Intravenous Workflow Management Systems (IVWMS) Implementation Checklist

Created by the Section Advisory Group on Compounding Practice

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Intravenous Workflow Management Systems (IVWMS) or IV Room Technology Assisted Workflow (TAWF) describe a technology system that identifies medications for compounding typically through bar code scanning, standardized compounding processes, photo capture (volumetric) or measurement of specific gravity or density (gravimetric) documentation for verification.[1] Literature exists on the demonstrated safety of using IVWMS in sterile compounding environments.[2,3,4,5] The pharmacy industry is on the pathway for IVWMS to be a best practice similar to the utilization of automated dispensing cabinets, and smart infusion pumps in healthcare facilities.[1] Many hospitals also use the new visibility into workload data, medication errors, and compounding standardization to guide practice change.

This checklist was designed to be a tool for the implementation, transition, or optimization of Intravenous Workflow Management Systems (IVWMS). A team involving compounding experts, informatics team members, medication safety pharmacists, front line staff (pharmacists and technicians), and financial/contracting personnel should be involved in this process. Often, vendors provide a project checklist to guide completion of implementation tasks specific to their system.

Key elements in an IVWMS implementation:

- Section 1: Return On Investment (ROI) Analysis
- Section 2: Equipment
- Section 3: Regulatory
- Section 4: Technology
- Section 5: Workflow design and staff planning
- Section 6: "Go Live" planning
- Section 7: Metrics

Section 1: Return On Investment (ROI) Analysis

In the ASHP 2020 survey on pharmacy dispensing and administration practice, IVWMS were used in just over 21% of hospitals.[6] This amount represents almost a 15% increase in hospitals using IVWMS since 2014 based on the annual survey results. For hospitals evaluating IVWMS implementation, safety, financial impact, and environmental considerations (e.g., physical space) are often primary factors.[7] Furthermore, the regulatory environment (USP <797>, USP <800>, legal and regulatory requirements by state) must be evaluated for the optimal solution for your facility.

Return on Investment (ROI) for implementing IVWMS at your facility may include the following parameters as part of your facility's initial assessment. Facilities may apply different weights to the parameters based on their organization's priorities.

Facilities should use a modeling tool to help stakeholders evaluate the cost savings and ROI from risk reduction efforts. Product vendors and/or consultants with expertise in compounding practices may be a resource to develop an ROI for your facility.

ROI inputs:
- <u>Production</u>: Current IV process review based on production volume and efficiencies (timing, redundancies, waste)
- <u>Labor:</u> Correlated staffing requirements
- <u>Waste</u>: Correlated inventory requirements
- <u>Safety:</u>
  - Correlated error detection data from IVWMS
  - Keeping patients safe (correct final product) - and staff safe (injuries, hazardous handling)

<u>Metrics and demographics related to ROI analysis:</u>
- Current volume of production by unit of time (shift, day, week, month)
- Current inventory management of compounding products (supplies, fluids, medications) (consider quantity, costs over unit of time) - break it down as appropriate for your facility
- Current staffing by role and responsibility (FTEs, shifts, corresponding salaries)
- Current timing for production (how long it takes to compound certain products) - from order entry to administration
- Capture exceptions (staffing shortages, inventory shortages, unique products, populations, workarounds, system failures, USP <797>, downtimes)
- Select a specific product line or clinic to pilot the process (i.e., critical care satellite, hematology/oncology, etc.)

Section 2: Equipment

<u>Universal Considerations</u>
- <u>Cleanability</u>: Look for washability, healthcare grade, and review list of approved cleaning agents
- <u>Peripherals</u>**:** Assess how many peripherals are involved with your IV workflow brand. Determine if a traditional tablet/laptop/PC can provide the required amount of data ports.
- <u>Consider workflow and aseptic technique</u>: Attempt to limit the number of times your staff will need to remove their hands from the Primary Engineering Control (PEC). Consider which peripherals could be used within the PEC to streamline workflow. Don't forget to assess the impact of the peripherals within the PEC with dynamic smoke videos. Memorialize smoke study information in guidance and education to staff about zones of turbulence caused by the equipment.
- <u>Ergonomics</u>: Prioritize compounder ergonomics when purchasing IV Workflow component staging and use. Practice actual placement of furniture and use of peripherals for an extended period. Evaluate if your staff will be repeatedly turning their necks, twisting their spines, or stretching their arms. Some twisting will be involved in every setup if a monitor is placed outside of the PEC.

- Primary Engineering Controls (PEC): If you are in the market for new hoods, consider purchasing customized features such as: integrated cameras, monitors, side wall data port access and/or power outlets

Equipment Types	Device Type	Potential for Placement in PEC	Desired Features	Site Specific Considerations
Camera	IV Workflow Component	Yes	High Resolution/ Clear pictures Durable against USP <797> grade cleaning/ disinfecting agents	• Mounting options: stand vs. wall mounting • Consider placement angle implication on first air in both horizontal and vertical laminar airflow
Scale	IV Workflow Component (if an included functionality)	Yes	Likely dictated by IV Workflow vendor	• Consider cleaning protocols and service needs
Workstation furniture	Furniture		Easily cleanable Sealed Cavities Cable organization	• Workstation on wheels vs. mounting arm vs. wall mounting • Consider powered workstations to provide temporary power in the event of an outage
Computer	Computing	Yes	Consider the impact of a PC/laptop fan motor on particle counts and airflow on classified areas	• Consider computing power and features of PC vs. laptop vs. tablet for your location. • Many laptops and tablets don't have an adequate number of data ports
Monitors	Peripheral	Yes	Does your IV workflow or electronic health record have screen size requirements?	• Is touchscreen required/desired? • A touchscreen monitor may eliminate the need for a mouse outside of the PEC

Printer	Peripheral	Not prohibited	Confirm label tearing in proximity to the PEC doesn't compromise particle count requirements (balance with ergonomics); Labels printed for IV workflow often require labels to be introduced within the PEC. Consider washable labels to ensure USP <797> materials disinfection standards can be followed	• Consider wireless options for printers to limit cords
Power strips	Peripheral		Power strips in hospitals/clean rooms should be medical grade (check if organization must meet UL standard 1363a or UL 60601-1)	• Do you have an available power supply near the PEC and IV Workflow equipment? • Will power strips or a powered workstation be needed to plug in the various peripherals?
Keyboards	Peripheral	Yes	Keyboard should be washable. Keyboards with individual keys would ideally have a disposable cover to increase cleanability (establish a cover replacement frequency in your SOPs)	• Consider a wired vs. wireless keyboard • Have your compounders practice using a sample model while gloved • Will you allow a keyboard within the PEC? If so, confirm it won't negatively impact first air in your DCA

Mouse	Peripheral	Yes	Mouse should be washable	• Practice using the mouse on the surface of your workstation to determine if it requires a mousepad • Consider a medical/clean room grade silicone mousepad • Consider having two mice, one inside the PEC and one by the workstation • Consider wireless mouse to limit cords
Barcode Scanners	Peripheral	Yes	Trigger-free scanning Minimize entries into the PEC for intermediate label scanning	• Aim to minimize bringing labels within the PEC for the sole purpose of scanning. USP <797> requires hand sanitization with sIPA • Having a second scanner outside of the PEC may limit hand entry into the PEC for scanning only purposes
Foot Pedal	Peripheral (if an included functionality)	Yes	Assess cleanability and consider labeling if dedicating for use in a PEC	• Does your IV workflow model have a foot pedal as an option to advance workflow steps or trigger image capture? • Will you place the foot pedal on the floor or within the PEC? • Consider a dedicated use once your SOP is established (don't let some staff use a foot pedal, while others use in the PEC) • Evaluate the cleanability of cords

Abbreviations:
DCA=Direct Compounding Area
PEC= Primary Engineering Control (ISO Class 5 Environment)
sIPA=Sterile 70% Isopropyl Alcohol
SOP=Standard Operating Procedure

Section 3: Regulatory

- ☐ Consult board of pharmacy regulations related to IVWMS (i.e., remote verification, vendor selection, authorization)
- ☐ What required elements must be on the second label/post verification label?
- ☐ How will beyond use dates be managed and determined?
- ☐ Do you have a quality control process in place as recommended by regulatory agencies or standards setting organizations (TJC, DMV, NABP, local board of pharmacy, USP <797>/<795>/<800>, ISMP)?
- ☐ Who reviews outcomes and how often are they reviewed?
- ☐ How will you verify that your equipment is safe to use during dynamic testing (smoke testing, inspection readiness)?
- ☐ Where will the master formulation record be located (external or within the system)?

Section 4: Technology

Electronic Health Record (EHR) Integration

- ☐ Review ASHP Resource Center for Informatics on IV Workflow Management Systems: https://www.ashp.org/pharmacy-practice/resource-centers/informatics/iv-workflow-management-systems
- ☐ ASHP Guidelines on the selection, implementation, and utilization of workflow and robotic technologies for preparing intravenous compounded sterile preparations (DRAFT): https://www.ashp.org/-/media/assets/policy-guidelines/docs/draft-guidelines/draft-guidelines-IV-workflow.pdf
- ☐ How does the system integrate with your EHR? Consult your IT partner to understand desired functionalities and security requirements (e.g., unidirectional vs. bi-directional, barcode interface, tracking)
- ☐ Does your EHR have a unique ID for each order (dispense ID or order ID)?
- ☐ How will staff be required to log into the system? Does the system allow for single sign on or is there a password reset process?
- ☐ Will the label come from the EHR or from the IV Workflow system?
- ☐ What are the limitations of the label format (if applicable):
  - Order comments
  - Barcodes to allow barcode medication administration
  - Pertinent patient information
  - Formatting (font size, orientation, font choice)
  - Physical size
- ☐ Is the system able to send information back to your EHR for Drug Supply Chain Security Act (DSCSA) tracking?
- ☐ How long does the company retain data/images? Are they cloud based or local file based?
- ☐ Does the system track doses and communicate with nursing where the medication is in the preparation process?
- ☐ What safeguards against cybersecurity threats are present in both the vendor software and EHR software (if an interface exists).

<u>System Maintenance</u>

- □ What is the process for managing updates (testing validation)?
- □ How is interface development managed?
- □ How does the vendor send communications through your organization's firewall that might be impacted by system upgrades?
- □ How frequently are downtimes required? Will these downtimes be scheduled at times that do not impact workflow? How long are the downtimes expected to last?
- □ Are there preventative maintenance requirements for hardware?
- □ Does the vendor have any guarantees around level of uptime vs. downtime?

<u>Volumetrics, Gravimetric, and Machine-Readable Coding Scanning</u>

- □ Will gravimetric, volumetrics, or both be used for verification?
- □ If using gravimetric, are there scale limitations?
- □ Are there preparations or volumes that should not use gravimetric?
- □ Who will ensure that the barcode works in the IVWFS as new products, NDCs, etc. are added?
- □ Who will have access to update or configure the IVWFS at your institution? Include backups for staff on leave or for management after hours (e.g., borrowing products from another hospital).

<u>Product Build</u>

- □ How will vial sharing be utilized? Can waste be recorded in the system?
- □ How will preservative free items be identified? Do they need to be identified separately?
- □ Are build changes required (product dispense types, nomenclature)?

<u>Equipment</u>

- □ Will the equipment be provided by the vendor or purchased by your organization?
- □ What data and electrical access is needed?
- □ Can you engage a human factors engineer or subject matter expert consultants to determine if workflow processes have flexibility (vendor specific)?

<u>Section 5: Workflow Design and Staff Planning</u>

<u>Workflow Design and Task Responsibilities</u>

- □ Who will be responsible for documenting lot/expiration (IV prep tech or compounder)?
- □ How will the order be initiated for compounding (queue vs. label)?
- □ What products will require a product (mid-prep) check or will the check be only at the end or double final check?
- □ Will double verification be used for high alert medications?
- □ How will batch preps be checked vs. on demand preps?
- □ How are products checked for particulates that may not be visible in pictures?
- □ How are discontinued or retimed doses managed?
- □ Who will manage the beyond use dates?
- □ Has the process been defined for rejected medications?

- □ Is there a process to review pictures to provide feedback on blurry images or incorrect or missing images?
- □ Who is responsible for building new preparations?
- □ Will nonsterile compounding also use this system? (Training for non-sterile compounding staff)
- □ How will medications and IV fluids that are pumped be managed?
- □ How will you manage tracking of preparation/approval for multi-dose medications that require reconstitution?
- □ Have you outlined the expected procedures for limited or long-lasting system downtimes?
- □ Who will manage alerts within the system for the user? Which alerts are soft stops vs. hard stops?
- □ Conduct failure mode and effects analysis (FMEA) to evaluate potential risk points and workarounds

Ergonomics and Relationship between Equipment and Personnel

- □ Where are barcode scanners in relation to the work being done?
- □ Does your equipment restrict you from printing labels based on being computer vs. tablet?
- □ Are printers in the right locations? Does the product have "autoprint" functions or will the printer be selected/clicked?
- □ Will the labels default to certain printers based on location?
- □ Will the labels default to certain printers as you move between different programs?
- □ Who will print the final verification label (pharmacist vs. tech vs. automatic)?
- □ Where are the pharmacists located in relation to the IV room?
- □ Does the equipment set up lend to ergonomic design?

Workload Assessments

- □ How long on average does it take your staff to currently prepare an IV prep?
- □ How many preps in an hour?
- □ With the additional time required for documenting the lot/exp., do you need to adjust staffing or batches to allow for preparations to be completed. (Example: Average prep: 3 minutes; 8-9 am has 50 preps on average; 50 X 3 = 150. You have two staff members. On average, they should be able to make 20 preps/hour based on average prep time. 60 minutes/3 preps/minute = 20 preps X 2 staff = 40 preps;
- □ Do staff work times or workload need to be shifted?

Section 6: "Go Live" Planning

- □ ASHP Learning Activity: Updates in IV Workflow Technology Planning and Implementation: https://elearning.ashp.org/products/9080/updates-in-iv-workflow-technology-planning-and-implementation
- □ Have superusers been trained for day of "Go Live" for all shifts or is there an on-call process for after hours?
- □ Has staff education been completed?
- □ Does the vendor provide education or must it be developed by your facility? Or will a combination of both be used?
- □ Have all staff involved been oriented to the general expected process?

- □ Have minimum standards for photo verification (if applicable) been defined?
  - o IV bag
  - o Diluent/additives
  - o Drug vials
  - o Tubing sets and infusion disposables (filters, filter needles, CSTDs, etc.)
  - o Lyophilized Powder Drugs (includes minimum standard above plus):
    - ▪ Reconstitution solution stock package
    - ▪ Reconstitution solution measurement (syringe or repeater pump)
    - ▪ Picture for each vial or dose drawn up into syringe
  - o Medications already in solution/suspension (includes minimum standard above plus):
    - ▪ Medication dose measurement (each dose in a separate syringe)
  - o Volume withdrawn from IV bag
    - ▪ If plain solution must be removed from an IV bag before medication is added, then the volume removed must be photographed with source bag/container
- □ Are there standard operating procedures to help guide staff during go live? Do you have "cheat sheets" for the most common processes distributed to be where the item is prepared/verified?
- □ Is there a standardized process for the early phase of go live for raising issues or communicating questions? (e.g., tickets, project email, white board, huddles)
- □ How will key team members be in contact with the vendors during go live (Open call on Day 1, Daily meetings during 1st week, etc.)
- □ How will items processed be evaluated for feedback for staff? Daily random review? Reject list?
- □ Will all locations go live at once or one location at a time?
- □ Will all medications go live at once or in phases?
- □ How will process improvements post go live be communicated to staff (email, huddle, etc.)
- □ Will additional staff be temporarily needed during go live?
- □ Have labels been reviewed and tested?
- □ Is there a process to review pictures to provide feedback on blurry images or incorrect or missing images?
- □ Is there a process to assess for work-arounds to be able to address practice drift?

Section 7: Metrics

General

- □ Does the site already have baseline data or metrics? (may refer to ROI piece)
- □ Does the vendor provide metrics and analytics through their program?
- □ Is the data being summarized by the vendor or pulled into a dashboard?
- □ Will the company give you access to the background data to run your own analytics?
- □ Who will be able to view and make changes (if needed) based on analytics?

Safety

- □ Bypass rate/missed step for portion of IV workflow system?
- □ Bypass rate for complete circumvention of IV workflow management system?
- □ Override percent (can also review each step)
- □ Override number by step/type
- □ Number of Warning Alerts fired

- □ Rate of Warning Alerts fired
- □ Number of preparations rejected by pharmacist review
- □ Number of preparations outside gravimetric weight tolerance range?
- □ Percent of preparations outside gravimetric weight tolerance range?
- □ Number of medication errors related to compounding actions? (can also break down into different error types or categories)
- □ Average severity of medication errors?

Productivity

- □ Number of doses dispensed per unit time?
- □ Average total pharmacy staff time per compounded dose? (can break into different product types [chemo, low- vs. med-risk based on ingredient number, etc.])
- □ Average time from verification to ingredient scan?
- □ Average time from ingredient scan to start of compound?
- □ Average time from ingredient scan to completion of compound?
- □ Average time from ingredient scan to dispense/send? (if dispense tracking is recorded/available)
- □ Average time from start to completion of compound?
- □ Turnaround time (order entered/signed/released to admin)?
- □ Number of canceled preparations
- □ Number of incomplete preparations
- □ Number of completed preparations

Waste/Cost

- □ Dollar amount reimbursed for documented vial waste (JW modifier billing for waste)?
- □ Direct cost of discarded or rejected ingredients/errors?
- □ Direct cost of added equipment (e.g., computers, tablets, cameras, etc.)
- □ Annual subscription cost?
- □ Cost per preparation?

Labor

- □ Current sterile compounding FTE number?
- □ Total labor cost savings? (Aggregate of indirect + direct labor cost savings)
- □ Total indirect labor cost savings (estimated time savings x compensation)?
- □ Total direct labor cost savings (decreased cycle time x compensation)?

References and Resources

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