CKD-REIN - Chronic Kidney Disease - Renal Epidemiology and Information Network

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General

Identification

Detailed name	Chronic Kidney Disease - Renal Epidemiology and Information Network
Sign or acronym	CKD-REIN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS, no 12- 360; CNIL DR-2012-469; CPP Kremlin-Bicêtre, ID-RCB 2012-A00902-41; International Review Board de l'Inserm n°13-108; Codecoh AC-2012-1624

General Aspects

Medical area	Urology, andrology and nephrology
Health determinants	Genetic Lifestyle and behavior Medicine Nutrition Social and psychosocial factors
Keywords	organization of care and cost-effectiveness of practices, Dialysis, quality of life, biomarkers

Scientific investigator(s) (Contact)

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Collaborations

Participation in projects, networks and consortia	Yes
Details	The Chronic Kidney Disease Outcomes and Practice Patterns Study (CKDopps); ISN iNET-CKD (International Network of Chronic Kidney Disease cohort studies)

Funding

Funding status	Mixed
Details	CKD-REIN is supported by a public?private partnership with funding from seven pharmaceutical companies (ANR 2011 "Investissements d'avenir"; Amgen, Baxter, Fresenius 105 Medical Care, GlaxoSmithKline (GSK), Merck Sharp & Dohme- Chibret (MSD France) since 2012, Lilly France since 2013, Otsuka Pharmaceutical since 2015 and Sanofi-Genzyme from 2012 to 2015.

Governance of the database

Sponsor(s) or organisation(s) responsible	PARIS-SUD UNIVERSITY
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Biomedicine Agency
Organisation status	Public
Sponsor(s) or organisation(s) responsible	NANCY UNIVERSITY HOSPITAL, PUBLIC HEALTH
Organisation status	Public
Sponsor(s) or organisation(s) responsible	LYON 3 UNIVERSITY, Economy
Organisation status	Public
Sponsor(s) or organisation(s) responsible	PICARDIE BIOBANK

Organisation status	Public
Sponsor(s) or organisation(s) responsible	CENTRE NATIONAL DE GENOTYPAGE
Organisation status	Public
Sponsor(s) or organisation(s) responsible	INSERM, I2MR, U858
Organisation status	Public
Sponsor(s) or organisation(s) responsible	ARBOR RESEARCH
Organisation status	Public
Sponsor(s) or organisation(s) responsible	AMIENS UNIVERSITY HOSPITAL, Nephrology
Organisation status	Public
Sponsor(s) or organisation(s) responsible	BORDEAUX 2 UNIVERSITY HOSPITAL, Nephrology
Organisation status	Public
Sponsor(s) or organisation(s) responsible	LYON 1 UNIVERSITY HOSPITAL, Nephrology
Organisation status	Public
Sponsor(s) or organisation(s) responsible	NANCY UNIVERSITY HOSPITAL, Nephrology
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Etablissement Français du Sang
Organisation status	Public
Presence of scientific or steering committees	Yes

Additional contact

Name of the contact	SPEYER
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Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	REIN administrative file of all nephrology care units classified by type and region will provide the source for selecting 10 nephrology clinics in each of the 5 inter-regions covered by 5 study co-coordinators. Participating clinics will be additionally required to care for at least 60 CKD patients Stage 3-5 per year.

Database objective

Main objective	The CKD-REIN cohort will provide a research platform to address key questions regarding a number of determinants and biomarkers associated with adverse CKD outcomes and to assess clinical practices and costs in patients selected at random from a representative sample of various types of nephrology consultations. In addition, it will meet the objectives of the starting international CKD Outcomes and Practice Patterns Study (CKDopps) designed principally to identify best treatment practices in patients with advanced CKD in several countries, including France. The objectives of the CKD-REIN study are: (1) to study a set of social, environmental,

	behavioral, clinical, and genetic factors, and their interactions in relation with the outcomes of CKD and its complications, including progression to ESRD and mortality, as well as the onset of several relevant acute and chronic clinical events : acute kidney injury, infections; cardiovascular diseases, cognitive decline, bone disease, and cancer ; (2) to assess several new biomarkers to predict adverse outcomes of CKD and its complications; (3) to evaluate the associations of provider practices (management of hypertension and of CKD complications such as anemia, nutritional abnormalities, and bone mineral disorder; timing of dialysis initiation and transplant wait-listing) with achievement of clinical practice guidelines, clinical outcomes (survival, ESRD, hospital admissions) and patient-reported outcomes (QoL, satisfaction). (4) to evaluate the associations of health care organization (e.g., multidisciplinary team, care network) and clinic services (e.g., for nutrition, educational programs) with clinical and patient-reported outcomes, and achievement of clinical practice guidelines; (5) to estimate the relative cost-effectiveness of different provider practices and clinic services. (6) to estimate the CKD incidence and prevalence in nephrology healthcare practices in France, depending on age, sex, social status, diabetes status, and depending on the stage and type of CKD.
Inclusion criteria	Study eligibility requires an eGFR < 60 mL/min/1.73 m2 for at least one month and no prior dialysis or transplantation. Inclusion criteria also requires less than 3 years of follow-up by the nephrology clinic for patients with CKD stage 3 in order to reduce survival bias due to prevalent cases. Patients <18 yrs old, pregnant, institutionalized, or unable to give inform consent are excluded, as well as patients who decline to participate.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	N18 - Chronic kidney disease

Gender	Male Woman
Geography area	National
Detail of the geography area	Nationwide cohort study in France, part of which is a component of an international study: the Chronic Kidney Disease Outcomes and Practice Patterns Study (CKDopps)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2013

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	3033 patients

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	Demographics, cause of CKD. Medication categories: RAS antagonists, statins, phosphate binders, ESAs therapy. Nutrition: Prescribed restrictions of protein, potassium, sodium and phosphorus. RRT planning: Vascular access referral, placement & procedures, services used (education programs, social worker, dietician), timing of decision about RRT modality, transplant wait-listing. Dialysis data: eGFR at dialysis initiation, clinical measures & dialysis dose. Clinical outcomes: Hospitalizations (IS), death (TF), study departure. Clinical measures: Blood pressure, weight, height, urine protein, biochemical measures
Declarative data (detail)	Paper self-questionnaire Face to face interview Phone interview

Details of collected declarative data	Patient-reported data: Quality of life instruments (SF 12, KDQOL-SF?), Mental health (CES-D scale), activities of daily living, family relationships, Global Physical Activity Questionnaire (GPAQ), Sleep, diet, Social, and demographic characteristics, Medical expenses and health insurance, Physician contacts, dietary and social services, Kidney disease education and planning, Satisfaction with care, Women health, Occupational history, using validated instruments when possible. > Medical Director Survey: Clinic protocols for achieving practice guidelines. > Physician practices not covered by protocol: Preferences for levels to initiate therapy and target for blood pressure, hemoglobine, phosphate, proteinuria - Treatment preferences, use of single vs. dual RAS antagonists. > Surveys of other health care providers: Nutrition, social work, vascular access, ESRD education programs; staffing levels; integration of care (multidisciplinary care clinic); palliative care services
Biological data (detail)	Blood, urine, DNA, RNA samples
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma Fluids (saliva, urine, amniotic fluid, ?) DNA DNAc/RNAm
Details of biobank content	Fasting blood and second morning urine samples will be collected in all participants at enrolment and at study end, as well as at the 1- and 3-year follow-up in a subsample of 1200 patients. Serum, plasma, DNA and RNA will be stored at ultra-low temperature at the Biobanque de Picardie,
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Quality of life/perceived health (detail)	Quality of life instruments (SF 12, KDQOL-SF?), Mental health (CES-D scale), activities of daily living, family relationships, Global Physical Activity Questionnaire (GPAQ), Sleep

Procedures	
Data collection method	Data collection instruments include patient-level and provider-level questionnaires
Quality procedure(s) used	CKD-REIN biobank received a bio-collection authorization from the French Ministry of Research, CODECOH n° AC-2012-1624 based on the Picardie Biobank quality standard
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.) Monitoring by crossing with a medical-administrative database Monitoring by crossing with a morbidity register
Details on monitoring of participants	Duration: 5 years
Links to administrative sources	Yes
Linked administrative sources (detail)	Linkage of CKD-REIN data to health insurance data is anticipated
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/CKD-REIN
Description	List of publications in HAL
Link to the document	https://pubmed.ncbi.nlm.nih.gov/?term=CKD-REIN
Description	List of publications in Pubmed
Link to the document	CKD-Rein.pdf
Access	
Dedicated website	https://ckdrein.inserm.fr/
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Data collected about CKD patients, their sociodemographic characteristics, their environment and their treatments, the organization of health care system based on a representative sample of providers in the field of CKD, and the

	biobank will provide a unique research platform of major interest for a number of public and private organizations involved in the field of CKD research and patient care. CKD-REIN will encourage innovative projects and broad use of these data by external research groups or firms. Accessibility of the database will be determined case by case by the governing board in agreement with the scientific committee. The IP and contractual issues will be examined by Inserm Transfert. Special attention will be paid on confidentiality, ethical issues and on the use of the biobank to yield the greatest scientific value to the community and avoid depletion of this finite resource.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only