INTRODUCTION

Managing test results (blood tests and other tests) is a complex process that is critical for patient safety. Lab test errors are among the most frequent in primary care, and are also among the most likely to cascade to patient harm when they occur. (West 2009) Improving how test results are managed and communicated to patients can also help primary care practices achieve savings in staff time and can improve the quality of care they provide.

The following issues make the process complex and time consuming:

- Primary care practices handle a large variety of tests that involve both onsite and offsite activities, involving multiple of organizations.
- Practices often interact with multiple laboratory providers based on the patient’s insurance. This requires practices to manage:
  - Multiple forms
  - Multiple electronic applications for preparing and tracking laboratory specimens
  - Multiple interfaces for receiving laboratory results (for instance, maintaining multiple dedicated printers, or maintaining multiple electronic interfaces between the practice’s electronic medical record and various laboratories)
- Tracking tests using reliable metrics is time consuming but critical to ensure that test results have not fallen through the cracks, that appropriate actions have been taken when test results are abnormal, and that patients are informed of their results.
- Processes both before sending samples to the lab and after receiving them back for use (referred to as pre- and post-analytic processes) require coordination among multiple team members: the clinicians who order tests and act on the results, the medical assistants who complete paperwork and process and track specimens, and the other office staff who route results to the appropriate clinician, file them as necessary, and keep patients informed.

TOOLKIT OVERVIEW

THE PURPOSE OF THE TOOLKIT

This Toolkit was developed with funding from the United States Centers for Disease Control and Prevention. The goal of making this Toolkit available is to assist primary care practices in their efforts to develop performance/quality communication indicators for clinically important gaps in pre- and post-analytic lab medicine. It offers concise, actionable information and recommendations about how to improve your lab testing process. It also provides tools, guiding questions, examples, and links to additional resources.

To use this guide effectively, first identify the lab testing improvement “champion” or lead in your practice. The lead should …

- Review this entire guide to become familiar with its overall contents and process.
- Make notes in the guide for you and your team.
- Review the key decision points below.
- Seek guidance from the rest of your practice team.

WHAT IS IN THIS TOOLKIT?
The guide is organized into short sections that address key decision points for practices:

- How do we get started? (page 5)
- Priority Alignment: What should we work on? (page 6)
- Making it real and preparing for change (page 8)
- What is our current process for lab testing? (page 9)
- How are we going to improve our process? (page 12)
- How will we know if we will make a difference? (page 14)
- Making the Change! (page 16)
- How do we know if we improved things? (page 17)

This guide is not a comprehensive review of all issues related to lab testing, the literature, or the evidence. Instead, the aim is to provide information about practical tools and processes to help improve critically important pre- and post-analytic lab testing processes. Each section has a brief narrative that describes the purpose of the step, followed by tools to guide your team.

Please understand that changing any process takes teamwork and commitment.

For optimal efficiency, primary care clinicians and staff should ideally perform as a high-functioning team, with a defined leadership structure (with a leader that has read the entire Toolkit), and a combination of frequent, substantial communication; a deep base of shared goals and knowledge; and mutual respect in taking on changes to any processes. It is also important to note that the process/quality improvements related to lab testing may qualify the practice or clinicians for certain requirements of Patient-Centered Medical Home designation, Maintenance of Certification, and/or Meaningful Use criteria. Check the following websites to explore these possibilities:

http://www.pcmh.ahrq.gov/portal/server.pt/community/pcmh_home_v2


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BACKGROUND ON LABORATORY TESTING AND PATIENT SAFETY

Over two billion laboratory tests are performed annually in the US, predominantly in ambulatory care settings, with errors occurring in more than 20% of all tests - that’s 400 million errors each year. A high volume of lab test ordering occurs in the ambulatory care setting, where pre- and post-analytic processes occur (Figure 1). Communication gaps among providers and staff are major contributors to errors when handling lab tests, which place patients at risk. Many Primary Care offices are working to improve their laboratory testing processes and there is a compelling need to develop performance metrics that will help to understand what impact improvement efforts have in primary care settings.

Recent estimates find that the average family physician and general internist orders lab testing in 29% and 38% of patient encounters, respectively. (Hickner 2008) Studies show that 15% to 54% of primary care medical errors reported by primary care physicians and their staff are related to the testing process. (Hickner 2008) Analyses of ambulatory-reported medical errors showed that laboratory testing errors were among the most commonly reported, and were among the types of errors likely to result in some type of harm to patient. (Fernald 2004; West 2009)

YOUR PRACTICE CAN IMPROVE ITS LAB TESTING PROCESSES

In developing this Toolkit, we worked with primary care practices that proved that they could make small improvements to their lab testing process and develop practical measures to know if their changes worked. Here’s what they did:

- **Lab tracking:** Generated EHR report of “unresulted” lab tests, followed by reminders mailed to patients to **decrease the number of missing lab test results.**
- **Patient notification:** Created new lab result routing “rules” and reviewed protocols for high-priority tests to **increase the number of results with a call to patients** documented in the EHR.
- **Lab test ordering:** Developed new process for electronic ordering of home health lab test requests to **improve the rate of documentation** of outside lab test requests.
- **Patient notification:** Created practice-wide review and notification process for normal lab results to **decrease the number of patient calls** to the clinic for results.

Your improvements and measures don’t need to be complicated; they should be feasible for your practice. The rest of this Toolkit will guide your practice through action steps and prompts to plan for, execute, and assess your quality improvement work around laboratory testing processes.
STEP 1: HOW DO WE GET STARTED?

Begin by sketching out a few ideas about the issues your practice may be experiencing in lab test processes, who can/should lead the improvement activity, and who can help. This information will be used in later steps.

1) **What issues do you have with lab testing in your practice?**
   Write down a quick list of the lab testing issues that your practice is thinking about, struggling with, or wants to fix (Don't worry if you get them all listed or exactly right; your team will help refine this list later). Here are some common issues that other practices have experienced:

   - No laboratory test reminder system
   - No laboratory test tracking system
   - Specimen collection quality (bad sample, wrong tubes, quantity not enough)
   - Lack of clarity in roles and responsibilities by staff
   - Inconsistency in notification by provider or laboratory of test result
   - Laboratory tests are not reconciled 100% of the time
   - Long period of time between result reviewed by provider and patient notification
   - Long period of time between notification and follow up with patient

   Your notes on lab testing issues in your practice:

   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________
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   ____________________________________________________________

2) **Who can work on improving your lab testing processes?**
   Write down names of a few people in the practice who can lead the improvement activity and who can help as a team member. (Think about people in different roles; it will help to have a multidisciplinary team)

   - Medical Providers
   - Medical Assistants
   - Practice Managers
   - Front Desk
   - Medical Directors
   - Administrative Staff
   - Residents
   - Other Team Members

STEP 2: PRIORITY ALIGNMENT

Successful practice improvements happen more easily when practice leaders agree that the proposed changes are important and are a high enough priority to begin committing resources to the process. Visible support from leaders in different roles (clinical and administrative) in the practice will help to set a practice-wide
expectation that the changes are important and will help to focus attention on the issue. Before starting a lab process improvement activity, convene key practice leaders and discuss issues around lab testing. **The discussion should include formal practice leaders and representatives from across clinical, clerical, and administrative roles.** Be prepared to have an open discussion about what the main lab testing issues are that need improving, what might be feasible, what effort will be required, and which issues are a high enough priority to attempt to fix now. When the leadership and representatives agree on the priorities, think about who can lead the effort and which resources and people can support the effort.

Once there is agreement on what the priorities are, be sure to communicate this to the entire practice—clinicians, clerical staff, medical staff, and administrators. Use your practice’s regular communication channels that work, knowing that it might take a few passes to make sure everybody is up to speed.

There are a few tools below to help get your practice leadership organized around the question: **What does your practice want to work on now?** These tools can help to develop some “talking points” about what’s important and why it’s important to your practice before your practice begins work on the issue. **Use this tool with a group of practice leaders or an existing leadership/executive team that already makes decisions about practice priorities.**
Tools for aligning priorities in your practice

A. What are your practice’s top concerns or issues related to notification and tracking of laboratory tests?

<table>
<thead>
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<th>TOP CONCERNS</th>
<th>How does this issue affect your practice or your patient care?</th>
<th>How high of a priority is this issue?</th>
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B. Which of the above concerns is the highest priority for your practice?
C. Why is this issue so important now?
D. How does this priority fit with our larger practice vision or mission?
E. Does the practice leadership still agree this is a priority?
   __ NO (STOP! Take more time to discuss; go back to B. and C.)
   __ YES (Continue to Step 3)

Go to Appendix 1 (page 20) to see the “10 Warning Signs” that your practice might not be ready to start making a change to its lab testing process.
STEP 3: MAKING IT REAL/PREPARING FOR CHANGE

Think of process improvement as a redesign of specific processes in your practice. In taking this on, quality and process improvement must become everyone’s responsibility. When getting started, be realistic about your practice’s readiness, capacity, and financial stability to engage in redesign activities. Include in your thinking your historic, financial, performance, and patient satisfaction data.

To make the journey to process improvement real, clearly define both short and long term goals and measurable objectives for redesign to discuss with members of the practice from different disciplines and roles. Reaching goals related to patient satisfaction, meaningful use criteria, maintenance of certification, and others can be strong motivators for the entire practice. A project planning and management template to record this information is provided in Appendix 2 (page 21). This tool can be very useful for moving the process forward and keeping the team on track.

It may be necessary to reconcile process improvement goals and objectives with organization and staff goals to address preconceived notions or conflicts within the practice. It is critical that process improvement engages everyone, and that all involved understand the need for change.

In establishing practice goals, reinforce those of the "big team" (the entire practice) so individuals can begin to understanding how their efforts fit within a larger picture. While the entire practice needs to understand the need for change, consider creating a quality improvement team from staff at all levels and qualifications to drive the process forward.

Empowering a team often includes the use of planning tools and templates to not only establish project goals, but also to break a project into logical pieces or milestones, each with assigned roles for practice members, and clear timelines for completion.

HOW DO YOU PREPARE FOR THE CHANGE?

Once the goals and objectives for change have been agreed upon, there are a few steps you can take to help make the change go more smoothly. Think about how you will communicate the plan for change to the entire office (staff, providers, and administrators).

Your **“Pre-flight” communication checklist** should include the following:

- Have you communicated with the entire practice about the planned change?
- Do you have a meeting set up to discuss the implementation details?
- Are any key people missing from the process?
STEP 4: WHAT IS YOUR CURRENT PROCESS FOR LABORATORY TESTING?

Process mapping can be a useful management tool for creating a visual representation of the laboratory testing process in your practice—basically, a display of the sequence of events involved in a process. Process mapping is an established and simple technique for streamlining work, helping to make implicit steps of a complex process both visible and clear. Perhaps the most important step in process mapping is to use the map to drive the discussion around what can be fixed, how it can be fixed, and how the process will look when it is fixed.

Before processes are mapped, identify who will conduct the observations and define the scope of the process to be observed. It is also necessary to define a beginning, an end, and a methodology for all of the processes to be observed. The mapping team should include staff from the core analytical team. Observation and mapping skills improve with time; therefore, standardization of the data collection tool and consistency in members of the team may be important. You don’t need to be an expert in process mapping and you don’t need any special software. Once you get started, it’s easy to make corrections and improvements as your team learns.

During process mapping, the following information is usually collected:

- Name of the process
- Process outputs or products
- Who is involved in delivering the process
- Who cares about the process
- Extent of the process to be mapped
- Activities that define the process
- Metrics associated with the overall process and key steps along the way
- Variations in the process
- Start point(s) and end point(s)

The tools and information below will help to develop and produce a process map for the laboratory testing process in your practice, including the key pathways for tracking and notification processes. (See Appendix 3 on page 22 for an example of lab testing process map)
TOOLS FOR MAPPING YOUR CURRENT PROCESS FOR LABORATORY TESTING

A. Get organized

- White board and markers OR larger piece of paper and pens
- Meeting space and time
- Assemble a small team
- Appoint a “mapper”—someone who will start capturing the process
- Appoint a note taker – someone who can capture ideas and thoughts about the map
- Think about the starting point (e.g., a decision to order a lab) and the ending point (e.g., a patient receives notification of results) to roughly define the boundaries of the process map

B. Create the map

1. Write down the name of the process at the top
2. Ask the team, “what happens first in the process?” and write it down on the far left
3. Draw a box around it
4. Ask the team what usually happens next in the process; write it down to the right of the first box; draw a box around it.
5. Draw an arrow linking the two boxes.
6. Ask the team if there are alternative ways to achieve the next step in the process.
7. Keep going, asking the team, “What happens next?”
8. Review the map and revise.

TIPS

- Don’t worry about getting everything exactly right the first time through
- Each box should contain an ACTOR (“who does this”) and an ACTION (“what do they do”)
- Avoid putting more than one action in a box; it might be better to break it into more than one step
- While mapping, if ideas come up for fixes or there are questions that can’t be answered, have the note taker keep track of these on a separate sheet of paper so you can come back to them later without slowing down the mapping process

Additional Process Mapping Resources

There are several websites that offer instructions for constructing good process maps: [better one to use from AHRQ]

http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit
C. Meet and review the map

1. Meet with critical staff relevant to the laboratory process and your quality improvement team (if applicable).
   - Review the map as a team
   - Describe the ideal state for laboratory process within your practice. That is, if it’s working well what should or shouldn’t be happening.

2. Look for the following types of events that can be changed to improve processes in a measurable way:
   - Where is there waste or waiting (e.g., searching, gathering, holding for information)?
   - Where are the bottlenecks?
   - Where are there redundant steps or repetitive work?
   - Where are the gaps in communication among providers or staff?
   - Where are the gaps in communication between practice personnel and laboratory(ies)?
   - Where are there consistent processes or steps?
   - Where are patients dissatisfied?
   - Is there someone already trying to fix a step?

3. Talk concretely about what can be changed in your practice
   - Which parts of the process can be addressed with your practice resources?
   - What does your team agree on that will improve the laboratory process?
   - What will the changed or improved process look like?
   - What information/data can we gather about the step we want to improve?

STEP 5: HOW ARE YOU GOING TO FIX THE PROBLEM?
Once you are able to take a good look at how your lab procedure currently works and how you would like to improve it, you will need to gather a team together to figure out how to best implement this change. Finding the right members for the team is a critical step. Look for members that will be most affected by this change and for those that will be most effective in making this change happen. Make sure that everyone is “on board” with the necessity of improving this piece of your practice’s lab work and come to a consensus about a plan to improve it. Use the guide below to help you develop concrete plans and a team to carry it out.

1. Meet as a team:
   - Include front-line staff whose job will be affected
   - Include leadership to support the overall activities from a high level
   - Include people who will be able to get data
   - Include a person who can kick off the activity (and help out if not everything works as planned)

2. Discuss the problem again:
   - Check with everyone to be certain that the problem “makes sense” from the patient’s view and from the practice’s view
   - Get buy-in from everyone that that this is the problem on which the practice will work

3. Choose the specific solution to the problem:
   - Does the solution involve changing specific tasks that people do?
   - Does the solution involve changing hand-offs between people?
   - Does the solution involve changing a specific flow of the patient or the patient’s specimen?

4. Define a specific goal to achieve:
   - Develop a statement for the goal; for example, “We would like our practice to reduce the number of x by y%!”
     (In this example, x could be unreturned lab tests and y could be 50%)

5. Develop an action plan and include the following elements:
   - List all who will be involved in performing and managing the change, including the staff and the leadership
   - Set deadlines for each step and for each person involved in performing and managing the change. Deadlines help keep people motivated and on-task, and help to prevent diffusion of responsibility
   - Be absolutely certain that the people who will be involved in the change help to develop the action plan, or they may not be fully invested, understand what is happening, or believe that the change is doable or meaningful! After all, they are the experts!

Helpful hints for leadership
- Express a sense of importance or urgency that you want to fix this problem
- Develop and communicate a vision of how the change may help
- Empower the team to act
6. Define the change:

Write down an aim statement for what you want to change and by when.

We aim to...

________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________

Who will make the change in the practice?
- Nurse?
- Assistant?
- Physician?
- Administrator?

Assign

What will be changed?
- Task?
- Hand-off?
- Combination?
- Flow or pathway?

Put it in writing!

________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________

How will the change be made?
Define the specifics of what will take place:

________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________

When will it be made?
- Pick a specific start date and time
- Pick a specific end date (when we can determine if the change was successful)

Make the timeline visible to all in the practice to maintain focus!

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Where in the practice will the change be made?
- Describe the details of the physical location where the change will take place

Write it down!

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STEP 6: HOW DO YOU KNOW IF YOU MADE A DIFFERENCE?
When thinking about what part of the laboratory testing process your team or practice wishes to improve, consider what information or metrics will tell you if your change made a difference. Metrics are critical to the redesign and improvement activity, especially the laboratory testing process within primary care. Metrics not only provides data about whether the improvement worked, but also gives evidence to staff and providers that there work is valuable, can make a difference, and helps to sustain their momentum. You might think about measuring pieces of process like:

- Reduction in steps involved
- More efficient use of time
- Reduction in repetitive work
- Better communication between practice personnel or practice and lab
- Increase in proportion of successfully completed labs
- Consistency in process (i.e. patient notification for all results)
- Fewer calls from patients asking for results

In the tool below we offer a few more specific types of metrics your practice can consider. Remember to use the process map as part of your discussion about metrics. The questions below will help to guide your decision process about metrics that fit with the part of the testing process your practice wants to improve.

**TOOLS TO HELP UNDERSTAND IF YOU MADE DIFFERENCE**

1. When considering metrics, some important considerations are:
2. There are several types of metrics that you might consider. You may wish to start by asking the following questions:

- Do you know if the patient actually had a lab test performed (that was ordered in your practice)?
- Do you know if the lab performed the test?
- Do you know if the practice received the test results back?
- Do you know if the patient was notified of the result?
- How long did this take?
- Are the pre- and post-analytic processes in your practice efficient?
- Are there any gaps in transitions or “hand offs”?
- Are patients and/or personnel satisfied with your lab processes?
- Is your documentation and billing process for lab effective and efficient?

If you answered “no” to all of these options for metrics in this step (2.), talk with the rest of your team about types of data they might already be tracking that can be a suitable metric for change. Or, you might need to create a simple paper tracking sheet for a smaller sample of lab tests, process steps, or patients.

3. Now, write down some details about how you will measure the change:

```
Define the data of the change

Define the specifics of what will take place:
- Describe the data you will collect after the implementation
- Make sure you have pre-change (“baseline”) data in order to determine your success
- Determine the data source (electronic health record, lab, etc.)
- Develop and use a data collection sheet
- Test the data collection sheet
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STEP 7: MAKE THE CHANGE!

The date has arrived for the practice to enact the new protocol. Before the workday begins, convene all practice personnel for a quick reminder of the new protocol and answer any last minute questions.

As your practice becomes more comfortable with the new lab testing process, you will need to check in with your participants to see how things are going. During the next few weeks, ask for feedback from everyone and see if there needs to be any small changes to the plan. If so, meet with your team to discuss the best way to make these small adjustments. If possible, look at the metrics you selected as you go to help sustain momentum for the project.

If the new system is creating large, disruptive problems, you should be prepared to go back to the original system until these problems can be addressed.

The best way to learn how effective this new protocol is in practice is to measure the improvements and compare them with how well your previous system worked. Refer back to Step 5 for a list of the different aspects of the lab process that you can compare. Just as you did immediately before the change, continue to measures these aspects.

Your practice should also pick a date for the new process to stop. At that time you will be able to review the process and see if there have been any improvements and decide then whether to continue with the new processes or revert to the old methods. This will be further covered in Step 9.

Write down a few key dates to help keep things on track:

- Start date: ___________________________
- Mid-point check-in date 1: ___________________________
- Mid-point check-in date 2: ___________________________
- End date: ___________________________
A critical component to improving laboratory processes is ensuring that it is a long term fix with a continuation of efforts from all staff. To ensure momentum is sustained with process improvement practices need to incorporate the use of evaluation and metrics. Metrics can provide staff with an aim to work towards and keep the staff informed.Metrics also provide ownership in the data being collected and the improvement being made within laboratory processes.

Assemble and analyze your data
- Set up time for data analysis based on action plan timeline (Step 5)
- Summarize and total all data collection forms
- Plot data visually to see the trends
- Determine if there are any gaps in the data (for example, if data collection did not occur for one week because a key person was away)
- Determine if existing gaps limit analysis and if more data collection is needed
- Determine if the amount of data is sufficient to reach some conclusions

Compare the data findings to the goal set in Step 5
- Did you reach it?
- Set a date to discuss formally with the entire change team

Set up a team meeting to discuss the project outcomes
- Invite all practice participants
- Share findings
- Discuss
  - What happened?
  - Did we meet the goal?
  - What went well in terms of methods?
  - What went poorly?
  - Did the implementation go as planned?
  - Discuss the barriers in
    - Implementation (Were providers and staff receptive to the change? Was there “buy-in”?)
    - Data collection (Are sufficient resources available to collect the needed data?)
    - Work tasks and hand-offs
    - Managing the project
  - Discuss the next steps
  - Celebrate the teamwork toward the goal and the work that went into the project

Get outside input on success or problems in the change
- Ask others in practice
- Ask patients
- Ask other stakeholders (for example, laboratories)

Next steps
- Determine if change will continue in the area of implementation
- Determine if changes in action plan will be made and change will continue or if an alteration in the action plan will be made
- Determine if change will be spread to other activities in the practice
- Determine if the overall goals of the project were met


Appendix 1: 10 Warning Signs

10 Warning Signs that Your Practice Might Not Be Ready for a Change

1. There is still disagreement about the priorities
2. Key leaders did not participate in the discussions above
3. Key staff or administrators did not participate in the discussions above
4. Key leaders have not voiced or visibly offered support for the improvement
5. Key leaders missed important discussions where decisions were made
6. No one volunteered to lead or help the improvement
7. Unwillingness to commit time or resources to the improvement
8. Unable to agree on a start date (i.e., keep putting it off to a later date)
9. Some clinicians or staff don’t know anything about the improvement
10. Silence, body language, or overly negative or sarcastic comments that suggest a key person is not ready (e.g., “Well, here we go again!” “This will never work.”)

What if you see any of these warning signs?

If you see these warning signs, take action before trying push ahead aggressively with changes to the lab testing process. Active participation across practice leaders, clinicians, staff, and administrators will improve the chances of a successful change effort. Here are some ways you can address the warning signs above:

- Meet individually with leaders, staff, or administrators who were absent during discussions or decisions about changes to the lab testing process. Bring them up to speed on what’s been discussed so far, remind them that their input is important to success, ask for their comments, and then ask how they would like to share their input with your practice or improvement team.
- When no one volunteers to take on a piece of the improvement, it might be that they don’t see how they can meaningfully contribute to the process being changed. Take the time to discuss the role each person has in the process and what an improvement would mean to them. You’re likely to find an ally who is willing to help—at least in a small way that might improve their own work.
- In a larger practice, keeping people up to date on changes can be a challenge. If possible, use formal and informal communication channels that already work (e.g., existing staff meetings, practice newsletter). Remember, that you will likely need to repeat important messages using different communication channels.
- When you detect objections, first invite the person into the conversation gently (“We haven’t heard from you on this topic yet. Is there anything you’d like to add?”). Or, you can ask neutrally, “What do we need to know about your role in this process? I want to make sure we haven’t missed something.”
## Project Summary
Describe the project in 3-5 sentences.

## Background: Problem/ Intended Impact
What is the historical/organizational context of the situation? Describe the intended impact of this project.

## Pre-Project State
Describe the current performance issues (in measurable terms) that you are currently experiences, as compared to the ideal state you have in mind for your practice.

## Data and Goals
What data must be collected? How do these data help to measure your progress toward project goals?

## Analysis
How can the practice best accomplish your goals? Describe the major drivers that need to be improved in order to achieve the goal(s), and describe why these are important.

## Improvements
What were the specific changes implemented/tested? How were these chosen? Do they lend themselves to measurement of improvement?

## Implementation Plan
Outline the steps that are to be accomplished (and people responsible for them) to realize the improved state/post-project state (see suggested tool).

## Results
Record the actual results versus goal(s), in quantitative format. Discuss any efficiency gains, service improvement, and cost reduction achievements.

## Sustainability
How the gains will be sustained? Who is responsible to maintain the new processes that show positive results?

## Lessons learned
What worked and what did not? What must change going forward?
Project Owner/Contact: ____________________________________________