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DOH 348-802

COVID-19 Vaccine Allocation: Considerations for Long-Term Approach

Executive Summary

COVID-19 vaccine allocation planning in Washington state, led by the Washington State Department of Health (DOH), began with poor visibility into federal planning, limited dose availability, and weekly allocation cycles. Initial rollout focused on health care workers, so allocation planning also focused on specific vaccine providers serving these populations. As vaccine phases rolled out to include other community members, vaccine administration expanded from closed points of dispensing (PODs) to open PODs and more vaccine settings and locations. The federal government also expanded its parallel efforts.

While vaccine availability remains limited (see Figure 1), allocation planning in Washington now uses a 3-week planning cycle, routinely assesses equity indicators, and monitors vaccine coverage by prioritization phase. In this stage of allocation planning, supply remains limited while demand remains higher than supply, and DOH's approach remains highly centralized with a focus on specific vaccine providers (see Figure 2).

The key elements that determined Washington's current approach to allocation planning – scarcity and limited supply chain predictability – are changing, and we need to adapt our approach accordingly. With ongoing high-volume production of currently authorized vaccines and as additional vaccine presentations are authorized, ultimately we will have sufficient supply to meet decreasing demand. Demand also will vary between communities rather than being uniform throughout the state.

This document provides a roadmap for adaptation to adequate vaccine supply, using elements that will be necessary for ongoing success in vaccine rollout: local flexibility, nimble responsiveness to community needs, quality assurance, and adhering to critical equity goals. This document outlines the key areas to consider as Washington moves into long-term planning. It focuses just on the planning and operational perspective around allocation, and use of the *COVID-19 Vaccine Prioritization Guidance and Allocation Framework* for information on prioritizing populations and other considerations. DOH continues to be guided by ethical and procedural principles toward our goal: to reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2.

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Introduction

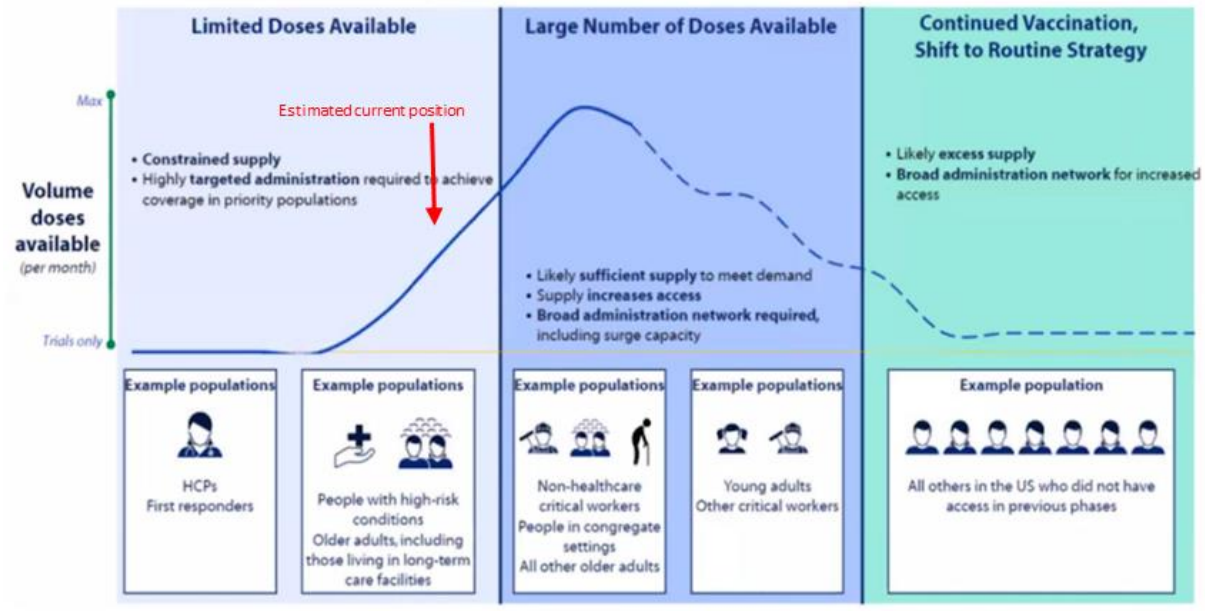
The initial stage of COVID-19 vaccine distribution in Washington state was very *ad hoc*. The CDC announced weekly the number of vaccine doses that the state would receive. DOH's COVID-19 vaccine allocation planning team then would apportion doses to a multitude of locations as quickly as possible, while considering both feedback from various sources and allocation criteria. In mid-February 2021, the CDC began providing 3-week vaccine dose projections to all states. For the past few weeks, the DOH COVID-19 vaccine allocation planning team has continued to develop weekly allocations while simultaneously trying to transition to 3-week allocation cycles (Appendix A). A limited supply of vaccine complicates both the weekly and 3-week allocation periods.

This document starts a discussion on how vaccine allocation should work when the state has adequate supply, variable demand, and continued challenges in achieving key health equity goals. The allocation process will need to pay attention to scale, flexibility, and accountability.

Long-Term Vaccine Allocation

With ongoing high-volume production of currently authorized vaccines and as additional vaccine presentations are authorized, Washington state eventually will have enough vaccine supply to meet demand (Figure 1).

Figure 1. Administration and Allocation Strategies Based on Vaccine Supply



Adapted from: Dooling, K. ACIP COVID-19 Vaccines Work Group. CDC, Aug. 2020

DOH will need to adapt our approach to allocation as the key elements of supply and predictability improve. As the state begins to develop a long-term approach to vaccine allocation, it must pay attention to five areas, each of which is discussed below:

- Supply and demand
- Roles and responsibilities
- Vaccination settings and locations
- Information systems including data to action
- Accountability and quality assurance

Equity is a cross-cutting focus that must be considered and discussed in each of these areas. Established ethical and procedural principles remain unchanged and, guided by these principles, the goal remains to reduce severe morbidity, mortality and negative societal impact due to the transmission of SARS-CoV-2. The ethical principles are:

- Maximum benefit
- Equal concern
- Mitigation of health inequities

Likewise, DOH will keep in place risk-based criteria to set general priorities among population groups and provide guidance that recognizes each group's distinct needs. These criteria are:

- Risk of acquiring infection
- Risk of severe disease or death
- Risk of negative societal impact
- Risk of transmitting infection to others

The DOH *Tribal Nations and American Indian/Alaska Native Engagement Plan* remains operational, and the agency is committed to upholding the responsibilities described in Chapter 43.376 RCW (Government-to-Government Relationships). The COVID-19 vaccine allocation planning team will continue using established channels to collaborate and consult with Tribal Nations and engage Urban Indian Health Programs. The COVID-19 vaccine community engagement team will work closely with the DOH Tribal Relations Director to plan and carry out culturally appropriate engagement with tribal organizations and urban Indian organizations.

Supply and Demand

In the coming weeks, DOH expects vaccine supply to slowly increase until it meets current demand. On the supply side, in addition to the increasing availability of Pfizer, Moderna, and Johnson & Johnson (Janssen) vaccines, other vaccine presentations may be added to the supply chain. For example, AstraZeneca may apply for FDA authorization soon. As vaccination efforts continue and supply increases, vaccine reluctance could create a barrier, especially among priority communities. This could compromise efforts to achieve equity goals. Plans for long-term allocation should recognize the need for vaccination approaches, settings, and locations to be responsive to community needs.

Roles and Responsibilities

Local health jurisdictions (LHJs) are key DOH partners, with a deep knowledge of their communities. They are the state's strongest vaccine program implementers, while DOH has handled monitoring and evaluation, data systems, quality assurance, and technical assistance. In Washington, DOH administers the centralized vaccine allocation process, selecting where vaccine is being distributed to and how many doses are being provided. Until recently, this was determined at the level of individual vaccine providers. LHJs largely served as advisors, with 25% or less of allocation being routed through LHJ partners. Recently, we shifted to a system in which LHJs work with vaccination entities and locations within their communities to equitably determine where vaccines should be routed. This allows DOH to focus more on monitoring and evaluation, data systems, quality assurance, and technical assistance.

Vaccine Settings and Location

An extensive range of entities across federal and state systems in Washington provide vaccinations to eligible individuals. Federal entities include long-term care facilities (LTCFs), retail pharmacies, federally qualified health centers (FQHCs), and others, such as the Department of Defense (DoD). State entities include hospitals, clinical providers (medical and public health facilities), mobile units, temporary community (pop-up) clinics, and mass vaccination sites. State and federal programs overlap in some areas, such as retail pharmacy and FQHCs. Tribal authorities have established additional settings for vaccination. It is important to consider thoughtfully where vaccine doses should be distributed to, taking equity and social vulnerability indices into account.

Information Systems and Data to Action

Assessment staff routinely generate top-line data on total vaccine doses received and vaccinations administered. Both internal and public dashboards show demographic data, including race and ethnicity of vaccine recipients. Current information systems, however, are fragmented and do not effectively distinguish between federal and state administration, and do not clearly identify vaccination settings and locations. A lack of information constrains allocation planning. The systems lack routine and robust tracking of vaccine coverage by priority population phase. Multiple entities for vaccine administration and fragmented information systems have limited timely and complete monitoring of vaccine rollout. DOH has not yet established routine reporting and feedback cycles for action by key partners, including LHJs. Going forward, DOH must plan for information systems that can adequately ensure well-informed analysis and allocation decisions. Data for action require confidence in data integrity and timeliness, both to allow course corrections as needed and to ensure that critical equity goals are being achieved.

Accountability and Quality Assurance

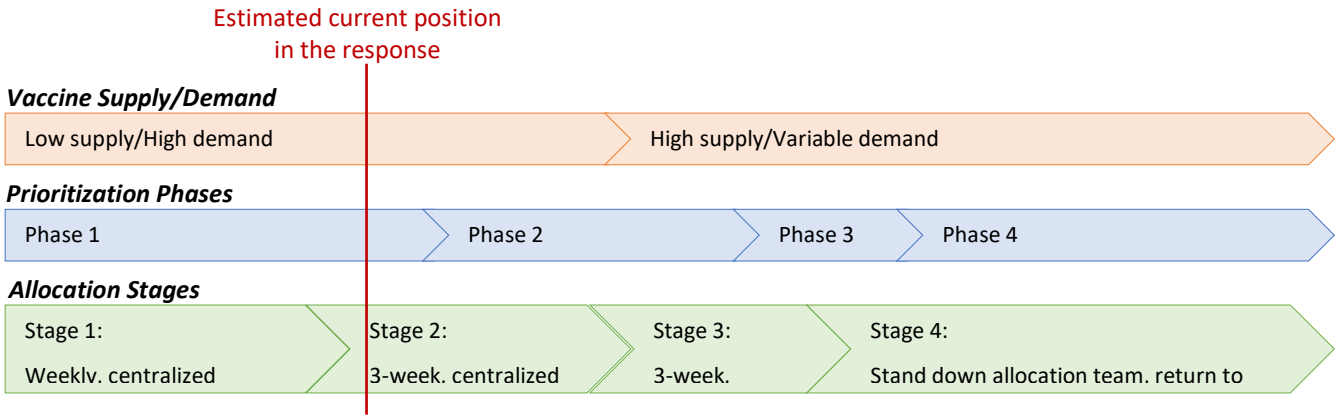
Any COVID-19 vaccine allocation process requires accountability and quality assurance, which according to WA Foundational Public Health Services includes upholding standards and accountability in accordance with local, state, and federal laws, regulations, and policies.

Particular attention to fairness and equity in rollout is critical, especially within a changing context. Going forward, DOH will continue to incorporate accountability and quality assurance by partnering with LHJs and vaccination settings and locations to provide timely and accurate data that are used to identify and resolve issues.

The Allocation Cycle

DOH's response will progress through several segments and timelines (Figure 2). The timelines must align with supply changes; for example, an allocation cycle used in prioritization phase 1, with vaccine scarcity, may not work in phase 2, 3, or 4. It must be adapted as needed to align in an evolving context.

Figure 2. Progression of Allocation Stages, Prioritization Phases and Vaccine Supply/Demand



Shifting to a flexible allocation system that is more responsive to community needs will require decentralization, and alignment of roles and responsibilities:

- LHJs will take the lead on local knowledge and partnership with vaccine providers.
- DOH will lead in information systems, monitoring and data to action, quality assurance, and robust tracking of coverage by priority population phase and progress towards equity goals.

Figure 3 below shows the main components of the proposed allocation cycle as we transition from the current allocation stage to the next one. Additional details, including specific timing of steps, will come later.

This allocation approach emphasizes the role of LHJs and maintains equitable distribution of vaccine doses across jurisdictions according to established pro-rata criteria. LHJs will determine administration sites and quantities for their overall county allocation. LHJs may direct vaccine doses to hospitals, medical offices, permanent and temporary clinics, public health entities, community health centers, and pharmacies. As shown in Figure 3, DOH may route some doses toward their own activities, such as mass vaccination clinics and contingency planning.

However, DOH will distribute the majority of doses according to LHJ recommendations. LHJs will develop these recommendations using these inputs from DOH:

- Total number of allocated doses from both state and federal sources, for a full jurisdictional perspective.
- Total number of doses on hand prior to any additional allocations, including any federally supported vaccine programs in a jurisdiction.
- Vaccine coverage by population and prioritization phase.
- Equity indicators.
- The DOH *COVID-19 Vaccine Prioritization Guidance and Allocation Framework*.

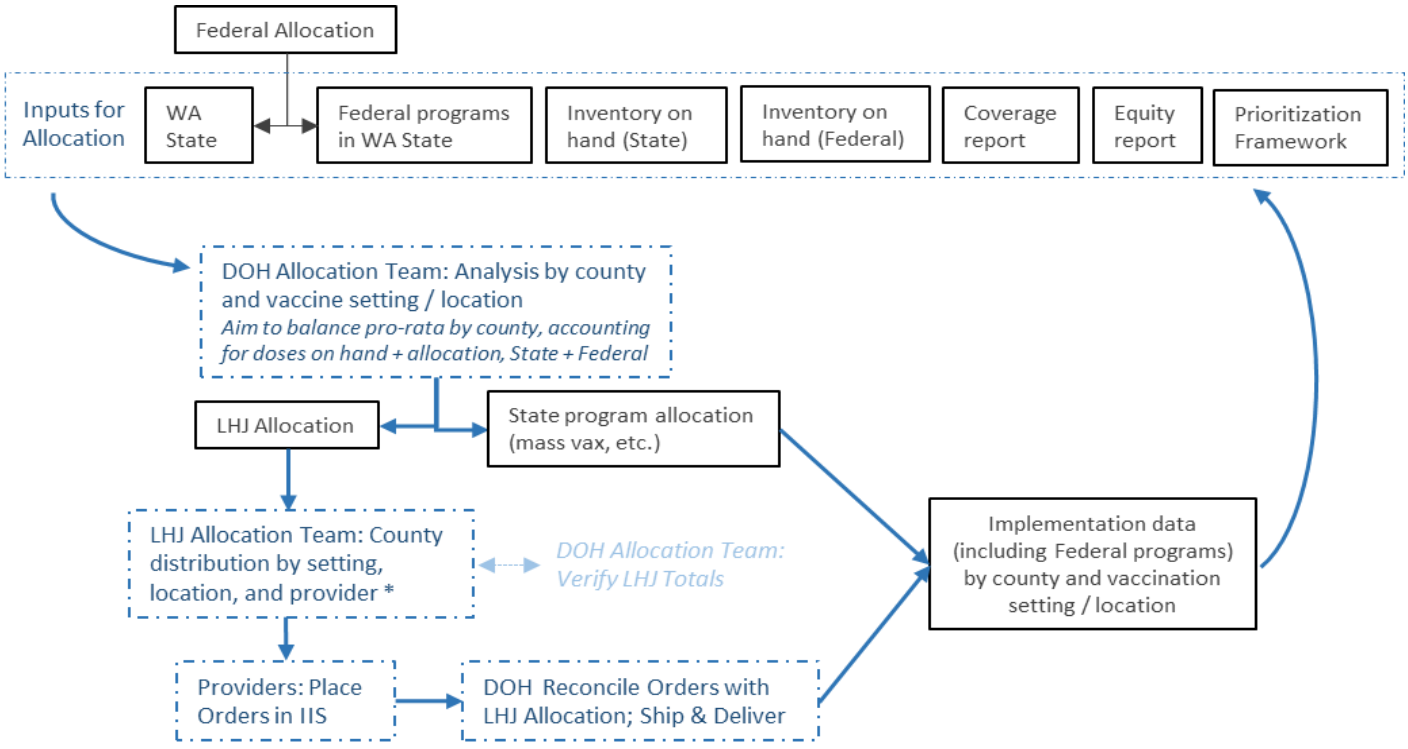
Provider performance information (doses on hand, equity indicators, etc.) will be disaggregated by facility type (e.g. hospital, pharmacy, mobile clinic). This is important for state public health partners to understand the most effective routes for reaching prioritized populations, as well as for accountability and quality assurance. The full allocation cycle depends on reporting to ensure these inputs are current, comprehensive, and useful for moving from data to action. As discussed elsewhere in this report, DOH information systems may need strengthening to ensure data integrity and confidence in the allocation process.

If a jurisdiction has a significant number of unused doses on hand, these count towards the pro-rata target and the jurisdiction may receive only small additional allocations. DOH may award larger allocations to jurisdictions with high throughput and few doses on hand.

Finally, with an increasing range of available vaccine products expected, the importance of a single vaccine presentation (i.e. one specific product offered) at each individual site may become increasingly important to manage complexity. Likewise, allocation planning may function most efficiently when considering a single vaccine product in a single allocation cycle. For example, if there are three vaccines available, the allocation cycle shown in Figure 3 would be conducted three times – once for each of the vaccine products. This may initially appear duplicative, but is likely faster, more reliable, and more feasible than interweaving COVID-19 vaccine products within a single allocation cycle.

Figure 3. Allocation Cycle Adapted for Changing Context

Cycle drawn for specific vaccine product (with three vaccine products, process should be conducted three times).
This provides an overview of a proposed allocation cycle – cadence and specific timing for each step to be specified.



**LHJ allocation can follow existing DOH guidance to manage partners who mismanage or under-utilize vaccine allocations*
Solid boxes – data points; Dash outline boxes – process elements

DOH and the LHJs will share responsibility for equity in vaccine distribution while continuing to quickly and safely vaccinate people in Washington, stifle the spread of COVID-19, and get the pandemic under control. Beyond the considerations in this paper, the underlying principles, allocation priorities, and assumptions remain unchanged and include:

- Using the DOH *COVID-19 Vaccine Prioritization Guidance and Interim Allocation Framework* as primary guidance.
- Safeguarding equity, with appropriate allocation to areas with high social vulnerability factors and an appropriate mix of vaccination settings and locations to ensure meaningful access.
- Incorporating provider- and site-specific information in allocation decisions, including consideration of existing inventory, storage capacity, and throughput capacity.
- Participating in systems that track vaccine errors and potential adverse events.
- Complying with state and federal reporting needs and all HIPAA and Joint Commission requirements for vaccine record keeping and retention.
- Identifying non-compliant sites, and ensuring vaccine is not continuously supplied to sites that hoard or improperly store, handle, or administer vaccine.

With this approach, LHJs may also elect to operate in inter-county or regional partnerships. While the total county-level pro-rata allocation would not change, pooling resources may allow more efficiency and effectiveness in reaching key populations.

Adaptation of Allocation Approach

This review reflects significant successes and identifies opportunities for development as vaccine roll-out changes. With increased supply, variable demand, and ongoing challenges in achieving key health equity goals, DOH will need an increasingly flexible and decentralized approach to allocation that is responsive to community needs.

With such a shift, information systems would become increasingly important: both to provide DOH with a mechanism for monitoring and assurance, and to support LHJs in tracking provider performance. Across local and state entities, robust tracking of coverage by priority population phase and progress towards equity goals is critically important. At a basic level, DOH information systems should be able to offer information that can be used for statewide decisions (coverage by phase, progress in equity) and LHJs (provider-level performance). Figure 4 is an example of a comprehensive, full-cycle information system.

Figure 4. Information System Needs

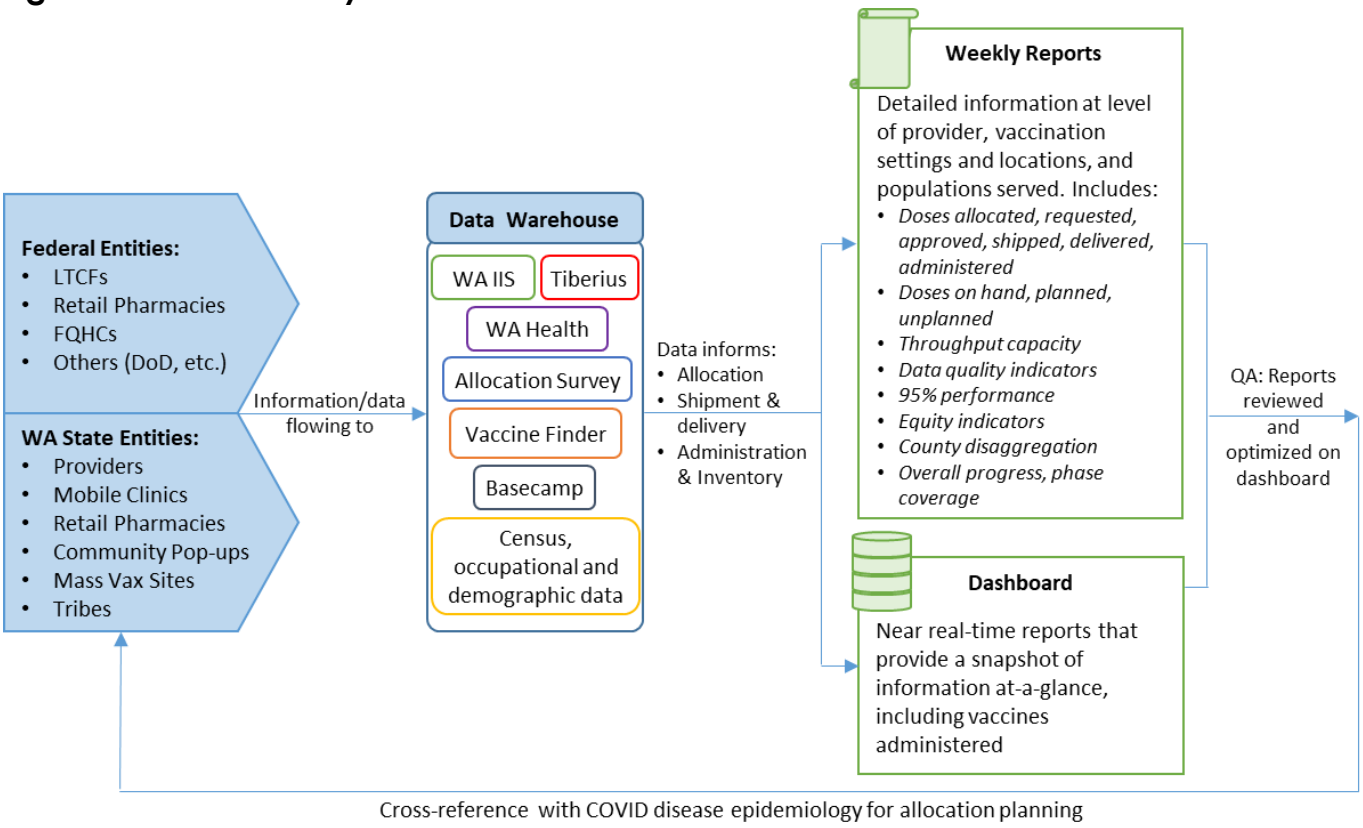
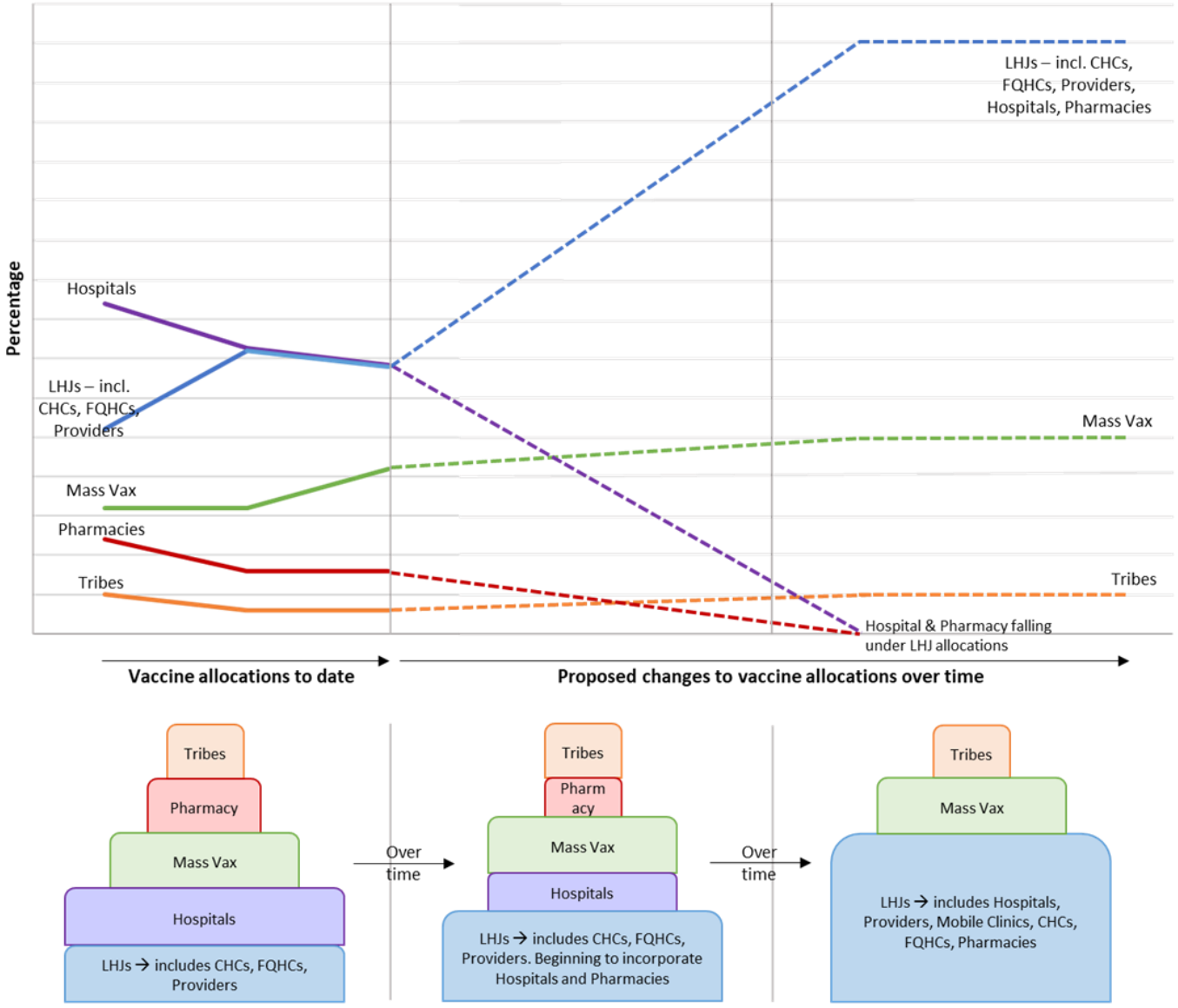


Figure 4 shows what data elements are needed for appropriate allocation planning, accountability, and quality assurance. A system that adequately supports data integrity is both a current need and necessary for successful transition to future allocation approaches.

Expected Outcomes and Next Steps

As vaccine supply increases, DOH will shift where it allocates doses. Figure 5 shows the shift of vaccine doses over time and who should be receiving vaccine. In a new system, DOH will continue to allocate vaccine to mass vaccination sites and tribes. The doses of vaccine allocated directly by DOH to hospitals and pharmacies should drop to zero, and doses allocated to LHJs should increase significantly, allowing LHJs to thoughtfully and equitably share vaccine among their county vaccine distribution sites, which will include hospitals, pharmacies, providers, and FQHCs.

Figure 5. Portrayal of Vaccine Allocation Over Time



With DOH no longer determining provider- and site-level allocations, the focus should shift to developing robust databases and systems, monitoring of vaccine distribution, maintaining equity among doses being administered, quality assurance, and robust tracking of coverage by priority population phase.

Key next steps to developing this new allocation approach include:

- Identifying a working group to detail and finalize the allocation cycle, including specific timing cadence and key indicators required in reporting cycles.
- Developing electronic tools to execute the allocation cycle.
- Aligning information systems to provide timely and accurate key indicator data.
- Developing tools to monitor and evaluate the long-term allocation process and adjust the process as necessary to maintain equitable distribution.

Summary

The allocation process developed in the initial stage of COVID-19 vaccine rollout has served Washington well. But we expect an increase in dose availability and variable demand. As the context changes, the allocation process may need to adapt. A new allocation system will need to be flexible and responsive to community needs. This points toward decentralization of the allocation process and an expanded role for local health jurisdictions, with increased DOH responsibility for robust information systems.