Quality Improvement Tool Kit

AmSECT
AMERICAN SOCIETY OF EXTRACORPOREAL TECHNOLOGY
Lead - Collaborate - Educate - Care

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What is Quality?

The Institute of Medicine defines health care quality as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."

In Perfusion, quality can best be described as the ability for a patient to get the best care available and the same level and excellence of that care at any center they are treated at.

Quality Assurance vs. Quality Improvement

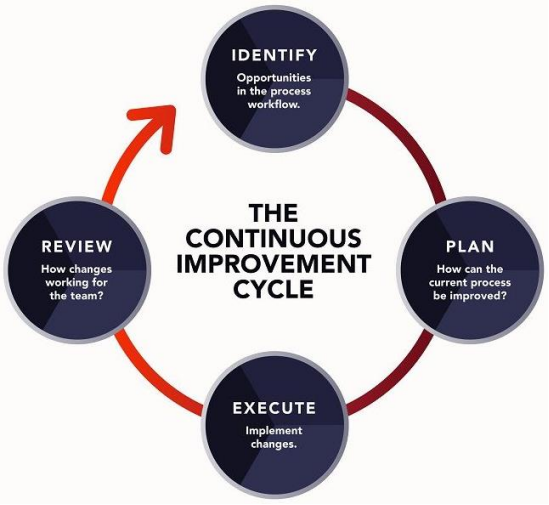
Quality can be further broken down into separate categories with distinctly different goals and implementation strategies for each. The two categories most commonly utilized to ensure quality in perfusion are Quality Assurance (QA) and Quality Improvement (QI).

Quality Assurance is the specification of standards for quality of service and outcomes, and a process throughout the organization for assuring that care is maintained at acceptable levels in relation to those standards.

- QA is on-going, both anticipatory and retrospective in its efforts to identify how the organization is performing, including where and why facility performance is at risk or has failed to meet standards.
- Examples in Perfusion
    - Knowledge of the AmSECT Standards and Guidelines
        - Ideally also implementation of them into your practice
    - Written protocols and policies for your practice for practitioners to reference
    - Consistent emergency drills and planning
    - Access to high fidelity simulation

Quality improvement the continuous study and improvement of processes with the intent to better services or outcomes, and prevent or decrease the likelihood of problems

- Accomplished by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement
- Examples in Perfusion
    - Non-routine event reporting and debriefing
        - Identifying systemic safeties and shortcomings for every event
    - Data mining to identify areas of the practice that can be improved
        - Lactate trends vs. flows
        - Nadir hct vs. AKI incidence



Together, QA and QI provide practices with an organized and standardized way to make sure they are achieving set targets and optimal results for their patients.

Identifying an Area for Improvement

The first step in a QI initiative is identifying an area of the program that has a quality metric that can be improved. If the quality metric being targeted is clinical/data based, this can be done via 2 pathways:

1. Using existing data that your program has, identify a data set that either seems like it has a larger than normal variance or contains values outside normally accepted parameters for your department, or that seems to show a potential safety issue.
    a. Once identified, complete a retrospective analysis of the data looking for specific trends or statistically important results
    b. Once the data has been analyzed, it can be presented (to the perfusion department, to the surgeons, to the anesthesiologists, etc.) and used to either support a practice change or reinforce current practices
    c. See "How To Use Excel" section for information on building databases and analyzing data
2. Identify an existing problem that is presenting (ex. Trend of first gas for post-CPB patients in the unit having higher than normal lactates)
    a. This requires prospective data collection
    b. The department will need to either update an existing database to include data points specific to the new QI study or build a database specifically for the QI study
    c. Data will be collected until the sample set is deemed large enough to be analyzed and presented

Some examples of categories that QI initiatives can fall into are:

- Potential Patient Safety Issues
    - Maximum rewarming water temperature used
    - Maximum cooling or rewarming gradients recorded
    - How long the suckers are running after the start of protamine administration?
- Quality of Care
    - Is there a noticeable difference in terminal lactates between surgeons or perfusionists?
    - Is there a noticeable difference between blood product administration between surgeons or perfusionists?
    - How does your institutions prime volume compare to other institutions?
- Non-clinical
    - Is there an established non-routine event or patient safety even reporting system in your program?
    - Do debriefs between all teams occur when necessary?
    - Does your department have written and accessible policies and procedures to reference?

Identify The Problem, The Want, and The Impact

A helpful way to think about potential QI initiatives is in terms of the three questions What, How, and Why. Answers to these questions will help weed out ideas that arise that aren't necessarily suitable for a QI initiative

- The Problem
    - What specific gap or improvement has been identified in the programs practice
- The Want
    - How do you envision the team studying/intervening on the identified "problem"
- Impact
    - Why does this matter to/benefit patients and the practice?

Thorough answers to these three questions should always be the first step of identifying a QI initiative. If there is not a good answer to any of these three questions, either it may not be an ideal topic for a QI initiative, or it may not be the right time for it. Keep a running list of topics that have been identified but haven't had the answers necessary to these three questions to pursue a QI initiative and revisit it periodically to see if that has changed.

Prioritization of Multiple QI Initiatives

Once QI initiatives have been identified, the perfusion team or QI leader will need to decide the best way to approach them. If only one has been identified, it can immediately be deemed the priority. If multiple QI initiatives are identified, determine if they can be implemented/studied concurrently or if they should be done one at a time

- Often it is easiest to do one at a time to avoid introducing too much change or increased work load all at once. However, non-clinical initiatives can often be completed or led by one person and then approved by the entire team before implementation. In this case, it may be feasible to be working on multiple QI initiatives at the same time
- See "Prioritization tool" in resources section
    - Should focus on one intervention at a time
    - If there are multiple things your team wants to tackle, figure out what is most important by weighing
        - Cost
        - Barriers to implementation
            - Executive-level support
            - Staff capability
            - Staff willingness
            - Time and effort
            - Ability to monitor progress
        - Likelihood to succeed and stay a practice change
        - Patient benefit, patient harm, etc

If the perfusion team or QI leader is having trouble isolating a QI initiative to start with, the AmSECT Standards and Guidelines can be used as a starting point. Is the department meeting all the recommended standards that have been set?

The following is not meant to be a substitution for thoroughly reading the AmSECT Standards and Guidelines. It is meant to be used as a summary of the major points that your institution should be following according to the AmSECT Standard and Guidelines. If you notice a gap in your institution's practice based on the following questions, you should reference the full AmSECT Standards and Guidelines.

Standard 1: Protocols

- Does your institution have written protocols
    - Clinical
    - Emergency
- Can everyone in your department access these protocols?
- When was the last time they were reviewed and updated? Are they current?

Standard 2: Qualification and Competency

- Are there designated ways to assess competency annually in your department?
    - Simulations
    - Managerial and department reviews
- Does everyone on your staff attend at least one CEU event annually?
    - Does your hospital/department support this (paid CEU days, CEU budget, ease of getting time off, etc)
- Do you operate on an n+1 model?
    - If not, how far away is support staff?
- Is there a standardized process for onboarding and training?
    - Do new hires feel that it is effective and that they are able to safely do their jobs upon completion?

Standard 3: Communication

- Do you have a designated process for participating in pre and post-op time outs, huddles, or debriefs?
    - Do you have a designated time/process to talk to the surgeon about the plan for each case
- Does your department use a set handoff tool for cases?
    - SBAR, IPASSTHECLAMP, etc
    - Is it written and accessible somewhere?
- Does your department have a policy around cell phone and other technology use in the OR?

Standard 4: Perfusion Record

- Does your record include everything required by the AmSECT S&G in Standard 4.2?
- Does your record have a way to document verbal commentary pertinent to the case?

Standard 5: Checklist

- Does your team have a standardized and thorough checklist used for every CPB case?
    - Does it cover pre, peri, and post op time periods?
- Do you have additional checklists for non-CPB operations?
    - IABP, ECMO, VAD, etc.
- Is the completed checklist saved and included with the patient's record?

Standard 6: Safety Devices

- Does your department employ all 11 of the safety devices recommended in Standard 6 of the AmSECT Standard and Guidelines
    - Pressure Monitoring
    - Bubble Detector
    - Level sensor
    - Temperature Monitoring
    - Arterial Filter
    - Vent one way valve
    - Retrograde flow prevention for centrifugal pumps
    - Anesthesia scavenge/WAGD
    - Hand Cranks
    - Back up gas supply
    - Back up power source
- If not why?
    - Oversight
    - Cost
    - Personal Preference
- If one or more is missing, would the team and department be open to exploring adding them into the practice?

Standard 7: Monitoring

- Does your departmet monitor all 10 of the recommended monitoring parameters in standard 7 of the AmSECT Standard and Guidelines?
    - Patient arterial blood pressure
    - Arterial line pressure
    - Arterial flow probe (distal to shunts)
    - CPG information (elaborated in S&G)
    - Patient and device temperatures
    - Blood gas analysis
    - Hematocrit
    - Gas flow
    - Venous line occlusion
    - Venous oxygen saturation
- If not why?
    - Oversight
    - Cost
    - Personal Preference
- If one or more is missing, would the team and department be open to exploring adding them into the practice?

Standard 8: Anticoagulation

- Does your program have a clearly defined anticoagulation management algorithm both for treating patients with indirect thrombin inhibitors (heparin) and treating patients with direct thrombin inhibitors (bivalirudin, argatroban, etc)

Standard 9: Gas Exchange

- Does your department calculate indexed oxygen delivery and consumption?
    - Is it calculated continuously or at designated intervals?
- Does your department have a set nadir indexed oxygen delivery?

Standard 10: Blood Flow

- Does your department have defined maximum and minimum blood flow rates agreed on with the surgeons (C.I. or cc/kg) for:
    - All patient ages and sizes
    - Ideal body weights
    - Different temperatures
    - Regional perfusion techniques

Standard 11: Blood Pressure

- Does your department have set blood pressure ranges for all patient ages and sizes that have been agreed upon with surgery and anesthesia?
- Does your department have a set algorithm for handling hypotension and hypertension?

Standard 12: Protamine and Cardiotomy Suction

- Does your department turn the suckers off at the onset of protamine?
    - If not, is there a set amount of protamine (1/3, 1/2, etc) that they get turned off at instead or is it surgeon specific?

Standard 13: Blood Management

- Does your department have defined nadir hematocrits for all patient sizes, ages, and populations?
    - Does this match current literature or should it be interrogated?
- Is your circuit as miniaturized as it can safely be for your practice?
    - Is your prime volume comparable to other centers that do similar case types as you or can it be optimized?
- Do you regularly calculate dilutional hematocrit pre-bypass to decide whether or not a blood exposure is needed for your patient?

Standard 14: Level of Readiness for Procedures that may Require CPB

- Does your department have defined standby procedure protocols?
    - Are they published and accessible to the entire team?
    - Are there different checklists for these cases?
- Is there an accepted standard “level of readiness” for different case types?

    - Cell Saver Only
    - Dry pump built but not in room
    - Dry pump in room
    - Wet pump in room but draped
    - Wet pump in room with lines handed up
    - ECMO ready

Standard 15: Staffing and On-Call

- Does your department utilize an n+1 staffing model at all times
    - If not, how far off from this are you?
- Does your department have a clearly defined call radius and do you feel that all team members are able to adequately meet it?

Standard 16: Duty Hours

- Does your institution clearly define the maximum amount of work hours that can be continuously worked without a rest time?
    - Is the amount of required rest time after hitting the maximum amount of continuous work hours clearly defined?
    - AmSECT defines these as 16 hours working and 8 hours off
- Does the institution appropriately enforce these rest periods?

Standard 17: Quality Assurance and Improvement

- Does your team participate in departmental QA and QI projects?
- Does your team participate in institutional QA and QI projects?
- Does your team utilize a safety event reporting system?
- Does your team participate in a clinical registry or database?

Standard 18: Maintenance

- Is there a schedule for cleaning and maintaining all equipment used by the perfusion department?
    - Is the institution's Biomed department involved?
    - Do they enforce this schedule or does your department?
- Does your department have a protocol or plan for equipment failures and back ups for any failed equipment?

Standard 19: Crisis Management

- Does your department have a collaborative crisis management plan/protocol?
    - Are all team members aware of and trained on this?

Preparing for the QI Initiative

Once you have identified a QI Initiative, you should complete the Pre-Planning Questionnaire found in the resource section of this document. It will help you organize everything you need and identify all the necessary information that should be given to the team in the following "Garnering Team Buy In" section.

Garnering Team Buy In

In order for a QI initiative to be successful, the entire team needs to commit to participating fully for the duration of it. This requires the process to be collaborative from start to end and necessitates team involvement and feedback during the process. It is essential to get full team buy in at the beginning of the QI initiative so that it is fully implemented by all team members in all relevant situations.

- Form a presentation on why this initiative is important
    - If this QI initiative is going to represent extra work for members of the team, they have to be convinced that this QI initiative is important enough to justify that
        - Will it improve patient safety? Make the practice better? Make the practice safer? Thoroughly explain the why of the project so everyone is on the same page.
    - Are there other programs that have implemented this and had good results?
        - PERForm and other multicenter databases…are you falling behind compared to other centers?
- Be upfront about the requirements
    - What work flows is this changing?
    - How much extra time is this going to require from each person?
    - How much extra effort is this going to require from each person?
    - Are they going to have to be the go between with different departments (i.e. nursing, anesthesia, etc.)?
- Allow for ownership of the process if people are interested
    - Having a designated QI leader is important to streamline the process and provide a point person for decision making and information dissemination, but are you able to let one or two other people be on a planning or steering committee for this QI initiative if there is interest?
    - Can names be on potential publications?
    - Can this be used as a step on a clinical ladder or as a push towards a promotion?
- Get higher ups on board first
    - If the surgeons or the hospital stand behind this QI initiative, it's harder for people to oppose it
- See the sample "Team Buy In" power point for an example of a presentation

Identify a QI Team

While a designated QI Leader is essential to make sure a project gets off the ground and runs smoothly, it can be helpful to have additional QI team members for support and guidance. Once there has been established buy-in from the perfusion team and all other relevant departments, determine who would

be helpful additions to a QI team assembled to support each QI initiative. Some examples of other QI team members are:

- Additional perfusion team members
- Surgeon Advocate(s)
- Anesthesia Advocate(s)
- Physician Advocate(s)
- Fellows or Residents
- Nurses, both OR and ICU
- Scrub Techs
- PAs and NPs
- RTs
- ECMO specialists
- Data Managers/Statisticians

Example: Implementing a QI initiative to make sure that suckers are turned off at the onset of protamine with 100% compliance in accordance with AmSECT Standards and Guidelines. QI Team established:

- Surgeon Advocate
    - This likely represents the largest work flow change for the surgeons. While it's known that it's best practice to immediately turn suckers off at protamine, some surgeons keep them on until a designated amount has been delivered to the patient. Having a surgeon on the QI team to advocate for the project may help with compliance from the entire surgical team
- Fellow/Resident or PA/NP
    - Having people from the team that covers surgical assistance is important. They can help with education and implementation focusing on switching to the cell saver or outside suction at the onset of protamine every case
- Scrub Techs or RNs
    - Similar to the surgical assistance team, having someone from this group that is at the field for cases is important. They can also help with implementation, focusing on removing the pump suckers from use/enforcing the use of the cell saver or outside suction as well
- Additional Perfusionists
    - Potentially helpful to have additional perfusionists designated as point people that can handle questions, issues, and pushback from team members that aren't in compliance with the QI initiative. Can also designate someone to make sure that the data (most likely just a yes/no answer to were the suckers turned off at the onset of protamine) is being properly collected and recorded for every case.

While it's possible for the designated QI leader to handle this initiative on their own, there is a greater chance for success with the right teams represented and taking ownership of the success of the initiative.

Once you have a designated team, set up a meeting to assign roles and make sure everyone is on the same page. Additionally, discuss how often the QI team would like to meet to discuss the project, any issues that arise, and overall progress. Make sure to maintain open lines of communication between team members and the QI leader throughout the duration of the project.

Setting Up a Timeline

Before implementing the project, set up a goal timeline. Answer the following questions for the QI project so there is a framework to go by once the project is implemented.

- When is the ideal time to start this project?
    - How much time is needed to get everything set up?
    - Are there major barriers for implementation that need to be accounted for?
- How often do you want the QI team to meet for check ins and updates?
    - Does this need to be done in person or can communication be done virtually (email, zoom, etc.)?
- What is the preferred amount of time for data collection?
    - Is it a time endpoint or a cumulative data points endpoint?
- How much time will the data analysis take?
    - Is it something that can be done by the QI team or will it require outside data managers or statisticians?
- What is the overall time from implementation to team debrief that the QI team is aiming for?

Make sure that space is left in the timeline for pivots and unforeseen complications arising. Consider if you want to budget time for a "roll out" period and also how necessary changes that arise as the project is going will impact the timeline

- A roll out period is a 1-2 week time period at the beginning of implementation used to iron out kinks and identify and fix project design issues
- Ideal time for team members to speak up about concerns or problems that are being encountered before the initiative "officially" starts
- Collected data during this time can be discarded from the study if the study design or endpoints change

Finally, decide how often you want to review and analyze the data during the QI initiative. Do you want to wait until the previously decided upon endpoint for the QI initiative is reached and no more data is being collected to analyze it? Or do you want to set specified check in periods (Q biweekly, Q monthly, etc.) to analyze the data as its being collected and begin to look for trends?

- If you have an external data manager/statistician managing your data analysis and review, make sure to have this conversation with them so expectations are set from the beginning of the project

Implementing QI Initiative and Gathering Data

Pilot Phase (Roll-out Period)

The first one to two weeks of a new initiative are always the hardest. No matter how thorough the planning, preparation, and education has been there will always be bumps and unexpected issues that arise as workflows change and the plan goes from theory to practice. It is critically important during the beginning stages of the initiative that the lines of communication remain open between the QI leader/QI team and the workers implementing the initiative

- Until everyone has had hands on, first person experience with the new initiative, the QI leader or someone from the QI team should be available at all times as a resource to answer questions and help walk people through their first case with the new initiative
    - This may require creative scheduling, longer hours, or access to the QI leader outside of normal work hours for a short period of time
- Ensure that there is an accessible study design and protocol available for team members to access that clearly lays out what is needed from them for each case
- Ensure there is a designated way for team members to voice questions and concerns in a timely manner and that answers to these questions get disseminated to the entire team, and not just the person that asked. It's likely easiest to designate a single communication point person, whether that be the QI leader or a QI team member, to be the person collecting the questions and concerns
    - Have the designated communication point person establish how questions and concerns should be raised and communicated and then ensure that everyone sticks to that process to avoid confusion
    - It's important to keep this process very organized so that important information doesn't fall through the cracks
    - Be wary of email fatigue and information overload. The team is going to potentially be fielding a lot of new information during this time period. Try to keep everything in one place with as few notifications as possible.
        - For example, instead of sending answers to questions out individually, perhaps try to get them all in one email from the designated communication point person to the entire team
        - Consider starting with a daily roundup up of questions that were asked and their answers and then shifting to weekly or biweekly as the process is smoothed out and there are less questions arising.

It's important to be flexible during the pilot or roll out period. The plan for the QI initiative was theoretical and the practical application may not always work in the way that was expected. If this is the case, don't be afraid to pivot in the moment and find a better option or solution than was originally planned for. It's more beneficial to pivot early and have a study design that runs smoothly and achieves the goal endpoints than to try to force the original plan to work even if it isn't the best option. Pivoting early is less work down the line for everyone and increases the chance of a successful QI initiative.

- Any pivots or changes to the study design that occur can also be included in the daily update email that the communication point person is sending

After the designated amount of time for the pilot phase has been reached, set up a meeting with the QI team to debrief and discuss next steps.

- Make sure everyone is aware of any changes that have been made to the study design
- Get feedback from the team about positives, negatives, and continued concerns
    - Both from the point of the QI team member individually, and from the feedback from their respective departments as a whole
- Ensure that there is still full buy in from all departments and that the initiative can continue to run smoothly
- If desired, set a meeting(s) for a follow up check in(s) with the QI team to discuss progress

Maintenance Phase

Once the team has made it through the pilot phase, established the study protocols, and ironed out any issues, the QI initiative should roll into the maintenance phase. There shouldn't be many (if any) changes to the study design once this point is reached and the main focus of the QI leader and team at this point should be compliance.

- Is everyone participating in the initiative at all points that they can be?
    - Allow a small accounting for human error (forgot to collect a data point, didn't have enough time for a sample, etc.) and special circumstances (emergencies, special cases that don't fit the established protocol etc.)
- Is everyone completing their tasks correctly according to the established study protocols?
    - Data points aren't helpful if they aren't be collected in the standardized way
    - Ensure no one got trained incorrectly or changed the way they comply with the study protocol so that there is no deviation in the data being collected
- Watch for pushback from other departments as the novelty wears off
    - If this occurs, have either the QI leader or the appropriate advocate from the QI team address it
- Ensure that the study continues to run smoothly for its agreed upon duration
- Set regular meetings (monthly, etc.) with the team to provide updates and address concerns

As the study goes on and people get more comfortable with it, it's easier for compliance to slip. Ultimately the **QI leader is responsible for maintaining compliance**.

Data Collection

Data collection and entry will most likely occur for the duration of the QI initiative. During the pilot phase, explore different options for the data collection to determine what is easiest and preferred by the team.

- For example, is it helpful to have a print out for each case that has all the data points needed listed on it?
    - Serves as a reminder of what data needs to be collected so nothing is forgotten
    - Also keeps everything in one place and hopefully make the data entry easier on the team

Offer multiple options to the team for data entry but ultimately, let everyone decide what is easiest for them as long as the data being collected stays standardized.

Either the QI leader or a designated data point person should be responsible for regularly reviewing the database for completeness and correctness.

- Are there any data points that seem like they're inappropriately deviated from the others?
    - Is this a units problem
    - Is it confined to a single team member
        - Are they collecting the wrong information or collecting in a way other than what the study protocol outlines?
- How is the data trending overall?
    - Is the data that is needed to analyze the primary goal endpoints being collected?
    - Is the data trending in a way that suggests the study should continue? Be stopped early? Be changed in some way?
- Is the data complete?
    - Is everyone inputting every data point for every case?
    - Are there gaps or holes in the data that need to be addressed?

Any issues that arise with the data collection need to be addressed and changed early in the study design. It's not ideal to make it to the data analysis portion of the initiative and then realize that data is missing or incorrect. Keep team members updated on data entry and early data analysis at the scheduled check-ins. Letting people know the results of what they're doing and why it matters as the process is occurring can help promote long term buy in and compliance for the initiative.

Remember that each new data point that needs to be collected ultimately represents an increased work load for the perfusion team. While individually the additional data points may not seem like a lot of extra work, cumulatively they can become taxing. As new data fields are added to the database to be collected, it's a good idea to review the existing database and see if any old data fields can be removed so the work load stays level instead of ever increasing. It can be helpful to visit this in the QI debrief as well. Once the initiative has been completed, does the data need to continue being collected permanently, or has enough of a change been shown that it can either be cut back or stopped completely?

Interpreting Data

As the QI project has been progressing, the data has been being collected by the perfusion team. Now it's time to decide what to do with it. The complexity of the statistics required plays a huge part in this decision making. In the example used in the identifying a QI team section earlier of achieving a 100% success rate with cardiotomy suckers turned off at the onset of protamine, the data points that you're collecting are a simple yes/no and the review of the data is just the percentage of yes answers out of the whole. That can easily be done by the QI team. Similarly, if the QI initiative required minimal data points being collected and compared such as a trend in a single value over time or, it's possible that the review and statistical analysis can be completed by you or another QI team member that is familiar with excel or a statistics program such as SPSS.

- Youtube has excellent resources and videos for excel education ranging from simple data entry and chart building to pivot tables and statistical analysis
- There are linked videos in the Excel Resources section in the Resources portion of the tool kit but this is just a small sample of what's out there. Explore youtube to find exactly what works best for you

As the number of data points that you're collecting and comparing increases, so does the complexity of the statistics required to accurately analyze the data and achieve appropriate statistical results. When the statistics required exceed what the QI team can reasonably do on their own, an outside data manager or statistician is needed. Ideally, the need for this person has been identified during the planning phase and a suitable person has already been made part of the QI team. It's important to bring the statistician in early so the targeted endpoints (exactly what the QI team hopes the data will prove or disprove) for the QI initiative can be communicated and the statisticians can confirm that the right data is being collected to achieve this specific analysis.

It's important to consider the possibility for the QI initiative growing and changing as it is underway. It's entirely possible that at the beginning of a project a statistician wasn't thought to be needed but by the middle or end of it, one clearly is. When this is the case, the team needs to find a statistician that will take on the project.

- If the perfusion department has done previous QI initiatives that have required statisticians in the past, they can likely be contacted for this project
- Many major academic hospitals have data managers and statisticians that work for the hospital. They are sometimes available to teams within the hospital doing research. This can be an excellent resource to explore.
- If there is a local university with a statistics department, there are potentially graduate level students that would be suitable candidates. Reach out to the statistics departments to see if they offer these opportunities to their students
- It's always an option to hire a contract or freelance statistician data manager if the above options fail. Make sure this is a cost that is accounted for during the planning phase so the QI initiative doesn't stall out at this phase
    - https://www.neuroworx.io/magazine/how-to-hire-a-statistician/
    - https://www.kolabtree.com/services/statistical-analysis
    - https://www.upwork.com/hire/statistics-analysts/

QI Debrief

The QI Debrief is one of the most important parts of the QI process. This is the part of the process where the QI leader is able to present the findings and outcomes of the QI initiative to anyone involved in the process, i.e. the perfusion, ECMO, or VAD team, the surgeons, any other specialties that were involved in the process, hospital administration, etc. It's important to provide feedback about the findings of the QI initiative so that all participants of the QI initiative can see tangible results that reinforce the necessity of any extra work that occurred or work flow changes that happened due to the QI initiative. Providing direct, easily understandable, transparent results of the QI initiative helps to reinforce why the QI initiative (and any extra work or

The main points that should be talked about during the debrief are:

1. Presentation of data collected and statistical analysis
    a. Was there a noticeable difference in between QI and non-QI initiative data?
    b. Was the data collected from the QI initiative statistically significant?
    c. Does the data point towards a positive, negative, or neutral endpoint to the QI initiative?
2. Plans specific to this QI initiative moving forward
    a. Does the QI initiative warrant a permanent implementation to the practice?
        i. Did the data that was collected and analyzed show that the QI initiative had a net positive outcome on the patients or the practice that would suggest that it should be a continued practice?
    b. If the QI initiative is being transitioned to a permanent part of the practice, is it a mandatory intervention for the entire team to implement in their practice or is it an optional intervention?
    c. Does it require continued data collection or can it be implemented without continuing to collect data?
        i. If continued data collection is required, is it already built in to the practice's data collection methods?
    d. Is this information something that warrants publication, does the team want to publish, and is there anyone on the team that wants to be involved in that process?
3. Does the QI initiative warrant further exploration even though the primary end point has been met?
    a. Was there additional gaps found or questions identified during this QI process?
        i. Do they warrant an additional QI initiative?
        ii. What would be required for that initiative and is it something that the team is interested in pursuing?

It's also important during this process to get feedback from anyone that was involved in the initiative. Find out what went well, what could have been done better, and suggestions for future initiatives. It can be deidentified information so that people feel comfortable being completely honest. The more information you can gather after a QI initiative, the more you can continue to improve the process for upcoming ones.

Resources

Prioritization Tool

Rank the following statements as they apply to each QI initiative on a scale of 0-5, 0 being does not apply at all, 3 being somewhat applies, and 5 being greatly applies. The higher the score, the higher priority the initiative should get.

1. There is a demonstrated need for this QI initiative
2. The QI initiative will directly improve patient safety
3. The QI initiative will directly improve patient care
4. The QI initiative will improve surgical measured points of success (ex. RBC exposures)
5. The QI initiative will improve hospital measured points of success (ex. Length of stay)
6. The perfusion department will “Buy In” to the QI initiative
7. Other relevant departments will “Buy In” to the QI initiative
8. There are manageable barriers to implementation for the QI initiative
9. The perfusion team has the time to take on the QI initiative
10. The perfusion team has the resources to take on the QI initiative
11. Other team members have expressed interest in the QI initiative
12. Surgeons, Anesthesia, Administration, etc. has expressed interest in the QI initiative
13. The QI initiative represents a manageable work load increase to relevant parties
14. There is a designated QI leader ready to take control of the QI initiative
15. There will not be significant changes required to staffing to accommodate the QI initiative
16. The data collection can be handled by the perfusion department or QI leader
17. The data analysis can be handled by the perfusion department of QI leader OR there is already a designated data manager or statistician on board
18. The QI initiative can be planned and implemented in a timely manner
19. The QI initiative will likely have long lasting efficacy on the practice
20. The QI initiative will overall improve the quality of care provided by the practice

Total _____ / 100

This is meant to be a guideline tool for use if there are multiple QI initiatives identified and the team is unsure of which to pursue first. Ultimately, preference should always be given to any initiative will directly improve patient safety or patient care.

Pre-Planning Questionnaire

- Is there a designated QI leader that will be in charge of the process from start to finish?
    - Does this person have the time to devote to this process?
        - Will non-clinical days need to be built in to accommodate this?
        - Do you have the staff to build in non-clinical days for someone?
    - Does this person have the authority to carry out all aspects of the QI initiative?
- If necessary, have you discussed this QI initiative with the surgeons to get prior approval to practice changes?
- Is there a financial cost to implementing?
    - Where will this money come from?
    - Can you get hospital/administrator or surgical approval to cover these costs?
- Do you have all the necessary equipment or supplies to implement this QI initiative/study?
    - If not, where are these things coming from and how long will they take to get?
    - Are there any current backorder issues that could affect this?
    - Do you have space to store extra equipment, disposables, drugs, etc. if needed?
- Is there a time cost to implementing?
    - Is this time cost limited to the QI leader?
    - If the time cost includes additional members of the perfusion team, have they been identified/are they willing to give this?
- Do you have/will you be able to get perfusion team buy in?
    - Has/will the entire perfusion department commit to this process and what it requires of them individually?
- Will you be able to get buy in from other departments if necessary?
    - Nursing
    - Surgeons
    - Anesthesia
- Is there a work flow change for the perfusion team?
    - Has it been adequately outlined and explained so that everyone is on the same page?
- Is there a work flow change for other teams?
    - Has this been adequately outlined and explained to anyone it will affect so that everyone is on the same page?
        - Nurses
        - Surgeons
        - Anesthesia
- Can you handle this data collection yourself or does the rest of the team have to help?
    - Retrospectively pulling data from charts
    - Prospectively pulling data from active pump cases
- Will you need IRB approval?
- Will the data collected require graphing, charting, or statistical analysis?
    - Can the QI leader handle this or will help be needed?
        - Can it be done in Excel or will it require a more complex program like SPSS?
    - If the QI leader will need help, can it be provided from within the perfusion team or will outside help be needed?

        - Does the hospital have a statistical team that can potentially help?
- What barriers to change exist?
    - From the perfusion team?
    - From the nurses?
    - From the Anesthesiologists?
    - From the surgeons?
- How likely is a practice change indicated by a QI initiative to have long lasting efficacy?
    - Will people comply at first but then fall into old habits?
- What are the overall goals of this QI initiative?

Excel Resources

Excel is an excellent, user friendly resource for collecting data, creating graphs and charts, and running basic level statistical analysis. Below are a list of educational resources ranging from introductory to advanced skills and functions. These are just a small sampling of the educational resources that exist as a jumping off point, there are a vast number of videos with step by step instructions on youtube for assistance with any function that excel can perform.

- Full Excel Overviews for Beginners
    - https://www.youtube.com/watch?v=LgXzzu68j7M
    - https://www.youtube.com/watch?v=wbJcJCkBcMg
- Building Charts and Graphs
    - https://www.youtube.com/watch?v=64DSXejsYbo
    - https://www.youtube.com/watch?v=DAU0qqh_I-A&t=10s
- Formulas and Functions
    - https://www.youtube.com/watch?v=Jl0Qk63z2ZY
    - https://www.youtube.com/watch?v=ShBTJrdioLo
- Creating and Utilizing Pivot Tables
    - https://www.youtube.com/watch?v=PdJzy956wo4
- Data Analysis
    - https://www.youtube.com/watch?v=_g5roKHj95o
- Descriptive and Differential Statistics and Quantitative Data Analysis
    - https://www.youtube.com/watch?v=EUeQRE5UJpg
- Qualitative Data Analysis
    - https://www.youtube.com/watch?v=j9A3ceOBihM
- Introductory Statistics
    - https://youtube.com/watch?v=I10q6fjPxJ0

National Resources for Quality Improvement and Education

The American Society of Extracorporeal Technology (AmSECT) provides many tools and resources to aid in promoting quality through standardizing practice across the entire perfusion field.

1. The AmSECT Standards and Guidelines:
   There are three versions of the standards and guidelines that are currently available:
   - Standard guidelines for perfusion practice
   - Guidelines for congenital and pediatric practice
   - Guidelines for mechanical circulatory support (MCS).

   Developed by AmSECT leadership with input from the AmSECT community, the standards and guidelines provide the "minimum requirements for safe cardiopulmonary bypass." These documents are an easy to reference starting place for streamlining perfusion practice and determining baseline levels of quality that should be met at every center.

   In addition to the Standards and Guidelines, AmSECT also provides resources/a toolkit for implementation at the bottom of the clinical resource page of their website.

2. Clinical Practice Guidelines and Protocols:
   Published in conjunction with the Society of Thoracic Surgeons (STS) and The Society of Cardiovascular Anesthesiologists (SCA), the **clinical practice guidelines** provide evidence based recommendations for standardization and improvement of clinical practice in various areas of CPB. There are currently 4 published sets and 1 update:
   - Anticoagulation during Cardiopulmonary Bypass
   - Temperature Management during Cardiopulmonary Bypass
   - Inflammatory Response to Adult Cardiopulmonary Bypass
   - Blood Conservation
     - Update on Patient Blood Management

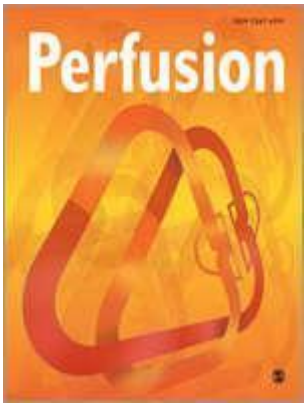
   The class of recommendation and level of evidence system is used to stratify importance of each published guideline. The "Classes of Recommendation" and "Levels of Evidence" sections of the ACC and AHA Clinical Practice Guidelines provide a thorough overview of this system for reference.

   The **clinical protocols** are compiled from multiple institutions, literature, and AmSECT committee member input. They serve as a great resource for institutions that don't currently have written protocols or that are in the process of updating protocols. There are currently 10 general and 2 pediatric specific protocols provided by AmSECT that focus on special patient populations and unique cases.
   - General Protocols Provided
     - Acute Normovolemic Hemodilution
     - Antiphospholipid Syndrome
     - Angiomax/Bivalirudin

        - Bleomycin Toxicity
        - Cold Agglutinins
        - Heparin Induced Thrombocytopenia
        - Jehovah's Witness
        - Malignant Hyperthermia
        - Pregnant Patient
        - Sickle Cell Disease
    - Pediatric Protocols Provided
        - PA Flow Study for Unifocalizations
        - Therapeutic Plasma Exchange during CPB

3. Publications

   Regularly reading the publications offered can help a team stay on top of quality within their practice. Publications and literature are often the first place that individual teams are made aware of trends in the field and new targets and goals that are being established such as was seen with DO2 levels and GDP. AmSECT manages the following 2 publications:
    - Journal of Extracorporeal Technology
        - It is the official journal publication of AmSECT
        - According to AmSECT's website, JECT "is the premier source of the most current research and information related to extracorporeal technology including cardiopulmonary bypass, extracorporeal life support, mechanical assist devices, and perioperative blood management."
    - AmSECT Today
        - AmSECT Today is the society's newsletter
        - Published quarterly and aims to "disseminate society, profession-level, and thematically-organized topical information"



The American Academy of Cardiovascular Perfusion (AACP)

The academy publishes the Perfusion Journal every month which can be a great resource for monitoring current research being done and a potential source for new QI initiatives

Extracorporeal Life Support Organization (ELSO)

According to ELSO, they are "an international nonprofit consortium of health care institutions, researchers, and industry partners. We provide support to those delivering extracorporeal life support through continuing education, guidelines, original research, publications, and a comprehensive registry of extracorporeal membrane oxygenation (ECMO) patient data.

- The continuing education, guidelines, research, and publications provided by ELSO can be a great resource for QI initiatives specific to the ECMO department

Multicenter databases that collect and analyze data to monitor trends in practice and identify areas that can be targeted for quality improvement are another resource for quality integration and improvement.

1. The **PERForm Registry**
   Run by the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) and the MSTCVS Quality Collaborative.
   - PERForm uses an online data collection form to gather standardized information about pump cases from all participating institutions
   - That data is then harvested at regular intervals and analyzed and presented at MSTCVS Quality Collaborative meetings
   - Participating institutions are also provided with quarterly benchmark reports for their practice
     - Allows centers to "to compare discrete perfusion practices to other institutions, and identify the relationship between these practices and clinical outcomes"
   - The current PERForm registry only collects and analyzes data for adult centers but a PediPERForm registry is in the works as well
   - In order to access the database and harvested data, your center needs to be a member of the PERForm registry. If interested in joining or learning more, fill out an application here.

2. Orrum
   Orrum is an organization created by Comprehensive Care Services (CCS) that offers a large multicenter database in addition to 4 other tools aimed at improving patient safety, quality, and care:
   - Core Registry
     - The core registry is a multicenter database dedicated to perfusion analytics that collects information on:
       - Patient preoperative risk factors
       - Procedural information
       - Laboratory information (preop, pre-CPB, CPB & Post CPB)
       - Intraoperative fluid management
       - Anticoagulation therapy & monitoring
       - CPB conduct & hemodynamic monitoring
     - Centers that participate in the core registry have data automatically collected and analyzed by orrum
     - This data is then used to provide information to the participating centers about benchmarking performances, identifying areas for improvement, evidence-based practice integration, and provide a look at how current practices tie into patient outcomes

    - Orrum also states that the registry is large enough to provide a representative outcome sample
- Patient Safety Organization
    - Perfusion-centric prospective incident reporting system to collect near-miss and patient harm incidents that occur during clinical practice in the United States
    - Quarterly reports and alerts regarding key safety events for members
    - Voluntary anonymous submission of incident reports
        - Orrum returns an analysis of the incident as well as future recommendations
- Center of Excellence (COE) Certification
    - The COE provides "a healthcare industry standard that recognizes and certifies qualified perfusion departments and hospitals in their commitment to Employee Satisfaction, Regulatory Compliance, Safety, Quality and Best Practices."
    - 4 levels of certification
        - Bronze
        - Silver
        - Gold
        - Platinum
    - Works to validate perfusion practices for their quality and best practice standards
    - Works to maintain compliance with regulatory agencies
        - JACHO
        - OSHA
- Organizational Performance
    - The Organizational Performance assessment is a "primary quality enhancement and compliance tool for any healthcare organization"
        - Realistic surveys enable a State of Perpetual Readiness
        - Uncover areas of risk & resolve Condition Level Deficiencies
        - Avoid sentinel events and Immediate Jeopardy
        - Provide the safest and highest quality patient care
- Healthcare Simulation Centers
    - Orrum provides high fidelity simulation centers to practitioners that "assess, educate, and reinforce positive behaviors."
    - Focused on 4 main areas and goals:
        - ECLS
        - Crisis Management Training
        - Interprofessional Training
        - Basic Life Support