

COSMOS

COhort Study on MObile Phone UserS (Cosmos)

Feasibility Study for
a Prospective Cohort Study
on the Use of Mobile Phones

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History (1)

IMBEI

1998/99 feasibility study for epidemiological studies after recommendation of IARC e.g. Germany

12./13. Nov. 1999 International Workshop in Heidelberg

Recommendation:

The participants recommended that the planned international case-control study should proceed but with tempered enthusiasm because of the restriction to a short induction time. ... Most participants **favoured cohort studies** though some criticized the **large costs** they would require.

➤ **Start of the Interphone-Study (15.10.2000)**

- 2002/03 feasibility study for a prospective Cohort study in UK and Sweden
- Juni 2003 Revision of the WHO „Research Agenda“
→ high priority of the cohort study
- 2003/04 SSK recommendation priority III
re-evaluation after public hearing

➤ Start of the German feasibility study (COSMOS)

Pro and Cons of a “cohort study” ?



Advantages:

- Follow up for a variety of diseases

Problems:

- Costly for rare diseases
- Costly for diseases with long latency periods
- Mixing of cohorts

Retrospective cohort:

- Historical database needs to be available

International Cohort Study of Mobile Phone Use and Health (1)

Aim: Set up a cohort of 250,000 mobile phone users aged 18 and above in up to five countries (D, Dk, Fin, Swe, UK), based on stratified samples of subscribers

Design: Prospective cohort study, internal comparisons by amount of mobile phone use

Major endpoints:

- Tumours of the brain and meninges
- Acoustic neuromas, salivary gland tumours and leukaemia
- Alzheimer, ALS, MS, Parkinson
- Cerebrovascular disease
- Changes in prevalence of specified symptoms evaluated with validated scales [headache, sleep disorder, depressive symptoms, tinnitus]

International Cohort Study of Mobile Phone Use and Health (2)

- **Follow up:**
 - Initial phase of five years
 - active or passive follow up thereafter for up to 25 years
- **Exposure assessment:**
 - Self-administered questionnaire,
 - repeated in year 4,
 - accompanied by annual downloads of 3-month traffic data from network operators

Feasibility Study „COSMOS“ Germany

01.08.2004-31.05.2005

Aim

Examination whether and under which condition a prospective cohort study on mobile phone users in Germany within an international frame will be possible.

Requests:

- Checking of Net Providers' registration lists on structure and contents of data
- International harmonizing of exposition classification
- Elaboration of data protection issues
- Elaboration of inclusion criteria
- Checking if inclusion criteria are practicable

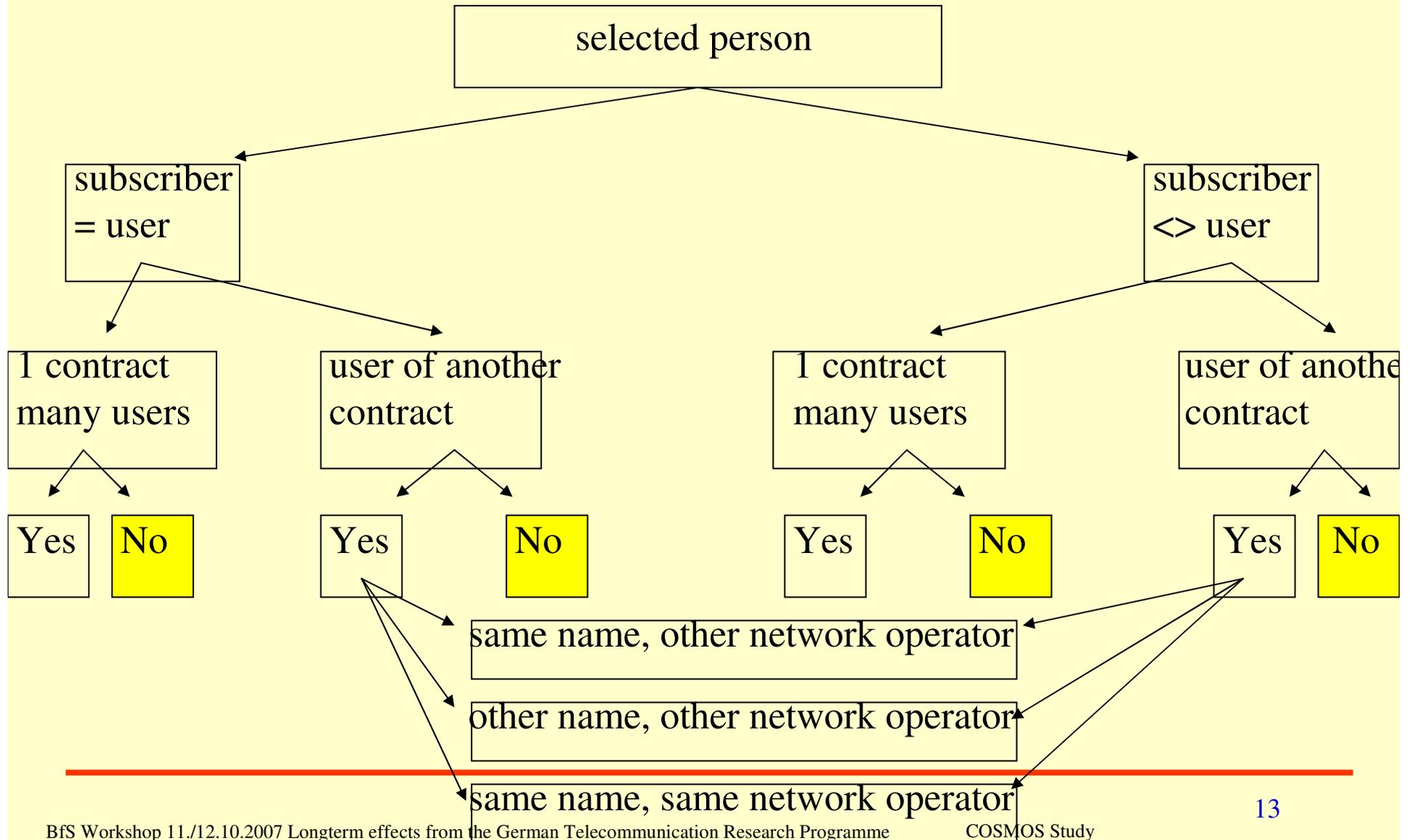
- Contact to all Net Providers:
 - T-Mobile
 - Vodafone
 - E-Plus
 - O²
- Residents' Registration office

- Evaluation of the Registration list of the Net providers
 - Contact to the Net providers
 - Structure of data and their content
 - Issues of data protection
 - Mechanism of selection
- General population
 - Mechanism of selection

Requests on data from NET Providers:

- Stability of the cohort members over time
- By exposition and, if applicable, random selection stratified by age and gender
- Classification of Exposure (low, middle, high)
 - based on average duration of phone use per month in minutes
 - based on number of calls per month

Who could be proband ?



- Type of mobile phone
- Frequency and duration of calls (incoming / outgoing)
- Use of mobile phones according to contract type
- Duration of storage of data on incoming and outgoing calls, SMD, etc. (every 3-month and yearly)
- Administration of data
- Use and handling of data
- If possible, localisation of base station first contacted
- Demographic data
- Data available at the begin of the study and at the follow-up

- Contact to data protection authorities
- Conditions of the Net Providers
- Ethic committees (local)
- Uniform “informed consent”

Questionnaire

- English version is available
 - Check of validity and comprehensibility has been performed by UK and Sweden
- Check if feasible in Germany
- Elaboration of supplements and modifications

- Informed consent
- Procedure of data collection

Aim: Evaluation of the response behaviour

- Performing Pilot study 1
 - 1000 Persons per Net Providers
 - 1000 Persons based on data of the residents registration offices
 - Selection of a random sample of 1000 probands
 - Collection of relevant exposure data from Net Provider data bases
 - Contacting probands
 - Disseminating and return of questionnaire
 - Definition of the study region for follow-up

Pilot Study 1

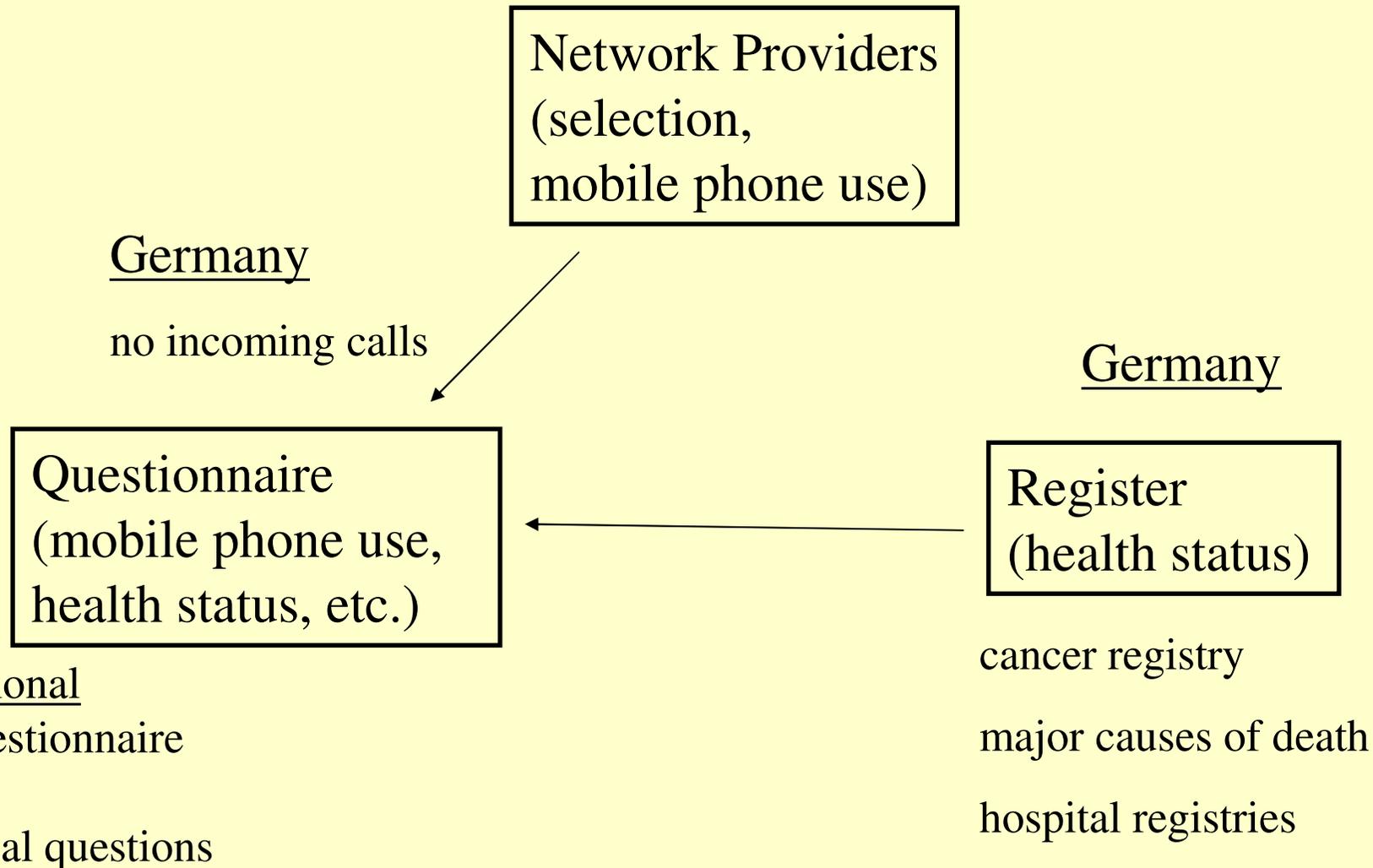
- Disseminating of letters of invitation 2./3. March
 - 1000 letters per net provider
 - 1000 letters from IMBEI
 - 500 Data of the Net Providers
 - 500 Without data of the Net Providers
- Return closed on 2. May 2005
- Scan-System used for data input
- Validation by manual input
- Data analyses started 6. May 2005

Result: Participation rate

	N1	N2	N3	N4	Inhab. without net data	Inhab. with net data	All Inhab. w. Handy
disseminated	1000	1000	1000	1000	500	500	
Not deliverable	15	208	9	0	84	79	
deliverable	985	792	991	1000	416	421	
No Reaction	904	729	917	940	326	332	
%	91.8	92.0	92.5	94.0	78.4	78.9	
Reaction received	81	63	74	60	90	89	121
%	8.2	8.0	7.5	6.0	21.6	21.1	14.5
Consent	51	42	53	45	59	46	77
%	5.2	5.3	5.3	4.5	14.2	10.9	9.2

N = Net provider

Result: Data collection procedure



Pilotstudie 2

Check of cell phone out put power under various conditions like:

- different size of communities
- standing, walking, moving in a car

Result: Pilotstudie 2

- 4 locations (repeated measurements)
- No influence: weekday and time of the day
- Influence of moving is dependant of the density of available nets and of the density of the population
- Power is increased in regions with lower population density
- Position of the base station is influencing the power output when moving

Summary of the feasibility studies

and

Recommendation for a prospective cohort study

Criteria for selection

- Germany:
 - Study should be performed only in special regions of Germany
 - only inhabitants of Rhineland-Palatinate and Saarland
 - (cancer register: completeness)
 - only post-paid-subscribers
 - no contract made for a company
 - only one contract
 - formation of equally sized groups
 - age groups ,18-49‘ and ,50-69‘
 - sex
 - exposure minutes of calls (5 minutes per day)

- Begin: June 2005
- 1. Sending of questionnaire: 2005-2006
- 2. Sending of questionnaire : 2009
- In-between evaluation of symptoms: 2010
- Comparison of mortality and incidence data: 2010
- Final evaluation (5 year-Follow-up): 2011

- Yearly exposure data from the Net Providers till 2010

Result: Pilotstudie 1



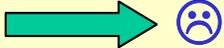
IMBEI

- Letters disseminated by the net providers
 - 4000 disseminated
 - According to net provider different numbers of undeliverable letters (0-200)
 - Response rate:
 - 4.2%-5.8% respondents
 - **3.2%-3.9% consent for participation**
- Letters disseminated by IMBEI
 - 1000 disseminated
 - Response rate:
 - 18.4 % respondents
 - **10.8 % consent for participation**

Conclusion (1)



IMBEI

- Construction of cohort
 - Net providers 
 - Residents' registration office 
- Recording of Exposure
 - Questionnaire 
 - Net provider (Validation) 
- Questionnaire
 - International „Core“-Questionnaire will be newly established
 - Supplementation for Germany 
- Follow-up
 - Mortality 
 - Morbidity 
(cancer registry if possible, questionnaire otherwise)

Conclusion (3)

The feasibility of the study in general was investigated:

- **Problem: Participation rate was too small (5% - 12%)**
- Exposure assessment very complicate
- High selection bias
- No complete endpoint evaluation possible for most of the diseases

We do not recommend to participate in the International Study.