Harmonisation Workshop
Growth Hormone

18th May 2017
Diagnosis of GH deficiency and acromegaly and funding for GH treatment depend on GH levels and consensus guidelines (i.e., defined clinical decision points).

**Problem** differences in measured GH levels between assays

**Candidate for assay harmonisation**

- 2 units used
- Differences in reference intervals and decision points
hGH units – mU/L and g/L

**g/L**

International Consensus statements

Growth Hormone Standardisation Group

EWP recommended µg/L for APUTS,

60% labs in Endo QAP still report in mU/L

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**UNITs**

<table>
<thead>
<tr>
<th>Units</th>
<th>Endo QAP</th>
<th>Cycle</th>
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<tbody>
<tr>
<td>mU/L</td>
<td>34</td>
<td>43</td>
</tr>
<tr>
<td>g/L</td>
<td>21</td>
<td>47</td>
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hGH Harmonisation issues

Lack of a single unit for hGH
μg/L accepted as unit – mU/L required for PBS form, RCPA QAP unable to change to reporting in g/L only

Between method differences in hGH
In principle agreement to using correction factors to harmonise hGH results if international harmonisation not imminent

Differences in reference intervals and decision points
If assays not harmonised- platform specific ref intervals/clinical decision points
Harmonisation process requires collaboration of all relevant groups laboratories, endocrinologists, industry

wide consultation and consensus

AACB, RCPA, Endocrine Society, APEG (OZGROW, GHAC)

Growth Hormone/IGF-1 Standardisation Group Australasia (GHSGA) Reformed 2016
hGH Harmonisation issues and GHSGA

Lack of a single unit for hGH

Recommend g/L– dual reporting for a period
Investigate modifying PBS form

Between method differences in hGH

Agreed harmonisation of assays clinically important and appropriate to further investigate possibility of harmonisation

Differences in reference intervals and decision points
Reporting in µg/L

1. Labs set a date to change eg Nov-December 2017
2. Report in both mU/L and µg/L for 6 months
3. Harmonisation Group to write letter to PBS (copy to APEG) of plan to change units nationwide
4. All labs should have GH as µg/L by July 2018. Clinicians will be using µg/L for diagnosis and monitoring, so PBS can implement change to documentation regarding GH.
Harmonisation Workshop
IGF-1

18th May 2017
Harmonisation issues

- Between method differences
- 2 units
- Within method Reference Interval differences

<table>
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<tr>
<th>UNITS</th>
<th>IGF-1/CPEP QAP</th>
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<tr>
<td>Cycle</td>
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<td>nmol/L</td>
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</table>

IGF-1 ng/mL - 1 NT, 1 NSW, 3 WA

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Liaison – Reference Intervals

IGF-1 (nmol/L) vs Age

M and F

Line representations for different methods:
- A -L: Modified Immulite
- A-U: Modified Liaison
- B-L: Immulite - L
- B-U: Immulite - U
- C-L: Modified Liaison
- C-U: Modified Immulite
- D-L: Immulite - L
- D-U: Immulite - U

Legend:

- 3 Liaison
- 2 modified Liaison
- 2 Immulite
- 3 modified Immulite
IGF-1 Harmonisation issues
AACB & GHSGA

Lack of a single unit for IGF-1
Decision deferred pending literature review and consultation
recommend reporting in nmol/L

Between method differences in IGF-1
Set clinical decision points not used - harmonisation not essential
Assess if harmonisation possible when restandardised Immulite assay in use

Differences in reference intervals
If assays not harmonised- platform specific ref intervals. Possibility of modifying the Bidlingmaier RI for iSYS for use with Liaison (S&N) and Immulite with a limited verification study.
IGF-1 Reference Intervals
Requirements for APEG

Verification of platform specific RI’s for main platforms
( Liaison, Immulite , iSYS)

Tanner stage-specific reference intervals

APEG have Paed Endos in each major centre happy to organise
- Tanner assessments
- assessments of skeletal maturity
- sample collection
IGF-1 Proposals for Harmonisation

1. Recommend reporting in nmol/L

2. Harmonised platform specific RI’s
Harmonisation Workshop
Macroprolactin

18th May 2017
AACB EWP SURVEY 2012

Survey to assess

- what labs are doing
- how they are reporting
- interest in a macroPrl QAP

Variability in every aspect of procedure from who to test to reporting

*Only standardised procedure - screening with 25% PEG*