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Implementation of Change to Audits and Inspections Using Action Research

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Submitted to the Program of Organizational Dynamics, College of Liberal and Professional Studies in the School of
Arts and Sciences in Partial Fulfillment of the Requirements for the Degree of Master of Philosophy in
Organizational Dynamics at the University of Pennsylvania
Advisor: Alan Barstow

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Implementation of Change to Audits and Inspections Using Action Research

Abstract

The audits and inspections process is a critical component related to a pharmaceutical firm's compliance in the industry. To be out of compliance has significant ramifications both on the safety and purity of the firm's products and its viability in the industry. Such firms are routinely audited by boards of health and customers that purchase the firm's products to ensure they are in compliance with expected standards. The success of hosting the audits and inspection program is the first line of defense in demonstrating compliance.

To succeed at these audits and inspections changing with the times is a necessity. The implementation of change in an organization is fraught with challenges. Issues such determining who in the organization are the right people to discover, develop, and diffuse change is a complex process for management. This study will describe how the use of Liberating Structures and coaching were used to change the audits and inspection process for a major pharmaceutical firm. The changes are evaluated through the lens of Adaptive Space and the use of action research to integrate theory and action with the goal of answering the following questions:

- How might I get the right people on the team to implement a digital auditing process?
- How might I implement a digital auditing process?

In the time involved with the completion of this action research study, COVID-19 hit. This led me to another question:

- What modifications to the auditing process must be made as a result of COVID-19, how can I modify the auditing approach to incorporate site restrictions

The outcome of this effort transformed the auditing process at the firm and was implemented at the firm's sites worldwide.

Keywords

liberating structures, coaching, adaptive space, action research, audits and inspections

Disciplines

Arts and Humanities | Philosophy

Comments

Submitted to the Program of Organizational Dynamics, College of Liberal and Professional Studies in the School of Arts and Sciences in Partial Fulfillment of the Requirements for the Degree of Master of Philosophy in Organizational Dynamics at the University of Pennsylvania

Advisor: Alan Barstow

IMPLEMENTATION OF CHANGE TO AUDITS AND INSPECTIONS
USING ACTION RESEARCH

by

Larry K. Hampton, Ph.D.

Submitted to the Program of Organizational Dynamics,
College of Liberal and Professional Studies
in the School of Arts and Sciences
in Partial Fulfillment of the Requirements for the Degree of
Master of Philosophy in Organizational Dynamics at the
University of Pennsylvania

Philadelphia, Pennsylvania

2021

IMPLEMENTATION OF CHANGE TO AUDITS AND INSPECTIONS USING
ACTION RESEARCH

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ABSTRACT

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To my extraordinary family: when I started this journey Phillip, Christopher and Selah were on the cusp of changing the world on their own terms. As this chapter comes to a close for me, I thank you for the inspiration to step boldly into each challenge, to be fearless, and to embrace change.

To my mother, who embodied the commitment to see this through. You have been the spirit that has continued to inspire me to look for the best in everything.

There is one individual, my wife Vickie, that I owe the most to. You have been there from the beginning and have supported me through the challenges and the triumphs with an unwavering devotion. I awake everyday wondering how I could have been so fortunate to walk beside you on this journey. I dedicate this capstone to you.

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CHAPTER 1

INTRODUCTION

The Genesis

It was a late-night television commercial in September of 1998 that started it all. It would have been ignored had the assistant pastor from my church not been one of the Penn Organizational Dynamic participants sitting at the table in the commercial. The participants at the table talked about how the Penn Organizational Dynamics program enhanced their leadership, gave them the opportunity to interact with other leaders in their field, and work with an extraordinary faculty. I, at the time, was new to management in a union shop and needed help. My goal then was as it is now – some twenty-two years later – was to be a leader in an organization and impact change.

I faced two challenges. First, leadership and change back then was constrained by a bargaining unit contract. I had entered management being asked how I would motivate and reward individuals when the tools used to accomplish this were based upon the tensions that exist in a union/management interaction. Second, how could I inspire change when the rules were predicated on consistency of a process and regulatory commitments? Now, today, some twenty-two years later, as a supervisor in an analytical quality control laboratory what I needed from the University of Pennsylvania's Organizational Dynamics program back then and what I planned to do with the lessons learned is not what I need from the program some twenty-two years later.

One reason for this different plan in what is needed is because the challenges have changed. In the beginning the plan was to complete the program and be the CEO of

Merck at this stage of my career. Ken Frazier, current Merck CEO, was a legal eagle spearheading Merck's VIOXX debacle at that time and had the inside track. After leaving the pharmaceutical industry in 2004 and returning in 2015 the plan is somewhat more humble - to figure out how to lead change in an organization. My certificate track in the program from the beginning (and is currently) is Leading and Managing Through Change.

While my hiatus from the pharmaceutical industry was eleven years there was a sixteen-year break from the Penn Organizational Dynamics Program. A large part of this return was due to the deep pockets of a major pharmaceutical company and their willingness to pay for the courses. Indeed, this benefit was a major reason I left the Food and Drug Administration (FDA) to accept a job offer to join the company in May of 2018. My initial role was to be a manager of in the Chemistry, Manufacturing and Control group. I shared with six others the responsibility to ensure that any unplanned deviations; master record updates; test plan changes; process changes; method changes; label changes; material evaluations; and regulatory inquiries meet the expectations that the company has told health organizations, e.g., the FDA, and contract customers that we would follow. This covered both domestic and international entities. It was an exercise in paper pushing. All seven of us managed paper and not people. We essentially were the ones that took the fall when someone asked, "why did we not follow the regulations?"

Seven months into the position this all changed for me. My management realized the value in having someone with my FDA investigational expertise – primarily because an FDA inspection team (site visit?) had just gone badly. I was asked about my interest in leading the Audits and Inspections (AI) for the site. This site is the largest and most

complicated manufacturing facility in the company's network. Everyone at the site has a goal in their objectives related to the success of inspections from regulatory authorities and customers. If the site performs poorly during these inspections everyone's bonus, merit increase, and stock awards are at stake. The AI team's role is ensuring that audits and inspections from domestic and international boards of health, customers, and internal audits are successful. The AI team's focus is to make sure the site is always in a state of inspectional readiness. This simply means that we are always ready for any audit/inspection by an entity that approves or purchases our products.

Since my concentration in the Organizational Dynamics program is on Leadership and Change, I recognized that the leadership role and the changes that will be a part of the AI team would be a great capstone topic. The intended focus of the thesis will be the challenges involved in taking the team lead role and implementing the changes that I felt were needed for success of the AI team.

The Need for Change

There are many changes needed both with the team and how it operates according to my manager. Not all the challenges for the team are focused on how to have a successful audit or inspection. There are strong personalities who have been with the company for forty plus years and have been doing things their own way forever. There are turf wars over who has what responsibility. There are concerns that the team has been neglected by management. There is an inspectional training program that is in dire need of updating. One individual in the team decided not to take advantage of a program that just ended offering early retirement and now has health issues that may force him to take

extended medical leave and retire anyway without the earlier incentive benefits. There are challenges with getting the site inspectional ready, running the audits when boards of health, customers, and internal audits must be completed, and moving the team into a more digital age.

This opportunity (taking the team lead position for this group) offers a unique laboratory for research related to my certificate track in leadership and the impact on change. The research will incorporate material I have obtained from classes taken such as Effective Collaboration in a Global Workplace, The Art and Science of Organizational Coaching, as well as Creative/ing? Adaptive Space in Response to Complex Challenge. In addition, I will use material obtained from courses completed sixteen years ago – courses that included the Psychology of Conflict and Its Resolution, Mastering Organizational Politics and Power, and Allocating Resources: Economical, Technological and Human. I know material from these courses is still relevant because I have consistently used the information in the sixteen years that I have been away from the program.

One of the critical components associated with the success of this action research study includes the individuals involved in the daily tasks of doing their job. In the beginning of this study there were six individuals that were a part of the team: Karen, Buck, Susan, Beulah, Charles, and Elvira. In the course of this study the team was increased to include Terry, Gary, and Yvette. In this section I will describe their job responsibilities, backgrounds, and interaction with the Audits and Inspection team.

The Audits and Inspections Team

Karen: Karen is the boss. She is the person that lured me away from the Food and Drug Administration (FDA) with a generous salary offer and an extraordinary opportunity. I started in her chemistry, manufacturing, and control (CMC) group for the first nine months of my tenure with the company. She then realized that my skill set for audits developed at the FDA could be better utilized as the team lead in the audits and inspection and the annual product report review teams. This type of transition – from manager to team lead is typically accomplished after five to seven years at the Kalamazoo site – I did it in nine months. Karen is Latina and been with the company for over twenty-five years working her way up from entry level to her current position as senior manager. She recently moved from a role in Quality Systems to Quality Compliance – essentially from making the product to monitoring how it is made. She has impressed me with the diversity that was a part of the CMC team. In fact, this team is one of the most diverse group of individuals at that level in the site. I have asked Karen if that was intentional. The answer was no but “fortuitous” that the most talented individuals selected just “happened” to be of such a diverse racial background. The group is made up of half being male the other female. There is representation of African American, Japanese, Indian, Caucasian, as well as an age range from 27 to 68. There is also a diverse level of experience ranging from novice to seasoned and corresponding titles from specialist up to manager. Karen is the senior manager for the group. Her management style is completely hands-off. She inherited the group during a reorganization and provides the CMC group complete autonomy. She is also the senior manager for the me and my two teams. She served as the leader for the audits and

inspection team until I was hired. There is a constant challenge to separate her role as senior manager and turn over the team to me.

Buck: By everyone's (including his own) definition Buck is an asshole. He is the most senior member of the Audits and Inspection team that I lead. He has been with the company for over thirty-six years and in his current position for the past eleven years. He has exceptional knowledge on the workings of an audit. The firm recently offered a generous early retirement incentive program. He opted not to take the deal but subsequently suffered another health issue that required him to take a four-month sabbatical. He returned only to have to leave again for six weeks due to another operation. This was the third such leave in the last three years. Upon his return he has been allowed to work from home. This is done through some agreement between him and Karen that does not have a "required" approval work arrangement agreement signed by management. He comes in when he feels the need and often sends emails at strange hours of the night requesting others to carry out tasks or let us all know how much he knows about a process and we don't. Previously, he accompanied inspectors on their walk-throughs of the site – a critical part of the inspectional process. Due to health issues – though he insists that there are no work restrictions associated with his health – he can no longer do this. In addition, due to throat cancer he cannot eat solid foods. He at one time was the wise voice in the inspection room providing insight on how things worked and played a critical role in resolving inspectional findings. Now he sits in the inspection room making everyone uncomfortable with remarks that are often viewed as offensive and demeaning on some level. Karen has stated she does not want him in the inspection room but has yet to figure out a way to prevent this. Another one of his reasons for

staying home was to take care of his mother who was in the last stages of cancer. Karen felt that this would require him to retire in order to tend to her full-time needs. She recently passed, and Buck is still being Buck. We have assigned him responsibility of our customer audits. There are firms that contract with us for raw materials and must audit us on an annual basis. His role is to coordinate all aspects of these audits. Buck is married to someone that also works at the company.

Susan: Susan wanted to be the new team lead for the Audit and Inspection team but lost the opportunity to me. She has been with the team for the past four years and has been with the company for the past twenty-one years. She communicates in a very passive aggressive manner that everyone seems to notice except her. This has cost her the team lead position and according to Karen is preventing her from being promoted. She has been told of her behavior and there has been improvement but over thirty years the damage has been done. She often embellishes information to make her appear more competent and knowledgeable than she is. When this becomes obvious to others rather than correcting her, she is often ignored or avoided. Her role on the team is to coordinate all the regulatory audits that are performed at the site. This would include the Food and Drug Administration and any Board of Health from another country that visits the site. She has a husband at the firm in a senior leadership position. They are separated but not divorced. They have two of their children working at the company. Another of her children has cerebral palsy and is confined to a wheelchair.

Beulah: There is something strange about Beulah. She has set up her office so that no one can see her behind her dual monitors. She wants to be seen as knowledgeable about policies and practices but does not want to be a problem solver. She can point out the

problem quite effectively but if asked to resolve it the hands go up and she often says she has no idea of how to accomplish this. My boss indicates that she has not always been like this. Since joining the audits and inspection team this has become a standard way of behaving for her. She joined the team a couple of years ago in an administrative role and has moved to be a lead auditor. Her role is to coordinate all our internal audits. This involves setting up walk-throughs through the site with subject matter experts to find issues before they are discovered by a regulatory authority or customer audit. Since I have joined the team she still prefers to communicate with my manager. In communicating with me she comes across as disinterested and is often defensive in our interactions. She and Susan sit opposite from each other in an area by themselves. Beulah wanted Susan to get the team lead position. She is recently married and is currently expecting her first child. She has stated that she must return after maternity leave due to financial concerns.

Charles: Charles has joined the audits and inspection team through a development opportunity. At the company this means an individual has accepted a job in another group for a year with the intention to learn new skills and return to the original group once the year is up. In reality what this means is that someone has poached someone from another team because we can't hire someone for the position. Few if any return to their original position. Charles's job is to complete all the reports no one else wants (or knows how) to do. This provides him high visibility and a seat at meetings next to, and in the hearts of, upper management. He is good at what he does and has the personality to get along with everyone. The challenge is an Icarus complex. Sitting so close to management makes him feel he has powers that he really does not have. For example, when a director could not

make a monthly meeting Charles unfortunately told others that he would be running the meeting. The Director had appointed a senior manager to complete the task.

Elvira: Elvira has the longest tenure, 39 years, at the company of anyone on the audits and inspection team. She also has the least skill set of anyone on the team. She has been relegated to completing weekly routine reports and is often overwhelmed by that task. She often has issues with Susan and they both have a very passive aggressive interaction. Asking Elvira to do anything out of routine is a waste of time. We have met on two occasions where I have provided her with direction on how impress the team with the use of Excel pivot tables to present data. Nothing has come of it. She has to take attendance at the management meetings and is quick to indicate that she will take on certain tasks with absolutely no follow-up. My boss has stated from my day one that she is trying to get her job eliminated. She is one of the few people in the Quality Unit without a bachelor's degree. She has made no attempt to in her 39 years to obtain a bachelor's degree despite the company's education benefit which will pay \$10,000 per year to complete a degree. Something that would have positioned her for advancement in the company. She is easily flustered with technology and does not see the writing on the wall related to her future with the company.

Terry: Terry is the newest member to the group. He has had three different managers in the last year. He is the type of individual where if he wanted to hear your opinion, he would tell it to you. There is nothing that he can do wrong but can point to what everyone else is not doing right. When you ask Terry, what is the letter that comes before "B" you are given a lesson in Egyptian hieroglyphics, every letter in the alphabet that comes after "B", and an explanation of why your question was not phrased right. All you want was

the letter “A.” His people skills are in dire need of revamping. He is quite detail oriented, overwhelmed with his job responsibilities – because deadlines and commitments are hard to keep due to the level of detail that only he is expecting. He has maxed out his salary scale – and will let you know it. But the next move in his career would be as a people leader, which upper management – well aware of his skills – will have no part of.

The Need for Collaboration

My previous position was with the Food and Drug Administration, FDA, and I am now with a major pharmaceutical company. Essentially, I have moved from a federal position to private industry. There are similarities between each position. Both involve regulatory concerns, both have a mission of helping the public, and both carry a significant impact if something goes wrong. To prevent something from going wrong there is an extensive amount of collaboration that must occur between and among both entities. This level of collaboration is critical to the success of both organizations. In this reflection paper I will explore how I experienced collaboration during each experience. I will focus on the collaboration from a management perspective rather than the symbiotic relationship that must exist between the Federal Government and a pharmaceutical company.

During my time at the FDA, I worked as a Consumer Safety Officer. My role was to go into drug manufacturers and determine how compliant they were to federal regulations. There was a strong sense of common purpose among all the investigators. We could not state that a firm was in compliance and then next week someone is harmed by their product. There was also a strong sense of trust from management for what we

did. We were the eyes and ears of the Agency. If we indicated a firm was out of compliance no one went back in to verify it. We simply had to have the data substantiating our opinion on their compliance status. Often two of us would go to a firm and each had our own area of specialization to inspect. In the afternoons we would discuss our findings, challenge assumptions and if things were bad, discuss the issue with a supervisor back at the office. At the close of the inspection, the firm is informed of our concerns and told what rights they had if they objected. We would go back to the office, write up the report, discuss it with our supervisor, and if the firm was found to be significantly out of compliance a discussion would occur at higher levels within the FDA. All of this involved my inspectional insights and my ability to document my findings.

With the company, things are different. My role is to determine if the manufacturing processes have adhered to our regulatory commitments to the FDA – essentially are we making the drugs the way we told the FDA that we would. It is either in the regulatory submission or it is not. If it is, then there are no problems. If it is not, then the process must be changed to get into regulatory compliance. There is collaboration among my team to discuss the idiosyncratic issues that we all see and offer advice on what may have been done before or how the issue can be handled. But the decision is solely mine. My boss does not question the decision. The mindset is I was hired with a set of skills, I am a professional; I am to use those skills in a manner that provides an adequate resolution to whatever problems are encountered. If I make the wrong decision and the FDA disagrees with my finding there could be considerable cost to the company.

There are ways to approach collaboration in the different manners that are associated with the FDA and the company. Nayar (2014) suggests that to foster collaboration companies should quickly define the problem, frame the challenges, and inspire people to come together to tackle the problem. With the FDA we were given specific reasons to go into a firm. We knew going in that the challenges were going to be to determine the level of compliance associated with the manufacturing of drug product. Each of us were inspired by the notion that the health and well-being of individuals was at stake – we shared a common sense of good. Often, we knew of individuals being administered the drugs manufactured at the site. For the success of the mission collaboration was critical. It was often an “us versus them” mindset.

At the company the approach is like what is described by Evans and Wolf (2005) in the HBR where they discuss the rules of collaboration. They provide five principles that companies laying the groundwork for high-performance collaboration should follow:

- Deploy pervasive collaborative technology – Tools should work together through common standards and be as compatible as possible
- Keep work visible – Let everybody see everybody’s real work
- Build communities of trust – When people trust one another, they are more likely to collaborate freely and productively
- Think modularly – Sacrificing static efficiency for the recombinant value of options

- Encourage teaming – Dismantle individualized performance metrics and rewards that pit people against one another

There are technological systems in place at the company that are required for finding and disseminating data. There must be a collaborative effort to find and share this information. The team meets three times a week to discuss the myriad of challenges that we face. The goal of the meetings is to ensure the same interpretation of the rules are being followed. These meetings foster a sense of trust because we are all in it together and the collective knowledge is a benefit to all. The modularity of the interaction is to find how to get a deviation, analytical method changes, or manufacturing updates to meet the regulatory requirements. For example, there is a difference in regulatory speak between “is” and “about.” In one it is black and white, you either meet the requirement or you do not – it is what it is. In the other there is wiggle room. If you are within a range, then you are fine. With the last point of Evans and Wolf rules of encouraging teaming - we all have the same performance goals and objectives. It is in our best interest to succeed as a team.

So, the question becomes what the better collaborative method is. Is it the shared sense of purpose or a list of rules that should be followed? As with most things it boils down to the individual. The sense of mission and carrying it out at the FDA fostered a collaborative environment that occurred extemporaneously. We were all in it together and there was no competition with achieving the goal. As stated often we viewed it as an us against them mindset. With the company everyone is on the same team. There is no “them.” We must figure out how to ensure that the company is not at risk for an action taken. The collaboration is in the sharing of knowledge. It is taking some getting used to

on my part. Since I have more experience in the shared sense of purpose mindset, I miss the type of collaboration that was involved with it. With the collaboration rules that I am now playing by it is a different paradigm that only time will tell how my experience will play out.

As the new leader of this team something had to change, and I needed a plan. I am the new leader of the Audits & Inspection (A & I) and the Annual Products Record Review (APRR) teams for one of the most complex and largest pharmaceutical manufacturing sites in the company's network. The Audits and Inspections (A&I) team's challenge is to insure the inspectional readiness of the site. The function of the APRR team is to review and report on the metrics we use to let customers and the FDA know about the deviations, stability, and metrics associated with the manufacturing of our over 150 products. There are unique challenges associated with each team. Since I am still struggling to still understand how the APRR team does what it does so well I will focus this project on the A&I team.

These two teams who have little to do with each other, their challenges are specific to those teams, and yet, they both play a critical role in making certain that the company avoids regulatory purgatory. Both teams are focused on providing the level of support that spares the company from adverse consequences that may result from audits and inspections by both external customers and both domestic and international regulatory boards of health. This capstone will detail the development, implementation, and evolution of a plan to transform this A&I motley crew from individuals operating in silos to a unified and more effective team.

The methodology to this plan revolves around a framework based upon the concept of the agile approach to team-building. The agile approach is defined by Cooke (2012, p 29) as “adaptive management.” She suggests that this is a “collective term for methodologies (and practices) that have emerged over the past two decades to increase the relevance quality, flexibility, and business value of software solutions.” While the agile approach has focused on solving problems within the informational technology industry its principles can be adapted to any number of business management challenges. I will use this capstone to describe the changes that I implement following the agile approach. This effort will be described here by first providing background/context on the relevancy of this approach as well as why I feel it is important. I will then provide an overview of the research that has been completed on this topic. This will then be followed by assumptions I am making on implementing the agile approach.

Background/Context

In this section I will discuss the importance of this topic and why it is important to me. The pharmaceutical industry is highly regulated by the Food and Drug administration in the United States and by the Boards of Health or other regulatory authorities internationally. The purpose of these regulatory authorities is to ensure the safety, efficacy, and security (“What We Do,” 2019) of medicines taken by the public. This is accomplished through oversight of the pharmaceutical industry in the form of rules and regulations established by each regulatory authority and enforced through submission of documents describing the manufacturing of pharmaceutical products and inspections of the companies submitting the documents.

There are significant consequences to companies that do not adhere to the documents submitted for approval to manufacture medicines that are not safe, effective, and secure. These consequences can range from a request by the authority to fix the issue, to consent decrees, to fines, up to jail time for management found to be placing the public's health in significant danger – not to mention the impact on bonuses and merit pay decreases. In addition, each of these has the potential to impact the company's stock price and the firm's viability in the industry. An industry that, according to the latest data by the Pharmaceutical Research and Manufacturers of America (2017), either directly or indirectly supported 4.8 million U.S. jobs and accounted for more than \$1.3 trillion in economic output in 2015 from the most recent available data.

I am responsible for ensuring the inspectional readiness of the manufacturing site for the company. This means that should any regulatory authority or customer audit come to the site my team's responsibility is to have the site prepared to respond to all inquiries and do our best to make certain no major observations are given to the site after the audit is complete. We manufacture both drug product and active pharmaceutical ingredients - think the cake is the drug product and the flour/sugar/salt etc., are the active pharmaceutical ingredients. These components are distributed both domestically and internationally. The annual budget for the site is over \$1.3 billion. There are over 2,500 employees and the corporate office recently selected the site for a \$450 million dollar expansion. One of last year's corporate objectives – impacting everyone's bonus – involved successful outcomes associated with audits.

For this reason, the success of this team is critical. Currently, we are struggling. Two of the most senior people have a deeply rooted dislike of each other. I am the new

team lead and one of the team members lost out in the competition for my job. We recently completed an early retirement incentive buyout. One team member that was eligible opted not to take advantage of it. He is now struggling with health issues that may require him to retire anyway. There are communication issues not only within the team, but also with our “customers,” those individuals we are responsible for being inspectional ready, have routinely complained about my teams’ communication styles. My boss feels one of the persons on the team should be let go because we no longer need the skills that she provides, and we could use someone more proficient in auditing. It has not been done because of concern for the risk of an age discrimination lawsuit. There is a mindset that none of the materials used for audits and inspections should be changed - and yet a significant amount of it is woefully outdated. There are microaggressions and passive aggression behaviors that have been tolerated way too long. Two new individuals – one being me – have joined the team and the angst and suspicions about implementing change are rampant. I have to fix all of this. My intent is to use action research for three goals:

1. Getting the right individuals on the team.
2. Transforming the audit process into a digital format; and
3. Discussing the unexpected impact of COVID-19 on the process.

CHAPTER 2

LITERATURE REVIEW

What can possibly be done to fix this mess? What techniques can be utilized? What management frameworks can serve as a template upon which the needed changes can be implemented? In this section, I will review relevant literature associated with getting the right person on the team, techniques such as coaching from a directing, mentoring, and supporting perspective. I will also define and explain the role of Liberating Structures. In addition, I will review literature related to how the ideals of agile management and action research impact the study.

The Right People on the Team

Collins (2001) describe how

“...executives who ignited transformation from good to great did not first figure out where to drive the bus and then get people to take it. No, they *first* got the right people on the bus (and the wrong people off the bus) and *then* figured out where to drive it. (p. 41)

He further provides “three simple truths” related to this theory:

- First, if you begin with “who” rather than “what,” you can easily adapt to changing world
- Second, if you have the right people on the bus, the problem of how to motivate and manage people largely goes away

- Third, if you have the wrong people, it doesn't matter whether you discover the right direction; you *still* won't have a great company. Great vision without great people is irrelevant.

Other examples of studies looking at getting the “right” people on the team include Hussain et al. (2020) who looked at software project managers, Maes and Weldy (2018) who examined virtual teams, and Sankaran (2017) who studied megaproject management and leadership. Each in some perspective discuss putting the “right” team together. Sankaran suggests that success depends upon, “Selecting the right people and giving them adequate training as well as challenging tasks and responsibility with authority was a key.” Hussain et al. conclude, “Obviously, success of every project based on right selection of team members that ensures to meet the desired requirements.” Maes and Weld looked at organizational development and indicated research shows, “... several components are needed to produce a successful virtual team. These include the right team make-up, the right size, the right clearly defined roles, the right leadership, the right technology, and the right organizational culture.”

Coaching

Once the right people are on the team, I felt that coaching would be in integral part of making the team successful. I had to first gain an understanding of what is coaching. For me it was somewhat confusing. Rogers (2016) states that “there seem to be a number of reasons for this puzzlement, many of them arising because the word coach is so loosely used.” Bachkirova (2016) suggests that “coaching is expected to generate a body of knowledge that, although shared in many aspects with other disciplines, also

addresses themes and issues that are specific to coaching and includes unique ideas, theories, methodologies and results of research.” Rogers (2016) also suggests that there is a “comparison with psychotherapy and counseling.” This aspect of psychotherapy is backed up by Crowe (2016), who suggests “coaching and psychotherapy as fields of knowledge have historically shared much in terms of theory and application in practice, even though there have been efforts to consider them as distinct professions.” Crowe suggests that “psychotherapy is referred more broadly to the work of mental health professionals, which may include counsellors, psychologists and so on.... Whereas psychotherapy rose from a ‘healing’ tradition to identify, understand and help people satisfy needs, free up blockages and clarify the way ahead, coaching emerged to more directly challenge and support people actively pursue their goals, and to improve performance.”

So, is coaching just for some psychological fix or is the goal improving performance? In a study Coutu and Kauffman (2009) conducted a survey of 140 leading coaches and discovered coaches were engaged for the following three reasons: 1. Develop high potentials or facilitate transition (48%) 2. Act as a sounding board (26%). And 3. Address derailing behavior (12%). The notion of therapy, according to this survey, was different from coaching in that therapy focused on the past and coaching focused on the future.

To focus on the future, I had to modify what my definition of coaching was and better understand when and why a coach was needed. I wondered on what grounds someone would bring in a coach. The personification of a coach was somewhat ambiguous to me. I struggled with the concept of a coach as counselors, consultants,

teachers, hand holders, therapist, and the list could go on. I came to realize that a coach might coach all those things at a moment's notice. But what made us each of these? Some of us came to the table with the skills to match the situation. Some of us were woefully unprepared for what was needed and struggled to find questions that allowed us to "fake till we make it". This effort on my part was about establishing credibility, building a relationship, and holding people accountable. Faking it is not really necessary.

Kets de Vries, M. (2005) talks about the impostor phenomenon and explores such concerns as "Why You Might Feel Like a Fake, How Your Fear Becomes Reality, and When Fakes Court Failure". In the beginning the moment the "you're the coach" arrives I had a sense of sorrow for the individual because I am not there to help them as much as I am there to have them help me. I fake a sense of unconditional positive support, I fake a sense of empathy, I act like I am patiently waiting for a response when it is just the opposite, and we somehow get through the initial interaction. I do not think it is the impostor phenomenon as much as it is sheer incompetence in the beginning on my part. This this phenomena has been seen before and is described as the Dunning–Kruger effect (Kruger and Dunning, 1999) and refers to the observation that the incompetent are often ill-suited to recognize their incompetence.

Improving how we do audits and inspections will involve my efforts to direct, mentor, and support the individuals involved. A large part of this will involve the information I recently learned in the DYNM 641 (Art and Science of Coaching) course. The goal of the course was to start us on the road to better coaching. A large part of the changes described in Chapter 1 that must occur will involve just that – better coaching.

My takeaway from the course was the six foundation principles (Rogers, 2016 pp 25-43) for coaching:

1. The client is resourceful.
2. The coach's role is to develop the client's resourcefulness through skillful questioning, challenge, and support.
3. Coaching addresses the whole person – past, present, and future.
4. The client sets the agenda.
5. The coach and the client are equal.
6. Coaching is about change and action.

The most significant aspect for me of the Rogers foundation principles is the concept that the client is resourceful. For me, this challenge involves a topic discussed in DYNM 461 as unconditional positive regard (Pennington, 2018). This concept, as espoused in the class, is the client know best what is needed. I initially thought this was a righteous pile of BS. However, just as I expect my team to be open to new ideas and embrace uncomfortable concepts, my mind was changed. To have effective change, this notion of unconditional positive regard will be critical to me believing my team has within them what is needed for change. My task is to help them find it.

A part of this quest – similar to a good audit – is asking the right questions. This is done by active listening and powerful questions (Pennington, 2018). Su (2014) suggests that good coaching involves asking questions that open dialogue and allow the coach to see things through a client's eyes. She also states that “the most important thing

to keep in mind while composing (and delivering) coaching questions is that you need to be genuinely curious about the answers.” Adams (2016) suggests that great results begin with great questions. She further suggests,

“Questions open our minds, our eyes, and our hearts. With our questions we learn, connect, and create. We are smarter, more productive, and able to get better results. We shift our orientation from fixed questions and easy answers to curiosity, thoughtful questions, and open-minded conversations, lighting the way to collaboration, and exploration, discovery, an innovation.”

To then ask the right question both in the audit and in coaching was a trial and error process. The goal in the audit and coaching was to obtain “great results” both from an exploration standpoint and to “learn, connect, and create” from a coaching perspective.

Liberating Structures

I participated in an Organizational Dynamics course DYNM 644 (Organizational Change: Applied Methods Dojo). There are a number of models of organizational change. Examples include Lewin’s change model and the As-Is/To-Be model. Lewin’s (1964) change model looks at the stages of organizational change that include unfreezing, change, and freezing where and focuses on the implementation of change. The Gleicher’s formula - which according to Pádár and Pataki (2020) was not published – outlines by symbolic inequality the preconditions of successful changes. The formula according to Pádár and Pataki is the following:

$$C = A \times B \times D > X$$

where

C: change,

A: level of dissatisfaction with the status quo,

B: clear or understood desired state,

D: practical first steps toward a desired state,

X: 'cost' of changing

The 'cost' can mean much more than money: it can comprise any kind of sacrifice the implementers must make for the success of the change effort (p. 62).

Another example is The As-Is and To-Be model (Revenaugh and Muretta, 2013). It describes how a company needs to assess the direction it is currently going now and determine what is the direction it wants to go in the future. The As-Is processes are an order of operations method while the To-Be processes are critical components that derive from the As-Is processes. Figure 1 depicts the key components of the As-Is and To-Be model.

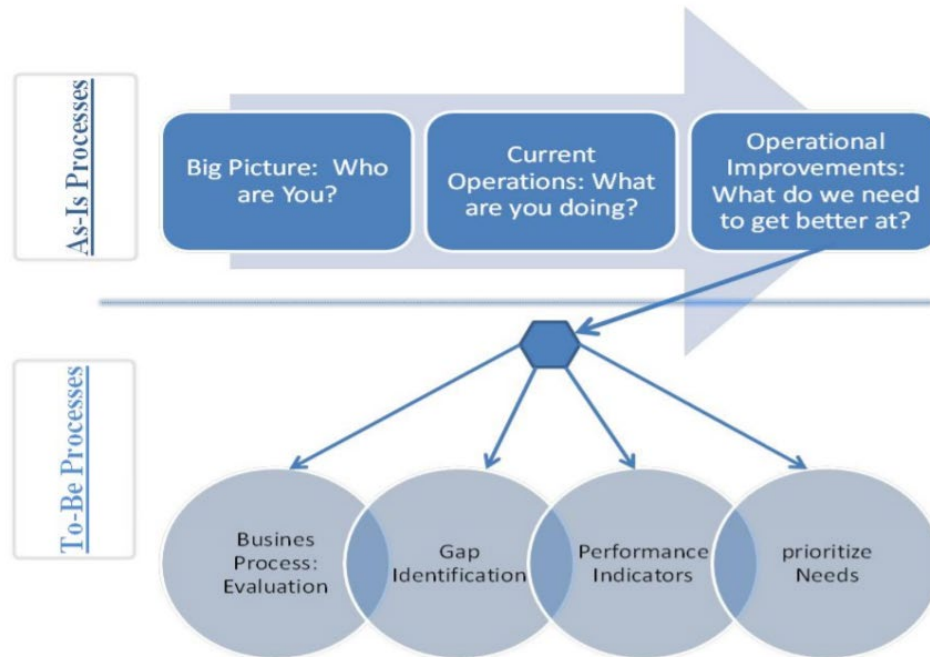


Figure 1. Moving from As-Is to To-Be Process

(Revenaugh and Muretta, 2013, p. 4)

Benjamin (2021) indicates that these models are based upon the following assumptions:

- Organizations are “real”
- Hierarchy matters and the top “knows best” and, therefore, has a duty to design and disseminate
- Change requires buy-in
- Knowledge changes behavior
- People make rational choices

Benjamin also suggests that these approaches do not work referencing Smith (2002).

Smith looked at forty-nine published across changes such as strategy deployment,

technology change, culture change - a total of ten types of changes and a total sample size 43, 426. He calculated that there was a median success rate of only thirty-three percent.

According to Benjamin (2021) there must be a new set of assumptions implemented to improve these odds. They include the following:

1. Organizations are complex adaptive systems
2. Individual relationships form networks
3. Hierarchy impedes knowledge sharing - the top doesn't know what the bottom does
4. Technical and adaptive problems require different solutions
5. Passion about something is contagious
6. Social capital matters – it's all about your friends
7. Creating boundaries and focus is essential

One of the different solutions that can be used to implement these components is through Liberating Structures. The DYNM 644 class focused on Liberating Structures. In our first class, we were admonished, “Nothing about me without me” (S. Benjamin, personal communications, May 28, 2020). The concept here was that any type of change that impacts an individual should include input on the change at some level by the individual impacted by the change. This simple notion would seem common sensical. Yet, in all too many instances organizations function in a command and control mindset where if management wanted your opinion, they would give it to you. Liberating Structures (LS), according to McCandless and Jackson (2018), is a way to invite leaders to release control over content. They define this process as “simple rules that make it possible to include and engage every voice in shaping next steps.”

In evaluating this approach, I examined the four fears that McCandless and Jackson (p 2, 2018) suggest are involved in implementing LS.

- When starting to introduce LS and choose not to share my mastery of content, will I lack credibility or look foolish and unprepared?
- Will I be able to generate better-than-expected results (tangible results!) without telling people what to do via pre-cooked goals, buy-in strategies, and imported best practices?
- Is LS a fad only?! Will I be able to prevent snapback to the old patterns and maintain momentum?
- Have I designed my own obsolescence as a leader? Have I worked myself out of a job?

The most significant of these for me and for my team in my opinion was the loss of credibility by not sharing my mastery of content. The notion of “quality control” by McCandless and Jackson where every outcome is predetermined in advanced struck a significant chord because I lead a “quality” group. Our task is to “control” the playing field. The notion that giving up this power over the outcome was a paradigm shift for both me and the team.

Lipmanowicz, H. and McCandless, K. (2013) have indicated that LS are small changes in people’s routine practices that produce big differences in the results they were getting. They currently describe thirty-five different LSs (Liberating Structures Including and Unleashing Everyone, 2021). They also suggest that while we are “aware that structures such as buildings and organizational policies and operating processes support

and constrain our activities. We tend to be much less conscious of smaller structures that influence our interactions with other people. In contrast to more tangible macrostructures, we call them microstructures.” They describe five “microstructures” that are commonly used:

- Presentations
- Open discussions
- Managed discussions
- Status reports, and
- Brainstorming sessions

According to Lipmanowichz and McCandless the key differences between LS and conventional microstructures include:

- The **Presentation** puts maximum control of content in the hands of one person and has no structure to include/engage others.
- The **Status Report** is essentially like a series of presentations, putting the control of content into the hands of one person at a time and with no structure to include/engage others.
- The **Managed Discussion** puts into the hands of one person the control for including/engaging a small number of participants.
- The **Brainstorm** provides a structure to include/engage a few people in expressing their ideas without constraints.

- The **Open Discussion** has no control of content and no structure to include everybody.

For me the answer to solving the challenges associated with my team, in my opinion, were obvious and the solutions easily implemented. Snowden and Boone (p 2, 2007) discuss the concept of “Simple Contexts,” which they state “are characterized by stability and clear cause-and-effect relationships that are easily discernible by everyone. Often the right answer is self-evident and undisputed.” In my instance, the wrong people were on the team; we were dysfunctional in both our team and customer interactions; and our processes were in dire need of updating. I needed to implement a response to these issues that were both relevant and rigorous, as described by Aram and Salipante (p 190, 2003). Relevance, according to these authors,

“... Is the practitioner’s primary interest. It is a concept in which the framing of research questions and results fits within the practicing managers world and is presented in terms understandable to the practitioners. Practitioners work with specific problems in specific situations. Knowledge, for them, must be customized, connected to experience, and directed to the structure and dynamics of particular situations. Knowledge becomes ‘relevant’ when it is context specific.

Rigor conveys the academic person’s commitment to build general theory. ...Theory constructed by ‘rigorous’ methods has a better chance of surviving challenges.”

With these concepts in mind, I examined the team dynamics to determine what could be construed as relevant. In this instance, it was the goal of improving the team’s

audits and inspections performance. The issue was not so much what decisions are made, but how are the decisions made. Who is involved? What data should be used? How does culture fit into the equation?

This organizational change – improving the `team’s audits and inspection performance - could best be approached by recognizing the five stages of adoption (Benjamin, 2021, slide 7) Figure 2:

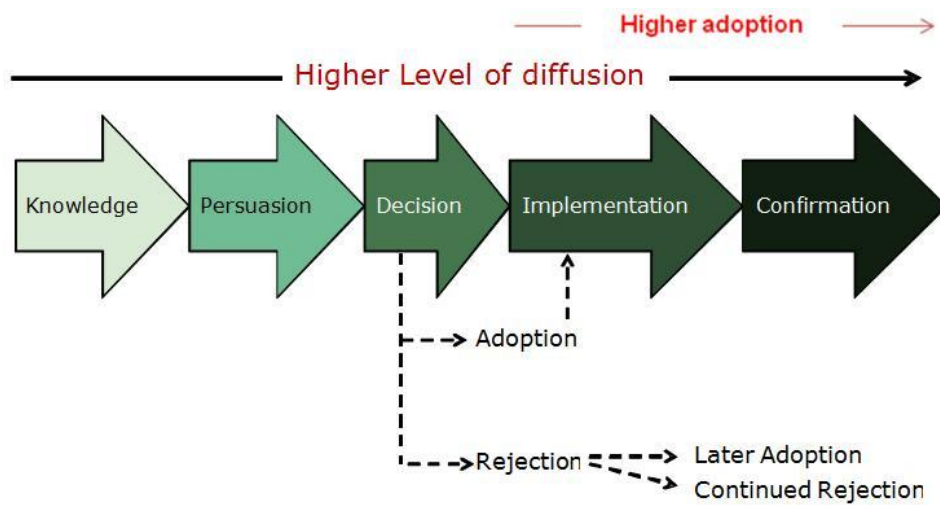


Figure 2. Change Basics: The 5 Stages of Adoption

(Benjamin, 2021, slide 7)

We began with determining the knowledge of the current process as well as what direction I wanted the team to move into. We utilized Liberating Structures (LS) as a framework for these conversations. I made the “decision” to move forward with concepts associated with the digital audit. Some of the decisions were adopted immediately and some were rejected only to be later adopted for some and others once rejected stayed on

the heaping pile of not to be looked at in the light of day again. Ultimately, as will be described later, we successfully implemented the digital audit process. Our confirmation was that our procedures were incorporated by other sites as part of their switch to digital audits.

My first foray into LS began with trying the 1-2-4-All as a prime (Lipmanowicz, H. & McCandless, K., p 167, 2013). The goal, as described in the reference, was to get everyone engaged in simultaneously generating questions, ideas, and suggestions. It was surprisingly simple. I followed the advice given in class to get the participants to “answer a question that matters the most” (S. Benjamin, personal communications, May 28, 2020). In one example, we needed to change our approach to how we completed audits. We had previously done them with a paper-based format for since forever. Systems were in place that had been in place for so long that nobody questioned or asked if this was the way the process still needed to be done.

Next came the concern for how I would increase the team’s engagement in thinking of and implementing change. My first mindset was that expressed by Snowden and Boone (2007) where “... managers rely on common leadership approaches that work well in one set of circumstances but fall short in others.” I needed a new approach to both solving the challenge of a team engagement, as well as releasing control of the process. With the concept of Liberating Structures, you give your team control to shape their own future (McCandless and Jackson, p 1, 2018). In presenting the idea, I used words, techniques and feedback that came from sources provided in the course. The first was trying to convince the team that I wanted all to be engaged and to contribute ideas and help shape how we as a team were going to address changing the audit process

(Lipmanowicz, H. & McCandless, K., p. 21, 2013). For this, I turned to the text related to Adaptive Positive Deviance. This concept discussed in Benjamin et al. (2017) describes how communities solve "... problems by identifying solutions from within the community and its available resources." I strongly believed that "transformation begins with the stories, knowledge, and experiences that already exists in the community" (Benjamin et al., p 12, 2017,). To get these stories, I started using primes at our weekly meeting. McGoff (2012) describes his text PRIMES as "a gyroscope that you and your group can depend on to chart your best path, keep oriented, right the ship should the unexpected happen, and get to where you want to be, when you want to be there." The text is also described as "a field manual for universe denters." The PRIMES (Appendix 3, McGoff, 2021) encapsulate essential insights into the universal human relations that show up when people get together to change or transform the way their world – or the world – works. The referenced link provides easy access to all the primes that can be used for the exercise.

Agile

Those Primes, in this instance, were paramount in the methodology to resolve this conundrum of making the team effective. These exercises served as the foundation for my implementing the Agile approach. Another aspect of implementing the Agile approach can best be personified by the credo of Morrison et al. (2019):

- We believe we have a responsibility to build a prosperous, sustainable future for ourselves and future generations.
- No individual, organization, or place can build that future alone.

- Open, honest, focused, and caring collaboration among diverse participants is the path to accomplishing clear, valuable, shared outcomes.
- We believe in doing—not just talking—and in behavior in alignment with our beliefs.

Morrison et al. state that the credo is “a statement of shared values that can help us overcome the silos that weaken our creativity. It is a statement of our inescapable interdependence.”

The first thought I had when I read the credo was the following quote:

“We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly, affects all indirectly.”

— Martin Luther King Jr., **Why We Can't Wait**

The statement of a “sustainable future for ourselves and future generations” underscores the notion that we are all in this one together. We need each other to build that future. The crux of this is the credo’s notion of being honest and caring. The polarity that the nation is currently experiencing will only be solved with “caring collaboration among diverse participants.” The challenge is how do we get to a point where we have “shared outcomes”? Especially, when it is so easy to go in our separate corners and ignore an alternate view. I think the answer is in “doing, not just talking.” However, if we only reach out to those “in alignment with our beliefs” we will not get to the middle ground. We must take the risk and reach out to those who may not share that “belief” and

have dialog on our differences and accept that we all “in an inescapable network of mutuality.”

The Agile approach in a manufacturing environment is discussed in a review of the literature related to attaining agility and its implementation by Ramesh and Devadasan (2007). Their review of the literature suggests a commonality among articles studying this topic that calls for, “radical changes in the system, culture and management styles being currently followed in traditional manufacturing environment.” They provide a roadmap that includes such issues as the involvement of top management; checking for anticipated support and commitment; identifying organizational structure; comparing existing practices with criteria they define through their review; estimating the deviations; and identifying a few vital activates that can be implemented.

Tseng and Lin (2019) define agility as the dominant competitive vehicle for all organizations in an uncertain and ever-changing business environment. They suggest that companies “require a high level of maneuverability encompassing the entire spectrum of activities within an organization.” They propose that, “for an enterprise to achieve agility, it is critical to create an effective, integrated procedure within the business that coordinates and ensures that the agility providers can satisfy the agility capabilities and cope with drivers, ultimately transforming all of these attributes into strategic competitive edges.” This is accomplished by utilizing what they describe as a “relationship matrix in the quality function deployment method (QFD).” This is a complicated quantitative formula that serves to deal with the “interface and alignment issues among the agility drivers, capabilities and providers using the QFD and fuzzy logic.”

A practical guide to implementing the agile approach is provided by the Project Management Institute (2017). This text “provides guidance on when, where, and how to apply agile approaches and provides practical tools for practitioners and organizations wanting to increase agility.” It was developed to serve “as a resource to understand, evaluate, and use agile and hybrid agile approaches.”

Things can go wrong with taking the agile approach. In DYNM 632 (Developing the Agile Leader and Their Organization) the text by Ribby, Elk, and Berez (2020) was used to indicate several ways that you can do agile wrong. They include:

1. Picking the incorrect framework
2. Not getting the correct balance between the bureaucracy and agile
3. Forgetting the role that the customer plays in the process
4. Removing operations and support team to pay for agile teams without reinventing business process
5. Not getting flow efficiency figured out correctly
6. Separating agile team from the rest of the organization
7. Not providing the team the autonomy needed to succeed
8. Putting the wrong team members on the agile team

There are other actions described by the authors for getting agile wrong, but my thinking is, in order to avoid these pitfalls, consideration should be given to what level of maturity is needed in an organization for agile to be effective and successful. In implementing the agile concept, I included the following questions:

1. Is there a need for an entrepreneurial culture?
2. Do you need management that is willing to turn loose the command and control mindset?
3. What level of risk-taking must management have?
4. Is an agile mindset easier when there is little at stake? Or, is this the last life preserver thrown at a sinking company?
5. In a regulatory environment what role can an agile approach take when there are exterior forces that must be dealt with?
6. While the authors may touch on this at some point, how do you know if you have picked the right “customer” to base your decision on if a subset is used?

Action Research

Action research (Coghlan & Brydon-Miller, 2014) is a term used to describe a family of related approaches that integrate theory and action with a goal of addressing important organizational, community, and social issues together with those who experience them. It focuses on the creation of areas for collaborative learning and the design, enactment, and evaluation of liberating actions through combining action and research, reflection, and action in an ongoing cycle of cogenerative knowledge. Action research as defined by French (1969) is a model that involved extensive collaboration

between consultant (whether an external or an internal change agent) and the client group, data gathering, data discussion, and planning. The process that French used included diagnosis, data discussion, feedback to the client group, data discussion and work by the client group, action planning and action. This is depicted in Figure 3.

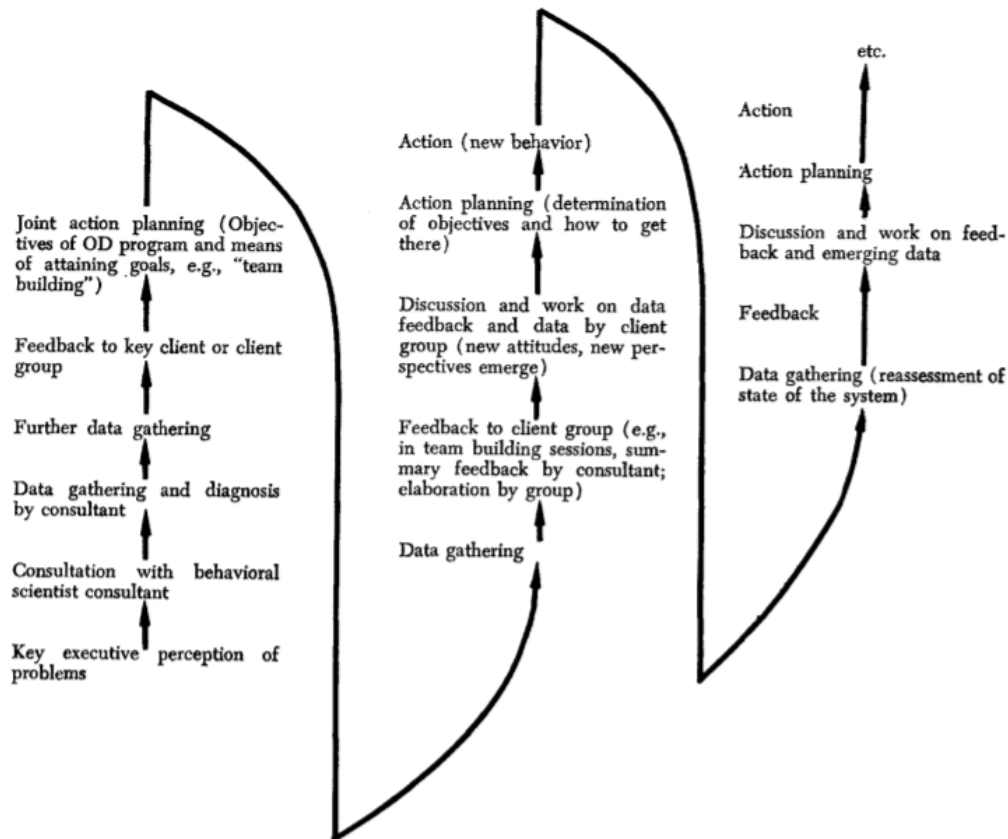


Figure 3. Model for Action Research

(French, 1969, p. 26)

While Figure 3 describes the process of action research in the a graphic of the components associated with the concept is demonstrated in Figure 4 (Sage Research Methods, n.d.)

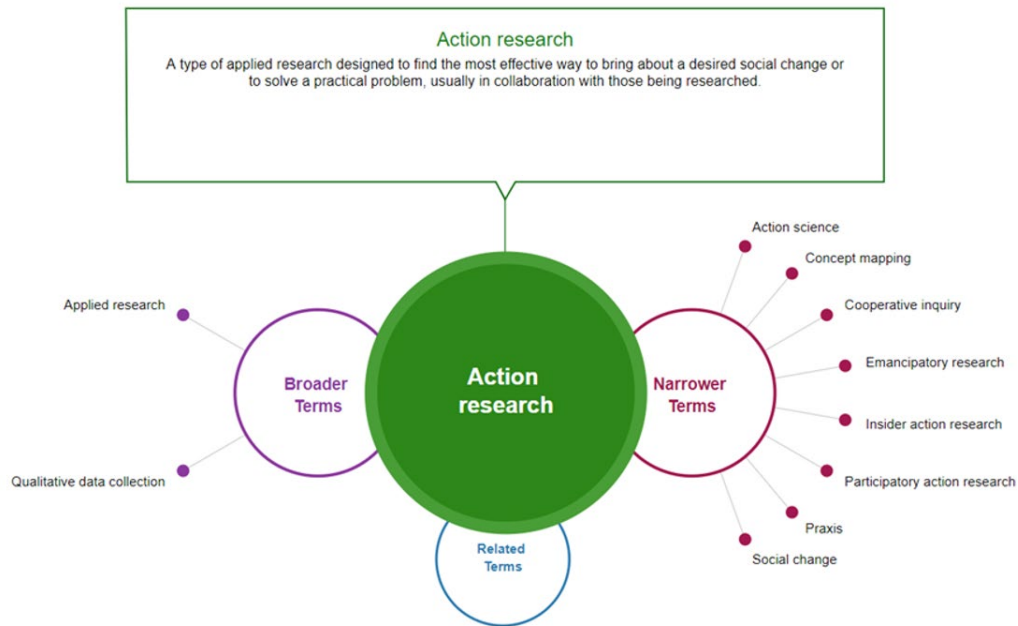


Figure 4. Components of action research
(Sage Research Methods, n.d.)

To determine the appropriateness of using action research (AR) as a research method I examined the work of Avison, Davison and, Malarent (2017), who explore barriers to use in action research. In addition, work by DePorres, Ferrante, Levy, Preston, and Tucker (2018) examined AR as an excellent model for organizational development. I will provide a brief description of each article, followed by a critique of each, and then a discussion on what role the concepts mentioned in each may play in my thesis.

The article by Avison et al., (2017) suggests that Action Research is “...an approach for understanding and improving organizational situations and for undertaking research and reporting new knowledge” (p 177). The focus of the article is on the use of action research on the information system (IS) discipline. The authors present an extensive review of the literature for action research and acknowledge genuine barriers, as well as perceived barriers that are “myths in actuality.” The authors suggest there are four barriers to completing action research (p 179):

1. AR is difficult to publish in leading IS journals.
2. AR requires a lot of time and resource investment.
3. AR is inappropriate for Ph.D. students.
4. AR is considered to be less scientific than other methods.

The research methodology utilized by the authors was to survey the population of 120 authors of papers on IS and AR published in select journals. The opinion of the 120 authors about issues connected with IS/AR was solicited without requiring them to focus exclusively on barriers to implementing AR. Avison et al. received 70 responses to their survey. After collating the results, the four impediments listed above to implementation of AR were identified. The 70 authors, as well as journal editors, were then asked to comment on how these impediments to doing AR could be counteracted. These findings were discussed, the future direction for research, as well as limitations of this study were then described.

My interest in this article was the hope that challenges to implementing AR would be identified, as well as a presentation of strategies that could be implemented to overcome them. The authors did a good job of defining AR and framing ways in which AR could be used. There was no effort by the authors to implement the tenets of AR as a part of completing their study. They acknowledged the challenge in determining the impediments to AR by stating: “We recognize that a review of the published literature would not be particularly revealing as the authors of published papers have generally overcome any barriers and therefore are unlikely to have reported them” (p 178).

The authors relied solely on the responses to surveys to formulate their conclusions. This self-selecting response could potentially be biased by those respondents. I found their use of quotes from the surveys to be compelling. It provided good insight into the responders’ thought processes. There is a brief discussion of the qualitative methods that were used to come up with the selected four barriers, but no detailed description of this process.

In addition, the paper’s authors provided a detailed discussion of the significance of the barriers and potential ways of overcoming them. I found that the barriers discussed had little relevance to my interest in AR. After reading the article, I realized that the application to organizational problems (such as developing teams with new leadership, dealing with difficult personalities, poor team communication, establishing a clear direction) was not discussed as deeply as I would have liked. My focus with AR has been on how to implement change being new to the team’s leadership. How to corral a group entrenched in their own ways, with dysfunctional relationships, and processes that needed updating into a cohesive, efficient, and customer focused to serve the site’s inspectional

interest. This again may be due to the background of the survey responders and the specific focus on IS data in identifying the challenges associated with AR.

The article by DePorres et al. (2018) describes AR as an excellent model for organizational development. It discusses reasons why AR is not widely practiced as a core leadership skill and presents options for rectifying the situation. Such issues as AR having an outsider status in leadership practice; there's no single model to base the practice on; leaders are unaware of it; the tools that can be utilized are not evident to users; there is a lack of consistency in the practice of AR; there is a lack of skill transference by practitioners; and there are corporate departments where AR might originate being invisible to potential users. The authors suggest that AR can serve as "a go-to method to solve problems" (p 47).

The paper is written in an easy-to-read, colloquial style. I appreciate the authors' suggesting that AR provides "a higher probability of achieving desired states" (p 47). They make the point that AR involves a type of "planning, action, and reflection [that] often yield[s] helpful and practical knowledge in virtually any setting" (p 47). Yet there is little supporting evidence to substantiate this claim and the authors do not provide a clear picture of what AR is.

The point is made that "every action research model portrays the same thing, but each says it in a slightly different way" (p 51), but no examples are provided. Their solution to the challenges faced with AR is a simplified acronym involving raising the "BAR" – Baseline, Action, Results. They acknowledge that this adds to the "plethora of existing AR models currently in use" (p 51). However, this "BAR" is not well explained,

nor does it indicate – other than its simplicity – how it should be implemented. There is a good discussion on the relationship between AR and leadership. The argument is made that AR is “the essence of leadership practice” (p 51). There is a poor effort by the authors to relate AR to values; instead, they describe tools that should be used in problem-solving. There is nothing insightful or new in this discussion. The conclusion of the article seems woefully inadequate. It is simply a plea for action.

Both articles indicate the difficulty that will occur in attempting to implement AR as a research method. They both provide evidence that the challenges they identified in implementing AR can be overcome. However, I did not find in either of the article’s applications to an organizational structure or direction in how AR could solve the challenges faced in my potential thesis topic. The article by DePorres et al. does make a weak association between AR and organizations, but my inquiry in how AR would be implemented was not addressed with either article.

And so, where do we go from here? Molineaux (2017) describes a range of techniques used to “implement successful organizational change” based on the use of “systematic thinking and system practices.” Examples of these include mapping the systems subject to change. The purpose is to make certain that the systems being changed are understood. Another involves “user-based design” in which the views of the “end-users” are incorporated into the change “in a way that meets the needs of the end-users of the system.” The author also suggests that prior to changing an organization the following questions should be asked:

- Is your organization ready for change?

- Are the leaders committed to the change?
- Who are the other key stakeholders that need to be involved?
- Who or what could derail the change?
- What process are you going to use to work with others in the design and implementation of change?
- What are the important systems and processes involved?
- What is the likelihood of resistance and inertia?

These questions are what I have taken into consideration when beginning my journey on implementing change in my action research project and will be expanded upon later in this document.

Conclusion

In this chapter I have examined relevant literature related to the path that I have taken in addressing the changes that will be needed for the audits and inspection teams. Through the framework of action research, I will next describe the implementation of these changes. A large part of this has been getting the right people on the team, coaching, use of Liberating Structures and the agile mindset for management. Each of these concepts have each been described in the literature presented here. I will now describe how they were involved in the methodology of the study.

CHAPTER 3 METHODOLOGY

Change Framework

This action research study was completed over a period of two years. The path followed to implement change is best demonstrated by the transition roadmap developed by Watkins (2021) Figure 5:

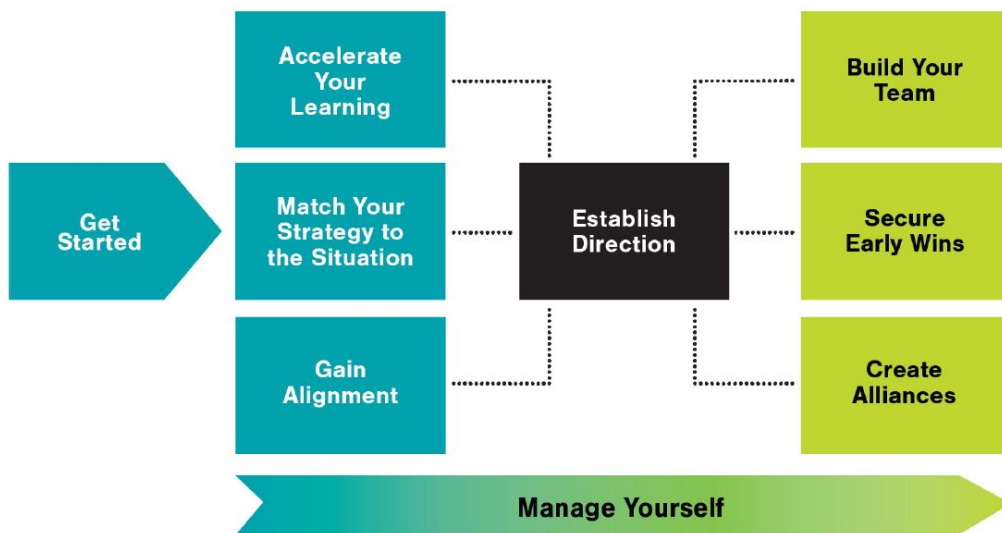


Figure 5. Transition Roadmap® Framework

(Watkins, 2021, slide 4)

In chapter four I will discuss exactly how I implemented this framework. The outcome of this implementation was fraught with challenges of personality, ego, unforeseen obstacles, and through it all a determination to establish direction. There were changes in team membership caused by forced retirement and individuals participating in development opportunities. There were changes in strategy to implement the digital

auditing process. And, there was the unforeseen impact of COVID-19. The changes in the team, the implementation of a digital audit process, and the adjustment to these due to COVID-19 were accomplished by my management providing me the autonomy to both develop a game plan and to implement it in an agile management approach.

During two years of implementing changes the team membership was transformed from a group of five original members to where, at the end, only one of the original members were still on the team. Two of them were told they will be part of the company's Opportunity for Growth. This program where the company restructured both divisions and people to focus on what management termed "priorities." This was a two-phase process where first individuals that had significant tenure in the company were given the option of accepting the "package" for elective retirement. The second phase involved an evaluation of performance and poor performers were not given an option but were told that they would be given another "package." Two of the team members left the group in phase two of the Opportunity for Growth program. One member left due to her interest in no longer putting in the number of hours required during the completion of the audits and the fourth left to accept a position in a development opportunity.

Part of the changes both to the team and the implementation of the digital audit process were completed by providing management with a discussion of the strategy that was being implemented and with routine updates on the status of the process. In addition, management was involved in the conducting of the audits. So, the played a role in implementation of the changes. Feedback was provided both during the update sessions as well as through feedback both from surveys completed after audits and in debriefing after the audits were done.

In approaching how the changes in this study were initiated, change management techniques using action research were implemented. These techniques involved Liberating Structures, coaching, adaptive space, and the agile approach. The process was guided by asking questions that, according to Riel (2010), will inspire one to look closely and collect evidence that will help find possible answers. Exploring these questions, according to Riel, helps the researcher to be progressively more effective in attaining their personal goals and developing professional expertise.

This chapter will delve into the methodology implemented in discovering the answers to those questions. The questions I will answer with this thesis are as follows:

- a. How might I get the right people on the team to implement a digital auditing process?
- b. How might I implement a digital auditing process?
- c. What impact did the COVID-19 pandemic have on implementing the digital auditing process?

At the conclusion of the study I was successful with getting the right team together to implementing the digital audit process and adapting to the challenges that COVID-19 provided the team.

Liberating Structures

A major management technique used to find answers to these questions involved the use of Liberating Structures (LS) and PRIMES. LS, as Lipmanowicz and McCandless (2013) indicate, provide the type of small changes in people's routine practices that produce big differences in the results. For McGoff (2021), PRIMES serve as tools to

provide clarity about information right in front of you. These tools illuminate common group dilemmas that slow progress and keep you from getting the extraordinary outcomes you want. A table of all LS can be found in Appendix 1 (Lipmanowicz, H. and McCandless, p. 163, 2013). Examples of Liberating Structures used during the course of this study include:

- 1-2-3-4-All – Conversing in cycles, self-reflection, small groups
- Heard, Seen, Respected – Practice deeper listening and empathy with colleagues
- Wise Crowds - Taping the wisdom of the crowd
- What, So What, Now What? – Reflecting on your progress and making adjustments as you go
- Nine Whys – Becoming clear about purpose
- Design Storyboards – Detailing design elements for meetings and innovative efforts
- What I Need From You – Surfacing needs and working across silos

To figure out which Liberating Structures to use, Lipmanowicz, H. and McCandless provide a tool for use in determining which LS to implement. The LS selection matchmaker (2021) (Appendix 2) to assist in this process. They describe the instructions a “simple way to get started on your first string of LS.” The choice of which LS to use during this action research study was completely mine and was the result of lessons on LS during the completion of DYNM 644: Organizational Change: Applied Methods Dojo (S. Benjamin, personal communications, May 28, 2020).

There are currently 46 different PRIMES (Appendix 3) described by McGoff (2021). Example of the ones used during this study were the following:

- Blind Men and the Elephant - Focus on managing disagreements by ensuring everyone has the same information on which to base their opinion
- Breach - Failing to do what you said you'd do
- Core Prime - Recognizes that context is decisive in causing or inhibiting change or transformation effort
- Fragmentation - Helps a leader visualize what kind of splintering is occurring
- Laggards - Different people adapt to change differently and good leaders identify each group quickly, working with Early Adopters who the rest of the organization will follow into the uncertainty ahead

Similar to the determination of which LS were used, the same process was implemented to determine which PRIMES were used. The selection of the PRIME involved my review of the description for the specific PRIME. The description of “In Action” which details how the effort should look in carrying it out, and “So What,” which describes the expected outcome from completing the event with the team were the criteria for selecting the PRIME. The team was simply told that a new approach would be used in facilitating both team interaction and communication.

Coaching

Throughout the entire study, coaching was both provided to the team and the leader. I provided the team coaching and my coaching was performed through activities

associated with activities related to the completion of DYNM 641: The Art & Science of Coaching (L. Pennington and A. Subramanian, personal communications, September 22, 2018). According to Caine (2020), a core component of coaching is the use of dialogue, inquiry, and effective questioning to encourage reflection. Caine indicates that a team coach is there to:

- Participate in team meetings
- Support the team in how they work together to achieve their goals and manage their relationships
- At times assume other roles (consultant, facilitator and/or trainer) to meet the learning needs of the team
- Move into an expert mode when functioning as consultant/facilitator/trainer

While the team coach may shift roles, they always come back to the role of team coach

The above summarizes the approach I used through the coaching process.

Adaptive Space and Agile

Work by Arena (2018) with *Adaptive Space* was the inspiration and provided the bravado to tackle the changes expected and implemented through action research for this study. Arena begins the text with the example of Netflix and Blockbuster to make the point for either being proactive in positively disrupting a system or suffering the consequences of being disrupted. Netflix “continually read market conditions and showed the willingness to make bold moves.” Blockbuster did not. Netflix took an agile approach to embrace and implement change. Blockbuster did not. Netflix was by far the best performer in the S&P 500 during the decade among companies currently in the index.

While it provided over 4000 percent rate of return (Levy, 2019), from 2000 to 2010, Blockbuster was bankrupt.

Adaptive Space discusses such concepts as:

- How to fill the space between entrepreneurial pockets and operational systems with *adaptive space*
- How to form interactions between those involved in discovery and development
- The role of social capital in adaptation
- The process of creating space by discovery, developing and diffusing ideas and solutions
- The impact of toxic energy on the team
- How an organization finds new ideas
- The different roles played by the teammates

The discussions on these issues can also be used to implement the agile approach.

The disruption can be viewed as the framing question: How might I transform the auditing process for a major pharmaceutical firm? To accomplish this, I have been working with three customers: 1. Upper management, 2. Program participants, and 3. Leadership at other sites. We have been working on the following agile components (S. Hart, W. Tarken, personal communications, January 20, 2021):

- Diagnostic and decider: Worked with management to decide what works, what prior approaches have not worked and what new approaches can be pursued

- Active agent of change: Worked with all customers and looked at how to implement change, the dynamics around it, and what strategies and conversations should be used to implement it
- Implementer of action: Worked with all customers on the roll-out of the program, on determining assets, and on how to work in manageable chunks
- Reflective learner: Implemented feedback loop for all customers, revised program after discussions with other customers

Such agile concepts discussed by Rigby, Elk and Berez (2020) as customer focus, speed, and leadership were implemented. In addition, Morrison et al. (2019) describe skills for agile leadership. Those implemented as a part of this study included:

- Skill 2 – Frame the conversations with the right questions
- Skill 3 – Identify your assets, including the hidden ones
- Skill 7 – Convert your ideas to outcomes with measurable characteristics
- Skill 8 – Start slowly to go fast – but start
- Skill 10 – Nudge, connect and promote to reinforce new habits

Conclusion

In this chapter, we have discussed the framework used in the completion of this study. Fostering open communication and improving team dynamics were worked on by using liberating structures. Coaching was utilized to improve dialogue, inquiry, and effective questioning. To foster a mindset of change, the concept of agile approach was utilized by implementing adaptive space mindset. This allowed me to link the pockets of

entrepreneurial with operational systems. In the next chapter, I will describe the outcomes of this effort.

CHAPTER 4

OUTCOMES AND OBSERVATIONS

Assumptions

Since being selected for this newly formed team lead position, I have made a number of assumptions. The first one was completely wrong. I was told during the interview process that one of the challenges the team lead would have to deal with is that a team member also had applied for the position. I knew all the individuals on the team and also assumed I knew which individual had also applied: surely it had to be the most senior person on the team. I was told who that person was after I received the offer for the role, and I was wrong. I had to redevelop my strategy to deal with the actual candidate.

This included acknowledging her subject matter expertise, letting her know how I would be counting on her, and that my management style was not a micromanagement approach. Once I was in the role, I set up individual meetings with everyone on the team. I discovered in subsequent conversations with her that she felt the team was ignored by upper management until something went wrong in an audit. She felt the lack of autonomy was an issue. And, as someone who had been at the company for the past 24 years with only one promotion, standard merit increases, and typical bonuses had run its course.

Other assumptions that I have made are that the agile approach will work for the changes that need to be implemented. The assumption with the agile approach is that it allows the flexibility to incorporate ideas incrementally and to change course or tactics as the need arises. There are a number of strategies that can be implemented to facilitate

change. My goal has been to follow the unconditional positive regard approach and utilize the skill sets of the individuals involved to facilitate the process. My assumption was that the team agreed that change was needed. This need for change had been pointed out by in discussions with senior management and other individuals who are impacted by the team's efforts. So far, the team had not accepted the idea that change is needed. In discussions with them, I stopped using the term "change" and replaced it with "improvements."

I established quarterly meetings with each individual on my team to discuss their ideas and sell them on the need for continuous improvement. We meet as a team every week to discuss challenges and efforts to address them. The individual and team meetings so far have been difficult. They have essentially resolved into gripe sessions either about someone on the team or why a team member hasn't not gotten something they want.

One suggestion that I made was that the team needed to take the 7 Habits of Highly Effective People course as a group. This is offered by the firm. I was informed that everyone on the team had completed the course – it simply, in practice, did not take. I also have suggested various other communication training to certain members of the team in the hope that communication both within and outside the team will improve. It has and will continue to be an ongoing effort. This is also where the Liberating Structures and Primes have come into play.

Other assumptions include that I will have the full support and cooperation of the organization and management in implementing improvements. In the beginning, I went on a "seek to first understand" (Covey and Collins, 1990) tour. I have met with members

of senior management to discuss what their ideas of improvement entail. They essentially said go figure it out. I spoke to other individuals in my position at other Pfizer sites around the world only to realize that during this time everyone was trying to develop a plan around digital audits.

For the purpose of this action research study and through the course of being engaged with this team, I boiled down my assumptions to initially two:

- I needed the right people on the team
- I needed to transform the audit process

In the time involved with the completion of this action research study, COVID-19 hit. This led me to another assumption:

- As a result of COVID-19, I needed to modify the audit approach to incorporate site restrictions

Toxic Energy

Arena (2021) describes how energy on a team is super contagious. If a teammate is excited about something, the chances of that individual sharing it with others, and they become excited about it are three times greater than if the individual is ho hum about that idea. Arena references in his discussion a study where he discovered if you took any random human being and you put them in a highly energized team or any other randomly selected human being and put them in a deenergizing team - he calls them toxic teams - almost immediately you see a dissipation of energy for those people dropped into what he refers to as the energy vampire pocket or the black hole. Figure 6 (Arena, 2021) charts

the energy drain on the team for individuals with high and low energy. Arena suggests that high-energy individuals on teams help with the discovery of new ideas and developing those ideas quickly. They then work to diffuse those ideas across the company in a radically positive way. If this is done well, teams are capable of positively disrupting themselves before being disrupted by someone else.

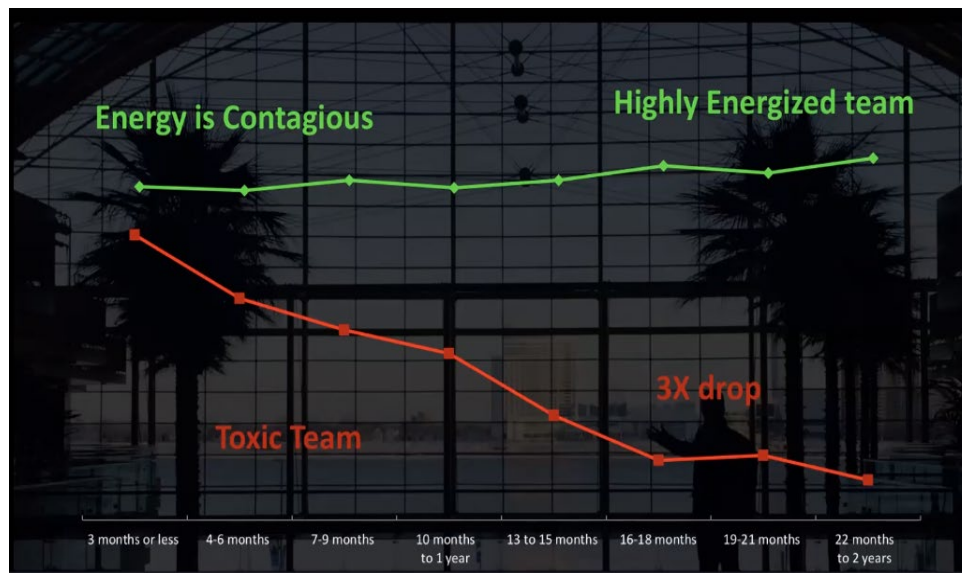


Figure 6. Chart of Team Energy
(Arena, 2021, slide 21)

I had come to view both Buck and Elvira as low-energy participants. Each was quite capable of explaining why something did not or would not work. Neither was interested in the discovery of new ideas or improvement on the old. And the notion that they could work to diffuse new concepts into the organization was met with stories of long ago where something was tried and why it did not work then and most likely wouldn't work now. They were what Benjamin (S. Benjamin, personal communications,

June 04, 2020) described as “laggards,” and the way to deal with them is by marginalizing, dispersing, or banning them from the organization.

As mentioned, when I became the leader of the team, I met individually with each team member. This was designed to understand each member’s perspective on the challenges the team faced, gain more insight on their backgrounds, and discuss with them what needed to be done to “improve” the audit process. It became quite clear that there was significant animosity between everyone on the team. Buck did not like anyone on the team or respect their skills set. Susan and Brittany felt Buck was of no help and that he looked upon them as his “secretarial” support. Elvira was easily overwhelmed with any task, yet felt she needed a promotion.

In individual meetings, all the members felt the team was ignored until something went wrong in an audit and then was blamed for it. There were supposed to be monthly meetings with the previous manager, but they were often cancelled. After attending the first meeting, I could see why. They were unstructured, they often evolved into finger-pointing and arguments over responsibility, and little direction or accountability was provided by the manager.

I implemented weekly meetings with a defined agenda. Each team member had five minutes to let the team know their priority for the week, what assistance they may need, or inform me of issues that either I could help with or should be aware of. The first few meetings were brutal. They still pointed fingers and argued. Buck attended most often via a video link on WebEx with his video off. It was in this environment that the Liberating Structures and Primes were implemented.

In our first class on Liberating Structures, we were admonished, “Nothing about me without me” (S. Benjamin, personal communications, May 28, 2020). Liberating Structures (LS), according to McCandless and Jackson (2018), is a way to invite leaders to let go of control over content. They define this process as “simple rules that make it possible to include and engage every voice in shaping next steps.” In evaluating this approach, I examined the four fears that McCandless and Jackson (p. 2, 2018) suggest come up when implementing LS.

- When starting to introduce LS and choosing not to share my mastery of content, will I lack credibility or look foolish and unprepared?
- Will I be able to generate better-than-expected results (tangible results!) without telling people what to do via pre-cooked goals, buy-in strategies and imported best practices?
- Is LS a fad only?! Will I be able to prevent a snap back to the old patterns and maintain momentum?
- Have I designed my own obsolescence as a leader? Have I worked myself out of a job?

The most significant of these was the loss of credibility by not Susanng??? my mastery of content.

My first request was that Buck attend meetings in person when possible. I did not see how using Liberating Structures and Primes could translate with him attending remotely. Sometimes he did; most times he did not. When he was in person, my initial

focus was on activities that fostered team communication and understanding of each other. We started with Heard, Seen, Respected. It did not go well. Each member provided superficial concerns in the meeting; yet, afterward went into great detail on why they felt were not being heard, seen, or respected and who was the person responsible for this.

We then tried the 1-2-4-All procedure (Lipmanowicz, H. & McCandless, K., p. 167, 2013). The goal as described in the reference was to get everyone engaged in simultaneously generating questions, ideas, and suggestions. It worked like a charm! The challenge was described simply as how do we complete a digital audit? The team, which has significant communication issues and struggles with working together, was all in on this effort. I set the procedure up so that individuals who I knew would be loggerheads would have to listen to each other first. By the time we got to the 4-All segment, either they were exhausted with being difficult or realized that their ideas had to be modified and they had to buy into the concept.

Getting the Right Person on the Team

Buck had been out for health reasons and worked remotely prior to this becoming a requirement due to COVID -19. The previous manager did not hold him accountable for supporting the team, and he had grown accustomed to shirking much of his responsibilities. Susan and Brittany expressed concerns that all the work not done by Buck had fallen on to them. Buck was the highest paid member of the team, and Susan and Brittany felt if they were doing his work, they should be justly compensated by being promoted. Buck freely expressed his opinion of their incompetence.

The previous manager forwarded me an email from Buck criticizing Susan and Brittany in what I felt were misogynistic and sexist terms. The manager indicated this type of communication was typical of Buck. She stated that Buck knew better, but they (the manager and Buck) had known each other for some time and had a relationship and a form of communication where she felt this was harmless. I completely disagreed and told Buck and the manager that, since I had been made aware of this type of communication, it would no longer be acceptable. They both indicated the communication was not meant for me to see. I stated it was irrelevant at this point and indicated to Buck what level of professionalism I expected of him. He acknowledged my concerns and I have since not seen such correspondence.

Near this time, the company was implementing another round of “Opportunity for Growth.” This was a companywide plan to redistribute resources to only those “opportunities” where there was a new focus. The first wave involved voluntary reduction in force. Employees meeting certain criteria could elect to accept a retirement package. On my team, Buck, Susan, and Elvira were eligible. None took advantage of this opportunity in the first round -- primarily because the company had indicated that the benefits in the second round would be better. But, the second round would not be voluntary. This resulted in a review of personnel to make decisions on who would have their job eliminated due to a refocus of resources. Everyone’s role and job performance were evaluated.

I was informed by my management that Buck’s and Elvira’s roles would be eliminated. They would be provided a full salary for two years and health benefits as part of the separation package. I did not protest the decision due to the challenges that the

team faced with Buck on the team. In addition, Elvira had long since been viewed as having not taken advantage of self-development opportunities in the 39 years she had been with the company. She no longer could or had an interest in supporting the team in performing tasks in the new direction that I planned to move toward. This included assistance with performing site audits and moving into a more digitized format.

All managers who had individuals impacted by the Opportunity for Growth were asked to attend a training session for delivering the news to those impacted. Of the two teams that I managed; three individuals were told on a really difficult day for me that their jobs were being eliminated.

Buck was appreciative of the buyout. His health had deteriorated, and he had indicated in our discussion that he had planned to retire anyway within the next couple of years. While he wanted to go out on his own terms, he recognized that this was not as bad an outcome as it could have been.

Elvira did not see it coming. Telling her the news was an extremely emotional event. There were tears, accusations, questions of why, and ultimately acceptance. We let individuals know in October. The last day with the company was in December. Buck disappeared and was little, if any, support for the team. I insisted that his cube – which in my opinion had become a fire hazard – be cleaned out prior to his last day. It took three large containers to dispose 30- plus years of hoarding. Even then, there were two additional containers needed to dispose items that he left behind.

Elvira, in her last month, continued to wonder why she was selected and not others who she felt were not as capable as she. Her cooperation in defining her tasks,

providing access to documents, and letting others know of where things were that only she knew was a challenge.

While Buck gladly accepted his last meal on the company's dime, Elvira refused.

Moving to Digital: Is It the Cart?

In 2017, my son participated in Delta Air Line's hiring of about a thousand new flight attendants. As a human resource professional, he monitored the process to ensure that no gaffs were made by Delta employees. During a discussion with me on how it was going, he described the effort as typical of the hiring process. Candidates submitted their information through a resume and cover letter; they came in for interviews; and the final determining factor: the evaluation of a task where they had to put together the cart that carries the beverages and other items served during the flight. A team of three would work with each other to put the cart together while being observed by human resource personnel.

My son found it amazing at how so many of the candidates would get to this final step in the hiring process only to lose the job when it was time to put the cart together. They were given instructions about the number of items and the location on the cart where they should be placed. At the end, the team simply presented their cart and most felt that if they followed the directions for organizing the cart, getting the job offer was a *fait accompli*. But not so fast. If one of the members took control and told the other two that s/he had this, and they could just watch – all three lost the job. The candidates were being evaluated on team dynamics and how they worked within the team.

It was not about the cart.

And so, how can I make certain that my focus on transformation is not misguided? What are the tasks that need to be completed so that, in the end, the team has succeeded in the digital transformation I felt was so desperately needed?

Failure Is One Option

The cart metaphor is an elegant way of explaining the challenges that I have as a team lead and transporting the team into the digital future that I envision. Understanding that it is not about the cart! The challenge, then, is figuring out the real challenge.

And, there were so many challenges! The largest for me involved implementing and adapting to change. How to implement it, how to prevent collateral damage, how to get everyone on board with the concept, and how to hold all of us accountable. The change in this instance was getting the team to embrace the digital future.

My first idea along this journey was what I thought would be a sure-fire win. A few months previously, I had suggested we switch to a digital software used during audits that other Pfizer sites around the world were using. This software kept track of document requests by auditors and the tracking of document access and movement. I began by saying how I had talked to other sites about the software, how they had success in implementing the software, and how easy it was to use. I even set up a WebEx where an international site showed us the software's use and practicality and provided the team with the opportunity to answer any questions that they had on implementing it. The team listened, asked polite questions -- and promptly killed the idea.

I soon learned why. After reading about Adaptive Positive Deviance, I realized based on an example detailed by Benjamin et al (p. 10, 2017) why that approach failed

miserably. I was the all-knowing and powerful wizard. It was a top-down solution. I had discovered the problem and provided the fix. In addition, I so wisely demonstrated to them how “others” had implemented this solution and there was no reason why we could not. I did not know at that moment that the cart was not the software; it was me and my approach to solving the challenge. I know better now.

Coming up with a Plan

Before the COVID-19, I had intended to move the audit to as much a digital approach as possible. Plans to have documents provided electronically, tracking information digitally, using WebEx or Zoom meetings, and digital recordings so that both synchronous and asynchronous meetings could occur were all concepts that I had either discussed or implemented with the team during previous audits. But to have them all a part of one audit, I needed buy-in from not only the team, but also from higher management.

In one instance, we were fortunate. The team and I decided to go all in with a digital audit. But we needed a guinea pig. We knew in our deliberations that going completely digital for a major board of health audit would not fly with management. We had a corporate internal audit that would serve as a test flight and was scheduled to be completed prior to knowing the impact COVID-19 restrictions would have on the site. While the big picture was to have a completely digital audit, the devil was in the details.

We knew that the software side of things had to be in place. For this, we met with the site’s digital lead. He is responsible for all software and computer systems at the site. We went into the discussions thinking that we would use systems that were tried and true.

He suggested a completely different approach. The site had been rolling out the Microsoft TEAMS platform, so the digital lead suggested we use TEAMS—even though, at the time, we did not know how it would be implemented or the amount of training that would need to be provided. From an agile management perspective, we set up a small team to solve these issues.

We met weekly with digital support and as a team to address other issues. We convinced management that the digital audit approach would be more efficient and cost-saving and would require less people resources than the previous way of doing audits on the site. This discussion also occurred during budget talks. In one example, we demonstrated how the use of paper would go from a typical 80,000 sheets (that then had to be stored and involved significant manpower to process) to less than 5,000 sheets. Instead of having to be printed, documents would simply be provided digitally.

The next step was to talk to the auditors about their willingness to assist us in implementing a digital audit. No one at any other site had previously attempted this, and we convinced them of the groundbreaking opportunity we could provide. We had to figure out how they would access and review documents digitally. Since they were Pfizer employees, we were able to work out the kinks associated with each task. There were three auditors: two were on board, one was not. This was actually fine because it provided a way to compare processes.

We worked with site colleagues to provide training on using the software. We went through simulations of completing the tasks. Before the auditors came on site, we ensured that the TEAMS platform met their needs for document access and review. The

site's audit team grew temporarily from a crew of five to 20. This still was a significant decrease from the typical number of individuals (up to 40 members) involved in the normal completion of an audit.

The big day arrived for the trial run. Everyone was in place and the audit's kickoff meeting - where both site personnel and the auditors attended a presentation on the process for the audit and provide relevant information on the site's manufacturing activities - had begun. Everyone was excited about this new frontier.

Microsoft TEAMS, the software that served as the foundation for the digital audit, had a corporate systemwide failure. Panic ensued.

We did not know the cause of the failure at the onset. Everything was placed on hold for two hours while I communicated with the technology group. I provided updates to the team, who provided updates to the site crew, the auditors and management. We were within a few minutes of taking management's advice of scraping the digital approach and going back to the tried and true. Once TEAMS came back online, however, the audit went as planned. The digital audit after the "minor" setback was a success. Survey data from both the site's participants, auditors and management pointed out areas where improvement could continue to be made, but an overwhelming number of respondents to the survey felt the digital audit was the way to go in the future.

The Gift

Part of the auditing process is to have the site in a consistent state of inspectional readiness. There are several processes associated with this, including completing supplier quality audits; internal auditing the site; customer audits of the site; and supporting audits

from both domestic and international boards of health. In trying to figure out which of these processes to improve, I was given an unlikely gift: the COVID-19 crises.

COVID-19 restrictions eliminated, for the moment, the internal audit requirement. We cancelled all internal audits out of a concern that having a group of auditors walking throughout the site would expose it to significant issues if someone on my team contracted the virus. The internal audit process requires auditors to visit every area of the site to ensure that we are adhering to current good manufacturing processes (cGMPs). The site implemented contact logs. This document was a record of everyone you came in contact with for more than 15 minutes. When a positive case of COVID-19 was detected, the contact logs determined who would be quarantined and what areas got extensive sanitizing. Having auditors traipse unfettered throughout the site was deemed too much of a safety risk, so the internal audits were cancelled until site restrictions were lifted. The same was true for customer-based audits, as well as supplier audits. There were all cancelled due to travel and site access restrictions.

The Auditing Process

Then, things got serious. The site was picked to manufacture the COVID-19 vaccine. To accomplish this, boards of health would have to complete audits of the site. My team was responsible for managing the audits. Historically, audits worked by inspectors arriving at the site. Preferably, they provided an agenda indicating document required for review and request to see specific manufacturing processes. We would set aside a room where they would carry out the auditing process. The auditors would request documents, we would find them and provide subject-matter experts to address

their concerns. Tours would be conducted, and the cycle would continue until the audit was complete. A closeout meeting would occur; we would then be told of findings that have to be addressed; and the process was done. In one instance, more than a hundred thousand pieces of paper were used in an audit, as well as considerable human resources and time.

It was my task to transfer this intense process from an onsite, paper-based event to an entirely digital accomplishment. How would I transform a process and team that were deeply entrenched into an old way of doing things to something entirely new? Fortunately, we had the foresight to transition to a digital audit process a few months before we had to go completely digital due to site COVID-19 restrictions. You can imagine the pressure on the site to deliver the COVID-19 vaccine. Not only were we prepared for this rapid transition, we became the standard at Pfizer by which this process was done. Our process was shared freely with other sites around the world.

Coaching

A large part of the Audits and Inspection team's transformation to the digital audit process involved coaching on my part. It was a lesson I first had to learn. My daughter called around midnight during this time. She is a recent graduate from an Ivy League institution with a degree in chemistry and certificates in African American studies and dance. Rather than going into the sciences – like her dad - she opted for a lucrative brand management position with a major retailer's e-commerce division. Earlier that day, I had read a report about how that retailer's e-commerce division was doing well and was poised to overtake Apple at the number three spot as the world's largest e-commerce

retailer. It made sense (to me) that this would be a topic that she would want to talk about and most likely the subject of her call. I answered the late-night phone call and, as soon as my daughter said hello, my wife snatched the phone from my hands to hold the conversation. She caught immediately what I had missed completely. While I was about to begin a conversation on e-commerce performance, my wife simply asked what's wrong. My daughter was distraught because she had just read the passage in Michelle Obama's new autobiography where she explains for the first time publicly the reasons, she has not returned to the same Ivy League school that my daughter had attended. This resonated deeply with my daughter. I wanted to lecture to her that this Ivy League experience was the world she had asked for. I intended to point out that she knew after attending one of the nation's top boarding school and selecting an Ivy League school, that this was the world she would be entering into and that she should be grateful for what it had allowed her to accomplish. Had she gone to an historically black college (like we wanted), she would have had a completely different "inclusive" experience.

My wife, knowing she married an unempathetic idiot, refused to give me the phone and instead put on a coaching clinic. She demonstrated a level of unconditional positive regard that would have made any coaching consultant proud. She allowed our daughter to explain why she was upset, how it impacted her and gently walked her through her issues to find a way to deal with them. I went back to sleep. Either I need to hurry and enroll in DYNM 614, another coaching course at PENN, or accept the fact that maybe this coaching stuff is not meant for me.

The coaching incompetence did not stop with my daughter. There were additional lessons to be learned. In my first effort at coaching at the site, my colleague felt the

stinging incompetence of my coaching. I refused to leave behind baggage that I had with the issue they wanted help with. I wanted my questions answered. I held the concept of unconditional positive regard (L. Pennington, personal communication, September 22, 2018) in contempt. This is the notion that the individual receiving the coaching has the skills to solve their own problem. I was supposed to foster a bridge to the best resolution to the issue at hand. How dare my colleague sit before me and wallow in self-pity. In one instance, I felt it was a gentleman's arrogance that allowed him to think that others did not see in his work the excellence that he did. Didn't he realize that rejection of his ideas was simply a part of what the job and he needed to get over it and move along or get out of the game? Others who I knew—who were attempting to do the same type of work—had figured this out -- why hadn't he?

This sounds harsh and almost abusive as I reflect upon it now through a new coaching lens, and I have since apologized to him for my approach. It was all wrong and the colleague knew it. Everyone I spoke to afterwards about my approach knew it, too. I did not think so then, but I do now. I started asking for feedback after the coaching sessions. I knew my flaws. I was told that I cut people off during responses – and I did. I showed no empathy – and I didn't. I was leading individuals towards a resolution that I felt was appropriate (get over it) – and I was. As a coach, my conceptual framework at this time was “my way or the highway.” I highly doubt this type of framework exists in the realm of coaching strategies. I remember at the end of the day discussing with my own coach how I felt she had her work cut out for her with me. If at the end of our interaction I somehow adapted my worldview of coaching where someone like Bill Belichick was not a coach – (as suggested by L. Pendleton, personal communications,

September 22, 2018); if I found a new respect for unconditional positive regard; and if some modicum of empathy for the colleague could be discovered -- then the interaction with my coach for me would be a success – a true tall order!

Questions that I have related to this involved: How do we as coaches create an opening for the client? How do we provide a way out of the spiral that the client has gone into?

My daily job is to explore the space that a colleague is in and figure out how to move the key that allows her/him to get out. I work in a regulatory environment, and there is no escape from the requirements of the job. To escape could result in harm to an individual down the line and there is always a path back to figure out how it happened. I have been fortunate that a path has never led back to me. My work experience has fostered a mindset that is not willing to allow unconditional positive regard. In writing this just now, I have realized that perhaps I really do have to develop that muscle that allows me to separate the notion of what my job responsibilities are from that of coaching someone through an issue. To be effective in what I do for a job, I take no prisoners. It is black and white. One follows the regulations or not -- and there are significant consequences for not following them.

It requires a mindset that is completely different than that of a coach. In coaching, there is a lot of grey. There are many different techniques (cognitive behavior theory, unconditional positive regard, appreciative enquiry) that are perfectly fine for coaching that simply would not work in the day-to-day tasks of my current role. But, I must (and

am) realize that I cannot let the traits that allow me to succeed in my current role as doorkeeper to regulations be prohibitive in those instances where coaching is required.

Rogers discussed six foundation principles that help to differentiate coaching from other similar disciplines:

1. The client is resourceful
2. The coach's role is to develop the client's resourcefulness through skillful questioning, challenge, and support
3. Coaching addresses the whole person – past, present, and future
4. The client sets the agenda
5. The coach and the client are equal
6. Coaching is about change and action

Throughout the journey, each of these foundational principles has come into play. Some of them have been much easier to put into action than others. Through the interactions, the coaching/client sessions and the feedback sessions, my method of coaching has become somewhat clearer. This has allowed me to decode my own strengths and better figure out my spectrum of versatility. My style is not for the faint of heart. While others have perceived an increase in my level of empathy, I am not so easily fooled. In my head, I'm still thinking, "Really?" That would send the person I'm coaching into a concern for whose side am I on. It's a mindset that would be a true violation of the foundation principles of coaching.

During the road to digital audits I have found a level of success. While it has been difficult to implement the unconditional positive regard, I have found value in the attempt. I have always told the team that I am uncomfortable with indecision. *Make a decision*. If it turns out that we made a good one, then we move forward. If we made a bad one, then we as a team are smart and capable enough to realize the error, resolve the issue, and figure out how to learn from the challenge. I had to extend this mindset to my colleagues. We made mistakes and had successes in our approach. Yet on the journey to digital, we figured out what those mistakes were, resolved them and did not repeat the error. Examples include dealing early on with Buck. Letting him rule the nest and provide direction worked at one point -- and then it did not for reasons that ranged from his intractable willingness not to embrace change to his inappropriate team interactions. With Susan, my coaching led to her figuring out how not to inform others on why their approach was wrong, to working with them to figure out how to improve their idea. A major part of our success has been my change in coaching style and a willingness to form that bridge between what needs to be done and belief in my colleagues that they have the roadmap to success.

And so, what has my coaching journey lead to? In the beginning, I thought of coaching more as mentoring or consulting. I was a hired gun to come in and say the lights needed to be brighter, the walls needed a fresh coat of paint, and the break room needed a Coke machine -- and everything would be alright. This has changed to where I feel a coach is a multitude of things but, most importantly, it is what the client wants/needs him or her to be. It is the coach's job to help the client do what Rogers (2016) defines as a coach's purpose: "... to close the gap between people's potential and their current state."

The tools used to close this gap can involve the notion of unconditional positive regard and a host of other techniques that a coach should use to develop their “muscle.”

In coaching sessions that I conducted and where I was being coached, I figured the real issue was layered underneath a number of other issues that somehow had to be addressed or removed before we could get to the crux of the matter. This sojourn into the coaching world has been a learning experience for me. I have built muscle mass where I had little in the past, which, on some level, has made my development as a coach a success.

Conclusion

The position that I took on with the Audits and Inspection team was new to the company. I had already been told that “improving” the function of the team would be a herculean task with all the different stakeholders involved. I thought I was selected for this position due to my background in conducting complicated audits for the Food and Drug Administration. My boss stated that a major factor for her selecting me was her observation of my people skills and my ability to communicate difficult issues in a way that left everyone feeling respected and opinions valued. Running the team has been a challenge. Not because the changes needed are not evident or the consequences of failure are so significant, but because the people side of the “improvements” requires the cooperation of individuals who feel they have been doing a good job all along and see little need for change. My task has been to walk that delicate line of letting them know that I value their input, but that the change will happen with or without their cooperation.

I entered the Organizational Dynamics program many years ago. I left when I transitioned from the pharmaceutical industry to follow a passion to teach. I do not remember the course where I learned this, but a text by Ackoff (1981) was used in which the premise was this: “plan, or be planned for.” It is a management tenet that I have never forgotten. I found it effective in dealing with many challenges and, my current situation, I find it has become more imperative. Each step involved in “improving” the inspectional readiness of the site requires me to plan how it will be taken -- or I and the site will be planned by the regulatory authorities that dictate the viability of our organization. The hope is that I can somehow work with a crew that learns to appreciate growth and innovation so that we develop, implement, and evolve a plan that will succeed.

There is a lot riding on it. An often over used cliché is to “change the world”. Well, we actually did it! We are exceedingly proud of our efforts to be the first pharmaceutical company to successfully manufacture and provide a safe, pure, and effective vaccine. Based on evidence from clinical trials, the vaccine was 95% effective at preventing laboratory-confirmed COVID-19 illness in people without evidence of previous infection (Centers for Disease Control and Prevention, 2021, April 16). The approval of the manufacturing for this vaccine was augmented in no small way by our efforts to transform the auditing process. The vaccine manufacturing process was named “Project Lightspeed” by the company. Had we not had the foresight to transform a manual, paper, and human resource intensive, laborious process into something that by comparison is moving at “lightspeed” changing the world would have been far more difficult.

CHAPTER 5

CONCLUSION

The goal of this action research study was focused on addressing three questions:

1. How might I get the right people on the team to implement a digital auditing process?
2. How might I implement a digital auditing process?
3. What impact did the COVID-19 pandemic have on implementing the digital auditing process?

To figure this out, I utilized tools involving liberating structures, coaching and frameworks related to adaptive space and the agile approach. For the company, this action research project has been viewed as a success. The auditing process was transformed into one that was in dire need of modernizing. This involved changing the process from one that was paper-based and required significant human resources for its success to one that became completely digital and requiring fewer human resources. We could not have predicted how the world would change due to the COVID-19 epidemic. The timeliness of this audit transformation enabled the site to be a leading influence on how the company implemented digital audits at company sites worldwide.

To accomplish this, I began with making changes to the audits and inspection team. The first step in this process was to figure out what was the right mix of team members to have on the project. It became clear in utilizing various Liberating Structures and Primes who was willing to discover, develop and diffuse the changes needed to implement digital audits. As a result of both company policies related to the Opportunity

for Growth program, coaching, embracing the adaptive space and the agile management approach, the team was able to get the right people in place to implement a successful digital audit process.

The work is not finished. There are still areas with the digital audit process that we will continue to work on. While we have solved issues around document access and review process, auditors want a virtual tour of the site. This will involve a paradigm shift in both management's and the legal department's mindsets. There is again traditional thinking that the use of cameras and video on site should not be allowed. This is more a concern for liability than anything else.

Epilogue

This has been a long time coming -- not just for this action research project but for my engagement in the University of Pennsylvania's Organizational Dynamics Program. What I had intended to do with the degree in the spring of 1999 - when I started in the program - has changed from my purpose in finishing the program some twenty-two years later. My growth in being a leader and embracing change has not been at a "lightspeed" pace. In the interim from starting and finishing the program life has found a way to both humble and fortify me in my journey. There have been significant changes in me from an arrogant, "I'm the king of the world" person to a let "us" figure this out leader. Learning how to "coach" others and be coached, implementing an agile management style, learning how to engage and value others in finding the answer, and learning all about risk taking and project planning have all been a part of the growth. Yet, what attracted me to the Organizational Dynamics program all those years ago on a sleepless night while

recognizing a familiar face on the television still holds true to today: the opportunity to learn from world-class instructors, interact with extraordinary individuals in their field, and to develop the skill set to lead and implement change. For that, I am forever grateful.

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APPENDIX

1: Liberating Structures

Source: Lipmanowicz and McCandless (p. 163, 2013)

 **Liberating Structures Menu: Including and Unleashing Everyone v 2.2**

 Impromptu Networking Rapidly share challenges and expectations, building new connections	 Min Specs Specify only the absolute "Must do's" & "Must not do's" for achieving a purpose	 Discovery & Action Dialogue Discover, spark & unleash local solutions to chronic problems
 9 Whys Make the purpose of your work together clear	 Wise Crowds Tap the wisdom of the whole group in rapid cycles	 Integrated Autonomy Move from either-or to robust both-and solutions
 What, So What, Now What? Together, look back on progress to-date and decide what adjustments are needed	 Wicked Questions Articulate the paradoxical challenges that a group must confront to succeed	 Generative Relationships Reveal relationship patterns that create surprising value or dysfunctions
 TRIZ Stop counterproductive activities & behaviors to make space for innovation	 Drawing Together Reveal insights & paths forward through non-verbal expression	 Critical Uncertainties Develop strategies for operating in a range of plausible yet unpredictable futures
 Appreciative Interviews Discover & build on the root causes of success	 Improv Prototyping Develop effective solutions to chronic challenges while having serious fun	 Purpose-To-Practice Define the five elements that are essential for a resilient & enduring initiative
 1-2-4-All Engage everyone simultaneously in generating questions/ideas/suggestions	 Agreement-Certainty Matrix Sort challenges into simple, complicated, complex and chaotic domains	 Ecocycle Planning Analyze the full portfolio of activities & relationships to identify obstacles and opportunities for progress
 User Experience Fishbowl Share know-how gained from experience with a larger community	 Shift & Share Spread good ideas and make informal connections with innovators	 Panarchy Understand how embedded systems interact, evolve, spread innovation, and transform
 15% Solutions Discover & focus on what each person has the freedom and resources to do now	 Heard, Seen, Respected Practice deeper listening and empathy with colleagues	 What I Need From You Surface essential needs across functions and accept or reject requests for support
 25-To-10 Crowd Sourcing Rapidly generate & sift a group's most powerful actionable ideas	 Social Network Webbing Map informal connections & decide how to strengthen the network to achieve a purpose	 Celebrity Interview Reconnect the experience of leaders and experts with people closest to the challenges at hand
 Troika Consulting Get practical and imaginative help from colleagues immediately	 Design StoryBoards Define step-by-step elements for bringing projects to productive endpoints	 Helping Heuristics Practice progressive methods for helping others, receiving help, and asking for help
 Conversation Café Engage everyone in making sense of profound challenges	 Open Space Liberate inherent action and leadership in large groups	 Simple Ethnography Observe & record actual behavior of users in the field

Keith McCandless & Henri Lipmanowicz www.liberatingstructures.com


All Liberating Structures are described in the same format. Each includes:

1. **An icon and name** plus a brief tag line that expresses its essential characteristic
2. **What is made possible:** a paragraph that describes what you can expect to achieve when you use this LS
3. **Structural Elements - Min Specs** (each LS is designed with the same structural "DNA")
4. **Why? Purposes:** a list of the kind of purposes that may incite you to use this particular LS
5. **Tips and Traps:** Advice and do's and don'ts that increase your chances of getting more value when you use this particular LS
6. **Riffs and variations:** Examples of alternatives or embellishments for you to try and to imagine others
7. **Examples:** a few actual applications to inspire you to think of opportunities that may exist in your context
8. **Collateral materials:** visuals, slides, videos that may provide you with additional support when using this Liberating Structure.

Liberating Structures

Simple Rules to Unleash A Culture of Innovation

- **Simple:** requires only a few minutes to introduce
- **Expert-less:** beginners can succeed after a first experience
- **Results-focused:** likely to generate better-than-expected, innovative results
- **Rapid cycling:** fast iterative rounds are very productive
- **Innovative:** sparks creative relationships with clients or customers
- **Inclusive:** together, everyone is invited to shape next steps
- **Multi-scale:** works for everyday solutions, big projects, strategy, and transforming movements
- **Seriously fun:** boosts freedom & responsibility
- **Self-spreading:** easy to copy without formal training
- **Adaptable:** spreads with fidelity and adapts to local conditions via Min Specs



APPENDIX

2: LS Selection Matchmaker

Source: Lipmanowicz and McCandless (p. 163, 2013)

LS Selection Matchmaker: What Serves Your Purpose?

~ Use with the LS Design Cards or the LS Menu on the next page ~

1. Rapidly share challenges and expectations while building new connections	12. Specify only the absolute "Must do's" & "Must not do's" for achieving a purpose	23. Discover, spark and unleash local solutions to chronic problems
2. Make the purpose of your work together clear	13. Tap the wisdom of the whole group in rapid cycles	24. Move from either-or to robust both-and solutions
3. Together, look back on progress to-date and decide what adjustments are needed	14. Articulate the paradoxical challenges that a group must confront to succeed	25. Reveal and understand relationship patterns that create value or dysfunctions
4. Stop counterproductive activities & behaviors to make space for innovation	15. Reveal insights and paths forward through non-verbal expression	26. Develop strategies for successfully operating in a range of plausible yet unpredictable futures
5. Discover & build on the root causes of success	16. Develop effective solutions to chronic challenges while having serious fun	27. Define the 5 elements that are essential for a resilient & enduring initiative
6. Engage everyone simultaneously in generating questions/ideas/suggestions	17. Sort challenges into simple, complicated and complex categories	28. Analyze the full portfolio of activities & relationships to identify obstacles & opportunities for progress
7. Share know-how gained from experience with a larger community	18. Spread good ideas and make informal connections with innovators	29. Understand how embedded systems interact, evolve, influence the spread of innovation, and transform
8. Discover & focus on what each person has the freedom and resources to do now	19. Practice deeper listening and empathy with colleagues	30. Surface most essential needs across functions and accept or reject requests for support
9. Rapidly generate & sift a group's most powerful actionable ideas	20. Map informal connections and decide how to strengthen the network to achieve a purpose	31. Reconnect the experience of leaders and experts with the people closest to the challenge at hand
10. Get practical and imaginative help from colleagues immediately	21. Define the step-by-step design elements for bringing initiatives or meetings to productive endpoints	32. Practice progressive methods for helping others, receiving help and asking for help
11. Engage everyone in making sense of profound challenges	22. Liberate inherent action and leadership in large groups	33. Observe and record actual behaviors of users in the field


































Write two or three sentences about the challenge you have in mind. Then, ...

1. Put a checkmark next to each objective you wish to achieve. [v]
2. Group objectives in a logical sequence of beginning, middle and end.
3. Trim your list by taking out the less critical objectives; save those for later.
4. If you are down to between 3 and 7 objectives you have your first string. *Voila!*
5. Develop one or two alternative strings, shorter, longer or different.
6. Share with others, compare, modify and choose one that makes good sense.
7. Match your string of objectives with its string of LS and check timing.
8. Save alternative objectives for improvising as needed during implementation.

Liberating Structures Menu

~ Use when LS Design Cards are not available ~

Each LS in this table is designed to achieve the objective with the same number.
Cut along the table lines to make separate cards easy to manipulate and string together.

1. Impromptu Networking 5-20 min. 	12. Min Specs 20-50 min. 	23. Discovery & Action Dialogue 25-75 min. 
2. 9 Whys 5-20 min. 	13. Wise Crowds 10-60 min. per person 	24. Integrated*Autonomy 60-90 min. 
3. What, So What, Now What 15-45 min. 	14. Wicked Questions 20 min. 	25. Generative Relationships 25 min. 
4. TRIZ 30-45 min. 	15. Drawing Together 30-40 min. 	26. Critical Uncertainties 60-100 min. 
5. Appreciative Interviews 30-60 min. 	16. Improv Prototyping 15-20 min. per round 	27. Purpose-to-Practice 25-120 min. 
6. 1-2-4-All 10-12 min. 	17. Agreement-Certainty Matrix 30-45 min. 	28. Ecocycle Planning 60-95 min. 
7. User Experience Fishbowl 25-70 min. 	18. Shift & Share 35-60 min. 	29. Panarchy 1-2 hr. 
8. 15% Solutions 15-20 min. 	19. Heard, Seen, Respected 25 min. 	20. What I Need From You 45-70 min. 
9. 25-to-10 Crowd Sourcing 20-30 min. 	20. Social Network Webbing 45-60 min. 	21. Celebrity Interview 25-30 min. 
10. Troika Consulting 15-30 min. 	21. Design Storyboards 25-70 min. 	32. Helping Heuristics 15 min. 
11. Conversation Café 35-60 min. 	22. Open Space 90 min. to 8 days 	33. Simple Ethnography 1-6 hr. 



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APPENDIX

3: List of Primes

Source: McGoff (2021)

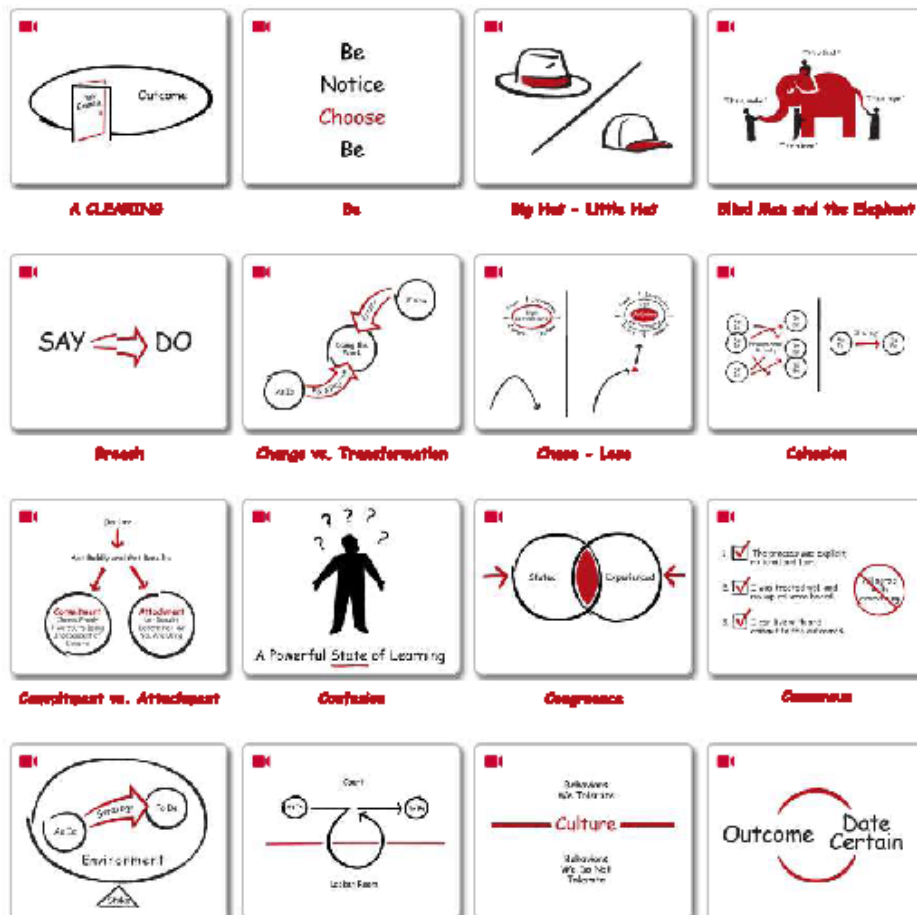
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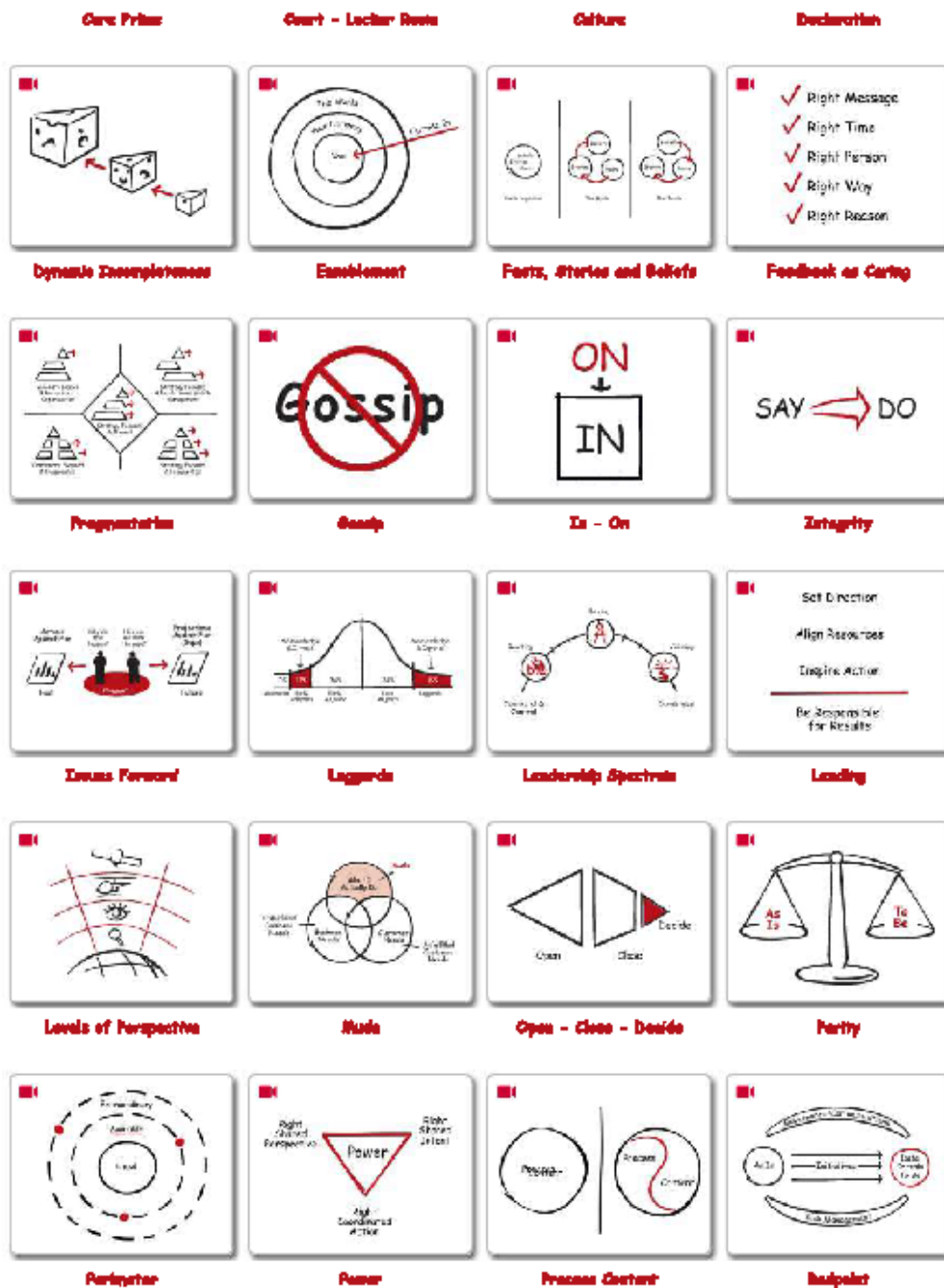
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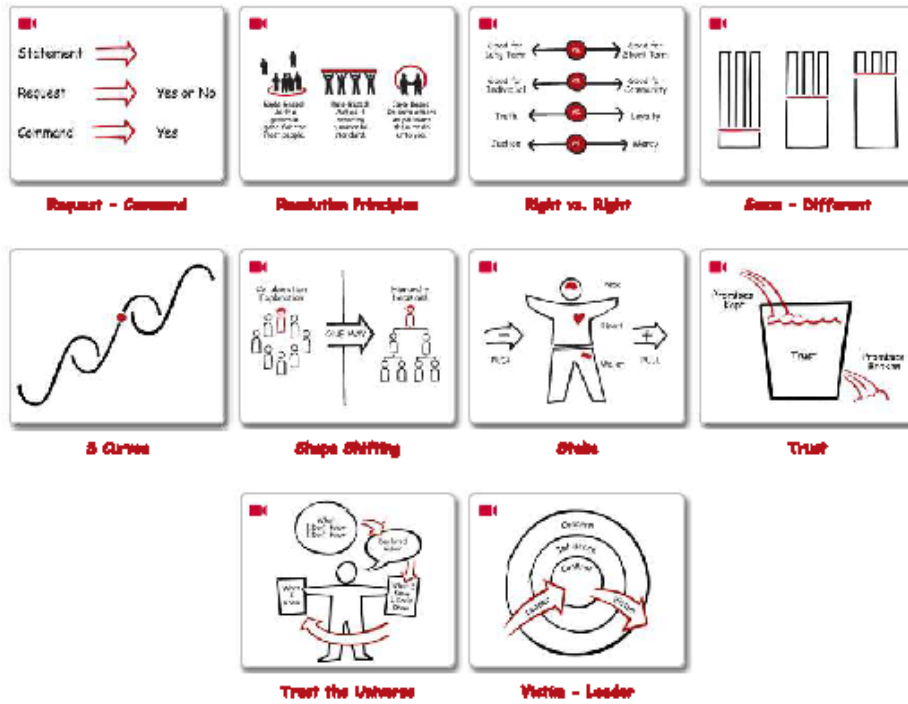
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