The acute kidney injury phenotype can be used as a cohort definition to generate real-world evidence in data sources with and without lab values

**Development and characterization of a phenotype algorithm to identify Acute Kidney Injury in real world data (RWD)**

**Background:** Acute Kidney Injury (AKI) is a common, harmful and potentially treatable disease defined by an abrupt kidney function decrease. Attempts have been made over years to reach consensus on an AKI definition for use in RWD to allow more replicable and reproducible research, but results remain lacking.

**Result 1:** Proposed phenotypes

The cohort definition process should start from a phenotype. Sensitive (Broad): • acute renal failure syndrome or • acute nephritis or • rapidly progressive nephritic syndrome

Including all descendants

Specific (Narrow): • acute renal failure syndrome

Including all descendants

**Inclusion criteria:**
• ≥1-year prior observation,
• No end-stage kidney disease, in the year prior,
• No chronic dialysis,
• 30 days pre-entry date no AKI washout period

**Methods**

**Figure 1. Differential diagnosis of AKI, acute kidney disease (AKD), chronic kidney disease (CKD) & no kidney disease (NKD)** [Figure adapted from Kellum* et al. 2012]

| AKI | ≤7 days | sCr > 1.50 mg/dl within 7 days, (sCr > 2.0 mg/dl within 2 days of oliguria for 6h) | – |
| AKD | <3 months | AKI or GFR <60 ml/min.1.73m² (GFR ≥35% over baseline sCr > 50% over baseline) | OR | elevated marker of kidney damage |
| CKD | >3 months | GFR <60 ml/min.1.73m² (stable GFR; stable sCr) | OR | elevated marker of kidney damage |
| NKD | – | GFR ≥60 ml/min.1.73m² (stable GFR; stable sCr) | AND | no marker of kidney damage |

sCr = serum creatinine; GFR = glomerular filtration rate

**Figure 2. Phenotype development approach***

**Limitation:** Measurement variations relative to a baseline are not supported as an entry event in ATLAS, thus clinical criteria based on serum creatinine (sCr) variation with respect to a baseline cannot be established in ATLAS cohort definitions without flawed workarounds. Sparsity in the data and lack of standardization of lab measurements units did not allow the use of laboratory values in the proposed phenotypes.