PERITONEAL DIALYSIS OUTCOMES AND PRACTICE PATTERNS STUDY (PDOPPS)

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Peritoneal dialysis (PD) is a key dialysis modality for ESKD patients. The major limiting factors for PD are peritonitis, technique failure, and patient survival. Australia has one of the highest peritonitis rates in the world and one of the worst rates of technique failure.
Global Peritonitis Rates

PD Peritonitis rate by treating unit,
Australia 2004-2013
A wide variability has been seen in the rates of peritonitis between different PD units within Australia. Suggesting that potentially differences in the way PD patients are managed may account for some of the differences seen between units.
AIMS OF PDOPPS

- PDOPPS is a prospective, multi-centre international observational study
- Its aim is to identify measureable and modifiable practices in peritoneal dialysis that will influence patient outcomes.
- Specific areas:
  - Catheter insertion practice
  - PD training practice
  - Infection control practice
DOPPS study used to develop PDOPPS

- It utilizes the successful study methodology of the (haemo) Dialysis Outcomes and Practice Patterns Study (DOPPS)
- >200 DOPPS publications to date, since starting in 1996
- Central coordinating and data collection centre in Arbor Research (Michigan, USA)
  - Obtained industry funding
- Countries are invited to participate but need to obtain their own funding
  - 6 countries currently involved in PDOPPS with more looking at joining.
STUDY METHODOLOGY - SELECTION

- Facility Selection
  - Utilised a stratified selection process to choose a representative sample of PD units for each country (to represent different dialysis facility types and geographic regions).
  - Total of 210 PD facilities from 6 countries currently recruiting
  - In Australia 20 out of a total of 36 suitable PD facilities were selected (the 36 units represents 94% of all PD patients in Australia)
STUDY METHODOLOGY – SELECTION (cont’d)

- Patient Selection
  - A census of all PD patients in each selected facility was established
  - From this a random sample of 20-30 patients, depending upon facility size, are offered participation in the study
  - Patients who drop-out are replaced (focus on incident pts)
STUDY METHODOLOGY – DATA COLLECTION

- Patient level data
  - Detailed clinical data is collected on all selected patients at baseline then every 4 months
  - Patient questionnaires completed annually
- Facility level data
  - Medical Director questionnaires annually
  - Nurse manager questionnaires annually
- Real-time, web-based data collection tools.
International PDOPPS Timeline

Study Design & Planning

2013
2014
2015
2016
2017
2018
2019
2020

US
Canada
Japan
Australia
UK
Thailand

Longitudinal Data Collection

Primary Research and Analysis

End of Phase 1
End of Phase 2
Table 2: Enrolment to date and projected counts through to 2020

<table>
<thead>
<tr>
<th></th>
<th>Australia</th>
<th>Overall (International PDOPPS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Prevalent</td>
</tr>
<tr>
<td>Original proposal*</td>
<td>640</td>
<td>340</td>
</tr>
<tr>
<td>Enrolment to date</td>
<td>411</td>
<td>349</td>
</tr>
<tr>
<td>(Dec 2016)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Projected enrolment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dec 2017 (end of 1st phase)</td>
<td>531</td>
<td>391</td>
</tr>
<tr>
<td>Dec 2020 (end of 2nd phase)</td>
<td>771</td>
<td>391</td>
</tr>
</tbody>
</table>

*For first phase, including original NHMRC proposal
<sup>a</sup> Assumes linear incident patient accrual through 2020 (rate ~3-5 pts/year/facility by country).
Facility size distribution
PDOPPS initial cross-section (2014-2016)

% of facilities

N patients:
- >100
- 71-100
- 51-70
- 30-50
- <30

N facilities:
- A/NZ: 21
- Canada: 20
- Japan: 32
- Thailand: 21
- UK: 19
- US: 109

Preliminary data as of February, 2017 among facilities completing the initial patient census
## Patient Characteristics*

**PDOPPS initial cross-section of sampled patients (2014-2016)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>A/NZ</th>
<th>Canada</th>
<th>Japan</th>
<th>Thailand</th>
<th>UK</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td># of facilities</td>
<td>20</td>
<td>20</td>
<td>31</td>
<td>21</td>
<td>18</td>
<td>106</td>
</tr>
<tr>
<td># of selected pts</td>
<td>320</td>
<td>403</td>
<td>623</td>
<td>536</td>
<td>182</td>
<td>2470</td>
</tr>
</tbody>
</table>

### Demographics

<table>
<thead>
<tr>
<th></th>
<th>A/NZ</th>
<th>Canada</th>
<th>Japan</th>
<th>Thailand</th>
<th>UK</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>64%</td>
<td>57%</td>
<td>63%</td>
<td>51%</td>
<td>64%</td>
<td>55%</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45</td>
<td>9%</td>
<td>13%</td>
<td>8%</td>
<td>18%</td>
<td>17%</td>
<td>19%</td>
</tr>
<tr>
<td>45-59</td>
<td>24%</td>
<td>28%</td>
<td>25%</td>
<td>38%</td>
<td>21%</td>
<td>33%</td>
</tr>
<tr>
<td>60-74</td>
<td>44%</td>
<td>39%</td>
<td>44%</td>
<td>38%</td>
<td>41%</td>
<td>35%</td>
</tr>
<tr>
<td>75+</td>
<td>23%</td>
<td>20%</td>
<td>23%</td>
<td>6%</td>
<td>20%</td>
<td>13%</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>27.6(4.9)</td>
<td>27.0(5.6)</td>
<td>23.0(3.5)</td>
<td>22.6(4.1)</td>
<td>26.7(5.6)</td>
<td>28.5(6.3)</td>
</tr>
</tbody>
</table>

### Comorbidities

<table>
<thead>
<tr>
<th>Cause of ESRD</th>
<th>A/NZ</th>
<th>Canada</th>
<th>Japan</th>
<th>Thailand</th>
<th>UK</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>31%</td>
<td>36%</td>
<td>32%</td>
<td>48%</td>
<td>20%</td>
<td>36%</td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>22%</td>
<td>21%</td>
<td>32%</td>
<td>4%</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>Other</td>
<td>48%</td>
<td>43%</td>
<td>35%</td>
<td>48%</td>
<td>58%</td>
<td>51%</td>
</tr>
<tr>
<td>CAD</td>
<td>32%</td>
<td>29%</td>
<td>18%</td>
<td>8%</td>
<td>29%</td>
<td>25%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>44%</td>
<td>47%</td>
<td>40%</td>
<td>52%</td>
<td>28%</td>
<td>54%</td>
</tr>
</tbody>
</table>

*Preliminary data as of February, 2017 among patients with baseline chart abstraction

Results are shown as mean (standard deviation), %
RESULTS TO DATE

- ISPD Guidelines (Perit Dial Int 2016)
  - Pre-op Abs at time of PD catheter insertion (1A)
  - Exit site prophylaxis (1B)
  - Antifungal prophylaxis (1B)
Antibiotic prescription, prophylaxis, and treatment as reported by PDOPPS medical directors

<table>
<thead>
<tr>
<th>Antibiotic prophylaxis for: (%)</th>
<th>A/NZ (17)</th>
<th>Canada (20)</th>
<th>Japan (28)</th>
<th>Thailand (19)</th>
<th>UK (32)</th>
<th>US (64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD catheter insertion</td>
<td>82</td>
<td>100</td>
<td>89</td>
<td>90</td>
<td>100</td>
<td>64</td>
</tr>
<tr>
<td>Complicated dental procedures</td>
<td>59</td>
<td>70</td>
<td>68</td>
<td>44</td>
<td>34</td>
<td>84</td>
</tr>
<tr>
<td>Genitourinary procedures</td>
<td>50</td>
<td>35</td>
<td>41</td>
<td>39</td>
<td>38</td>
<td>54</td>
</tr>
<tr>
<td>Gynecological procedures</td>
<td>56</td>
<td>40</td>
<td>32</td>
<td>44</td>
<td>38</td>
<td>66</td>
</tr>
<tr>
<td>Lower endoscopy</td>
<td>59</td>
<td>65</td>
<td>36</td>
<td>35</td>
<td>66</td>
<td>67</td>
</tr>
<tr>
<td>Wet contamination</td>
<td>94</td>
<td>90</td>
<td>68</td>
<td>63</td>
<td>78</td>
<td>91</td>
</tr>
</tbody>
</table>

Empiric Antibiotic for Peritonitis Treatment*: (%)

<table>
<thead>
<tr>
<th>Empiric Antibiotic for Peritonitis Treatment*</th>
<th>A/NZ (17)</th>
<th>Canada (20)</th>
<th>Japan (28)</th>
<th>Thailand (19)</th>
<th>UK (32)</th>
<th>US (64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cephalosporin, 1st &amp; 2nd generation or higher</td>
<td>24</td>
<td>45</td>
<td>41</td>
<td>90</td>
<td>0</td>
<td>31</td>
</tr>
<tr>
<td>Vancomycin &amp; 2nd generation Cephalosporin or higher</td>
<td>18</td>
<td>20</td>
<td>0</td>
<td>5</td>
<td>19</td>
<td>48</td>
</tr>
<tr>
<td>Cephalosporin (1st generation) &amp; Aminoglycoside</td>
<td>53</td>
<td>30</td>
<td>19</td>
<td>11</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Vancomycin &amp; Aminoglycoside</td>
<td>24</td>
<td>25</td>
<td>7</td>
<td>5</td>
<td>56</td>
<td>28</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>25</td>
<td>37</td>
<td>5</td>
<td>25</td>
<td>20</td>
</tr>
</tbody>
</table>

*Some overlap among listed therapy; values add up to over 100%; Preliminary data as of February 2017

Adapted from Perl et al. EDTA abstract (2016)
Exit Site Antimicrobial Prophylaxis*

Question asked: What is the predominant antibiotic/antimicrobial prophylactic strategy in your center?

Preliminary data as of February 2017

Medical Director Survey (MDS)
Antifungal prophylaxis during antibiotic therapy

% of Patients

- Always
- Occasionally
- Never

A/NZ: 12 Always, 18 Occasionally, 71 Never
Canada: 45 Always, 25 Occasionally, 30 Never
Japan: 7 Always, 93 Occasionally, 74 Never
Thailand: 26 Occasionally, 74 Never
UK: 19 Occasionally, 88 Never
US: 51 Occasionally, 46 Never

N facilities: 17 A/NZ, 20 Canada, 28 Japan, 19 Thailand, 32 UK, 63 US

Question asked: Under what circumstances do you give fungal prophylaxis when using antibiotics in PD patients?

Preliminary data as of February 2017

Medical Director Survey (MDS)
Country peritonitis rates

Peritonitis rate (95% CI), events per patient year

<table>
<thead>
<tr>
<th>Country</th>
<th>Facilities</th>
<th>Patients</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>20</td>
<td>723...</td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>26</td>
<td>736...</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>5</td>
<td>55...</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>27</td>
<td>585...</td>
<td></td>
</tr>
<tr>
<td>A/NZ</td>
<td>14</td>
<td>237...</td>
<td></td>
</tr>
</tbody>
</table>

Perl et al. ASN oral abstract (2016)
Facility peritonitis rates*

Peritonitis rate (95% CI), events per patient year

*Restricted to facilities with at least 5 patient years of follow-up (n=79)

Perl et al. ASN oral abstract (2016)
PDOPPS - SUMMARY

- Large observational cohort study that is a representative sample for each country
- Provides detailed Patient and Facility level data with follow-up information
- Already demonstrated wide facility differences in practice patterns
- Also demonstrated similar rates of peritonitis between countries but wide inter-facility variability
ACKNOWLEDGEMENTS

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Canadian Institute for Health Research (Canada)
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National Institute of Diabetes and Digestive and Kidney Diseases (USA)