IMPLEMENTING A FREESTANDING ED/URGENT CARE

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LEARNING OBJECTIVES

- Describe the regulatory requirements for testing
- Demonstrate collaboration with stakeholders to make decisions for operations
- Design a working project plan for implementation and operation

DEFINITIONS

- Urgent Care Center (UCC)- a walk-in clinic focused on the delivery of medical care for minor illnesses and injuries in an ambulatory medical facility outside of a traditional hospital-based or freestanding emergency department (ED).
  - There were 10,728 active urgent care clinics in the U.S. as of February 2024.
  - Free-standing emergency department (ED)-licensed facilities that provide emergency care and are structurally separate from hospitals. They are often located in areas without easy access to a full-service hospital.
  - The United States has 770 freestanding emergency departments (FSEDs) as of March 2024, which is 13.4% of all emergency departments.
- Free-standing ED/UC- Combines both ED and UCC, cost depends on level of care needed.

BENEFITS OF ED/UC MODEL

- It eliminates the need to choose between visiting an ER or Urgent Care
- Efficient door-to-door times and no waiting
- Convenient retail location and positive consumer health experience
- Concierge-level customer service
- Billing is based on level of care

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BENEFITS OF ON-SITE TESTING

- Lab results inform 70% of clinical decisions, so it is critical to have quick turnaround time.
- Lab results important to clinical care are available within a short time frame.
- Patients can be treated and discharged or admitted to a hospital based on faster lab results.

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CONCEPT

- Presbyterian Health System realized the community need; chose Intuitive Health as partner.
- Meetings were set up with all stakeholders: medical staff, lab, POCT, Quality, nursing, Radiology, Respiratory, Pharmacy, etc., as well as Intuitive
- First Intuitive site in NM; needed to address differences in regulations, patient demographics, etc.
- Original plan was for 6 sites eventually, all using the same model. Currently we have 4 sites open.

PLANNING

- Testing desired for patient population; because of testing desired, the sites had to be mod complex.
- Potential POCT devices; what is currently available.
- Specifications for devices, reagents, QC, etc.
- Available space
- Will all testing be done on site, or will some testing be sent out?
- Project management is essential, set up calls to monitor progress and address any issues.

TEST LIST

- Depends on available point of care devices.
- Decision was for hematology, chemistry, urinalysis, coagulation, infectious disease testing, urine drug screen, ketones, immunochemistry.
- STAT list was developed for tests not available on POCT devices that are needed urgently to disposition patients.

DEVICE LIST

- Depends on testing desired; preference is for devices already in use within the system
- Not all requested tests have POCT possibilities
- Space needed/drains, etc.
- Multiple analytes on devices
- Approved for use case
- Ability to interface
- Peripheral equipment

PERSONNEL

What model will be used?

- All personnel test specimens as part of patient care
- Dedicated lab staff
- Staff with MLT or lab assistants/EMTs?

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REGULATORY

- For US sites, a CLIA Certificate needed
- Other possible accrediting agencies
- CLIA medical director for mod complex testing
- Technical consultant for mod complex testing
- Qualifications for testing personnel

BUILDING BASICS

- Lab space
  - Counters
  - Devices
  - Storage space
  - Refrigerator/freezer
  - Temperature/humidity monitoring
  - Electrical outlets
  - Data ports
  - Sinks
  - Computers
  - Processing space/centrifuge

PHYSICAL PLANT AND SAFETY

- Adequate space
- Door that can close
- Counter height
- Appropriate storage space
- Safety shields
- Temperature and humidity monitoring

SEND-OUT TESTS

- Tests that can’t be done POC need to be processed
- Courier system
- Where will non-POC tests be performed?
- Who is responsible for processing equipment and training?

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SUPPLY AND INVENTORY

- Contracts for all devices and reagents; use existing if possible
- Determine quality control and calibration verification materials needed
- Decide on PAR levels based on expected patient volumes
- Ensure supplies are ordered for validation and training

IT CONSIDERATIONS

- POCT middleware choice
- Devices should be interface-capable if possible
- Validation of interface

IT IMPLEMENTATION

- Project opened with middleware vendor for new site with multiple instruments
- Test panels built in middleware, LIS, EMR
- Work with network teams to get all devices connected
- Test sessions set up for all devices/panels
- Are Lantronix boxes or other hardware required?

TEST VALIDATION

- For our sites, we follow U.S. regulations.
- Ensure adequate time to complete validations on all devices.
- All mod complex devices must be validated on site.
- Required: accuracy, precision, analytical measuring range, normal reference intervals.
- If IQCP is needed, ensure adequate time to complete.

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TRAINING

- Training program is developed by technical consultant
- All training should be completed on site as much as possible
- Vendors can assist with training
- Training should include hands-on return demonstration.
- Follow accrediting agency, manufacturer’s IFU and/or state guidelines.

COMPETENCY ASSESSMENT

- Electronic learning management system used; only needed to be completed once.
- Competency assessment must be completed at the site of testing.
- Since many devices are mod complex, assessment needs to be done by technical consultant.
- Many staff cover more than one site, complicating the competency schedule.
- Nursing floor staff performed waived testing only, so could be assessed by lab staff without degrees.

PROFICIENCY TESTING

- Order proficiency testing (PT) for all devices and kits.
- Ensure training for non-lab personnel about importance of PT and the laws related to its performance.

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GOVERNANCE

- Collaboration between lab, nursing, ED physicians, Quality, Compliance, etc.
- Monthly meetings with all concerned (POCT, medical directors, lab staff, site leadership, ED clinicians) to address any issues.
- Monthly meetings between lab leads, operations director, and TriCore POCT team.

ONGOING OPERATIONS

- Weekly audits
- Supply issues
- Device issues
- Quality control/proficiency testing issues
- Assess test list and other operational concerns
- Point of Care team is on call 24/7 for lab staff.

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OUR BIGGEST LESSONS LEARNED

- Staffing models changed significantly, both at the sites as well as within POCT.
- Staffing with non-laboratorians meant a lot of misunderstandings.
- Competency assessments for those working more than one site were problematic.
- We work with clinicians to understand their needs. This is ongoing, as needs change depending on several factors.

CELEBRATE!!

Once open for business—kudos to all involved!

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QUESTIONS?

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