Implementation of Remote Management of Compounded Sterile Products through the use of a Telepharmacy System

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Do you believe telepharmacy will replace pharmacists or increase patient access to good quality care?
Background

- This impact had a negative impact on profit margin and made it difficult for the private physician office to stay in business.
- Healthcare organizations have been transitioning many of these practices under “provider base” organizations.
Background (cont)

- Under the health-system structure all of the regulatory requirements are applicable in the office settings.
- The introduction of pharmacists oversight and USP <797> regulations have been significant additions in cost as well as time with a new workflow.
- The “normal” practice in private oncology practices was to have nurse prepare and infuse chemotherapy.
- NIOSH and USP standards were generally not followed.
Major Obstacles to Compliance

- Pharmacist oversight in remote and often small volume infusion sites may not be cost-effective
- A shortage of oncology trained pharmacist makes it difficult to provide “live” oversight at all of the infusion locations
Options

- Close the site and transfer care back to the main hospital infusion center
- Consolidate sites to fewer locations so that a pharmacist on site may be cost-effective
- Prepare all chemotherapy at the main infusion center and utilize a courier service to provide medication
Innovative Option

- The previous options may be inconvenient to patient care and caregivers as the distance from home increases.
- A courier service may result in slow turn-around-time or delayed service depending on distance.
- Telepharmacy oversight keeps the patient close to home and does not result in service delay while being cost-effective.
telepharmacy Model Advantages

- Enhanced patient safety through standardized practices and pharmacist involvement in patient care where there were not pharmacy services before.
- Enhance the patient experience through improved quality, access, and consistency of preparation.
- Promote integrated and coordinated care through the use of telepharmacy technology to expand the role of the pharmacist in patient care.
- Maintain and/or reduce the cost by creating efficient processes, reducing waste, and reducing staffing overhead costs.
- Allow future expansion into remote settings and to improve access to quality oncology care.
Role of the Tele-Pharmacist

- Technician monitoring
  - Pharmacy Technician will be remotely monitored utilizing network camera technology positioned to view the technician working in the hood.
  - Video from remote sites will be monitored by the pharmacist. The pharmacist will review the mixing technician technique, disposition, and proper attire for IV preparation.
Role of the Telepharmacist

- Assessment Procedures
  - Technicians at the remote sites will contact the pharmacist at the pharmacy site upon arrival. They will be required to answer any questions the pharmacist may ask of them under direct supervision of web camera. The technician will proceed to check-in with the charge nurse or site supervisor.
  - Technicians will continually be monitored remotely by visual and audio surveillance through the day.
Role of the Pharmacy Technician

- With proper training, a technician CAN:
  - Scan chemotherapy for pharmacist verification.
  - Prepare IV admixtures following USP <797> guidelines as directed by a pharmacist.
  - Place orders with distributor for supply of medications, excluding Schedule II medications.
  - Receive and put away medication orders from a drug distributor, ensuring that proper handling and storage are maintained at all times.

- Identify and quarantine outdated medications
Can you use Telepharmacy in Ohio?

- What are the rules related to direct supervision of technicians in Ohio?
- Do pharmacy technicians need to be registered?
- Do pharmacy technicians need to be certified?
- What special training do Pharmacy technicians need to prepare chemotherapy?
Can you use Telepharmacy in Ohio?

- Can you do remote order entry in Ohio?
- What is the main difference between remote order entry and remote management of a pharmacy technician?
- Are both of these “telepharmacy”?
- As a pharmacist do you believe you should be able to do remote pharmacy technician management in the State of Ohio?
- Is there a need for it?
Case example: Telepharmacy in Connecticut

- Legislative obstacle was that Direct supervision of a technician was defined as the pharmacist being present and able to monitor the activities of the technician.
- Additional language set pharmacist to technician ratios for direct supervision depending on the setting.
- Remote order entry is not the same as “telepharmacy” and would not include remote management of chemotherapy preparation.
If it is Illegal than Don’t do it! or… Change the Law!!

- Step 1
  - Meet with Connecticut Drug Control and the State Board of Pharmacy to discuss the Concept
  - Solicit input and support for a trial to demonstrate safety

- Step 2
  Design the trial and define the metrics to measure and monitor the process.
Practice changes so the laws need to support the change or drive the change

- **Step 3**
  - Find a legislator and lobbyist to explain the safety and patient care

Design the Trial and present for consideration under the guidance of the Connecticut Drug Control Division
3 Phase Trial

- Phase I
  - Demonstrate the use of digital camera, barcode, surveillance camera and phone with a remote pharmacist with technician in usual setting.

- Phase II
  - Move technician to a remote setting with pharmacist in main hospital but just making standard stock medications.
Phase III

- Technician in off-site ambulatory setting preparing chemotherapy under the remote management of the pharmacist in the hospital setting.

- All Phases were visited and demonstrated with final approval coming at the completion of Phase III.

- Time frame for all 3 phases was 9 months.
Telepharmacy Legislation Passed in Connecticut

- During the 2012 Legislative Session, the Connecticut Legislature enacted Public Act No. 12-28, An Act Concerning The Use Of Telepharmacy by Hospitals. CHA sponsored the legislation, which was passed unanimously by both the House and Senate and signed into law by Governor Malloy on May 14.
Limitations

- Public Act 12-28, effective on July 1, 2012, permits all of Connecticut’s hospitals to use telepharmacy in the dispensing of sterile products. According to the Act, a sterile product is “any drug, as that term is defined in section 20-571 of the general statutes, that is compounded, manipulated or otherwise prepared under sterile conditions during the dispensing process, is not intended for self-administration by a patient and is intended to be used in a hospital, or its satellite, remote or affiliated office-based locations.”
Patient Advantage

- The Act allows patients to receive IV care and treatment closer to home, with a pharmacist at a hospital providing real-time audio and visual review of the activities of a pharmacy technician working at a satellite location. In addition, the pharmacy technician takes photographs of the sterile products at each step of the process for real-time review and verification, as well as long-term technical storage and quality review.
Under the new law, use of electronic technology or telepharmacy must include the following elements:

1. The dispensing process for the sterile product must be verified through the use of a bar code tracking system and documented through digital photographs, which are recorded and preserved.

2. A pharmacist must monitor the pharmacy technician’s activities through both audio and video communication.
Under the new law, use of electronic technology or telepharmacy must include the following elements:

3. The pharmacist to technician ratios outlined in section 20-576-33 of the regulations of Connecticut state agencies must be met. Currently, the pharmacist to technician ratio for hospitals is:
   - 1. In an outpatient pharmacy, two pharmacy technicians to one supervising pharmacist, unless the Pharmacy Commission grants a petition based on demonstrated need. In that case, the ratio is up to three pharmacy technicians to one supervising pharmacist.
   - 2. In an inpatient or satellite pharmacy, three pharmacy technicians to one supervising pharmacist, unless the Pharmacy Commission grants a petition based on demonstrated need. In that case, the ratio is up to five pharmacy technicians to one supervising pharmacist.
Under the new law, use of electronic technology or telepharmacy must include the following elements:

4. In the event of a malfunction of the technology, no sterile products prepared by a technician may be distributed to patients unless a pharmacist either personally reviews and verifies the accuracy of all processes used to dispense the product, or upon the restoration of the technology, which recorded the actions of the technician to confirm that all the steps were followed appropriately in dispensing the sterile product.

5. All orders shall be verified by a pharmacist prior to the delegation of such orders to a technician.
Under the new law, use of electronic technology or telepharmacy must include the following elements:

- 6. A hospital shall verify that only appropriately licensed personnel administer medications that were dispensed through the use of telepharmacy.
- 7. The hospital’s use of telepharmacy shall reside under the purview of the hospital’s director of pharmacy.
- 8. Hospitals using telepharmacy must conduct periodic quality assurance evaluations at least once per calendar quarter, which includes prompt review of any discovery of an error in medication administration when telepharmacy was used to dispense such medication. Quality assurance evaluations must be made available to the Departments of Consumer Protection and Public Health upon their request.
SMMA led this initiative through the consultation at YNHH

- This issue grew out of a successful pilot program at Yale-New Haven Hospital.

- SMMA was charged with drafting the legislative language, limitations and requirements as well as management of the pilot program.
Contemporary Technology and Equipment

- Personal protective equipment must be used by personnel handling chemotherapy (USP <797> standard)
- Appropriate environment must be maintained for the preparation of compounded sterile products (USP <797> standard)
- Appropriate biologic safety cabinets (BSC) must fit the risk factor exposure according to USP <797> standards
Contemporary Technology and Equipment

• All components of sterile chemotherapy preparation will be directly supervised by a licensed pharmacist.
• The assistance of audio and video link and digital photography will be used.
• Automated scanning technology (i.e Pyxis Connect®) will be utilized for medication order transmission to the pharmacist, storage of medication orders, and laboratory result data. Nurses will also have access to the medication order and lab data.
• Scanning technology can be eliminated with the implementation of bidirectional interfaced computer order entry system (i.e Epic).
View of Digital Camera in Biological Safety Cabinet
Camera installation for observation/telepharmacy set up
Externally vented Biologic Safety Cabinet with Hydraulic adjustable Stand
Hands Free Sink/Eye wash station separate from the sink and Hand Dryer
Chemotherapy Pharmacy Technician
Dose Verification

Error: This Dose does not have a Verified status.
Workflow

Physician sees patient

Provider enters medication orders

Pharmacist enters order into EPIC and verifies

Order transmits to DoseEdge

Pharmacist views pictures to verify product

Tech prepares product, takes pictures of each step

Nurses administer medication to patient
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Real Time Remote Telepharmacy Management!
Future Tele-Pharmacist!!