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Development of an Accredited External Quality Assessment (EQA) Programme for Renal Calculi

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Background

Renal stones (calculi), and renal stone disease (nephrolithiasis or urolithiasis), are a common problem worldwide with a prevalence of approximately 10% in men and 7% in women and an estimated 5-year recurrence rate of up to 50%. Renal stones are associated with systemic diseases like Type 2 diabetes mellitus, obesity, dyslipidemia, and hypertension. Stone analysis plays a valuable role in the diagnosis of kidney stone patients, specifically in infrequently encountered kidney stones such as infection-induced, drug-induced, ammonia urate stones and in the rare cystine and xanthine inborn errors.

Aim

The aim was to establish whether participating laboratories could correctly identify the chemical composition of calculi, could recognize and act appropriately when faced with unusual samples, and to establish an EQA Programme that provided an ongoing assessment of the performance of calculi analyses in the laboratory.

Method

The chemicals and the ratio of chemical components (matrix mixing) in the samples were selected to cover the appropriate pathological range of calculi constituents that laboratories would encounter. Kidney stones are composed of 97–98% mineral salts and 2–3% organic matrix. Proteins are the most abundant component of the organic stone matrix and constitute approximately 64%.

To minimize the risk of an inhomogeneous product, the matrix was well-mixed and refined to a powdered consistency. For a single chemical material such as 100% Calcium Phosphate the appropriate amount of chemical was weighed gravimetrically and ground with a pestle and mortar until an even powdered consistency was obtained.

Samples were analysed using FTIR spectroscopy and compared with a reference library to validate the chemical composition of each matrix. All samples were stored at -20°C, however they were distributed to participants at ambient temperature. Six rounds were distributed per year, with each round consisting of four different “stone” materials of combinations of pure and mixed chemicals containing 75-125 mg material.

Performance Criteria

For qualitative analysis participants get 1 point for each sample component they correctly identify and lose 1 point for each component incorrectly identified. PI scores are assigned for each sample, and an overall performance category is assigned per distribution. Each sample will have a maximum score depending on how many chemicals are present.

Results

Pools 121 – 126 were made up of single chemicals, some with multiple components, some with single components. Table 2 shows the % of participants who correctly identified the component(s) in the sample for pools 121-124, each distributed on 2-3 occasions. For Calcium Phosphate, separate pools made up of Brushite ($CaHPO_4 \cdot 2H_2O$) and Hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) were distributed. 100% of participants correctly identified the Calcium Phosphate on both distributions for the Hydroxyapatite pool. For the Brushite pool, 100% of participants correctly identified the Calcium Phosphate for the first 2 distributions but only 98% for the 3rd distribution; 3 participants incorrectly reported presence of Magnesium Ammonium Phosphate (MAP) and 2 incorrectly reported Oxalate.

		% participants who identified correct component		
Pool	**Composition of Stone (%)**	**Sendout 1**	**Sendout 2**	**Sendout 3**
121	100% Calcium Phosphate (Brushite)	100	100	98
122	100% Calcium Oxalate (Monohydrate)	100	100	96
123	100% Magnesium Ammonia Phosphate	100	100	
124	100% Calcium Phosphate (Hydroxyapatite)	100	100	

Table 2: % of Participants who identified correct component for Pools 121-124

Pool 125 – Calcium Carbonate – was distributed on 2 occasions with participants correctly identifying the presence of Calcium (93% and 94% for each distribution respectively). For the first distribution 100% of participants correctly reported Carbonate. For the 2nd distribution of the same pool, only 61% participants correctly reported Carbonate. On this occasion, 1 participant incorrectly reported the presence of Silicon Dioxide and 1 incorrectly reported the presence of Oxalate.

For Pool 126 – Uric Acid – 100% participants correctly identified the component on both occasions the pool was distributed.

Pools 127-129 all contained a mixture of 2 chemicals, with multiple components. Pool 127 contained Calcium Phosphate in a mixture of Brushite and Hydroxyapatite, 100% of participants correctly identified both components. Some participants reported whether they have identified Brushite and / or Hydroxyapatite but wet chemistry methods reported only the presence of the components Calcium and Phosphate.

Pool 128 contained a mixture of 70% Magnesium Ammonia Phosphate & 30% Calcium Phosphate (Hydroxyapatite). Table 3 shows the % of participants who identified correct component for Pool 128 for 2 distributions. Only 80 and 81% of users correctly identified the Calcium in the sample but this component only made up 30% of this sample.

		% participants who identified correct component	
Distribution	**Composition of Stone (%)**	**MAP**	**Calcium**
1	70% Magnesium Ammonia Phosphate & 30% Calcium Phosphate (Hydroxyapatite)	100	81
2	70% Magnesium Ammonia Phosphate & 30% Calcium Phosphate (Hydroxyapatite)	96	80

Table 3: % of Participants who identified correct component for Pool 128 for 2 distributions

Pool 129 was a mixture of 50% Calcium Oxalate & 50% Uric Acid. For distribution 1 98% reported Calcium Oxalate with only 80% reporting Uric Acid. For the 2nd distribution 98% of participants reported both Calcium Oxalate and Uric Acid.

Pools 131 and 132 represented rare renal calculi and were only distributed once each throughout the 12-month period, with 84% correctly identifying Xanthine and 73% correctly identifying Silicon Dioxide.

Discussion

Although the majority of participants correctly identified most the components present, the main performance issues appeared to be the inability to correctly identify all the components present. Users of wet chemistry kits need to be aware of the limitations of their methods when rare constituent is present. The Weqas EQA programme for Renal Calculi is now fully accredited to ISO 17043.