

How to Manage Any Organization

By Norman M. Goldfarb

This article sets forth a straightforward management system for integrating any organization's long-term goals with the day-to-day business of achieving those goals. A comprehensive system is presented, but individual components can be adopted or modified to meet the needs of a specific organization.

This article first discusses principles of management to provide a rationale for a proposed system of management. After reviewing the implementation section, readers may wish to return to the principles section, which will then sound less theoretical.

Management and Organizations

Management, in the simplest terms, involves six steps:

- Set goals
- Create plan to accomplish goals
- Implement plan
- Measure performance against plan
- Adjust plan, as necessary, or change the goals themselves.
- Iterate

Regardless of the size and function of an organization – even if it consists of a single person – without defined goals, plans and performance measurement, it is easy for the organization to drift off course.

Management and leadership are different but overlapping concepts – the best leaders are effective managers and the best managers are effective leaders. The differences between management and leadership are beyond the scope of this article. However, we will discuss management methods that are useful to both leaders and managers.

The existence of a manager, at least a manager of people, requires the existence of an organization to manage. An organization, in the simplest terms, consists of a group of people with more-or-less common goals. Organizations can be relatively hierarchical, with multiple levels of management, or flat, with few or no levels of management. In the absence of any hierarchy, the group of people in the organization collectively assumes the role of manager.

For purposes of discussion, this article will consider two clinical research departments with three-level hierarchies:

- At the Sponsor, the Director of Clinical Operations supervises Study Managers, who supervise Clinical Research Associates (CRAs).
- At the Site, the Director of Research supervises Site Managers, who supervise Clinical Research Coordinators (CRCs).

Reporting structures can be much more complex. For example, the Regulatory Specialist at a research site may report to both the Site Manager and the Director of Regulatory Affairs. The Manager of Study Start-up may report to the Director of Clinical Operations and a

changing cast of Study Managers. This article will present management methods that can be used regardless of the reporting structure.

Management Systems

A management system is more than a collection of management methods. To be most effective, its components should integrate harmoniously into a coherent whole. Each component serves one or more specific purposes in relationship to the other components. Once coherence is achieved, it is relatively easy to anticipate the effect of any change, e.g., a proposed improvement, by predicting its effect – for better or worse – on the system. After the change is made, unexpected disruptions to the system are relatively obvious, so adjustments are relatively easy to make.

In very small organizations, informal management methods may work fine; there is no need to burden the organization's limited resources with more complex systems. However, as an organization grows, the advantage of informal processes – their flexibility – can degenerate into chaos. As mentioned above, some structure is advantageous for any size organization. The challenge, of course, is to create a management system with enough structure to ensure forward progress, but not stifle it.

Management and Communications

The practice of management consists largely of communications. In very simple terms:

- Managers inform their subordinates of goals and plans.
- Subordinates report progress to their managers.
- Managers and subordinates mutually address opportunities and challenges.

The tools most commonly used to accomplish these communications are:

- Written goals & objectives
- Written progress reports
- Meetings
- Conversations, telephone calls, email messages, etc.

The VGORAM System of Management

The VGORAM (Vision, Goals, Objectives, Reports and Meetings) system of management consists of five basic elements:

- **Vision.** Over the long term, what does the organization want to achieve?
- **Goals.** In the medium-term (one year), what goals will the organization accomplish to achieve its vision?
- **Objectives.** In the short-term (one day to three months), what specific actions will the organization take to achieve its goals.
- **Reports.** How will the organization monitor its progress towards achieving its vision, goals and objectives?
- **Meetings.** How will the organization employ personal interactions to facilitate achieving its vision, goals and objectives?

Each of these elements plays an important role in a coherent system of management. Many organizations use some or all of these elements, but without understanding their strengths and limitations, or how they relate to one another to create a coherent, effective and efficient system of management.

Goals and Objectives

A plan is a set of goals and objectives to accomplish an organization's vision. The organization's leadership typically establishes the long-term vision, and then works with members of the organization to create the goals and objectives. The goals and objectives for each level of an organization consist of the combined goals and objectives of the next lower level. In conceptual terms, the only difference between the goals and objectives of each individual contributor and each level of the organization is scope. For example:

- **At the Sponsor.** Each CRA has the goal this year to monitor 10 research sites every six weeks. Each Study Manager has the goal to monitor 100 research sites every six weeks. The Director of Clinical Operations has the goal to monitor 1,000 research sites every six weeks.
- **At the Site.** Each CRC has the goal to enroll 10 subjects in a study. Each Site Manager has the goal to enroll 100 subjects at his/her site. The Director of Research has the goal to enroll 1,000 subjects at all the sites.

In the VGORAM management system, a goal is something the organization wants to accomplish. An objective is an action it will take to accomplish that goal. For example:

- **At the Sponsor.** In order for a CRA to accomplish the goal of monitoring 10 research sites every six weeks, he/she must accomplish the objectives (actions) of scheduling the visits, conducting the visits, writing the visit reports, etc.
- **At the Site.** In order for a CRC to accomplish the goal of enrolling 10 subjects in a study, he/she must accomplish the objectives (actions) of writing the recruitment advertisement, talking to 100 potential subjects on the telephone, conducting 20 screening/enrollment visits, etc.

Objectives must be substantive: "Conduct planning meeting" is not substantive. "Reach agreement on plan" is substantive.

Objectives must be measurable, so it is clear when they have been accomplished: "Evaluate" is not measurable. "Write report" is measurable.

Goals can extend over multiple planning periods, but objectives cannot. At the end of the planning period, an objective is complete or it is not complete. For example:

- **At the Sponsor.** The goal this year is: "Enroll 100 subjects." One of the objectives this quarter is: "Initiate 10 sites, each of which enrolls a minimum of one subject."
- **At the Site.** The goal this year is: "Obtain 10 new Phase III studies." One of the objectives this quarter is: "Identify three sponsors who are not current customers and are conducting Phase II trials in our therapeutic areas."

Objectives are not routine activities such as attending meetings; it is assumed that those activities will happen without significant management attention. However, if the organization has the goal of improving timely attendance at meetings, "Create attendance form and implement at three meetings," could be an objective.

To be useful, goals must be limited in number, typically one to seven for each person in the organization. Objectives must also be limited in number, typically one to three for each goal and 12 overall.

Establishing goals and objectives means creating priorities. It is, therefore, advisable to craft the goals and objectives so they do not create other problems. For example, recruiting inexperienced sites can cause data quality problems. Accelerating subject enrollment can reduce subject retention. If potential problems cannot be addressed explicitly in the goals and objectives, they should be monitored, with the clear understanding that current levels

must be maintained. Incentive compensation amplifies these distortions, so choose your goals carefully. Instead of writing complex rules to prevent gaming the system, include an explicit provision for management discretion.

In a dynamic environment, goals and objectives can become obsolete. Maintaining course in the wrong direction is a bad idea, but so is changing course with every shift in the wind. Flexibility is required, but changes should be well-documented and explained for purposes of accountability, compensation reviews, and learning how to plan better in the future.

Delegation

Delegating responsibility for goals and objectives without the necessary authority to accomplish them is a recipe for frustration. Delegating authority without responsibility (accountability) is a recipe for havoc. Clear goals and objectives provide a framework for delegating authority and responsibility.

Modern management theory favors pushing responsibility down as close as possible to the "front line." This practice is especially effective when:

- Responsibilities are complex and highly-variable.
- Decisions must be quick and require detailed knowledge of the situation.
- Supervisors are not experts in their subordinates' jobs.

These conditions generally apply, for example, to investigator management of study coordinators.¹

Delegation is not the same as abdication. For example, research sites record delegations of study responsibilities from the investigator to other personnel in the delegation of authority log. However, the investigator retains ultimate responsibility and is well-advised to ensure that study activities are performed correctly.

Outside the delegation of authority log, there are degrees of delegation:

1. May not take the action.
2. Obtain permission from the supervisor before taking the action.
3. Inform supervisor before taking the action.
4. Take the action and inform the supervisor later.
5. Take the action without the requirement to notify the supervisor.

When drafting goals and objectives, list significant actions, including decisions, required to accomplish the goals and objectives, and classify them by degree of delegation. If there is no delegation, ownership of the goals and objectives remains with the supervisor. For example:

- **At the Sponsor.** The CRA is delegated Level 5 authority to buy airplane tickets under \$500, Level 2 authority to buy tickets between \$500 and \$1,000, and Level 1 authority (none) to buy more expensive tickets.
- **At the Site.** The study coordinator is delegated Level 4 authority to place print ads and level 3 authority to place TV ads.

Planning Periods

In a given year, there are nested planning periods, typically quarterly, monthly and weekly. Annual goals and objectives are divided into quarterly goals and objectives, and so on. Quarterly goals and objectives may be divided into monthly goals and objectives. The degree of granularity in planning periods can vary by level of organization and functional

area, depending on the granularity of the goals and objectives. A study coordinator, for example, can manage a subject recruiting plan on a weekly basis, while the study manager may manage it on a monthly basis.

For the purposes of this article, it is assumed that goals and objectives are set annually and quarterly, and monitored monthly and weekly.

Written Reports

In order for managers to manage their responsibilities, they need to know what is happening inside and outside the organization. Written reports take time to prepare, but, properly structured, they offer several advantages over informal, verbal reporting:

- Content is relatively consistent over time and across personnel.
- Missing information is obvious.
- Communication of bad news is encouraged.
- Information is retained.
- Saves time in meetings and informal reporting processes.

Goals and objectives provide a framework for organizing reports. Reports should include only key information that relates to the goals and objectives. If a piece of information does not relate to a goal or objective, it is not important enough to be in a report. The process of writing the reports helps people organize their work and track their progress. It also creates the deadlines that many people need to make progress.

Individual contributors may not prepare reports if their work is routine and there is nothing interesting to report. Even a receptionist, however, can collect and report useful information such as the number of people who call about study advertisements.

Reports consist of two types of information: quantitative and qualitative. Quantitative information consists of metrics such as number of sites initiated or subjected enrolled. Qualitative information consists of prose: descriptions, explanations, projections and other information that is not captured in the metrics. In general, metrics, properly presented, are easier to understand and monitor than prose. Prose requires writing skills and the desire to communicate, rather than conceal, the true state of affairs.

In the VGORAM management system, there are weekly, monthly and quarterly progress reports. These reports are consolidated at each level of management and roll up the organization. The reports consist of the quarterly goals and objectives with updates on progress under each objective. Metrics are typically reported on a separate sheet.

Meetings

Meetings consume time, can be tedious, and are tough to fit into everyone's calendar. However, they are a necessary supplement to written reports.

In the VGORAM management system, there are three types of meetings:

- Weekly one-on-one meetings between supervisor and subordinate. The agenda mostly consists of a review of his/her weekly progress report. Ideally, the supervisor receives the progress report in advance so the meeting can focus on the interesting topics: opportunities and challenges.
- Weekly staff meetings between the supervisor and all of his/her subordinates. Ideally, everyone in the group has already received everyone else's progress reports in advance, so the meeting can focus on the interesting topics: opportunities and challenges.

- Monthly “all-hands” meetings. Management (a) sets and reviews progress towards goals and objectives, and (b) “motivates the troops.”

Between the weekly bottom-up meetings and the monthly top-down meetings, everyone knows what is happening in the organization and how their role is essential to its success.

Different organizations will prefer different meeting frequencies. For example, staff meetings can be held every two weeks. All-hands meetings can be held once or twice per quarter. In general, the more dynamic and challenging the environment, the more frequent the meetings should be.

Conclusion

Any organization – or any part of an organization – can adapt the VGORAM management system to its culture and circumstances. It may seem obvious that effective management makes effective organizations, but you wouldn’t know it by looking at a lot of organizations. It takes some effort to establish a structured approach to management, but maintaining it takes surprisingly little time, and saves large amounts of wasted effort. The VGORAM management system supports weak managers and helps them become better managers. By spreading out responsibility for the system, no single person in the organization is overburdened and everyone is connected to the organization’s vision.

Reference

1. “Who You Calling a Study Coordinator?”, Norman M. Goldfarb, Journal of Clinical Research Best Practices, August 2006.

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.