Overview of Lab Meeting 51

During the 51st Vaccines and Therapeutics Lab Meeting we heard from several stakeholders about the Test-to-Treat program. First, Dr. Michael Ganio of the Association of Health System Pharmacists described the new Test-to-Treat program which is intended to provide patients a one-stop option for COVID-19 testing, prescription for oral antivirals, and dispensing of these medications. Next, Dr. Julia Skapik of the National Association of Community Health Centers (NACHC) described efforts to bolster the capacity of data infrastructure at community health centers. Finally, TJ Griffin of PharMerica, described the vital role of long-term care (LTC) pharmacies in caring for and vaccinating high-risk populations, such as elderly living in LTC facilities, throughout the pandemic.

COVID-19 Oral Antivirals & the Test-to-Treat Program

Dr. Michael Ganio, Center on Medication Safety & Quality, American Society of Health-System Pharmacists

COVID-19 Oral Antivirals – Paxlovid (12 years+) & Lagevrio (18 years+) both authorized in December 2021 as the oral outpatient treatments for mild-to-moderate COVID-19 in non-hospitalized patients at high risk for progression to severe COVID-19 within 5 days of symptom onset.

Test-to-Treat Program

- “Co-located” clinic with pharmacy – one-stop place for patients to get COVID tested, prescribed an oral antiviral for COVID if needed, and obtain that prescription
  - Federal pharmacy partners
  - State- or jurisdiction-identified locations
  - Also, Federal Qualified Healthcare Centers & long-term care facilities
- Intended to address the short window of time (5 days) patients have to start the oral antiviral treatment following symptom onset

Test-to-Treat Impact

- 2k+ sites enrolled (majority CVS) – 2.5-3.5% of pharmacies in the US
- 60-70k retail pharmacies in the US
- 91% of Americans live within 5 miles of a community pharmacy
- 33% of Paxlovid and 20% of Molnupiravir going to the Test-to-Treat program
- Courses dispensed – hard to obtain this information because utilization and inventory data are voluntarily reported by provider sites (~41k provider sites have received oral antivirals, ~1.6k with unknown inventory or not reported within the last 2 weeks)
• Challenges – physicians unfamiliar with the new medications and more hesitant to prescribe given significant drug-drug interactions, large swaths of the country with no test-to-treat facilities accessible (e.g., none in Wyoming), 600,000 courses of Paxlovid sitting unused

Conclusions
• Test-to-treat intended to expedite access and increase availability of COVID-19 antivirals
• Challenges with prescriber and patient awareness and financial barriers remain
• Accessibility can be further improved by leveraging the knowledge, skills, and availability of pharmacists

Building Data Capacity of Community Health Centers
Dr. Julia Skapik, National Association of Community Health Centers (NACHC)

Prior Approach to Public Health Crises
• Solutions and funds typically reactive & overly specific to the situation of the crisis
• Funds and programs are too late to have maximum impact
• Innovation approach suggests early investment in infrastructure would improve timeliness and effectiveness of the response
• Proposed approach: to use COVID-19 funds to build reusable, flexible data infrastructure for public health.

NACHC-CDC COVID-19 Multi-State Project
• Approach
  o Build infrastructure for data aggregation, data quality improvement and connect health center partners to Health Information Technology (HIT) innovation opportunities.
  o Collaborate with partners to support utilization of existing data, systems, and data collection of their patient populations to describe the health burden, disparities, and overall impact of COVID-19.
• 6 Health Center Controlled Networks and state Primary Care Associations
• Partners provided data on a monthly basis described in COVID-19 Data Dictionary using UDS, USCDI, C19 Interoperability Alliance, CDC immunization definitions
• NACHC created a cloud data warehouse for public health data cleaning, normalization, and analytics within first 6 months containing nearly 1 million individual patient records by year end
• First year of project revealed major challenges and advantages of using patient-levelHER extracted data to understand the scope of the pandemic

COVID-19 Challenges
• Data Extraction
  o COVID-19 concepts created and released throughout pandemic, so data capture approach has shifted – limited validation is performed on emerging concepts at most orgs.
  o Partner EHRs do not provide dashboarding or extraction support in a standardized way – some partner EHRs do not meet 2012 meaningful use (MU) requirements for standardized terminology
  o Partners using third party data vendors took 6-9 months to get their initial COVID-19 data extracts
• Data Quality
  o “Negative” test results reporting highly variable – misspelling, different terminology used, etc.
  o Non-mappable test results – data inputted as test results that were not actually test results, or unable to interpret their meaning
  o Social Determinants of Health (SDOH)
    ▪ 4.7k+ distinct name/value pairs in the SDOH data set
    ▪ Some measures are easier to manage/map
    ▪ Working on standardizing through NACHC PRAPARE and FHIR Gravity model
• Operations in the Pandemic
  o Staffing challenges throughout the pandemic, steadily worsened through the Omicron surge → vacancies on data teams, reduced pandemic activities due to staff shortages
  o Lab supplies, vaccines, therapeutics are not evenly distributed – some organizations obtained materials more easily depending on state/local infrastructure, duplication in reporting and supply chains results in waste, PPE a major problem during initial wave
  o Health center facilities and operations not designed for infection disease crisis and organizations had to make rapid shifts – payment for health centers is not equal in many parts of the pandemic causing financial losses for centers offering pandemic services

Phase One: Accept (virtually) anything
  • Data can be categorized into three buckets: registry data, “poorly” extracted data, acceptable data extract

Phase Two: Automate Everything
  • Migrate to OMOP at NACHC
  • OHDSI OMOP → automation/scalability, consistency, rigor, privacy, community

Data Analytics Overview
  • ~1.8 million patients – 30% white, 25% Latino, 14% black, 4% Asian pacific islander, 19% blank, 5% other
  • 5.4 million encounters, 2.4 million vaccines, ~1 million tests
  • Testing has declined overtime, 13% of tests had a positive result

Opportunity to Reframe Our Public Health Data Approach
  • How would this infrastructure change our approach to a future pandemic? – would enable us to get a picture of equity more rapidly
  • Extensible nature of this architecture allows us to use it for any domain or context in which we want to perform analytics on real patient-level data
  • Using FHIR data feeds, machine learning, automating data normalization will support future use of data from community health centers
COVID-19 Through the Eyes of Long-Term Care Pharmacy

TJ Griffin, PharMerica

Long-Term Care (LTC) Pharmacies – provide medications for medically complex populations, frail elderly populations, intellectual or developmental delay (I/DD) populations, licensed as retail pharmacies but are more of a hybrid between hospital and retail pharmacies

PharMerica – national lead in pharmacy services for skilled nursing, senior living & independent living, I/DD behavioral health & hospice services, specialty infusion, 6k+ employees, 180+ pharmacies worldwide, networked with 70k+ back-up pharmacies, 370k+ beds serviced in 50 states, 33 million prescriptions filled each year

Silver Tsunami – 2020-2030 there will be a 49% increase in the percent of the population that is 75+ years old, increased need for long-term care & LTC pharmacies

Long-term Care Market

- Independent living – 0.5m in this type of living, mobile & active, can walk/drive, 4-8 medications, utilizing non-LTC pharmacies (retail pharmacies, local pharmacies, mail order, etc.)
- Assisted Living & Memory Care – 1.0m using these services, usually 9-10 medications, limited mobility, help with daily tasks needed, use combination of LTC pharmacies and other pharmacies
- Skilled Nursing – 1.4m, 75% senior care, 25% short-term rehab, 10-12 medications, mainly using LTC pharmacies

Response to Pandemic

- February 2020 – sent first clinical alert to facilities providing clinical presentations, infection control recommendations, and Q&A
- March 2020 – additional alerts sent out, suggested screening visitors for acute respiratory symptoms and introduced pandemic planning, clinical alert about nebulizer treatments and increased exposure risk for healthcare professionals, supply chain prevention procedures enacted along with remote working rules for all non-pharmacy locations
- Best practices in the first 100 days of COVID
  - Consultant pharmacy activities transitioned to remote
  - Medication delivery – centralized drop points, disposable paper-based delivery containers, 7-day quarantine for returned medications
  - Employees screened and temperatures recorded daily
  - Weekly updates to infection control policy & procedures

Vaccination – Why LTC is so important

- LTC residents account for 1.1% of COVID cases, 14.4% of deaths from COVID in the US
- Majority of COVID-associated hospitalizations for patients 75+ years old were admitted from a long-term care facility
- Deaths & cases drastically declined when vaccinations became available
Operation Warp Speed

- Involved in discussions with partners (logistics companies, pharmacies, CDC & HHS, McKesson, and LTC pharmacies) about distribution, administration and billing processes
- PREP Act enables pharmacists to perform vaccinations
- Federal Pharmacy Partnership Program – September 2020
  - Walgreens, CVS, five regional partners to distribute vaccines once available
  - CDC requested LTC pharmacies’ assistance in taking over post 3rd clinics in the LTC space
  - Several responsibilities and rapid turnaround to prepare – CDC/state agreements, CDC mandatory reporting system, HRSA billing registration, first time administering vaccinations, etc.
  - 70k+ vaccinations administered and counting

Federal Pharmacy Partnership Programs

- Operation SPEED – standing up access for our clients to monoclonal antibodies, engaging other lines of business such as Amerita, partnerships with other vendors for infusion support
- CDC surveillance of prescribing trends in LTC during COVID
- CDC LTC Pharmacy Partner Program
  - Monoclonal antibodies and oral countermeasures (antivirals) – helping provide several treatments through LTC pharmacies