# UMCG Biobanking and the Lifelines Cohort


Dr. Han Boter – UMCG Coordinator Biobanking
h.boter@umcg.nl.

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# What is a Biobank

An infrastructure for *future* scientific research of:

- biomaterial (eg. urine, serum, DNA) and
- linked –follow-up– data (eg. medical, lifestyle, Quality of Life) from
- many donors (patients, general population),
- systematically collected, stored, and delivered.

# Two kinds of Biobanks (in eg. the NL)

- 'De novo' Biobank: material collected for research purposes (eg. extra blood tube)
  - clinical Biobanks (eg. Parelsnoer Institute [PSI])
  - population Biobanks (eg. Lifelines)
  - '**Opt in**', donor can '*withdraw*'
  - One purpose: scientific research

- 'Secondary use/residual tissue' Biobank: material remaining after diagnostic/treatment procedures (eg. NL & Denmark)
  - eg. Dep. Pathology: cells from body fluids, biopsies, resections
  - '**Opt out**', donor can '*object*'
  - Primary purpose: medical care (eg. tumor recurrence)
  - Secondary purpose: scientific research

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# Why Biobanking

- Improve health care
  - Research products: diagnostics, prognostics, treatment, personalized medicine, prevention
  - Biobank process: streamlining diagnostic and follow-up protocols, reduced patient visits and patient waiting times*
- 'Quality' - For genetic studies many samples are needed, with different genetic background (need for international collaboration)
- 'Efficiency'
- Attractive for sponsors (eg. profit organizations)
- Attractive for research talents
- **Facilitates international collaboration**

* Douglas & Scheltens Eur J Hum Gen 2014, 1–3

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# Legislation (or self regulation) is important

Set (ethical) criteria for:

- Transparency – 66% of Europeans never heard of Biobanks
  - Dutch television showed that people were shocked that tissue is stored in pathology lab
  - If donors don't trust researchers, they will not give 'broad' consent ('narrow' consent for each study: costs ↑)
- Donor empowerment ('opt in' vs. 'opt out')
- Donor privacy (pseudonymized *versus* direct/indirect identifiable personal data)
- Ownership (donor? hospital? Biobank manager?; researcher? profit organization? authorities/police?)

Also Journals require evaluation of the research protocol by an ethics review board.

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# Code of proper use of human tissue (code Goed Gebruik)

In the NL, since 2011

- Self regulation by/for relevant stakeholders
- Fills vacuum in current laws & regulations
  - Gives a direction: “apply or explain”
  - Not a law, not a standard protocol

In UMCG, since 2012

- UMCG Biobank organization
- UMCG Biobank Framework


https://www.federa.org/sites/default/files/images/print_version_code_of_conduct_english.pdf

# Biobanking UMCG – local/national

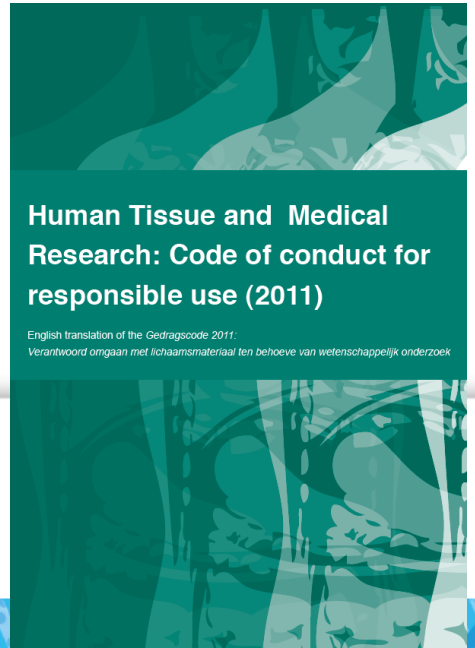
- Long history in Biobanking – general population, eg.:
  - Vlagtwedde-Vlaardingen (1965, n=8,000) https://www.youtube.com/watch?v=181AStvcMW8 (in Dutch)
  - Prevend (1997, n=41,000, >120 publications)
- National collaboration (NFU infrastructures):
  - BBMRI-NL: collaboration between all Dutch Biobanks, part of BBMRI-ERIC
  - Parelsnoer Institute: federated clinical Biobank in all UMCs
  - Lifelines: large population based Biobank in the Northern provinces of the Netherlands

# Biobanking UMCG – international

- International collaboration eg.:
  - BBMRI-ERIC (European Research Infrastructure)
    - BBMRI-LPC (FP7; Large Prospective Cohorts – harmonization and catalogue)
    - BioSHaRe-EU (FP7; tools/services for data sharing until 2015)
  - ABRAHAM (transatlantic Alliance to assess risk factors of several diseases while using BioSHaRe tools)
- Collaboration Oldenburg/Germany:
  - Collaborate in development Biobank infrastructure Oldenburg and Northern Netherlands – prof. dr. A Timmer (ELLA)
  - NAKO Gesundheitsstudie (Prof.dr. R Stolk, scientific committee)

# UMCG Biobank Framework

- Operationalization of 'Code of proper use of human tissue (2011)'
  - Biobank manager submits specific Biobank Guideline (BG) to the Ethics Review Board (ERB) which is assessed against the UMCG Biobank Framework
  - Each delivery of data and/or biomaterials for scientific research is evaluated by ERB against the specific BG
- Implementation of this Framework in 2 years



# Content UMCG Framework (1/5)

- Scope Framework: start, manage, use of 'de novo' and 'secondary use' Biobanks for future research
- Start a Biobank: based on specific Biobank Guideline and ERB advice, the Board of Directors gives permission if:
  - No extra risk for donor
  - Importance of Biobank is clear
  - Adequate information for donor on collection, storage, and delivery of biomaterials & data of 'secondary use' and 'de novo' Biobanks (Transparency)

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# Content UMCG Framework (2/5)

Biobank manager: person/committee responsible for

- compliance with specific Biobank Guideline
- collection, processing, storage, and delivery of data/material to researcher
- contact with treating physicians
- procedures included in quality system and audits

# Content UMCG Framework (3/5)

Easy to read donor information:

- Purpose of Biobank
- What biomaterials/data
- How privacy is protected
- 'de novo' Biobank:
  - General brochure + *Biobank specific letter*
  - Incidental findings
  - Broad Informed Consent (including question on Incidental findings) & Withdrawal form (empowerment)
- 'secondary use' Biobank:
  - General brochure with Objection form (empowerment, i.e. brochure on internet; electronic registry of objection in electronic patient record)

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# Content UMCG Framework (4/5)

- Delivery of material/data to researcher
  - Check on donor's withdrawal/objection
  - If applicable, a Biobank scientific committee advises the Biobank manager about research protocol (biomaterials are finite resources) e.g.:
    - Study aim
    - Procedure to inform donors about Incidental Findings
    - How donor's privacy is protected
  - ERB advises on research protocol (eg. If use of material is in agreement with consent/no objection of the donor)
  - Material & Data Transfer Agreement (MDTA)
- Delivery of material/data to other Biobank
  - Permission of Board of directors of the UMCG
  - MDTA

# Content UMCG Framework (5/5)

- Donor privacy
  - Biomaterial and data are coded and stored / delivered according to the act WBP ("Wet Bescherming Persoonsgegevens");
  - Eg. personal data stay in Biobank (name, etc.), pseudonymized biomaterials & data send to researcher (key codes stay with Biobank manager);
- Complaint procedure
- Monitoring
- Procedure to liquidate/stop the biobank

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# Implementation UMCG Framework

- Templates
  - Biobank Guideline (includes a Biobank protocol: procedure of processing/storage of biomaterials)
  - research protocol for delivery of data/ material (in progress)
  - Material & Data Transfer Agreement (MDTA; in progress)
  - 'de novo' Biobank donor letter/IC form/Withdrawal form
- Donor brochures
  - 'secondary use' Biobank
  - 'de novo' Biobank
- Electronic registry of objections ('opt-out')

- *Central Facility Biobanking (CFB)*
- *Toolbox – checklists for researchers to start a Biobank or deliver data/biomaterials, with links to relevant docs, brochures, templates, experts contact details, etc.*

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# Geras (see factsheet)

- *UMCG Healthy Ageing* start-grants for cohort or Biobank
- Focus on:
  - Complex care (frailty, multi-morbidity)
  - Cultural change
  - Total care chain
  - Patients' functioning and wellbeing
- 3 Cohorts:
  - FraiLifeS
  - NeoLifeS
  - Groningen Spine Cohort
- 2 Biobanks:
  - OncoLifeS– Cancer patients
  - CardioLines– Cardiac patients (coronary artery disease, myocardial infarction, heart failure)

Other Biobank:

- TransplantLines – Transplant recipients

# The Lifelines Cohort Study

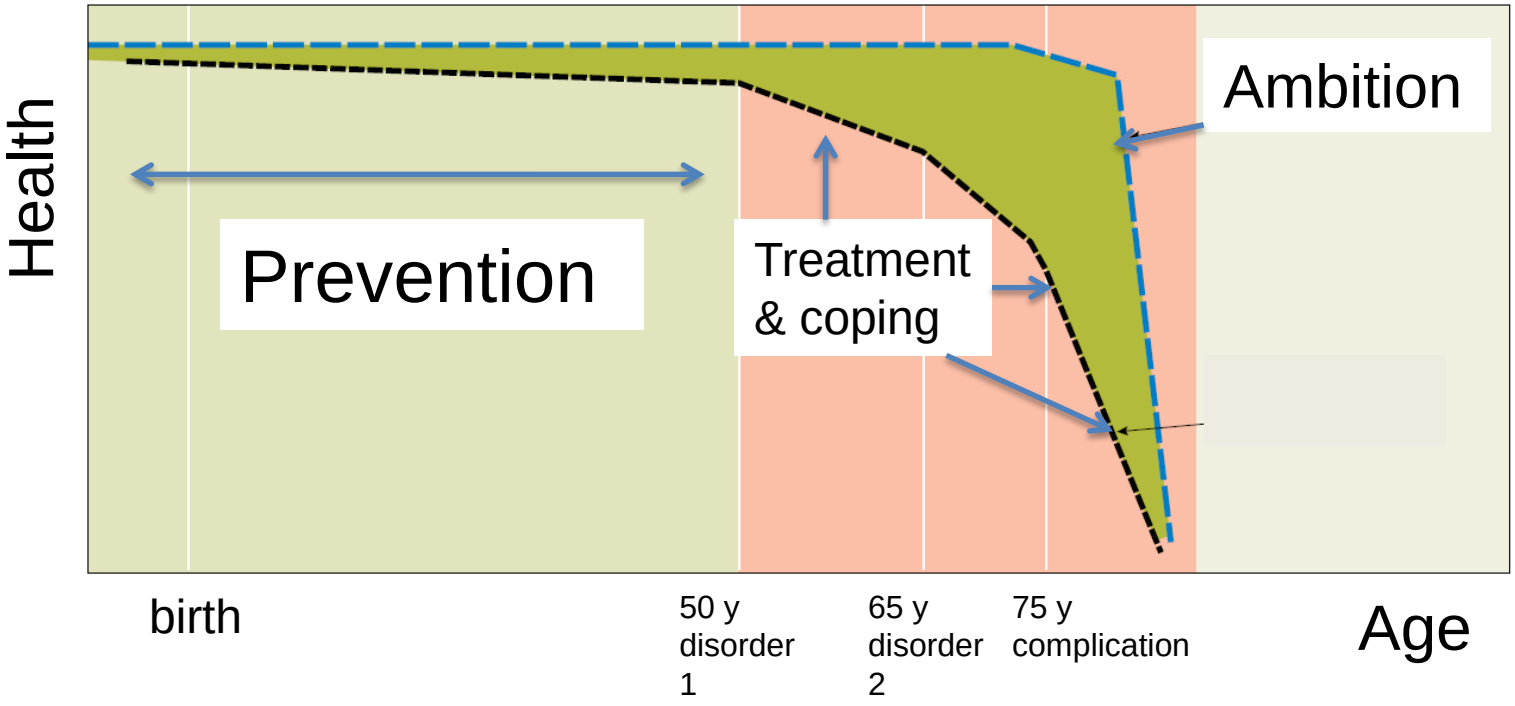
## What is Lifelines?

- Start 2006
- General population
- >165.000 participants
- 30 years follow-up
- 3 generation design
- Collection of data and biomaterials

- Research infrastructure
- Worldwide available

lifelines

lifelines




## Aims Lifelines

- Study why some people get old in a healthy manner, while others experience severe diseases early in life
- Enable research on complex interactions
- Translate group associations into individual risk estimates

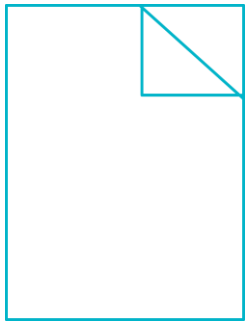
lifelines

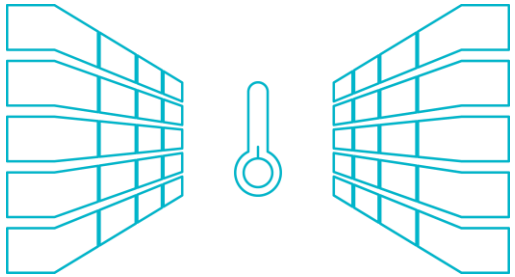
# Baseline prevalences in Lifelines (n=152,000 adults)

| | Total cohort | | NL |
|---|---|---|---|
| | Male | Female | |
| Overweight | 62,8% | 49,9% | 48,3% |
| Obesity | 14,6% | 16,6% | 12,7% |
| Diabetes | 2,9% | 2,3% | 4,3% |
| Heart attack | 2,0% | 0,4% | |
| Cancer | 3,8% | 5,3% | 3% |
| Depression | 6,8% | 12,3% | 10% |

# lifelines Data collection

- Questionnaires – hardcopy and online (every 1,5 year), eg:
  - Medical history
  - Lifestyle
  - Quality of life
  - Mental health
  - Social network
  - Daily activities
  - Sleep
  - *Additional questionnaires:*
    - *input from researchers*
    - *For specific subgroups*
- Measurements (every 5 years)
  - Anthropometry
  - Blood pressure
  - ECG
  - Long function
  - Cognition
  - Psychiatric interview
- Biomaterials (every 5 years)
  - DNA (baseline only)
  - Blood
  - Urine
  - Feces
  - Scalp hair





# https://catalogue.lifelines.nl/

LifeLines Catalog Upload Admin Account

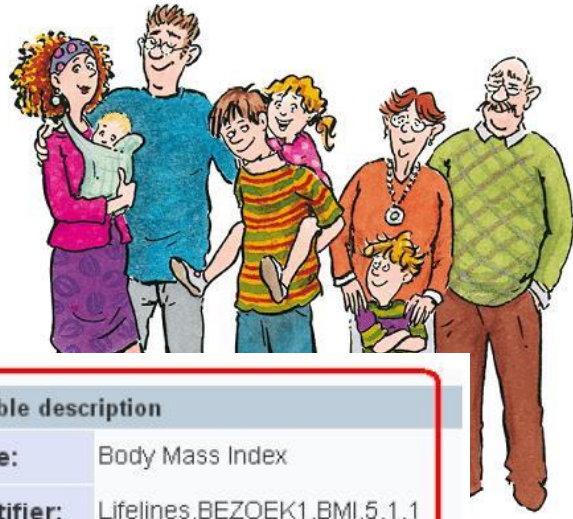
## Welcome at the LifeLines Data Catalogue!

The LifeLines Data Catalogue provides an overview of all the data collected in LifeLines and is only available for researcher with a research proposal fitting within the theme of Healthy Ageing and which is approved by the Scientific Board.

When you click 'catalogue' you can browse all available data items from questionnaires, measurements and (blood and urine) sample analysis. Also, you can make a selection of data items that you will need for your research, and download the list.

If you want to save your selection and apply for LifeLines data, you need to register first. You can register by clicking the 'login' button on top. After you have registered, you will receive a confirmation email. Subsequently, you are able to download your selection or submit the selection together with you proposal.

The catalogue will regularly be updated with new collected data items. For questions regarding the catalogue or submission of your proposal, please contact the LifeLines Research Office LLscience@umcg.nl



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**Browse variables**

- Lifelines
  - Adult 18 - 65 years
    - Add-on studies
    - Baseline
      - Default items
      - GIS data
      - Geographical information
      - Interview
      - Laboratory assesment
      - Measurement
        - Age reader
        - Antropometry
          - Body Mass Index
          - Hip
          - Length
          - Position
          - Span

**Variable description**

| | |
|---|---|
| **Name:** | Body Mass Index |
| **Identifier:** | Lifelines.BEZOEK1.BMI.5.1.1 |
| **Description (en):** | Body Mass Index (kg/M^2) |
| **Description (nl):** | Body Mass Index (kg/M^2) |
| **Data type:** | decimal |

**Variable selection**

No variables selected

# Biobank and cohort studies Knowledge and Expertise center

BiKE

- Partnership of UMCG and Lifelines
- Part of UMCG Dean's Office
- Many experts in Groningen available through BiKE
- BiKE's mission is to make available the knowledge, expertise and (ICT) infrastructure built over decades of biobanking research
- Fundamentals of Biobanking course (20 – 24 June 2016 in Groningen)
- www.biobank.bike / bike@umcg.nl

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# www.umcg.nl

h.boter@umcg.nl