Impact of IWS/IVRS in Clinical Trials on Resource Utilization

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Abstract
There has been an increase in sponsor use of electronic inventory management and patient treatment assignment systems. These systems may be either web-based (IWS: Interactive Web-based System) or telephone-based (IVRS: Interactive Voice Response Systems), and require that staff have unique account logins and passwords for access.

Typical activities using IWS/IVRS include inventory receipt and acknowledgment. More importantly, patient visits (enrollment & off treatment) and treatment assignments are increasingly obtained via IWS/IVRS, and these often need to occur in real-time once the patient has been evaluated on site, so that patient weight or other factors may be assessed prior to obtaining the assignment.

Time studies in Research Pharmacy (RP) indicate a 48% increase in effort for a given task when IWS/IVRS is involved. In addition, Cancer Center study coordinators time studies in November 2015 showed that 0.25 FTE is currently required to obtain patient treatment assignments across all the studies managed by the Clinical Trials Office.

Introduction
There has been a rise in the use of interactive voice response (IVRS) and interactive web-based systems (IWS) for the supply chain management of investigational product (IP) used in clinical trials. From a sponsor perspective, these systems improve efficiency in IP distribution, real-time inventory tracking, and enhanced data management of IP assignments to subjects. Through real-time inventory tracking and assignment, sponsors minimize IP waste and improve data capture, leading to overall benefit in the management of IP in clinical trials. 1, 2

The Clinical Trials Office (CTO) serves as the centralized core facility of all clinical research trials conducted by investigators at the University of Michigan Comprehensive Cancer Center (UMCCC). Likewise, the Research Pharmacy (UM RP) provides comprehensive IP management and support services via delegation from the investigators. Over the last 5 years, there has been an increase in the number of clinical trials at UM CCC utilizing IWS/IVRS, and continued growth is anticipated:

- FY10: 18% of studies with IP were managed via IWS/IVRS
- FY14: 49% of studies with IP were managed via IWS/IVRS
- FY14: 60% of new studies with IP were managed via IWS/IVRS

While industry sponsors have demonstrated benefit on supply chain and data management from use of IWS/IVRS, there has not been a formal assessment of the impact of these systems on study team and site supportive personnel efforts. At present, the majority of IWS/IVRS activities at UMCCC are performed by either the CTO Study Coordinators (Data) or Research Pharmacy technicians and pharmacists. Specific activities include:

- Patient IP treatment assignments → CTO Study Coordinators (Data)
- Patient dispensing using assigned IP →Research Pharmacy
- Inventory management (receipt, expiration tracking, returns) →Research Pharmacy

Workload metrics collected for the previous 6 months by the UMCCC showed that overall study coordinator effort is greater (see Chart 1) as nearly 1% of industry studies at UMCCC include IWS/IVRS (see Chart 3). Anecdotal evidence from both the Clinical Trials Office and Research Pharmacy staffs indicated that there were specific activities that require significantly more effort than when IP is not managed via these systems. Based on staff impressions, 2 specific tasks were chosen for evaluation.

This project was designed to quantify the impact on staff effort for two specific activities: Patient Treatment Assignments (UMCCC) and IP Shipment Receipt (Research Pharmacy).

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Methods and Materials

UMCCC Study Coordinator Treatment Assignment Effort:

- For 6 months (Nov’14–Apr’15), staff recorded effort in minutes spent on each treatment assignment.
- Total effort per treatment assignment was measured from the time of request in the clinic to the entry of the assignment into the order.

UM Research Pharmacy IP Shipment Receiving Effort:

- For 6 weeks (Aug’14–Sep’14), staff recorded effort in minutes spent on each IP shipment.
- Total effort per IP shipment was measured from the time the shipment was opened until it was logged into inventory and placed in appropriate storage.

Results

UMCCC Study Coordinator Treatment Assignment Effort:

- Total effort for the IVRS/IWS step adds >25 minutes per treatment assignment.
- Length of study:
  - SC(D) study lasted 3 months
  - SC(C) study lasted 6 months
- This does not include the time lost between hand-offs and extending patient visits.

UM Research Pharmacy IP Shipment Receiving Effort:

- Average SC effort per treatment assignment
- Average IP shipment effort per IP shipment (n=169 shipments)

Discussion

UMCCC Study Coordinator Treatment Assignment Effort:

There was an increase in effort required for the treatment assignment process when studies utilize IWS/IVRS. Variation over time is likely due to characteristics of the specific studies that were active in each month. In the current UMCCC workflow, the involvement of non-clinic based study coordinators (SC) is an additional hand-off for IWS/IVRS studies compared to non-IWS/IVRS studies. The inclusion of this exchange in the workflow was done due to the ease of accessibility of IWS/IVRS for desk based staff over clinic based staff, particularly as the use of IWS/IVRS increases. While it is possible that clinic-based staff or pharmacy staff may be able to complete this task more efficiently (due to ease of access to patient status and other clinical information), it is clear that the use of IWS/IVRS for treatment assignment adds significantly to overall site effort and is likely to negatively impact patient care due to extended wait times and other supply related issues. At our site, we are currently working to identify optimal workflow and staff to be involved in treatment assignment activities, given the significant effort required and the impact on patient care.

Research Pharmacy IP Shipment Receiving Effort:

There was a significant increase in effort required for IP Shipment Receiving activities when IP was managed with IWS/IVRS. There are a number of other Research Pharmacy activities related to delegated roles that would likely be impacted in a similar fashion for studies utilizing IWS/IVRS management of IP. These include IP return, conduct of periodic monitor visits (due to the increased time required for CRAs to match IP with records for dispensing and current inventory), and patient care activities, in which specific treatment assignments must be used and verified per standard pharmacy dispensing procedures.

Conclusions

A Research Pharmacy and in UMCCC CTO staff increased effort is currently not captured in fee structures, effort estimates, or staffing models.

An IWS/IVRS Workgroup comprised of CC CTO Leadership and RP Leadership has been formed to evaluate optimal staffing patterns and task assignment for activities such as obtaining IP treatment assignments.

Based on the results of this project, it is anticipated that additional FTE support for these activities can be justified.

Additional time/effort studies are needed to assess impact of IWS/IVRS on other IP related tasks in both Research Pharmacy and UMCCC CTO. These may include impact on patient wait times.

References

Acknowledgments
1. Research Pharmacy, CTO-EHR Integration and UMCCC, Comprehensive Cancer Center: Further research embracing ancillary treatment area, quality assurance, and adherence will be valuable.

Impact of IWS/IVRS in Clinical Trials on Resource Utilization: There was an increase in effort required for the treatment assignment process when studies utilize IWS/IVRS. Variation over time is likely due to characteristics of the specific studies that were active in each month. In the current UMCCC workflow, the involvement of non-clinic based study coordinators (SC) is an additional hand-off for IWS/IVRS studies compared to non-IWS/IVRS studies. The inclusion of this exchange in the workflow was done due to the ease of accessibility of IWS/IVRS for desk based staff over clinic based staff, particularly as the use of IWS/IVRS increases. While it is possible that clinic-based staff or pharmacy staff may be able to complete this task more efficiently (due to ease of access to patient status and other clinical information), it is clear that the use of IWS/IVRS for treatment assignment adds significantly to overall site effort and is likely to negatively impact patient care due to extended wait times and other supply related issues. At our site, we are currently working to identify optimal workflow and staff to be involved in treatment assignment activities, given the significant effort required and the impact on patient care.