Chapter 2
Assisted Reproductive Technology Practice Management

C. Matthew Peterson, Ahmad O. Hammoud, Erika Lindley, Douglas T. Carrell, and Karen Wilson

Abstract A basic knowledge of management issues is required in the operation of any medical practice. This chapter highlights the critical practice management principles necessary for effective interaction with other professionals in business management, human resources, payer organizations, legal counsel, accounting, and risk management who interface with the practice.

Keywords Management • Regulations • Legal rulings • Quality assurance • Accounting • Root cause analysis

2.1 AIM

The successful practice of reproductive endocrinology and infertility demands strict attention to service and educational missions, and in the academic setting, research. Whether operating under a profit or not-for-profit, hospital-based or free-standing setting, these missions cannot be adequately addressed without policies and procedures as well as active management strategies that direct the practice’s business operations. While many physicians and scientists prefer to avoid this aspect of their career, a basic knowledge of these management issues is required. This chapter highlights the critical practice management principles necessary for effective interaction with other professionals in business management, human resources, payer organizations, legal counsel, accounting, and risk management who interface with the practice.

2.2 Revenue Cycle

The revenue cycle begins with patient registration (Fig. 2.1). Critical information that must be collected and verified before each visit includes demographics, primary and secondary insurance information, policy holder/responsible party, eligibility for benefits and coverage, and updating patient account balances for the collection of copays/balances at the point of service. Studies estimate that 42% of practice-generated denials are attributable to a failure to set up the patient’s insurance correctly and that 88% of patient-generated errors are due to inaccurate personal information. Thus, insurance verification and updated information from the patient at each encounter are critical steps in the revenue cycle [1]. Industry experts estimate that it costs $25 or more to rework a single claim [2]. Registration can be accomplished over the telephone, on-line, or using written forms. Key strategies to successful registration include appropriate staffing, training, and monitoring of performance indicators. Time studies can be performed to determine new and follow-up patient registration requirements, and staffing should respond appropriately to the findings. The dollar amount of claims denied for registration/insurance related reasons as a percentage of total denied dollars may be used to assess registration function. Furthermore, registration edit reports track locations and individuals on the team who would benefit by additional training.

Healthcare providers in best practices submit the encounter form, commonly called a superbill, within 24 h of the encounter. Monitoring strategies include nightly reconciliation of missing encounter forms with schedules documenting
“arrived” patients. Superbills should be designed to facilitate coding the ICD-9 diagnostic codes and CPT procedural codes common to the practice. The superbill should be reviewed annually and reviewed with professional coders. Chart audits insure appropriate documentation of the encounter and its codes. New providers should be audited the first few months in the practice to insure appropriate and maximum coding and completion rates.

Charge entry after a patient encounter should be completed within 48 h. Within 24 h after the encounter, the superbills are collected and batched. In the next 24 h period, the charges should be entered. Best practices reconcile missing charges daily to weekly.

Submission of claims and subsequent payments are improved by the use of a clearinghouse that filters the claim for errors or through the use of a claim scrubber. Claim scrubbers allow the provider to utilize the same software that payers use to deny claims and hold reimbursements longer. Furthermore, practices can identify undercoding in services. Larger volume practices may find the cost/benefit ratio favors automated claim scrubbing. Payment posting should be reconciled to the maximal contracted amount. Payer policy changes are techniques designed to reduce payments and must be monitored carefully. Larger organizations can consider software that will monitor charges, and contracted payments to actual payments to insure payers adhere to contracted rates.

Analysis/assessment tools include practice metrics and reports that will flag difficulties with the revenue cycle. Useful metrics include accounts receivable (AR), claim denials, write-offs, collection rates, patient complaints, volume of unanswered payer and patient correspondence, claim edits, timely submission of charges, lag days, missing charges, and turnover in revenue cycle employees. An example of a functioning revenue cycle metrics report is found in Fig. 2.2 and in the Appendix. Periodically, supervising individuals should call for a reevaluation of the revenue cycle and the metrics being utilized. Strategic management of the revenue cycle will result in greater margin for the missions undertaken by the practice. Of all improvements that can be recommended for revenue cycle processes, standardization is proven to benefit not only revenue, but also quality and patient satisfaction [3]. Continuous training and cross training in job specific policies and procedures, technology and systems, and practice-specific revenue-cycle-activities will also result in improved financial and patient, provider and employee satisfaction scores. Open discussions of revenue cycle activities will reveal bottlenecks, dropped handoffs, and duplication of work. Figures 2.3 and 2.4 are examples of ambulatory services dashboards, which can facilitate discussions regarding critical practice parameters that affect the revenue cycle. Instituting controls on cash handling/deposits for point-of-service collections, reconciliation of missing charges, batching/hashing for charge entry, productivity measures for A/R follow-up and job specific information system access will protect the assets of the practice.

Useful resources regarding the revenue cycle include The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid by Deborah L. Walker, MBA, FACMPE; Sara M. Larch, MSHA, FACMPE; Elizabeth W. Woodcock, MBA, FACMPE, CPC (ISBN 1-56829-230-9) and Financial Management for Medical Groups by Ernest J. Pavlock, PhD, CPA (ISBN 1568290217). The Medical Group Management Association (MGMA) is a professional association providing many resources (http://www.mgma.com) (Figs. 2.5 and 2.6, respectively).

### 2.3 Employment Cycle

Staffing issues are a time consuming aspect of REI practice management. Concerns related to hospital-based settings include staff unionization and difficulty in providing performance incentives. Furthermore, in hospital-based settings, a clinic staffing model is often applied inappropriately. An optimal staffing ratio for an ART program can be higher than the standard clinic staffing model and ranges from 4 to 12 full-time equivalents per physician with efficiencies gained in multiple provider models. This relatively high fixed cost
<table>
<thead>
<tr>
<th></th>
<th>2008/Feb</th>
<th>2008/Mar</th>
<th>2008/Apr</th>
<th>12 Mo Total</th>
<th>12 Mo Avg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rej Count</strong></td>
<td>10</td>
<td>2</td>
<td>11</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td><strong>Rej Count</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td><strong>Rej Count</strong></td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td><strong>Rej Count</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**TOP 5 REJECTIONS - OP**

1. 28-CLIENT NOT ELIGIBLE ON DATE OF SERVICE
2. 91-120 DAYS
3. 257-91-120 DAYS
4. > 180 DAYS
5. 112-SVC NOT DOCUMENTED

---

**Assisted Reproductive Technology Practice Management**
requires a significant volume of ART cycles to be economically viable. For these reasons, sound employment principles are mandatory.

Employment advertising should include only the requirements of the position, Equal Opportunity Employer (EEO) statement and avoidance of problematic language which could be construed as discriminatory. Key components of the employment application are found in Table 2.1.

In the offer letter or contract an Employment-At-Will statement is helpful, if applicable in the clinic’s governance situation: “You should understand that you will be employed at-will, which means that either you or the company can terminate your employment at any time.”

Interviewing questions are governed by federal and state laws. The Department of Labor for each state often has websites that detail laws concerning employment. There are a number of illegal questions to avoid, which can be worked around through proper questioning noted in
# REPRODUCTIVE ENDOCRINOLOGY

*Ambulatory Dashboard*

## 2008 Q1

<table>
<thead>
<tr>
<th>Measures</th>
<th>2008 Q1</th>
<th>2007 Q1</th>
<th>% Δ</th>
<th>Trend Indicator</th>
<th>YTD</th>
<th>Prior YTD</th>
<th>% Δ</th>
<th>Trend Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg Retrieval</td>
<td>80</td>
<td>77</td>
<td>3.9%</td>
<td>▲</td>
<td>80</td>
<td>77</td>
<td>3.9%</td>
<td>▲</td>
</tr>
<tr>
<td>ET Totals</td>
<td>97</td>
<td>95</td>
<td>2.1%</td>
<td>▲</td>
<td>97</td>
<td>95</td>
<td>2.1%</td>
<td>▲</td>
</tr>
<tr>
<td>IVF ET</td>
<td>73</td>
<td>70</td>
<td>4.3%</td>
<td>▲</td>
<td>73</td>
<td>70</td>
<td>4.3%</td>
<td>▲</td>
</tr>
<tr>
<td>Cryo ET</td>
<td>25</td>
<td>22</td>
<td>13.6%</td>
<td>▲</td>
<td>25</td>
<td>22</td>
<td>13.6%</td>
<td>▲</td>
</tr>
<tr>
<td>Ovum Donar</td>
<td>5</td>
<td>5</td>
<td>0.0%</td>
<td>■</td>
<td>5</td>
<td>5</td>
<td>0.0%</td>
<td>■</td>
</tr>
<tr>
<td>Surrogacy</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td>■</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td>■</td>
</tr>
<tr>
<td>Insemination</td>
<td>291</td>
<td>300</td>
<td>−3.0%</td>
<td>■</td>
<td>291</td>
<td>300</td>
<td>−3.0%</td>
<td>■</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>762</td>
<td>747</td>
<td>2.0%</td>
<td>■</td>
<td>762</td>
<td>747</td>
<td>2.0%</td>
<td>■</td>
</tr>
<tr>
<td>Viability</td>
<td>67</td>
<td>68</td>
<td>−1.5%</td>
<td>■</td>
<td>67</td>
<td>68</td>
<td>−1.5%</td>
<td>■</td>
</tr>
<tr>
<td>Super Ovulation Start</td>
<td>109</td>
<td>116</td>
<td>−6.0%</td>
<td>■</td>
<td>109</td>
<td>116</td>
<td>−6.0%</td>
<td>■</td>
</tr>
</tbody>
</table>

## PRODUCER PRODUCTIVITY

### New IVF

![Graph showing new IVF visits among providers](image)

### New Gynecology

![Graph showing new gynecology visits among providers](image)

### New Infertility

![Graph showing new infertility visits among providers](image)

---

*Fig. 2.4* Reproductive endocrinology ambulatory dashboard (for illustrative purposes only and does not represent actual operational data)
A minimum wage for all hours worked and one-and-one-half times their regular rate of pay for all hours worked over 40 h in a single work week (state laws may differ). Employees in this category include medical assistants, receptionists and financial representatives. Pay practices, withholdings, and allowed deductions are best handled by professionals conversant with the Fair Labor Standards Act (FLSA) and regulations of the Wage and Hour Division of the Department of Labor (DOL).

Employee files should contain personal information (name, address, Social Security number, date of birth and education); job application and resume; licenses or certifications required for the job; a signed employee handbook receipt or employment contract; attendance and leave records; payroll records; performance appraisals, commendation letters, merit awards; disciplinary records; and, job description, title, location and schedule. Employees can examine this file once per year in the presence of a designated representative. The employee has the right to request a correction or a deletion or write a statement of disagreement with any item in the file in the presence of a designated representative. The employee may not remove any item from the file. Employers can require a written request to view the file. Exempted information regarding personnel files include potential job assignment information, and the prediction of any future salary or career path information. It is recommended that personnel file be kept for 4–7 years after an employee leaves the practice.

Employee discipline should provide, where possible, advance notice of the consequences of misconduct; written documentation; and actions that are timely, consistent and impartial. In the articulation of a disciplinary policy, reserve the right to choose the level of discipline, up to and including termination without resorting to less severe
measures. There should be a nonexhaustive list of the types of infractions that will result in immediate termination. If your policy includes progressive discipline, it is mandatory that it is followed to avoid a breach of contract or discrimination action. Disciplinary actions including warnings and counseling should be documented in the personnel file. Future expectations should be written and state clearly, “we expect that you will...”.

Federal employment laws have compliance thresholds based on the number of employees outlined in Table 2.4, and these laws are briefly described in Table 2.5. Successful ART Programs create a level of professionalism that is expected in the practice by conducting the employment cycle and employee relations with the same level of attention required in the practice of ART. HIPAA is a standard all employees must clearly understand as the standard of patient confidentiality required in the practice. A brief summary of its core elements are outlined in Table 2.6.

### Table 2.2: Illegal employment questions and their legal workarounds

<table>
<thead>
<tr>
<th>Category</th>
<th>Illegal questions</th>
<th>Legal questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>National origin/citizenship</td>
<td>Are you a U.S. citizen?</td>
<td>Are you authorized to work in the United States?</td>
</tr>
<tr>
<td></td>
<td>Where were you/your parents born?</td>
<td>What languages do you read, speak, or write fluently? (This question is okay, as long as this ability is relevant to the performance of the job)</td>
</tr>
<tr>
<td></td>
<td>What is your native tongue?</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>How old are you?</td>
<td>Are you over the age of 18?</td>
</tr>
<tr>
<td></td>
<td>When is your birth date?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>When did you graduate from high school?</td>
<td></td>
</tr>
<tr>
<td>Marital/family status</td>
<td>What’s your marital status?</td>
<td>Would you be willing to relocate if necessary?</td>
</tr>
<tr>
<td></td>
<td>With whom do you live?</td>
<td>Travel is an important part of the job. Would you be able and willing to travel as needed by the job? (This question is okay, as long as all applicants for the job are asked it)</td>
</tr>
<tr>
<td></td>
<td>Do you plan to have a family? When?</td>
<td>This job requires overtime occasionally. Would you be willing and able to work overtime as necessary? (Again, as long as all applicants for the job are asked it)</td>
</tr>
<tr>
<td></td>
<td>How many kids do you have?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>What are your child care arrangements?</td>
<td></td>
</tr>
<tr>
<td>Affiliations</td>
<td>What clubs or social organizations do you belong to?</td>
<td>List any professional or trade groups or other organizations that you belong to that you consider relevant to your ability to perform this job</td>
</tr>
<tr>
<td>Personal</td>
<td>How tall are you?</td>
<td>Are you able to lift a 50-pound weight and carry it 100 yards, as this is part of the job? (Questions about height and weight are not acceptable unless minimum standards are essential to the safe performance of the job)</td>
</tr>
<tr>
<td></td>
<td>How much do you weigh?</td>
<td></td>
</tr>
<tr>
<td>Disabilities</td>
<td>Do you have any disabilities?</td>
<td>Based on the job description, are you able to perform the essential functions of this job?</td>
</tr>
<tr>
<td></td>
<td>Please complete the following medical history</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have you had any recent or past illnesses or operations? If yes, list and give dates</td>
<td>Can you demonstrate how you would perform the following job-related functions?</td>
</tr>
<tr>
<td></td>
<td>What was the date of your last physical exam?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>How’s your family health?</td>
<td>Are you willing to complete a medical exam after we’ve made you a job offer? (The results of the exam must be kept strictly confidential, except medical/safety personnel may be informed if emergency medical treatment is required, and supervisors/managers may be informed about necessary accommodations to the job, based on the results of the exam)</td>
</tr>
<tr>
<td></td>
<td>When did you lose your eyesight? How?</td>
<td>Do you understand that any offer of employment is conditional based on the results of a medical exam?</td>
</tr>
<tr>
<td></td>
<td>Do you need an accommodation to perform the job?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Can be asked only after a job offer is made)</td>
<td></td>
</tr>
<tr>
<td>Arrest record</td>
<td>Have you ever been arrested?</td>
<td>Have you ever been convicted of _______? (The crime named should be reasonably related to the performance of the job in question)</td>
</tr>
<tr>
<td>Military</td>
<td>If you’ve been in the military, were you honorably discharged?</td>
<td>In what branch of the armed forces did you serve?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What type of training or education did you receive in the military?</td>
</tr>
</tbody>
</table>

Illegal questions are problematic and information gained in such questions may be used to discriminate against members of protected classes. In order to avoid illegal questions ask objective questions that determine if an applicant can fulfill the legitimate job requirements. Human Resource personnel should frequently assess federal and state employment laws regarding legal and illegal questions.

### Table 2.3: Critical components of the employee handbook

- Employment At-Will Disclaimer Statement (if applicable)
- Handbook Acknowledgement Statement
- Employee Confidentiality Agreement
- Equal Employment Opportunity (EEO) Statement
- Sexual Harassment and Other Harassment Guidelines
- Summary of Benefits
- COBRA
- Family Medical Leave Act (FMLA), if applicable
- Patient Confidentiality/Substance Abuse Statement
- Electronic Communications and Internet Use Policy
Table 2.4  US Federal Employment Law Compliance thresholds by number of employees

| Discrimination laws and application of the statute | The respective state Department of Labor and attorney should be consulted regarding application
<table>
<thead>
<tr>
<th>Federal statutes</th>
<th>Minimum employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Americans with Disabilities Act of 1990</td>
<td>15</td>
</tr>
<tr>
<td>Age Discrimination in Employment Act of 1967</td>
<td>20</td>
</tr>
<tr>
<td>Civil Rights Act of 1964 Title VII-Equal Employment Opportunities</td>
<td>15</td>
</tr>
<tr>
<td>Consolidated Omnibus Benefits Reconciliation Act (COBRA)</td>
<td>20</td>
</tr>
<tr>
<td>Fair Labor Standards Act of 1938 (FLSA)</td>
<td>1</td>
</tr>
<tr>
<td>Family and Medical Leave Act of 1993 (FMLA)</td>
<td>50</td>
</tr>
<tr>
<td>Health Insurance Portability and Accountability Act of 1996 (HIPAA)</td>
<td>1</td>
</tr>
<tr>
<td>Immigration Reform and Control Act of 1986 (IRCA)</td>
<td>1</td>
</tr>
<tr>
<td>Occupational Safety and Health Act of 1970 (OSHA)</td>
<td>1</td>
</tr>
<tr>
<td>Pregnancy Discrimination Act (PDA)</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2.5  US Federal Employment Laws Summary

US Federal Employment Laws Summary

Please check with your state DOL, and / or attorney.

**Americans with Disabilities Act**
Prohibition of discrimination based on disabilities
Requires “Reasonable Accommodations” for disabled individuals
Provide equal opportunity in application process
Enable performance of “Essential functions” of position
Enable equal benefits and privileges
Avoid undue hardship in the workplace

**Age Discrimination Act of 1967**
Prohibits discrimination with respect to any term, condition, or privilege of employment, including hiring, firing, promotion, layoff, compensation, benefits, job assignments, and training
Protects employees and job applicants 40 years of age or older from employment discrimination
Prohibits retaliation against an individual for opposing employment practices that discriminate based on age or for filing an age discrimination charge, testifying, or participating in any way in an investigation, proceeding, or litigation under the ADEA

**Title VII of the Civil Rights Act of 1964**
Prohibits race, color, gender, national origin, and religious discrimination
Applies to hiring, discharge, compensation, promotion and other terms and conditions of employment
Gender discrimination includes pregnancy discrimination and sexual harassment

**Comprehensive Omnibus Budget Reconciliation Act of 1985 (COBRA)**
If an employer provides health coverage, it is required to comply with COBRA unless it falls within the following exceptions:
Small businesses that employ fewer than 20 employees on at least 50% of its working days during the preceding calendar year
**Note:** Employers must provide COBRA-type coverage to employees on uniformed service leave, pursuant to the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA), regardless of the number of employees they have

**Fair Labor Standards Act (FLSA)**
The Fair labor Standards Act (FLSA) prescribes standards for wages and overtime pay
The act is administered by the Wage and Hour Division of the Employment Standards Administration

**Requires employers to pay covered employees who are not otherwise exempt at least the federal minimum wage ($5.15/h) and overtime pay of one-and-one-half-times the regular rate of pay**

**The Family and Medical Leave Act (FMLA)**

**Federal Eligibility Requirements**
To be eligible for Federal FMLA leave, an employee must be employed by a covered employer:
For at least 12 months
For a minimum of 1,250 h in the 12 months immediately preceding the commencement of the leave
At a worksite employing 50 or more employees within a 75-mile radius of the worksite

FMLA (1993) gives eligible employees the right to take up to 12 weeks of unpaid leave, or paid leave if it has been earned, in any 12-month period:
For the birth of a child or the placement of a child with the employee by adoption or foster care
If the employee is needed to assist in care for a family member with a serious health condition
If the employee’s own serious health condition renders the employee unable to do his/her job

FMLA entitles employees to be restored to the same or an equivalent position with equivalent pay, benefits, and working conditions upon their return from FMLA leave

In determining whether a company’s workforce falls under the FMLA, are part-time employees included in the 50-employee count? Yes, every employee on the payroll must be counted. Employers also must also include workers on paid or unpaid leave and who are reasonably expected to return to active employment

When calculating the 1,250 h, should time spent on vacation, suspensions, etc., be included? No. Time spent on vacations or holidays, disciplinary suspension, medical leaves, etc., are not considered time worked in calculating the 1,250 h

**Health Insurance Portability and Accountability Act of 1996 (HIPAA)**
Ensures that all medical records, medical billing, and patient accounts meet certain consistent standards with regard to documentation, handling and privacy
Requires that all patients be able to access their own medical records, correct errors or omissions, and be informed how their personal information will be shared and used

**Immigration Reform Control Act (IRCA)**

(continued)
Table 2.5 (continued)

Table 2.6 Health Information Privacy Act Requirements and Authorizations (HIPAA) for Release of Information

Requirements of the Privacy Rule
1. Notifying patients of the office privacy policy
2. Making a good faith effort to receive acknowledgement that the patient has received the office privacy policy
3. Training employees in the privacy procedures adopted by the office
4. Designating a privacy officer to oversee the implementation and progress of the privacy procedures
5. Securing patient information so that they are not readily available to unauthorized persons

Additional notifications required in the authorization
1. A description of the information to be used or disclosed
2. Identification of the person (or class of persons) authorized to use or disclose the personal health information
3. Identification of the person (or class of persons) authorized to whom the covered entity may make the authorized disclosure of the personal health information
4. A description of each purpose of the use or disclosure
5. An expiration date or event
6. The patient’s signature and date

2.4 Site of Service Designation

Site of service considerations in the practice of reproductive endocrinology and infertility are multilayered. A recent study suggests that IVF is underutilized in the United States (<250 cycles /100,000 women) and this is primarily due to the lack of insurance coverage [4]. Comparing states with mandated insurance coverage to nonmandated states shows a significant increase in available providers, and higher utilization rates. The same study shows a positive correlation between the number of physicians in a fertility center and the number of cycles performed by each physician, encouraging a group model for physicians desiring a robust REI practice.

Over the last 30 years, there has been a shift from academic REI practices to private practice. Soules pointed out that the resources of an academic medical center should provide a competitive advantage to an academic ART program. However, a number of impediments found in the academic model must be addressed in order to create a successful marriage between academics and REI [5]. One of the first issues is to determine the site of service designation and hence management model. In order to complete effectively, many would argue that the academic ART program must designate the practice as a free-standing clinic also known as a site of service 11 designation, or function as such within a provider/hospital-based, site of service 22 clinical designation.

Recent developments in federal reimbursements for provider-based ambulatory services within academic medical centers (AMC) have prompted a reevaluation of outpatient reimbursements on the basis of site of service designation. Although Medicare is not a supplier of fertility services,
many of the codes that apply to procedure and evaluation and management codes are based indirectly on Medicare reimbursement levels. Furthermore, most ART Centers began within the confines of the academic umbrella, but increasingly have found this financial and governance arrangement to be suboptimal in achieving maximal efficiency, growth and competitive footing. Thus, the ART centers associated with academic institutions must be aware of the history, advantages and disadvantages of various site of service designations and their resultant flow of funds and governance models.

In the early 1980s, Medicare implemented cost control mechanisms including an inpatient prospective payment system (PPS). Hospital payments were based on the cost-basis, but the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) included a 40% discount on professional fees for Medicare services in provider-based facilities. Accordingly, many outpatient practices were designated as freestanding to avoid these professional fee discounts. In 1989, Medicare regulations relating to indirect medical education (IME) costs were changed so that IME was to be paid only for costs incurred in provider-based settings. Additionally, the resource-based relative value scale (RBRV) was deployed. The TEFRA discount was replaced with a site-of-service discount to be applied only to only certain services. In order to adjust to these Medicare reimbursement course changes, many AMCs countered by converting many outpatient freestanding clinics to hospital-based clinics in order to enhance Medicare reimbursements.

In 1997, the Balanced Budget Act (BBA) changed the reimbursement structures again and later implemented an outpatient PPS (2000). This system replaced a host of hospital outpatient payment mechanisms (e.g., lower of costs or charges, fee schedules, blended payment amounts) with 350+ ambulatory payment classifications (APCs). These changes caused significant concern that the APC implementation would remove the advantages of provider/hospital-based clinics. However, simultaneously the BBA established specific detailed guidelines defining provider/hospital-based clinics, causing AMCs serious reservations about converting these clinics to free-standing clinics because of the costly and labor intensive governance and operational changes that would be required, which were not familiar to many of these AMCs.

At present, designation as a freestanding or provider-based clinic affects the dollar value of the professional fee received and whether a facility fee is to be paid. Specifically, in free standing clinics, the physicians receive a full Medicare RBRV payment rate but no separate facility fee since the full RBRV payment includes a practice expense payment component. In the provider/hospital-based clinic, the physicians receive a reduced Medicare professional fee (meant to cover work and malpractice expenses and a reduced practice expense component). The hospital in a provider/hospital-based clinic model receives a separate facility fee from Medicare (i.e., practice expense reimbursement). The provider/hospital-based clinic receives a significantly higher amount when both the professional and facility fee are combined compared with the free-standing clinic model. Despite this fact, many services, including ART practices find that a detailed analysis of reimbursement flow of funds, and governance shows a distinct advantage to the free-standing clinic model.

Many academic medical centers have found it useful to evaluate the potential advantages/disadvantages of site of service designation, in a clinic-by-clinic fashion, using a detailed analysis of patient billing information that includes CPT codes, CPT code volumes, and location of service for all Medicare and third party payer charges. The patient level data must be categorized based on APCs, and relative values units calculated under both the freestanding and provider-based scenarios and adjusted by the various third party payer contracted rates.

Potential benefits of provider/hospital-based clinics include a significantly higher combined Medicare reimbursement, which likely does not affect an REI clinic; higher reimbursement from selected payers; opportunity for joint hospital-physician management; and, potentially greater flexibility to finance/grow physician practices through increased hospital revenue sharing. The potential disadvantages of provider/hospital-based clinics include: higher practices costs related to the hospital’s employment wage and benefit rates, costly facilities and less efficient cost control; greater governance complexities and regulatory burdens and their associated inefficient bureaucracies; compliance issues related to hospital-based clinic standing, and the negative impact of split billings.

Advantages found in free-standing clinics include a practice expense payment component, which in the case of many REI practices outweighs the Medicare-based reimbursement model; a higher reimbursement from selected payers determined through an analysis of codes and reimbursements; the opportunity to solely manage the operation without restrictions imposed on the provider-based model; and greater flexibility and freedom in directing profit margins solely to the practice missions. Disadvantages include capitalization of the practice including clinic, equipment (ultrasound, laboratory, furnishings, supplies), and staff; assuming responsibility for employment and discipline and other human resource management issues; assuming responsibility for all regulatory burdens associated with the practice including the College of American Pathologists (CAP); Certified Laboratory Improvement Amendments (CLIA), Society for Assisted Reproductive Technology (SART); and Food and Drug Administration regulations.
ART facilities in the United States have a complex mixture of self pay, and third party payers who base their reimbursement levels indirectly on Medicare rates. Many academic ART centers have, over the years, found the loss of or inadequate sharing of facility fee payments made to the hospital gradually drains the incentive of hardworking practitioners. In these cases, either an unfortunate complete separation of the ART center from academia, or a less drastic separation of the ART clinic from the hospital have been the outcome. Alternatively, well governed and transparent hospital systems accounting for the differences between the site of service designations have been successful despite the designation. Regardless of the site of service designation utilized, transparency and clear communication regarding the facts surrounding the individual practice must be visible and understood by departmental, hospital and school of medicine leadership in order to perpetuate the successful union of academia and ART.

2.5 Optimizing Practice Outcomes Through Quality Improvement

Because REI practices combine both medical and laboratory medicine, understanding of a number of quality improvement management tools is required. Fertility practices function under a number of federal regulations [HCFA (CMS)-88; FDA-21CFR 606 and 21CFR211; FDA GTPs-21CFR 1271; CMS-CLIA 42 CFR] and accrediting organizations (Joint Commission on Accreditation of Healthcare Organizations (JACAHO), the College of American Pathologists (CAP); and, the Society for Assisted Reproductive Technology (SART)). Recent establishment of the Food and Drug Administration’s Good Tissue Practices regulations (Section 361 Public Health Services Act 21 CFR 1271.160) regarding egg and sperm donors and surrogacy arrangements mandate that each center establish and maintain a quality program which is designed to prevent, detect, and correct deficiencies that could lead to the risk of introduction, transmission, or spread of communicable diseases.

The major requirements of these regulations are to develop standard operating procedures (SOPs) for the following: the organization’s quality improvement program; training and education; resource management; equipment management and upkeep; supplier and client issues; process control; documents and record management; deviation, nonconformance, and adverse (error) event management; internal and external assessment (audits); process improvement through corrective and preventative actions; and facilities management and safety programs. Furthermore, any software that is part of the center must be validated (installation, operational, and product qualification). In the past, the majority of these regulations could be managed through the andrology/embryology component of the fertility center. However, the broad reach of the regulations now applicable require the full participation and adherence of both REI and andrology/embryology supervisors and staff. Supervisors of academic, free-standing or hospital-based clinics must assume these responsibilities and insure that an effective and functional program is operational.

The optimization of practice outcomes also suggests a reworking of the SART CORS IVF data collection system, which is considered by many to be inadequate for the appropriate biostatistical analysis of outcomes from IVF. Hopefully, future leaders will accept this challenge and make the necessary changes.

The American Society for Reproductive Medicine (ASRM) recommends that all ART practices participate in the Centers for Disease Control (CDC)-SART registry data collection. From this data, each practice releases identifiable, clinic-specific success rates. The embryology laboratory is required to maintain a policies and procedures manual and personnel employment, training, evaluations, and continuing education. Details of employees who handle gametes and embryos during a cycle must be documented. All of the laboratory records and documentation must be maintained for time periods specified in federal, state and local laws or for a minimum of 10 years beyond the final disposition of embryos or gametes. The records must be maintained on site for 2 years. In the event that the laboratory ceases operation, provisions must be made for these records to be maintained according to the time frame required.

Practices must adhere to ASRM, SART, and Federal Trade Commission guidelines relating to advertising and the use of SART statistics [6]. These guidelines, presently under revision, state that all claims be supported by reliable data and avoid misleading the public into believing that the chances for success are greater than they actually are. Furthermore, practice statistics should include all initiated cycles, including research cycles, and that the method used to calculate success. The numerator and denominator must be specified (such as live births per cycle initiated, retrieved, and transferred). The number of cycles that comprise both the numerator and denominator must also be reported. If advertised procedures or protocols are investigational or experimental, authorization by a properly constituted institutional review board (IRB) must be documented. Whenever rates are quoted the following statement must be included, “A comparison of clinic success rates may not be meaningful because patient medical characteristics and treatment approaches may vary from clinic to clinic.” This statement clarifies for patients that comparing success rates between practices is invalid. Using SART Clinic specific data for advertising/marketing that ranks or compares clinics or practices is unacceptable and is not permitted.
2.6 Uniform Laws, Regulations, and Case Law Pertaining to ART

In light of the complex situations that can evolve in ART, many now recommend separate legal counsel for couples undergoing nontraditional parenting arrangements, such as sperm donation, egg donation, surrogacy, disposition of frozen genetic materials, and same-sex parenting. Laws regarding these issues vary by state. A nonexhaustive review of case law and Uniform Laws regarding ART and its variations is included below to highlight potential conflicts that may arise. The ART practice requires competent legal counsel in developing appropriate informed consent and disposition documents.

2.6.1 Case Law Regarding Sperm Donation

(laws vary by state)

2.6.1.1 Re Marriage of Witbeck–Wildhagen (IL 1996)

Consents required for sperm donation from both intended parents. Married couple utilized sperm donation, but husband had not consented to sperm donation, therefore husband could not be held responsible to assume parentage.

2.6.1.2 Laura G. v. Peter G. (NY 2007)

Intended fathers allowing donor sperm give implied consent. State law required written consent for sperm donation, however, husband’s actions implied consent and child support was required from the intended father. Intended fathers should sign consent in writing for sperm donation.

2.6.1.3 Thomas S. v. Robin Y. (NY 1994)

Sperm donor authorization document determines donor status. Same-sex female couple were using a friend as a known donor without consent document. The court awarded the donor the right to pursue visitation privileges, which likely would not have occurred if a sperm donation consent had been signed.

2.6.1.4 Stevens v. Deborah D. (CA 2005)

Single women using donor sperm should obtain “donor” consent. A single woman with a known partner provided sperm without consent or agreement. The court held that the sperm donor was not the legal father despite the lack documentation of “donor” status. A sperm donor has no rights and the fertility center should verify that the sperm donor is actually a “donor” and that there is no other alternative understanding.

2.6.1.5 Ferguson v. McKierman (PA 2004)

Sperm donor authorization required to avoid responsibility. A verbal agreement between a single woman and male friend, whereby male would act as a sperm donor and have no obligations to the child, was challenged. Court held that sperm donor was liable for child support and oral agreement was not enforceable.

2.6.1.6 Jackson v. Jackson (OH 2000)

Contemporaneous consent with end dates advised. Husband had initially consented to sperm donation and wife then used donor sperm 2 years after original consent and husband had the burden of proof to document a withdrawal of consent. Consents should have end dates.

2.6.2 Egg Donors

ART practices should be cautious to consider the rights of both the intended parents and the egg donor. Both indeed are patients, and in consideration of the potential complications associated with egg donation, many ethicists and legal scholars suggest that a supplemental insurance policy should be purchased by the intended parents for the donor. Furthermore, some would recommend that the donor be treated by a physician other than the physician monitoring the egg recipient cycle to avoid conflicts of interest. A study by Mastroianni revealed that potential donors were given inadequate information regarding potential risks of the donation stimulation regimen, retrieval and post procedure risks [7].

2.6.2.1 Case Law Regarding Egg Donation

(laws vary by state)

McDonald v. McDonald (NY 1994)

Intent governs parenthood when questions arise regarding parenthood after egg donation. Husband argued for the custody of child born through donor egg IVF based on ex-wife’s lack of a genetic relationship to the child. Court ruled that the gestational intended mother is considered the mother.
2.6.3  **Traditional Surrogacy**

(laws vary by state)

2.6.3.1  **Baby M (NJ 1988)**

Risk of traditional surrogacy includes potential for parental rights to the surrogate. Traditional surrogate asserted and was granted parental rights and visitation. Baby M has since terminated the rights of her intended parents and was adopted by the surrogate.

2.6.3.2.  **C of on behalf of T. v. G. (NY 2001)**

In traditional surrogacy, parental rights could be granted to the surrogate. Same-sex male couple who executed a traditional surrogacy arrangement, but after birth, the surrogate sought and was granted custody if she would return the fee paid by the intended parents and pay child support.

2.6.3.3.  **T. v. G. (NY 2001)**

Risk of traditional surrogacy includes potential for parental rights to the surrogate. Same-sex male couple entered into traditional surrogacy and surrogate later sought custody of the children. Despite unenforceable contract, there was evidence of intent and visitation, only privileges given to surrogate if she relinquished the fee to intended parents and to paying child support.

2.6.4  **Gestational Surrogacy**

(laws vary by state)

2.6.4.1  **Belsito v. Clark (OH 1994)**

Gestational surrogacy upheld by court that deemed genetics over birth in assigning motherhood. Court in this case held that birth test is secondary to genetics in determining “motherhood.”

2.6.4.2  **J.F. v. D.B. (PA 2006)**

Genetics over birth in gestational surrogacy upheld. Surrogate took physical custody of triplets. Court ruled that no law permits genetically unrelated surrogate to have custody.

2.6.4.3  **Johnson v. Calvert (CA 1993)**

Couple with intent to parent are the parents. Couple entered agreement with a surrogate, and court ruled that where there is a tie between giving birth and a genetic connection, the court will look at the intent to procreate in deciding parentage.

2.6.4.4  **Re Buzzanca (CA 1998)**

Couple with intent to parent are the parents. Couple utilized egg donor, sperm donor, and gestational surrogate and husband later claimed nonparent status because there was no genetic connection. Court ruled that intent justified his responsibility.

2.6.5  **Disposition of Frozen Genetic Material**

(laws vary by state)

2.6.5.1  **Litowitz v. Litowitz (WA 2002)**

Consent document options are critical in disposition. Embryos remained after using donor egg IVF. Couple separated with wife desiring another child and husband choosing donation of the embryos to third party. Court ruled embryos would be destroyed as noted on the consent document.

2.6.5.2  **Roman v. Roman (TX 2006)**

Courts look to consent forms in the event of a dispute. Married couple with three frozen embryos. In divorce proceedings, the wife sought use of frozen embryos to have a child on her own. Husband wanted embryos discarded. Court ruled consent option of disposition in the event of divorce as enforceable.

2.6.5.3  **A.Z.v.B.Z. (MA 2000)**

Consent documents must be administered properly. Cryopreservation document stated that, in the event of separation, the wife could use the cryopreserved embryos. Consent document was not properly administered to husband. After divorce, husband wanted to prevent use of the embryos and court ruled that involuntary parenthood was not enforceable.

2.6.5.4  **Davis v. Davis (TN 1992)**

When there is no consent, there is a right to not procreate. Divorced couple with frozen embryos, wife wanted to donate to third party and husband chose to discard. No consents. Court ruled without consent there is a right to not procreate.
2.6.6 Same-Sex Issues

(laws vary by state)

2.6.6.1 K.M. v. E.G. (CA 2005)

Same-sex cases pose unique intent, birth test and genetic questions. Same-sex female couple with K.M. donating the egg to E.G. who carried the child. EG refused to allow KM visitation after breakup. K.M. had signed donor form relinquishing rights as a parent. Court deemed both K.M. and E.G. as “mother.”

2.6.6.2 Chambers v. Chambers (DE 2002)

Nongenetic same sex partner can be held responsible. A biological mother who used donor sperm to conceive a child with former nonbiological intended “mother” sued for support. Court held that, despite absence of genetic connection, the ex-partner’s actions constituted a symbolic act of procreation and intended parenthood.

2.6.6.3 Re Parentage of A/B. (IN 2004)

Nongenetic same-sex partner can obtain parental rights. Former nongenetic partner sued for parental rights and was granted these rights.

2.6.6.4 Kamierazak v. Query (FL 1999)

Nonbiological partner refused parental rights. In a custody dispute between lesbian partners, the court held that since no statute allowed nonbiological partners parental rights, she would not be allowed custody.

2.6.6.5 Re Adoption of A.W., J.W. and M.R. (IL 2003)

Nonbiological partner refused parental rights. Former lesbian copartner refused parental rights to children born during the relationship because the nonbiological partner had no standing.

2.6.6.6 Jacob v. Shultz–Jacob and Frampton (NY 2007)

Three-way parenthood ruling. A sperm donor who fathered two children, voluntarily contributed financial support and interacted in their lives was found to be a biological father with obligations to the children which their rearing mothers could not waive. Case ensued after separation of the same sex-couple.

2.6.7 Posthumous Use of Genetic Material

(laws vary by state)

2.6.7.1 Estate of Woodward v. Comm of Social Services (MA 2000)

Wife delivered child conceived with sperm from deceased husband. Social Security benefits denied for offspring.

2.6.7.2 Gillett–Netting v. Barnhart (AZ 2004)

Husband banked sperm secondary to cancer for later use. Husband confirmed desire to father child after death using his frozen sperm. Wife had twins and applied for Social Security benefits on behalf of children. Benefits denied by Social Security because children were not dependent of husband at the time of death. Court found that Social Security should provide benefits.

2.6.7.3 In the Matter of Martin B, 2007 NY Slip Op (NY 2007)

Two children born to their widowed mother conceived from her deceased husband’s sperm are considered his children and as such, are entitled to inherit from their grandfather’s estate. The ASRM has clearly defined guidelines on posthumous donation summarized in Table 2.7 [8]. Case law relevant to assisted reproduction can be found at: http://www.asrm.org/Media/LegallySpeaking/legally_index.html

2.6.8 Uniform Laws

In addition to regulations affecting a fertility practice, a number of Uniform Laws affect our practice. It is not unreasonable to view the practice of assisted reproduction as one of the most regulated medical specialties in the world. The Uniform Parentage Act (UPA) and Uniform Status of Children of Assisted Conception Act (USCACA) establishes regulatory guidelines by which our specialty operates (Table 2.8).
CFR 1271.160) regarding egg and sperm donors and
regulations (Section 361 Public Health Services Act 21

Recent establishment of the FDA’s Good Tissue Practices
2.7   Resolving Problems
Husband and wife must provide written consent for donor insemina-
Table 2.8
2 Assisted Reproductive Technology Practice Management
30 days of birth.

Many programs for assisted reproduction have consent forms that
stipulate the disposition of gametes and embryos, including
disposition after death of one or both gamete donors or after a
certain period of time. If donation after death is declined, this
should be honored. Whether a time limit should be put on how
long after death such gametes or embryos might still be used is
problematic. It is not clear how the interval between death and use
would affect the process and the outcome, but the general
presumption is that such use should occur within an interval of no
more than a few years. Programs are urged to insist that donors
make their wishes known. If no decision on disposition after death
has been made, one would expect that in most instances this would
preclude any posthumous use.

A request by a husband or wife for use of stored gametes or embryos
to override a prior denial of posthumous reproduction by the
deceased spouse should not be honored. A spouse’s request that
sperm or ova be obtained terminally or soon after death without the
prior consent or known wishes of the deceased spouse need not be
honored. Such requests pose judgmental questions that should be
answered within the context of the individual circumstances and
applicable state laws. Many programs stipulate that unless
otherwise instructed, frozen embryos will be discarded after death
of either or both partners. Sperm banks are not uniform in the way
they deal with saving or discarding samples from deceased donors,
and a sperm bank may or may not know of a donor’s death if all
testing of the donor to exclude infection already has been
performed.

Table 2.7 Posthumous donation

Table 2.7 Posthumous donation

Many programs for assisted reproduction have consent forms that
stipulate the disposition of gametes and embryos, including
disposition after death of one or both gamete donors or after a
certain period of time. If donation after death is declined, this
should be honored. Whether a time limit should be put on how
long after death such gametes or embryos might still be used is
problematic. It is not clear how the interval between death and use
would affect the process and the outcome, but the general
presumption is that such use should occur within an interval of no
more than a few years. Programs are urged to insist that donors
make their wishes known. If no decision on disposition after death
has been made, one would expect that in most instances this would
preclude any posthumous use.

A request by a husband or wife for use of stored gametes or embryos
to override a prior denial of posthumous reproduction by the
deceased spouse should not be honored. A spouse’s request that
sperm or ova be obtained terminally or soon after death without the
prior consent or known wishes of the deceased spouse need not be
honored. Such requests pose judgmental questions that should be
answered within the context of the individual circumstances and
applicable state laws. Many programs stipulate that unless
otherwise instructed, frozen embryos will be discarded after death
of either or both partners. Sperm banks are not uniform in the way
they deal with saving or discarding samples from deceased donors,
and a sperm bank may or may not know of a donor’s death if all
testing of the donor to exclude infection already has been
performed.

Ethics Committee of the ASRM. Posthumous donation. Fertil Steril
2004; 82; S260–S262

Table 2.8 Uniform Parentage Act Summary (1973)

Husband and wife must provide written consent for donor insemina-
tion. Furthermore, the donor must sign a consent to act solely as a
donor. The Donor is not considered the father but the intended
father is assigned this right. Section 7 (2000 amendment) extends
the act to include assisted reproduction including IVF and
addresses death and divorce. Section 8 applies to gestational
agreements and allows a written agreement between the gesta-
tional mother, her husband, donor and intended parents. No
limitations are placed on an egg donor’s or gestational carrier’s
right to make decisions regarding their own health and/or the
health of the embryo or fetus. The intended parents must be
married and both must sign the agreement. The court is to be
petitioned for validation of the agreement. The court will validate
the agreement, only if: the couple have lived in the state for 90
days; there is a medical necessity; a home study has been
performed; the intended parents, gestational carrier; and donor, if
any, have all entered into the written agreement; a provision is
made for all reasonable health care expenses, but insurance is not
required; a reasonable compensation is allowed for the gestational
carrier. The intended parents must file notice with the court within
30 days of birth.

2.7 Resolving Problems

Recent establishment of the FDA’s Good Tissue Practices
regulations (Section 361 Public Health Services Act 21
CFR 1271.160) regarding egg and sperm donors and

Table 2.8 Uniform Parentage Act Summary (1973)

Husband and wife must provide written consent for donor insemina-
tion. Furthermore, the donor must sign a consent to act solely as a
donor. The Donor is not considered the father but the intended
father is assigned this right. Section 7 (2000 amendment) extends
the act to include assisted reproduction including IVF and
addresses death and divorce. Section 8 applies to gestational
agreements and allows a written agreement between the gesta-
tional mother, her husband, donor and intended parents. No
limitations are placed on an egg donor’s or gestational carrier’s
right to make decisions regarding their own health and/or the
health of the embryo or fetus. The intended parents must be
married and both must sign the agreement. The court is to be
petitioned for validation of the agreement. The court will validate
the agreement, only if: the couple have lived in the state for 90
days; there is a medical necessity; a home study has been
performed; the intended parents, gestational carrier; and donor, if
any, have all entered into the written agreement; a provision is
made for all reasonable health care expenses, but insurance is not
required; a reasonable compensation is allowed for the gestational
carrier. The intended parents must file notice with the court within
30 days of birth.

2.7.1 Six Sigma

Six Sigma is a quality improvement methodology to reduce
errors in manufacturing originally formulated by Bill Smith, a senior engineer at Motorola in 1986 [9].

Six Sigma provided Motorola the ability to address manu-
factoring quality concerns and support functions throughout
its organization, from manufacturing to support functions.
The application of Six Sigma also contributed to Motorola
winning the Malcolm Baldrige National Quality award in
1988. The impact of the Six Sigma process on improving
business performance has been dramatic and applicable to
other organizations, such as General Electric, Allied Signal,
and Citibank.

Six Sigma methodology is increasingly considered a mis-
ion-critical best practice, among mid-sized and smaller
firms. Motorola claims over 20 years a $17 billion dollar
(US) in savings as of 2006, which they attribute to the
program.

Six Sigma asserts the following guiding principles:

1. Continuous efforts to reduce variation in process outputs
   is key to success.
2. Healthcare and laboratory processes can be measured,
   analyzed, improved and controlled.
3. Succeeding in achieving a sustained quality improvement
   requires commitment from the entire organization, par-
   ticularly from top-level management.
The applicability of this quality manufacturing methodology has been modified for retail and healthcare applications. The method has two techniques DMAIC (Table 2.9) and DMADV (Table 2.10) which were inspired by W. Edward Deeming’s Plan-Do-Act-Check cycle [10]. DMAIC is used to improve the business process and DMADV is used to develop new successful processes. Critics of the program report that a number of large companies have failed to realize the benefits noted by Motorola and that it is designed to fix existing processes and doesn’t help define new, innovative methodologies. Regardless of the potential weaknesses in the program, it has shown success in the laboratory-based medical service industry.

Training in these techniques is available through Motorola University online and in regional classes. (http://www.motorola.com/motorolauniversity.jsp?ref=modules)

### 2.7.2 Root Cause Analysis

In the analysis phase, useful techniques include Root Cause [11] and Ishikawa Fishbone Analysis [12].

The goal of a Root Cause Analysis is to find out

- What happened
- Why did it happen
- What to do to prevent it from happening again

Root Cause Analysis is a tool for identifying prevention strategies utilized within a culture of safety and beyond the culture of blame. In Root Cause Analysis, basic and contributing causes are discovered in a process similar to diagnosis of disease – with the goal always in mind of preventing recurrence.

Root Cause Analysis is a process that is:

- Inter-disciplinary and involves experts from the frontline services
- Involves all who are the most familiar with the situation
- Layered, and continually digs deeper by asking why, why, why at each level of cause and effect
- Reformative, and identifies changes that need to be made to systems
- Impartial and avoids the assignment of blame

Root Cause Analysis must include the:

- Determination of human and other factors
- Determination of related processes and systems
- Analysis of underlying cause and effect systems through a series of why questions
- Identification of risks and their potential contributions
- Determination of potential improvement in processes or systems including evidence-based information

The Five Whys used in Root Cause Analysis are an analysis tool that doesn’t involve data segmentation, hypothesis testing, regression or other advanced statistical tools, and in many cases can be completed without a data collection plan thus making it useful in all situations, with or without a Six Sigma project. Through repeatedly asking the question “Why” (five is not an absolute rule), organizations can peel away the layers of symptoms which can lead to the root cause of a problem. Not infrequently, the reason for a problem will lead to another question (Table 2.11).

### 2.7.3 Ishikawa Fishbone Analysis

An Ishikawa fishbone (cause and effect) diagram (Fig. 2.7) helps groups explore visually all potential or real causes that result in a problem or process failure. Major inputs to the
development of the problem can be established on the fishbone such as: People; Policies; Procedures; and Technology and then the participants use the Five Whys technique to drill down to the root causes.

To create a fishbone diagram, start with stating the problem as a question, such as “Why is the no show rate so high?” The team should agree on the statement of the problem and then place this question in a box at the “head” of the fishbone. Posing it as a “why” question will help in brainstorming, as each root cause idea answers the question.

The rest of the fishbone then consists of one line drawn across the page, attached to the problem statement, and several lines, or “bones,” coming out vertically from the main line. These branches are labeled with different categories. The categories you use are up to you to decide. There are a few standard choices: people, policies, procedures, and technology.

### 2.7.4 Lean Process

In 1913, Henry Ford integrated interchangeable parts and defined work tasks with conveyors to create what he called “flow production.” The revolutionary “assembly line” concept provided simultaneous delivery of perfectly fitting components directly to line side. The problem with his system was limited variety of the product.

To provide variety, automobile production systems regressed toward process areas with much longer throughput times. More efficient machines lowered costs per process step, but in most cases increased throughput times and inventories. Furthermore, more robust information management systems were required.

In the late 1940s, Kiichiro Toyoda and Taiichi Ohno, and others at Toyota determined that a series of simple innovations, known as the Toyota Production System, would provide both continuity in process flow and a wide variety of products. This system changed focus from individual machines and their utilization, to the flow of the product through the process. By right-sizing machines for the actual volume, introducing self-monitoring machines to ensure quality, lining the machines up in process sequence, pio-
neering quick machine setups so each could produce small volumes of many parts, and having each process step notify the previous step of its current needs for materials, it would be possible to obtain high quality, low cost variety with rapid throughput in order to meet changing customer preferences. The process of LEAN was outlined in the book *The Machine That Changed the World* (1990) by James P. Womack, Daniel Roos, and Daniel T. Jones. ISBN-10: 0743299795 (Fig. 2.8). Subsequently, the same authors distilled the lean process into five key principles adjusted for medical processes in *Lean Thinking* (1996), ISBN-13: 9780684810355 (Fig. 2.9).

Lean Process principles:

- Specify the value(s) desired by the patient
- Identify the process stream for each product that provides the specified value and challenge all of the wasted steps in that process
- Make the process flow around the patient adding value-added steps
- Introduce points where continuous flow is possible
- Manage toward perfection so that the number of steps and the amount of time and information needed to serve the customer continually falls

Tables 2.12 and 2.13 provide overviews for determining value and the Lean Process, respectively.

2.8 Capital, Capital Management and Capital Expenditures

Capital is defined as any asset, tangible or intangible, that is held as a long-term investment. Capital, combined with operating cash flows is the currency that allows practices to fulfill their missions of clinical care, education and in academic settings, research. Capital allows the practice to expand, buy equipment, add staff and faculty, finance receivables, conduct preliminary research with the goal of obtaining extramural funding, and build reserves.

Every medical practice must deal with capital and capitalization issues on a continuous basis. Three types of capital and their management are required:

- Investment Capital: comes from your institution, department or division in an academic setting, individual physicians/embryologists, and/or an investor or donor. If you are in a University setting and you have created a site of service 11 clinic/private clinic, some combination of the above is likely. Capitalizing the operation is like buying stock in a publicly traded firm, except the investments made these small medical practices differ from other investments because there is no after-market for the contribution. Therefore, you typically won’t get your invested capital out until you sell the clinic. For this reason investment capital is commonly kept as low as possible. This is particularly true in the University setting, even if the
Table 2.13  Lean process overview

1. **Map the current state.** Determine the beginning and ending points of the process from the patient’s perspective. Map all the main steps. To insure accuracy, walk the process, considering how, when and where people move and act during the process. Determine who the customers and providers are, when and how information is recorded and exchanged and what technologies are applied, sequencing of the steps, what triggers each work activity, and how much time is spent at each step, and for the entire process including waiting time. Stay focused on high-level steps and focus on the usual process, not on the exceptions.

2. **Identify waste.** Next, identify any flow problems and/or any steps that do not add value. These flow constraints and value-devoid activities are the waste in your process. Lean design identifies seven categories of waste, which can be applied to the practice setting:
   - **Overproduction** involves completing any work that isn’t needed for an encounter, this could include discussing unproven adjuvant to therapeutic regimens with no proven benefit.
   - **Motion** refers to any unnecessary movement of patients, staff or physicians. This can be associated with inadequate space planning for high utilization periods or lack of equipment (ultrasound).
   - **Material movement** refers to any unnecessary transfers of materials or information, such as the hand-off of patient intake forms from the front office to the back office to the physician. Chart and paper shuffling are common material movement waste areas.
   - **Waiting** refers to any delays or idle time involving the patient, physician or staff, such as patients waiting for an exam room to be readied, physician or staff waiting for a report to be faxed, physicians waiting for equipment or disposables.
   - **Inventory** involves any information or materials waiting to be used, such as sonohysterography catheters, a stack of unread laboratory reports or piles of patient booklets sitting in the waiting area.
   - **Inappropriate processing** refers to handling work in a way that is excessive, such as completing all paperwork in triplicate or scheduling separate visits for various evaluations when one visit would suffice. These inappropriate processing encounters are often driven by our payer systems.
   - **Rework** involves any unnecessary work required because of an error, such as sending the patient back to the laboratory because a lab order was incomplete.

3. **Plan the future state.** As plan the new process, build in the changes that will eliminate waste problems and maximize value. Some design features to consider in rebuilding the process include the following:
   - **Bring work to the patient.** Eliminate needless work. Eliminate handoffs or outdated steps you’re completing out of obsolete routines.
   - **Make sure your process involves direct communication between parties.** Employ technology to improve your process.
   - **Create broad work roles so your staff can complete their work more efficiently and reduce the number of handoffs.**

4. **Test and revise the new process.** With the redesigned process map, test it. Identify your test procedures, who will be involved, duration of the test, and how you will measure efficacy. There are a number of excellent resources for using the plan-do-study-act cycle for rapidly testing and implementing change.
clinic is a site 11 clinic/private clinic, the University is the ultimate owner and the proceeds of sale would typically be property of the University.

To capitalize in a University setting, the practice could propose investment by the university medical group with or without a return on investment. Another option is to tax departmental or divisional revenues to create an investment reserve. Additionally, the practice could request departmental tax reductions to increase cash flow for investment. Last, gifts from donors are a potential source of capitalization. Gifts from donors are usually given for a specific purpose, but not always. The donor should be approached with a business plan and the return on investment terms to using their donation for capitalization. These funds could be granted or borrowed with some return. The communications should be documented in writing and coordinated through the University Development Office.

- **Retained Earnings**: represents the profit made that is left in the clinic, after all expenses have been paid, including physician compensation, for strategic initiatives; growth, staff, clinical expansion, research, or educational endeavors. This earned income must be transparent and on the table for discussion within the academic setting. Institutions that cannot create a balance sheet showing annual direct earnings will have difficulty growing this service line and retaining quality faculty. Both supervising institutions and bankers appreciate seeing retained earnings on your balance sheet, perhaps even more than investment capital because it conveys two things: (1) your medical practice operates profitably; (2) there is fiscal responsibility in the organization which looks to future strategic plans rather than immediate distribution. In a University setting, there are not tax disincentives to Retained Earnings as there are in the for profit setting where Retained Earnings are taxed in addition to distributions made to owners. This advantage allows the practice to keep the profit margin to reinvest in the strategic mission.

- **Borrowed Funds**: are used to capitalize new space, equipment, faculty, staff, or other capital expenditures which are borrowed from a bank, individual, or in the university setting, the division, department, institution, or an individual donation based on institutional guidelines. Debt is the most common way to capitalize your practice. Debt never sleeps or takes a holiday and must be serviced creating an incremental drain on the practice’s liquidity. The cash flow of the practice must be capable of making these payments. Debt should be used as a tool, along with the other capitalization mechanisms to meet the initiative and goals of the practice.

To determine the clinic’s capital requirements your financial advisor and clinic directors must know projected volumes and reimbursements and how much is required to operate the clinic. A clear estimate of how long it will take you to collect, and the terms of payment for purchases will be required to plot a financial operating timeline. The timeline will initially reveal negative numbers on startup of a clinic and often with major capital expenditures and identify new capital required monthly.

Some common sense rules are instructive in allocating capital. First, don’t deplete operating cash to purchase large capital items when interest rates are low. Second, avoid borrowing money for operating expenses. Third, the long-term goal of the clinic should be to fund growth more from retained earnings and less from debt.

Every dollar of profit left in the clinic as retained earnings is a step toward financial security and the power to move nimbly on strategic initiatives determined by your group. Retained earnings is the working capital that you don’t have to borrow from the bank, institution, individual, and dilute your ownership stake with other investors. It is the safety net required for uncertain economic times that may dramatically affect volumes in a medical clinic providing primarily non-reimbursed medical procedures. Having said that, most clinics need growth capital faster than profits will generate in retained earnings. Thus, the risk/benefit discussions and analyses that require professional business management combined with supervising physician/embryologist input.

### 2.8.1 Capital Expenditures

Capital expenditure analyses are required not only in the initial practice plan, but with each major capital expenditure in all medical clinics. There are multiple project valuation methods including payback, average return on book value, internal rate of return and the most comprehensive: the Net Present Value (NPV) analysis. This calculation estimates the project’s impact on the clinic’s overall valuation and whether this number will be positive or negative long-term. Three steps are required for the NPV analysis: first, a forecast of Net Cash Flow (after taxes if a for-profit organization); second, a determination of the present value of each year’s cash flow by discounting cash flows; and finally, subtraction of the project’s up-front cost from the discounted cash flows.

For the net cash flow analysis, a number of questions should be considered regarding the incremental revenues and costs. When considering incremental volumes and revenues, one should determine whether if the service is offered by competitors; how current practice patterns will impact utilization whether new technology will eventually render the project useless; how present and future payer mix will affect reimbursement; and whether reimbursement will remain stable over time. The incremental cost analysis includes consideration of the additional staff requirements; the additional
supply and equipment required; depreciation; and, expected increases in the incremental expenses.

- Net Income
- + Interest Expense
- + Depreciation and Amortization
- - Capital Expenditures
- - Working Capital

Net Cash Flow

The time value of money assumes that money earned today can earn interest and money earned tomorrow is of less value due to inflation. Therefore, future cash flows projected for the capital expenditure analysis must be discounted resulting in a Present Value for each year’s cash flow. The discount rate for most projects is 8–12% and is based on the riskiness of the project and the opportunity cost of investing the money in the project. Revenues, expenses and resulting cash flows are calculated for 5 or 10 years. Beyond that a residual year calculation is used. Residual calculations are determined by taking the cash flow of the last year, adding back the working capital investment and dividing by a cap rate (difference between the discount and inflation rate). The final step of the analysis subtracts the up-front project costs from the Present Value determination.

Present Value (Project Period + Residual Year) — Initial Investment = Net Present Value

2.9 Employee Requirements

To maximize the success of treatments that involve the laboratory handling and manipulation of human gametes and embryos, the American Society for Reproductive Medicine (ASRM) has established guidelines for personnel within the ART practice [13] (Table 2.14).

2.10 Conclusion

Studies estimate that 42% of practice-generated denials are attributable to a failure to set up the patient’s insurance correctly and 88% of patient-generated errors are due to inaccurate personal information. Thus, insurance verification and updated information from the patient at each encounter are critical steps in the revenue cycle. The dollar amount of claims denied for registration/insurance related reasons as a percentage of total denied dollars may be used to assess registration function. Healthcare providers in best practices submit the encounter form, commonly called a superbill, within 24 h of the encounter. Monitoring strategies include nightly reconciliation of missing encounter forms with schedules documenting “arrived” patients. Charge entry after a patient encounter should be completed within 48 h. Within 24 h after the encounter, the superbills are collected and batched. In the next 24 h period, the charges should be entered. Best practices reconcile missing charges daily to weekly. Submission of claims and subsequent payments are improved by the use of a clearinghouse that filters the claim for errors or through the use of a claim scrubber. Claim scrubbers allow the provider to utilize the same software payers use to deny claims and hold reimbursements longer. Furthermore, practices can identify undercoding in services. Analysis/assessment tools include practice metrics and reports that will flag difficulties with the revenue cycle. Useful metrics include: accounts receivable (AR); claim denials; write-offs; collection rates; patient complaints; volume of unanswered payer and patient correspondence; claim edits; timely submission of charges; lag days; missing charges; and turnover in revenue cycle employees. Of all improvements that can be recommended for revenue cycle processes, standardization is proven to benefit not only revenue, but quality and patient satisfaction.

Employee files should contain personal information (name, address, Social Security number, date of birth and education); job application and resume; licenses or certifications required for the job; a signed employee handbook receipt or employment contract; attendance and leave records; payroll records; performance appraisals, commendation letters, merit awards; disciplinary records; and, job description, title, location and schedule. Employees can examine this file once per year in the presence of a designated representative. The employee has the right to request a correction or a deletion or write a statement of disagreement with any item in the file in the presence of a designated representative. The employee may not remove any item from the file. Employers can require a written request to view the file. Exempted information regarding personnel files include potential job assignment information, and the prediction of any future salary or career path information. It is recommended that personnel file be kept for 4–7 years after an employee leaves the practice.

Employee discipline should provide, where possible, advance notice of the consequences of misconduct; written documentation; and actions that are timely, consistent and impartial. In the articulation of a disciplinary policy reserve the right to choose the level of discipline, up to and including termination without resorting to less severe measures. There should be a nonexhaustive list of the types of infractions that will result in immediate termination. If your policy includes progressive discipline, it is mandatory that it is followed to avoid a breach of contract or discrimination action. Disciplinary actions including warnings and counseling should be documented in the personnel file. Future expectations should be written and state clearly, “we expect that you will…”.
Table 2.14  ASRM guidelines for personnel within the ART practice

**Personnel**

There should be a backup system in place for all personnel essential to a program. A single individual may fulfill the requirement for expertise in one or more areas. An ART program must include the following personnel:

- A designated overall practice director, medical director, and laboratory director. One individual may fulfill more than one of these positions, but the medical director must be a licensed physician.
- An individual with training and experience in reproductive endocrinology, particularly in the use of ovulation-inducing agents and hormonal control of the menstrual cycle. An individual who has completed an American Board of Obstetrics and Gynecology (ABOG)-approved fellowship in reproductive endocrinology and infertility fulfills this requirement.
- An individual with experience in laparoscopic and ultrasound-guided oocyte retrieval techniques.
- An individual with specialized training and experience in gynecologic sonography who provides the monitoring of follicular development.
- An individual experienced in male reproduction (andrology) with special competence in semenology. If this individual is not a urologist, a consultant urologist with expertise in reproductive surgery should be available.
- An embryology laboratory director with personal experience in the organization and maintenance of a clinical embryology laboratory and in tissue culture techniques.
- A consultant/mental health professional with expertise in reproductive issues.
- An individual with specialized training and experience in gamete and embryo cryopreservation techniques, when gamete and/or embryo cryopreservation is offered.
- An individual with specialized training in gamete biology and micro-operative techniques, if oocyte and/or embryo micro-operative techniques are offered.
- Appropriate personnel to perform hormonal assays. An outside laboratory that has demonstrated adequate competence, quality control, and service, may be used for rapid assays of all the necessary reproductive hormones (including estradiol and progesterone). Such hormone assays should be performed by a laboratory that meets Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards.
- Appropriate nursing support.
- An individual or consultant with specialized expertise in genetics or genetic counseling.


**Laboratory director**

An earned doctorate degree (Ph.D.) from an accredited institution in a chemical, physical, or biological science as the major subject, or a medical degree (M.D. or D.O.) from an accredited institution, or have qualified as a laboratory director prior to July 20, 1999.

Effective January 1, 2006, all new laboratory directors should hold High Complexity Laboratory Director (HCLD) or American Board of Bioanalysis Embryology Laboratory Director (ABB-ELD) certification or its equivalent. Laboratory directors grandfathered in are strongly encouraged to seek HCLD or ELD certification.

- Expertise and/or specialized training in biochemistry, cell biology, and physiology of reproduction with experience in experimental design, statistics, and problem solving.
- Experience in formulating laboratory policies and protocols and communication with the medical director regarding patient progress and protocols as they affect the laboratory aspects of treatment.
- Two years of documented pertinent experience in a program performing IVF-related procedures. This experience should include:
  1. Familiarity with laboratory quality control, inspection, and accreditation procedures.
  2. Detailed knowledge of cell culture and ART and andrology procedures performed in mammalian systems.
- A period of training of at least 6 months (may be concurrent with documented experience) and have completed at least 60 ART procedures under supervision. A procedure is defined as a combination of the examination of follicular aspirates, insemination, documentation of fertilization, and preparation for embryo transfer. Satisfactory completion of this period of training should be documented by a signed letter from the laboratory director of the training practice.
- 12 h of annual accredited continuing education in assisted reproductive technology or clinical laboratory practice.
- Demonstration of technical competence in the embryology laboratory by documenting performance of specific procedures and results that are within acceptable standards for that program.

Specific responsibilities of the embryology laboratory director include:

- Providing accessibility for on-site, telephone or electronic consultations as needed.
- Ensuring that the physical plant (space, facilities, and equipment) and environmental conditions of the laboratory are appropriate and safe.
- Maintaining aseptic conditions in the laboratory.
- Ensuring that patient confidentiality is maintained throughout the laboratory ART process.
- Providing an approved procedural manual to all laboratory personnel and establishing and maintaining a laboratory quality assurance program.
- Providing consultation to physicians and others, as appropriate, regarding laboratory aspects of treatment.
- Employing a sufficient number of qualified laboratory personnel to perform the work of the laboratory. At a minimum, there should be two qualified embryologists. The table below provides minimum staff sizes for the volume of cycles (retrievals and cryopreservation cycles).
- Additional laboratory staff may be required if andrological and/or endocrinological duties are also assigned.
- Ensuring that all personnel receive appropriate training for the ART laboratory procedures to be performed, obtain the required number of annual continuing education hours, and demonstrate continued competence for the ART laboratory procedures performed.
Table 2.14 (continued)

<table>
<thead>
<tr>
<th>Number of laboratory cycles</th>
<th>Minimum number of embryologists</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–150</td>
<td>2</td>
</tr>
<tr>
<td>151–300</td>
<td>3</td>
</tr>
<tr>
<td>301–600</td>
<td>4</td>
</tr>
<tr>
<td>&gt;600</td>
<td>1 additional embryologist per additional 200 cycles</td>
</tr>
</tbody>
</table>

Off-site embryology laboratory director

An “off-site” laboratory director supervises another physical facility, which has a separate identification number (SART number) and medical director.

An off-site director has the same responsibilities as the on-site director and can direct no more than five separate laboratories of any type.

While the laboratory is actively treating patients, the off-site director must physically visit the laboratory at a frequency that ensures the proper patient care during ART.

The “off-site” director should visit no less than once per month, while the lab is active.

The lab director should be available at all times by fax, phone, or email for any issues that may arise.

The off-site director must be present on site for any accreditation or certification procedures.


Embryology laboratory supervisor

Embryology laboratory supervisors, under the direction of the embryology laboratory director, and as authorized in writing, provide day-to-day supervision of laboratory personnel performing ART procedures. If the medical director is also the laboratory director, there should be a designated laboratory supervisor. If the embryo laboratory director is located off-site, there should be a designated laboratory supervisor. The embryology laboratory supervisor should either meet the qualification requirements designated for laboratory director, or fulfill both of the following requirements:

- Have an earned bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution.
- Have documented training, which includes performing, at a minimum, at least 60 ART procedures under supervision.

In addition to meeting these requirements, the embryology laboratory supervisor should:

- Obtain at least 12 h of accredited continuing education annually in assisted reproductive technology or clinical laboratory practice.
- Perform at least 20 ART procedures per year.

Responsibilities of the embryology laboratory supervisor include the day-to-day supervision and oversight of the embryo laboratory and laboratory director responsibilities as authorized in writing by the embryology laboratory director.

Embryology laboratory technologist

Embryology laboratory technologists who perform ART laboratory procedures should either meet the qualification requirements for laboratory supervisor, or fulfill both of the following requirements:

- Have an earned bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution.
- Have documented training, which includes performing, at a minimum, at least 30 ART procedures under continuous supervision of the laboratory director or supervisor.

In addition to meeting these requirements, the embryology laboratory technologist should:

- Annually obtain at least 12 h of accredited continuing education in ART or clinical laboratory practice.
- Perform at least 20 ART procedures per year.
- Experience and documented training in cell culture, sperm-egg interaction, or related areas of animal reproduction are desirable.

Programs for the appropriate training of embryology laboratory technologists should be in place with documentation of completion for each employee.


Medical director

As of January 1, 2000, a new program’s medical director must be board-certified in reproductive endocrinology and infertility by the ABOG, be an active candidate for the same, or be grandfathered as a medical director, provided the individual has training and experience equivalent to a board-certified reproductive endocrinologist.

Practice director

The practice director is responsible and accountable for the activity of the practice relating to ART, and is responsible for officially communicating with the Society for Assisted Reproductive Technology (SART) and ensuring that the practice follows SART requirements for membership.

Physician performing oocyte retrievals

Each physician performing oocyte retrievals should have performed at least 20 follicular aspirations under direct supervision within a practice that meets these standards. Satisfactory completion of this training should be documented by a signed letter from the practice director.

Each physician should continue performing a minimum of 20 aspirations per year.

(continued)
Comparing states with mandated insurance coverage to nonmandated states shows a significant increase in available providers, and higher utilization rates. The same study shows a positive correlation between the number of physicians in a fertility center and the number of cycles performed by each physician, encouraging a group model for physicians desiring a robust REI practice.

At present, designation as a freestanding or provider-based clinic affects the dollar value of the professional fee received and whether a facility fee is to be paid. Specifically, in free standing clinics, the physicians receive a full Medicare RBRV payment rate but no separate facility fee since the full RBRV payment includes a practice expense payment component. In the provider/hospital-based clinic, the physicians receive a reduced Medicare professional fee (meant to cover work and malpractice expenses and a reduced practice expense component). The hospital in a provider/hospital-based clinic model receives a separate facility fee from Medicare (i.e., practice expense reimbursement). The provider/hospital-based clinic receives a significantly higher amount when both the professional and facility fee are combined compared to the free-standing clinic model. Despite this fact, many services, including ART practices find that a detailed analysis of reimbursement flow of funds, and governance shows a distinct advantage to the free-standing clinic model.

Many academic medical centers have found it useful to evaluate the potential advantages/disadvantages of site of service designation, in a clinic-by-clinic fashion, using a detailed analysis of patient billing information that includes CPT codes, CPT code volumes, and location of service for all Medicare and third party payer charges. The patient level data must be categorized based on APCs, and relative values units calculated under both the freestanding and provider-based scenarios and adjusted by the various third party payer contracted rates.

Potential benefits of provider/hospital-based clinics include: a significantly higher combined Medicare reimbursement which likely does not affect an REI clinic; higher reimbursement from selected payers; opportunity for joint hospital-physician management; and, potentially greater flexibility to finance/grow physician practices through increased hospital revenue sharing. The potential disadvantages of provider/hospital-based clinics include: higher practices costs related to the hospital’s employment wage and benefit rates, costly facilities and less efficient cost control; greater governance complexities and regulatory burdens and their associated inefficient bureaucracies; compliance issues related to hospital-based clinic standing, and the negative impact of split billings.

Advantages found in free-standing clinics include include: a practice expense payment component which in the case of many REI practices outweighs the Medicare-based reimbursement model; a higher reimbursement from selected payers determined through an analysis of codes and reimbursements; the opportunity to solely manage the operation without restriction imposed on the provider-based model; and greater flexibility and freedom in directing profit margins solely to the practice. Disadvantages include capitalization of the practice including clinic, equipment (ultrasounds, laboratory, furnishings, supplies), and staff; assuming responsibility for employment and discipline and other human resource management issues; assuming responsibility for all regulatory burdens associated with the practice including the College of American Pathologists (CAP); Certified Laboratory Improvement Amendments (CLIA), Society for Assisted Reproductive Technology (SART); and Food and Drug Administration regulations. Regardless of the site of service designation utilized, transparency and clear communication regarding the facts surrounding the individual practice must be visible and understood by departmental, hospital and school of medicine leadership in order to perpetuate the successful union of academia and ART.**

Recent establishment of the Food and Drug Administration’s Good Tissue Practices regulations (Section 361 Public Health Services Act 21 CFR 1271.160) regarding egg and sperm donors and surrogacy arrangements mandate the development of standard operating procedures (SOPs) for the following the organization’s quality improvement program; training and education; resource management; equipment management and upkeep; supplier and client issues; process control; documents and record management; deviation,
nonconformance, and adverse (error) event management; internal and external assessment (audits); process improvement through corrective and preventative actions; and facilities management and safety programs. Furthermore, any software that is part of the center must be validated (installation, operational, and product qualification). In the past, the majority of these regulations could be managed through the andrology/embryology component of the fertility center. However, the broad reach of the regulations now applicable requires the full participation and adherence of both REI and andrology/embryology supervisors and staff. The embryology laboratory is required to maintain a policies and procedures manual and personnel employment, training, evaluations, and continuing education. Employees who handle gametes and embryos during a cycle must be documented. The ART practice requires competent legal counsel in developing appropriate informed consent and disposition documents.

Public Health Services Act 21 CFR 1271.160 regarding egg and sperm donors and surrogacy arrangements, require that each center establish and maintain a quality program which is designed to prevent, detect, and correct deficiencies that could lead to the risk of introduction, transmission, or spread of communicable diseases.

Six Sigma asserts the following guiding principles:

- Continuous efforts to reduce variation in process outputs is key to success.
- Healthcare and laboratory processes can be measured, analyzed, improved and controlled.
- Succeeding in achieving a sustained quality improvement requires commitment from the entire organization, particularly from top-level management.

The goal of a Root Cause Analysis is to find out

- What happened
- Why did it happen
- What to do to prevent it from happening again.

Root Cause Analysis is a tool for identifying prevention strategies utilized within a culture of safety and beyond the culture of blame. In Root Cause Analysis, basic and contributing causes are discovered in a process similar to diagnosis of disease – with the goal always in mind of preventing recurrence. Root Cause Analysis is a process that is:

- Inter-disciplinary and involves experts from the frontline services
- Inclusive of all who are the most familiar with the situation
- Layered, and continually digs deeper by asking why, why, why at each level of cause and effect
- Reformative, and identifies changes that need to be made to systems
- Impartial and avoids the assignment of blame

Root Cause Analysis must include the:

- Determination of human and other factors
- Determination of related processes and systems
- Analysis of underlying cause and effect systems through a series of why questions
- Identification of risks and their potential contributions
- Determination of potential improvement in processes or systems including evidence-based information.

By repeatedly asking the question “Why” (five is not an absolute rule), organizations can peel away the layers of symptoms which can lead to the root cause of a problem. Not infrequently the reason for a problem will lead to another question (Table 2.11). An Ishikawa fishbone (cause and effect) diagram (Fig. 2.7) helps groups explore visually all potential or real causes that result in a problem or process failure. Major inputs to the development of the problem can be established on the fishbone such as: People; Policies; Procedures; and Technology and then the participants use the five Whys technique to drill down to the root causes.

Lean Process principles:

- Specify the value(s) desired by the patient
- Identify the process stream for each product that provides the specified value and challenge all of the wasted steps in that process
- Make the process flow around the patient adding value-added steps
- Introduce points where continuous flow is possible
- Manage toward perfection so that the number of steps and the amount of time and information needed to serve the customer continually falls

Tables 2.12 and 2.13 provide overviews for determining value and the Lean Process, respectively.

References

5. Soules MR (2005) Assisted reproductive technology has been detrimental to academic reproductive endocrinology and infertility. Fertil Steril 84(3):570–572
Appendix

Business operations require close attention to detail. Most billing systems have the ability to extract significant amounts of data. The organization of the data is critical, to ensure appropriate and maximum oversight of the financial health of your practice.

The Operational Indicator (see figure 2.2 for example of full report) has been designed to provide a visual overview of the financial status of your practice. This picture gives access to allow for review of the most immediate month’s data, trending for 13 months, benchmarking and variances – all at a quick glance. This important review can be completed quickly and efficiently. Concerns are readily identified to allow the implementation of timely corrective action. The operational indicator provides a view of financial issues. By having this information reported consistently it allows you to recognize problems and make adjustments quickly. With relevant, understandable data you can ensure that your goals are being met.

The following is a step by step review of the data, shows the importance of the assessment of the data, and gives detailed examples of areas that should be given additional review.

Please note that for best data review the indicators should allow for 13 months of data. Figure 2.2, section 1 reflects 3 months in the interest of space. You will want to include the most current month that has closed and 12 prior months.

1-1. **Charges** – Gross charges keyed into your billing system for that specific month. You will want to ensure consistency in productivity and posting.

1-2. **Payments** – Gross payments, prior to refunds posted in that specific month.

It is important to remember that post dates have no correlation to the date of service, or the date the charge was posted in the system; especially when it relates to

1-3. **Net Payments** – Gross payments less refunds

1-4. **Contractual Adjustments** – This is the amount that has been negotiated with contracted payers and must be written off.

If you have contractually agreed to $1000 reimbursement for a specific code(s), you may bill any amount you wish.

<table>
<thead>
<tr>
<th>Billed Amount</th>
<th>$1500</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allowed</td>
<td>$1000</td>
</tr>
<tr>
<td>**</td>
<td>$500 **</td>
</tr>
</tbody>
</table>

** This is a contractual adjustment that must be credited, and may not be billed to the patient or secondary insurances. Watch for unanticipated spikes by specific payers in their contractual adjustments. This could indicate changes in their bundling and other payer policies.

1-5. **Refunds** – Money returned to insurances and/or patients. Refunds are costly. Are there billing practices that are contributing such as continuous submission of claims instead of actual follow up? The Federal Payers expect timely processing of refunds.

The following measures are basic but critical to the health of your practice.

1-6. **Work RVU** – Is a measurement that is used for productivity. Most CPT codes are assigned a relative value unit. An office consult 99243 has a 1.88 wrvu value, while an established patient 99203 is 1.34. The wrvu is a fairly consistent number that allows for the month to month, and year to year trending on productivity in your practice.

1-7. **Total Discounts** – Provides you with a roll up total of adjustments for hardship, bankruptcy, administrative, etc. If this number increases, further evaluation of why is important.

<table>
<thead>
<tr>
<th></th>
<th>2007/Apr</th>
<th>2008/Mar</th>
<th>2008/Apr</th>
<th>12 Mo Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-1 Charges</td>
<td>$556,065</td>
<td>$567,332</td>
<td>$485,866</td>
<td>$4,395,934</td>
</tr>
<tr>
<td>1-2 Payments</td>
<td>$241,785</td>
<td>$280,658</td>
<td>$274,525</td>
<td>$2,317,468</td>
</tr>
<tr>
<td>1-3 Net Payments</td>
<td>$239,779</td>
<td>$278,667</td>
<td>$278,568</td>
<td>$2,296,101</td>
</tr>
<tr>
<td>1-4 Contract Adj</td>
<td>$182,506</td>
<td>$243,076</td>
<td>$258,305</td>
<td>$1,665,848</td>
</tr>
<tr>
<td>1-5 Refunds</td>
<td>$2,096</td>
<td>$1,991</td>
<td>$3,958</td>
<td>$21,367</td>
</tr>
<tr>
<td>1-6 Work RVU</td>
<td>$3,730.18</td>
<td>$4,371.16</td>
<td>$3,367.12</td>
<td>$41,471.43</td>
</tr>
<tr>
<td>1-7 Total Discounts</td>
<td>$24,348</td>
<td>$20,170</td>
<td>$9,204</td>
<td>$177,087</td>
</tr>
</tbody>
</table>

Figure 2.2 section 1
This section provides trending for the measures in figure 2.2.1. On a landscape report the above information would be to the immediate right (see figure 2.2 for example of full report).

2-1. **Previous 12 Month Total** allows a comparison between two complete 12 month time periods. This compares seasonality, conferences, etc. between years.

2-2. **12 Month Variance** shows the difference between the two 12 month periods.

2-3. **12 Month Average** allows you to identify the one month average for the last 12 months of information.

2-4. **Current Month Variance** shows the difference between the most current month and the 12 month average. In this example the last complete month was April. Charges were $445,066. (See figure 1) When compared to the 12 month average of $400,494 (2.3) you can quickly see the operation has a gain of $44,571 in charges. Each measure from figure 1 can be quickly reviewed with this structure.

2-5. **Prior Fiscal Year to Date** allows an exact month(s) review compared to the exact number of months in the current fiscal year. For this example, the fiscal year begins in July. By April there would be a total of seven months reported. 2-5 looks at the seven months of the prior fiscal year and compares them to the seven months of this fiscal year.

2-6. **Fiscal Year to Date** as explained above looks at where the operation stands at the end of seven months.

2-7. **Fiscal Year Variance** provides a quick snapshot of whether the operation is above or behind at this same period in the fiscal year (seven months).

Collection agency/bad debt is an area that must be tracked to ensure consistent review of aged self-pay and appropriate transfer to bad debt (Figure 2.2. section 3). Are self pay accounts being reviewed monthly? Are broken payment plans for non responsive patients being sent monthly to collections? This type of A/R has your lowest return on staff time and effort and should be managed accordingly.

Figure 2.2 section 3

<table>
<thead>
<tr>
<th>ORIGINAL INSURANCE INFO CAPTURED</th>
<th>12 Mo Totals</th>
<th>12 Mo Avg</th>
<th>Mix 12 Mo</th>
<th>Prev 12 Mo Tot</th>
<th>Prev 12 Mo Mix</th>
<th>Mix CM</th>
<th>Mix PYTD</th>
<th>Mix FYTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLUE SHIELD</td>
<td>$ 93,326</td>
<td>$ 122,022</td>
<td>$ 134,471</td>
<td>$ 1,097,827</td>
<td>$ 91,489</td>
<td>22.84%</td>
<td>372,628</td>
<td>25.68%</td>
</tr>
<tr>
<td>COMMERCIAL INS</td>
<td>$ 3,253</td>
<td>$ 5,761</td>
<td>$ 1,759</td>
<td>$ 46,191</td>
<td>$ 3,849</td>
<td>0.96%</td>
<td>19,659</td>
<td>1.36%</td>
</tr>
<tr>
<td>CONTRACTS</td>
<td>$ 143,248</td>
<td>$ 161,619</td>
<td>$ 109,720</td>
<td>$ 1,410,186</td>
<td>$ 117,516</td>
<td>29.34%</td>
<td>548,134</td>
<td>37.78%</td>
</tr>
<tr>
<td>MEDICAID</td>
<td>$ 156,184</td>
<td>$ 166,431</td>
<td>$ 111,425</td>
<td>$ 1,309,426</td>
<td>$ 109,119</td>
<td>27.25%</td>
<td>351,728</td>
<td>24.24%</td>
</tr>
<tr>
<td>MEDICARE</td>
<td>$ 542</td>
<td>$ 3,912</td>
<td>$ 358</td>
<td>$ 17,699</td>
<td>$ 1,475</td>
<td>0.37%</td>
<td>4,764</td>
<td>0.37%</td>
</tr>
<tr>
<td>MISC GOVT</td>
<td>$ 18,941</td>
<td>$ 18,580</td>
<td>$ 14,582</td>
<td>$ 131,397</td>
<td>$ 10,950</td>
<td>2.73%</td>
<td>35,577</td>
<td>2.43%</td>
</tr>
<tr>
<td>OOS MEDICAID</td>
<td>$ 24,952</td>
<td>$ 10,037</td>
<td>$ 8,688</td>
<td>$ 103,897</td>
<td>$ 8,658</td>
<td>2.16%</td>
<td>30,351</td>
<td>2.99%</td>
</tr>
<tr>
<td>SELF PAY</td>
<td>$ 75,989</td>
<td>$ 98,971</td>
<td>$ 64,063</td>
<td>$ 689,266</td>
<td>$ 57,439</td>
<td>14.34%</td>
<td>88,001</td>
<td>6.07%</td>
</tr>
</tbody>
</table>

Figure 2.2 section 4
4-1. **Mix Current Month** lets you know the population mix for the most current post month.

4-2. **Mix Prior Year to Date** allows you to compare last prior year (exact same number of months) to the current fiscal year.

4-3. **Mix Fiscal Year to Date** allows you to look and see if you are trending up or down of the last prior year’s insurance category.

The difference between Original Insurance information capture vs. Payer, is the Payer section reflects what percentage of your collections is paid by which Insurance Company. The measures and columns work the same as above.

If you compare the original insurance information captures in Fig 2.2 section 4 to payer category in Fig 2.2 section 5, you can ensure that you do not have a payer category that is significantly behind on payments.

Look at Blue Shield in 4-3 you will see the current mix is 22.83%. Compare this to Blue Shield the payer in 5-3, and you will see Blue Shield comprises 24.16% of the total collections.

Self-pay (figure 4-3) represented 15.25% of the original insurance charges but only 8% of the total collections. Reasons may include that many of the invoices initially reflect no insurance information and subsequently insurance is identified, billed and paid. The difference and primary concern would be the actual amount you must adjust off to bad debt – see figure 3.

Comprehensive data compilation of your outstanding accounts receivable (A/R) allows you to review the specific performance of your revenue cycle processes. If you generate a large month of billings, did it ultimately get collected? Is it being collected timely? Do you have payer/rejection issues? Do you have a billing office performance issue? How are we doing compared to others? All questions you can answer quickly with the data capture and organization indicated below in section 6 and 7.

Section 6 provides a succinct summary of aging of your outstanding A/R, whereas section 7 expands it to payer category. You may want to expand to payer – the report is much longer. The key area here to focus on is the aged A/R. If your percent of A/R > 20 is higher than the benchmarks (section 6-5 to 6-7) you wish to compare your practice to, then you need to begin the process of drilling down data and processes to identify the reasons for the aging. With complete data you can determine on what and where you want to focus your business office resources.

Benchmarking reflected in 6-5 through 6-7 is Faculty Practice Solutions (FPSC). This is appropriate if you are an academic institution. Another good source is Medical Group Management (MGMA). Also, some societies provide specific numbers based on surveys of their members.

The categories listed in 7-2 through 7-5 are standard A/R breakouts. For space purposes the first two categories of A/R 0-30 and 31-60 were removed. An important note – A/R is a good thing. You have to have it to collect it. It is the age of the A/R that must be managed carefully.

In this example, April reflects 37.63% (section 6.4; $182,719 + $76,879 + $78,029 + $121,490 - $127,462 - $82,893 - $13,827 - $6,740 - $6,850 = $182,719) of total A/R outstanding is 0-30 days old. The corresponding benchmark indicates that the majority of members reported they have about 50% in this category 0-30. The first few categories is where you

<table>
<thead>
<tr>
<th>PAYER MIX</th>
<th>5-1</th>
<th>5-2</th>
<th>5-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLUE SHIELD</td>
<td>$66,414</td>
<td>$68,320</td>
<td>$57,137</td>
</tr>
<tr>
<td>COMMERCIAL INS</td>
<td>$1,321</td>
<td>$3,046</td>
<td>$1,463</td>
</tr>
<tr>
<td>CONTRACTS</td>
<td>$77,682</td>
<td>$91,017</td>
<td>$69,635</td>
</tr>
<tr>
<td>MEDICAID</td>
<td>$67,049</td>
<td>$79,316</td>
<td>$83,450</td>
</tr>
<tr>
<td>MEDICARE</td>
<td>$619</td>
<td>$230</td>
<td>$2,110</td>
</tr>
<tr>
<td>MISC GOVT</td>
<td>$6,450</td>
<td>$4,654</td>
<td>$9,208</td>
</tr>
<tr>
<td>OOS MEDICAID</td>
<td>$6,740</td>
<td>$9,115</td>
<td>$14,846</td>
</tr>
<tr>
<td>SELF PAY</td>
<td>$13,827</td>
<td>$22,023</td>
<td>$34,270</td>
</tr>
</tbody>
</table>

**Figure 2.2 section 5**

<table>
<thead>
<tr>
<th>OUTSTANDING ACCOUNTS RECEIVABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CURRENT INSURANCE</td>
</tr>
<tr>
<td>A/R 0-30 Days</td>
</tr>
<tr>
<td>% A/R 0-30 Days</td>
</tr>
<tr>
<td>A/R 31-60 Days</td>
</tr>
<tr>
<td>% A/R 31-60 Days</td>
</tr>
<tr>
<td>A/R 61-90 Days</td>
</tr>
<tr>
<td>% A/R 61-90 Days</td>
</tr>
<tr>
<td>A/R 91-120 Days</td>
</tr>
<tr>
<td>% A/R &gt;120 Days</td>
</tr>
</tbody>
</table>

**Figure 2.2 section 6**
Assisted Reproductive Technology Practice Management

want the majority of you’re A/R. Aged accounts receivable is usually due to rejections, pending appeals, and self-pay.

A/R over 90 days identifies some potential problem areas. The second section breaks out the A/R by category. The category should be able to be drilled down to specific insurance company.

The aging category information allows you to quickly see where the largest areas of concern lies. Self pay, by its nature, will trend older. If an account has insurance, the insurance will be billed, paid (perhaps 2-3 months later), account will be 3-4 months old as it comes into the self-pay category.

By Looking at Total A/R column on the far right you can see that Self Pay is 39% of total A/R $308,072/$788,640. The second highest is all contracted payers, and in third place is Medicaid.

Contracted payers generally are expected to pay within a 30-60 day time period for clean claims. This is a category that you would expect to be more timely than self pay.

In this example A/R still listed as outstanding for Contracted Payers is 20.33% of all my outstanding accounts receivable. Of the 20.33%, 18.5% [6.84+2.66+2.93+6.11=18.5] is over 90 days. According to the FPSC benchmarks above the other practices surveyed showed their A/R over 90 was about 15% (8.8% and 6.34%). Is this due to rejections, information requests, poor follow up by staff or by insurance? Some of these questions can be answered in the next section under rejections, others may require an analysis focusing on different payers.

Rejections are costly. Having to touch a claim several times takes staff time and possibly physician time. Ignoring rejections allows insurances to not fulfill their contractual obligation and in fact increases your “free care”. Rejections must be managed in a timely manner. In addition to working the rejections you need to know what and why you are receiving them.

The data in section 8 is grouped into three categories. This allows you to break out where the problem may be occurring and what resources are necessary to fix process. The three categories we established are Coding (8-1), Registration (8-2) and Follow Up (8-3).

- Coding (8-1) allows you to potential documentation and coding practices that are not in alignment with payer policies.

<table>
<thead>
<tr>
<th>CURRENT FSC</th>
<th>91-120 DAYS</th>
<th>121-150 DAYS</th>
<th>151-180 DAYS</th>
<th>≥ 180 DAYS</th>
<th>TOTAL AR</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLUE SHIELD</td>
<td>$2,284</td>
<td>$2,330</td>
<td>$409</td>
<td>$272</td>
<td>$123,507</td>
</tr>
<tr>
<td>% OF BLUE SHIELD</td>
<td>1.85%</td>
<td>1.89%</td>
<td>0.40%</td>
<td>0.22%</td>
<td>100.00%</td>
</tr>
<tr>
<td>COMMERCIAL INSURANCE</td>
<td>$405</td>
<td>$504</td>
<td>$118</td>
<td>$1,461</td>
<td>$13,167</td>
</tr>
<tr>
<td>% OF COMMERCIAL INS</td>
<td>3.08%</td>
<td>3.87%</td>
<td>0.90%</td>
<td>11.09%</td>
<td>100.00%</td>
</tr>
<tr>
<td>CONTRACTS</td>
<td>$10,971</td>
<td>$4,261</td>
<td>$4,698</td>
<td>$9,799</td>
<td>$160,320</td>
</tr>
<tr>
<td>% OF CONTRACTS</td>
<td>6.84%</td>
<td>2.66%</td>
<td>2.93%</td>
<td>6.11%</td>
<td>100.00%</td>
</tr>
<tr>
<td>MEDICAID</td>
<td>$11,165</td>
<td>$8,693</td>
<td>$4,685</td>
<td>$12,632</td>
<td>$108,126</td>
</tr>
<tr>
<td>% OF MEDICAID</td>
<td>10.33%</td>
<td>8.04%</td>
<td>4.33%</td>
<td>11.68%</td>
<td>100.00%</td>
</tr>
<tr>
<td>MEDICARE</td>
<td>$2,039</td>
<td>$236</td>
<td>$2,571</td>
<td>$694</td>
<td>$25,643</td>
</tr>
<tr>
<td>% OF MEDICARE</td>
<td>3.71%</td>
<td>2.44%</td>
<td>4.03%</td>
<td>66.97%</td>
<td>100.00%</td>
</tr>
<tr>
<td>MISC GOVERNMENT</td>
<td>$4,980</td>
<td>$901</td>
<td>$5,244</td>
<td>$19,798</td>
<td>$45,819</td>
</tr>
<tr>
<td>% OF MISC GOVERNMENT</td>
<td>7.95%</td>
<td>0.92%</td>
<td>10.03%</td>
<td>2.71%</td>
<td>100.00%</td>
</tr>
<tr>
<td>OOS MEDICAID</td>
<td>$5,000</td>
<td>$901</td>
<td>$5,244</td>
<td>$19,798</td>
<td>$45,819</td>
</tr>
<tr>
<td>% OF OOS MEDICAID</td>
<td>10.87%</td>
<td>1.97%</td>
<td>11.44%</td>
<td>43.21%</td>
<td>100.00%</td>
</tr>
<tr>
<td>RESPONSIBLE PARTY</td>
<td>$50,897</td>
<td>$22,908</td>
<td>$32,102</td>
<td>$26,625</td>
<td>$308,072</td>
</tr>
<tr>
<td>% OF RESPONSIBLE PARTY</td>
<td>16.52%</td>
<td>7.46%</td>
<td>10.42%</td>
<td>8.64%</td>
<td>100.00%</td>
</tr>
<tr>
<td>TOTAL AR</td>
<td>$82,893</td>
<td>$39,936</td>
<td>$50,078</td>
<td>$73,923</td>
<td>$788,640</td>
</tr>
<tr>
<td>% OF TOTAL</td>
<td>10.51%</td>
<td>5.06%</td>
<td>6.35%</td>
<td>9.37%</td>
<td>100.00%</td>
</tr>
</tbody>
</table>
Figure 2.2 section 8

- Registration (8-2) are generally rejections that may have been avoided with better point of service processes.
- Follow Up (8-3) are often issues with payers. They may be requesting additional information, which if not sent, claim will not be paid. Payers may have system constraints so they are not reading modifiers, and denying claims as duplicates – again requiring an appeal with documentation.

The data captured in section 9 provides greater trending then figure 8. This section provides comparisons between the months and years. Rejections are calculated as a percent of
charges. So if charges (9A) have gone up, either through fee schedule increases or increased productivity, it will reflect on the % of change in this row. When you review the Coding Category (9B) of rejections – the dollar amount of change between fiscal years is up 232% (9-6), but because charges were up 264% the actual change in coding rejections is actually down as a percent of total charges (.11%).

The key to this data and any other that you are reviewing is to ensure you understand the parameters of the data you are analyzing so that it provides accurate and valid information. Insufficient or flawed data will impact your responsiveness and accurate resolution of issues.

Whether you call it your financial analysis, dashboard, scorecard or operational indicator; the final objective is to have timely, manageable data in a format that allows you to monitor and manage your business. It must provide you a tool to process and manage key information to support your strategic growth and operational decisions.