SELECTION OF IV TECHNOLOGY WITH DRUG ERROR REDUCTION SYSTEM

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ABSTRACT

The complexity of current Infusion Therapy technology, which incorporates Drug Error Reduction System (DERS) for tracking, monitoring, and control is becoming the standard for delivery of medication in IV therapy. Integration with existing hospital Information Systems such as Admission Discharge Transfer (ADT) and Pharmacy Systems, along with Risk assessment and analysis on adverse events due to medication errors are expected from health care facilities. The acquisition of this technology requires a clear understanding of both clinical and technical needs of the facility. Without adequate tools, guidance and advice, the process of selecting and implementing this technology can become very expensive and time consuming.

The choice of IV therapy requires close collaboration between healthcare professionals at all levels. Equally, clinicians and nursing staff as the end users, Pharmacy, Risk management, and other disciplines within the organization contribute to the discussion on the acquisition of this technology. Clinical or Biomedical Engineering has a greater role to play in this process. Therefore, there is a need for discussion, collaboration and sharing ideas on how different hospitals are implementing and supporting the technology

This paper discusses the acquisition of IV therapy technology in general, and the process of selection of smart infusion devices with Drug Error Reduction System in particular. It provides the reader with a matrix approach as one of the tools to facilitate the selection of the vendor based on technical specifications. The aim is to open up a discussion within the Clinical and Biomedical engineering community about this technology. Also to share our experience by highlighting some technical and clinical considerations that should be taken into account during the exercise of selecting the required technology for the healthcare facility. A matrix approach based on technical specification is used as a tool to help the project team to compare technologies offered by different vendors.

INTRODUCTION

The acquisition of IV therapy with DERS requires systematic assessment in order to establish short and long term benefits of safety and efficacy of this technology. A traditional pre-market study by only comparing medical devices before selection of the right technology to purchase is no longer applicable. Evidence based assessment is becoming common practice in evaluation and selection of technology in healthcare. Systems integration have improved the safety of patients while at the same time have created dilemma to the Clinical/Biomedical Engineering personnel who now requires a wide knowledge in different disciplines in order to accordingly advise the healthcare facilities on the acquisition of any given system.

Our existing IV technology is at the end of its life cycle and no longer supported. “Smart Technology” or IV therapy with DERS is currently the only option that the market can offer. Considerable effort has been made in the design of these systems which incorporates many aspects of patient safety and user’s error reduction in medication delivery. The combination of technologies that make current systems is becoming very complex. To identify a potential vendor in a very objective way or to select a suitable system is becoming a very expensive and time consuming process. Therefore there is a need for evidence based tools to facilitate this process and reduce the assessment time.

Our approach consisted of the use of a technical specification based on a Request for Proposal (RFP) to generate a matrix for data collection, analysis and scoring. This method gives us a better understanding of similarities and differences between vendors and their systems. The matrix was also used as a reference indicator during technical and clinical evaluation. After site visits suggested by vendors, the matrix was rescored and analyzed in order to identify the difference between what the vendor presented in the RFP and their current situation as observed by the

core project team. Due to confidentiality, the matrix variables below are for indication only.

MATERIALS AND METHOD

1. Design of technical specification

From literature review, Canadian Council on Health Services Accreditation (CCHSA) and Canadian Patient Safety Institute (CPSI) recommendations on patient safety, DERS system was identified as a new technology improving current practices in the delivery of IV therapy. A technical specification was designed as part of the request for proposal. As most systems are primarily designed for the adult population and adapted to pediatric needs, this technical specification was designed with a maximum set of requirements identified by the project team as critical for pediatric population. Our approach to the technology assessment was to look for a system that will match these requirements within a tolerable degree of accuracy.

Table 1: Example of technical specification

Technical requirements	
1	SickKids needs
1.1	Population
1.2	IV therapy system
2	General requirement
2.1	Display and controls
2.2	Human Factors Design
2.3	Controls
2.4	Alarms and indicators
2.5	Battery and Power supply
2.6	Decontamination
2.7	Pole clamp and Docking station
2.8	General Safety
2.9	MRI compatibility
3	Particular requirement
3.1	Accuracy
3.2	Flow rate
3.3	Volume to be infused
3.4	KVO rate
3.5	Occlusion pressure range
3.6	Bolus
3.7	Purge /Prime
3.8	PCA Device
3.9	Multiple channels infusion devices
3.10	Syringe Device
4	IV supplies and accessories
4.1	Disposable set
4.2	Disposable set economic option
4.3	Quantity and configuration
4.4	Set specification
4.5	Bar-coding
4.6	Wireless communication
5	Dose Error Reduction System
5.1	DERS in IV Devices
5.2	DERS System
5.3	Continuous Quality Improvement
5.4	DERS Implementation
6	Hardware and Operating System
7	Training and education
7.1	Users training
7.2	Technical training
7.3	Training cost
8	Safety
9	Service and support
10	Preventive maintenance
11	Technical evaluation
12	Clinical evaluation
13	Warranty
14	Future enhancement
15	Project implementation plan
16	References
17	Standards
18	Cost
19	Others
20	Compliance

2. Design of Matrix based technical specification

The matrix can be designed in a variety of ways. In order to simplify our analysis we designed the matrix below by comparing the technical specification criterion with the RFP response received from different vendors. The fixed elements of the matrix are the detailed technical specification criteria's and different IV therapy with DERS vendors. The variables are the scores for each specified criteria.

Table 2: IV therapy evaluation matrix

Criteria Worksheet			Vendor A	Vendor B	Vendor C	Vendor D	Vendor E
Criteria	Sub criteria	Specification Criteria's	Score (0-10)	Score (0-10)	Score (0-10)	Score (0-10)	Score (0-10)
1		SickKids needs	10	10	9	8	10
	1.1	Population	10	10	8	10	10
	1.2	IV therapy system	10	10	10	6	10
2		General requirement	7.1	7.5	8.3	8.3	8
	2.1	Display and controls	9	9	8	9	8
	2.2	Human Factors Design	9	7	7	7	6
	2.3	Controls	9	9	9	9	9
	2.4	Alarms and indicators	9	9	9	9	9
	2.5	Battery and Power supply	7	8	8	8	8
	2.6	Decontamination	7	9	7	8	7
	2.7	Pole clamp and Docking station	5	8	9	8	7
	2.8	General Safety	7	8	8	8	8
	2.9	MRI compatibility	0	0	9	8	8
3		Particular requirement	7.9	8.6	7.2	7.9	9
	3.1	Accuracy	9	9	8	9	9
	3.2	Flow rate	9	9	8	9	9
	3.3	Volume to be infused	9	9	8	9	9
	3.4	KVO rate	9	9	8	9	9
	3.5	Occlusion pressure range	9	9	8	9	9
	3.6	Bolus	7	8	8	9	9
	3.7	Purge /Prime	0	7	8	8	8
	3.8	PCA Device	9	9	8	9	9
	3.9	Multiple channels Large IV devices	9	8	0	0	9
	3.10	Syringe Device	0	0	8	9	9
4		IV supplies and accessories	7.6	6.3	6.6	8.13	8.3
	4.1	Disposable set	8	8	8	8	8
	4.2	Disposable set economic option	6	9	5	8	9
	4.3	Quantity and configuration	7	8	8	8	8
	4.4	Set specification	8	9	7	8	8
	4.5	Bar-coding	8	0	6	9	8
	4.6	Wireless com.Techn.	9	4	6	6	9
5		Dose Error Reduction System	8.24	7	7	8.13	8.75
	5.1	DERS in IV Devices	9	7	7	9	9
	5.2	DERS System	8	6	7	8	9
	5.3	Continuous Quality Improvement	8	7	8	8	8
	5.4	DERS Implementation	8	7	6	8	9
6		Hardware and O.S.	9	7	8	8	9
7		Training and Educ.	6.3	8.6	8.4	8	9
	7.1	Users training	9	9	6	8	9
	7.2	Technical training	5	9	6	8	9
	7.3	Training cost	5	8	7	8	9
8		Safety	9	8	8	9	9
9		Service and support	8	9	9	8	7
10		Preventive maintenance	8	8	6	9	9
11		Technical evaluation	9	9	6	9	9
12		Clinical Evaluation	8	8	4	4	9
13		Warranty	4	4	4	6	7
14		Future enhancement	7	0	0	8	7
15		Project implementation plan	8	0	6	8	7
16		References	9	9	6	9	9
17		Standards	8	9	6	9	6
18		Cost	8	5	5	8	7
19		Others	8	8	6	8	8
20		Compliance	8	8	5	6	8
		Total Score	7.91	6.92	7.35	6.32	8.15

3. Adding scoring elements

The scoring elements of the matrix are added by:-

a. Assigning every box in vendor's rows a numbers between 0 and 10. The number is given to the box based on evaluator's judgment on how each vendor satisfies the requirement on each sub-criterion of the technical specification. The question to be answered by the assessor is: - *Based on your knowledge, experience and response to the RFP, decide whether the vendor satisfies the requirements of the sub-criteria by indicating with a number. Where 10 is the maximum and 0 the minimum.*

b. Adding all sub-criteria's scores and then obtain the average scores for each criteria.

c. Adding all criteria's for each vendor to obtain the total average score per vendor.

d. The comparison of total average scores gives an indication and information on how the proposed system will meet the technical specification criteria.

e. Reassign the scores to the matrix after technical and clinical evaluation and after the site visits.

MATRIX RESULT AND DISCUSSION

The matrix was completed separately by different members of the project team. In order to simplify the process, an automated matrix without variable elements was supplied. When a variable was entered for any sub-criteria, the matrix was able to calculate the average value for the criteria and also the total score for every vendor. Data was collected, compared and analyzed using a simple statistical analysis; excel plot and Matlab database toolbox. The analysis of the matrix shows that:-

a. From criteria 1: All systems presented by vendors can be used for pediatric population

b. From criteria 2: The general requirements show that there is a big similarity between these devices. However, major improvement in human factor's design by some manufacturers. (Sub-criteria 2.2.). Others have made their devices MRI compatible. (Sub-criteria 2.9.)

c. From criteria 3: The particular requirement reveals that only a few vendors can offer the complete IV therapy with DERS solution which includes: - syringe pumps, large volume pumps, PCA pumps, etc.

d. From criteria 4: Some systems can only use dedicated sets for drug delivery, when others can accommodate third party accessories. Barcode has become a standard tool for identification of patient, clinicians and drugs. Wireless capability has been identified as a major component for data transfer and communication between different components of DERS. Where wireless is not available some manufacturer's uses routers and other wireless mobile devices while others still prefer RS232 or a wired connection to the hospital's network for data communication and updating the drug library on the infusion device.

e. From criteria 5: The DERS criteria highlights the interaction between different sub systems such as drug library, pharmacy formulary system, servers for data collection, storage and analysis, report generation for quality improvement and education purposes, etc., It also provides more information on the software and hardware that is used for every subsystem and how DERS will integrate with hospital existing systems such as pharmacy, charting, Information technology and Continuing Quality Improvement and risk management. The number of IV devices required, the server, Wireless capability, paging system, bar-coding and other hardware emerging from the RFP response gives a clear picture of the hardware needed for the system to be selected.

f. From criteria 6: Some manufacturers have open platforms that allow easy integration with other technologies. In this case some companies may supply the server and other Information technology hardware, operating system for the server, etc. The hospital will have to decide whether they want to manage its own CQI reports and may decide to use a bar-coding system from a third party. When other vendors have a dedicated complete solution. In this case, the IT infrastructure is managed, supported and maintained by the vendor. This criteria allows us to investigate further and understand the components of DERS that different vendors are offering.

- As for Information technology integration with DERS system, key elements of the IT infrastructure components of the solution below were identified and looked at in details for every vendor:-
- Standards supported:(HL7, IEEE 802.X, compliance and RF compliant communication protocols);
- Integration to hospital information systems: (ADT, Pharmacy, storage, etc.,);
- Security and Encryption: (System, Application, Network and Audit capability);
- Authentication: (Users and devices);
- System redundancy availability: (Clustering, load balancing, etc,);

g. From criteria 7: “Training is a key element in device safety”. There is a need for a clear “*medical device training policy*” where DERS is implemented. The policy will ensure that all training requirements are met and also will explain the role and responsibility of those actively involved in IV therapy with DERS implementation. Greater collaboration between Clinical Engineering department, Pharmacy, Clinical nurse trainers and manufacturer is needed in order to ensure that users are competent and confident to operate the devices with DERS.

h. From criteria 8: As these systems are designed to improve patient safety, it is important to understand how the proposed system will contribute to medication safety; e.g.:- emergency shut down for large volume pumps.

i. From criteria 9 & 10: Service and support, preventative maintenance (PM), trading and warranty criteria’s are very good indicators of how committed vendors are with regard to long term support of their products. It is worth to mention that some manufacturers took the advantage of the advancement in computer software to incorporate a self PM checks for their devices.

j. From criteria 11: The technical evaluation, (hands-on) gives a better understanding of every component of the system. It shows how all sub-systems interact with each other. Also allows the team to rescore the table as unclear questions are answered in this process.

k. From criteria 12: Most vendors’ are now in favor of clinical simulation. This is set and conducted by clinical staff team in collaboration with the vendor. It allows the user first hands-on the product, highlight the deficiencies in human factors engineering sub criteria and other criteria’s. It also helps the team to rescore the table before a second re-evaluation.

CONCLUSION

The choice of IV technology with DERS requires evidence based approach for the selection of the technology in order to avoid bias, reduce acquisition process time, and improve understanding of the outcome.

Although the matrix analysis above is not very accurate due to evaluator’s judgment in the allocation of variables, it is a useful tool that helped us with:-

1. Identification of companies that might meet our requirements;
2. Elimination of companies with very low total score for short listing purposes (“B” and “D” on table 2);
3. Identification of areas in the RFP where further exploration and understanding is required for every proposed solution;
4. It highlights the similarities and differences of different technologies
5. Preparation of technical and clinical evaluation.
6. The technical evaluation and the site visits gave us the opportunity to rescore the matrix and get a better understanding of the functional and technical specifications of the systems.
7. The re-evaluation of matrix after re scoring allows the team to identify the emerging technology (the vendor with the highest total score) that could best meet the Hospital’s requirements.

The matrix alone will not provide enough evidence to allow the selection of the technology. Other considerations such as: - clinical simulation, technical simulation, Pricing, availability, support, etc., have to be taken into account equally in order to determine the best system that will meet the clinical needs of the Hospital.

With the above method, we are only opening up a discussion within clinical/biomedical engineering community on how to assess the technology within a reasonable time without leaving out some elements of the system. Our hope is to see the matrix model used, improved or help to produce more accurate way of assessing this complex technology within a reasonable time.

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