

# Observations from a National Multiple Institution Autotransfusion (ATS) Quality Indicator Program

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**Abstract:** A process to collect universal, mandatory autotransfusion (ATS) procedure quality indicators to measure and monitor ATS quality improvement was designed and implemented by Fresenius Medical Care Extracorporeal Alliance (FMCEA) an outsource provider of extracorporeal services. The indicator program collected and evaluated data that reflect real-world extracorporeal clinical practices and outcomes. The indicator reports provide our clinicians, client physicians, and partner institutions with confidential reports that allow comparison of their practice to evidenced-based performance standards. All ATS procedures reviewed were performed on non-open-heart surgery procedures (on pump or off pump), including vascular, thoracic, orthopedic, and general surgery. After continuous collection and analysis of the indicator data, a hospital is given a report with three components: 1) data analysis that reports summary results and benchmarks the hospital against the other reporting hospitals, 2)

corrective action plan that allows the clinical manager to document their investigations and outline plans for continuous quality improvement; and 3) raw data tabulation that allows the clinical manager to identify individual cases that are outliers from the target goal to facilitate local chart reviews. This communication describes FMCEA's ATS Quality Indicator Program and presents the collective results for the first 13 months (January 2002–January 2003) of data collection. Physicians and ATS service client hospitals value the Quality Indicator Process Reports. ATS service managers use the reports and the subsequent process improvement to meet AaBB (American Association of Blood Banks) and JCAHO (Joint Commission on Accreditation of Healthcare Organizations) standards and guidelines for providing safe patient-care services. **Keywords:** autotransfusion, quality indicators, process improvement. *JECT. 2004;36:153–157*

## INTRODUCTION

The healthcare industry talks about quality in healthcare and every healthcare professional feels they deliver quality care (1). However, defining and demonstrating quality care can be tedious. One may have a good idea about what quality would mean in purchasing a new car, or a cordless drill, but how does this relate to operating a cell processor on a patient undergoing an abdominal aortic aneurysm resection?

Is it possible to define what is meant by quality of an autotransfusion (ATS) procedure? If the quality of an ATS procedure can be defined, can it be measured? How can it be measured, and who does the measuring? What is going to happen to the results of measuring the quality of an ATS procedure?

The first step in the process of developing a quality indicator program that will define and measure the quality of an ATS procedure is to choose a given standard and

then minimize the variation or deviation from that standard (1). A standard defines the key elements of care essential to defining quality and adequacy of the procedure. What guideline (parameter) should be used to measure the adequacy of an ATS procedure? The purpose of setting a standard is to establish aspects of care or key elements that are essential to defining quality ATS procedures.

Choosing a standard is setting a goal for a specific clinical quality indicator. Frequently standards come from established guidelines that are published by professional or regulatory agencies, as is the case for ATS standards. The American Association of Blood Banks (AABB) has published guidelines that detail standards for several different process areas of an ATS procedure to demonstrate quality of care (2). In instances where standards are not readily available, evidence-based, peer-reviewed published literature can be helpful in developing standards.

The case for developing standards of care has never been stronger (3). A recent publication in the Journal of the American Medical Association demonstrated wide variations in how doctors treat patients with similar disease states and the lack of standards is a critical factor in

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both quality and cost of patient care (4). Furthermore, regulatory agencies, such as Joint Commission on Accreditation of Hospitals (JCAHO), AABB, and Centers for Medicare and Medicaid Services (CMS), require hospitals to implement quality assessment and improvement programs.

**METHOD**

In January 2002, Fresenius Medical Care—Extracorporeal Alliance (FMCEA) initiated a universal (every clinician participates) and mandatory ATS quality indicator program to measure and monitor the quality of ATS procedures. ATS quality indicators were carefully selected based on the following criteria.

1. The perfusionist/technician has some direct control/management of the quality indicator.
2. The quality indicator is known to have a demonstrated impact on patient outcomes.
3. The information collected would be integral to process improvement.
4. There should be evidence from the scientific literature supporting #1 and #3.

A total of nine quality indicators were initially selected:

1. type of procedure
2. maximum vacuum (as measured during total occlusion of suction line)
3. total collected blood (loss) volume
4. total wash volume
5. total anticoagulant used
6. total volume returned
7. wash volume ratio
8. ratio of anticoagulant to volume collected
9. blood processed in automatic mode?

Patient target values (standards) were chosen for five of these nine indicators (Table 1). Patient target values were easily identified for “maximum vacuum,” “wash volume ratio,” “ratio of anticoagulant to volume collected,” and “blood processed in automatic mode?” quality indicators, as the standards for these indicators are identically defined by both the AABB (2) and in most manufacturer cell processor procedure manuals. The rationale for selecting the target value of  $\leq 1000$  mL for indicator, “Total volume returned,” was to identify those procedures in which this amount of plasma loss may lead to coagulation complica-

**Table 1.** ATS report format.

<i>Account Name:</i>	<i>Location:</i>
<i>Clinical Manager:</i>	<i>Reporting Period:</i>

Indicator Name	Count	Monthly Mean	3 Month Rolling Average	Patient Target	% Compliance	Corporate Derived Facility Goal	Benchmark Percentage Rank
Maximum vacuum (mmHg)				$\leq 150$ mmHg		$\geq 95\%$ Maximum negative pressure is $\leq 150$ mmHg	
Total collected blood (loss) volume (mL)							
Total wash volume (mL)							
Total anticoagulant used (mL)							
Total volume returned (mL)				$\leq 1000$ mL		$\geq 80\%$ of the time the total volume returned is $\leq 1000$ mL	

Indicator Name	Count	Patient Target	% Compliance Monthly	Compliance 3 Month Rolling Average	Corporate Derived Facility Goal	Benchmark Percentage Rank
Blood is processed in the automatic mode		“Yes”			$\geq 95\%$ of the time, blood is processed in automatic mode	
Maintained 1:5 to 1:10 ratio of anticoagulant solution to total collected blood (loss) volume		“Yes”			$\geq 80\%$ of the time, a 1:5–1:10 ratio of anticoagulant to collected blood (loss) volume is maintained	
Wash volume exceeds volume returned by $>3$ times		“Yes”			$\geq 95\%$ of the time wash volume exceeds volume returned $>3X$	

tions and/or replacement of plasma with homologous blood components (i.e., plasma, platelets).

The collection of these ATS quality indicators is a universal and mandatory process for our group’s clinical practice. Every clinician has to participate in the indicator program. The data are collected after each ATS procedure using several different collection technologies, which include, personal computers, integrated voice recognition system and Palm™ devices. The data are collected from about 390 participating hospitals representing more than 21,500 annual independent of open-heart surgery ATS procedures and is stored in a centralized data server. ATS procedures performed in conjunction with open-heart procedures participate in a separate indicator program.

There are three components to the indicator reports. First, a data table reports individual account results and benchmarks their data against the rest of the FMCEA experience (Table 1). The table reports the following information for each indicator.

1. count—the total number of observations or data points collected
2. monthly mean—the 1 month arithmetic average value
3. 3 month rolling average—the average value for the past 3 months
4. patient target—an evidenced-based value that a “normal” case should meet
5. % compliance—the percentage of cases that meet the patient target value
6. corporate derived facility goal—percentage of cases that should meet the patient target
7. benchmark percentage rank—ranks the individual account results and compares this to all FMCEA hospitals

Second, there is a corrective action page that allows the clinicians to document their investigation and outline plans for continuous improvement (Figure 1). Third, there is a raw data (spreadsheet) report that allows the clinicians to identify individual cases that are outliers from the target goals for further study.

Confidentiality of medical information is a fundamental patient right: as well, outcomes and benchmarking are an important part of the continuous quality improvement process (CQI). HIPPA (Health Insurance Portability and Accountability Act) considers CQI part of hospital operations, and therefore, the release of patient health information does not require authorization for release. It is recommend, however, that your informed consent indicate that information is released for benchmarking and quality improvement (5)

The corporate derived facility goal is established by carefully analyzing three interdependent clinical factors.

1. How influential is the quality indicator on patient outcome?

SERVICE TYPE:     ATS  
 Page 2 of 2  
 INDICATOR:        ATS\_20 ATS Management  
 ACCOUNT:           xxxx

Review report and investigate as necessary. Enter the action taken as applicable. If action is not applicable enter explanatory statement.

CORRECTIVE ACTION:

Vacuum     Wash Ratio     Anticoagulant Ratio     Automatic Mode

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Submitted By: \_\_\_\_\_ Date: \_\_\_\_\_

Acknowledge By: \_\_\_\_\_ Date: \_\_\_\_\_

**Figure 1.** FMC cardiovascular resources, CQI—Indicator program.

2. How obtainable are the corporate derived facility goals, in the real-world clinical setting?
3. Is there evidence from peer-reviewed scientific literature to support the goal?

The ATS quality indicator reports are produced monthly and are made available on the FMCEA intranet site. The clinical manager can, at any time, sign on to the FMCEA Intranet site and choose the time frame for which he or she wants to view and download his or her ATS quality indicator reports. Every month, the clinical manager verifies that the results of the ATS quality indicator reports are investigated, especially the outliers. The clinical manager also discusses the results with the clinical staff involved and ensures that the appropriate actions are implemented. The clinical manger will also, as required, present the ATS quality indicator reports to the appropriate quality managers at the client hospital.

An important component of an ATS quality program involves end product testing. This process is a requisite of the FMCEA ATS quality program, however, at this time, it is separate from our quality indicator program.

**RESULTS**

The following four charts (Figures 2–5) represent the collective results from the FMCEA ATS client hospitals, pertaining to four of our ATS quality indicators during a 13-month time period (January 2002–January 2003).

Figure 2 represents the monthly average maximum vacuum applied during an ATS procedure. The chart data

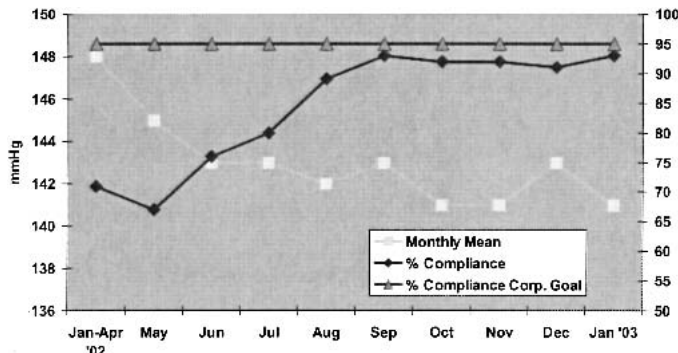


Figure 2. Maximum vacuum ( $n = 19,066$ ).

demonstrate an overall improvement in reducing the maximum vacuum used during an ATS procedure. Consequently, compliance has improved during this period and is nearing our corporate compliance goal of 95%.

Figure 3 represents the number of outliers for ATS procedures in which the returned blood was not washed with the target/required saline volume. The chart data demonstrate an overall improvement in ensuring that the wash volume exceeds, by more than three times, the volume returned. The compliance level has exceeded the corporate facility goal for 13 consecutive months.

Figure 4 represents the number of outliers for ATS procedures in which the proper ratio of anticoagulant to blood collected was not achieved. The chart data show an overall improvement in the number of outliers with the exception for December 2002 and January 2003. This is the same period of time when the target value was changed to represent the regulatory guideline better.

Figure 5 represents the number of outliers for ATS procedures in which the automatic mode was not used on the cell processor. Both the number of outliers and compliance with this indicator has fluctuated; however, compliance has steadily increased over the past 9 consecutive months.

**DISCUSSION**

The goal of an ATS quality indicator program is to

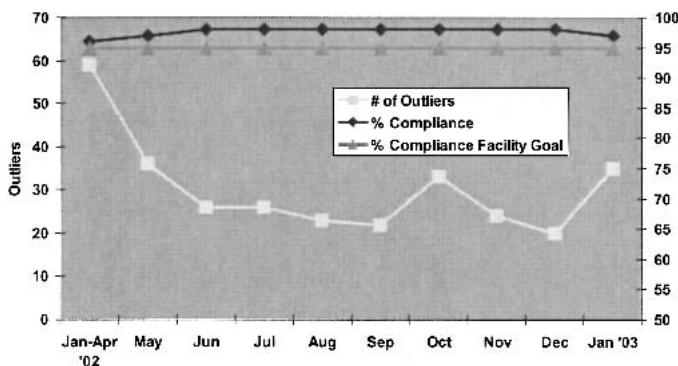


Figure 3. Wash volume exceeds volume returned > 3x ( $n = 15,223$ ).

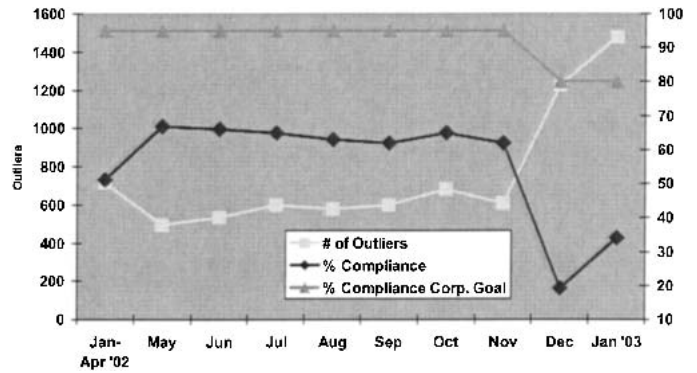


Figure 4. Ratio anticoagulant: blood collected ( $n = 18,833$ ).

evaluate actual ATS practices and outcomes. The data may reveal deficiencies in performance that lead to an opportunity to change and improve clinical practices. Furthermore, the ATS quality indicator program provides our group's clinicians, physicians, and partner healthcare facilities with confidential reports that allow comparison of their practice to evidence-based performance standards. Through this process, our clinicians are provided information to improve processes and increase their level of knowledge and education as it pertains to consistently performing high quality ATS practices. The ATS quality indicator program is not used as an audit tool to identify poor performance. The resultant data from the program are used to assess and improve the quality of care processes. If a facility does not meet our defined corporate compliance levels, the clinical manager investigates the root cause for the outliers.

One of the benefits of the ATS quality indicator program is that it fulfills the regulatory process requirements stipulated by JCAHO, AABB, CMS (Centers for Medicare and Medicaid Services), and other agencies. The program has the ability to demonstrate both quality assessment and quality improvement. In addition, utilizing an ATS quality indicator program that demonstrates the value and commitment to quality assessment and improvement will likely lead to a greater partnering relationship

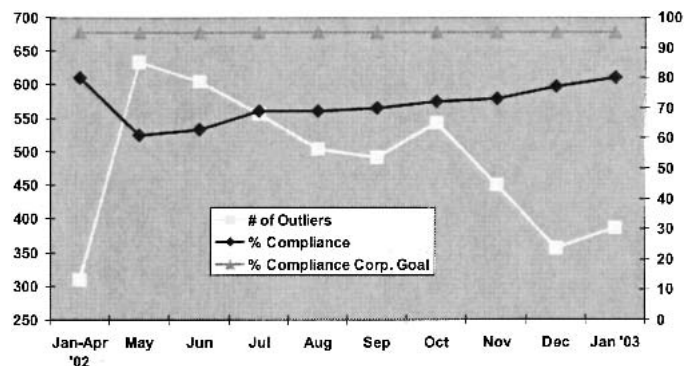


Figure 5. Blood processed in automatic mode ( $n = 20,023$ ).

with the facility (i.e., hospital administrators, physicians, care givers). Consequently, if these customers see value in our work this often time leads to increased job security (6).

One of the most powerful attributes of the quality indicator program is its ability to establish benchmarks. Our national network of hospitals allows us to provide client hospitals and clinicians the opportunity to improve local processes through comparison to a national process. Benchmarking can contribute to a framework for achieving both best practice and value, by focusing on:

1. resource investment in quality
2. commitment to improvement
3. collaborative problem solving/process improvement

Achieving these three tenets through the use of benchmarking sends a message and supports a culture within a workplace that motivates clinicians to continually improve the quality of the service provided (7).

The ATS indicators listed in this paper are a sample of clinical process information that can be collected and analyzed. ATS end product blood measurement and analysis is another example of an ATS process quality indicator. There are acceptable considerations when choosing indicators. First, the indicator should be important to the facility, the clinician, and to patient care. The indicator should be easily measured during the daily clinical practice routine.

In developing an ATS quality indicator program start with the basics and choose a few quality indicators to study that are important and possible to change. Follow the results and use a continuous quality improvement process (CQI) to document changes. An excellent example of a simple and concise CQI process is outlined by Rath and Strong (8). They have distilled problem solving into a simple 5-step process (DMAIC):

1. Define—define the problem
2. Measure—gather information on the problem
3. Analyze—identify root causes of the problem and confirm with data

4. Improve—try-out and implement solution the address root cause(s) of the problem
5. Control—evaluate the solutions and outline and maintain the gains by standardizing the process

In summary, we have illustrated a national, multi-institution ATS quality indicator program. We have demonstrated that it is possible to define and measure the compliance to quality standards in an ATS procedure. By measuring the quality of ATS procedures and addressing our outliers through the utilization of a continuous quality improvement technique, we have successfully shown improved ATS practices over time. An ATS quality indicator program has the ability to assist and support the provision of high quality care by exceeding the minimum standards of regulatory compliance, while enhancing the professional practice and defining a standard of care. As practicing healthcare professionals, we have an obligation to strive continuously to improve the care we deliver to patients.

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