GOTV!® Get Out the Vaccine!®

COVID-19 Vaccine Distribution & Management System

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Executive Summary

In an effort to put an end to the COVID-19 Pandemic, the United States must coordinate and administer one of the largest mass-vaccination campaigns in history. To maximize accessibility and equitable allocation of the vaccine to patients with the greatest need, the Centers for Disease Control and Prevention (CDC) has identified local Public Health Agencies (PHAs) and various Vaccine Delivery Organizations (VDOs) as instrumental in delivering immunizations to over 213 million Americans. To achieve this feat, VDOs and PHAs will rely on the *GOTV!® (Get out the Vaccine!) COVID-19 Vaccine Distribution & Management System* to manage all aspects of patient flow, vaccine distribution, and inventory control.

This document provides an overview of the *GOTV!® System's* features and development, detailing its implementation over the vaccine-distribution process. As stand-alone software, the *GOTV!® System* can be easily integrated into existing electronic health records (EHRs), giving providers access to a self-contained patient and inventory management, scheduling, and documentation system that is designed to streamline the vaccine delivery process and reduce staff burden. This proposal further outlines the goals and objectives of the *GOTV!® System*, which includes registering and inoculating over 60% of the population through a phased delivery of the vaccine that prioritizes high-risk patients.

From its inception in May 2020, the proposal's planning, designing, and training phases must be completed in seven months, before immunizations become available to the public in December 2020. The *GOTV!® System* will be further evaluated and updated throughout the vaccine delivery process. We anticipate a budget of approximately 1.2 billion dollars toward software development, implementation, training, evaluation, and any relevant overhead expenses, to ensure seamless integration of the *GOTV!® System* into existing EHR systems.

GOTV!® Vaccine Distribution & Management System

In December 2019, a novel and highly infectious strain of Coronavirus was first identified in Wuhan, China. Within three months, the Director-General of the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic; noting that the virus had gained a foothold in 114 countries, claiming over 4,000 lives (World Health Organization, 2020). In the one year since its identification, the death count has risen to over 1.5 million, with almost every country around the world struggling to contain the virus's spread (Johns Hopkins University, 2020). Given the high efficacy of vaccine candidates that have been developed against the SARS-CoV-2 virus (Johnson & Steckelberg, 2020), there is newfound hope that the end of the pandemic is near. With these findings, the United States Food and Drug Administration (2020) is expected to grant Emergency Use Authorizations (EUAs), for two vaccine candidates, before the end of 2020.

Anticipating a limited number of doses in the earliest months of vaccine distribution, the Centers for Disease Control and Prevention (2020a) recommend a phased approach that prioritizes health workers and other high-risk patients. As Vaccine Delivery Organization (VDOs) and Public Health Agencies (PHAs) prepare for one of the greatest logistical challenges our already-burdened healthcare system has ever faced, the need for a user-friendly and centralized COVID-19 immunization information system that aims to reduce the strain on an already overburdened healthcare system is paramount. Thus, we recommend that the PHAs and VDOs, nationwide, adopt the Get Out the Vaccine! (GOTV!®) Vaccine Distribution and Management System to administer all aspects of the vaccine delivery process.

Let's be done with COVID-19…

Get Out The Vaccine!

Needs and Problems

As of December 2020, the United States maintains its lead as the country with the largest number of reported COVID-19 cases, topping 14.8 million since the beginning of the outbreak (Johns Hopkins University, 2020) Given that "herd-immunity" against the coronavirus is expected to occur when 60-70% of the population gains immunity to the novel coronavirus, over 213 million Americans would have to gain immunity through either immunization or infection before the Pandemic can come to an end (Fiore, 2020). The sheer loss of life that would occur in an uncontained COVID-19 outbreak would be a tragedy, the likes of which has never been seen before.

Anticipating a shortage of vaccine doses at the earliest stages of distribution, the CDC's *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (2020a) has recommended that state and local PHAs and VDOs implement a phased delivery of the COVID-19 vaccine, ensuring that patients at the highest risk for infection or death receive their vaccines first. During the earliest phases of distribution, "critical populations" of health care and other essential workers, those with preexisting conditions, older adults, or those living in high-risk living situations, will be eligible for immunization before the general public. See Appendix A for an overview of vaccine delivery phases, as delineated by the CDC. See Appendix B for an overview of comorbidities that increase the risk for severe COVID-related illness. See Appendix C for a list of critical industries. A complex risk stratification system like this is best served by an algorithm that considers age, health factors, and socioeconomic conditions to assign each patient to the appropriate phase of vaccine distribution.

With both of the soon-to-be-authorized vaccine candidates requiring multiple doses to achieve full immunity (Johnson & Steckelberg, 2020), concerns over patient scheduling and vaccine availability become even more apparent. According to Cooper et al. (2020) of the National Academy for State Health Policy, "Immunization registries…will be needed to record vaccination information, identify individuals in need of a first or second dose of a vaccine, remind individuals to get vaccinated, and track

follow-up." Furthermore, 45% of statewide vaccine registries, or Immunization Information Systems (IIS), do not have their entire populations enrolled. Given the wide variation in statewide IISs, it is apparent that local and statewide PHAs and VDOs would benefit from a centralized and fully interoperable vaccine distribution management system that can track dose availability, vaccine uptake, inventory control, and patient flow, in real-time.

Goals and Objectives

The goal of the *GOTV!® Vaccine Distribution Management System* is to help bring an end to the COVID-19 Pandemic through equitable allocation of vaccine doses, via a centralized immunization information system to manage patient flow and inventory control.

The first objective is to increase the number of patients enrolled in the *GOTV!® System* through health information echanges with statewide IISs and local healthcare delivery organizations. This will allow statewide and local PHAs to manage inventory, anticipate demand, and track individual immunization statuses along with community immunization rates.

The second objective is to accurately assign and schedule all patients to the appropriate phase of vaccine delivery, using the *GOTV!® System*'s patient-centered Risk Determination Algorithm and Scheduling functions. This is imperative to ensure equitable allocation of the vaccine and that patients are receiving the correct number of vaccine doses, within a reasonable amount of time.

The third objective is to use the *GOTV!® System's* data capture, documentation, and reporting function during every vaccination events. Through structured data entry and a friendly user interface, the *GOTV!® System* promotes complete and accurate data collection, allows for enhanced post-market research on vaccine efficacy, and provides regulatory organizations with valuable statistical information about vaccine uptake, in real-time.

The fourth objective is to use the *GOTV!® Dashboard's* inventory management system to ensure VDOs receive a needs-based allocation of COVID-19 vaccines, centered on vaccine uptake and

anticipated demand. This is imperative to ensure that patients receive the correct number of vaccine doses, within the appropriate amount of time, all while avoiding waste.

Procedures and Scope

Procedure

The *GOTV!® Vaccine Distribution & Management System* is a multifunctional dashboard that can be easily integrated into a VDO's existing Electronic Health Record (EHR) and is administered by local and statewide PHAs. Within the *GOTV!® Dashboard*, VDO staff will be able to access various applications, at different points in their workflow, to streamline patient management and vaccine administration.

One of the *GOTV!® Dashboard*'s most valuable applications is the patient-centered *Phase Assignment Tool*, which uses a smart form and patient-centered algorithm to assess a patient's COVID-related risk and assign them to the appropriate phase of vaccine delivery. The simple-to-use risk assessment questionnaire first gathers data on four, pertinent COVID-related risk factors, including the patient's age, profession, living situation, and comorbidities. This data is then fed into the patient-centered algorithm, which assigns each patient to the appropriate phase of vaccine distribution. The questionnaire's structured data entry and simple user-interface are designed to be completed by either VDO staff, through the *Phase Assignment Portal* application, or by the patient, through their patient portal. This step is essential in registering the patient with *GOTV!®* and must be completed in order to schedule an immunization appointment. The responses to this questionnaire, along with the patient's phase assignment will automatically populate in the patient's EMR and will be sent to the appropriate regulatory bodies, to monitor vaccine allocation.

Once a patient's Risk Determination has been processed, *GOTV!® System*'s *Scheduling and Administration Portal* will open. First, the software will consider whether the patient is eligible for vaccination by comparing the patient's phase assignment to the local phase of vaccine delivery in the VDO's jurisdiction, as determined by local PHAs. To promote social distancing, it will be imperative to

use a “smart” appointment scheduling system that ensures the COVID-19 vaccine is being distributed to those with the greatest need, first. Once at the appointment, staff will use the *Scheduling and Administration Portal* to guide their workflow: confirming a patient’s eligibility during the check-in process and providing any necessary paperwork or patient education resources.

The *GOTV!®Dashboard*’s documentation and reporting functionality is integrated into the VDO’s workflow, to ensure pertinent information is documented, through structured data entry. This information will be directly available to local PHAs to help anticipate demand and manage supply, while also providing valuable information on vaccine efficacy or adverse events.

Lastly, The *GOTV!®Dashboard*’s inventory management system will be used to streamline vaccine ordering and ensure that the appropriate number of vaccine doses are supplied to each provider. During the earliest phases of distribution, it will be very important for local PHAs to monitor vaccine uptake and demand in their jurisdictions, to help determine how many vaccine doses to supply at a given time.

Recruiting and Training

Developing and implementing a nationwide *Vaccine Distribution and Management System* will require an extensive and multidisciplinary team.

Recruiting

Public Health Officials (PHO). Using real-time immunization data, PHOs will track vaccine uptake, anticipate demand, and manage dose allocation. National PHOs will be responsible for identifying critical groups and determining which will receive priority in vaccine distribution. Local and Statewide PHOs will be responsible for determining the phase of vaccine distribution in their respective jurisdictions.

Technical Staff. These will be divided into two main categories: core informaticists and mobile technical staff. Core staff will be responsible for designing, building, and maintaining the *GOTV!® System*,

while also performing large-scale evaluation and data analysis, after roll-out. Mobile technical staff will be stationed in every state to provide technical support and assist with community-wide evaluation and monitoring. Many mobile technical staff members will serve as Implementation specialists and are responsible for integrating the *GOTV!® System* into a VDO's existing EHR, and must ensure that complete and accurate data conversion occurs with existing statewide IISs.

Clinical Staff. As the main end-users of the *GOTV!® System*, clinical staff includes all individuals employed at VDOs. Each VDO must designate a minimum of two superusers, from different occupational groups (i.e., a Pharmacist and a Pharmacy Technician).

Training

Clinical staff must be trained using the *GOTV!® System's* various functions and will complete a series of interactive modules before and during the implementation phase. After completing the modules, each VDO will hold a "mock vaccination" event to practice using the *GOTV!® Dashboard* and identify areas of concern, in their workflows. Designated superusers will be enrolled in a subsequent training course to improve their technical troubleshooting skills.

Timetable and Budget

The *GOTV!® System's* timetable can be divided into five main stages: *Planning, Design & Implementation, Training, Go-Live*, and *Evaluation & Monitoring*, see Appendix D. The *Planning* stage is expected to last two months, beginning in mid-May 2020, during which workflow analysis will be completed, qualified staff will be recruited, and the project plan will be completed. The *Design and Implementation* stage, which is expected to last seven months, will allow for software and training module development, adequate testing, a month-long pilot program, and nationwide implementation. The *Training* stage will commence during the final month of *Implementation* and will last until the vaccine becomes available for public use. The *Go-Live* stage will last until the majority of local PHAs, around the country, shift to Phase 2 of vaccine delivery. At this point, the project will move to the

Evaluation & Monitoring stage, in which the *GOTV!® System* will be evaluated against its metrics and optimized. The budget for this project is $1.2 Billion and covers *Product Design, Implementation, Training, Evaluation,* and *Overhead Expenses.* For budgetary considerations, see Appendix E.

Key Personnel

Designing and implementing a nationwide Vaccine Distribution and Management System will require a multi-disciplinary team, see Table 1.

Table 1

Key Personnel and Stakeholders involved in the GOTV!® System

Key Personnel	
Project Manager	Head of *GOTV!® System*
Principal Public Health Official	Dr. Anthony Fauci
Public Health Agencies	State and County Public Health Officials
Core Technical Staff	100-150 Health IT Professionals
Mobile Technical and Training Staff	1500 Health IT Professionals, Nationwide
Clinical Staff at VDOs	~ 100,000 Vaccine Providers, Nationwide

Evaluation

The *GOTV!® Vaccine Distribution & Management System* will undergo a strict evaluation process to quantify progress throughout the project. The first objective, increasing the number of registered patients, will be met when 70% of the population has completed the *Phase Assignment* questionnaire. The second objective, prioritizing critical populations, will be met if 1) 60% of patients assigned to a given phase are vaccinated before local PHAs trigger the subsequent phase and 2) 90% of patients requiring multiple vaccine doses receive them within the required timeframe. The third objective, complete and accurate documentation, will be met as long as less than 95% of nationwide vaccination encounters occur within the *GOTV!® System.* The fourth objective, effective inventory management, will be met as long a minimum inventory is maintained at 95% of VDOs.

Endorsements

The *GOTV!® Vaccine Distribution & Management System* has been endorsed by various PHAs, including the CDC, WHO, and local/state organizations. The National Academy of Science, Engineering, and Medicine also endorses the *GOTV!® System,* for upholding the principle of equitable allocation of the COVID-19 Vaccine. Statewide vaccine registries, clinical licensing boards, and health information exchanges also endorse this project.

Next Steps

In anticipation of the impending Emergency Use Authorizations for two vaccine candidates, the *GOTV!® Vaccine Distribution & Management System* must complete the finals stages of implementation and training, to ensure that all VDOs and local PHAs are prepared to begin receiving and administering vaccine doses. PHAs should also be ensuring that appropriate infrastructure exists to deliver vaccine doses from the manufacturer to VDOs. Clinical staff should be reviewing their online modules and preparing for the largest mass vaccination campaign, in American history.

Conclusion

As Americans continue to struggle through the undue hardship that the COVID-19 pandemic has brought upon them, many turn to the vaccine as a beacon of hope in an otherwise bleak situation. When considering the disproportionate effect this virus has had on the vulnerable and hard-working, vaccine delivery organizations must do what they can to prioritize equity, while streamlining the immunization process. The *GOTV!® Vaccine Distribution & Management System* aims to do exactly that: as the only, nationwide immunization information system currently available, the *GOTV!® System* gives providers and public health agencies access to a functional and user-friendly tool that will help bring an end to the greatest healthcare tragedy of the century.

The end of the Pandemic is in sight.

We've just got to do it right…

Let's be done with COVID-19.

Get Out The Vaccine!®

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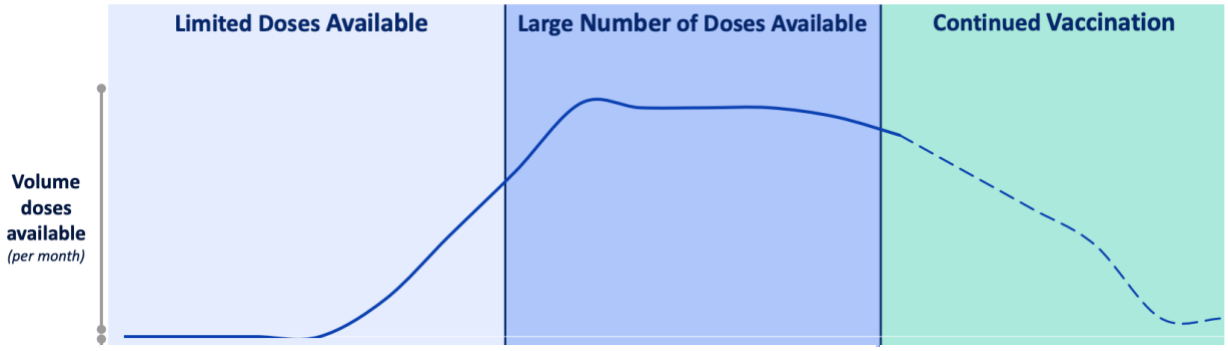
Appendix A

Patient Risk Stratification in Phased Distribution of COVID-19 Vaccine



Phase 1: Critical Populations

- Phase 1a: Healthcare Workers and Adults 65+ living in long-term care facilities
- Phase 1b: Essential Workers
- Phase 1c: Adults 65+ and Patients with Underlying Conditions

Phase 2

- Increase access to Critical Populations
- General Public

Phase 3

- Increase access to Critical Populations
- General Public

Note: Vaccine Phase Distribution as delineated by the CDC (Dooling, 2020).

Appendix B

High-Risk and Moderate-Risk Comorbidities

High-Risk Comorbidities	Moderate-Risk Comorbidities
Underlying conditions that *might* increase the risk of severe COVID-Related Illness.	Underlying conditions that *might* increase the risk of severe COVID-Related Illness.

- Cancer
- Chronic Kidney Disease
- Immunocompromised State from:
  - Solid Organ Transplant
- Obesity
- Serious Heart Complications
  - Heart Failure
  - Coronary Artery Disease
  - Cardiomyopathies
- Sickle Cell Disease
- Type 2 Diabetes
	- Asthma
	- Cerebrovascular Disease
	- Cystic Fibrosis
	- Immunocompromised State from:
	  - HIV
	  - Blood & Bone Marrow Transplant
	  - Immune Deficiencies
	  - Corticosteroids
	  - Other Medications
	- Neurologic Conditions
	  - Dementia
	- Liver Disease
	- Pregnancy
	- Pulmonary Fibrosis
	- Smoking
	- Thalassemia
	- Type 1 Diabetes

Note: High-Risk and Moderate-Risk Comorbidities as determined by the CDC (2020b).

Appendix C

Critical Infrastructure Sectors

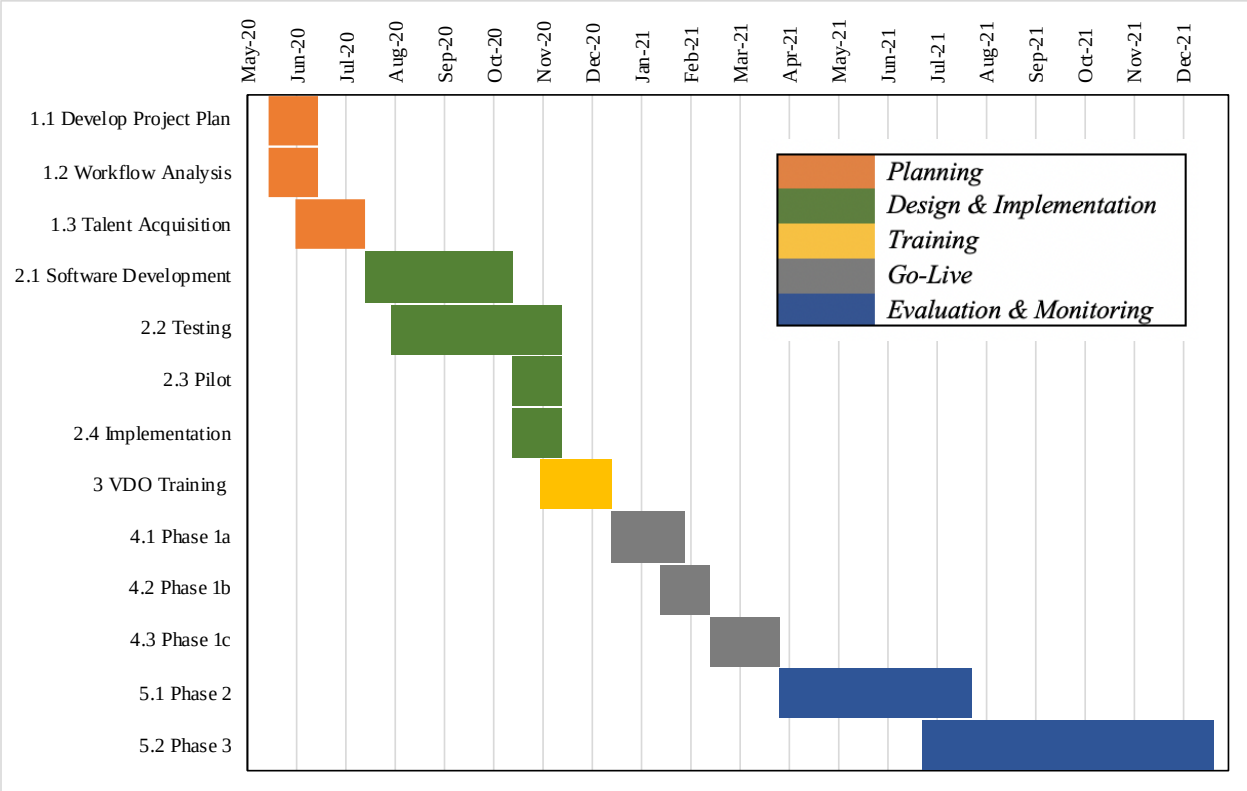
- Chemical Sector
- Commercial Facilities Sector
- Communications Sector
- Dams Sector

  Defense Industrial Base Sector
- Emergency Services Sector
- Energy Sector
- Financial Services Sector
- Food and Agriculture Sector
- Government Facilities Sector
- Healthcare/Public Health Sector
- Information Technology Sector
- Nuclear Reactors/Materials/Waste Sector
- Sector-Specific Agencies
- Transportation Sector
- Water/Wastewater Systems Sector

Note: Essential Workers are employed in one of the Critical Infrastructure Sectors, which according to the Cybersecurity and Infrastructure Security Agency (2020) are essential to the functioning of the economy.

Appendix D

Proposed Timetable for GOTV!®Vaccine Distribution & Management System Proposal



Appendix E

Proposed Budget for the GOTV!® System

Section	Budget	Responsibility
Product Development	$ 50 Million	Project Manager Principal PHO Core Informaticists
Implementation	$ 400 Million	State/Local PHO Mobile Technical Staff Implementation Specialists Clinical Staff
Training	$ 300 Million	Training Staff Clinical Staff
Evaluation and Monitoring	$ 400 Million	National/State/Local PHOs Mobile Technical Staff Clinical Staff
Overhead	$ 50 Million	Legal and Regulatory
Total	**$ 1.2 Billion**	

GOTV!®

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COVID-19 Vaccine Distribution & Management System

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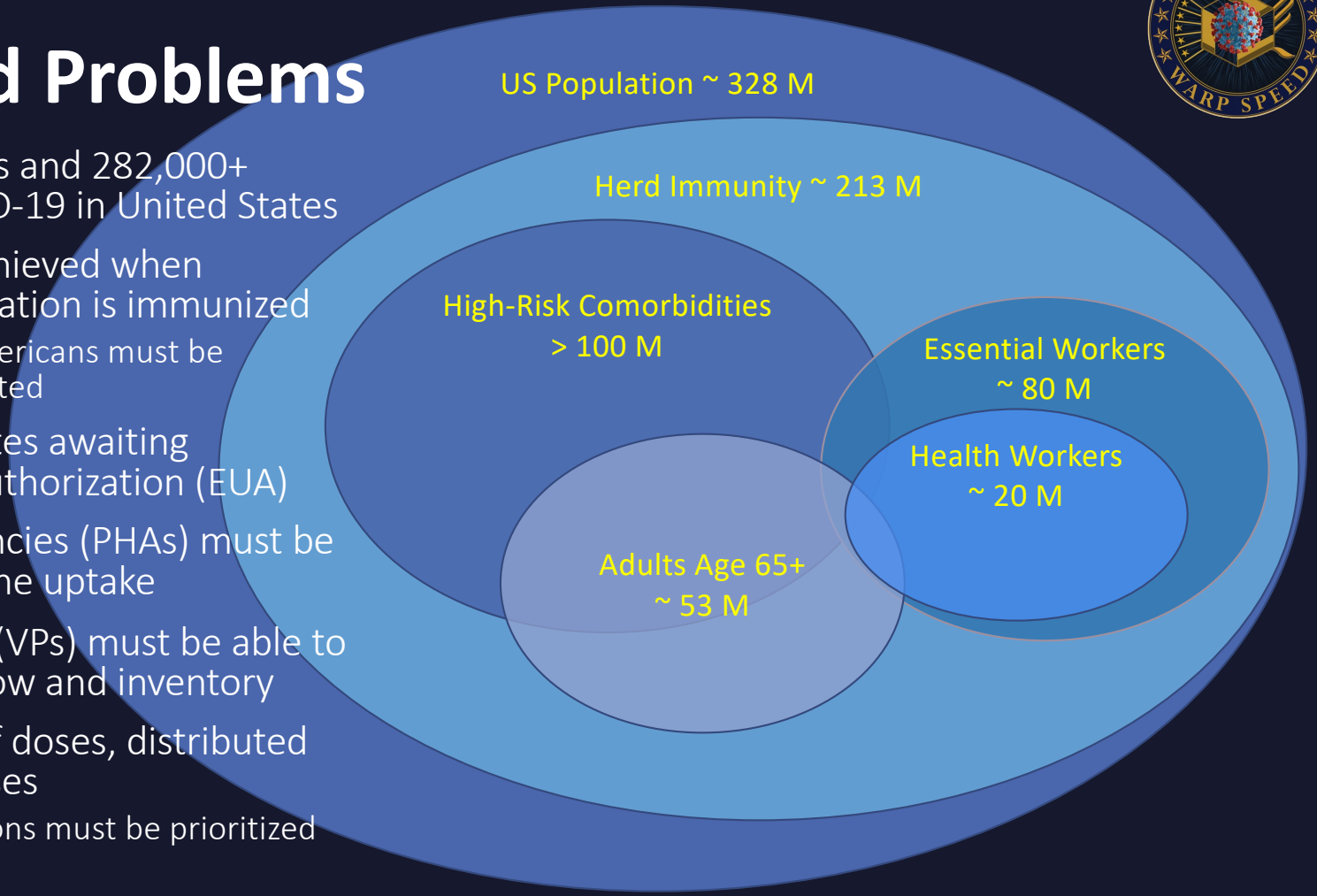
Needs and Problems

- 14.7+ Million cases and 282,000+ deaths from COVID-19 in United States
- Herd Immunity achieved when ~60-70% of population is immunized
  - 213+ Million Americans must be vaccinated/infected
- 2 Vaccine candidates awaiting Emergency Use Authorization (EUA)
- Public Health Agencies (PHAs) must be able to track vaccine uptake
- Vaccine Providers (VPs) must be able to manage patient flow and inventory
- Limited number of doses, distributed over multiple phases
  - Critical Populations must be prioritized



Goals and Objectives

- Goal: To bring an end to the COVID-19 Pandemic by giving VPs and PHAs access to a **centralized immunization dashboard**, GOTV!®, to manage:
  - Vaccine Distribution
  - Patient Flow
  - Inventory Control
- Objective 1: Increase the # of patients and VPs registered with GOTV
- Objective 2: Use GOTV!® to prioritize critical populations and administer vaccine doses
- Objective 3: Use GOTV!® for all documentation, reporting, data capture and storage requirements
- Objective 4: Use GOTV!® for all inventory management

Vaccine Distribution Timeline

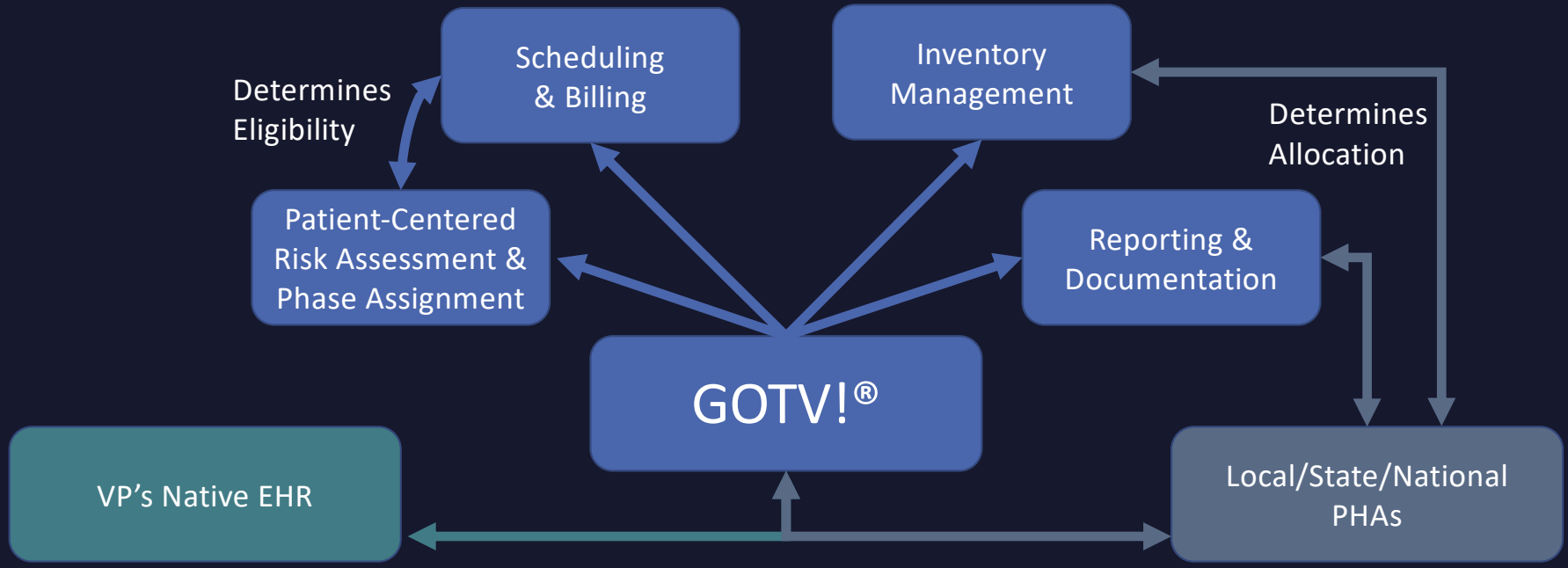
Phase 1
- 1a: Health Workers
- 1b: Essential Workers
- 1c: High Risk Patients

Phase 2
- Critical Populations
- General Public

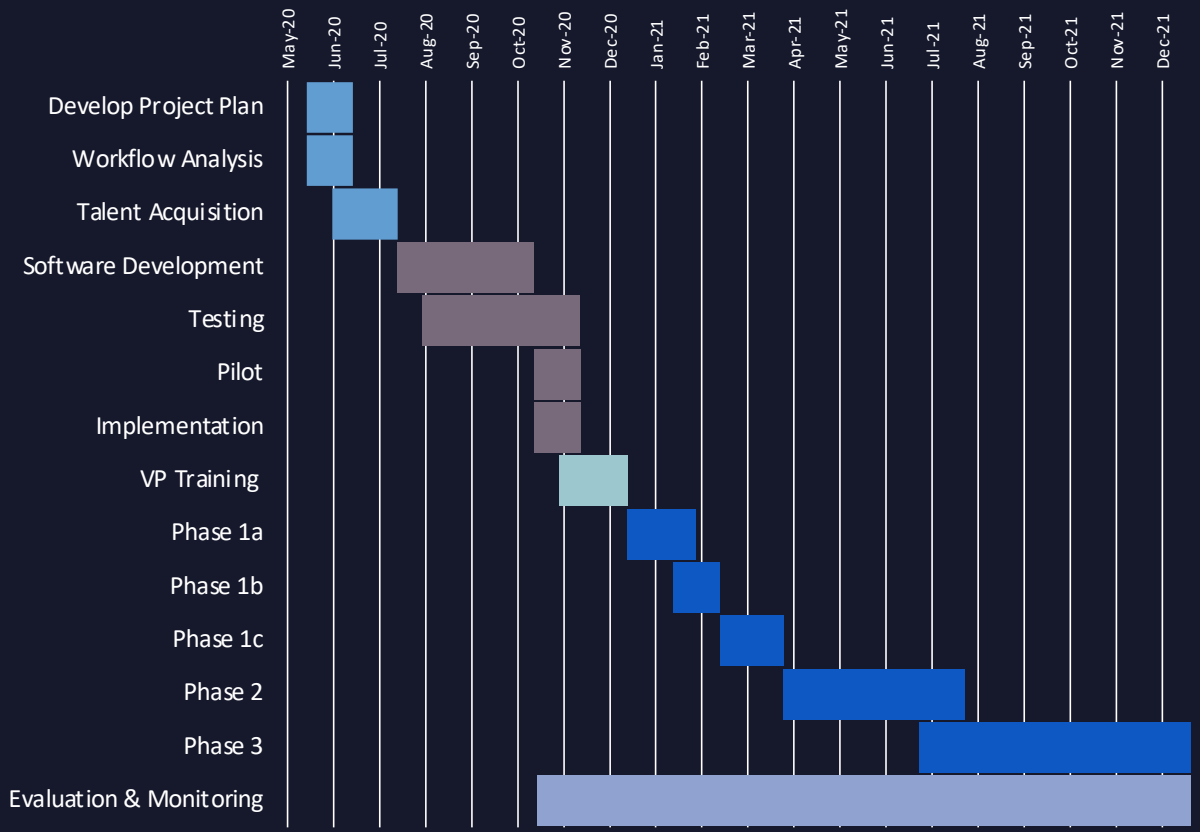
Phase 3
- General Public

Procedures and Scope

GOTV!® is a standalone Vaccine Distribution Management System that aims to **streamline** COVID-19 vaccine delivery for VPs and PHAs, nationwide.



Timetable and Budget



Item	Budget
Software Development	$ 50 M
Implementation	$ 400 M
Training	$ 300 M
Evaluation & Troubleshooting	$ 400 M
Overhead	$ 50 M
TOTAL	**$ 1.2 B**

Evaluation and Call to Action

GOTV!® Metrics for Success:

1. >95% of immunization encounters scheduled and documented using GOTV!®
2. Maintain minimum inventory at 95% of VPs
3. Register and assign 70% of Population to the appropriate phase of distribution (Before the beginning of Phase 2)
4. Immunize 60% of all patients assigned to a given phase (Before beginning the subsequent phase)
5. Ensure 90% of patients requiring multiple vaccine doses receive them in a timely matter

The end of the pandemic is in sight.
As long as our vaccine distribution goes right

For Herd Immunity **without** the Tragedy
Make sure to log into GOTV.

Let's be done with COVID-19.
Get out the Vaccine!

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