Clinical Exposome of Patient-Reported Outcomes for Patients with Metastatic Breast Cancer

RWD96

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INTRODUCTION

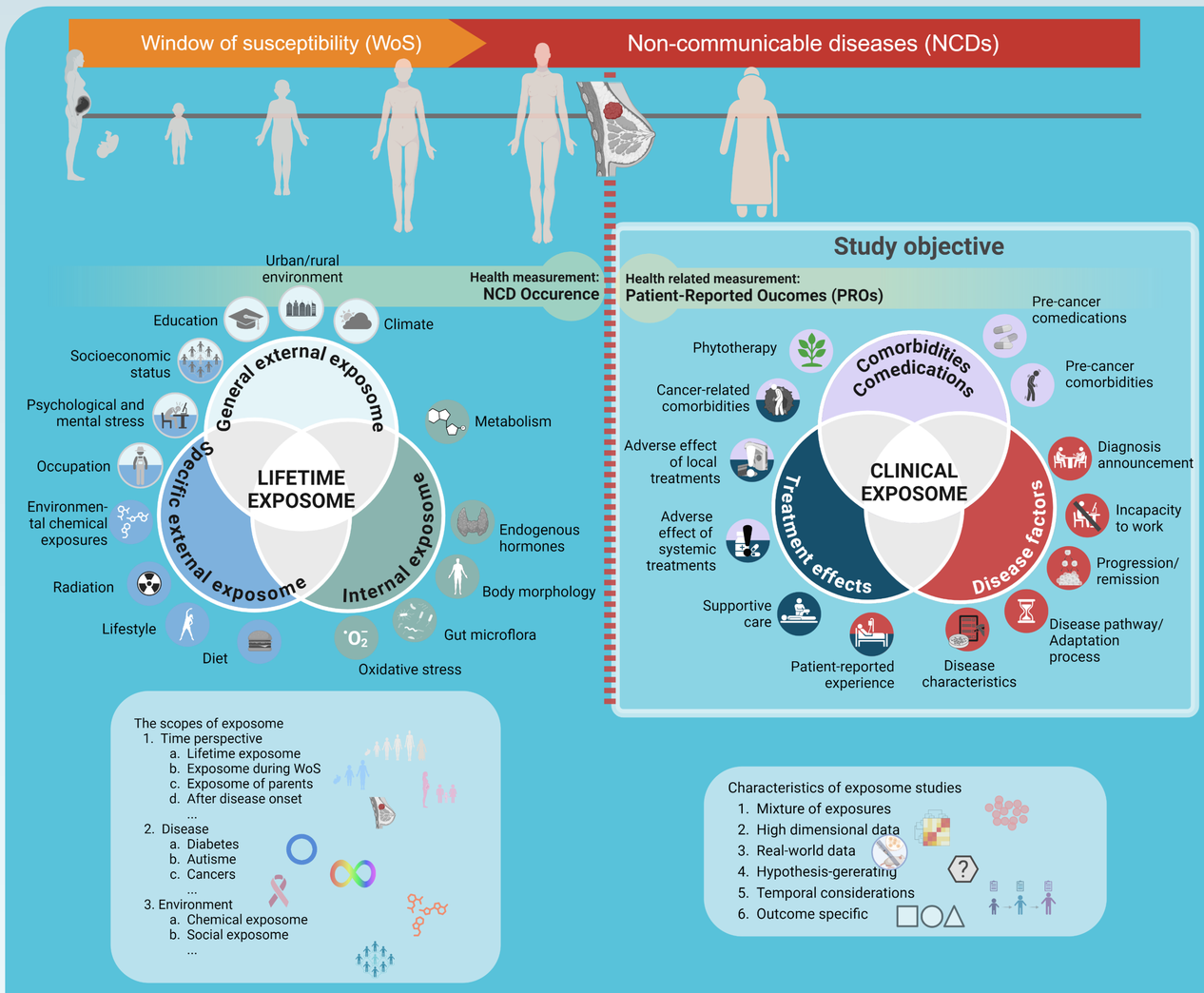
The exposome refers to all exposures to which an individual is subjected through out lifetime. The most immediate sphere for patients with severe conditions such as metastatic breast cancer is likely to be the clinical than the environmental exposome. Recently, clinical research data and Electronic Health Records (EHRs) have become a potential source for tracing the clinical exposome. Since Patient-Reported Outcomes (PROs) are sensitive to the exposome, this conceptual study examines the methodological implication of conducting clinical exposome research on PROs.

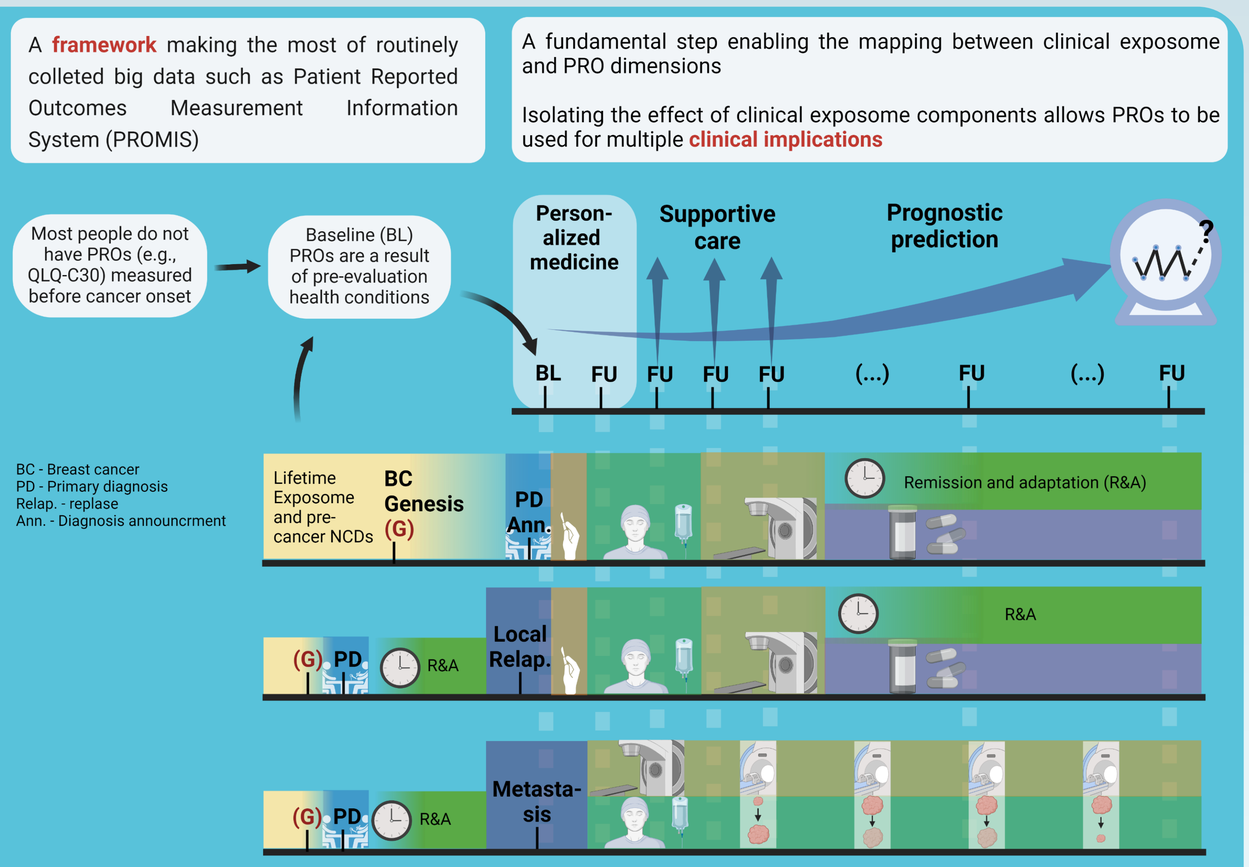
METHODS

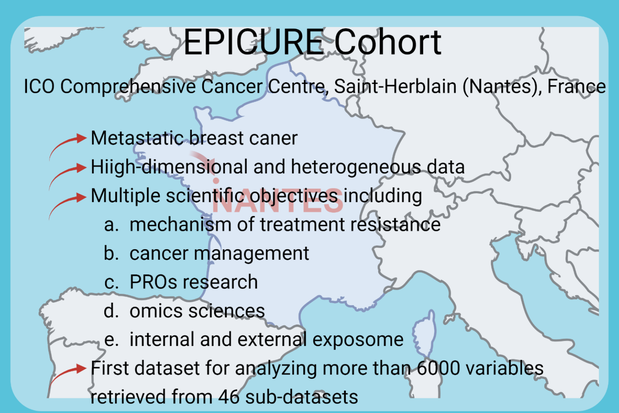
We performed a scoping review along with an analysis of real-world clinical data. We adapted exposome methods to clinical information by focusing on hypothesis-driven processes within high-dimensional data and on generating new insights into how specific clinical exposures are mapped to specific PRO dimensions.

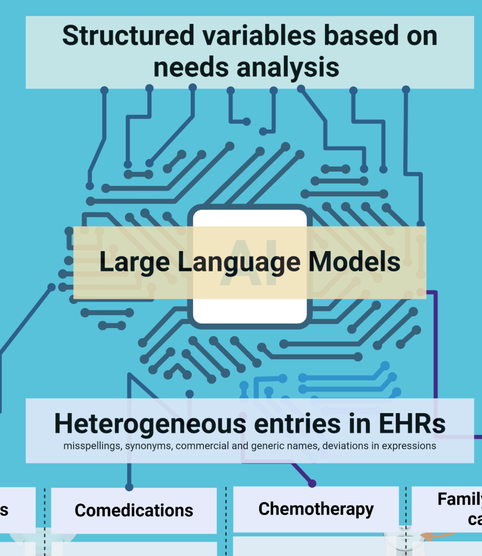
RESULTS

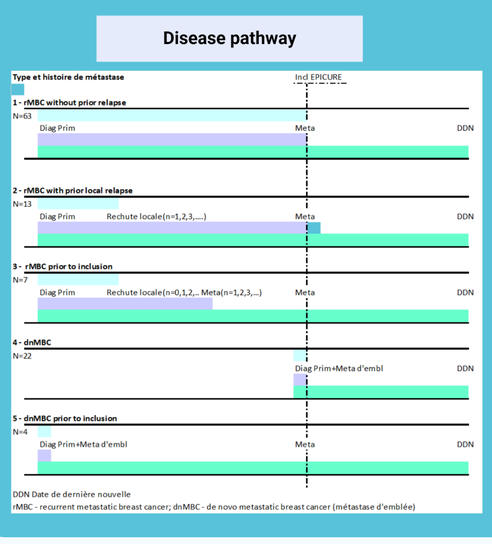
Unstructured information in electronic Clinical Research Forms (eCRFs) and EHRs including heterogeneous entries (e.g. misspellings, synonyms, commercial and generic names, deviations in expressions) will be refined into specific structured variables (e.g. co-medications, family history or occasional symptoms) using large language models (LLMs). Structured data in eCRFs, such as disease characteristics, treatments, comorbidities, critical clinical events, psychometric measures, and medical procedures in EHRs, will be used directly and in combination to describe the clinical patterns of the disease and treatment pathway. A minimum of 200 longitudinal clinical variables times the number of repeated measures will be used. The exposome-wide association study (ExWAS) will then screen each clinical exposure with individual PRO questions and dimensions. We will use cross-validated Lasso regression models to assess how a set of clinical variables affect PROs.

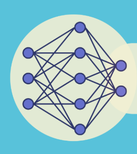








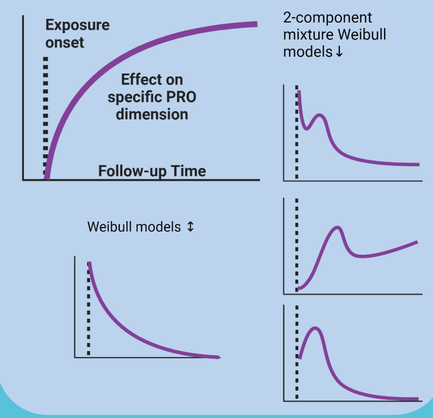




Mapping from Clinical Exposome to PRO dimensions

Clinical exposome components :	possible effects on:	PRO dimensions :
Diagnosis announcement	EF (...)	AP - Appetite loss
Conservative Surgery	EF, PA, FA, CF (...)	BI - Body Image
Mastectomy	BI, BS, SF (...)	BS - Breast Symptoms
Chemotherapy protocol A protocol B	FA, PF, NV (...) FA, PF, AP (...)	CF - Cognitive Functioning CO - Constipation
Imaging progression report	EM, SF (...)	DI - Diarrhoea
Imaging remission report	EM, FU (...)	EF - Emotional Functioning
Hormonotherapy	ST (...)	FA - Fatigue
Phytotherapy	CO, FA (...)	FU - Future perspective
Diabetes	AP, CO, DI, PF (...)	HL - Hair Loss
Tendinopathy	PF, PA (...)	NV - Nausea and Vomiting
Rheumatoid arthritis	PF, PA, SF (...)	PA - Pain
Parkinson's disease	PF, SF, CF (...)	PF - Physical Functioning
Chronic respiratory diseease	PF, SF, CF (...)	SF - Social Functioning
Family history of cancer	EM, FU (...)	ST - Systemic side effects
35 years of breast cancer survival since PD	EF, SF, FU (...)	(...)
Triple negative breast cancer	EM, FU (...)	
(...)		

Temporal considerations



Statistical methods for clinical exposome variables selection and analysis

ExWAS - Exposome-wide association study

ENET - Elastic-Net

DLNM - Distributed Lag Non-linear Models

sPLS - Sparse Partial Least-Squares Regression

DSA - Deletion-Substitution-Addition Algorithm

NPLS - Sparse N-Way Partial Least-Square

BKM - Bayesian Kernel Machine

Jugement critereia:

Sensitivity

False discorery rate

(...)

CONCLUSION

The clinical exposome framework is a critical component for both the patient-centered care and research on PROs. It helps map patient clinical exposures to PROs dimension and isolate their effects to specific dimensions. This serves the value-based care ultimately.

CONTACT INFORMATION

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