Published in final edited form as:

Plast Reconstr Surg. 2016 January ; 137(1): 361–366. doi:10.1097/PRS.0000000000001888.

Surgery and Research: A Practical Approach to Managing the Research Process

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Abstract

Following a practical project management method is essential in completing a research project on time and within budget. Although this concept is well developed in the business world, it has yet to be explored in academic surgical research. Defining and adhering to a suitable workflow would increase portability, reusability, and therefore, efficiency of the research process. In this article, we briefly review project management techniques. We specifically underline four main steps of project management: (1) definition and organization, (2) planning, (3) execution, and (4) evaluation, using practical examples from our own multidisciplinary plastic surgery research team.

Keywords

Project management; Work Breakdown Structure; Research process; Research planning; Data management; Gantt Chart; Project leadership; Milestones; Milestone charts; Workflow; Kaizen

Introduction

The healthcare landscape in the United States is rapidly changing. Today, with an increasing emphasis on improving access to quality care, reducing healthcare costs, and preventing surgical complications, there is an urgent need for medical professionals and surgeons to intensify their research efforts. From clinical trial studies [1] to economic analyses of different treatments, [2] new topics in surgical research range the gamut. Despite opportunities for surgeons to engage in impactful research, time constraints facing surgeons on a day-to-day basis hamper progress. Research requires a commitment to drafting literature reviews, writing grants, working with Internal Review Boards (IRB), managing study logistics, analyzing data, and writing manuscripts. Devoting bandwidth to such time-intensive processes is difficult for surgeons who spend more than 50 hours per week on surgery, patient visits, paperwork, and other administrative obligations. [3]

To effectively pursue their research goals, many surgeons choose to work with teams of clinical investigators, health economists, statisticians, and other health professionals. Although teams can augment the capability of any one surgeon in the research process, the additional responsibility of managing team dynamics and group workflow can pose significant challenges. For surgeons interested in collaborating with other researchers, there exists a set of project management principles and practices to maximize their effectiveness and efficiency in the research process. Borrowing from the realm of business and industry, project management is the combination of people, systems, and techniques required to coordinate the activities and resources needed to complete such projects within the defined parameters.[4] In addition to providing structure to workflow, project management enables principal investigators (PIs) to sense potential problems and course-correct before the problems become major setbacks or failures. [4]

Our aim in this paper is to discuss the specific systems and techniques surgeons can leverage to effectively manage the research process. Specifically, we discuss best practices related to defining and organizing the research effort, planning the project, and managing progress so that surgeons and their teams can deliver impactful results on time and within budget. Many of the management techniques discussed have been pressure-tested within our own multidisciplinary surgical research group. To ensure the generalizability of our study to surgical groups of all types and sizes, we dovetail practical examples from our group with general principles and paradigms of project management.

Projects and Teams

A project is defined as the unique set of activities intended to produce an outcome within the parameters of cost, time, and quality. [4, 5] In surgery, projects can range from case reports, which might involve a half-day of work and minimal financial cost, to larger, more resource-intensive prospective cohort studies which can necessitate months to plan, approve, execute, and publish. [1] Every research project requires a different level of resource commitment from a PI and his or her team. It is important to highlight that different project types require research teams of different sizes, functions, and expertise. These teams, then, require various levels of management and engagement. For example, our surgical research group is unique in that we pursue a wide range of research interests within the realm of hand and plastic surgery. Thus, the composition of our research projects can vary from a team member working independently with minimal support from the research group to a team of three to six researchers from different fields of study who communicate on a regular basis. By employing some best practices in project management, we ensure that each project is completed on time and receive the needed level of oversight and attention for quality and effectiveness.

Engaging the Management Process Model

Regardless of project size and complexity, our group follows one management process model that provides the necessary structure and directionality to the project workflow. The four primary stages of the process model include (1) defining and organizing the project, (2)

planning the tactical aspects of the project, (3) tracking and managing the project, and (4) evaluating outcomes (Figure 1). [5]

1. Define and Organize

First, a PI spearheads the establishment of the research protocol, frames the team's organizational structure, defines team norms for communicating and collaborating, and identifies a funding source for a project. [5] In our lab, for example, a PI takes a primary role in staffing the project team based upon availability within the resource group and the specific skills and expertise needed to tackle the research project. For larger teams, the PI may designate one team member as a project lead. The project lead plays a surrogate role for the PI in managing day-to-day responsibilities. After recruiting a team, the PI assigns roles and responsibilities to each team member and establishes a reporting structure within the team. For larger teams, knowing "who reports to whom" is imperative for ensuring accountability and minimizing unproductive communications.

To kick-off the project, the PI communicates high-level project goals to the team, sets time, quality, and cost parameters for the project, and charges the team to devise a comprehensive research plan. For us, this communication typically occurs in person. Face-to-face interaction allows team members to better communicate their concerns and receive immediate feedback. Moreover, engaging in informal and small-group meetings helps the team members to know one another better. This is particularly helpful in meetings between surgeons and researchers from different fields. For example, just recently we were working on a project relating to studying national variation of care in thumb carpometacarpophalangeal joint (CMCJ) arthritis. By taking advantage of a one-on-one meeting and a simple drawing board, one of our hand surgeons clearly described various CMC treatment options for our team's health economist. Open, informal, and regular communications among team members who are engaged in the same project ensures that they all understand the aims and constraints of the project from the beginning. When face-to-face meeting is not possible we find that "video conferencing" and "teleconferencing" are effective alternatives.

After onboarding the team, our PI designates one team member to manage research plan development. The research plan, which consists of objectives, research questions, hypotheses, conceptual frameworks, and methods, serves to highlight the scientific value and feasibility of carrying out research on a particular topic. In addition to providing a framework for the general research project, the research plan serves as the basis for grant and IRB applications. Although one team member can take on the entire research plan, we find that allocating workload to match the strengths, bandwidths, and developmental goals of each team member to be most effective. For example, we engage a number of medical students and research assistants to sift through published literature and data, prepare literature reviews, and write the content in many of our research plans. These students and research assistants work closely with health economists, statisticians, and surgeons, who are often engaged in several other research efforts. Leveraging the abilities of each team member early in the research process ensures timely completion of the research plan.

2. Plan

In Stage 2, the PI or project lead works with the team to devise a Work Breakdown Structure (WBS) of all activities and tasks necessary for executing on the project objectives (Figure 2). [5] Benefits of leveraging the WBS are three-fold: (1) the WBS provides a framework for organizing scope of work; (2) it ensures that all tactical activities necessary for project completion are identified; and (3) it provides a framework for allocating resources. [6]

For a surgical research project, the WBS usually consists of at least four major activities: (1) managing the funding and ethics approval process, (2) organizing study logistics and managing the execution process, (3) analyzing data, and (4) publishing results. Each major activity is disaggregated into smaller, sub-activities or tasks to which the PI can assign an “owner” who remains accountable for completion of the task. [7] In Figure 2, for example, “Activity A: Managing Funding and Ethics Approval,” includes all tasks involved with organizing project finances and managing communications with IRB. For example, our PI has designated one team member to manage all financial transactions within our institution across all research projects. Because this process requires unique expertise, our group leverages the skills of this one team member to enhance the efficiency of the entire group. Our labs take a similar approach to managing IRB requirements. Rather than asking each team member to process his or her IRB applications individually, our lab leverages the IRB-expertise of one or two team members to effectively manage the IRB approval process for all projects.

In addition to accounting for all activities and ensuring ownership, the WBS allows the PI to pinpoint resource-costs for each activity, identify potential risks, and devise a plan from mitigating those risks. [7] With respect to the “Activity A” in Figure 2, the PI must assess the likelihood of receiving institutional funding. If the likelihood is uncertain, the PI must determine an alternative source. In seeking ethics approval from the IRB, the PI must anticipate how delayed IRB approval could affect the timeline for the project. From our experience working with the IRB, some projects may require months of iteration with the IRB before achieving approval. Knowing this up front allows our PI to plan more downstream activities and tasks.

After identifying all activities and tasks required to complete the project, the PI can then fit the WBS into a timeline, represented by a Gantt chart (Figure 3). In the chart, each activity and task is plotted on a linear calendar. The process of building the chart requires the PI to consider all interdependencies between tasks. For example, in Figure 2, IRB approval is linked to study subject recruitment. Since the IRB approves methods for subject recruitment, the PI must wait for IRB approval before recruiting subjects. In addition to serving as a planning tool, the Gantt chart provides us with an effective way to communicate timelines to teams and relevant stakeholders. Importantly, Gantt charts can be easily created in Excel® [8] or other third-party programs like Smartsheet®, [9] transferred to an email or Microsoft PowerPoint®, and disseminated. The chart is an easy and efficient way to keep track of progress of the project, and it can be easily created and updated.

With a WBS and Gantt chart in hand, the PI can begin developing activity milestones for using in-progress tracking during the execution phase. Milestones are achievement dates that

stand as “guideposts” for monitoring critical completion dates within a given activity. [4] A milestone chart graphically displays all milestones for a given activity, along with a description of the milestone, scheduled deadline, actual date completed, and delay (Figure 4). In the execution phase of the project, team members should regularly update columns for “Actual Date Completed” and “Delay (days)” to provide a realistic timetable for completion of the project. Additionally, team members can add specific comments each week in the “Notes” column to provide further granularity on progress made since the last update and any anticipated challenges or roadblocks ahead. Knowing what projects are delayed or are at risk of delay is imperative to PIs who may need to intervene or reallocate resources accordingly.

3. Execute

During Stage 3, or the Execution phase, the PI actively tracks the progress of the project. Best practices in reporting strive to minimize time and efforts required of each team member and maximize the quality of information reported. [10] Regular updating of the aforementioned milestone charts allows team members to quickly and effectively update the PI on their process (Figure 4). At a gross level, the PI sees the milestones that are on track for completion along with milestones that are delayed. For additional information, the PI may refer to the notes provided by the activity owner. In our group, for example, updates are provided weekly, not only to the PI but also to our extended research group. This internal and regular socialization allows our group to leverage its diversity in expertise to the fullest capacity and stay engaged and interested in other projects being carried out by our team. Although milestone charts are generally useful tools, PIs must determine what method of progress tracking is most effective for their teams. In a small team, a simple email thread for weekly updates may suffice. For larger projects with more complex interdependencies, use of a formal reporting system (e.g., Microsoft Project®) may be necessary. [11]

In addition to establishing a method for the tracking progress, the PI must determine how all study data is gathered, stored, and shared. One of the main challenges facing data-driven research is the lack of effective data and file management. This includes inadvertently deleting, losing track of changes, duplicating, and mislabeling primary data files (Figure 5). Challenges in effective data management extend to the analysis of the primary source data. Failure to track the code used in generating a given analysis or failure to update the version number for the analysis may create significant obstacles for research teams, especially if the analysis is revisited weeks or months later.

To ensure effective data management within our research team, we all follow a practical and easy-to-use data and file management protocol, which addresses the following: (1) naming files, (2) tracking updates within files, (3) sharing files, (4) backing-up files and (5) ensuring file security (Figure 5). Establishing a common file-naming convention ensures that the most up-to-date version is used by all team members. Communicating best practices in tracking updates within a file enables transferability of that file to other team members and ensures that, if the file is revisited at a later point, the user understands any modifications made to the file. For example, we name our files based on “project name” + “YYYYMMDD of the last edit” + “initials of the last team member to edit the file.” Therefore, when a folder

containing multiple iterations of an individual documents or analysis is opened, the most recent version appears at either the top or bottom of the list when sorted by date.

Additionally, our workflow structure has substantially helped us avoid losing important files. We maintain copies of all files related to educational purposes (e.g., seminars, workshops, etc.), manuscripts submitted for publication, and grant proposals submitted to different agencies for funding. For each category, we have project-specific folders containing the latest versions of all files (e.g., manuscript, tables, figures, cover letter, etc.) and earlier revisions. This structure facilitates all our team members to access files as needed for different projects. For example, recently, our lab needed to develop a questionnaire for a cost-effectiveness analysis. Knowing that our research group had developed a similar questionnaire in the past, we were able to quickly search through our document database to obtain desired files and to modify them accordingly. Documenting workflow of all databases and all final files reduces redundancy, protects against data loss and makes the team more efficient, ultimately saving time and money. Having a workflow in place and following it is an investment that pays substantial dividends over time.

Furthermore, following a practical file management protocol increases reusability and therefore efficiency within a group. In our group, for example, we occasionally used to lose or misplace source codes of our data-driven projects. Instead of doing research, we wasted precious time looking for files. Then, we decided to collect all the source codes and keep them in one central location under the project name. This has helped us to (1) reuse the code for similar projects, (2) teach our new data analysts how to code, and (3) over time, expand the aims for the same project without losing time redoing initial data management. Additionally, we check that everything, including source codes, is fully annotated and can be followed by other programmer analysts. This ensures reusability and portability of source codes within our research group.

Sharing files via a “common folder” on a network server or in a secure third party “cloud” can effectively reduce risk of data and file management mishaps. Moreover, all files should be backed-up via an alternative storage device. An external hard-drive provides an easy safeguard and can be locked in a cabinet for security assurance. Diligent tracking and effective data and file management empowers the PI to successfully progress the project from execution to data analysis to publication and dissemination of findings.

4. Evaluate Outcomes and “Kaizen”

W. Edward Deming, a business consultant credited with inspiring Japan’s rise as an economic superpower after World War II, believed that success in management is dependent upon continuous improvement of systems and process. [12] Deming’s philosophy of continuous improvement, known as “Kaizen” in the Japanese workplace, champions activities that continually improve functions throughout an organization. [13] The Toyota Production System, a socio-technical system developed by the automotive giant Toyota, is one example of Kaizen put into practice. [14] The system allows Toyota employees to provide regular feedback to management regarding their work and productivity. By inviting feedback from those closest to inherent inefficiencies in a process, as might be seen on an

assembly line, Toyota's management is able to best assess potential problems and take corrective action. [14]

The philosophy of continuous improvement, or Kaizen (改善, change to the better), is directly applicable to the world of surgical research. By soliciting feedback from research team members, PIs can take action that minimizes inefficiencies and maximizes effectiveness. In our research group, the PI takes an active role in evaluating the overall project outcome through individual meetings with team members. In the spirit of continuous improvement, our PI then applies key learning from team feedback to future research efforts.

Conclusion

For busy surgeons interested in conducting medical research, the principles of project management are a powerful tool for maximizing efficacy and efficiency in the research setting. Whether working independently or teaming with a large multidisciplinary research team, PIs can leverage the management process model and management practices, such as progress tracking and data management, to drive the successful completion of their research projects. Although overt practice of project management in the realm of medical research has been limited, [15] we hope that this brief introduction to the principles and practices of project management will both encourage and enable surgeons as they strive to advance medical knowledge.

Acknowledgments

Research reported in this publication was supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health under Award Number 2 K24-AR053120-06 (to Dr. Kevin C. Chung). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

References

1. Song JW, Chung KC. Observational studies: cohort and case-control studies. *Plast Reconstr Surg*. 2010; 126(6):2234–42. [PubMed: 20697313]
2. Cavaliere CM, Chung KC. A cost-utility analysis of nonsurgical management, total wrist arthroplasty, and total wrist arthrodesis in rheumatoid arthritis. *J Hand Surg Am*. 2010; 35(3):379–391 e2. [PubMed: 20193858]
3. Peckman C. Medscape Plastic Surgeon Compensation Report 2014. [cited 2015 March 12].
4. Dinsmore, PC. Human Factors in Project Management. 1990.
5. Project Management Manual. Harvard Business School; 1996.
6. Hamilton, BA. Module 2: Work Breakdown Structure. Earned Value Management Tutorial;
7. Kerzner, H. Project Management: A Systems Approach to Planning, Scheduling, and Controlling. 2. New York, New York: Van Nostrand Reinhold Company; 1984.
8. Sorensen, J. How to Create a Gantt Chart in Excel. Product, Tips. 2013. [cited 2015 March 12]; Available from: <http://www.smartsheet.com/blog/gantt-chart-excel>
9. Create an Online Gantt Chart in Minutes. [cited 2015 March 13]; Available from: <http://www.smartsheet.com/gantt-chart-software>
10. Harvard Business School Publishing Delivers Two New Multimedia Management Programs. *Information Today*. 1996; 13(5):53–53.
11. Managing Projects and Portfolios Using Microsoft Project Online. [cited 2015 March 12]; Available from: <http://guides.officeignite.com/Project%20Guides.htm>

12. Aguayo, R. Dr. Deming: The American Who Taught the Japanese About Quality. Touchstone; 1991.
13. Masaaki, I. Kaizen: The Key to Japan's Competitive Success. New York: Random House; 1986.
14. Toyota Production System. [cited 2015 April 16]; Available from: <http://www.toyota.com.au/toyota/company/operations/toyota-production-system>
15. Payne JM, et al. Researchers' experience with project management in health and medical research: results from a post-project review. BMC Public Health. 2011; 11:424. [PubMed: 21635721]

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Figure 1.
Management Process Model

Figure 2.
Work Breakdown Structure

Figure 3.
Gantt Chart

Activity B: Study Logistics and Execution				Today's date: 20 April		
#	Task/Milestone	Description	Scheduled Deadline	Actual Date Completed	Delay (Days)	Notes
1	Obtain Materials for Study: X-Ray images	Submit request for x-ray images to honest broker office (HBO), obtain approval, and acquire images	18 July	1 August	14	<ul style="list-style-type: none"> Approval from HBO taking longer than expected Made phone call to check on expected approval time
2	Obtain Materials for Study: All other	Print survey questions, obtain x-ray film box, stopwatch, etc.	18 July	18 July	0	<ul style="list-style-type: none"> Finished preparing survey questionnaire Contacting equipment services for film box next week
3	Organize Study Date, Time, and Location	Make room reservation with hospital; communicate study date, time, location to subjects	18 July	18 July	0	<ul style="list-style-type: none"> Obtained contact for room reservations at the hospital Will make contact next week
4	Recruit Subjects	Send recruiting email to potential subjects and follow up with personal phone calls	17 August	24 August	7	<ul style="list-style-type: none"> Still building out list of potential recruits; waiting on input from surgery colleagues
5	Execute Study	Conduct all experimental procedures at study site and prepare data for handoff to analysis team	16 Sept	16 Sept	0	<ul style="list-style-type: none"> Despite minor delays noted above, we are still on track for execute study as planned

Figure 4.
Milestone Chart

Figure 5.
Data Management