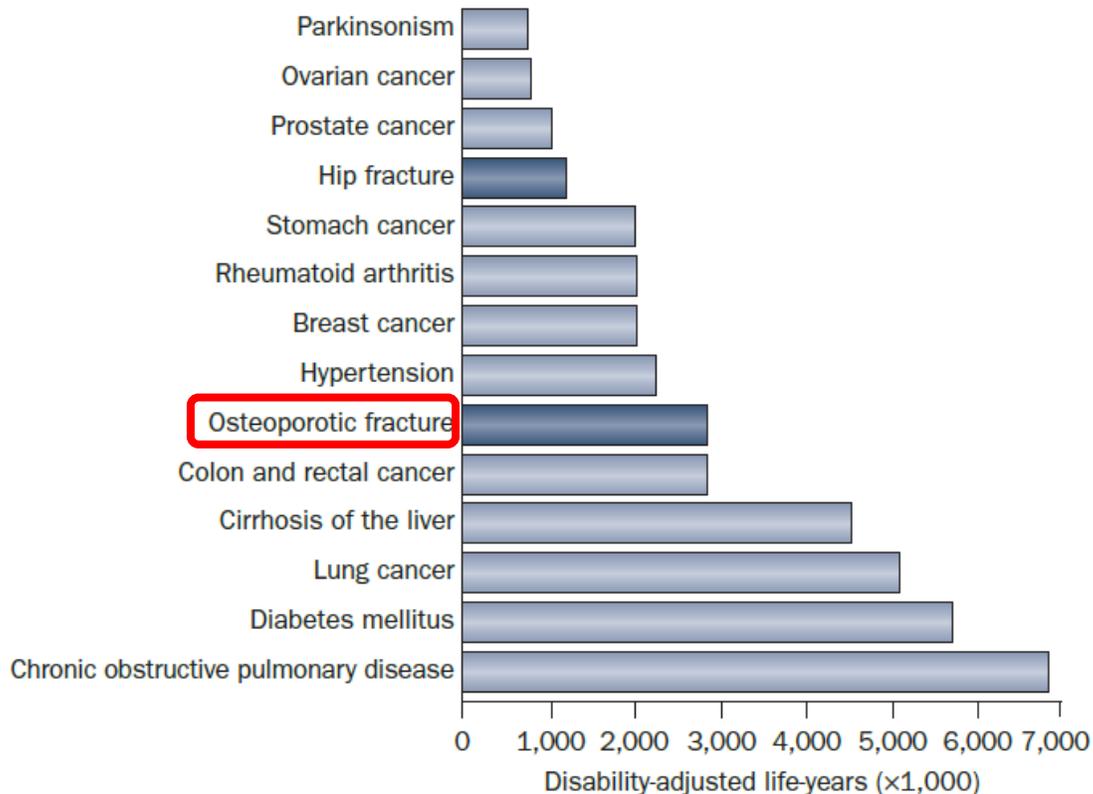


# PoCOsteo: PoC in-office device for fracture risk prediction

Patricia Khashayar, MD, PhD



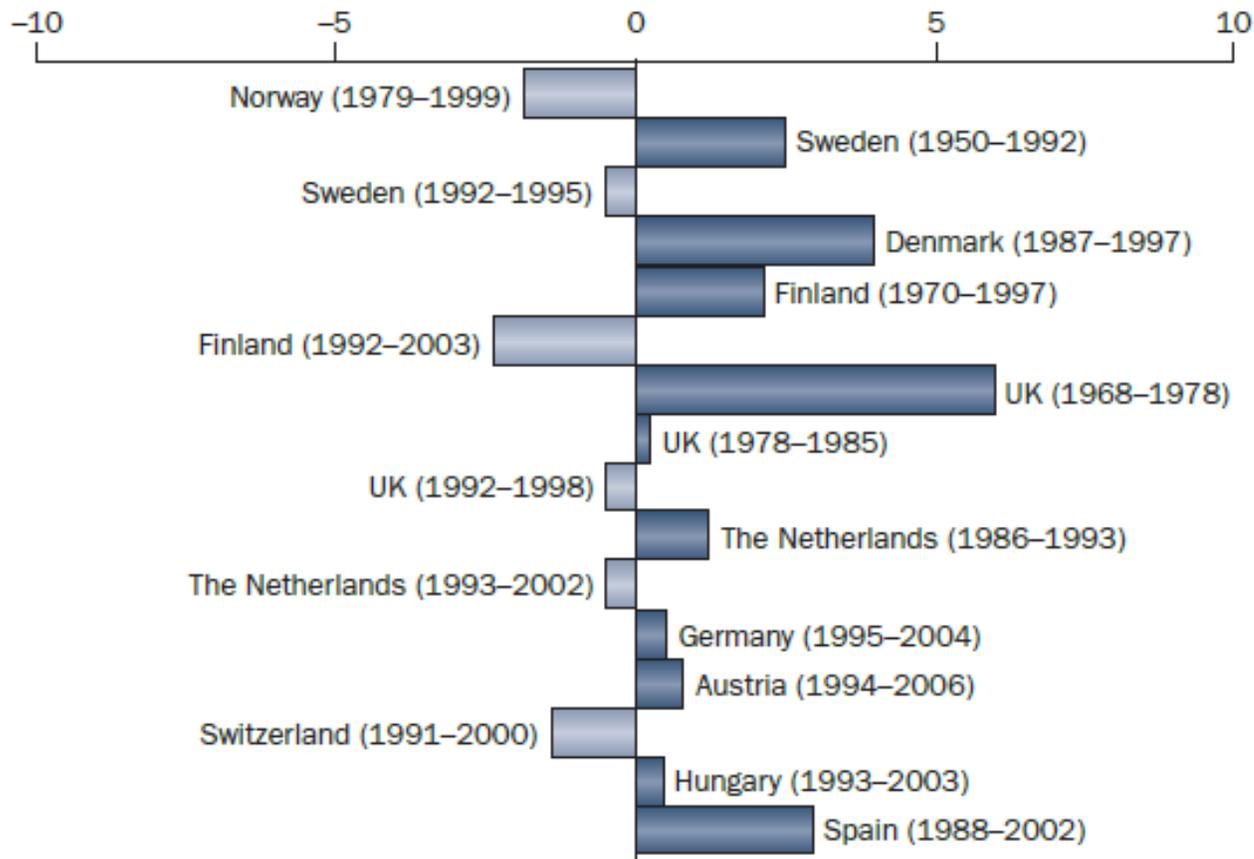
# Disability Caused by Osteoporosis



- Osteoporotic fractures are **associated with more disability** than many other chronic NCDs
- Fragility fractures account for **0.83%** of the burden of NCD **worldwide** and **1.75%** in **Europe**
- Combined **annual costs** of all osteoporotic fractures are:
  - **\$20 billion** in the **USA**
  - **\$30 billion** in the **European Union**

Harvey, 2010

# Trends for Osteoporotic Fractures



- Burden of osteoporosis has significantly **increased** in most countries over the past decades

- Every osteoporotic fracture leads to a **7-10-fold increase** in the **risk of subsequent fractures**

Figure 4 | Secular trends for hip fracture in Europe.<sup>40</sup>

# Screening, Diagnosis, and Treatment: Current Status

Osteoporosis is under-recognized

Fractures are not recognized as sentinel events

Osteoporosis is under-treated

# Needs

- There are **two important gaps in the clinical armamentarium of osteoporosis management:**
  - Early-stage identification of high-risk individuals who would best benefit from intervention
  - A low cost, accessible monitoring solution for those affected.

# New Diagnostics

- In the **-omics era**, tremendous technological advances and ample venture capital are combining to produce **new medical diagnostics**.
- **New biomarkers** are being identified to predict or detect a wide range of diseases;
- **New devices** are being developed to continuously monitor biologic parameters.

**Vision:** These new diagnostics can transform medicine from treating disease to **promoting health**, from being reactive to **being proactive**, and from being general to **being personal**.

# Proteomics in Bone Research

- Unlike imaging techniques such as DXA, measurement of bone turnover markers allows for a **dynamic assessment** of bone remodeling
- The application of **proteomics** has led to discovery of new and sensitive bone turnover markers (BTMs) , which provide **unique information** for clinical diagnosis and treatment of patients with bone diseases
- **Quantitative proteomics** can be employed for detection of signaling dynamics, biomarkers which leads to **discovery of therapeutic targets**.

# PoCOsteo Approach

- Combining **panels of circulating biomarkers**, rather than a single molecule, consisting of bone formation and resorption markers, is a dynamic approach that could confirm, complement, or quite often provide more elaborate information on high turnover patients as well as treatment compliance and efficacy beyond that obtained by other high-throughput approaches.
- In PoCOsteo, based on a developed modeling, the markers will be adjusted based on a group of variables to reduce the effect of preanalytical variability as much as possible.

# Genetics and Osteoporosis

- The **heritability of osteoporosis** is estimated at **60% to 80%** in families and twins
- Certain **genetic determinants** contribute to **osteoporosis** and enhance the risk of fracture
- **Genomewide association** studies have identified polymorphisms in several genes related to low bone density and **osteoporosis**

*Collet, Corinne, et al. "Primary Osteoporosis in Young Adults: Genetic Basis and Identification of Novel Variants in Causal Genes." **JBMR Plus 2.1 (2018):** 12-21.*

# PoCOsteo Approach

- PoCOsteo Genomics is based on the results of a GWAS and Mendelian studies on 25 cohorts in Europe, US, East Asia and Australia.
- The 15 fracture associated loci identified in this study would be assessed in PoCOsteo.
- These genetic determinants of osteoporotic fracture are shown to also influence BMD, reporting BMD has a major causal effect on fracture

## Research

### Assessment of the genetic and clinical determinants of fracture risk: genome wide association and mendelian randomisation study

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# PoCOsteo Approach

- While several genes were identified by **genomics** technologies to be specifically related to osteoporosis, the function of such genes and data interpretation in the context of functional networks require the power of **proteomics**.
- Little information is available regarding the combination of **proteomic, genomic** and **CRF** data.

# PoCOsteo

- The overall objective of the **EU funded H2020 project PoCOsteo (No. 767325)** is the development, clinical validation and preparation for commercialization of a POC tool for osteoporosis prevention, detection and treatment.
- The final device, which brings together **biomarker measurement, profiling of genetic variations** and **assessment of the underlying risk factors**, would be used as an **in-office tool** by physicians to **enhance the predictive accuracy of fracture prognosis** and to provide the affected individuals with **personalized care**.

# Our Team



## Engineering Partners (Research Centers)



## Clinical Partners



## Engineering Partners (SMEs)





**Industrialization and manufacturability**  
Industrial proof-of-concept demonstrating mass manufacturability at acceptable cost.



**Integration**



1

Requirements



2

**Proteomic Sensor Development**

Fabricate a cost-effective, reproducible and robust electrode array to be used in electrochemical sensing of biomarkers

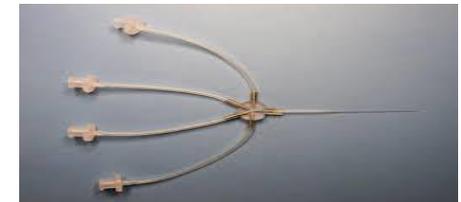
3

**Genomic Sensor Development**

Fabricate a cost-effective, reproducible and robust electrode array to be used in electrochemical sensing of genetic profile

4

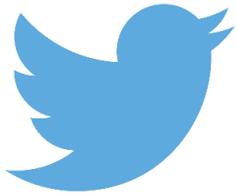
**Microfluidic Manifold Development**





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