Experience in the Operating Room with the Codonics Smart Syringe Labelling System

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WHO 2000 report Singapore Ranked 6th in overall health performance

<table>
<thead>
<tr>
<th>Country</th>
<th>City</th>
<th>State</th>
<th>Population of 5 million</th>
<th>WHO ranked 6 in healthcare</th>
<th>Land area 712.4 sqkm</th>
<th>Life expectancy 81.8 yrs</th>
<th>Infant mortality 2.9 per 1000 live births</th>
<th>Doctor to Population 1:540</th>
</tr>
</thead>
</table>

Anesthesiologists only person in hospital that select, draw and administer medications unchecked with tight time constraints

Our second commonest serious reportable event in Singapore is Medication Error

Unsecured label

Anaes Tray with Conventional labelled syringes
Medication Error in OT

- OR is a unique environment in which the Anesthetist is the only one who Selects, Draws up and Administers a drug without double checking that is normally occurred outside of OR.
- 0.3 med error per 100 administration. (Alan Merry 2011)
- Medication Error in OT (Australia Study) – 50% in drug preparation. Out of this, common errors are:
  1. Drug swap - 41% comes from Drug swap & Label swap
  2. Label swap
  3. Syringe swap - 37% comes from Syringe swap

The Smart Label System - Improve Labelling - Audio and visual check.

- Generate your own account barcode from machine
  - Drug Vial Identification & verification - Bar code
  - Label printing for syringes
  - Visual & Audio read-back
  - Label printing for syringes
  - Bar code Scan syringe prior to administration
  - Not integrate with automatic electronic documentation

We aimed to test aspects of the codonics machine vs conventional labelling

- Compliance to labelling - name/conc/colour code/ secure
- Efficiency - the time required to prepare drugs using the Codonics SLS
- Safety - Preventing drug swaps in look-alike drugs
- Safety - Prevent syringe swap
**Compliance Study**

- **Data collection Period**
  - 22/10/12 to 10/12/2012 – 6 weeks
- **Methodology**
  - Randomized if anesthetist was to use Conventional (control) or Codonics (case) for that day
  - Quietly but continuously observed from start to end of the operation by research fellow
  - Observe for compliance and medication error
- **Total no. of participants in Study**
  - Primary Anaesthetists – 13; 1 opts out
  - Assistant Anaesthetists - 16

**Safety – Compliance determined by JCI and ASA standard of labelling (American Society of Anesthesiologists)**

- **Labelling Compliance**
  - All non-immediate use IV med should be labelled properly
- **Labelling non-compliance**
  - Non-immediate used IV med without labels
  - Non-secure labels
  - Incorrect Colour Code label (ASA standard)
  - Illegible labels (e.g. unreadable hand writings within half-arm distance)
  - Incomplete contents (e.g. no concentration)

[Standard MMU5.2, JCI 2011]

When a medication is removed from its original packaging or prepared and dispensed in a different form/container—and not immediately administered—the medication must be labelled with:

- **NAME** of the medication,
- **DOSAGE/CONCENTRATION** of the medication,
- **Date of PREPARATION,** and
- **Date of EXPIRATION**

**Safety**

**Baseline Study**

<table>
<thead>
<tr>
<th></th>
<th>Baseline (Non-Codonics)</th>
<th>Case (Codonics)</th>
<th>Control (Non-Codonics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>111</td>
<td>137</td>
<td>74</td>
</tr>
<tr>
<td>Non-compliance</td>
<td>79</td>
<td>2</td>
<td>42</td>
</tr>
<tr>
<td>Grand Total</td>
<td>190</td>
<td>139</td>
<td>116</td>
</tr>
</tbody>
</table>

**Case Control Study**

<table>
<thead>
<tr>
<th></th>
<th>Baseline (Non-Codonics)</th>
<th>Case (Codonics)</th>
<th>Control (Non-Codonics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>98.6%</td>
<td>63.8%</td>
<td>100%</td>
</tr>
<tr>
<td>Non-compliance</td>
<td>1.4%</td>
<td>36.2%</td>
<td>0%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>98.6%</td>
<td>63.8%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Exclusion Criteria**

<table>
<thead>
<tr>
<th>Level</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>• Anesthesiologists does not wish to participate</td>
</tr>
<tr>
<td>Drug</td>
<td>• Drugs directly given in drip from manufacturer container</td>
</tr>
<tr>
<td></td>
<td>• 2 combined drugs counted as one syringe</td>
</tr>
<tr>
<td>Syringe</td>
<td>• Non-labelled syringes for immediate use</td>
</tr>
</tbody>
</table>

**Sample Size**

<table>
<thead>
<tr>
<th>Randomization</th>
<th>No. of CASE observed</th>
<th>No. of DRUG used</th>
<th>No. of SYRINGES prepared</th>
<th>No. of SYRINGES encountered for labelling compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codonics</td>
<td>22</td>
<td>179</td>
<td>165</td>
<td>139</td>
</tr>
<tr>
<td>Control</td>
<td>27 (2 opts out)</td>
<td>187</td>
<td>165</td>
<td>116</td>
</tr>
<tr>
<td>Total</td>
<td>49 (-2)</td>
<td>366</td>
<td>330</td>
<td>255</td>
</tr>
</tbody>
</table>

- Total number of syringes immediately use after preparation - 75
- Total no. of syringes encountered for labelling compliance – 255
Safety

- Compliance at Control Group – 63.8%, zero if we include preparation date and time
- Compliance at Codonics Group – 98.6%

<table>
<thead>
<tr>
<th>Significant Difference</th>
<th>Not Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Label Secure</td>
<td>2. Legibility</td>
</tr>
<tr>
<td>3. Concentration</td>
<td>3. Name as content</td>
</tr>
<tr>
<td>4. Preparation Date &amp; Time</td>
<td></td>
</tr>
<tr>
<td>5. Expiration Date &amp; Time</td>
<td></td>
</tr>
<tr>
<td>6. Preparer</td>
<td></td>
</tr>
</tbody>
</table>

Drug Category (Actual Count)

<table>
<thead>
<tr>
<th>Types of Drugs</th>
<th>Case</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcotics/Opioids</td>
<td>37</td>
<td>31</td>
</tr>
<tr>
<td>Induction Agent</td>
<td>29</td>
<td>23</td>
</tr>
<tr>
<td>Muscle Relaxants</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Local Anaesthetics</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>Others</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Anticholinergic</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Vasopressor</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Relaxant Antagonist</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Hypotensive</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Diluent</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Grand Total</td>
<td>139</td>
<td>116</td>
</tr>
</tbody>
</table>

Drug Category (%)

Not much different between 2 groups

No difference is the status of patients -- ASA score (American society of anesthesiologists score)

P value – 0.549, Not Significantly Different

Work Flow

NO SIGNIFICANT DIFFERENCE b/t 2 groups

Type of Label

Case

Control

- Barcode Label
- Codonics Printed
- Manually Handwritten
- Manual Preprinted

More unlabelled in control group
Security of Labels (stick well)

- Two tailed p value – 0.0092
- The two groups are SIGNIFICANTLY DIFFERENT

Colour Code of labels

- Two tailed p value – 0.8375
- The two groups are NOT SIGNIFICANTLY DIFFERENT

Legibility of Labels

- Two tailed p value – 0.2484
- The two groups are NOT SIGNIFICANTLY DIFFERENT

Contents of labels (Drug Name)

100% mentioned on all labels in both of Case and Control

Contents of labels (Presence of Preparer’s name)

- Two tailed p value < 0.0001
- The two groups are SIGNIFICANTLY DIFFERENT

Contents of labels (Concentration)

- Two tailed p value – 0.0001
- The two groups are SIGNIFICANTLY DIFFERENT
Labelling compliance improved from 63.8 to 98.6% (ASA and JCI Standards)

- Two tailed p value – 0.0001
- The two groups are SIGNIFICANTLY DIFFERENT

Summery
- Overall Labelling Compliance in Control group is improved to 63.8% (58.4% in baseline)
- The Difference between 2 groups is

<table>
<thead>
<tr>
<th>Significant</th>
<th>Not Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Stickiness of Label</td>
<td>2. Legibility</td>
</tr>
<tr>
<td>3. Concentration</td>
<td>3. Name as content</td>
</tr>
<tr>
<td>4. Preparation Date &amp; Time</td>
<td>5. Expiration Date &amp; Time</td>
</tr>
<tr>
<td>6. Preparer</td>
<td></td>
</tr>
</tbody>
</table>

- Neither actual medication error nor near miss

Efficiency of Codonics SLS
- Findings
  - Average time to prepare drug set
    - (4 drugs with SLS – 239.63 seconds)
  - Average time to prepare drug set with
    - 160.33 seconds
  - Conventional method
    - Increased in time – 79.296 sec (44.52%)

  - Propofol, Atracurium, Atropine and Ephedrine

Test Safety --- Ability to prevent Drug Swaps in lookalike drugs
Quite rare event so we increased the risk (simulated no real patient)
**Iatrogenic Drug Error Situation.**

9 ampules of Ephedrine and 1 Dexamethasone. (Look alike) placed in Dexa Compartment. Anesthetists are not aware of this. Generating a very high risk of picking the wrong drug.

**Introduce Distractions - Real Life Situation which is when med errors are most likely to occur**

- Methodology - simulating the actual OT environment
  - Computer Generated alarms and verbal requests
  - Constant interruption - Alarm from Anaesthetics Machine
  - ‘move the table up’, ‘move the table down’, ‘increase oxygen flow to 10L/min’ and ‘decrease oxygen flow to 1L/min’
- Each subject had to prepare
  - Dexamethasone

**Findings**

<table>
<thead>
<tr>
<th></th>
<th>Codonics Yes</th>
<th>Codonics No</th>
<th>Conventional Yes</th>
<th>Conventional No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect Wrong Ampoule-Pick ephedrine instead of dexa</td>
<td>31</td>
<td>30</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Broke Wrong Ampoule</td>
<td>36</td>
<td>24</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

Did not follow workflow
Break then scan ampule

**Prevention of Drug Swap**

<table>
<thead>
<tr>
<th></th>
<th>Codonics</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collected Wrong Ampoule</td>
<td>41</td>
<td>30</td>
</tr>
<tr>
<td>Collection P=0.89 Non-significant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broke Drug</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Died</td>
<td>2</td>
<td>26</td>
</tr>
<tr>
<td>Totally Overlooked</td>
<td>0</td>
<td>7</td>
</tr>
</tbody>
</table>

**Findings- Drug Swap**

<table>
<thead>
<tr>
<th></th>
<th>Codonics Yes</th>
<th>Codonics No</th>
<th>Conventional Yes</th>
<th>Conventional No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drew Wrong Drug</td>
<td>41</td>
<td>32</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Totally Overlooked-Labelled Syringe with Wrong Label Drug ampule swap error</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Codonics error only if they broke draw before scanning - wrong work flow

**Use of Read-back function to prevent syringe swaps Darkened Room and Similar Look a Like Labelled Syringes**

- Method 83 subjects both codonics and control
  - Subjects in Codonic Group were encouraged to use the Bar code verbal and oral Read-back/Scan-back function before they administered in a darkened room
  - Detect the rate of Syringe Swap
  - Findings
    - No significant difference in pick up rate between Codonics SLS and Conventional Method
    - All picked up the correct syringes
Scan prior to administration of Drug

Reluctance to use this step
Seen as additional STEP
Perhaps in future when there is link to electronic charting

Compliance Study Published

Summary

- **Efficiency**
  - Longer Time by 44%
- **Safety**:
  - Improve labelling compliance to 98% (63.8%)
  - Reduce risk of Drug Ampule Swap
- **Read-back/Scan-back Function**:
  - No significant different detected for prevention of Syringe Swap.

Challenges

- **Hardware** – no wireless scanner
  Only 1 size label at 1 time
  No battery back up.
- **Software** – administrator required to update library (new work created)
- Limited bar code recognition ability-recoding required for some drugs.