

Is Medication Safety with an Oncology Information Management System (OIMS) Maintained in a Paediatric Setting?

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Introduction:

The implementation of Elekta's Oncology Information Management System (OIMS), Mosaiq, was a joint project across Sir Charles Gardiner Hospital and Princess Margaret Hospital for Children (PMH), Western Australia. This is the first implementation of an OIMS in a paediatric hospital for Elekta and also the first complete implementation of an OIMS within a paediatric hospital in Australia.

Paediatric oncology has many inherent challenges. The variation in physiological function across the age groups combined with complex multidrug regimens, variable dose calculations and dose adjustments means that a "one size fits all" approach, common in adult oncology, is not possible in paediatrics.

Implementing a commercial, adult orientated, OIMS in a paediatric setting potentially presents configurational challenges when system functionality is limited. In order to address protocol and physiological variations, system workarounds may be necessary during system configuration.

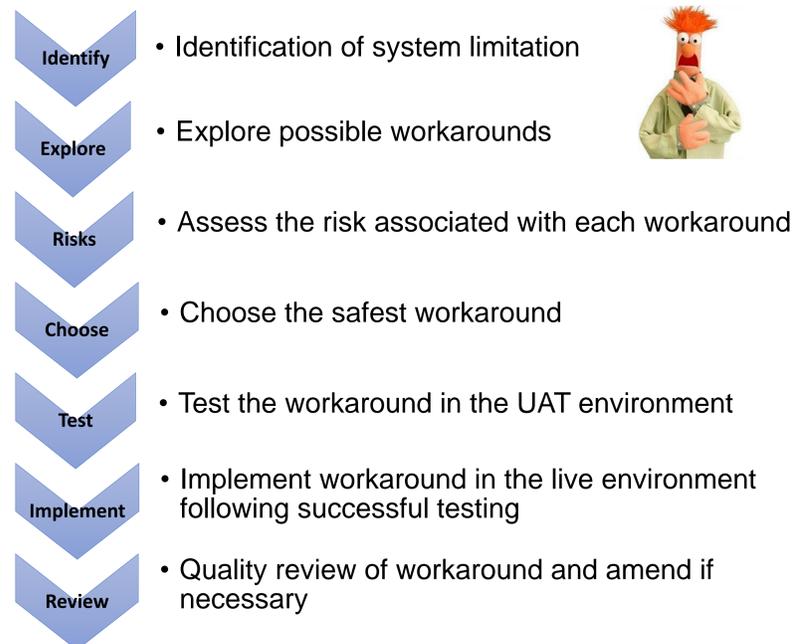
The combination of system workarounds with high risk medications in a high risk population potentially increases the risk of medication errors and safety in each stage of the medicines management process.

Is OIMS medication safety maintained when workarounds are implemented in a paediatric oncology setting?

Method:

A phased implementation of Mosaiq was initiated at PMH with non clinical "go live" in October 2015 and a clinical "go live" in February 2016.

During configuration, identified system limitations were reviewed and managed by the process below.



Results:

During the configuration of Mosaiq a number of significant limitations were identified. These limitations, workarounds and risks were identified;

Limitations	Workaround		Risk																		
BSA < 2 years not calculated.	<ul style="list-style-type: none"> • Manual calculation required • physically entered into the dosing calculation 		<ul style="list-style-type: none"> • Variable calculation methods for calculating BSA resulting in variable BSA , • Potential transcription error • Decreased transparency of BSA used in dose calculation 																		
No dose banding functionality according to age.	<ul style="list-style-type: none"> • Dosing information added into the administration instructions according to patients age. Manual entry by physician into electronic prescription 	<table border="1"> <tr> <td>Admin Instructions:</td> <td>Age (yrs)</td> <td>Dose (mg)</td> </tr> <tr> <td></td> <td>0 - 0.99yrs</td> <td>6mg in 4mL</td> </tr> <tr> <td></td> <td>1 - 1.99 yrs</td> <td>8mg in 6mL</td> </tr> <tr> <td></td> <td>2 - 2.99 yrs</td> <td>10mg in 8mL</td> </tr> <tr> <td></td> <td>3 - 8.99yrs</td> <td>12mg in 10mL</td> </tr> <tr> <td></td> <td>> 9yrs</td> <td>15mg in 10mL</td> </tr> </table>	Admin Instructions:	Age (yrs)	Dose (mg)		0 - 0.99yrs	6mg in 4mL		1 - 1.99 yrs	8mg in 6mL		2 - 2.99 yrs	10mg in 8mL		3 - 8.99yrs	12mg in 10mL		> 9yrs	15mg in 10mL	<ul style="list-style-type: none"> • Manual entry open for user error, misinterpretation of admin instructions, • risk the dose is not amended according to dose banding as child age changes
Admin Instructions:	Age (yrs)	Dose (mg)																			
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System restricted to a single dose rounding rule per drug in the formulary. Wide variation in volume/dose of drug from infant to adolescent.	<ul style="list-style-type: none"> • Dose rounding rules added administration instructions, physician to manually amend dose according to rounding guide • Multiple variations of the same drug added to the formulary with different rounding rules 	<p>dose rounding:</p> <table border="1"> <tr> <td>< 250mg</td> <td>nearest 10mg</td> </tr> <tr> <td>250mg<= dose<1000mg</td> <td>nearest 20mg*</td> </tr> <tr> <td>>= 1000mg</td> <td>nearest 100mg</td> </tr> </table> <p>"Doxorubicin" rounded to nearest 2mg "Doxorubicin [infant]" rounded to nearest 0.4mg</p>	< 250mg	nearest 10mg	250mg<= dose<1000mg	nearest 20mg*	>= 1000mg	nearest 100mg	<ul style="list-style-type: none"> • Risk of dosing errors > +/- 5% especially for small or large volumes of drug based on age of child and dose. Protocol violation if > +/- 5% dosing, • Risk of information overload and Drs not identify need for manual dose change based on dose and dose rounding instructions • Loss of system functionality associated with drug allergy and drug interaction checking 												
< 250mg	nearest 10mg																				
250mg<= dose<1000mg	nearest 20mg*																				
>= 1000mg	nearest 100mg																				
Inability of system to assign/calculate final (total) volume based on age, BSA, protocol or drug.	<ul style="list-style-type: none"> • Manual entry of final (Total volume) by pharmacists according to duration and child's age (BSA) and fluid requirements, • instructions in the "dispensing instruction" field • Creating careplans specific for age and/or dosing basis 	<ul style="list-style-type: none"> • Busulfan - final volume such that concentration is 0.5mg/mL, rounded to nearest mL divisible by 3 <table border="1"> <tr> <td colspan="2">Total volume depends on childs BSA</td> </tr> <tr> <td>BSA < 0.7</td> <td>30mL (total volume)</td> </tr> <tr> <td>0.7 <= BSA < 1.2</td> <td>60mL (total volume)</td> </tr> <tr> <td>1.2 <= BSA < 1.7</td> <td>90mL (total volume)</td> </tr> <tr> <td>BSA >= 1.7</td> <td>120mL (total volume)</td> </tr> </table> <p>AREN0533 DD4A (2) Cycle 3+4 (Week 7-12) Infant <1y AREN0533 DD4A (2) Cycle 3+4 (Week 7-12) Child 1-2.99y AREN0533 DD4A (2) Cycle 3+4 (Week 7-12) Child >=3y</p>	Total volume depends on childs BSA		BSA < 0.7	30mL (total volume)	0.7 <= BSA < 1.2	60mL (total volume)	1.2 <= BSA < 1.7	90mL (total volume)	BSA >= 1.7	120mL (total volume)	<ul style="list-style-type: none"> • inappropriate volumes added based on age, • Discrepancy between manual entry volumes and volumes on labels of products compounded by pharmacy • Error in calculation based on "dispensing instructions" • Selection error by physician when assigning a careplan 								
Total volume depends on childs BSA																					
BSA < 0.7	30mL (total volume)																				
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Inability of system to deal with complex fluid regimens, complex timing of medications and concurrent fluids	<ul style="list-style-type: none"> • Adding hour/timing to drugs and fluids in ordersets • Adding lumen directions to ordersets 		<ul style="list-style-type: none"> • Issues with miscommunication between nursing staff regarding timing and fluids associate with changing shifts • Timing not strictly adhered to which can result in protocol violation 																		



Discussion:

The unique challenges inherent with configuring an adult orientated OIMS in a paediatric setting is not without significant risk. Inflexible fixed system logic lacks the necessary variable logic functionality required to meet the complexity of paediatric oncology.

Lack of system functionality results in configurational workarounds. A dedicated team is necessary to effectively manage workarounds in-order to reduce undesirable or unintended consequences (risk) of each introduced workaround.

In addition to this, training, onsite support and continued quality improvement plays a critical role in reducing risk.

It is important that OIMS vendors are receptive to paediatric orientated system requirements and adopt a "will do" rather than a "can do" approach.

OIMS workarounds in the paediatric setting poses a potentially serious risk to patient and medication safety. Without appropriate review, management, training and support of workarounds the inherent safety advantages of OIMS in paediatric oncology is reduced.