Techniques

Total quality improvement in the IVF laboratory: choosing indicators of quality

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Abstract

The purpose of this paper is to describe a programme of total quality improvement (TQI) within the IVF laboratory and to provide specific examples of indicators that could be used in such a TQI programme. Although TQI is sometimes confused with quality control (QC) and quality assurance (QA), there are major differences between the three quality plans: (i) QC is an activity designed to ensure that a specific element within the laboratory is functioning correctly; (ii) QA is a comprehensive programme designed to looks at a laboratory as a whole and to identify problems or errors that exist in an attempt to improve the entire process; (iii) TQI is also a comprehensive monitoring process designed not only to detect and eliminate problems, but also to enhance a laboratory's performance by exploring innovation and developing flexibility and effectiveness in all processes. Indicators used in a TQI plan should be objective, relevant to the laboratory, and measure a broad range of specific events or aspects of treatment that reflect the quality of care. Threshold values for each of the indicators should be based on how the specific protocols used in the laboratory impact the outcomes and the nature of the indicators on quality of care.

Keywords: *assessment, improvement, indicators, IVF, laboratory, quality*

Introduction

There is a common misconception that an embryology (IVF) laboratory's only responsibility is to perform 'clinical lab procedures'. In fact, proper laboratory function requires the clinical IVF laboratory to engage in a cycle of activities beyond the realm of clinical assisted reproduction technology (ART) procedures. Some of these types of activities include consultation with the physician and clinical staff about the patient's treatment plan, ensuring that appropriate procedures are ordered, and proper identification of the patient/patient's specimens. In addition, there are a number of important activities that are continuous throughout the period of laboratory operation. Among these non-procedural function are a series of activities that are often confused (Rothmann, 1995): (i) Quality control (QC): these are activities designed to assure that a specific element within the laboratory is correct. An example of a common QC activity is documentation of refrigerator temperature on a daily chart. These measurements are compared to a range of acceptable limits that had been previously defined. This assures that one element of laboratory function, e.g. reagent storage, is being properly conducted. It should be noted that a QC programme treats each element that it monitors as an independent unit and does not attempt to measure the activities of the IVF laboratory as whole. (ii) Quality assurance (QA): quality assurance is a comprehensive programme for monitoring and evaluating an entire process. For an IVF laboratory, some common components of a QA programme would include: QC activities, a comprehensive written procedure manual, continuing educational activities, a programme for employee evaluation, a safety programme for the protection of both laboratory staff and patients, and the use of an external proficiency programme. QA programmes are designed to identify

problems or errors that exist in the laboratory and correct these defects. In this way, a QA programme looks at a laboratory as a whole and attempts to improve the entire process. (iii) Total quality improvement (TQI) is also a comprehensive monitoring process. However, TQI tries objectively to evaluate the quality of the IVF laboratory services provided to patients, employees, students, physicians, the parent institute, and the community. TQI does not seek simply to correct problems, nor is it a way to proactively eliminate errors. TQI also looks at ways to enhance a laboratory's performance by exploring innovation and developing flexibility and effectiveness in all processes.

The purpose of this paper is to describe TQI within the IVF laboratory, and to provide some examples of IVF laboratory activities that could be monitored and evaluated as part of a TQI programme.

TQI in the IVF laboratory

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) describes 10 steps for the development of a TQI programme for a healthcare organization (JCAHO, 1991):

(i) Assign responsibility for overseeing the TQI plan

In most cases, it will be the Laboratory Director who assumes overall responsibility for the laboratories TQI programme.

(ii) Determine the scope of care for your facility

The plan should identify all of the activities performed by your laboratory. This includes, but is not limited to, types of procedures, types of staff involved with these procedures, and when and where these services are provided. More specific examples of the kinds of questions that can be asked in order to determine the scope of care for an ART laboratory are: Does the laboratory perform IVF? GIFT? ZIFT? Does the laboratory offer use of donor spermatozoa in your treatment protocols? Does the laboratory treat single women or only married couples? Does the laboratory provide treatment every day of the week?

The TQI plan should use the responses to these and other questions to develop a description of exactly what is the nature and extent of laboratory function.

(iii) Identify important aspects of care

List those important aspects of care and service that need to be monitored. Some aspects of care chosen for an IVF laboratory might include specimen collection, embryo culture, embryo assessment, transfer, and maintaining sterility.

(iv) Identify indicators

For each aspect of care identified in step iii, a few indicators of quality need to be chosen in order to monitor the related quality of care. Greater detail on this phase of TQI will be discussed in the following section.

(v) Establish thresholds

The threshold sets the critical level of quality laboratory performance for each indicator. Greater detail on this phase of TQI will also be discussed in the following section.

(vi) Collect and organize the data

The plan should indicate what data are to be collected. It should also specify how and by whom, the data will be collected. Decisions will need to be made also as to the nature of the data. Is it collected prospectively or retrospectively? Also, the samples size and frequency of collection will need to be established.

(vii) Evaluate data

After the data are collected, they need to be evaluated.

(viii) Take action to improve care

When an opportunity for improvement is recognized, an action plan is created and implemented to generate the improvement in patient care. The action plan represents an informed judgment about what needs to be changed to improve performance.

(ix) Assess the effectiveness of the action plan

Data continue to be collected and analysed to evaluate whether or not the action plan has really resulted in an improvement in patient care.

(x) Documentation and reporting

The conclusions, recommendations, actions and follow-up are all developed into a report and presented to the appropriate individuals. In an IVF setting, it is best to present the report to a TQI committee made-up of representatives from the entire ART team, physicians, nurses, laboratory staff, and administration.

This preceding section was a quick summary of the elements necessary for the creation of a TQI programme. The remaining portion of this manuscript will concentrate on giving further details and suggestions for implementing step iv (identify indicators) and step v (establish thresholds) of a TQI plan for an IVF laboratory.

Identify indicators within the IVF laboratory

The indicators that are selected should have a number of specific characteristics. Indicators should be selected that are relevant to the aspects of care that have been identified for the IVF laboratory (see step iii). These indicators should also be related to the laboratory processes and outcomes. They should measure specific events or aspects of treatment that reflect the quality of care. It is also best if indicators are objective, since they are more easily measured and quantified.

Often, it is helpful if the entire IVF team is asked to help identify and establish these indicators. Non-laboratory staff

from within the IVF team have a different perspective of patient care, and may be able to identify important indicators that may not be as evident from a laboratory viewpoint.

A number of indicators have traditionally been used for IVF laboratories. Normal fertilization rates, polyspermic rates, embryo cleavage rates, intracytoplasmic sperm injection (ICSI) degeneration rates, implantation rates, pregnancy rates and thaw survival rates have been used as potential indicators of overall laboratory quality (Wiemer *et al*., 2001). True TQI involves more than an aggregate review of these indicators. If these same indicators are also monitored from other points of view, they can yield greater detail on the laboratory's performance and can help to indicate the type of corrective action needed to improve the quality of care.

For instance, these same indicators could be used to assess the performance of individual laboratory staff, individual pieces of equipment, and specific supplies used in the in-vitro process.

Technically demanding procedures such as ICSI are usually assessed through intra-laboratory comparisons of individual performance. Normal fertilization (2PN) rates, degeneration rates, implantation rates and pregnancy rates are all commonly used to determine if an individuals is able to perform the ICSI procedure at a technically acceptable level. Monitoring of individual performance usually results in the development of an action plan involving staff training or continuing education activities.

Likewise, individual pieces of equipment can also be the target of performance assessment. For example, individual incubator chambers may be compared using such indicators as fertilization rates, cleavage rates or pregnancy rates. Action plans derived from reviews of equipment performance often suggest changes in equipment maintenance and replacement activities.

Specific supplies used in the in-vitro process can be assessed using some of these same indicators. Different lots of media could be examined for changes in fertilization rates, cleavage rates, average embryo grade, average embryo cell number, or pregnancy. Such information may suggest that making changes in storage or shipping of supplies or even making a change in a vendor could improve quality.

In addition to the clinical indicators that are most often measured in laboratories, other areas related to laboratory performance should also be incorporated. Safety indicators may include accident reports, incidents reports, specimen identification issues and patient infection rates. Indicators concerned with communication could involve clerical error rates on reports, timely dissemination of reports and mislabelling of specimens. Patient satisfaction indicators can be an important part of the effort to improve overall quality.

Table 1 shows a few examples of the indicators an IVF laboratory may wish to use in its TQI plan. Clearly, a great number of other potential indicators could also be listed. Rather than try to use all possible indicators, a laboratory should decide on a manageable number of indicators that would be most critical to patient care. In other words, prioritize the indicators and select those most likely to yield useful information for improving laboratory performance.

The indicator chosen for a laboratory's TQI plan should initially cover as broad a range of laboratory activities as possible. After the TQI programme is established, it will then be important to periodically modify the selected indicators. More promising indicators should replace elements of laboratory performance that do not yield useful information.

Establish thresholds for selected indicators

For each indicator incorporated into the laboratory's TQI programme, an appropriate threshold needs to be established. The threshold sets the critical level of quality laboratory performance for each indicator. Thresholds can be set in either positive or negative format. For example, the threshold for normal fertilization after ICSI could be expressed as:

Normal fertilization after ICSI should be at least 60% (positive format); or less than 40% of ICSI oocytes should fail to fertilize normally (2PN – two pronuclear) (negative format).

Often, the form in which the threshold value is expressed is a function of how the data are being collected.

Since clinical protocols are not uniform among IVF laboratories, the threshold values for many indicators may be different from laboratory to laboratory. This point can be illustrated with the following examination of different applications of cryopreservation protocols. Some IVF laboratories have established policies to only freeze high quality embryos. Since it has been shown that embryo quality can impact cryosurvival (Cohen *et al*., 1986), the threshold level for an indicator of embryo cryosurvival should be relative high in such an IVF programme. Other IVF laboratories have a different approach, and will freeze all non-transferred embryos regardless of quality. Because the overall quality of embryos being frozen is lower, the expectation for survival should also be set at a lower level.

On the other hand, other indicators by their nature will have threshold values that will be common to all IVF laboratories. Indicators that measure extremely serious events will be universally set at very low levels. For example, the incidence of insemination with the wrong sperm sample, or the incidence of transferring embryos to the wrong patient will, by their nature, always have a threshold value of zero.

Setting the proper threshold value for each indicator is a difficult but extremely critical task for a successful TQI programme. Threshold values for each of the indicators need to be based on how the specific protocols used in the laboratory impact the outcomes and the nature of indicator's effect on quality of care. As illustrated in **Table 2**, thresholds that are set too high will erroneously indicate a problem with the laboratory performance. Conversely, a threshold set too low may fail to detect a laboratory deficiency or a poor level of performance.

Finally, once a threshold is established, it is important to remember that it is not necessarily an absolute value. When a laboratory fails to meet its expected level of performance for a particular indicator, it is important to determine why the laboratory did not meet this expectation. Investigations may

Table 1. Examples of indicators of laboratory performance.

Aspect of care	*Indicators*	*Area of laboratory performance*
Oocyte collection	% improper paper work; % retrieval >36 h post-HCG	Communication
Sperm collection	% delayed collection; % rejected semen specimen; % improper paperwork	Communication
Gamete preparation	% motile sperm yield; % oocyte degenerate post-stripping	Technical skill or supply (enzyme)
Specimen identification	% mislabelled semen; % mislabelled oocytes; % insemination mix-up; % thaw error; % transfer mix-up	Communication
Fertilization	% normal fertilization (2PN); % abnormal fertilization; % normal fertilization ICSI; % degenerated post-ICSI	Technical skill or equipment or supply (medium) or lab environment
Cleavage	% no cleavage; % 4-cell 60 h post-insemination; % 8-cell 60 h post-insemination; % blastocyst on day 5; % hatching blastocyst; average embryo grade; average number of cells	Equipment or supply (medium) or lab environment
Cryopreservation	% patients with embryo freezing; % survival post-thaw; % cleaved embryos 100% intact; % embryos that cleave post-thaw	Technical skill or equipment or supply (medium) or lab environment
Embryo transfer	% retained embryos in catheter; % transfers – good quality embryos	Technical skill or supply (medium) or lab environment
Laboratory report	Average time to final report; Average no. clerical errors;	Communication
Laboratory safety	% lab staff injuries; % patients with infection post-oocyte retrieval or transfer	Staff safety; patient safety
Outcomes	% multiple pregnancies; % ectopic; % spontaneous abortion	Technical skill or equipment or supply (medium) or lab environment

reveal an acceptable reason for a lower threshold value. For instance, an indicator like 'average embryo grade at transfer' could fall below an establish threshold value if the patient population contains a higher than usual number of patients undergoing preimplantation genetic diagnosis (PGD). Since selection of embryos for transfer with a PGD procedure is based on genetic makeup and not necessarily on embryo grade, a drop in the average grade may not be indicating a problem with laboratory performance. It is important to understand that threshold values need to be constantly reviewed and adjusted to the appropriate settings.

Table 2. Impact of setting the threshold.

Threshold values	*Result*
Threshold values set too low	Failure to detect lab errors and correct poor performance
Threshold value set too high	Standards are impossible to achieve; improvement efforts are misdirected
Threshold values appropriately set	The laboratory has true view of its performance and can effectively direct its effort towards improvements

Targeted improvements

Unlike QA, which simply seeks out problems/errors and corrects them, a TQI programme seeks to improve laboratory performance in all phases of laboratory activity, not just those indicating poor performance. In the programme at the Jones Institute, areas to be targeted for improvement are periodically identified. These targets are laboratory activities currently functioning at expected levels of performance, but which could significantly impact patient care if improved. This type of activity is philosophically different, since it attempts to proactively improved laboratory performance. QA programmes help laboratories live up to their potentials, while targeted improvements allow TQI to take a laboratory performance to a higher level.

By way of illustration, some of the targeted improvements attempted at the Jones Institute over the last few years have included: application of the Spindle View system (LC Polscope, CRI Cambridge, MA, USA) to improve ICSI outcomes; improved embryo culture with the use of a low O_2 (5%) culture system; improved outcomes from freeze/thaw cycles with change in the timing of embryo thawing; and improvement in embryo culture with the use of intra-incubator air filters.

Each of these ideas was suggested from the literature or from colleagues. They were incorporated into the laboratory in a controlled fashion for the purpose of improving a specific aspect of laboratory performance. In some cases, improved outcomes were achieved, while in others no improvement was detected.

Conclusion

The goal of a TQI programme is to improve patient care and satisfaction using a proactive strategy of ongoing evaluation and monitoring. Three key elements of TQI are: (i) understanding the situation; (ii) analysing data; and (iii) improving performance. Considerations and examples of how TQI initiatives may be introduced into an IVF laboratory have been provided.

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