SAS is a Unifying Tool that Manages Hospital and Research Pharmacy Data and Reporting

Arman Altincatal, MS , Evidera, Inc.
Robert B. MacArthur, PharmD, MS , www.ampharmstatistics.com

ABSTRACT

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Hospital Information Technologists are faced with a dilemma: how to get the many pharmacy databases, dynamic datasets and software systems to communicate with each other and generate useful automated real time output. SAS serves as a unifying tool for our hospital pharmacy. It brings together data from multiple sources, generates output in multiple formats, analyzes trends, and generates summary reports to meet workload, quality and regulatory requirements.

Datasets originate from multiple sources, including drug and device wholesalers, web based drug information systems, dumb machine output, pharmacy drug dispensing platforms, hospital administration systems, and other sources. SAS output includes CSV files that can be read by dispensing machines, report output for Pharmacy and Therapeutics committees, graphs to summarize year to year dispensing and quality trends, emails to customers with inventory and expiry date notifications, investigational drug information summaries for hospital staff, inventory trending with restock alerts, and quality assurance summary reports. For clinical trial support additional output includes randomization codes, data collection forms, blinded enrollment summaries, and study subject assignment lists, to name a few of many possible standard documents. For business operations output includes invoices, shipping documents, and customer metrics.

SAS brings our pharmacy information systems together and supports an efficient, cost-effective, flexible, and reliable workflow.

INTRODUCTION

Abstract

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Pharmacy Dispensing

Drug Inventory Purchasing Decision

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This presentation will describe three basic services provided by nearly all hospital and research pharmacies, and how SAS has been integrated into each one, to support safe and efficient processes. The three areas are hospital pharmacy dispensing, drug inventory purchasing decision making, and investigational drug packaging (e.g. clinical trial material packaging or “CTM”).

For dispensing, most hospital pharmacies utilize a single software platform that includes modules for prescription order entry, label generation, fill list generation, hospital formulary maintenance, inventory maintenance and other functions. By design, and despite best efforts to provide a user friendly experience, these large software systems are not a perfect solution for all pharmacies, and customization is difficult, time consuming and expensive.

As a result of this pharmacists and technicians often work with generic, rather than customized documents and labeling. It is common to see pharmacists and pharmacy technicians working with crude fill lists and reams of label printouts that require hand sorting, secondary calculations, and data transcription. This can lead to dispensing errors, as staff create their own undocumented “work around” procedures. These *work around* activities can be addressed by creating a more customized system that better supports workflow and documentation.

Regarding hospital pharmacy drug purchasing and inventory maintenance, costly drug purchasing decisions are made daily, in an environment where drug shortages and major swings in both drug availability and cost are common place. Hospital pharmacies work under fixed budgets. They must be able to respond to these changes quickly in order to ensure that patients receive all medications as ordered, while the department stays within budget. We will present a process that allows a pharmacy to use its own purchasing and dispensing data, along with publicly available information, to make more informed purchasing decisions.

For CTM packaging, pharmacies at academic medical centers often must provide a “Research Pharmacy” service that manages all aspects of investigational drug handling per Good Manufacturing Practices (GMP) and Good Clinical Practice (GCP) requirements. The drug packaging activities must be performed in a manner consistent with FDA requirements, which requires a level of data management and document control that is vastly different from all other hospital pharmacy activities. It requires familiarity with FDA GMP documentation practices and 21CFR part 11 compliance. The packaging procedures in place need to be similar to those followed in a FDA registered GMP facility. We will present a SAS supported data, document, and label generation flow process that can be used in either setting.

METHODS

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- The processes described herein, including the use of SAS, have been put into practice in the hospital pharmacy setting (specifically a Long Term Acute Care “LTACH” hospital) , an academic medical center setting, and in a licensed GMP establishment. This Eposter briefly describes those experiences.

- Base SAS/ACCESS package version 9.2 (or higher), running on a PC, was utilized to support all processes described. All data required where either directly accessible on the PC or were delivered to the PC by the hospital dispensing/packaging machines or pharmacy dispensing software platform.

- All SAS programming was performed by the authors.

- Data entry was performed by trained staff using either a departmental Research Pharmacy ACCESS database or specific MS excel spreadsheets. In all cases the data entry process was secure, and performed in a 21CFR part 11 compliant manner.

- Fill lists, batch records, and all other documents were generated using the SAS ODS system. SAS generated datasets for labels were exported as CSV files which were imported into the Zebra Designer Pro label system for printing on a variety of Zebra printers.

- For hospital dispensing, prior to implementation, all output was validated 200% against multiple reports generated by the existing standard pharmacy software platform, over the course of 4 weeks. The Quality Control process described in the flow charts was performed daily, and consisted of reports that provided a comparison of the basic input data sets against the final output datasets.

- For CTM packaging, the study protocols were supplied by the trial sponsors, and a “Packaging Plan”, was prepared by the packaging team, for approval by the study sponsor prior to the start of packaging. All data needed for the batch records and labeling was included in the packaging plan, for sponsor review and approval. For each batch the quality control process compares all relevant raw input data, including random code treatment assignments, all label fields, and product specifications, against the final output datasets and documents. The printed labels and documents also undergo a 200% visual quality control check against study file source documents, prior to release. .

HOSPITAL PHARMACY DISPENSING

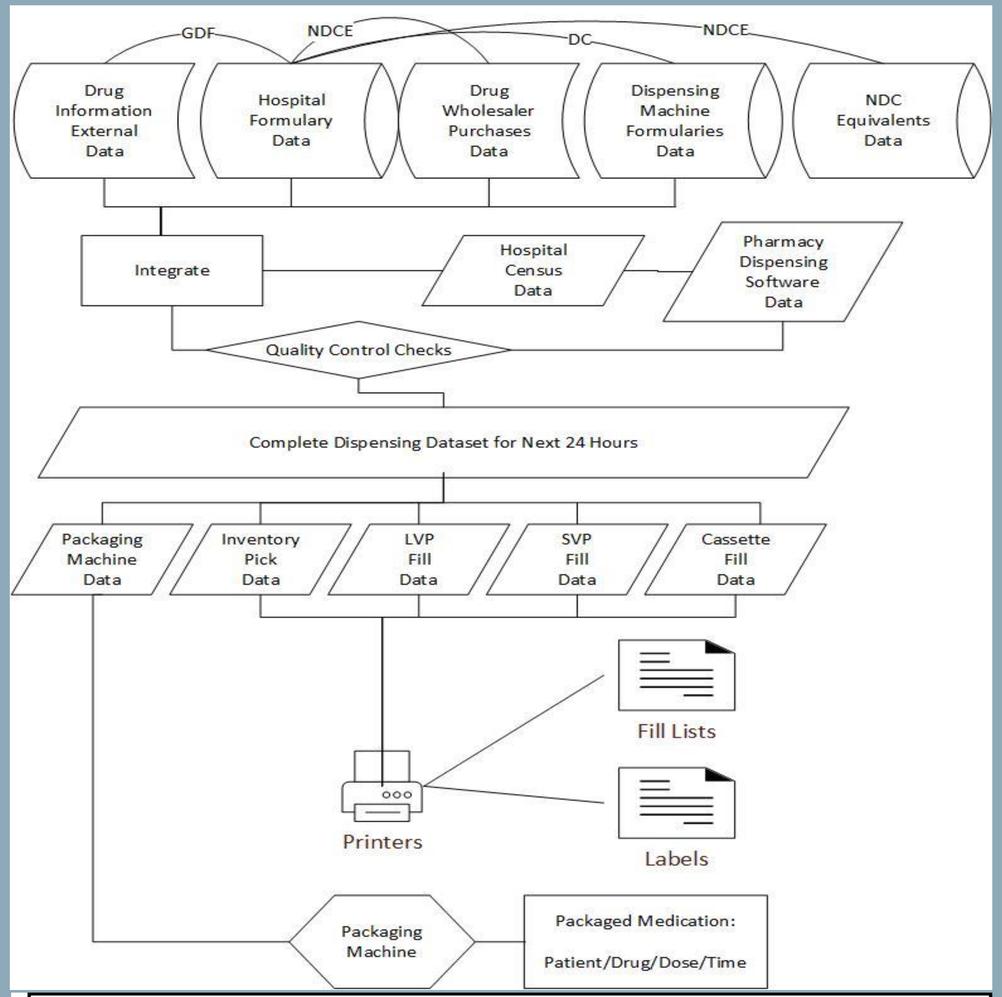

Figure 1: Dispensing Information and Process Flow, Using SAS
See Table 1 for index variable definitions
SVP = Small volume parenteral
LVP = Large volume parenteral

Table 1: Data, Indexing Variables, Quality Control Checks, and Output from the SAS Supported Dispensing System

Key Variables	Description
Data Primary Indexing Variables	Master Drug Code - MDC - Hospital Formulary Drug Code
Secondary Indexing Variables	Drug Code - DC - Dispensing machine formularies GenDoseDF - GDF - Composite variable Patient MRN - MRN - Patient medical record number NDC Equivalents - NDCE – Equivalent products by NDC no
Quality Control Checks	No duplicate drug orders per patient Order dates and times within cassette exchange time window Number of orders/patient Total number of orders Product NDC numbers agree with external NDC dataset Agrees 100% with Medication Administration Record Name, MRN, location Other
Output	Packaging machine data file – CSV file uploaded into dispensing machines Inventory Pick List – Pharmacy Technicians use to pull bulk products (oral, parenteral, topical, other) from inventory for use in dispensing LVP Fill Data – Used to generate labeling and fill lists for Large Volume Parenteral products SVP Fill Data – Used to generate labeling and fill lists for Small Volume Parenteral products Cassette Fill Data – Used to generate fill list for all oral medications

The flow chart (Figure 1), depicts the entire information management, labeling and medication distribution process utilized by the pharmacy. SAS was used to perform all activities described in the flow chart. The process was started daily, at 2PM, and provided all medications needed over the ensuing 24 hour period, starting with 4 PM doses

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DRUG INVENTORY PURCHASING DECISIONS

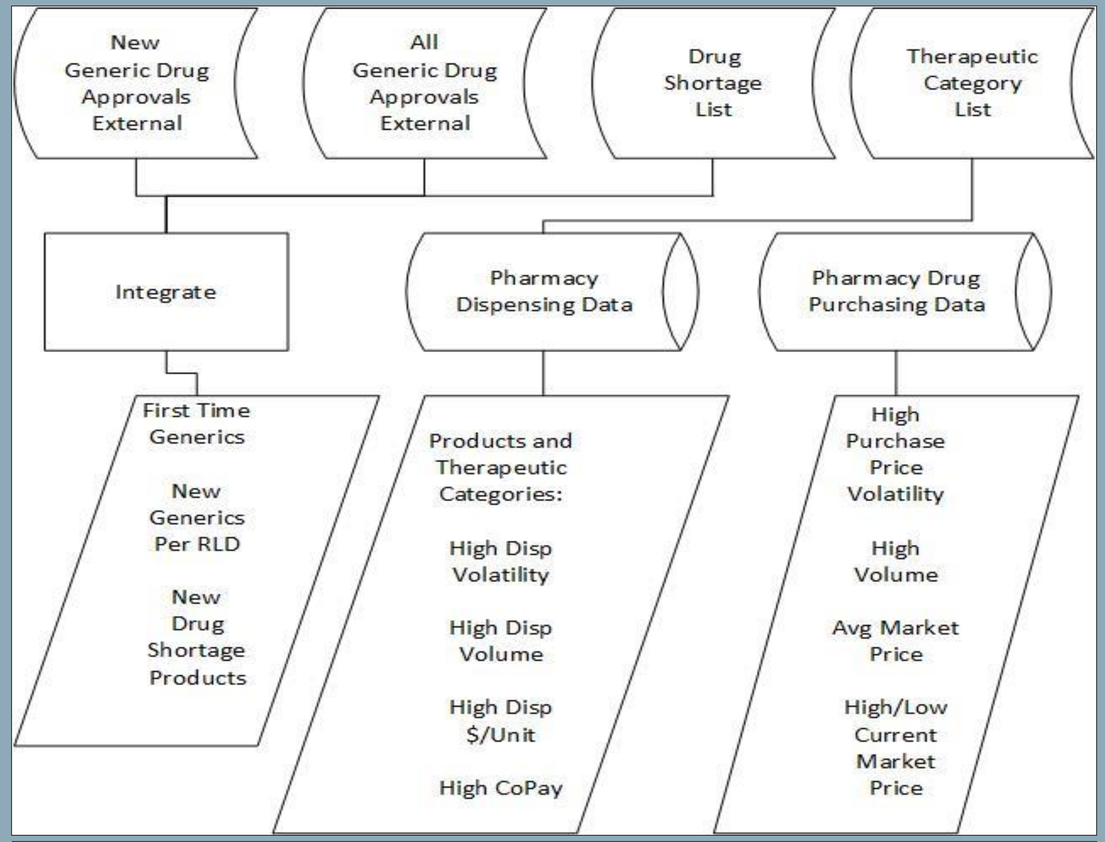

Figure 2: Data Used to Inform Purchasing Decision

Depicted in Figure 2 is how in-house pharmacy dispensing and drug purchasing data were brought together with external datasets (FDA Generic Drug Approvals, and Drug Shortage Listing, and other sources) to inform the drug purchasing process.
For example, when a significant increase in a product price is detected by the system, an alert is generated. In the case of a high volume product where such a price increase would significantly impact pharmacy profit (or hospital margin given fixed per patient reimbursement) the purchasing agent is alerted to look for new generic equivalent products that may be more reasonably priced. Conversely, any price decrease for a high volume: high value product will trigger an alert to purchase the product at the reduced price, and also recommend the number of products to purchase.

Table 2: Comparisons Made by The SAS System, to Support Purchasing Decisions

Dispensing Data	**Other Data**	**Action**
High Disp Volume :	High Avg Market Price : Low Current Price	Purchase
High Disp Volume :	High Avg Market Price : High Current Price	Check other Wholesalers
High Disp Volume :	New Generic Approved	Monitor for price change
High Disp Volatility :	High Avg Market Price : Low Current Price	Purchase, if current volume high
High CoPay:	Marketing Incentives	Encourage new customers
High Volume Therapeutic Category:	Marketing Incentives	Encourage new customers

In Table 2, there is a listing of the most basic alerts produced by the system. These are generated daily, for review by the pharmacy purchasing agent.

CLINICAL TRIAL MATERIAL PACKAGING

Clinical Trial Material Packaging

Table 3: Sample Phase 1 Double Blinded Ascending Single-Dose Dose Escalation Trial Supported by SAS CTM Programming

Tx Grp	No. of Subjects*	Study Doses (mg)	Active Treatment			Placebo Treatment	Total No. Capsules Per Bottle
			No. Placebo Caps	No. 50 mg Caps	No. 100 mg Caps	No. Placebo Capsules	
1	6 (4A:2P)	0 or 50	2	1	0	3	3
2	6 (4A:2P)	0 or 100	2	0	1	3	3
3	6 (4A:2P)	0 or 150	0	3	0	3	3
4	6 (4A:2P)	0 or 200	1	0	2	3	3
5	6 (4A:2P)	0 or 250	0	1	2	3	3
6	6 (4A:2P)	0 or 300	0	0	3	3	3

* A = Active ; P=Placebo

An example of a typical phase I study CTM packaging project is outlined in Table 3. The process by which the treatments described were packaged into a final form in a GMP compliant manner is illustrated in Figure 3.

Using established SAS program sets, the study randomization code, batch record documentation, CTM labeling, have been generated for many clinical trials across study phases I, II, III, and IV.

In this example the study randomization code (produced using PROC PLAN) along with the labeling specifications, packaging material specifications, investigational drug product specifications, and finished product specifications, are brought together to prepare a complete preprinted batch record and all required labeling. This system has advantages in that the labels and batch records produced can be narrowly defined and generated in a step-wise fashion over time. Also, the CTM source data from the sponsor and packaging plan (including Table 3 data) can be used directly via import into SAS, rather than relying upon creation and testing of study specific data entry screens.

For example, in a phase I study, step-wise control over the process allows packaging to run in parallel and just ahead of study dose groups. That can save CTM and resources if the trial does not run thru all planned dose groups. For a phase III study, packaging runs can be performed as active and control drug supplies become available, to accommodate CTM expiration dating and supply chain constraints.

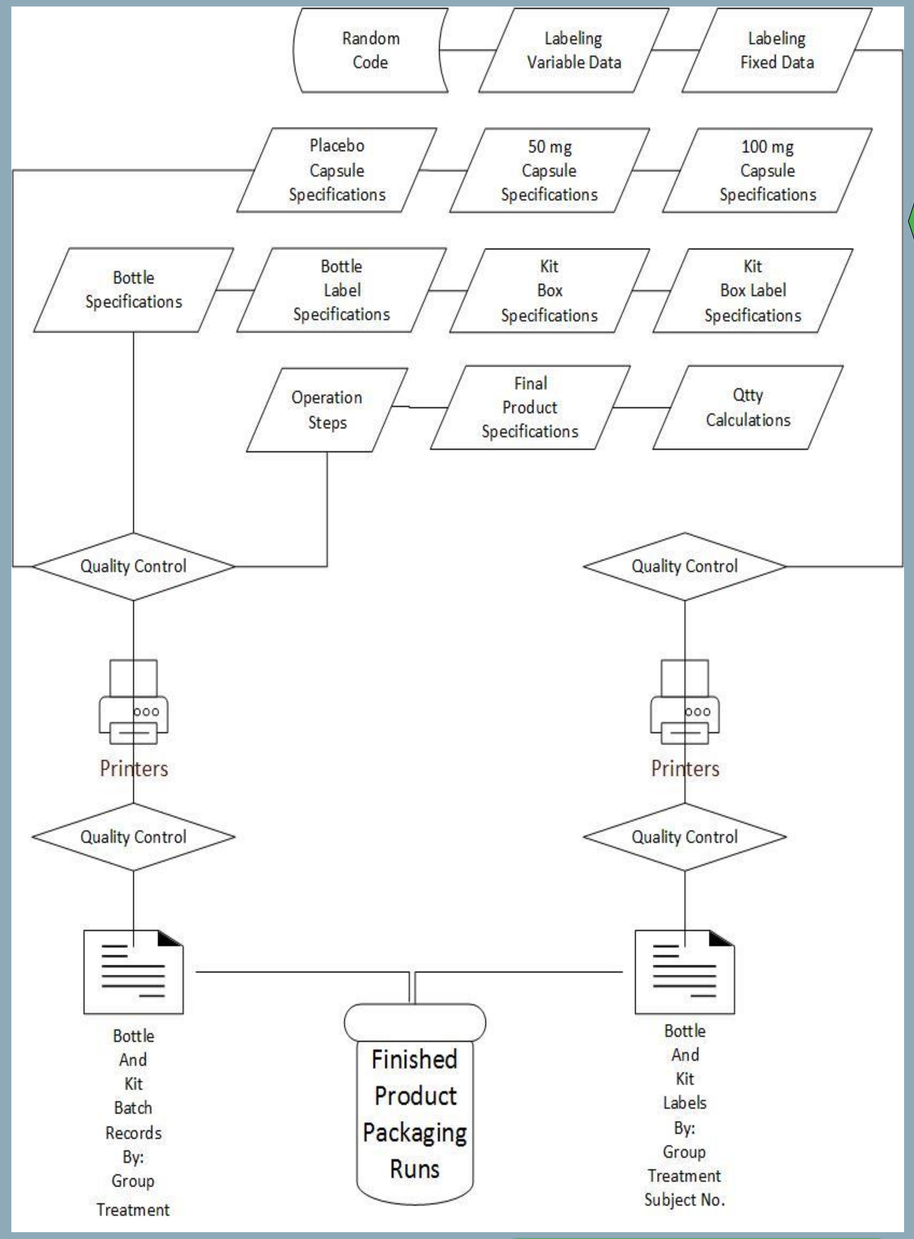

Figure 3: Clinical Trial Material GMP Packaging Process

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CONCLUSION

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SAS can function as a unifying software tool for hospital pharmacies, research pharmacies, and CTM packaging operations.

For the hospital pharmacy, it brings together data from drug wholesalers, pharmacy dispensing software systems, automated drug dispensing machines, and drug information databases. SAS output supports safe medication dispensing via interfacing with automated dispensing machines, and production of customized labeling data, fill lists, and pick lists. SAS can also assist with business metrics and maintenance of cost effective inventories.

SAS can also support GMP CTM investigational drug packaging operations, for all clinical trials in phases I thru IV.

Contact: Robert B. MacArthur, PharmD, MS
rmacarthur@researchpharmacy.com
www.ampharmstatistics.com