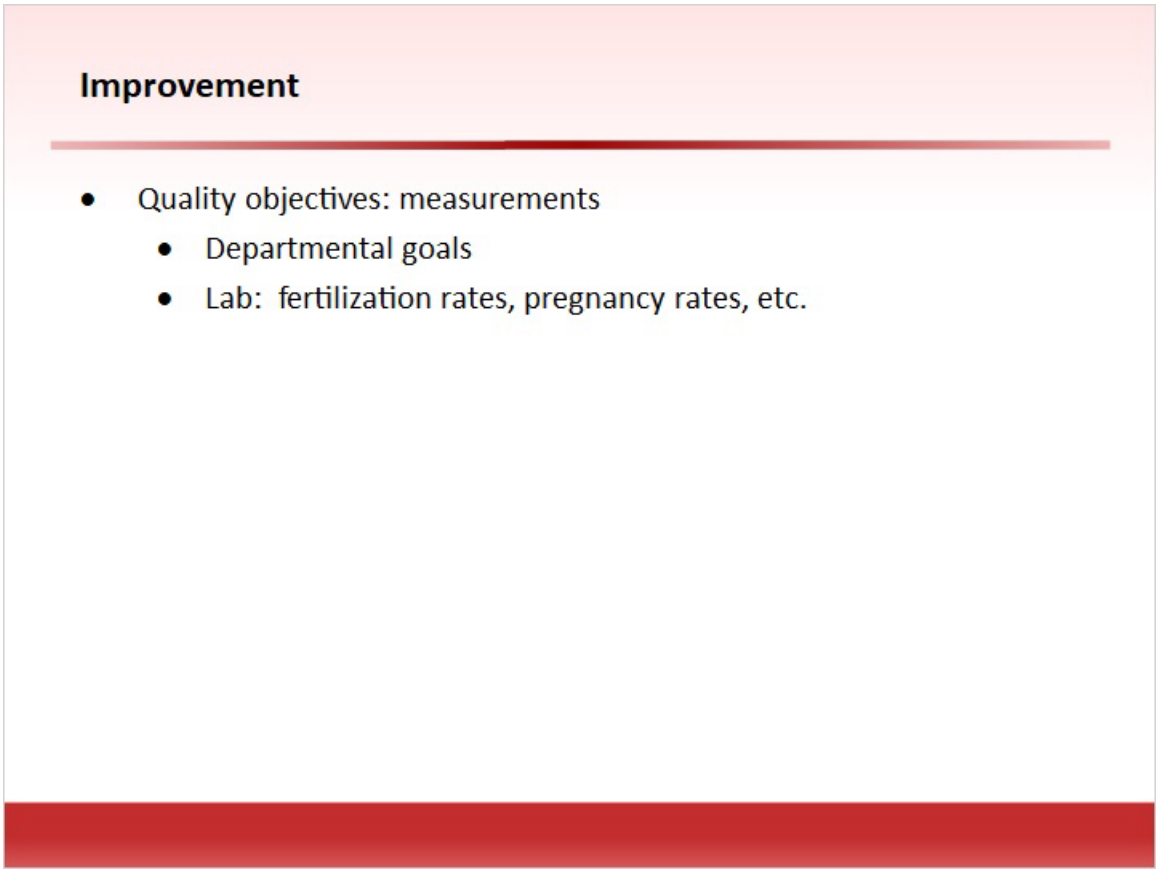
1.59 External Audits



Notes:

The ISO quality standard requires annual external audits by a company registered to perform these audits. Certified auditors evaluate all aspects of the system and make recommendations for remediation and improvements.

1.60 Improvement



Notes:

The ISO 9001 quality standard requires that measurable objectives be established and monitored, and, if the objectives are not met, that corrective action be applied. The following section will show typical examples of quality objectives for an IVF laboratory.

1.61 Quality Objectives for Andrology/Embryology

Quality Objectives for Andrology/Embryology

#	Quality Indicator	Quality Objective	Measurement Tool	Report interval	Report by Report to	CAR required
	General					
1	Technician Competency	in range values for 4 Q	Individual Statistical Analysis	Quarterly	Data coordinator Lab director	**As needed**
2	Process Monitoring	Compliance with the quality system	Nonconformance reports	Quarterly	Employee Lab manager/director	**As needed**
3	Lab Administration And/Emb.	<5 errors per category with record keeping	Logic checks Database audits	Monthly	Lab QI supervisor	**As needed, see report**
	Andrology					
4	QC program	External PT results within agency guidelines	CAP and AAB PT events	Biannual	Lab QI supervisor	**See PT form**
5	**Daily QC review**	**100% in range values**	**Daily QC worksheets**	**Monthly**	**Lab supervisor**	**As needed see report**

Notes:

Some quality objectives can be monitored in the laboratory. Some examples are shown here.

1.62 Monitoring Embryologist Competency

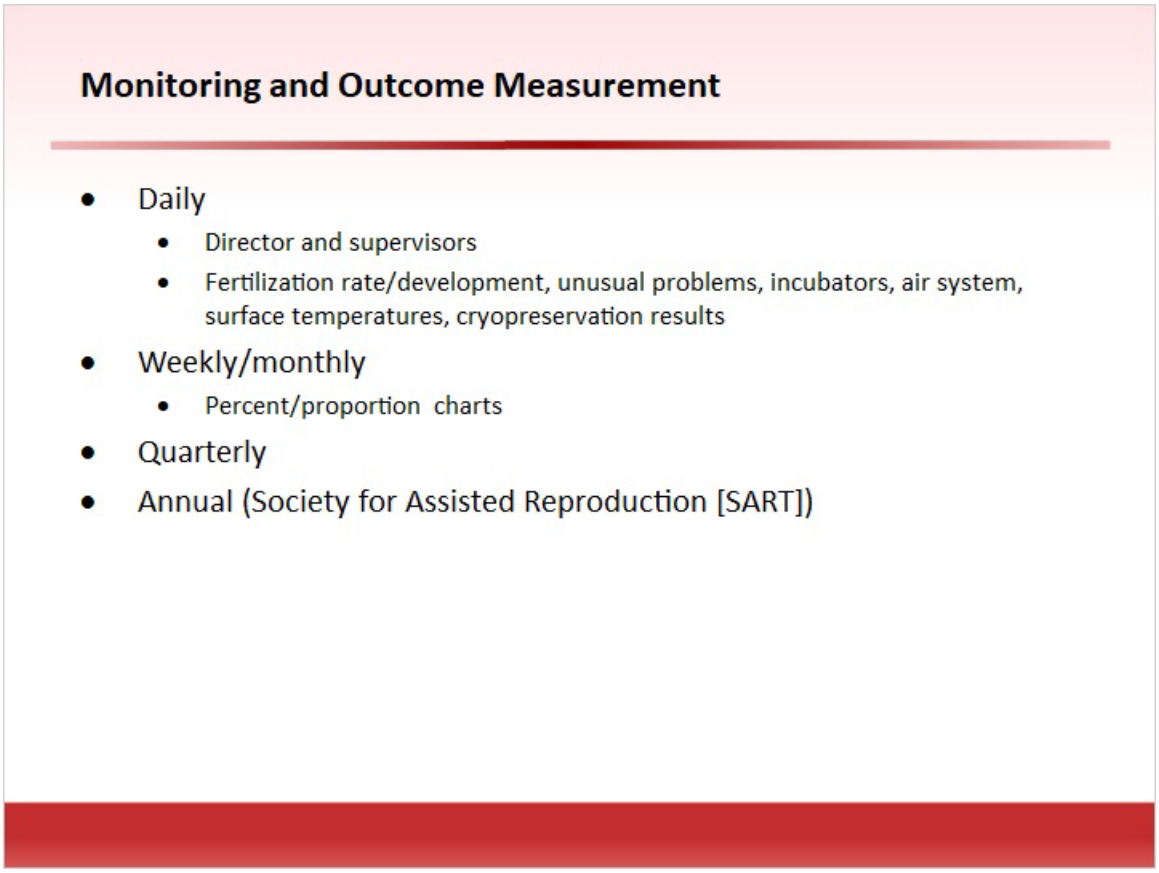
Monitoring Embryologist Competency

	Q211-Q112	Q311-Q212	Q411-Q312	Q112-Q412	Q212-Q113	Q312-Q213	Q412-Q313	Q113-Q413	Q213-Q114	N
All transfers	40.3	40.7	43.1	44.7	49.2	52.7	53.4	55.5	55.5	2389
A	-1.8	5.1	9.8	0	1.6	1.4	-2.1	-2.5	7.1	91
B	0.5	1	-1.2	-5.2	-5.9	-4.6	-5.8	-1.3	-3.6	156
C	1.3	-0.5	-2.1	-3.6	-5.4	-5.2	-1.9	2	1.2	134
D	9.7	3.5	2	2.7	3.2	2.9	0.3	-3.6	3.7	71
E	4.5	9.6	9.8	7.8	3.9	-0.7	-1.5	-0.3	1.8	248
D	-1	-3.7	-5.7	-8.3	-7.2	-6.9	-7	0.2	0.2	97
F	4.8	-1.3	-2	-0.2	-2.1	3.1	-0.3	-0.3	-0.5	160
G	1.8	-1.3	2.4	5	0.2	-3.4	-2.6	-4.6	-0.8	117
H	6	5.9	4.8	3.9	4.4	3.5	0.8	-0.5	-9	101
I	5.5	6.3	1.8	0.7	-0.9	-0.6	1.4	0.9	0.4	127
J	-2.7	-2.7	-4.7	-2.6	-0.3	1	1.4	-2	-5.9	137
K	-8.2	-2.4	1.1	1.4	6.7	2.9	1.1	-3	-6.6	139
L						13	8.8	6.2	5.5	300
M						0.5	-0.1	-1.4	0.8	295
N								-0.5	-7	101

Notes:

Many aspects of the performance of the embryologists can be monitored including: pregnancy rate per transfer, ICSI fertilization rate, thaw survival rate, etc. This chart documents each embryologist's pregnancy rate per quarter. The overall pregnancy rate for each embryologist can be compared with the overall average for all transfers and the difference calculated and recorded in the chart. Embryologists who are consistently below average can be monitored and/or retrained as needed.

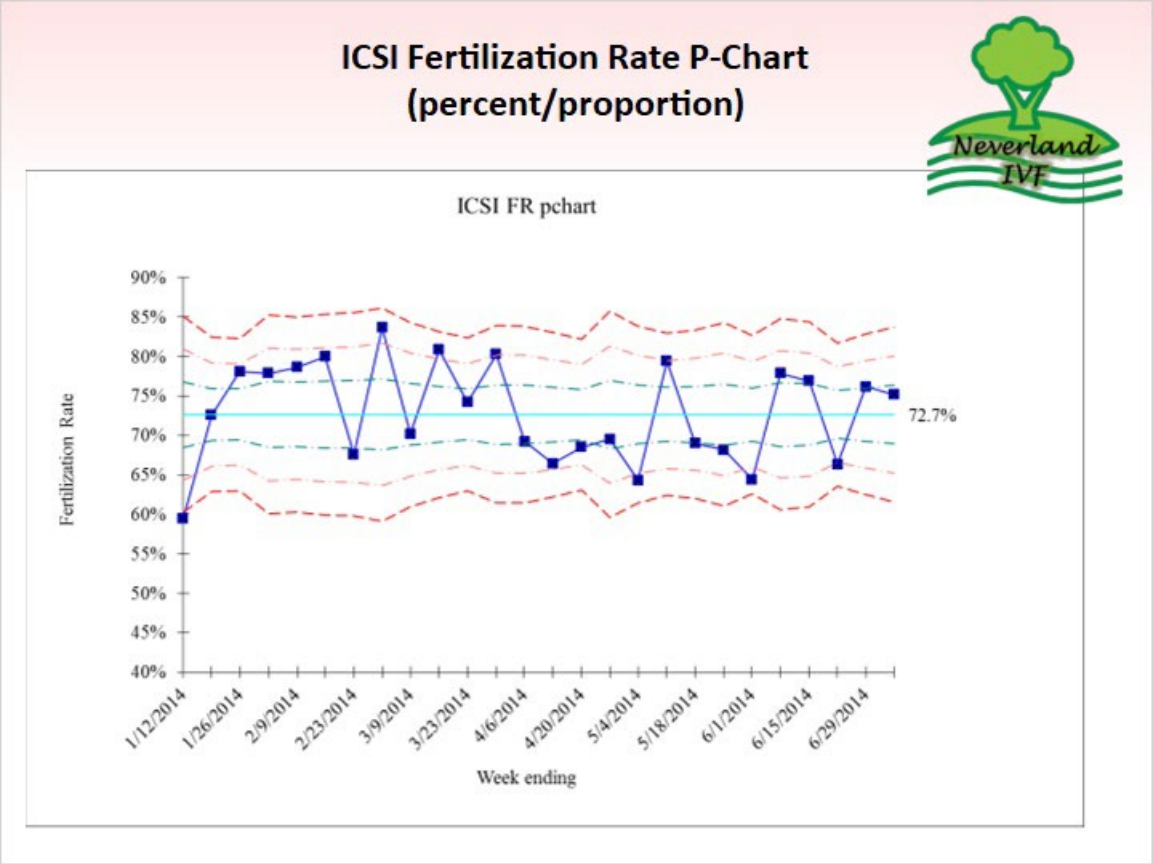
1.63 Monitoring and Outcome Measurement



Notes:

One of the most important quality objectives for the lab relates to embryology statistics. Rates can be monitored on a daily, weekly, monthly, quarterly, and annual basis. The frequency will depend on the size and volume of the clinic. Out-of-range values should be identified, reviewed, and as needed, changes in procedures should be implemented.

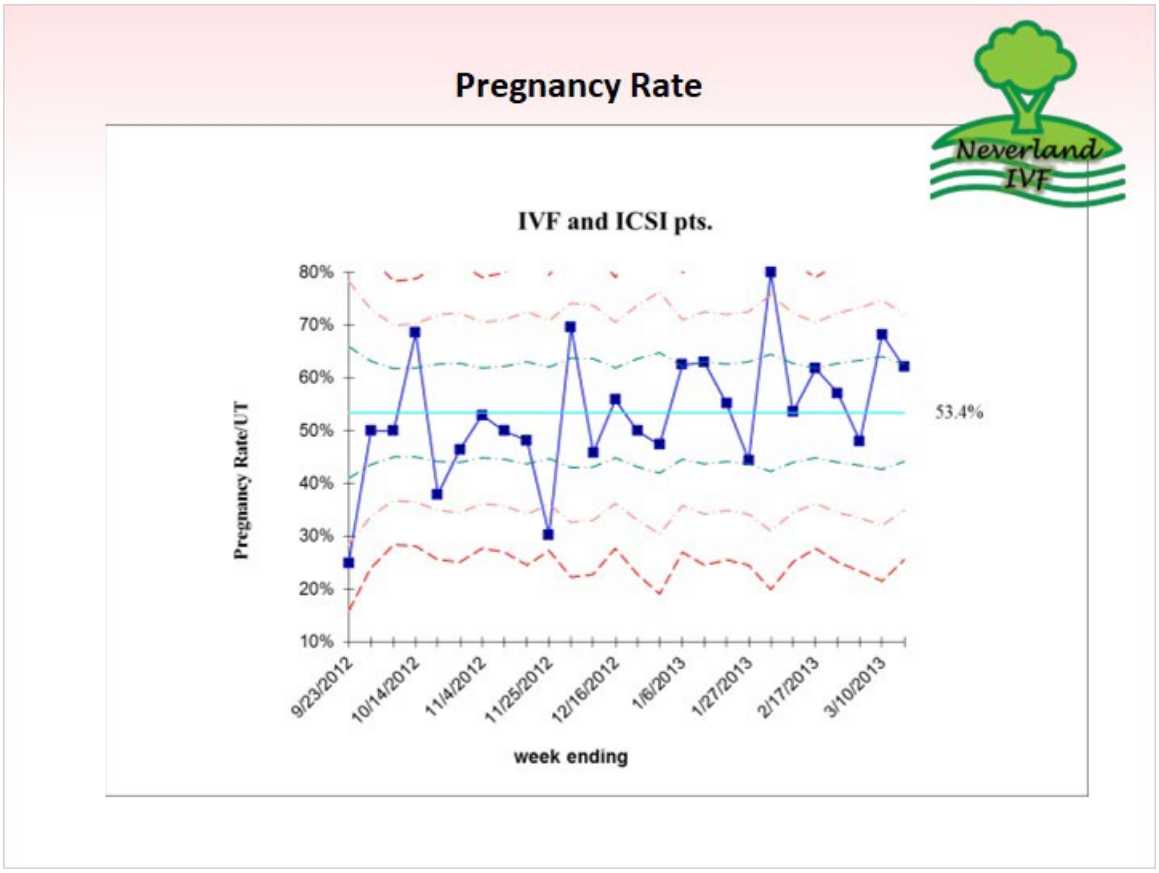
1.64 ICSI Fertilization Rate P-Chart



Notes:

There are many different ways to monitor how well an IVF lab is performing. One method, the p-chart (the "p" stands for percent or proportion), is a statistically validated method which is often used in health care settings. It is specifically designed to graph data represented by a percentage or rate. This applies to much of the data gathered in an IVF lab, such as fertilization rate and pregnancy rate. An example of a p-chart showing the ICSI fertilization rate over a period of time is shown here. Each point in the chart represents the ICSI fertilization rate for a week and the average for all the weeks plotted (72.1%) is shown by the aqua-colored line. One, two, and three standard deviations above and below the average are also graphed. Out-of-range values can be defined by each individual user and points that are out of range can be easily identified. Consecutive measurements above or below the average, as well as trends in the data, also can be seen easily.

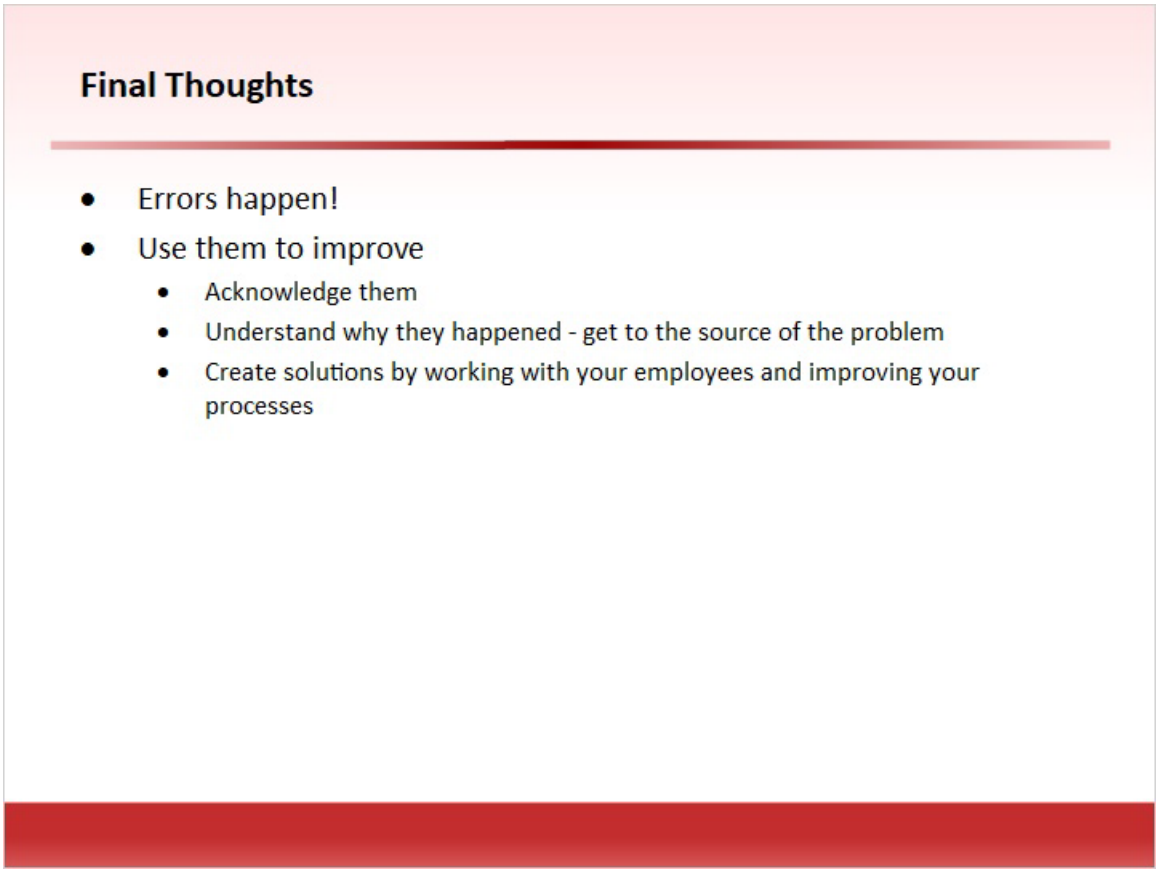
1.65 Pregnancy Rate



Notes:

This is another example of a p-chart showing the pregnancy rate over a six-month period. Notice that a gradual increase in the pregnancy rate can be easily seen in the graph.

1.66 Final Thoughts



Notes:

Over the past 25 years, there have been extraordinary improvements in the techniques and lab procedures used in ART and the delivery rates of patients have concomitantly improved significantly. There has been far less emphasis placed on improving the quality of our processes and on identifying and correcting the errors that accompany any complex endeavor such as IVF. We must first acknowledge that whenever humans are involved, errors are inevitable, and, once this is understood, we can then use these errors to improve our processes. Along with others in different medical fields, we should be willing to discuss this difficult subject and, as a community, learn from each other.

1.67 Thank you!

Notes:

Thank you for participating in this educational activity.