Rapidly Modernizing Medical Capabilities via Middle Tier of Acquisition

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For anyone who sees a new medical product being advertised and wondered "why can't we have that product in our sets, kits, and outfits?" or asked "how long will it take to field it?" take heed, as change is in the air! The Department of Defense (DoD) enacted important changes to the Defense Acquisition System (DAS) to improve its ability to develop prototypes rapidly, conduct early operational assessments, optimize the desired effects, and expedite fielding to support the operational mission. These reforms will especially enhance the development of materials and technologies that have dual military and civilian applications, with the intent to enable military developers and partners to utilize commercial processes for developing and fielding more effective and affordable capabilities. These reforms will have a significant impact on development and fielding of military medical products, of which at least 95 percent have dual military and commercial applications.

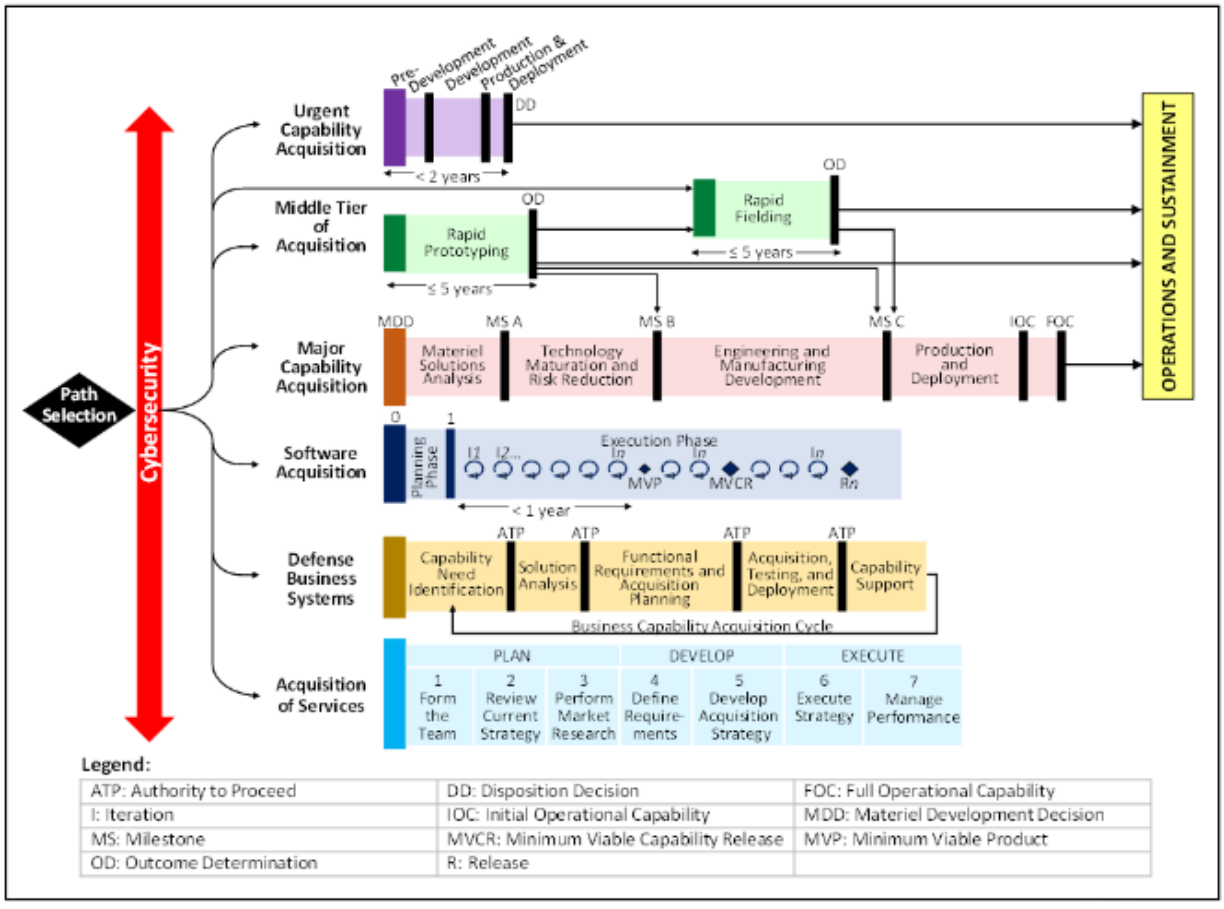
But first, it is important to understand how we got here. In the last couple of decades, the DoD and Congress implemented various reforms to the defense acquisition system to improve how the DoD develops and fields new capabilities to their operational mission as well as how to address existing problems better, optimize existing systems, and implement enhanced technologies. The initial launch of the DoD 5000 series for acquisition management in the early 2000s was heralded a success, as it replaced the unaligned multi-service approach to system development that was wrought with significant cost overruns, unsustainable systems that did not meet user requirements, and technologies that failed to transition to the service members who needed them to execute the mission. The initial DoD instruction 5000.02 essentially implemented dozens of best practices for managing projects and

programs to *avoid* making mistakes. It required frequent, high level in-progress reviews and centralized decision making. While the new instruction did reduce the number of failed DoD acquisition programs, the DoD still experienced program delays, cost overruns, and failures to deliver new capabilities in a timely fashion. Program managers noted the main issue was that the unintended objective to avoid mistakes significantly increased the number of reviews, documentation required, and over-administration of projects and programs. The new system unintentionally established a dichotomy of program managers who had detailed knowledge of projects and programs but lacked decision authority, and the decision makers who held decision authority, lacked detailed knowledge about the projects and programs and subsequently asked for more and more project and program information. In subsequent revisions of DoD Instruction 5000.02, the DoD addressed these issues with revisions such as tailoring of the administrative programmatic oversight to only what the program required to meet statutory and regulatory requirements. However, tailoring measures were largely ineffective as the decision authority for tailoring was not delegated and did not address the dichotomy causing the issue. Essentially, the DoD acquisition system needed to have just enough oversight of projects and programs to ensure they were being effectively and adequately managed, but allow enough flexibility to allow for creative approaches to develop and enable project and program managers to take advantages of opportunities when they occurred. Basically, a "somewhere in the middle" approach was needed.

Over the last few years the various program offices and elements of the DoD acquisition community experimented with various processes for expediting development and fielding of new capabilities. The initial focus for acquisition reforms was how to rapid prototype new or enhanced technologies and rapidly field these capabilities. This lead to the realization that rapid prototyping must be coupled with early user assessments and feedback, conducted in an iterative process that applied lessons-learned to revise user requirements after every iteration, repeated until the capability being developed successfully achieved the desired effect safely in the spectrum of operational environments, conditions, and

employments as determined by the end-users. To incorporate this realization into acquisition reforms, multiple pathways or models for project and program management were developed to allow managers to make "pre-tailoring" decisions based on the unique aspects of each project or program. The multi-model approach was named Adaptive Acquisition Framework (AAF) and has six distinct pathways as detailed in the revised 2019 DoD Instruction 5000.02 *Operation of the Adaptive Acquisition Framework (AAF)*:

Figure 1: Adaptive Acquisition Framework



Another outcome of the new acquisition reforms was the establishment of the six tenets of the Defense Acquisition System to guide the management of programs and projects regardless of the pathway that will be followed:

1. Simplify Acquisition Policy
2. Tailor Acquisition Approaches
3. Empower Program Managers
4. Conduct Data Driven Analysis
5. Actively Manage Risk
6. Emphasize Sustainment

Each pathway has its own powerful effect of streamlining the acquisition system to reduce waste, improve throughput, reduce time required for fielding, improve affordability, and enhance warfighter's capabilities to execute successfully the operational mission. However, Ms. Ellen Lord, the Under Secretary of Defense for Acquisition and Sustainment and driving force behind the development of the AAF, stated that the hallmark of this new policy is how it centers on delegating decision authority to the program offices and empowering program managers. This enables program managers to pre-tailor acquisition approaches to the unique requirements of each program in order to deliver rapidly effective and cost affordable capabilities when needed. The delegation of decision authority directly addressed the paralyzing dichotomy of knowledge and decision authority that existed in previous iterations of the Defense Acquisition System. Also gone were the days of a single "one-size-fits all" model of acquisition management that applied the same acquisition pathway for overseeing the development major weapon systems like aircraft carriers to the development of small projects or rapid fielding of a urgently-required capabilities. Another key aspect of these acquisition reforms is that it requires active, continuous involvement by end-user representatives to ensure the project or program meets or exceeds their needs, from start to finish and beyond with sustainment. Another important distinction from the policies of old is that everyone is encouraged to *manage* risk actively, not *minimize* risk, as mistakes

should be expected and tolerated if they lead to improvements in processes, designs, and overall capabilities. After all, minimizing risks by avoiding mistakes is ultimately achievable by not taking any chances and by doing nothing.

Uniqueness about Medical Product Development

Rapid Development/Fielding: For medical product development, the Middle Tier of Acquisition (MTA) is the most applicable pathway to use as it is designed to utilize, apply, and exploit leading-edge commercial development processes and technologies to reduce developmental costs, encourage competition, maintain high reliability, ensure affordability, and retain availability. The MTA pathway supports, encourages, and executes rapid prototyping and rapid fielding of safe, effective, and affordable capabilities which directly align with medical product development goals and objectives of quickly fielding safe and effective medical products to save lives, minimize/eliminate health effects of illnesses and injuries, improve health and readiness, and enhance/optimize human performance. As established for rapid prototyping, MTA programs must field a prototype that can be demonstrated in an operational environment and ensure the operational capability meets end-user requirements within five years of an approved requirement. After the end-users' acceptance, MTA programs must begin production within six months and complete fielding, all within the five year period after a requirements document is approved (Figure 1). This accelerated cycle is ideal for fielding enhanced, advanced, and optimized medical products that are desperately needed on the battlefield, in operational units, or in the clinics and Medical Treatment Facilities (MTF).

Reduced Duplicity: Companies that manufacture medical products already follow commercial developmental processes, practices, and pathways that were created to ensure products meet the stringent requirements of the Food and Drug Administration (FDA). As a regulatory oversight

organization, the FDA is unique in that they do not just base their approval or certification of a medical product on final testing results, but also evaluate the quality systems for manufacturing processes, the design history file which guided the development, the biocompatibility of the materials being used in the medical product, and much more. By following commercial developmental processes, companies are spared the redundancies of also meeting military-unique acquisition development processes which they may not be familiar with, thereby saving funding, time, and manpower.

Speed of Relevancy: In the medical product development market, there is often intense competition to offer better medical products than the competition in order to "corner the market". Innovations drive reductions in costs, size, weight, and power use while improving reliability, capabilities, and enhancements. Companies often re-invest their profits into development of new medical products which drives innovation faster than the Joint Capabilities Integration and Development System (JCIDS) could generate warfighter requirements documents. As a result, warfighters often request to incorporate advanced medical products into their sets, kits, and outfits that are already FDA approved and used in the commercial health care industry, but do not have a capability development document written to support fielding. To address this, the MTA pathway exempts MTA-declared projects and programs from following JCIDS requirements, and instead requires services to implement a truncated process for rapid establishment of abridged capability development documents to support fielding. As such, each of the military services already implemented unique processes to enable this streamlined approach. The Army, for example, uses an abbreviated Capabilities Development Document (CDD) while the Air Force is using a Rapid Prototyping/Fielding requirements document to distinguish MTA projects and programs from major weapon system programs. In accordance with MTA guidance, an abridged requirements document must be written and finalized within six months of an operational need being declared. In addition, the abridged requirements document can be easily revised after a

project iteration to ensure it clearly identities the refined direction(s) to meet prioritized end-user requirements.

Larger Markets = Improved Affordability: Military use of medical products represents such a small market that companies must design medical products to sell to larger communities such as hospitals, clinics, emergency medical responders, and others external to the military market to be viable. Medical products that are designed for military-use only often result in small sale volumes, which drive individual unit costs up and essentially result in medical products becoming unaffordable and companies unable to keep the product line open and the medical product available.

Conclusion

The Middle Tier of Acquisition (MTA) pathway is representative of a larger shift in culture and focus in the acquisition community to identify capabilities suitable for rapid prototyping and fielding, use of streamlined processes, delegated decision making, empowered program managers, and emphases of risk management versus risk minimization. Because of the emphases of utilizing commercial developmental processes, the MTA pathway is ideal for supporting medical product development, given that a vast majority of DoD medical products have a dual military and commercial application. The MTA process is also ideal for medical product development given the necessity for rapid prototyping, development, and fielding for both the competitive commercial markets and military users that urgently require the most effective medical products to complete their operational missions.

How to Get Started:

As it is now a DoD instruction, the MTA pathway is one of many new acquisition tools available to service program managers, and having flexible requirements and other flexible acquisition mechanisms enables medical program and project managers to leverage commercial practices, commercial innovation funding, advanced medical technologies, and novel medical products to enhance and support military medical operations and modernize the force. Learn all that you can about MTA pathway, the abbreviated (flexible) requirements processes, the rapid prototyping/rapid fielding that lead to MTA, the flexible contracting vehicles like Other Transaction Authority (OTA) that enabled rapid prototyping/rapid fielding, and ask senior medical acquisition leaders and decision makers about using MTA pathway, first as a prototype, then as a standard process, perfecting it as we go. The Honorable Frank Kendell, then Under Secretary of Defense for Acquisition, Technology and Logistics, noted when he issued the 2013 interim DoD Instruction 5000.02, that the DAS was created to be continually updated and revised, and that its "not about the rules that acquisition professionals have to follow, it's about us all working together to make the acquisition system as efficient and effective as possible." The MTA pathway has moved us forward, and we are obligated to our end-users to apply it for providing better, faster, and higher quality support to our warfighters.