Using Clinical Decision Support to Facilitate Equitable Allocation of the COVID-19 Vaccine

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Executive Summary

Mass vaccination against the SARS-CoV-2 virus will prove to be an incredibly challenging logistical undertaking, requiring vaccine delivery organizations to prioritize patients based on their COVID-related risk while managing patient flow. Given anticipated shortages in the vaccine at the earliest phases of vaccine distribution, domestic and international public health agencies have recommended a phased distribution of the COVID-19 vaccine to prioritize high-risk patients in the earliest phases of vaccine distribution. In October 2020, the National Academies of Science, Engineering, and Medicine released the *Framework for Equitable Allocation of the COVID-19 Vaccine,* which organizes patients into four main phases based on a patient's occupation, age, living situation, and comorbidities. This complex algorithm of clinical and socioeconomic risk-determination factors can best be facilitated by Clinical Decision Support (CDS) technology that aims to streamline a patient's phase assignment, eligibility determination, and immunization-appointment scheduling while upholding the principle of equitable allocation of the COVID-19 vaccine. This CDS intervention will be developed and implemented in a community pharmacy over approximately five months, followed by six to eight months of evaluation and monitoring, through the entire mass vaccination campaign. Given the timetable, scope, and complexity of the project, this intervention has been budgeted $1.4 Million, to cover the various stages of software development, public outreach, training, and extra staffing.

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Global COVID-19 infection rates set new records every day, and the United States currently stands alone among developed nations, boasting over 17 million cases (Johns Hopkins University, 2020). As our health care system struggles to cope with the constant influx of patients, media outlets continue to project this beacon of herd immunity—the apparent endpoint of the global pandemic—when "enough people become immune to the disease that the spread of the virus from person to person becomes unlikely." (Booker, 2020) Infectious disease experts from the World Health Organization (WHO, 2020) anticipate that approximately 65-70% of the population would have to become immune to COVID-19 to achieve herd immunity, which according to Fiore (2020) means that over 213 million Americans would have to gain immunity, through either vaccination or infection and recovery. As the virus continues to claim lives and livelihoods, every day, the only solution to end this pandemic is to administer an efficient and equitable mass vaccination campaign that aims to prioritize and protect the most vulnerable members in the community.

COVID-19 Vaccine Supply Shortages

The U.S. Food and Drug Administration (FDA, 2020) issued the first Emergency Use Authorization (EUA) for a vaccine candidate against the Novel Coronavirus on December 11, 2020, with a second EUA expected before the end of the month (Hensley, 2020). Once distribution began on December 14, 2020, the Centers for Disease Control and Prevention (CDC, 2020a) tabulated that each state and federal jurisdiction would receive enough vaccine doses to completely immunize a total of approximately 2.9 million Americans. The CDC's Advisory Committee on Immunization Practices (ACIP) notes that "even if one or more vaccine candidates receive authorization for emergency use, demand for COVID-19 vaccine is expected to exceed supply during the first months of the national vaccination program." (Dooling et al., 2020 p. 1857)

As vaccine manufacturers and the appropriate regulatory bodies work together to increase supply, Vaccine Delivery Organizations (VDOs) and local and state Public Health Agencies (PHAs) will be required to prioritize vaccine recipients based on their individual risk of infection or severe COVID-related illness.

Equitable Allocation

While the majority of COVID-19 cases range from asymptomatic to mild (CDC, 2020b), the plurality of patients who experience serious illness must be prioritized in vaccine distribution.

Critical Populations

Critical Populations, identified by the CDC (2020c) for having specific clinical or socioeconomic risk factors include older adults, patients with specific comorbidities, those in crowded living situations, essential workers, and specifically healthcare workers, must be prioritized during the vaccine distribution process.

Comorbidities. The CDC (2020d) has indicated that certain comorbidities can increase the risk for severe COVID-related infection or death and are designated as either *High-Risk* or *Moderate-Risk.* See Table A1 for a list of *High-Risk* and *Moderate-Risk Comorbidities.*

Age. According to the CDC (2020e), approximately 80% of all COVID-related deaths occur in patients who are over 65 years old, with the risk of severe illness increasing significantly with age.

Healthcare Workers and First Responders. Importantly, the CDC (2020f) has identified *Healthcare Workers and First Responders* as one of the highest-priority *Critical Populations* to receive the vaccine, due to their increased risk of exposure, to protect patients, and to reduce the burden of under-staffing on an already-struggling healthcare system. See Appendix B for a list of all *Healthcare Workers and First Responders.*

Essential Workers. The CDC (2020c) has recognized that *Essential Workers* are at an increased risk of exposure since they are oftentimes unable to practice social distancing in their workplaces. The

Cybersecurity and Infrastructure Security Agency (CISA, 2020) defines *Essential Workers* as those working in one of the sixteen *critical infrastructure sectors*, which are essential to the functioning of the economy and include industries such as the food supply and transportation sectors. See Table C1 for a list of *critical infrastructure sectors.*

High-Risk Living Conditions (*HLRC*): The National Academies for Science, Engineering, and Medicine (NASEM, 2020) has recognized specific housing conditions that increase the risk of exposure due to a lack of social distancing, crowded conditions, or large populations. *HLRC* can range from long-term care facilities to multigenerational homes and homeless shelters; see Table D1 for a list of *HRLC*.

Framework for Equitable Allocation of COVID-19 Vaccine (FEACV)

Given the wide disparities that exist between age groups, health statuses, professions, and living conditions, a vaccine distribution framework that emphasizes is imperative to ensure equitable patient-prioritization. Given the HHS (2020a) notes that each state or jurisdiction will decide how to prioritize vaccine recipients, the CDC (2020c) has listed the *Framework for Equitable Allocation of COVID-19 Vaccine (FEACV)* as one of the approaches to patient prioritization that guides the CDC's decision-making process. The *FEACV*, which was developed by the National Academies of Science, Engineering, and Medicine (NASEM, 2020), at the direction of the CDC and in conjunction with the National Institutes of Health, organizes Americans into four main phases, assigning Critical Populations with the greatest risk of exposure or severe illness at the earlier phases of vaccine distribution. See Figure E1 for an overview of the *FEACV*.

Phase 1a. In this phase, all *Healthcare Workers* and *First Responders* are immunized.

Phase 1b. In this phase, all adults over 65 years old who live in *HRLC*, patients with one or more *High-Risk* comorbidities, and patients with two or more *Moderate-Risk* comorbidities are immunized.

Phase 2. This phase includes all adults over 65 years old, all patients with one or more *Moderate-Risk* comorbidities, anyone in *HRLC*, and high-risk *Essential Workers*.

Phase 3. This phase includes all individuals under 30 years old, and low-risk *Essential Workers*.

Phase 4. This phase includes all remaining individuals.

Clinical Decision Support to Facilitate Equitable Allocation

Previous studies have shown that patient-centered algorithms are useful clinical decision support (CDS) tools that can assist in risk assessment or diagnosing. Kunhimangalam et al. (2014) present a similar CDS intervention that uses clinical information and a fine-tuned algorithm to accurately diagnose 93.27% of peripheral neuropathies when not in the presence of an expert clinician. Diagnostic tools like these are incredibly beneficial since they convey pertinent information, in an easy-to-follow format, to improve patient outcomes and increase efficiency. Accordingly, a patient-centered algorithm that aims to extract relevant diagnostic information on a patient's health and socioeconomic status would serve as a useful risk-assessment tool, to ensure efficient vaccine-recipient prioritization.

Communities Pharmacies as Vaccine Delivery Organizations

Anticipating the imminent EUAs for many of the COVID-19 Vaccine candidates, the HHS (2020b) announced that it would grant emergency COVID-19 Vaccine-prescribing authority to registered pharmacists nationwide, identifying them as an instrumental part of the impending mass vaccination campaign. According to the National Association of Chain Drug Stores (NACDS, 2020), Pharmacies are expected to serve as convenient immunization clinics, as they did during the Swine Flu Pandemic of 2009-2010, in which approximately one-quarter of all mass influenza-vaccinations occurred in community pharmacies.

Aside from qualified staff, many pharmacies already possess much of the necessary infrastructure to conduct a successful mass vaccination campaign: including robust, corporate supply chains able to consistently procure supplies, along with adequate refrigeration systems that can ensure that vaccine ampules remain at the ideal temperature, during storage. Pharmacy management systems can contend with the record-keeping requirements of a mass vaccination campaign. Most importantly,

community pharmacies are generally located in central locations that can serve as convenient venues to provide a large number of vaccines to a large number of patients. (Amburgh et al., 2001; NACDS, 2020; Poulose, et al., 2015).

For many of the reasons listed above, the CDC (2020g) has identified Pharmacies as important VDOs and recommends that specific infection control mechanisms, such as immunization appointments, are implemented to facilitate social distancing and improve efficiency. A patient-centered, risk-determination algorithm would aim to reduce the cognitive and administrative burden placed on VDO staff by decreasing the number of assessments and volume of paperwork that clinicians would otherwise have to complete. By streamlining the scheduling process, VDOs would be able to stratify, schedule, and immunize a larger volume of patients very efficiently.

Proposed Method

While the *FEACV* provides a useful framework to prioritize patients, VDOs like a community pharmacy would still be responsible to determine a patient's *Phase Assignment* and eligibility before scheduling their immunization appointment. Given the complexity of the *FEACV*'s risk-stratification process, an opportunity arises for a CDS intervention designed to accurately assign patients to the correct phase of vaccine distribution. A patient-centered algorithm would aim to reduce the cognitive and administrative burden placed on pharmacy staff by allowing patients to complete the screening and scheduling process, improving patient flow and efficiency.

Goal, Objectives, and Approach

Goal

The goal of this intervention is to facilitate mass immunization against SARS-CoV-2, in a single community pharmacy, by using a patient-centered questionnaire/algorithm that promotes equitable allocation of the vaccine.

Objectives

Objective 1. Increase the number of patients being vaccinated against the novel coronavirus.

Objective 2. Promote equitable allocation of the COVID-19 vaccine.

Objective 3. Reduce the administrative and scheduling burden on staff.

Objective 4. Give patients more autonomy over their healthcare.

Approach

Through a community-wide public awareness campaign, patrons at a local pharmacy are educated about the COVID-19 mass vaccination, the importance of equitable allocation, and how to receive their *Phase Assignment.* Patients seeking a COVID-19 vaccine are directed to their Pharmacy's patient portal to schedule an immunization appointment. Patients complete a simple *Risk-Determination Questionnaire* which triggers the *Phase Assignment Algorithm* to determine if a patient is eligible to receive their vaccine at that time. If the patient is eligible, the CDS tool allows the patient to request an appointment, pending staff confirmation. If not, the patient is asked to return at a later time to schedule their appointment.

Clinical Decision Support Rule Integration

According to the Agency for Healthcare Research and Quality, (AHRQ, n.d.) the "CDS Five Rights model" can serve as a useful tool to guide CDS integration projects toward success.

Right Information

The *Risk-Determination Questionnaire* aims to gather data on a patient's COVID-related risk, through a series of highly structured questions and *Risk Factor Verification* steps. When a patient indicates they are in a high-risk occupational group or suffer from comorbid infections, the *Questionnaire* will prompt the patient to submit evidence of the risk factor to ensure the integrity of the *Phase Assignment Algorithm*. See Appendix F for a detailed overview of the *Risk-Determination Questionnaire* and *Risk Factor Verification* process.

The structured responses to the *Risk-Determination Questionnaire* are used to determine a patient's *Phase Assignment*, via the algorithm presented in Figure G1. A patient's *Eligibility* is determined by comparing their *Phase Assignment* to the current phase of vaccine distribution, as determined by local or state PHAs.

Right Time and Right Person

Understanding the role of the patient and pharmacy staff in the context of the workflow is imperative to designing a successful CDS intervention. In 2018, the CDC released a general overview of vaccine administration for clinicians, detailing the various steps from scheduling the appointment, checking the patient in, reviewing their immunization history and screening for contraindications, providing patient education, preparing and administering the vaccine, and completing any documentation or reporting. This CDS intervention would be triggered during the appointment-scheduling stage of the immunization process and would allow eligible patients to request an immunization appointment, pending *Risk Factor Verification,* and confirmation. See Appendix H for a detailed overview of the CDS intervention, in the context of the workflow. Once the patient's appointment request is approved, the patient will receive a confirmation email, which they use to check-in on the day of their appointment. Once checked in, the vaccination process will proceed, as per the CDC-recommended guidelines, listed above.

Right Channel and Right Format

Due to the high degree of patient involvement in this CDS intervention, a straightforward user interface is paramount. The *Risk-Determination Questionnaire* must be designed to only allow for structured data entry and builds *Risk Factor Verification* into the questionnaire. Since pictures will be used to verify certain risk factors, the questionnaire must be user-friendly on both a desktop and mobile platform, to facilitate picture-upload. The Smart Form must be dynamic and interactive, using a patient's

response to prompt the appropriate next step, all while guiding the patient through the *Questionnaire.* See Figure I1 to see a sample question.

Implementation and Management

The *COVID-19 Risk-Determination Questionnaire and Phase Assignment Algorithm* CDS intervention would be implemented alongside the vaccine development and distribution process.

Key Stakeholders

Key stakeholders in this project can be divided into three main teams: the *Technical Team*, the *Vaccination Team*, and the *Public Outreach Team.* The *Technical Team* includes the *Informatics Staff* who will be responsible for designing and maintaining the CDS rule, along with *Training Staff* who develop modules and train the Pharmacy Staff. The *Vaccination Team* is a designated, rotating team of two Pharmacists and three Pharmacy Technicians who will be solely responsible for managing all aspects of the vaccination process, including *Risk-Factor Verification,* vaccine administration, and managing patient flow, during their shift. The *Public Outreach Team* is composed of various *Public Relations Specialists* who manage all aspects of community and provider outreach. See Table J1 for an overview of each stakeholder's responsibilities and hourly wage estimates, using average salaries provided by the U.S. Bureau for Labor Statistics (BLS, 2020a; BLS, 2020b; BLS, 2020c; BLS, 2020d; BLS, 2020e).

Implementation Timetable

The first three stages of this process, which include *Planning*, *Development,* and *Training,* should be completed in anticipation of vaccine authorization, in mid-December 2020. The final two stages, deployment and evaluation, begin once vaccine delivery commences, see Figure K1.

Planning – 2 Months

The *Planning* stage would commence in Mid-August 2020 and involves the various stages of project planning, such as recruiting technical and pharmacy staff, performing workflow analyses, standardizing data, and engaging both stakeholders and the public. During this stage, a team of five

informaticists is recruited to help develop the project plan and eventually build and monitor the CDS rule. Any data conversion and standardization would have to occur during this time, to ensure that a patient's preexisting clinical data is accounted for. Also, public outreach coordinators will be designated to manage stakeholder outreach and the necessary public awareness campaign.

Development – 1.5 Months

During this phase, which would begin in Mid-October 2020, informatics staff would be responsible for building the *Risk Determination Questionnaire* and *Phase Assignment Algorithm*. Once integrated into the pharmacy management system, technical staff would be responsible for various types of testing and would have to ensure operational readiness, including hardware/software testing, and especially usability testing from both the pharmacy's and patient's perspective. Importantly, technical staff would need to ensure that the CDS rule integrates with the ePrescription system flawlessly and that the verification process can be completed efficiently.

Training – 1.5 Months

The *Training* stage would commence in November 2020 and would be comprised of one month of planning, followed by two weeks of intensive training (before deployment). While developing the training program, informatics and training staff will produce online modules to teach staff how to use and troubleshoot the CDS intervention. At the beginning of December 2020, staff would begin completing online modules, either on or off-site, which would be followed by a mock-immunization event during the week proceeding Vaccine authorization. During this time, on-site technical support will be made available to assist in the training and deployment processes.

Deployment – 1 Month

In the week preceding vaccine distribution, patients begin scheduling immunization appointments. Once vaccines are delivered, in mid-December 2020, the *Deployment* stage begins and will last through the end of Phase 1a. During this time, the pharmacy will need to staff a *Vaccination*

Team comprised of at least 2 extra Pharmacists and 3 Pharmacy Technicians, in every shift, to focus on the vaccine administration process. Given that vaccine delivery will begin within a few days of authorization (HHS, 2020a), the Pharmacy will have to contend with a "Big-Bang" implementation, and adequate technical and pharmacy support staff will be necessary.

Evaluation – 6 to 8 months

At the end of Phase 1a, which is expected to last approximately one month, the team will transition into the *Evaluation* phase, to monitor the tool's effectiveness and optimize the intervention to improve efficiency and usability for patients and staff. At this time, the pharmacy can reduce its *Vaccination Team* to 1 Pharmacist and 2 Pharmacy Technicians, since by this time, staff are expected to be more comfortable working with the CDS tool. The *Evaluation* phase will last through the end of Phase 4, to ensure the intervention facilitates the vaccine distribution process.

Budgetary Considerations

The entire CDS tool development is budgeted $1.02 million, based on the estimated costs for each stage of the implementation process. The *Planning* stage is budgeted $75,000, to complete 250 hours of workflow analysis, planning, and data conversion. The *Community Outreach* stage is budgeted $ 200,000, based on 6 months of public outreach and an estimated $100,000 in advertising costs, as determined by Kansagra et al.'s (2012) cost-analysis of one of New York's H1N1 mass vaccination campaigns. The CDS *Development* stage is budgeted $100,000 for an anticipated 300 hours of building and testing. The *Training* stage is budgeted $45,000, to develop online modules and provide a week's worth of training for all Pharmacy Staff (at half of their hourly rate). The *Deployment* stage is budgeted $200,000 to cover on-site technical support and extra staffing needs for the *Vaccination Team.* The *Evaluation* Stage is further budgeted $400,000 to cover six months of monitoring and extra staffing at the pharmacy.

Evaluation and Monitoring

In the pursuit of equitable allocation, the *Risk-Determination Questionnaire and Phase Assignment Algorithm* must be evaluated on specific metrics, based on the objectives of the tool.

Objective-based Metrics

Metric 1

To increase vaccination rates, the first metric is met if the pharmacy immunizes 60% of all patients assigned to a given distribution phase before the start of the subsequent phase.

Metric 2

To promote equitable allocation, the second metric is met when *Risk-Determination Questionnaires* and *Phase Assignments* are completed for 80% of patients.

Metric 3

To reduce the administrative burden on staff, the third metric is met if the ratio of denied appointment requests to approved appointment requests is kept below 10%.

Metric 4

To give patients more autonomy over their healthcare, the fourth metric is met if patients' abandonment rate while completing the Risk-Determination Questionnaire is kept below 10%.

Evaluation Process

Following the first phase of vaccine distribution, the team will enter the *Evaluation* stage of the implementation process, where the CDS rule will be evaluated for its usability, efficiency, along with patient and staff satisfaction. Usability and efficiency metrics must be evaluated frequently, since the tool will play such a fundamental role in the vaccine distribution process.

As such, the *Informatics Staff* will be responsible for monitoring the tool's success, on a biweekly basis, with large-scale evaluations scheduled at the end of each phase of vaccine distribution. Ideally, the majority of inefficiencies should be rectifie, before the vaccine becomes available to the public.

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Appendix A

Table A1

High-Risk and Moderate-Risk Comorbidities

High-Risk Comorbidities	*Moderate-Risk* Comorbidities
Underlying conditions that increase the risk for severe COVID-related Infection	Underlying conditions that *might* increase the risk for severe COVID-related Infection

• 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: Table A1 lists High-Risk and Moderate-Risk Comorbidities as delineated by the CDC (2020d).

Appendix B

List of Health Workers and First Responders

The CDC (2020f) lists *Healthcare Workers and First Responders* as paid or unpaid employees at a variety of healthcare delivery organizations, including:

- Emergency Medical Service Personnel
- Nurses and Nursing Assistants
- Physicians
- Technicians
- Therapists
- Dentists
- Dental Hygienists and Assistants
- Phlebotomists
- Pharmacists
- Students and Trainees
- Contractual Staff
- Dietary/Food Services Staff
- Environment Services Staff
- Administrative Staff (CDC, 2020f)

Appendix C

Table C1

Critical Infrastructure Sectors and other Essential Workers

Essential Worker	
High-Risk Essential Workers	*Low-Risk* Essential Workers
• Commercial Facilities Sector • Emergency Services Sector • Food and Agriculture Sector • Healthcare/Public Health Sector • Transportation Sector • School/Childcare Workers ** • Staff working in *any* HRLC **	• Chemical Sector • Communications Sector • Dams Sector • Defense Industrial Base Sector • Energy Sector • Financial Services Sector • Government Facilities Sector • Information Technology Sector • Nuclear Reactors/Materials/Waste Sector • Sector-Specific Agencies • Water/Wastewater Systems Sector

*Note: Table C1 delineates the 16 Critical Infrastructure Sectors, as delineated by CISA (2020), that are essential to the functioning of the economy. **NASEM (2020, p. 12) further recommends stratifying these Essential Workers based on their risk of exposure and includes School/Childcare Workers and Staff working in HRLC—like prisons or group homes—in the High-Risk category, as well. NASEM notes that this list is not exhaustive and since regional differences must also be accounted for, each jurisdiction must determine which workers are considered low or high-risk.*

Appendix D

Table D1

High Risk Living Conditions (HRLC)

Critical Populations in *HRLC*	
Target Population for CDS	*Non*-Target Population for CDS
Vaccine-Recipients living in: • Congregate Setting • Group Homes • Multigenerational Homes • Homeless Shelters	Vaccine-Recipients living in: • Long-Term Care Facilities • Nursing Homes • Prison Population

Note: Table D1 lists specific HRLC, as defined by NASEM (2020, p. 10-12). Crowded or unstable housing conditions are shown to increase the risk of exposure. While some patients in HRLC might benefit from the convenience of receiving their immunizations at a community pharmacy, others, like those living in long-term care facilities or the prison population would be unable to receive immunizations at the Pharmacy. While the CDC (2020g) has partnered with large retail pharmacies to administer vaccines at long-term care facilities, this is outside of the scope of this CDS intervention.

Appendix E

Figure E1

Framework for Equitable Allocation of COVID-19 Vaccine (FEACV)

Note: The FEACV (NASEM, 2020, p. 10) provides an evidence-based structure for stratifying patients based on COVID-related risk of infection, prioritizing those with the greatest need for vaccination in the earliest stages of vaccine distribution.

Appendix F

Risk-Determination Questionnaire Overview

The *Risk-Determination Questionnaire* aims to gather data on a patient's COVID-related risk, through a series of highly structured questions and *Risk Factor Verification* steps:

1. The *Questionnaire* prompts the patient to enter contact and demographic information, including birthdate, race/ethnicity, and address. Once all information is entered, the patient clicks next.
2. The *Questionnaire* prompts "Are you a *Healthcare Worker*, *First Responder, Essential Worker,* or *School/Childcare Worker;* Yes or No?" (Refer to Appendices B and C for specific occupations.)
    a. If the patient selects "Yes," then they are prompted to select their specific occupation from the checklist that presents
    b. Once the occupation is chosen, the *Employment Verification* step becomes available, where the patient is asked to upload picture evidence to confirm their employment, which can be in the form of a badge, recent paystub or W2 form, or any other document.
3. The *Questionnaire* prompts "Have you been diagnosed with any of the following conditions; Yes or No?" listing *High-Risk* and *Moderate-Risk* Comorbidities (Refer to Appendix A)
    a. If the patient selects "Yes," they are prompted to select their specific comorbidity(ies) from the checklist that appears.
    b. Once their comorbidities are selected, *Provider Verification* becomes available, where the patient can search for and select the clinician managing their condition.
        i. If *Provider Verification* is required, the CDS intervention automatically generates a "Diagnosis Code Request – COVID-19 Vaccine," which is sent to the provider via the existing ePrescription system, similar to how refill requests are processed.

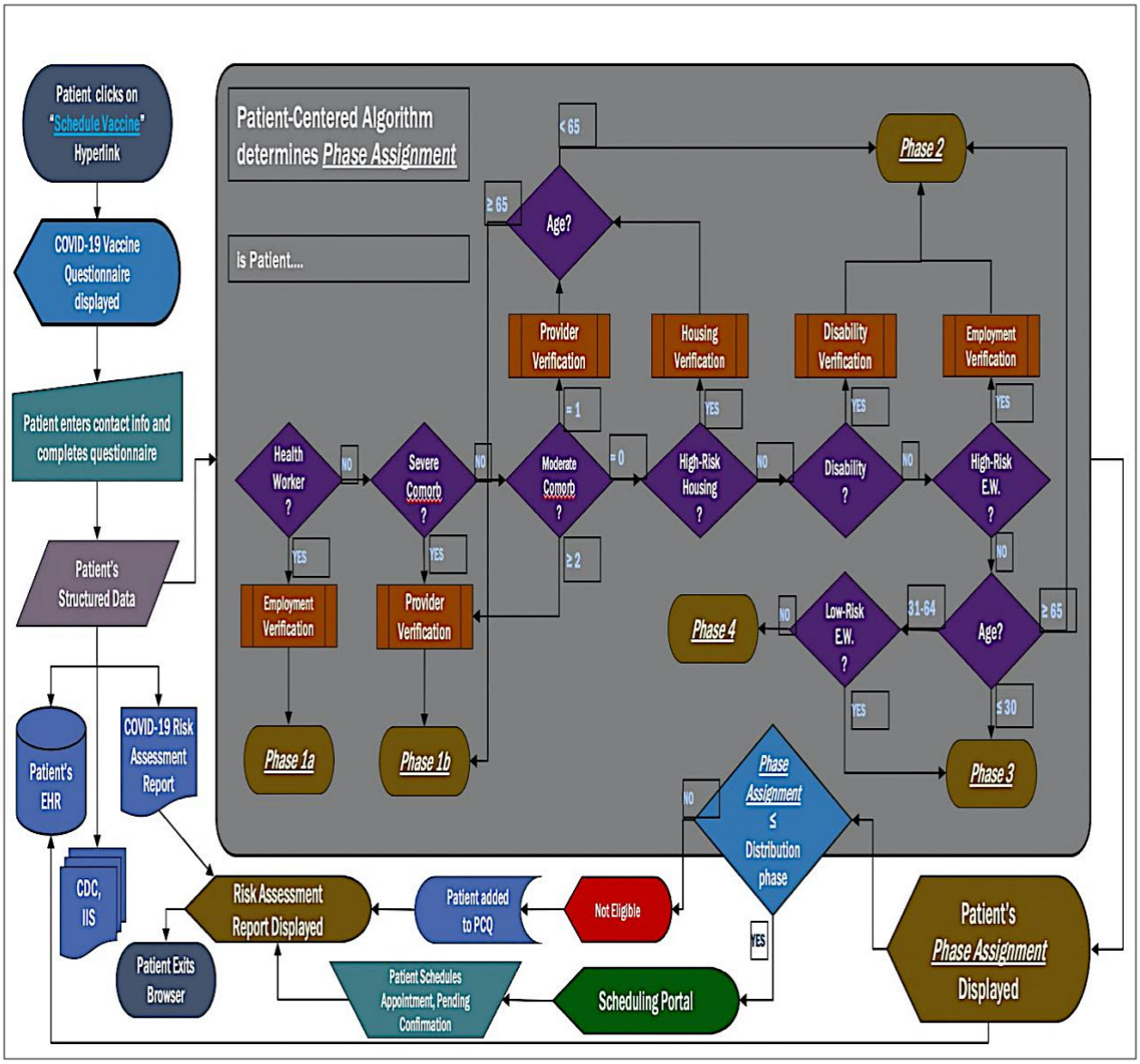
ii. *Provider Verification* is not required if the Pharmacy Management System contains a diagnosis code for one of the previously identified comorbidities.

4. The *Questionnaire* prompts, “Do you have any disabilities; Yes or No.”
    a. If the patient selects “Yes,” they are prompted to complete *Disability Verification*, where the patient is prompted to upload a picture of an official document, like a benefit verification letter, that proves a patient’s disability.
5. The *Questionnaire* prompts, “Do you live in a high-risk living condition; Yes or No.” and lists examples of HRLC, as determined by NASEM (see Appendix C).
    a. If the patient selects “Yes,” they are prompted to select their specific HRLC from the checklist that appears.
    b. Once HRLC is selected, the *Housing Verification* step becomes available, where the patient is prompted to submit their address or other picture evidence of unstable or crowded housing.

Appendix G

Figure G1

Phase Assignment Algorithm



Note: The Phase Assignment Algorithm uses structured data from a patient's responses to the Risk-Determination Questionnaire to determine the patient's Phase Assignment and eligibility to receive a vaccine, based on the current phase of distribution

Appendix H

Detailed Workflow Analysis of the CDS intervention – Right Time and Right Person(s)

This CDS rule is trigged during the Pre-Encounter stage of the vaccination process:

1. Pre-Encounter: Patient: Log-In – The patient logs into their portal and clicks on the Schedule COVID-19 Vaccine Appointment hyperlink, after submitting the appropriate contact information, the CDS intervention is triggered.
2. Pre-Encounter: CDS Intervention: *Risk Determination Questionnaire* and *Phase Assignment Algorithm* – The patient will access the *Risk-Determination Questionnaire* which will gather structured data on the patient's clinical and socioeconomic risk factors. If the patient indicates they are at risk for COVID, *Risk-Factor Verifications* will be prompted to ensure an accurate phase assignment. Using the patient's responses to the questionnaire, the *Phase Assignment Algorithm* determines the appropriate phase to place the patient in and determines if the patient is eligible to receive a vaccine at that time by comparing the patient's *Phase Assignment* to the local phase of vaccine distribution. If the patient is eligible, the appointment scheduling portal opens and allows the patient to request an appointment. If the patient is not eligible, he or she is asked to return at a later time and exits the website. The patient is placed in the appropriate *Phase [#] Patient Care Que* (*PCQ*) within the pharmacy management system, so that pharmacy staff can contact the patient, later.
3. Pre-Encounter: Eligible Patient: Appointment Request – Once in the scheduling portal, the patient must request an appointment, which is then marked as *"Pending Verification."* The patient is added to one of the *Vaccine Verification PCQs* and should be notified of confirmation within 48-72 hours.
4. Pre-Encounter: Pharmacy Staff: Verification– Pharmacy staff are responsible for verifying the validity of a patient's answers and must determine whether a patient's *Risk-Factor Verifications*

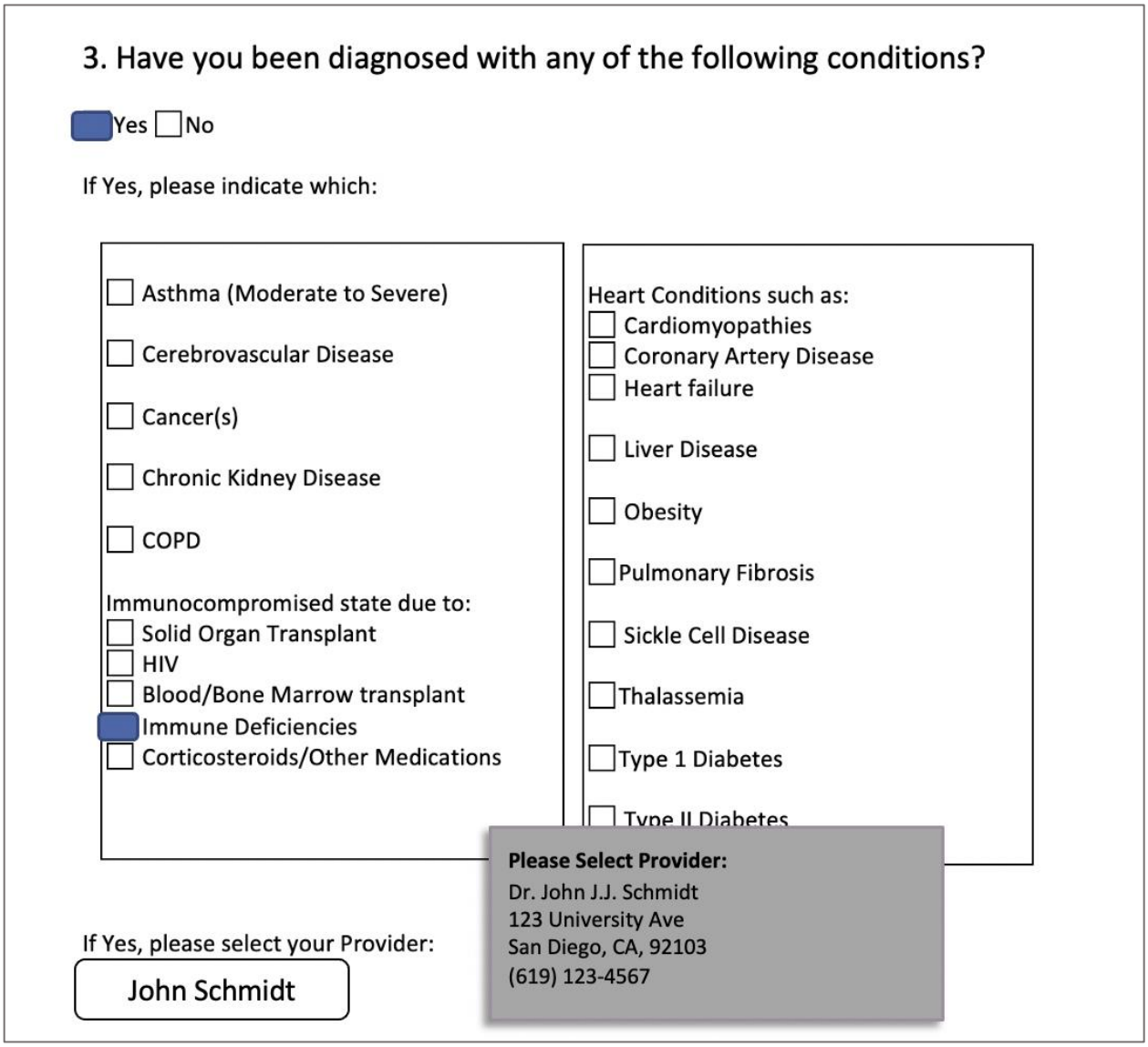
are sufficient to justify immunization during the current phase of vaccine distribution. Pharmacy staff must confirm or deny each appointment request, which can be completed on or off-site since all patient information is collected through the *Questionnaire.* Approved requests result in an automatic confirmation email to the patient, with instructions for their appointment day. Staff are instructed to contact patients directly if they choose to deny a request.

5. Encounter: Pharmacy Staff: Checking in and Vaccination – On appointment day, the patient enters the pharmacy, approaches the vaccination stand, gives their confirmation number, and proceeds with the standard vaccination protocol.

Appendix I

Figure I1

Sample Questionnaire Question



Note: When a patient selects "Yes," as shown in Figure I1, the Questionnaire automatically prompts the patient to select which comorbidity they suffer from, and to indicate which provider they are seeing. The provider's name will auto-populate, if they are contained within the pharmacy's ePrescription system.

Appendix J

Table J1

Key Stakeholders and Team Members

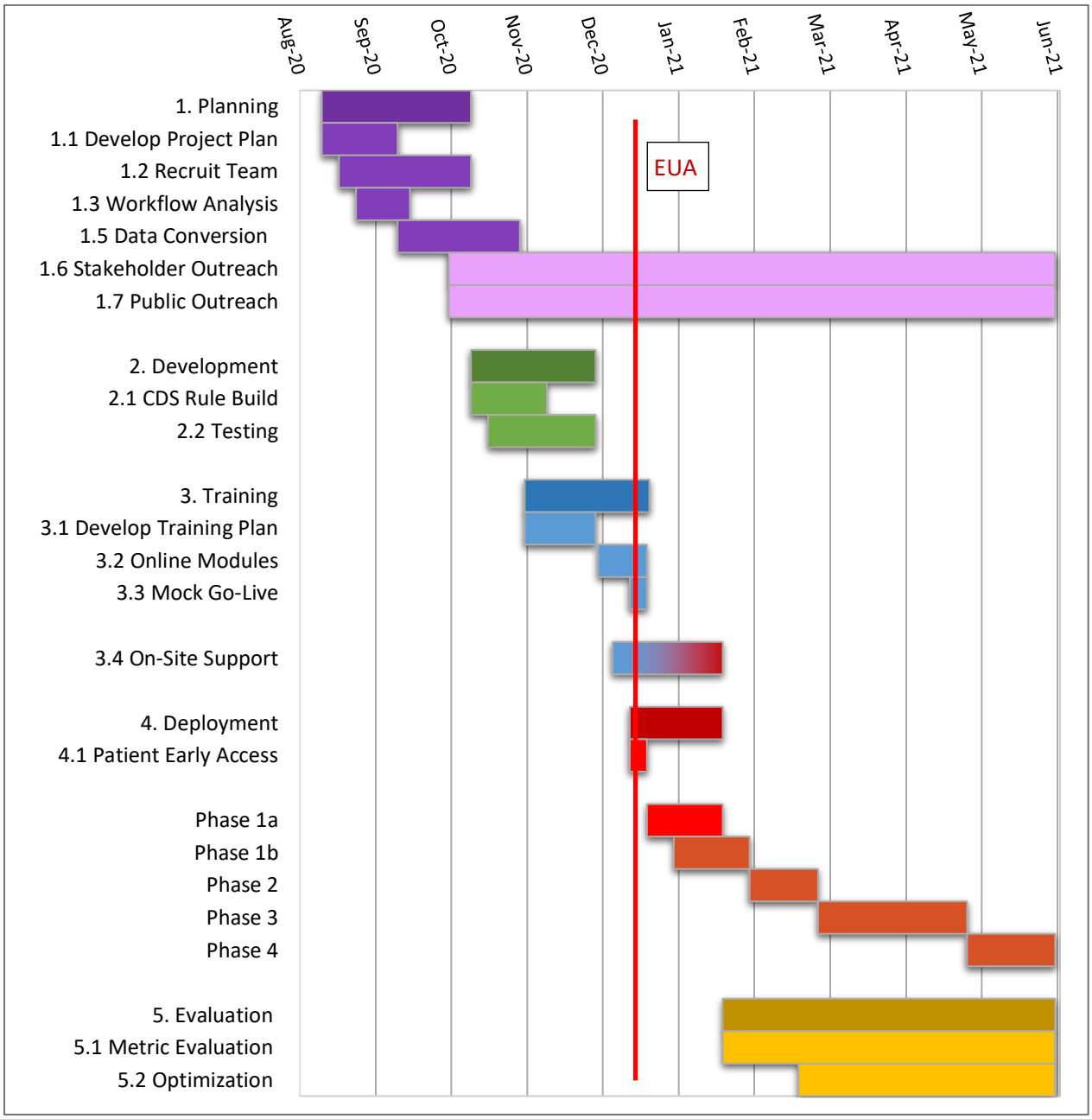
Team	Responsibility	Hourly Wage Estimates
Technical Team		
Project Manager	Liaison between Pharmacy and PHAs Manages Project Plan and Scheduling	--
Informatics Staff (5) • Coders • Analysts	CDS Rule Build and Testing Evaluation and Monitoring Data Analysis On-Site Support	Average: ~$40/hour Allocate: ~ $60/hour Team Total: $300/Hour (BLS, 2020a)
Training Staff (3)	Developing Modules On-Site Support	Average: ~$20/hour Allocate: ~ $35/hour Total: $75/Hour ((BLS, 2020b)
Vaccination Team		
Pharmacist (2)	Vaccine Administration Approving Appointments	Average: ~$60/hour Allocate: ~$90/hour Total: ~$180/hour (BLS, 2020c)
Pharmacy Technicians (4)	Risk-Factor Verification Approving Appointments Assisting with Patient Care	Average: ~$17/hour Allocate: ~$20/hour Total: ~$80/Hour (BLS, 2020d)
Public Outreach Team		
Community Outreach Coordinator	Manages public awareness campaign Point	Average: ~$30/hour Allocate: ~$40/hour Team Total: ~120/hour (BLS, 2020e)
Provider Coordinator (s)	Liaison to local medical clinics and providers	
Media Coordinator(s)	Liaison to local media	
Phone-banking Staff [Volunteer]	Responsible for raising awareness Provide some technical support	---

Note: Table J1 lists responsibilities and estimated hourly wages for each stakeholder.

Appendix K

Figure K1

Timetable for CDS Intervention Implementation



Note: Figure K1 shows a Gantt Chart detailing the implementation timeline, The Phase Assignment CDS intervention will be implemented in five stages beginning in August 2020,, in which Planning (purple), Development (green), Training (blue), Deployment (red), and Evaluation (yellow), until June 2021..

Appendix L

Table L1

Budgetary Considerations

Item	Expense	Justification
Planning	$ 75,000	Based on *Informatics Staff* Personnel Costs 250 working hours @ total hourly cost of $300 • 50 hrs of Planning • 100 hrs of Workflow Analysis • 100 hrs of Data Conversion
Community Outreach	$ 200,000	Based on Advertising and *Public Outreach* Personnel Costs: • 800 working hrs @ total hourly cost of $ 120 • Approx $ 100,000 in Advertising Costs (Kansagra et al., 2012)
CDS Development	$ 100,000	Based on *Informatics Staff* personnel costs 300 working hours@ total hourly cost of $ 300 • 100 hrs of CDS Rule Build • 200 hrs of Testing
Training Stage	$ 45,0000	Based on personnel costs for *Training Staff* and all Pharmacy Staff • *Training Staff*: 320 hrs @ total hourly cost of $7 5 • Pharmacy Staff: 40 hrs @ total hourly (training) cost of $ 430/hour (assuming 3 Pharmacists and 8 Technicians)
Deployment Stage	$ 200,000	Based on on-site support and extra-personnel costs for *Informatics Staff a*nd *Vaccine Team* • *Informatics Staff*: 360 hrs @ total hourly cost of $ 300 • *Vaccine Team*: 360 hrs @ total hourly cost of $ 260
Evaluation Stage	$ 400,000	Based on monitoring and extra-personnel costs for Reduced** *Informatics Staff a*nd *Vaccine Team* • *Informatics Staff*: 800 hrs @ total hourly cost of $ 200 • *Vaccine Team*: 1600 hrs @ total hourly cost of $ 130 ***Informatics Staff* reduced by 2 members ***Vaccine Team* reduced by 1 Pharmacist and 2 Pharm. Technicians
Total	$ 1.02 M	

Note: Table L1 delineates and justifies the cost for each stage of implementation, totaling $ 1.02 M.

Costs are calculated by multiplying the number of working hours for each team by the total hourly cost.

See Table J1 for more information hour cost

COVID-19 MASS VACCINATION: PATIENT PRIORITIZATION TOOL

JAMES AFSHAR-RITTER

HCIN 552: ELECTRONIC MEDICAL RECORD SYSTEMS

PROF. CINDY REED

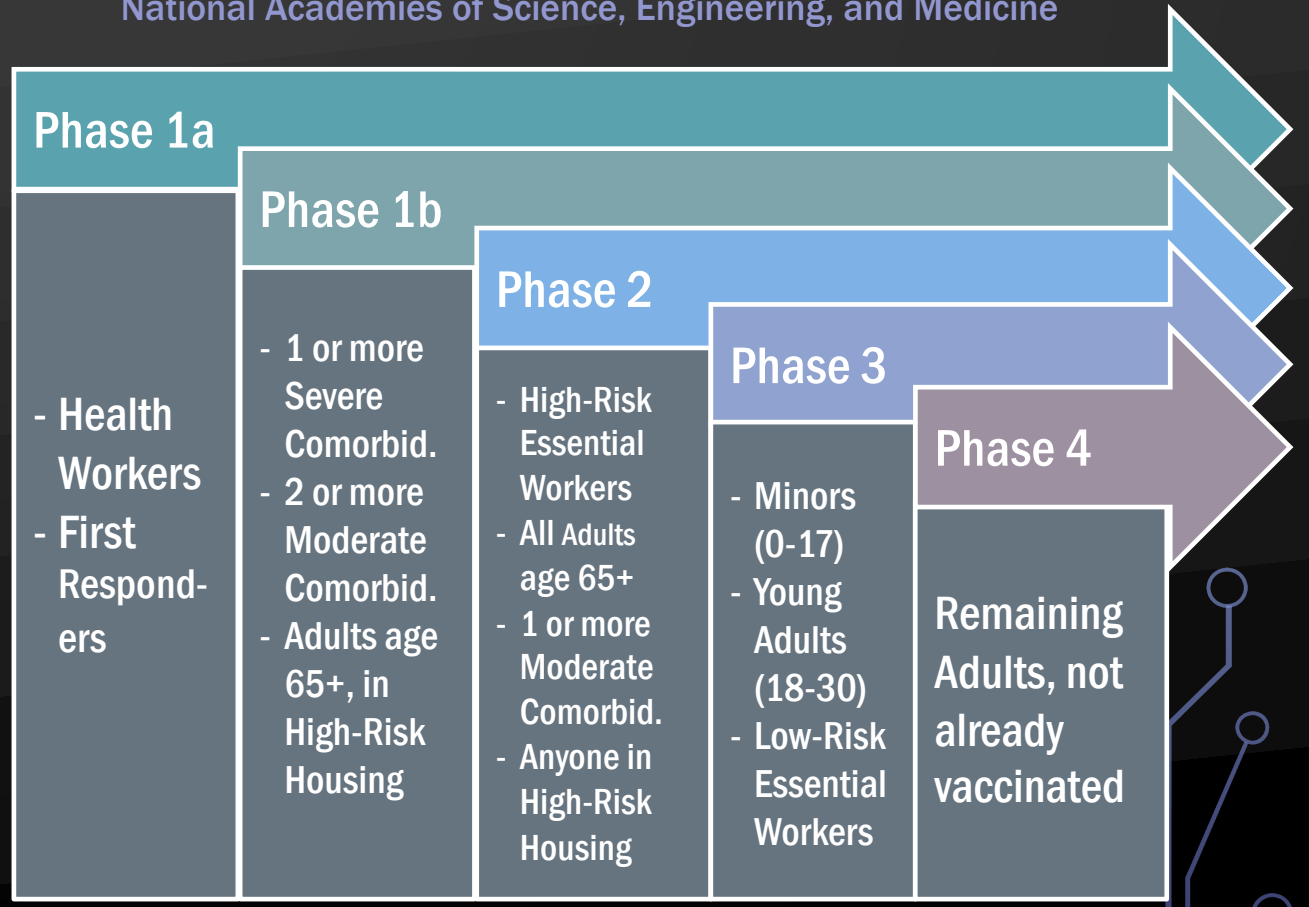
DECEMBER 10, 2020

MASS VACCINATION CAMPAIGN

- FDA issued EUA for Pfizer's vaccine today!
- 15.3M+ Cases and 290K+ Deaths in US
- Mass Vaccination is the only way to end the Pandemic
  - 213M+ Americans need to be immunized to ach
- US Gov't has ordered vaccine doses for 100M people, TBD June 2021 (?)
  - 200M doses, 2 doses/person
    - Pfizer: 100M Doses
    - Moderna: 100M Doses
  - 6M doses available by December 2020
- CDC, WHO, NASEM recommend *Phased* vaccine distribution to prioritize high-risk patients based on:
  - Occupation
  - Housing
  - Underlying Conditions
  - Age

Framework for Equitable Allocation of the COVID-19 Vaccine

National Academies of Science, Engineering, and Medicine



(October 2020)

CDS TO SUPPORT EQUITABLE ALLOCATION

- Problem: How to manage patient flow?
- Complex algorithm of risk factors determines a patient's *Phase Assignment*
  - 8+ Severe Comorbidities (CDC, 2020a)
  - 14+ Moderate Comorbidities (CDC, 2020a)
  - Essential Workers - School/Childcare Workers + 15 "Critical Infrastructure Sectors (Cybersecurity and Infrastructure Security Agency, 2020)
- Goal: Facilitate mass immunization against SARS-CoV-2, in a community pharmacy, by using a patient-centered questionnaire/algorithm that promotes equitable allocation of the vaccine
- Objective 1: Increase the number of patients getting vaccinated
- Objective 2: Promote equitable allocation of the vaccine
- Objective 3: Reduce the administrative/scheduling burden of staff

Serious Comorbidities

- Cancer
- Chronic Kidney Disease
- COPD
- Immunocompromised State from:
  - Solid Organ Transplant
- Obesity
- Serious Heart Conditions
  - Heart failure
  - Coronary Artery Disease
  - Cardiomyopathies
- Sickle Cell Disease
- Type 2 Diabetes

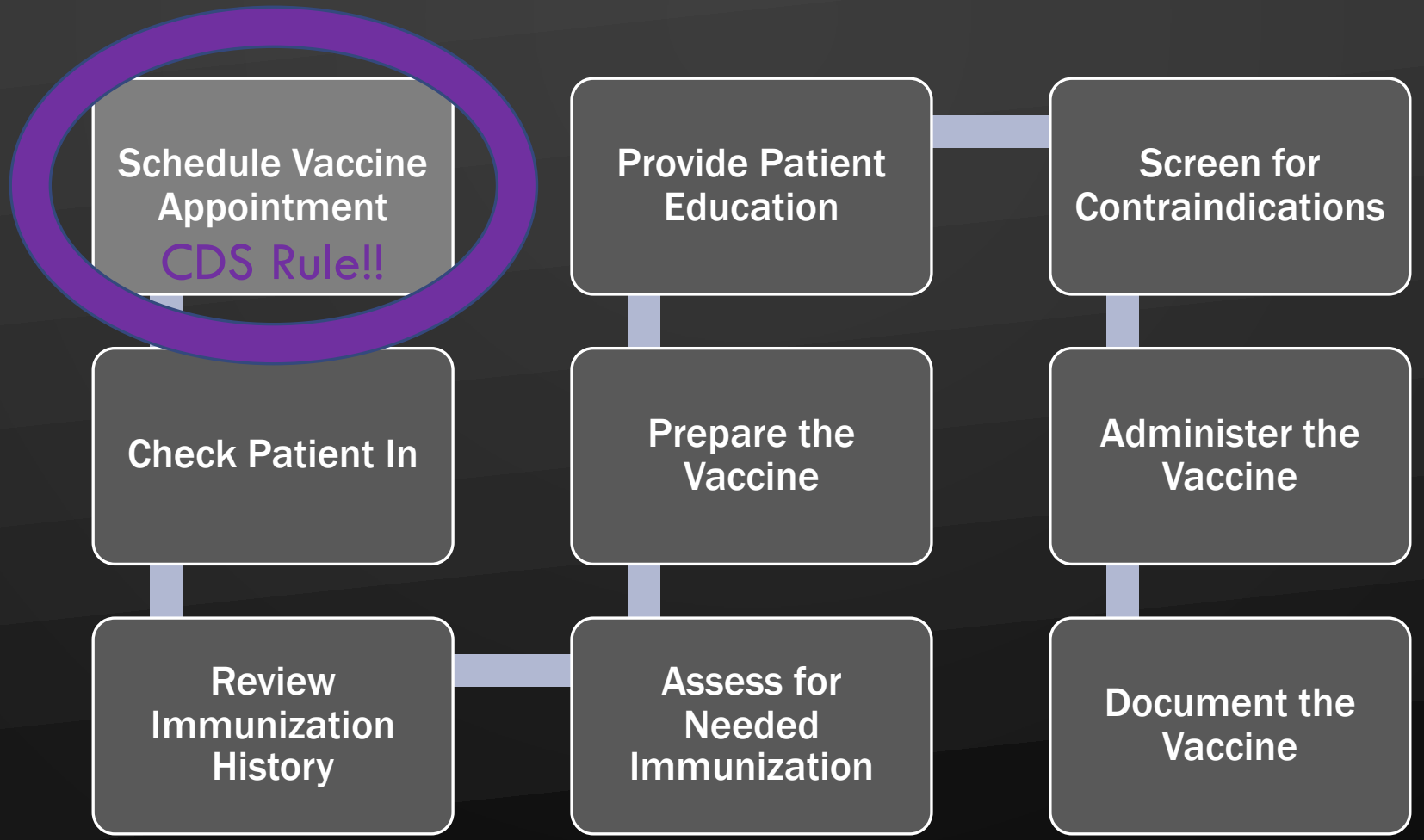
Moderate Comorbidities

- Asthma (moderate to severe)
- 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

Critical Infrastructure Sectors

- Childcare/Education
- Chemical Commercial Facilities
- Communications r
- Critical Manufacturing
- Dams
- Defense Industrial Base
- Emergency Services
- Energy
- Financial Services
- Food and Agriculture
- Government Facilities
- Information Technology
- Nuclear Reactors, Materials, and Waste
- Transportation Systems
- Water and Wastewater Systems

CURRENT AND PROPOSED WORKFLOWS



CURRENT AND PROPOSED WORKFLOWS

Pre-Encounter: Patient

- Log into Patient Portal
- "Schedule Vaccine Appointment"
- Terms and conditions
- Enters contact information
- Risk-Determination Questionnaire
  - Verifications, as prompted:
    - Provider Verification for Comorbidities
    - Employment Verification for Essential Workers
    - Disability Verification
    - High-Risk Housing Verification

CDS: Phase Assignment Algorithm

- Use Questionnaire to determine patient's *Phase Assignment (PA #)*
- Determine eligibility by checking if Patient's *PA #* corresponds with local vaccine distribution phase
- If patient is eligible, open appointment scheduling portal
- If patient is *not* eligible, prompt error message and add to Rx PCQ.

Pre-Encounter: Patient Appointment Request

- Patient Schedules Vaccination Appointment
- Appointment Status is marked as "Pending Verification"
- Patient will be notified of confirmation within 48 hours of request.
- Patient/Responses added to "Vaccine Verification PCQ"

Pre-Encounter: Rx Staff Verification

- Rx staff responsible for verifying validity of answers
  - PCQ lists for each verification type
- Provider Verifications submitted automatically through eRx system
- Employment, Disability and Housing Verifications completed on/off site.

Pre-Encounter: Rx Staff Confirmation

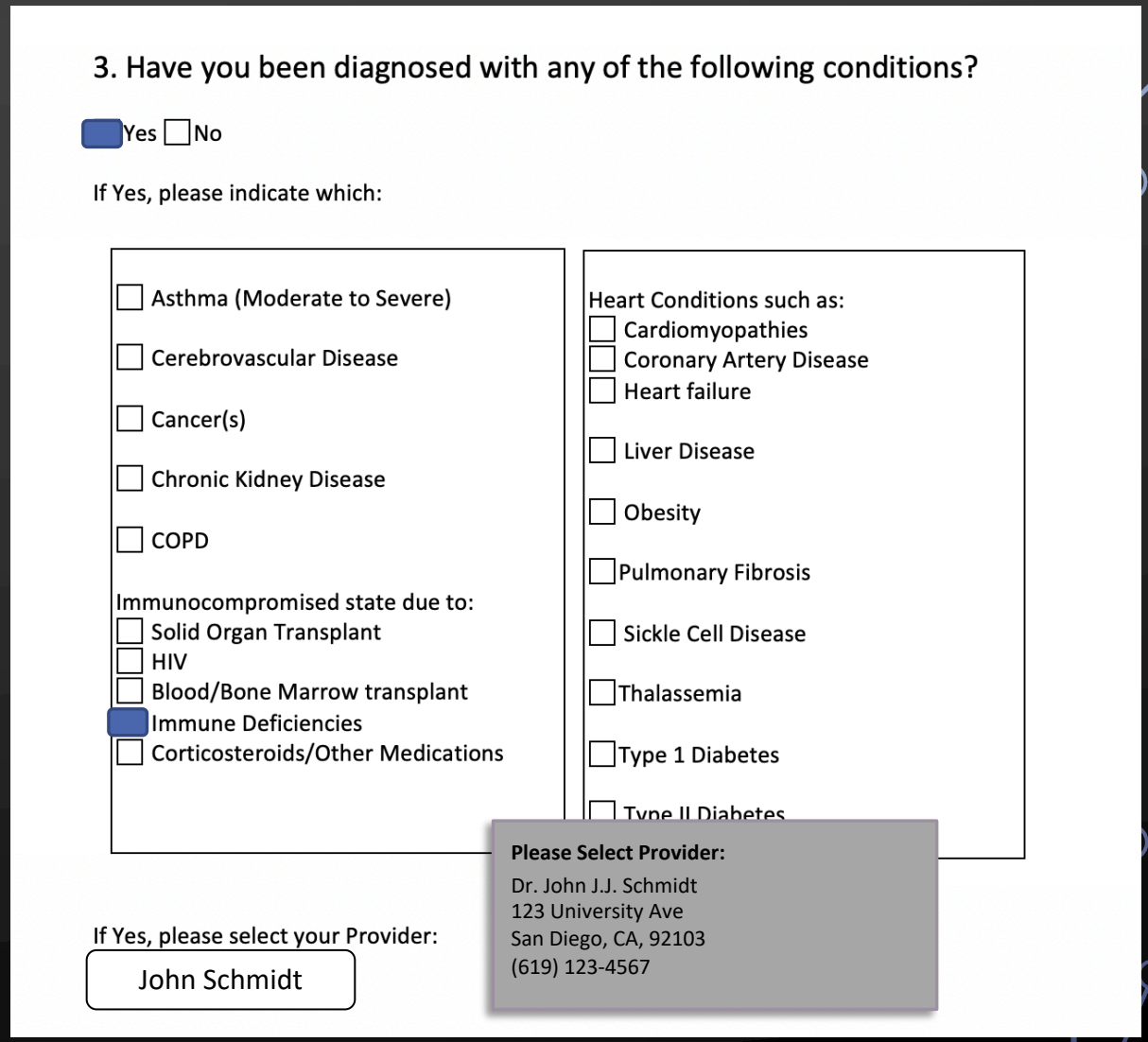
- Rx Staff either Approve or Deny appointment requests
  - Approved requests: automatically generate confirmation email
    - Vaccine ordered automatically
  - Denied Request: added to PCQ, Rx Staff should contact patients directly

Encounter: Rx Staff Vaccination

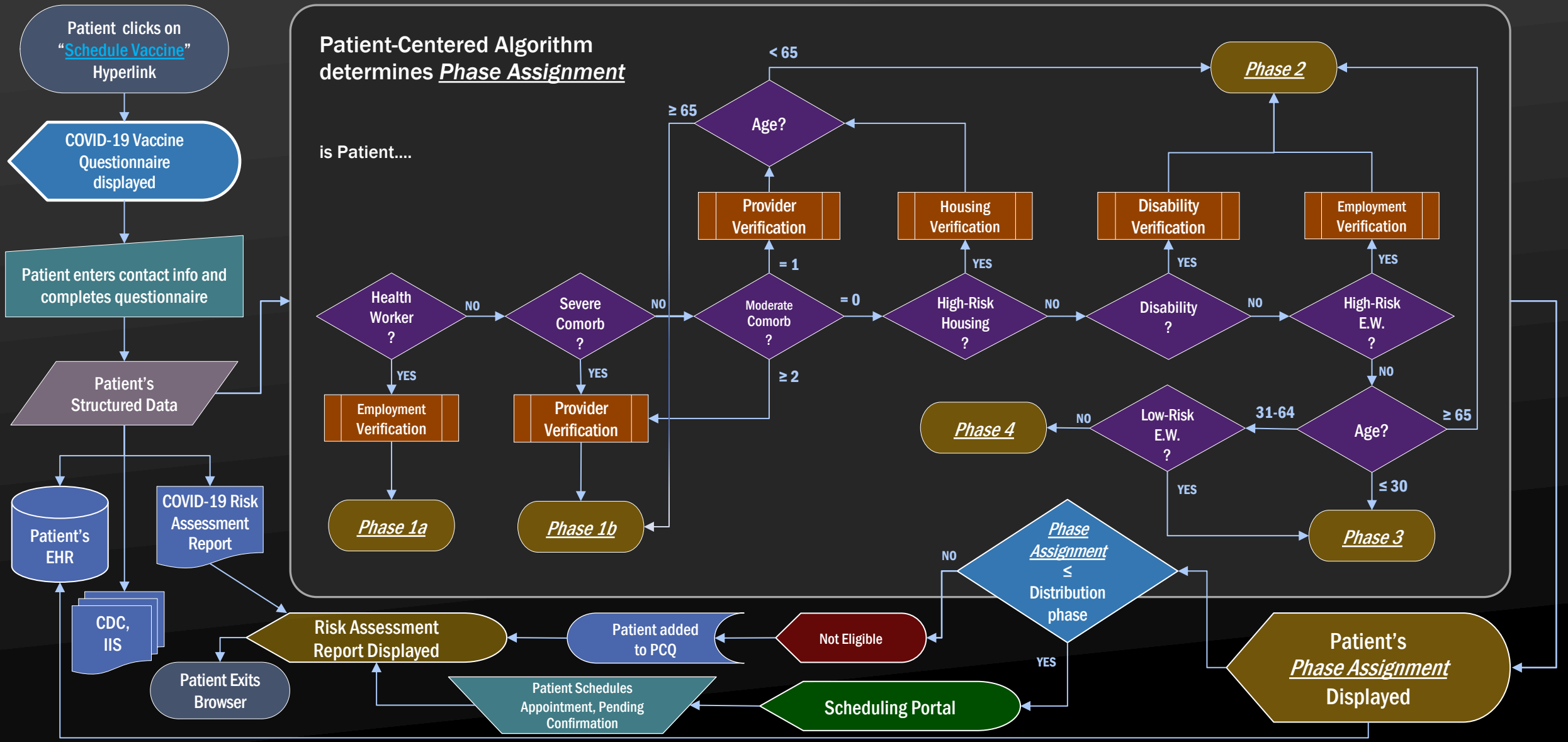
- Verify Patient's Identity Upon Arrival!

PATIENT EXPERIENCE

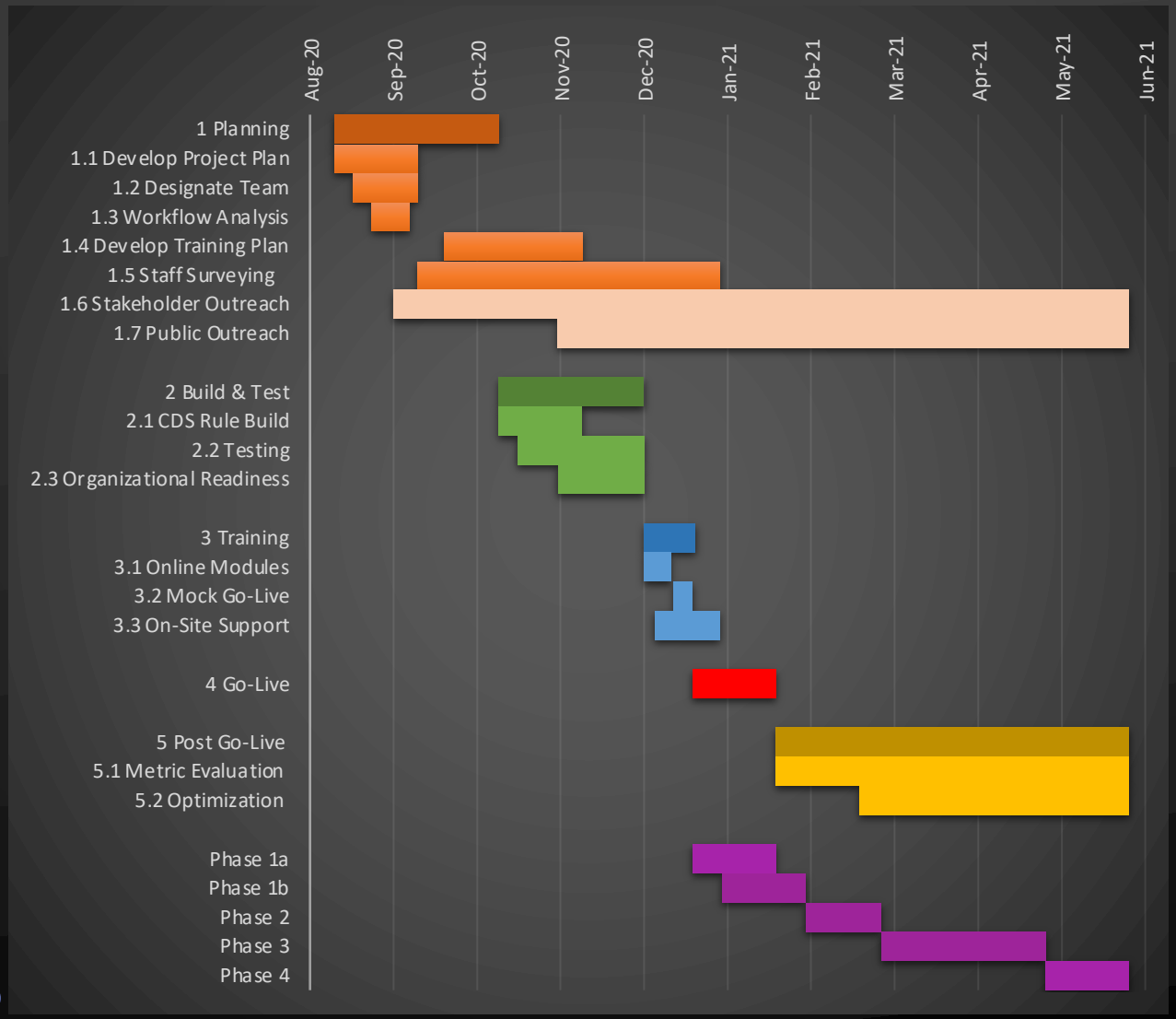
- User Experience is Paramount!!
- Only Structured Data!
- Risk-Factor Verification designed into questionnaire
  - Patient searches for provider's name
  - Matching Providers with configured eRx systems auto-populate
  - "Diagnosis Code Request – COVID-19 Vaccine" is auto-generated and sent via eRx system
    - CDS also checks to see if appropriate diagnosis code is contained within Pharmacy Management System
  - Patient is placed in Severe or Moderate PCQ, pending verification



CDS RULE: PHASE ASSIGNMENT ALGORITHM



IMPLEMENTATION AND MANAGEMENT



Key Stakeholders	Public Awareness
Project Leader	Providers
Informatics Staff (5-6)	Community Outreach Coord.
Support Staff (2-3)	Canvassers
Rx Staff	Local Media

Item	Expenses	Justification
Planning	$ 75 K	250 Hours
Community Outreach	$ 300 K	Based on NYC H1N1 MVC Cost
Build & Test	$ 75 K	250 Hours
Training	$ 20 K	Online Modules, Mock MVC
Evaluation & Monitoring	$ 150 K	6 month of salary for 2 Informaticists
Extra Rx Staff	$ 600 K	6 months of extra Rx Staff to support MVC @
Overhead	$ 10 K	
Total	$ 1.31 M	

MONITORING AND EVALUATION

- Quantitative and Qualitative Metrics determine Success!
  - Metric 1: Vaccinate 60% of patients assigned to a given phase, before the start of the next phase
  - Metric 2: Administer complete and accurate Risk-Assessment for 80% of pharmacy patients
  - Metric 3: Reduce the ratio of denied appointments to approved appointments at less than 10%
  - Metric 4: Reduce the number of unfinished Risk-Assessments to less than 10%, for all pharmacy patients

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