COVID-19 Experience & Impact on Oncology Pharmacy Practice

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Faculty Disclosure

• Sylvia Bartel declares no existence of a financial interest in any amount related to the content of this activity.

• Advisory Board members and other individuals, not previously disclosed, who may review, propose recommendations, and/or edit the content of PharmCon CE activities declare no existence of a financial interest in any amount related to the content of this activity.
Learning Objectives

At the conclusion of this activity, participants should be better able to:

1. Outline the areas of pharmacy practice that were affected by the COVID-19 pandemic
2. Identify specific operational and clinical practice changes that were implemented during the COVID-19 pandemic
3. Discuss how these practice changes will shape the future of oncology pharmacy

COVID-19 Global Cases Johns Hopkins

<table>
<thead>
<tr>
<th>Cases by Country/Region/Sovereignty</th>
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<tbody>
<tr>
<td>29,621,768 Global Cases</td>
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<tr>
<td>6,609,770 United States</td>
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<tr>
<td>5,020,559 India</td>
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<tr>
<td>4,382,263 Brasil</td>
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<tr>
<td>1,075,485 Russia</td>
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<tr>
<td>738,020 Peru</td>
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<tr>
<td>728,590 Colombia</td>
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<tr>
<td>676,487 Mexico</td>
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<td>651,521 South Africa</td>
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<td>603,167 Spain</td>
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<td>577,338 Argentina</td>
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<td>499,287 Chile</td>
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<tr>
<td>433,905 France</td>
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<tr>
<td>410,334 Iran</td>
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<tr>
<td>376,676 United Kingdom</td>
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<tr>
<td>342,671 Bangladesh</td>
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</table>
Global Oncology Pharmacy Experience

• International Society of Oncology Pharmacy Practitioners (ISOPP) survey
  • 42 practice leaders from 28 countries
  • Timeframe 4/10 to 4/22/2020
  • Determine impact of COVID 19 on access and delivery of cancer care

• Results
  • PPE supply issues noted in 12/28 countries
  • Difficulty in access of anticancer medications noted in 12/28 countries – increased
time to procure and reduced access
  • Anti-infective and supportive care medications also impacted
  • Changes to cancer treatment delivery
    • Curative intent
    • Palliative setting

Global Oncology Pharmacy Experience

• Pharmacist role changed or expanded in 8/28 countries
  • Redeployment to areas outside of usual practice
  • Expansion of pharmacy technician role
  • Increased utilization of digital technologies (e.g. telehealth, digital
    conferencing, telephone follow-up)
  • Remote dispensing & special consideration of high-cost, narrow therapeutic
    index, temperature controlled clinical trial and opioid medications

(Alexander et al, 2020)
Global Experience – France

- Guidelines for providing pharmacy services to oncology patients during COVID-19 pandemic from French Society for Oncology Pharmacy
- Developed by 7 oncology pharmacy practice experts
- Outlines 26 recommendations in the following categories:
  - Infection control practices for
  - Human resources/staffing

Global Experience - France

- Clinical pharmacy services
  - Home care
  - Dose reductions or changes in administration sequence to decrease risk of neutropenia
- Pharmaceutical and supply management
- Crisis management response
Global Experience - Netherlands

- Community pharmacies in the Netherlands response to COVID-19
- Survey sent to community pharmacies covering the following topics May 2020:
  - Changes in pharmacy setting/operational procedures
  - Communication about medications
- Results showed the following changes in practice:
  - More strict hygiene protocol
  - Use of plastic screens at pharmacy counters
  - Limit direct patient contact including patients coming to the pharmacy
    - Use of electronic prescriptions
    - Increased use of medicine self-service dispensing locations or special medication pick-up counters
    - Increase in mail order/delivery to patient’s home
  - Use of telepharmacy for pharmacy medication education

(Koster et al, 2020)

US Experience – Community Practices

- Need for agility, flexibility and rapid changes
- Communication and leadership a priority
- Prescriptions delivered via mail order or curbside pickup
- Infection control practices for staff, patient and the environment
- Regular patient communication critical via internet, social media, signage in physical space areas
- On site patient volume reductions and increase in telehealth
- With rapid changes, important to uncover issues and acknowledge mistakes

(Donovan, 2020)
US Experience – Oncology Practice

• Pharmaceutical and PPE supply chain
  • N95 masks, sanitizers, cleaning supplies, gowns, gloves
  • Shortages of medication such as sedatives, antivirals, inhalers
• Increase in utilization of medication patient assistance programs
• Alternate infusion sites such as home administration
• Increase in telehealth
• Pause for patient cancer screenings and reduction in new patient volumes
• Staffing schedule changes including a reduction in hours
• Staff taking on roles outside of usual practice
• Remote work for order verification and product checking
• Mail order of commercial and investigational prescriptions to patients
Cancer Centers COVID-19 Experience

Impact in the following areas:

- Human resources
- Provider/clinic practice
- Research
- Pharmacy operations & infusion practice
- Outpatient/specialty pharmacy

Cancer Centers Group COVID-19 Experience

Human Resources
- Remote work successful based on review of metrics & customer feedback
- Remote work expected to become part of normal operations including:
  - Order verification
  - Final product checking
  - Staffing reductions, hiring pauses, furloughs

Provider/Clinic Practice
- Combination of telehealth and onsite care during return to normal volume
- Verbal/telehealth consenting process adopted

Research
- Decrease in new patient protocol accrual
- Decrease in new protocol approvals
- Desire to continue:
  - Mailing patients investigational take home medications
  - Virtual sponsor monitor visits and site initiation visits
Cancer Centers Group COVID-19 Experience

**Pharmacy Operations & Infusion Practice**
- Implemented PPE conservation strategies
- Changes made to scheduling and physical space to accommodate social distancing
- Staff required to wear masks
- Drive-up/curbside injections
- Increased medication advance preparation
- Increase in volume at satellite locations
- Patient visitors/companions restricted

**Outpatient/Specialty Pharmacy**
- Mailing prescriptions to patients increased
- Patient prescription pick up reconfigured to deliver to patient beds/chairs or curbside pick-up

DFCI COVID-19 Response

- Hospital Incident Command Center Structure in place
  - Pharmacy included within Clinical Operations
  - Set-up Pharmacy Incident Command Structure with management team
- Rapidly changing – daily or twice daily updates
  - Communication via Incident Command meetings, department and Institute-wide weekly meetings, daily huddles, and email distribution
- Preparations for the unknown and unexpected
- Data analytics enhanced for real-time monitoring of clinical, operational and financial impacts
DFCI COVID-19 Response

- Infrastructure changes
  - Employee & visitor screening implemented
  - Changes to visitor/companion policy
  - PPE conservation at the Institute level and within pharmacy
  - Staff relocation, office & pharmacy work space reorganization to allow social distancing
  - Remote audits and interviews within pharmacy
- Increased monitoring of pharmaceuticals and supplies

DFCI COVID-19 Response

- Financial mitigation
  - Hiring pause for all positions
  - Elimination of annual pay increase
  - Reductions in retirement contributions
  - Senior leadership bonuses eliminated
- Pause and re-prioritization of existing projects
  - Pharmacy renovations
  - Satellite expansion projects
  - Specialty pharmacy expansion
DFCI COVID-19 Experience

• Reduction in new patient volume and non-chemotherapy infusion visits
• Institute Staffing
  • Large number of staff pushed to remote work (~4,000)
• Pharmacy Experience
  • Staffing
    • Remote work for clinical, dispensing, research, informatics, medication safety pharmacists, administrative assistants, billing compliance, regulatory staff, pharmacy students and residents
    • Leadership remote with on-site rotation
    • Implementation of telehealth for pharmacy visits
    • Re-assess ability for staff to cross-cover across the enterprise, not just their “home” site

Guiding Principles for Practice Changes

• Reduce the duration and frequency of patient in-person visits
• Maintain decrease in pharmacy medication turn around times achieved in the early phase of COVID-19
• Maintain safe medication practices
• Maintain compliance with regulations including waivers, emergency orders, etc.
• As rapid response transitioned to recovery, return to pre-COVID-19 infusion and new patient volumes
Pharmacy Operational, Clinical, and Clinical Research Changes

Dana-Farber Cancer Institute

### Pharmacy Structure

<table>
<thead>
<tr>
<th>Pharmacy Operations</th>
<th>Clinical Initiatives</th>
<th>Clinical Trials</th>
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<tbody>
<tr>
<td><strong>Key Initiatives</strong></td>
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<tr>
<td><strong>Infusion Services</strong></td>
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<tr>
<td>1. Mixing in advance</td>
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<td>2. Maximizing meds in ADC</td>
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<tr>
<td>3. Workflow enhancements (clean room)</td>
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<td>4. Staff regionalization</td>
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<tr>
<td><strong>Outpatient/Specialty Services</strong></td>
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<tr>
<td>1. Outpatient med pick up (includes adult, pediatrics, LMA and satellites)</td>
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<tr>
<td><strong>Medication Safety</strong></td>
<td></td>
<td></td>
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<tr>
<td>1. Route of administration changes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Decrease in frequency of administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Standardized dosing of specific medications</td>
<td></td>
<td></td>
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<tr>
<td>4. Verbal/telehealth consenting process</td>
<td></td>
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<td>5. Weight variance</td>
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<tr>
<td><strong>Regulatory</strong></td>
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<tr>
<td>1. Oral investigational drug mailout</td>
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<tr>
<td>2. Remote monitor visits</td>
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<tr>
<td>3. Research Pharmacy operations efficiency</td>
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**Infrastructure**

- Infection control guidelines
- PPE
- Remote work
Pharmacy Operations – Infusion Services

- Advance medication/chemotherapy preparation
- Optimizing Automated Dispensing Cabinets (ADC)
- Drug compounding workflow enhancements
- Staffing by geographic area and team assignments inclusive of compounding staff

Advance Drug Preparation

**Goal:** Have medication prepared for the nurse to administer when the patient checks into infusion

- Drugs selected based on stability data, high likelihood patient will receive treatment and no dose adjustments will be needed
  - Keytrada (pembrolizumab)
  - Opivo (nivolumab)
  - Herceptin Hylecta (trastuzumab hyaluronidase – oysk)
  - Herceptin (trastuzumab)
  - Perjeta (pertuzumab)
  - 5-Fluorouracil pumps
Advance Drug Preparation

**Workflow changes**
- Identification of patients by a report
- Staff assigned to manage these preparations and drug delivery to the infusion unit prior to the patients checking into infusion
- Preparations for morning appointments completed at the end of the day prior and the morning of appointment for afternoon patients

**Expected outcomes**
- Reduce patient wait-time in clinic
- Smooth out clean room operation by maximize mixing throughout the day instead of everything during peak times

**Next steps**
- Review metrics for medications
- Identification of additional medications suitable for advance preparation
- Explore with providers the options of having exam and infusion on different days for specific treatments/patients
Optimizing ADC Utilization

Goal: Identify additional medications that can be added to the ADC and will not need to be dispensed from the clean room

- Adjust PAR levels of existing medications in the ADC
- Examples of medications added to ADC include:
  - Zometa (zolendronic acid) 4mg
  - Xgeva (denosumab)

Pharmacy Operations – Outpatient/Specialty Pharmacy

- Mailing prescriptions to patients both within the state and into other states
- In addition to picking up prescriptions at the outpatient pharmacy, the pharmacy will deliver the prescriptions to the patient in the infusion area
- Process being discussed for the dispensing or oral contrast medications to the patient prior to their radiology appointment
Clinical Pharmacy Practice Changes

- Routes of administration changes from IV to SC or oral
- Decrease in frequency of administration
- Fixed and standardized dosing
- Use of oral medications where possible
- Administration of less myelosuppressive regimens where possible during pandemic e.g. paclitaxel before doxorubicin/cyclophosphamide
- Addition of verbal/telehealth consents

Routes of Administration

- Increase utilization of subcutaneously administered products
  - Herceptin Hyclea (trastuzumab hyaluronidase – oysk)
  - Rituxan Hycele (rituximab/hyaluronidase human)
  - Darzalex Faspro (daratumumab & hyaluronidase - fihj)
- Increased utilization of pegfilgrastim and Neulasta On Body Injector
Decrease in Frequency of Administration

- Keytruda (pembrolizumab) 400 mg every 6 weeks from 200 mg every 3 weeks
- Opdivo (nivolumab) 480 mg every 4 weeks from 240 mg every 2 weeks
- Kyprolis (carfilzomib) weekly from twice weekly
- Therapeutic interchanges of darbepoetin alpha (Aranesp) for epoetin alfa and leuprolide 22.5 mg every 12 weeks from leuprolide 7.5 mg every 4 weeks

Clinical Trials Changes

- Ability to mail out oral investigational medications
- Oral investigational patient medication returns paused
- Remote clinical trial monitor visits, site initiation visits
COVID-19 Vaccines in Development

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Partners</th>
<th>Current Phase</th>
<th>Type/Technology</th>
<th>Initial Doses Expected</th>
<th>Dose Capacity (global)</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>Oxford</td>
<td>Phase III</td>
<td>Adenovirus</td>
<td>300 million</td>
<td>1 billion</td>
<td>Began phase 3 in July 2020 with 30,000 patients. Expected delivery in Oct of vaccine to the UK only. U.S. ordered 300m doses for when vaccine is approved.</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>Moderna, Biontech, Acuitas Therapeutics</td>
<td>Phase III</td>
<td>Adenovirus</td>
<td>100 million</td>
<td>1.3 billion</td>
<td>Phase II moved up from Sept to mid-July. Phase III began in Aug 2020 with 30,000 patients. Expect vaccine to be ready in Dec 2020.</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Moderna, Biontech, Acuitas Therapeutics</td>
<td>Phase II</td>
<td>mRNA</td>
<td>100 million</td>
<td>1.2 billion</td>
<td>Seeking approval in late Oct. Expected delivery in Jan 2021.</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>WARP SPEED GlaxoSmithKline</td>
<td>Phase I</td>
<td>Recombinant Technology + Adjuvant</td>
<td>100 million</td>
<td>500 million</td>
<td>Expect a viable vaccine for approval by Feb 2021.</td>
</tr>
<tr>
<td>Merck</td>
<td>Themis, IAVI</td>
<td>Phase I</td>
<td>Vesicular Stomatitis</td>
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<td>Working on 2 different potential candidates. Expected delivery in year.</td>
</tr>
<tr>
<td>Novavax</td>
<td>WARP SPEED</td>
<td></td>
<td>Rec. Protein Nanoparticle</td>
<td>100 million</td>
<td></td>
<td>First doses for U.S. only</td>
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<tr>
<td>Valneva</td>
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<td>Company based in France; may only produce doses for EU due to limited capacity.</td>
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COVID-19 Vaccine Operational Considerations

- Distribution process
- Vaccine storage and stability
  - AstraZeneca, J&J, and Sanofi Pasteur: current product requires refrigeration only
  - Pfizer: current product requires storage at -94°F and may be stable for 24-48 hours refrigerated
- Anticipate vaccine demand
- Vaccine administration considerations
- Electronic health record ordering, preparation and administration considerations
Oncology Practice – Future State

• Continuation of some level of remote work, telehealth, approval & utilization of therapies that reduce the time spent in infusion
• Work with regulators to establish ongoing ability to mail investigational drugs and continue mailing of commercial medications
• Review PPE requirements and propose longer term PPE conservation strategies
• Maintain and continue to realize efficiencies gained during COVID-19 response
  • Current analysis underway to review staffing model, processes and volumes to see where regionalizing staff into teams will allow for optimized and improved communications which directly impact patient safety and efficiencies

Lessons Learned

• Ability to make change happen quickly during this COVID-19 time; need to keep this approach to continue to move the practice of pharmacy forward
• Communication is critical for:
  • Advancing our work forward
  • Engaging staff and leadership
• You cannot over communicate
• Resiliency of staff
• Importance of data analytics even if not 100% accurate can be used as a directional indicator to make changes, create targets and monitor progress is “real time”
• Resurgence planning is critical as we continue to see COVID-19 cases rise across the country
References


2. Pourroy, B, Tournamille JF, Bardin, C, et al: Providing Oncology Pharmacy Services During the Coronavirus Pandemic: French Society for Oncology Pharmacy (Societe Francaise de Pharmacie Oncologique (SFPO) Guidelines. JCO Oncol Pract 16@2020 ASCO.


Thank You