IFCC General Conference 2018
Laboratory medicine: Preparing for the 2020's
10th – 11th November 2018
Hotel Novotel Budapest City, Hungary

Advancing excellence in laboratory medicine for better healthcare worldwide

Thematic approach
The exemple of bone metabolism
Etienne Cavaller
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What is the actual situation?

3 Working groups:
WG for standardization of PTH
WG on standardization of vitamin D metabolites
WG on standardization of Bone markers

3 different stades of evolution!

- PTH: No reference method yet, but a WHO standard
- VTD: Reference methods, NIST standards, VDSP certification
- Bone markers: no reference method, no standard (and no good QCE)

Rationale

ENDOCRINOLOGY
NEPHROLOGY
OSTEOPOROSIS
ENDOCRINOLOGY
Primary and secondary hyperparathyroidism: PTH, 25(OH)D
Establishment of good references values for PTH: need 25(OH)D determination!
Other parathyroid diseases
Genetic idiopathic infantile hypercalcemia: 24,25(OH)2 25(OH)D PTH
A PTH result cannot be interpreted without calcium and vitamin D

NEPHROLOGY
KDIGO guidelines: PTH, 25-OHD and Bone alkaline phosphatase
OSTEOPOROSIS

Looking for secondary causes of osteoporosis:
PTH, 25(OH)D

Monitoring the compliance to treatment
PTH, 25(OH)D, CTX, PINP

Challenges

WG on PTH
Different PTH forms and fragments
Non-oxydized PTH?
Lost of standardization in CKD patients?

WG on vitamin D
Impact of diseases, physiological status and ethnicity on standardization?
(CKD, pregnancy, DBP polymorphisms)
25(OH)D2 (different crossreactivities,...)
Which limits to be used to consider that a method is standardized
Poorly standardized ELISAs (emerging countries)

WG on bone markers
Harmonization of CTX not yet possible
Easier for PINP
bALP
New markers! Sclerostin, FGF23,...
Emerging countries

Difficult to have a PTH determination in many African countries
Reference ranges adapted???
Polymorphism of DBP
Prices of the reagents compared to local incomes

Conclusions

Standardization of PTH, vitamin D and bone markers is far from being achieved.
Even with the most advanced WG, many questions remain and full standardization is not achieved yet.
Importance of the partnership with Manufacturers
Joining the efforts of the 3 WG into a Committee has a lot of sense since these analyses are often requested together.
Conclusions

Standardization of PTH, vitamin D and bone markers is far from being achieved.

Even with the most advanced WG, many questions remain and full standardization is not achieved yet.

Manufacturers need to play the game

Joining the efforts of the 3 WG into a Committee has a lot of sense since these analyses are often requested together.

**Constitution of a new IFCC Committee on standardization of PTH, vitamin D and bone markers, with a call for candidates from national societies.**

Current terms of reference

Evaluate commutability of PTH IS 95/646 and encourage its worldwide implementation

Constitution of an appropriate panel of sera and plasma to establish reference intervals

Development of a reference measurement procedure for PTH(1-84)

Standardize or harmonize two bone turnover markers: CTX and PINP.

Re-evaluate current VDSP performance guidelines for 25(OH)D

Establish VDSP performance guidelines 24,25(OH)2D

Standardization of 25(OH)D2 and in patients

Biological variation of 25OHD and 24,25(OH)2D

New markers: FGF23, TRAP-5b, bALP, sclerostin...