

Advancing ambulatory pharmacy practice through a crisis: Objectives and strategies used in an ambulatory care action team's response to the COVID-19 pandemic

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Purpose. The objectives and strategies used by an ambulatory care action team operating within a large health system's pharmacy incident command structure during the initial response to the coronavirus disease 2019 (COVID-19) pandemic are discussed.

Summary. In a time of crisis, a pharmacy ambulatory action team was formed to provide ambulatory clinical pharmacy expertise and meet an immediate and ongoing need to limit nonemergent care during the COVID-19 pandemic. By building a strong communication infrastructure and partnership with ambulatory care providers, clinic medical and operational leaderships, clinical laboratory staff, and infusion centers, the team was able to swiftly execute solutions and respond to new issues and requests. Ambulatory care pharmacy practice continued to advance through provision of services to vulnerable patient populations with chronic conditions that were anticipated to experience gaps in care management during the COVID-19 pandemic. These efforts resulted in expansion of pharmacists' involvement in collaborative drug therapy management, support of patients' transition from in-clinic injection to home self-administration, provision of medication assistance support, and management of 1,300 patients via protocol-based warfarin management. Additionally, ambulatory pharmacy services in 15 primary care, anticoagulation, and specialty clinic sites were transitioned to telehealth. The ambulatory action team also implemented several strategies to manage medication therapy associated with COVID-19-related shortages and implemented electronic decision support to guide prescribing of hydroxychloroquine and azithromycin.

Conclusion. Building a strong communication infrastructure and a pharmacy ambulatory action team were essential to respond to a crisis and continue ambulatory clinical pharmacy services expansion.

Keywords. ambulatory care, coronavirus, COVID-19, pharmacy practice advancement, pharmacy service

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The coronavirus disease 2019 (COVID-19) pandemic has tested the emergency preparedness of healthcare facilities and created new challenges and opportunities for the delivery of ambulatory care, including pharmacy services. Yale New Haven Health System (YNHHS) is a large academic health system consisting of 5 hospitals (with a total of 2,563 licensed beds in fiscal year 2018) and a physician foundation of more than 130 community practices in Connecticut, Rhode Island, and New York. YNHHS

had 2.4 million outpatient encounters in fiscal year 2018. The largest hospital in the system, Yale New Haven Hospital, houses its own retail pharmacy, and all YNHHS hospitals are networked to an integrated specialty pharmacy.

Prior to the COVID-19 pandemic, the YNHHS pharmacy department was implementing strategic expansion plans that aligned with American Society of Health-System Pharmacists (ASHP) Practice Advancement Initiative 2030 goals to ensure patients

have access to a pharmacist in all care settings.¹ One of these strategies was to integrate and advance ambulatory clinical pharmacy services across the health system. At the onset of the pandemic, the pharmacy department's strategic plan projects were temporarily halted to respond to the immediate need to limit nonemergent care and create surge capacity for patients with COVID-19. In response, YNHHS initiated a hospital incident command structure (HICS) for system oversight of system incident management (SIM). A pharmacy incident command structure (PICS) was deployed to integrate with the HICS and create an infrastructure to manage long-term emergency response demanded by the pandemic. The PICS included a commander, domain chiefs, and action teams. Action teams were diverse and functional workgroups formed to execute identified objectives and strategies during the pharmacy department and health-system emergency response.

An ambulatory action team was formed. The team comprised a team lead, alternate lead, and membership across the system pharmacy enterprise, including adult, pediatric, and oncology ambulatory clinical pharmacy services, specialty pharmacy services, and retail pharmacy services. The lead and alternate lead of the pharmacy ambulatory action team also participated in the SIM ambulatory action team. To plan for our response, each PICS action team, including the ambulatory action team, completed comprehensive planning facilitated by the ASHP COVID-19 Pandemic Assessment Tool for Health-System Pharmacy Departments² and scenario planning exercises with incident action plans. The main scenario for ambulatory care was that vulnerable populations with chronic conditions would experience gaps in care management.³ Objectives and strategies developed from the action team planning were added to a standardized project plan template (Figure 1), which facilitated execution of strategies and reporting to the PICS on progress and barriers. Newly identified ambulatory

KEY POINTS

- The formation of a pharmacy incident command structure and ambulatory care action team facilitated a strong communication infrastructure and connection with all key stakeholders.
- Ambulatory pharmacy practice can advance during a time of crisis through identification and closure of gaps in care management for vulnerable populations with chronic conditions.
- Focusing on patient access to clinical and laboratory services, medication access, and drug use policy management is important in maintaining patient-centered care during a pandemic.

patient care or medication concerns conveyed from the SIM structure or front-line pharmacy practitioners were discussed at daily PICS meetings in order to develop collaborative strategies and response timelines and assign an action team to execute them. A timeline for the COVID-19 response can be seen in Figure 2.

Though the pandemic initially stopped ambulatory pharmacy strategic expansion plans, the integration of pharmacy practice with the SIM structure highlighted the pivotal role pharmacy has in emergency response and ambulatory patient care. This approach allowed for ambulatory pharmacy practice at YNHHS to continue to advance and for expansion of services to vulnerable populations. In response to the COVID-19 pandemic, the ambulatory action team was able to execute the key objectives of establishing clear and effective communication with key stakeholders, ensuring patient access to clinical and laboratory services, and managing drug shortages related to COVID-19.

Communication

One of the first objectives assigned to all the YNHHS pharmacy action teams was to establish clear and effective channels for communication with key stakeholders across the health ecosystem. The key strategies were to (1) identify key partners, (2) confirm methods of communication, and (3) facilitate sharing of information. The key partners for the ambulatory action team were identified as the ambulatory care providers, clinic medical and operational leaderships, clinical laboratory staff, and infusion centers. The main methods of communication were reporting at SIM ambulatory action team meetings and electronic communication via an SBAR (situation-background-assessment-recommendation) format.

Patient access

Another objective of the ambulatory action team was to ensure ambulatory pharmacy services supported outpatient care as providers and nurses were redeployed to inpatient care areas in response to increased surge capacity. Prioritization was given to supporting areas with established ambulatory pharmacy services, where existing relationships and infrastructure facilitated operationalizing new virtual workflows. Thus, support was provided within 1 to 2 weeks for requests that aligned with current ambulatory pharmacy services offered, such as diabetes, hypertension, anticoagulation, and outpatient parenteral antibiotic therapy management. However, new patient population or service additions, such as postpartum hypertension management, were only planned during the initial acceleration phase of the pandemic, but program implementation did not occur until a recovery phase, when sufficient pharmacist resources were available. Strategies implemented by the ambulatory action team to maintain patient access included expansion of chronic disease state management and anticoagulation services through use of telehealth. As a result, the total number of pharmacist visits increased from

Figure 1. Action plan implemented by ambulatory action team in response to coronavirus disease 2019 (COVID-19) pandemic. REMS indicates medications subject to risk evaluation and mitigation strategy requirements.

Pharmacy Incident Command Structure (PICS) Section: CLINICAL Action Team: AMBULATORY CARE							
PICS Section Chief (Alternate): Director, Clinical Pharmacy Services (Associate Director, Ambulatory Clinical Pharmacy Services)				Report Out to Section Chief: Mon-Fri Daily Clinical Huddle (30 minutes)			
Action Team Lead (Alternate): Manager, Ambulatory Clinical Pharmacy Services (Manager, Specialty Pharmacy Clinical Services)				Action Team Meeting Time: Mon/Wed (60 minutes)			
Team Members: Encompasses all delivery networks, oncology, women and children's, and outpatient pharmacy services							
Objectives	Strategies/Tactics	Resources Required	Assigned To	Due Date	Status ● Planned ● Behind ● On Track ● Completed	Transformation Assessment	
						Continue, Change, or Stop	Project Required (Y/N)?
Communication: Establish clear and effective communication channels with key stakeholders in the health ecosystem	<ul style="list-style-type: none"> Identify key partners Confirm methods of communication Facilitate sharing of information 						
Patient Access: Ensure and maintain patient access to clinical and laboratory services	<ul style="list-style-type: none"> Transition appointments to telehealth Support anticoagulation management Assess essential labs for ambulatory treatment initiation and monitoring (include specialty pharmacy medications and REMS) Create updated guidelines 						
Medication Access and Drug Use Policy: Manage medication therapy related to shortages and/or COVID-19 treatment	<ul style="list-style-type: none"> Create guidelines for outpatient prescribing Implement electronic prescribing decision support for hydroxychloroquine and azithromycin 						

approximately 1,000 visits per month to more than double that figure by July 2020 (Figure 3).

Telehealth transition. Transitioning patient appointments to telehealth (telephone or video visits) became a priority during the initial pandemic response to ensure compliance with the Centers for Disease Control and Prevention's guidance for social distancing, quarantine, and isolation.^{4,5} With the need for rapid video visit training, one of the ambulatory clinical pharmacists with experience conducting video visits trained clinic staff and led a virtual training for 17 ambulatory clinical pharmacists. Within a week all patients were converted to telehealth visits.

Pharmacist telehealth visits were used to provide injection training and patient counseling for self-administration of biologic therapies for 27 patients in the pulmonary clinic. Partnering with our health system specialty pharmacy ensured efficiency in

safe patient transitions and medication assistance program copayment support from external, manufacturer-sponsored programs or grants from disease state-focused organizations for patients with financial need. For medications not available through our pharmacy, use of 340B Drug Pricing Program-contracted pharmacies was advised. In collaboration with the pharmacy and medical leaderships, consensus guidance was developed to provide for consideration of patient self-administration of medications that did not have labeled indications for home self-administration (eg, omalizumab).

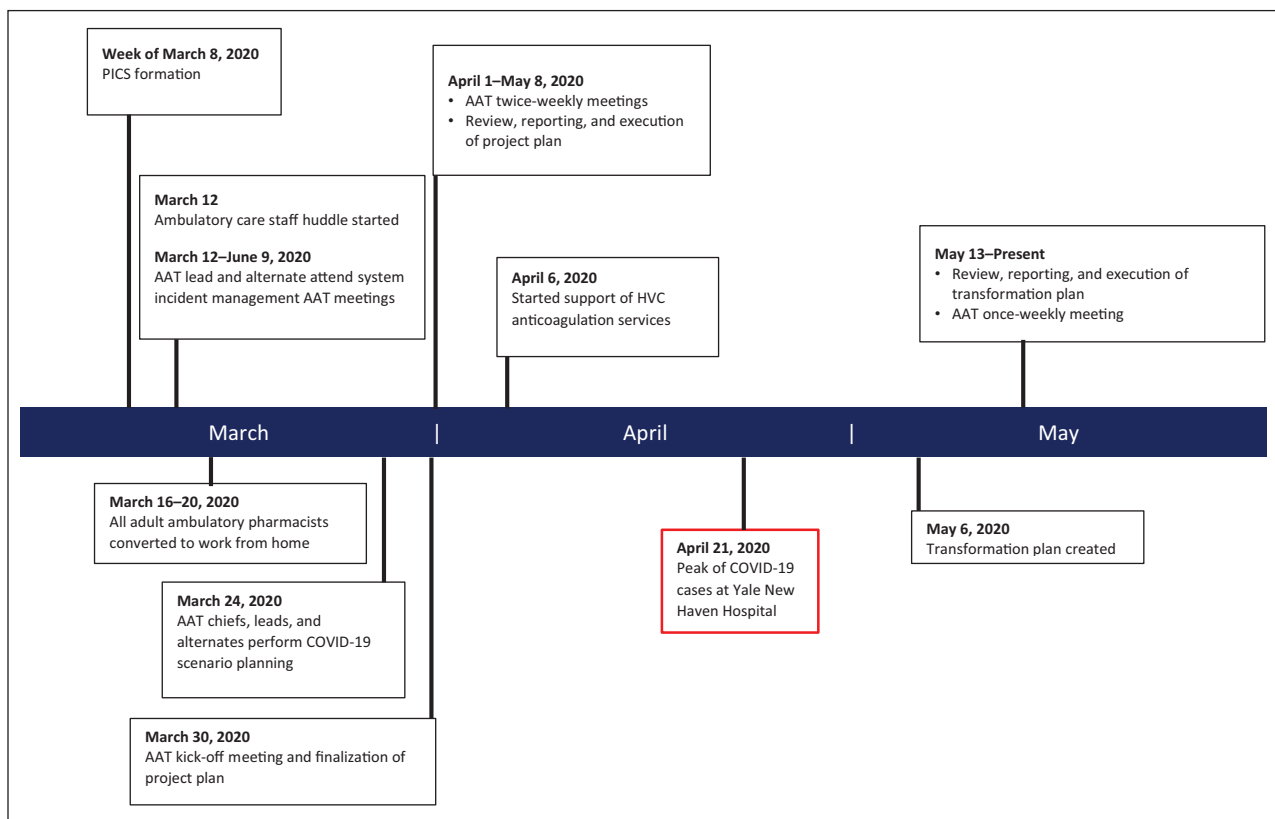
The ambulatory clinical pharmacists also used the telehealth visits as a way to facilitate triage of patients for further care and assessment. If there were any concerns for COVID-19-related symptoms, patients were triaged to the responsible provider and/or call center. This workflow aligned with the SIM ambulatory action team's COVID-19 symptoms triage pathway.

Anticoagulation management.

As ambulatory nurses were redeployed to meet inpatient care needs, ambulatory clinical pharmacists assumed responsibility for protocol-based warfarin management for approximately 1,300 patients. Seven ambulatory clinical pharmacists, 2 ambulatory care postgraduate year 2 pharmacy residents, and 5 pharmacy technicians were trained. Three to 5 pharmacists and 3 to 4 technicians were assigned each day to support this patient population. Assigned pharmacy staff and remaining nursing staff participated in a daily huddle to assign roles and ensure effective communication.

The ambulatory action team created a guidance document to clearly outline what action should be taken when patients reported urgent concerns, including potential COVID-19 symptoms. To decrease the risk of potential COVID-19 transmission, opportunities to extend the International Normalized Ratio (INR) monitoring interval to up to

Figure 2. Timeline of ambulatory action team (AAT) strategic planning and transformation plan implementation during early months of response to coronavirus disease 2019 (COVID-19) pandemic. PICS indicates pharmacy incident command structure; HVC, heart and vascular.



12 weeks in patients with stable doses of warfarin and consistently therapeutic INRs were identified.⁶⁻⁸ Pharmacists also identified opportunities to transition patients to direct oral anticoagulant (DOAC) therapies to decrease the required monitoring frequency.

An ambulatory anticoagulation management workflow document was prepared and disseminated across the health system through the SIM ambulatory action team to provide multidisciplinary providers with strategies for management of the target population. It included considerations for DOAC conversion in eligible patients, INR monitoring interval extension, options for home INR monitoring, and availability of laboratory testing locations exclusively for patients with confirmed or suspected COVID-19. Through this communication, the ambulatory action team had the opportunity to share

guidance to enhance care of patients across the health system.

Through this collaboration, opportunities to optimize and standardize workflows between departments managing warfarin therapy were identified. Standardization improved efficiency and consistency through creation of 21 documentation templates and a centralized workflow resource, which were continually updated as new processes were implemented. This standardization led to important protocol clarifications and more streamlined and consistent workflows across the health system.

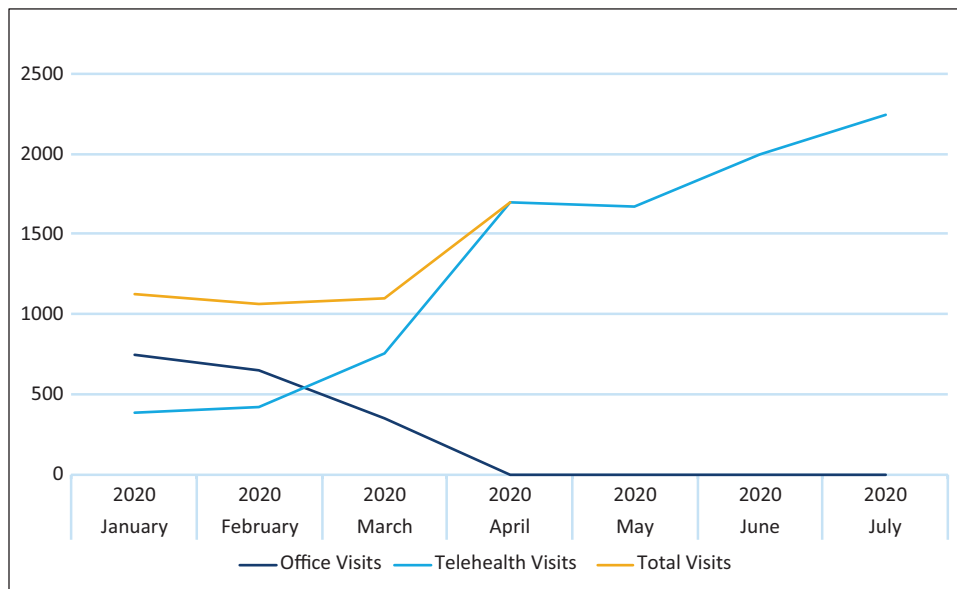
Essential laboratory monitoring. To ensure effectiveness of medication therapy while minimizing risks of staff exposure to COVID-19, the ambulatory action team completed an assessment of current ambulatory clinical pharmacy services and essential laboratory tests for initiation and monitoring

of medications. Guidelines outlining essential laboratory monitoring parameters and those for which testing could be delayed for patients with diabetes, hypertension, heart failure, and/or other chronic diseases were created.

Medication access and drug use policy

A final objective of the ambulatory action team was to ensure that patients retained access to critical chronic medications during the pandemic and that prescribers received clear guidance on drug prescribing and monitoring during this period. Disruptions in the drug supply chain, as well as emerging evidence supporting use of approved drugs for the treatment of COVID-19, led to drug shortages that would potentially impact patients receiving chronic therapy with affected drugs. The team worked to develop

Figure 3. Ambulatory care pharmacist visits by type (10,895 visits in total) during early months of pandemic response.



prescribing guidance, information technology restrictions within the computerized order entry system, and inventory management strategies to retain drug supply for the health system’s patients who were receiving these medications chronically. Risk management programs for frequent monitoring of some medications were modified in response to the COVID-19 pandemic to reduce the need for patient laboratory visits, and it was essential to communicate these changes to prescribers.

Risk evaluation and mitigation strategies (REMS) management.

The US Food and Drug Administration’s release of the guidance document “Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency” provided temporary relief from selected laboratory testing requirements or days’ supply limitations for drugs subject to REMS requirements.^{9,10} To provide awareness of REMS program requirement changes, the team compiled a list of medications subject to REMS requirements prescribed within the health system, the updated requirements, and the manufacturers’ letters about the updates. During a 13 month period prior to the start of the COVID-19 pandemic, 14 such medications were prescribed within the health system, with formal

guidance from the drug manufacturer provided for 7 medications and a change from the usual REMS process for 6.

Drug shortages management.

During the early weeks of the COVID-19 pandemic, several readily available medications were demonstrated to have possible activity against the virus in hospitalized patients, including hydroxychloroquine, azithromycin, and HIV-1 protease inhibitors. The increased demand and utilization of these medications for the acute treatment of COVID-19 in hospitalized patients resulted in supply shortages in the community for outpatients receiving the medications chronically. Several strategies were implemented to manage medication therapy associated with COVID-19-related shortages, including outpatient prescribing guidance, prescriber decision support within the electronic medical record, internal pharmacy validation of prescriptions, and dispensed quantity limitations. Guidelines for outpatient prescribing of hydroxychloroquine, HIV-1 protease inhibitors, and azithromycin were developed in collaboration with members of the pharmacy and medical leaderships with expertise in infectious diseases, pulmonary medicine, rheumatology, and dermatology; the guidelines recommended that these

medications be reserved for patients with medical conditions for which their use had been established and there were no alternatives. Dermatology and rheumatology prescribers identified patients whose hydroxychloroquine therapy could be decreased via once-daily dosing to conserve supply and also recommended avoiding new-start hydroxychloroquine therapy.

Implementation of electronic decision support for hydroxychloroquine and azithromycin prescribing resulted in generation of an advisory warning upon medication prescribing that outlined restrictions on prescribing of these medications in the outpatient setting. These prescriptions also required an associated diagnosis code and contained a hard-stop limit on days’ supply per fill (ie, a maximum of 30 days). Upon receipt of any new hydroxychloroquine prescriptions, clinical pharmacists within the health-system specialty pharmacy reviewed electronic medical record documentation to validate indications for use and escalated cases to the rheumatology leadership if compliance with the outlined guidelines was unclear.

The strategies implemented to manage COVID-19-related drug supply shortages in the outpatient

setting allowed YNHHS pharmacies to continue to fill hydroxychloroquine and azithromycin prescriptions for patients chronically treated with these therapies and ensured a sustained supply in the community. Stabilization of supply also allowed YNHHS pharmacies to accept prescriptions for new-start hydroxychloroquine therapy or for patients receiving chronic hydroxychloroquine therapy who had previously filled prescriptions specifying certain approved indications at outside community pharmacies.

Discussion

The COVID-19 pandemic has presented an unprecedented crisis, which has required the YNHHS ambulatory pharmacy team to respond in a nimble manner. The unique challenges encountered have tested our ability to adapt, accelerated timelines, changed previous workflows, and led to creation of new processes. During the initial response to the pandemic, we identified that there was a need for a new communication infrastructure that spanned across all levels to allow for clear coordination and to facilitate collaboration. To ensure the success of the PICS and the ambulatory action team, they were introduced to the pharmacy staff at town halls and huddles. The ambulatory action team and pharmacy leadership also reminded staff of the correct method of escalation if there was a deviation in the process. The ambulatory action team became the hub of all ambulatory care-related issues, improvements, and opportunities by receiving and relaying new information and data related to ambulatory care. This approach allowed the team to pivot strategically to address each new or evolving issue with modified tactics or strategies in a short time frame; it also prevented any duplication of efforts in the pharmacy department. Thus, a key to the ambulatory action team's successful execution and implementation of the objectives in the action plan was to create and maintain a robust communication framework.

Successful execution of the action plan also involved coordination and teamwork. Therefore, equally important was the continual fostering of a positive environment that ensured all team members were heard, involved, and engaged. Frontline pharmacists and pharmacy residents were members of the ambulatory action team and were a part of executing and implementing the action plan. Use of the diverse skill sets and clinical expertise of the entire team enabled quick execution of the action plan.

The project tracker and action plan were useful tools for organizing the objectives and tactics during the initial phase of the pandemic. Towards the subsequent recovery and practice transformation phase, these tools were used to plan some of the pharmacy department's strategic initiatives. Strategies that required further resource assessment, modification of workflow, and maintenance, such as the anticoagulation management and postpartum hypertension management strategies, were added to the 2021 strategic plan for implementation by separate project teams.

Conclusion

Ambulatory care pharmacy plays an essential role by providing support to the community, patients, department, and multidisciplinary team. The formation and work of the ambulatory action team was critical for the continued advancement of YNHHS' ambulatory pharmacy practice during the early weeks of the COVID-19 pandemic. The experiences gained during the COVID-19 pandemic have made the YNHHS ambulatory pharmacy team better prepared for future crises and equipped the team with new tools and skills that will remain in a transformative state.

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Disclosures

The authors have declared no potential conflicts of interest.

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