

코호트 연구의 최근 동향 및 발전 방안

한국의 지역주민 대상의 코호트 연구 현황

- 조직은행 코호트를 중심으로 -

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Population based cohort

Benefits

- Well defined population
- Longitudinal evaluation: Causality of Ex-Ds
- Representatives : External validity
- Ds rate : prevalence, incidence
- Time trend of Ex, of Ds

Limitations

- High cost
- Manpower
- Complexity
- the others

Definition of Population

- Same geographic boundary
- Same insurance member
- Same occupation

Classification

- Population-based cohort :
PAR, parameter of target population
- Volunteer : participation, FU maintenance,
cost-effective

Objectives of Cohort study

- Parameter estimation – probability sampling
- Ex-Ds causality test – priority : response

Community

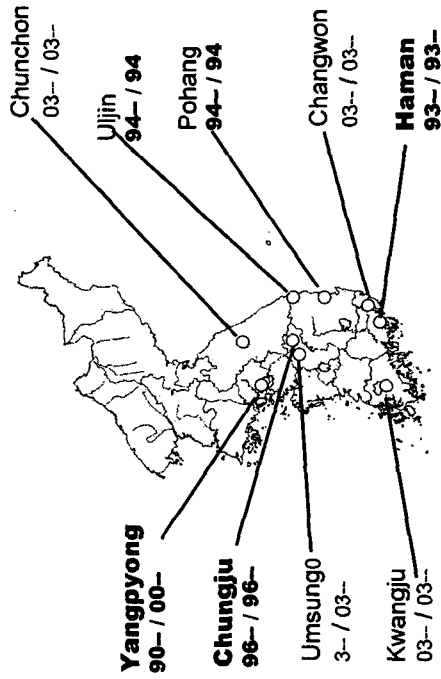
- same culture, history or religion
- geographical boundary
- publicity : accessibility, cost, generalization

**Community-Based Cohort Study
With Biological Materials Bank**

Objectives

- Ex : environmental factors, life-styles, host factors and so on
- Ds : cancer (some : CAD, CVD)
- Susceptibility : studies on biomarkers
genetic susceptibility
phenotypic susceptibility

Locations (area, started yr of quest. survey / of tissue bank)



Area

Project areas	Locations	Year began Quest./Tissue	Remarks
Haman	southern	1993/1993	rural
Chungju	middle	1996/1996	urban/rural
Yangpyong	middle	1990/2000	rural
Ulsin	mid-eastern	1994/only94	rural
Pohang	mid-eastern	1994/only94	rural
Umsung	middle	2003/2003	rural
Yongkwang	south-western	2003/2003	rural
Chuncheon	middle	2003/2003	U/R?
Changwon	southern	2003/2003	U/R?

General Population Cohort

Eligible

- men : women = about 4:6
- adults aged over 30 yr (Yangpyong >20 yr)
- voluntary participants
in cross-sectional survey for cancer screening
- almost rural, some urban

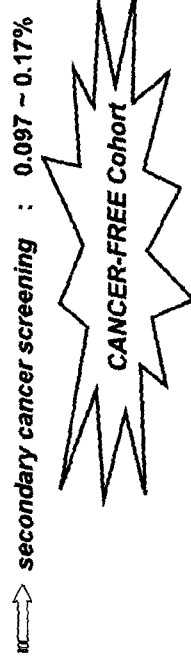
No. of subjects and tissues

Areas	subjects	Tissue	Remarks
Haman	6,488(5,848)	6,378(5,754)	P3/B1/R3/S1-2
Chungju	6,467(6,362)	6,386(6,371)	P3/B1/R3/S1/W1
Yangpyong	896	896	S/W (after 2000)
Uijin	1,144	1,103	S1-2 (1994)
Pohang	311	311	S1-2 (1994)
At present	15,616(14,961)	15,274(14,631)	

* Year 2003 : new enrollment about 4000-5000

Cancer Screening Procedure

- **persons who had**
 1. Recommendation after physical examination by physicians
 2. High risk for cancer based on questionnaire
 3. Abnormal clinical laboratory findings
 4. Some : highly positive for tumor markers



Research groups

- ◆ National Cancer Center, Korea
- ◆ Seoul National University College of Medicine
- ◆ Konkuk University College of Medicine
- ◆ Hanyang University College of Medicine
- ◆ Dongguk University College of Medicine
- **New** -
- ◆ Seoul National University School of Health
- ◆ Chonnam National University College of Medicine
- ◆ The others : no-confirm

Sponsorships

- **Research grants**
 - Seoul National University Hospital (1992)
 - Korea Electric Power Corporation (since 1993-)
 - Korean Ministry of Health and Welfare (1995-1997)
 - Korean Ministry of Science and Technology (2001-)
 - 2000 Human Genome Project in Korea
 - Korean National Cancer Institute (2003-)
- **Administrative supports**
 - local governments (County) / district health care centers
- **Technical supports**
 - NCI-USA, Division of Cancer Epidemiology and Genetics

Processing

- | | |
|---------------------------------|------------------------|
| Baseline survey | Follow-up |
| • Questionnaires | • Passive surveillance |
| • Measurement | • Active surveillance |
| • Clinical lab. test | |
| • Biological material bank | |
| • Special test by each location | |

Questionnaires

- **Interview** by trained interviewers
- Standardized **questionnaire-coding** structure
- **Editing** by senior interviewer after interview
- **ID confirmation** by ID certification program
- **Telephone interview** to fill up missing information and missing or wrong ID
- **Data warehouse** with regularly backed-up files from 2003

Questionnaires

- **9 pages questionnaire and 1 informed consent**
- **Partly modified in 2001**
- **Informed consent from 2002**
- **Life styles**
 - Demographic characteristics
 - Smoking and drinking
 - Family history
 - Residential history
 - Medical examination and medication history
 - Diet (35 FFQ with 4 or 5 frequency categories)
 - Exposure history to hazardous chemicals
 - Exposure history to electro-magnetic fields
 - Reproductive history (women)
 - Physical activity
 - Occupational history

Measurement

- height
- weight
- abdominal circumference
- hip circumference
- body fat composition (some)

Clinical Lab. test

- Hematologic tests hemoglobin, hematocrit, WBC, RBC, platelet, etc.
- Urinalysis u protein, u glucose, etc.
- Chemistry t protein, albumin, GOT, GPT, creatinine, BUN, glucose, t cholesterol, Tg, HDE dtol
- Tumor markers aFP, CEA (some)
- Specific tests HBsAg, anti- HBs, antiHCV, stool exam.
- CA19 & CA125, PSA, etc. (some)

Biological material bank

1. **10 ml PB in EDTA tube → 2 Set**
(-2002 : heparinized tube)
Centrifuged within 12 hours
1 set of plasma - 3 (1.5cc screwed E-tube), & buffy layer - 1 (1 cc screwed E-tube), & RBC - 2 tube (1 cc screwed E-tube)
Stored under -70 °C
2. **Over 5 ml urine in 15cc urine tube**
Stored under -20 °C
On going discussion : storage under -70 °C (at least 2cc E-tube)

Special exam. in each locations

- Osteoporosis (portable DEXA)**
- Fat composition (inbody 3.0)**
- Full diet survey (SNU SH)**
- Pesticides survey and cholinesterase test (KU CM)**
- Stress**
- Nicotine and alcohol addiction survey**
- CAD and CVD related Quest.**

FU – Passive surveillance

By Data of

Health insurance DB and chart review
National / regional cancer registries
National death certificate

From 2003

chart review Cancer Staging

FU – Active surveillance

Through survey by key person in community

Death – date, cause
Change of address / host-name of each subjects
CAD, CVD, DM & HT (some) – new incidence
first admission of diagnosis,
hospitals visited

Addictive telephone survey in center (some)

Chart reviews

- On-going study -

Reliability and validity test between
real cancer morbidity & key-person survey

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Ongoing processing in management of cohort study

1. Data warehouse with regularly backed-up files
2. Web approach
3. Regulation of survey-protocol
4. Consolidation of FU
(ex. Active surveillance of cancer)
5. FU committees (criteria for evaluation of FU results)

Future remarks in execution of Cohort study

1. Strict informed consent for genetic and proteomic-related studies
2. Approval of Ethical Committee
3. QC and QA committee
4. Storage facilities for tissue banks
5. Active FU survey
6. Establishing a model of gene cohort study
7. Establishing international collaborative study