Dialysis Technology:
Is the Patient Receiving the Treatment as Prescribed?

NANT New York Regional Meeting
1 - 2 December 2012
LaGuardia Airport Marriott

Joe Johnston
Sr. Vice Pres. Biomedical Services & Technology Integration
Fresenius Medical Care
Question – True or False

The dialysis machine, given it is approved by the FDA to be safe and efficacious, will not allow the user to place the machine in an unsafe state.
a) Safety is “relative”, i.e., one prescription doesn’t fit all.

   Is a 2 kg/hr UF rate safe for all patients???

b) Nearly all medical devices are intended to be used by a trained, competent, supervised individual. This is a key component of the risk analysis and the FDA approval.

   **The machine is only safe if you use it safely**
Question – True or False

When I enter a prescription into the machine, I know that is exactly what the patient will receive.

Answer - False

Errors, random variations, and design details about how the machine functions all affect the delivered prescription.
A deviation is a difference between reality and what is expected, normal, or prescribed.

- **Random Variation**
  - Assignable cause is not known, or is not knowable
  - Is implicit in the process

- **Design Tolerance**
  - Deviation that is “built-in” or planned at the time of the design
  - Should be developed using a risk based method

- **Error**
  - Has a known assignable cause, although perhaps not quantified
  - Can be prevented or corrected (repaired)
Dialysis Technology:
The Process of Delivering a Treatment

- Prescription
  - Staff
    - Errors in set up, mixing, mix-up, operation, timing variation ...
  - Disposables
    - Mfg. variation, pump segment fatigue, ...
  - Equipment
  - Treatment
    - Mis-calibration, breakdowns, alarms, design features
Key Points

Objective – to show how misusing or misunderstanding the technology in a dialysis clinic can affect the prescription delivered.

Examples:
- 3 - Stream proportioning
- Blood lines
- Alarms and staff responsibilities
- Impact of conductivity different than target
- Significance of pressure alarm limits and pressure tests
- Impact of using sodium variation
Three Stream Proportioning Systems
How They Really Work
Proportioning

Final Rx

2 sources of Na+

Na+

Bicarb –

Single source of Bicarb

Na+

Cl-

K+

Ca+2

Mg+2

Glucose

HAc / Diacetate

H2O
Concentrate proportioning

- 3 stream proportioning (45X)
  - Acid concentrate + Bicarb + Water

<table>
<thead>
<tr>
<th>Type</th>
<th>Symbol</th>
<th>Mixing Ratio</th>
<th>Post Reaction Na+ / Bicarb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobe</td>
<td>45x</td>
<td>1.00 : 1.72 : 42.28</td>
<td>[137] / [33]</td>
</tr>
</tbody>
</table>

Default proportioning

If this is used, you will get the acid label concentrations in dialysate
<table>
<thead>
<tr>
<th></th>
<th>Setting</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na(^+)</td>
<td>137 mEq/L</td>
<td>137 mEq/L</td>
</tr>
<tr>
<td>K(^+)</td>
<td>2 mEq/L</td>
<td>2 mEq/L</td>
</tr>
<tr>
<td>Ca(^{2+})</td>
<td>2.5 mEq/L</td>
<td>2.5 mEq/L</td>
</tr>
<tr>
<td>Mg(^{2+})</td>
<td>1.0 mEq/L</td>
<td>1.0 mEq/L</td>
</tr>
<tr>
<td>Ac(^-)</td>
<td>4.0 mEq/L</td>
<td>4.0 mEq/L</td>
</tr>
<tr>
<td>Bic(^-)</td>
<td>33 mEq/L</td>
<td>33 mEq/L</td>
</tr>
</tbody>
</table>
### Concentrate proportioning

#### 3 stream proportioning

<table>
<thead>
<tr>
<th>Setting/Label</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na&lt;sup&gt;+&lt;/sup&gt; 140 mEq/L</td>
<td>Na&lt;sup&gt;+&lt;/sup&gt; 140 mEq/L</td>
</tr>
<tr>
<td>K&lt;sup&gt;+&lt;/sup&gt; 2 mEq/L</td>
<td>K&lt;sup&gt;+&lt;/sup&gt; 2.06 mEq/L</td>
</tr>
<tr>
<td>Ca&lt;sup&gt;2+&lt;/sup&gt; 2.5 mEq/L</td>
<td>Ca&lt;sup&gt;2+&lt;/sup&gt; 2.57 mEq/L</td>
</tr>
<tr>
<td>Mg&lt;sup&gt;2+&lt;/sup&gt; 1.0 mEq/L</td>
<td>Mg&lt;sup&gt;2+&lt;/sup&gt; 1.03 mEq/L</td>
</tr>
<tr>
<td>Ac&lt;sup&gt;-&lt;/sup&gt; 4.0 mEq/L</td>
<td>Ac&lt;sup&gt;-&lt;/sup&gt; 4.12 mEq/L</td>
</tr>
<tr>
<td>Bic&lt;sup&gt;-&lt;/sup&gt; 33 mEq/L</td>
<td>Bic&lt;sup&gt;-&lt;/sup&gt; 33 mEq/L</td>
</tr>
</tbody>
</table>
### Concentrate proportioning

#### 3 stream proportioning

<table>
<thead>
<tr>
<th>Setting/Label</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺ 137 mEq/L</td>
<td>Na⁺ 137 mEq/L</td>
</tr>
<tr>
<td>K⁺ 2 mEq/L</td>
<td>K⁺ 1.96 mEq/L</td>
</tr>
<tr>
<td>Ca⁺² 2.5 mEq/L</td>
<td>Ca⁺² 2.45 mEq/L</td>
</tr>
<tr>
<td>Mg⁺² 1.0 mEq/L</td>
<td>Mg⁺² 0.98 mEq/L</td>
</tr>
<tr>
<td>Ac⁻ 4.0 mEq/L</td>
<td>Ac⁻ 3.92 mEq/L</td>
</tr>
<tr>
<td>Bic⁻ 35 mEq/L</td>
<td>Bic⁻ 35 mEq/L</td>
</tr>
</tbody>
</table>
The display on the machine for the blood flow rate is the exact blood flow rate of the dialysis treatment, right?

Well, ........
Blood flow displayed by dialysis machines: is it accurate?

Stragier A, Wenderickx D, Jadoul M.
Cliniques Universitaires St-Luc Service de Néphrologie, Brussels, Belgium.

Abstract
Blood flow is a major determinant of dialysis efficiency. We reported in 1980, at the EDTNA conference in Prague (1), that the actual blood flow may be much lower than displayed by the dialysis machines. We demonstrated that the Negative Inflow Pressure (NIP), induced by the arterial needle and therefore generally referred to as arterial pressure, partly collapses the proximal blood pump segment whose inner volume is decreased. Thus the actually pumped volume per revolution is lower than the displayed blood flow.

PMID: 10723300 [PubMed - indexed for MEDLINE]
Blood flow
Blood flow

7. Tubes:
- The optimum mix between wall thickness and sure hardness makes our tubes:
- Withstand pressure and manipulations
- Antikink.
- Accurate and consistent flow rates over time. Excellent performance under conditions of high flow rates and pressure in the dialysis circuit.
- Highly biocompatible as been tested in the world most recognizable laboratories.
- Available in clear and frosted versions.

8. Pump segment:
- Resist fatigue which insure that the patient received the prescribed Kt/V without increasing negative pressures.
- Pump segment material insure maximum refilling after roller pump strokes even in case of high negative arterial pressure.
ALARMS !!!!!!!

• Today’s Culture – Tight Schedules, Busy Staff

– What is the clinic “culture” on machine alarms?

a) We determine the cause and address problem at the moment.

b) Don’t worry so much, the machine will stop or not reset on a really important alarm.

c) Quite Please !!!!
### How Should Things Be?

<table>
<thead>
<tr>
<th>Arterial Pressure</th>
<th>Venous Pressure</th>
<th>Level Detector</th>
<th>Blood Leak</th>
<th>Blood Pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMP</td>
<td>Conductivity</td>
<td>Dialysate Flow</td>
<td>Temperature</td>
<td>Water Flow</td>
</tr>
</tbody>
</table>

- What do these alarms indicate?
- How should the staff react to each alarm?
- What does pushing “reset” really do?
- In a typical treatment, how often do these occur?
- Which alarms are preventable, and how should the clinic staff go about preventing them?
## Patient and facility variation

<table>
<thead>
<tr>
<th>Facility</th>
<th># patients</th>
<th># tx</th>
<th>% Tx with hypotension</th>
<th>Alarms/Tx</th>
<th>Alarm min/Tx</th>
<th>Alarm min/alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility 1</td>
<td>140</td>
<td>5097</td>
<td>17.7%</td>
<td>4.07</td>
<td>3.8</td>
<td>0.92</td>
</tr>
<tr>
<td>Facility 2</td>
<td>67</td>
<td>3005</td>
<td>23.0%</td>
<td>2.91</td>
<td>2.9</td>
<td>0.98</td>
</tr>
<tr>
<td>Facility 3</td>
<td>107</td>
<td>2852</td>
<td>21.6%</td>
<td>2.45</td>
<td>2.2</td>
<td>0.91</td>
</tr>
<tr>
<td>Facility 4</td>
<td>100</td>
<td>2296</td>
<td>15.3%</td>
<td>2.53</td>
<td>2.3</td>
<td>0.89</td>
</tr>
<tr>
<td>Facility 5</td>
<td>116</td>
<td>1855</td>
<td>17.1%</td>
<td>4.31</td>
<td>4.7</td>
<td>1.09</td>
</tr>
<tr>
<td>Facility 6</td>
<td>57</td>
<td>803</td>
<td>30.8%</td>
<td>5.83</td>
<td>5.5</td>
<td>0.94</td>
</tr>
<tr>
<td>Facility 7</td>
<td>83</td>
<td>1600</td>
<td>18.9%</td>
<td>2.68</td>
<td>2.5</td>
<td>0.95</td>
</tr>
<tr>
<td>Facility 8</td>
<td>67</td>
<td>1684</td>
<td>17.6%</td>
<td>2.62</td>
<td>2.4</td>
<td>0.91</td>
</tr>
<tr>
<td>Facility 9</td>
<td>193</td>
<td>5403</td>
<td>12.5%</td>
<td>3.57</td>
<td>3.2</td>
<td>0.91</td>
</tr>
<tr>
<td>Total/avg</td>
<td>930</td>
<td>24595</td>
<td>17.9%</td>
<td>3.37</td>
<td>3.2</td>
<td>0.94</td>
</tr>
</tbody>
</table>
Machine Alarms
“MUTE PLEASE”

DID YOU KNOW?

– Pressures can migrate with each reset
– You may be marching toward limit extremes

What’s the effect on the Tx?

Patient Centered Care
Fresenius machines allow the user to shift the conductivity limits from the default position. Shifting the limits can result in deviations from prescribed Na\(^+\) of as much as:

a) ~ 2 mEq/L  
b) ~ 4 mEq/L  
c) ~ 8 mEq/L  
d) ~ 10 mEq/L

Machine settings: 137 mEq/L Na\(^+\) / 35 mEq/L Bicarbonate – TCD = 13.56 mS
Machine Alarms
Conductivity

- Conductivity
  - Limits are +/- 0.5mS/cm around theoretical or target conductivity (TCD)

- TCD is the target conductivity for the prescribed concentrate, Base Na+ and Bicarbonate value
Conductivity Limits

• Limits can be adjusted either up or down an additional 0.5mS/cm
  – Maximum alarm setting is + 1.0mS/cm of TCD with the lower limit at TCD
Conductivity Limits

- Minimum alarm setting is – 1.0mS/cm of TCD with the upper limit at TCD
- 0.9mS/cm variation from TCD
Question 3

Answer

Shifting conductivity limits from the default position can produce variations in NaCl from prescription of:

a) ~ 2 mEq/L
b) ~ 4 mEq/L
c) ~ 8 mEq/L
d) ~ 10 mEq/L

It’s about 1 mEq/L Na⁺ for each 0.1 mS

Machine settings: 137 mEq/L Na / 35 mEq/L Bicarbonate – TCD = 13.56 mS
Question 3a

**Question**
True or False
Deviations in the prescribed sodium are only an issue for Fresenius machines. Other manufacturers don’t allow shifting of the conductivity alarm limits.

**Answer**
False
The default alarm limits are wider (+/- 5% vs. 0.5 mS). Variations from Rx can still be significant.
Dialysis Technology: Is the Patient Receiving the Treatment Prescribed?
Machine Alarms
TMP

• Transmembrane Pressure (TMP)
  – The force that causes ultrafiltration to occur across the dialyzer membrane
  – TMP limits center around actual TMP at the start of TX or when reset is pushed
  – Approx. +/- 40 mmHg (+/- 60 for low flux).

Did you know ....
When you started the Tx, or pushed reset for a TMP alarm, you are telling the machine “the TMP is exactly where I want it, leave it there”
Question 4

**Question**
When using a high flux dialyzer (e.g., Optiflux 180) the TMP alarm activates when UF removal changes by:

a) $\leq 0.5$ kg/hr
b) $\sim 1.0$ kg/hr
c) $\sim 1.5$ kg/hr
d) $\geq 2.0$ kg/hr
Machine Alarms

TMP

- Ultrafiltration Coefficient (Kuf) is a specification of each dialyzer.
Example:
• 18 NRe (low flux, Kuf = 12 mL/hr/mmHg)
• 180 NRe (high flux, Kuf = 60 mL/hr/mmHg)

Same TMP will pull 5 times more water per hour through the high flux dialyzer, compared to the low flux equivalent.
For a TMP alarm setting of -40 mmHg:

18 NRe alarms at 0.480 L per hour

180 NRe alarms at 2.4 L per hour
Question 4

Answer
When using a highflux dialyzer such as the Optiflux 180, TMP alarms when UF removal changes by:

a) \( \leq 0.5 \text{ kg/hr} \)

b) \( \sim 1.0 \text{ kg/hr} \)

c) \( \sim 1.5 \text{ kg/hr} \)

d) \( \geq 2.0 \text{ kg/hr} \)
Machine Alarms

• Online Pressure Holding Test
  – Assure this feature is turned ON!!!!
    • Runs every 12 minutes during a treatment
    • Catches hydraulic leaks of 300 ml/hr
Dialysis Technology: Is the Patient Receiving the Treatment Prescribed?
Improper use of Sodium Variation can result in patient sodium loading of:

a) 2.8 gm NaCl for every 5 mEq/L over pt. base
b) 4.5 gm NaCl for every 5 mEq/L over pt. base
c) 8.7 gm NaCl for every 5 mEq/L over pt. base
# Default Setting

<table>
<thead>
<tr>
<th></th>
<th>Acid</th>
<th>Bicarb</th>
<th>Dialysate</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM 100</td>
<td>100.00</td>
<td>37.00</td>
<td>137.00</td>
</tr>
<tr>
<td>POTASSIUM 2.0</td>
<td>2.00</td>
<td></td>
<td>2.00</td>
</tr>
<tr>
<td>CALCIUM 2.5</td>
<td>2.50</td>
<td></td>
<td>2.50</td>
</tr>
<tr>
<td>MAGNESIUM 0.75</td>
<td>0.75</td>
<td></td>
<td>0.75</td>
</tr>
<tr>
<td>CHLORIDE 105.25</td>
<td>105.25</td>
<td></td>
<td>105.25</td>
</tr>
<tr>
<td>SODIUM ACETATE 0.0</td>
<td>0.00</td>
<td></td>
<td>0.00</td>
</tr>
<tr>
<td>ACETIC ACID (ACETATE) 4.0</td>
<td>4.00</td>
<td></td>
<td>4.00</td>
</tr>
<tr>
<td>BICARB</td>
<td></td>
<td>37.00</td>
<td>33.00</td>
</tr>
<tr>
<td>TOTAL BUFFER</td>
<td></td>
<td>37.00</td>
<td></td>
</tr>
<tr>
<td>DEXTROSE, gm/L 200</td>
<td>2.00</td>
<td></td>
<td>2.00</td>
</tr>
<tr>
<td>THEORETICAL CONDUCTIVITY</td>
<td></td>
<td></td>
<td>13.50</td>
</tr>
<tr>
<td>THEORETICAL pH</td>
<td></td>
<td></td>
<td>7.22</td>
</tr>
</tbody>
</table>

Can be changed by the operator/machine
## Raise Sodium to 150 mEq/L

<table>
<thead>
<tr>
<th></th>
<th>Acid</th>
<th>Bicarb</th>
<th>Dialysate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SODIUM 100</strong></td>
<td>112.50</td>
<td>37.50</td>
<td>150.00</td>
</tr>
<tr>
<td><strong>POTASSIUM 2.0</strong></td>
<td>2.25</td>
<td>2.25</td>
<td></td>
</tr>
<tr>
<td><strong>CALCIUM 2.5</strong></td>
<td>2.81</td>
<td>2.81</td>
<td></td>
</tr>
<tr>
<td><strong>MAGNESIUM 0.75</strong></td>
<td>0.84</td>
<td>0.84</td>
<td></td>
</tr>
<tr>
<td><strong>CHLORIDE 105.25</strong></td>
<td>118.41</td>
<td>118.41</td>
<td></td>
</tr>
<tr>
<td><strong>SODIUM ACETATE 0.0</strong></td>
<td>0.00</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td><strong>ACETIC ACID (ACETATE) 4.0</strong></td>
<td>4.50</td>
<td>4.50</td>
<td></td>
</tr>
<tr>
<td><strong>BICARB</strong></td>
<td></td>
<td>37.50</td>
<td>33.00</td>
</tr>
<tr>
<td><strong>TOTAL BUFFER</strong></td>
<td></td>
<td></td>
<td>37.50</td>
</tr>
<tr>
<td><strong>DEXTROSE, gm/L 200</strong></td>
<td>2.25</td>
<td></td>
<td>2.25</td>
</tr>
<tr>
<td><strong>THEORETICAL CONDUCTIVITY</strong></td>
<td></td>
<td></td>
<td>14.78</td>
</tr>
<tr>
<td><strong>THEORETICAL pH</strong></td>
<td></td>
<td></td>
<td>7.17</td>
</tr>
</tbody>
</table>

Can be changed by the operator/machine
Improper use of Sodium Variation can result in patient sodium loading of:

a) 2.8 gm NaCl for every 5 mEq/L over pt. base
b) 4.5 gm NaCl for every 5 mEq/L over pt. base
c) 8.7 gm NaCl for every 5 mEq/L over pt. base
(recommended dietary intake is approx. 2.0 gm/day)
Key Points for Review

Objective – to show how misusing or misunderstanding the technology in a dialysis clinic can affect the prescription delivered.

Specifically:

- Kinds of variation in dialysis
- 3 - Stream proportioning
- Blood lines
- Alarms and staff responsibilities
- Impact of conductivity different than target
- Significance of pressure alarm limits and pressure tests
- Impact of using sodium variation
Key Points for Review

• Know your stuff
  – How the devices work
  – What alarms mean
  – What happens when the noise is ignored or just silenced

• It does matter! Tx’s are affected!

• Patients come first! The rest will be just fine.
Questions

Thank You