DISCLOSURES
The study was funded by Bi; under a contract with RTIHS granting the research team independent publication rights. AC, CR, EP, LR, MPV, and SP are RTIHS employees: SPF, ADL, and KGB are employees of Bi. The original study was approved by CRPD ISC as protocol 16_075RA, and the study was registered in the EU PGS (EURN154324, http://www.encepp.eu/encepp/viewResource.htm?id=16154).

BACKGROUND
• In database studies, a 3-month time window around time of diagnosis is commonly used to validate acute kidney injury (AKI) and acute liver injury (ALI), and it is based on clinical criteria defining chronic liver disease and chronic kidney disease (CKD), rather than on specific timing of acute events.

OBJECTIVE
• To evaluate the validity of the 3-month time window used to identify cases of ALI and AKI in the Clinical Research Datalink (CRPD) in the United Kingdom.

RESULTS
• In the AKI cohort, among 21,621 new users, 75 potential ALI cases were identified (Figure 2), of which 6 fulfilled the laboratory criteria within 3 months of diagnosis (Table 1).
• None of the potential ALI cases had a specific code for ALI (e.g., acute liver failure or acute necroizing liver disease).
• The majority of the potential ALI cases were identified through non-specific Read codes indicating "abnormal liver enzymes" or "jaundice".

Figure 2. Codes That Identified Patients With a Potential ALI Diagnosis

Table 1. Time Between Laboratory Criteria Related to Diagnosis Codes by Outcome Cohort

METHODS
• Two cohorts of new users of specific oral glucose-lowering drugs for type 2 diabetes (one to evaluate the outcome ALI and one for AKI) were identified (August 2014-September 2017).
• Patients with a previous diagnosis of ALI were excluded from the "ALI cohort" and patients with previous diagnosis of AKI were excluded from the "AKI cohort." The latter had previous abnormal laboratory criteria but were not classified as ALI.
• Cases were identified using codes suggestive of ALI and AKI (Figure 1).
• Among potential cases of ALI/AKI, we evaluated the number of patients who fulfilled the AKI or ALI criteria for the period extending from 3 months before to 3 months after diagnosis.
• In addition, we assessed the number of patients who fulfilled the laboratory criteria irrespective of being a potential case of ALI/AKI.
• Laboratory criteria were based on the Food and Drug Administration definition for ALI, 1 and the adapted Risk, Injury, Failure, Loss, End-Stage (RIFLE) definition for AKI. 2

Figure 3. Codes That Identified Patients With a Potential AKI Diagnosis

CONCLUSIONS
• Of patients who had a diagnosis code and fulfilled the laboratory criteria, 85% in the ALI cohort and 44% in the AKI cohort fulfilled the laboratory criteria within 1 week of the diagnosis code, bringing into question the relevance of using a 3-month time window in database studies.
• A high number of patients in the AKI cohort fulfilled the laboratory criteria but did not have a code suggestive of an acute event. These patients may have CKD.
• Evaluation of repeated renal laboratory test results may help identify patients with undiagnosed CKD.

REFERENCES

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Presented at: 34th International Conference on Pharmacoeconomics & Therapeutic Risk Management; August 22-26, 2018; Prague, Czech Republic