# Ethics, Privacy, etc.

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# Treatment of Human Subjects: The Belmont Report

1979

Ethical Principles and Guidelines for the
Protection of Human Subjects of Research

- Balancing (societal) benefits vs. (individual) risks
- History of abuses
  - Nazi "experiments" ⇒ Nuremberg code
  - Tuskegee syphilis study

# Nazi Medical Experiments

- Freezing / Hypothermia
- Genetics
- Infectious Diseases
- Interrogation and Torture
- Killing / Genocide
- High Altitude
- Pharmacological
- Sterilization
- Surgery
- Traumatic Injuries

A cold water immersion experiment at Dachau concentration camp presided over by Professor Ernst Holzlöhner (left) and Dr. Sigmund Rascher (right). The subject is wearing an experimental Luftwaffe garment

http://en.wikipedia.org/wiki/Nazi_human_experimentation

# Tuskegee Syphilis Experiment

- 1932-1972 experiment to study natural progression of disease
- 399 African-American sharecroppers w/ syphilis
- failed to treat even after penicillin was shown to be an effective treatment in 1940's

Public domain image from Wikimedia Commons.
http://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment

# Practice & Research

- The term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.
- The term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge.
- Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. ... if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

From the Belmont Report

# Basic Ethical Principles

- Respect for Persons
- Beneficence
- Justice

From the Belmont Report

# Respect for Persons

- Each person is an autonomous agent, capable of deliberation about personal goals and of acting under the direction of such deliberation
- Persons with diminished autonomy are entitled to protection: e.g., children, physically or mentally disabled, prisoners.
- Requires *Informed Consent*
  - Adequate information
  - Voluntary participation

From the Belmont Report

# (Informed Consent)

- Study involves research, purpose of research, duration, procedures, what is experimental?
- Foreseeable risks and discomforts
- Possible benefits to participants or others
- Alternative procedures that might be beneficial
- How confidentiality will be maintained
- For research involving more than minimal risk, what compensations and treatments may be available, and where to get further information
- Participation is voluntary; no penalty for refusal

http://www.hhs.gov/ohrp/policy/consent/index.html

# Beneficence

- Do no harm
  - one should not injure one person regardless of the benefits that might come to others
  - minimize risk to participants
- Maximize possible benefits
  - to society
  - but, research subjects may not benefit directly
- Some tradeoffs are unavoidable

From the Belmont Report

# Justice

- Varied views of equal treatment
  - equal share
  - individual need
  - individual effort
  - societal contribution
  - merit
- Select participants fairly
- Distribute benefits fairly

From the Belmont Report

# Enforcement:
# The Common Rule

- Applies to all US Government funded projects involving human subjects
- Institutional Review Boards (IRB) review and must approve all such proposed research; responsible to protect subjects
  - yearly review of research protocols, informed consent, training of researchers, etc. Criteria of Belmont Report.
  - expedited review for research involving "no more than minimal risk"; consent may be waived
  - exemptions for educational research, food quality research, and retrospective research on public or de-identified data
- IRB's also responsible for protection of confidentiality
- MIT's IRB is the Committee on Use of Humans as Experimental Subjects (COUHES)

http://www.hhs.gov/ohrp/policy/consent/index.html

# Privacy
# vs.
# privacy

# Protecting…

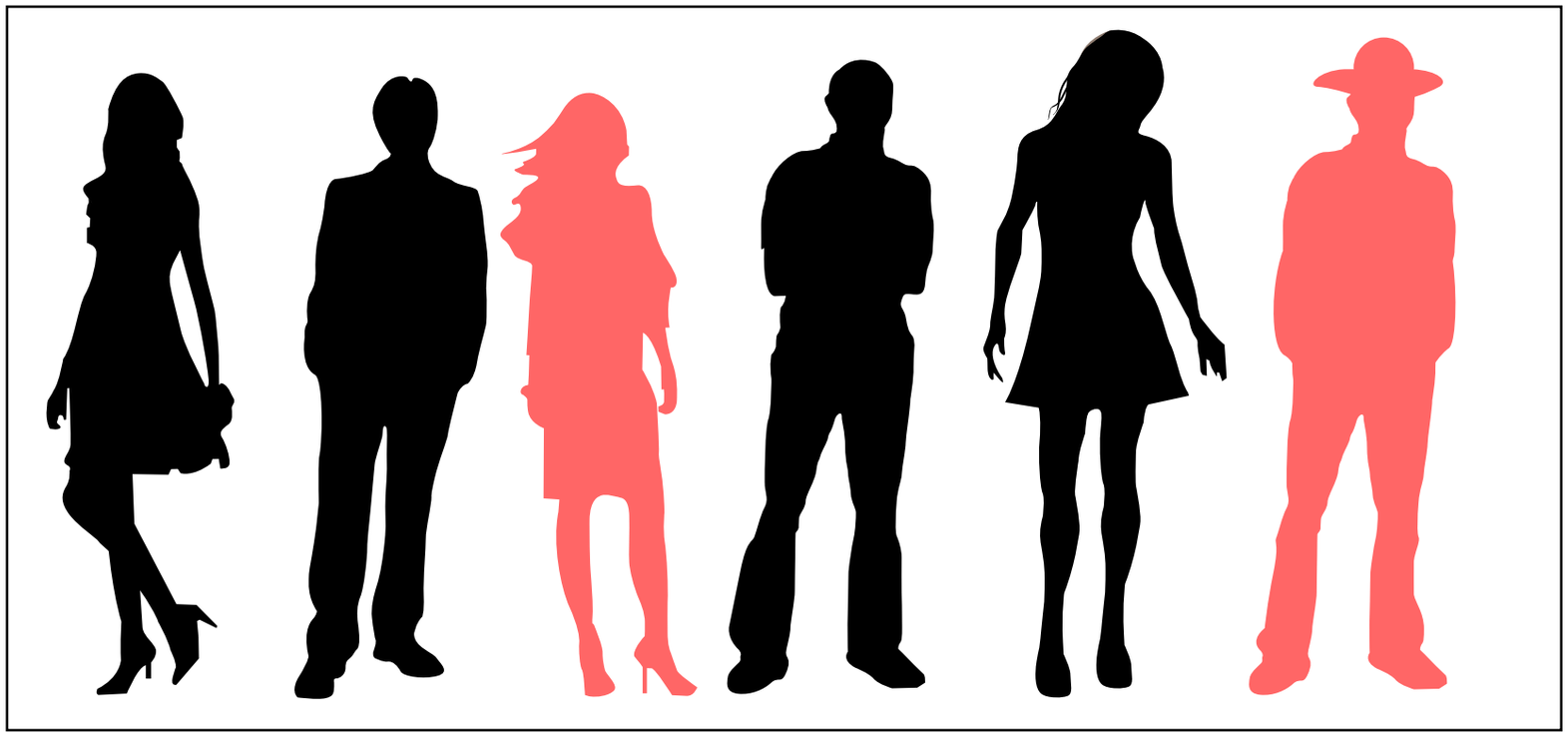
- What?
  - Privacy
    - Individual's desire to limit disclosure of personal information
  - Confidentiality
    - Information sharing in a controlled manner
  - Security
    - Protecting information against accident, disaster, theft, alteration, sabotage, denial of service, …
- Against what?
  - "Evil hackers"
  - Malicious insiders
  - Stupidity
  - Information Warfare

# Privacy

- Right to be let alone; e.g.:
  - snooping on Dan Quayle by J. Rothfeder
  - "outing" of Arthur Ashe (HIV), Henry Hyde (adultery)
  - celebrity medical problems (Tammy Wynette, Nicole Simpson)
- … applies mostly to known individuals

# Privacy in obscurity

- Right to remain unknown



Images by MIT OpenCourseWare.

- Correlation among pervasive databases:
  - census
  - marketing
  - health

# Confidentiality

- Use and sharing of information by multiple users at many institutions
- Should be controlled by coherent policy
- Enforced by appropriate technology

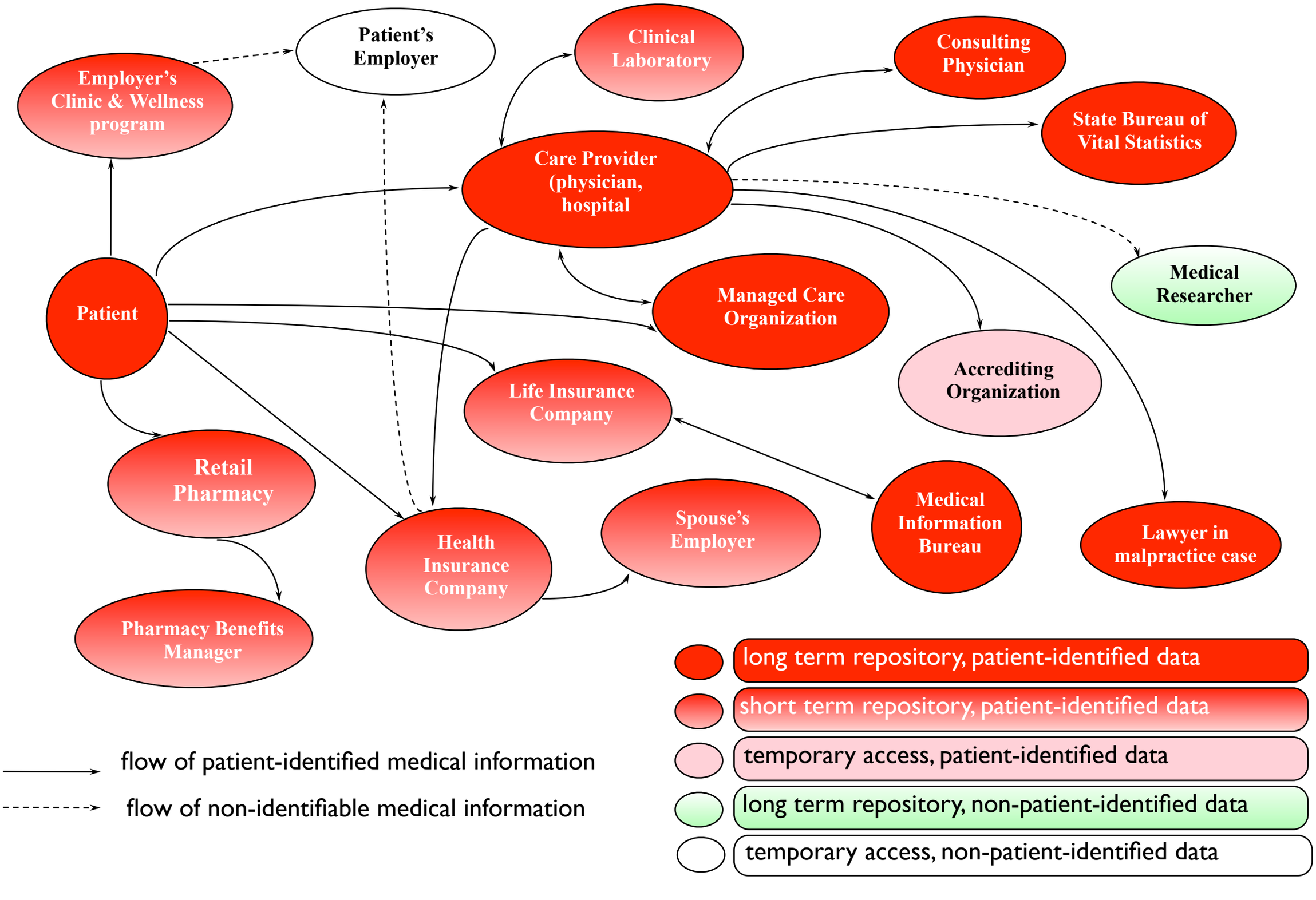
- E.g., who may use results of your life insurance physical exam, for what purposes?

# Legitimate Concerns
## (some may be ameliorated by ACA)

- Difficulty getting insurance
  - "Individual insurers may deny you coverage based on your medical history if it includes:
    - Use of prescription drugs to treat anxiety, depression or a physical condition, including Ativan, Klonipin, Paxil, Prozac, Serzone, Zoloft, Xanax and Wellbutrin.
    - Counseling for anxiety, depression, grief or an eating or sleep disorder. Even if you briefly sought counseling as a way to cope with the Sept. 11 terrorist attacks, you could be denied individual health insurance, according to researchers with Georgetown's Health Privacy Project." (MSN, March 9, 2004)
- Medical Information Bureau
  - Data on all applicants for private life insurance in past 7 years

# Additional Legitimate Concerns

- When employer pays insurance premiums, you may lose your job
  - Self-insured companies
  - Small employers facing "experience rated" policies
- Non-employment discrimination based on health
  - Adoption
  - Politics
- Social stigma


Patient's Employer
Employer's Clinic & Wellness program
Clinical Laboratory
Consulting Physician
State Bureau of Vital Statistics
Care Provider (physician, hospital
Medical Researcher
Patient
Managed Care Organization
Accrediting Organization
Life Insurance Company
Retail Pharmacy
Medical Information Bureau
Spouse's Employer
Health Insurance Company
Lawyer in malpractice case
Pharmacy Benefits Manager
flow of patient-identified medical information
flow of non-identifiable medical information
long term repository, patient-identified data
short term repository, patient-identified data
temporary access, patient-identified data
long term repository, non-patient-identified data
temporary access, non-patient-identified data

# Security

- Integrity of data
  - No unauthorized modifications
  - No “dropped bits”
- Availability
  - Natural disaster
  - Adversary attack
  - Inadequacy of backup, fail-over
- Enforcement of confidentiality policies

# De-Identification

# Identifiable

- **HIPAA:** Name, address, phone number, fax number, email address, URL, IP address, social security number, medical record n., health plan n., account n., certificate/license n., vehicle id, device id, biometric id, full-face photo, date of birth, zip code, gender, race, profession
  - "any other unique identifying number, characteristic, or code"
  - "actual knowledge that the information could be used … to identify"
- Patterns of doctor visits, immunizations, etc.
  - identifiable by inference
  - depends on knowledge and abilities of data user
- Small bin sizes lead to identifiability
  - Aggregate data into larger bins
    - dob => age
    - 3 digits of zip code

# Sweeney's Cambridge

- 1997 Cambridge, MA voting list on 54,805 voters
  - Name, address, ZIP, birth date, gender, …
- Combinations that uniquely identify:
  - Birth date (mm/dd/yy) 12%
  - BD + gender 29%
  - BD + 5-digit ZIP 69%
  - BD + 9-digit ZIP 97%
- Unique individuals
  - Kid in a retirement community
  - Black woman resident in Provincetown

# Problem of "other information"

- Governor Weld's data found in Mass "de-identified dataset"
- Dates you visited a health care provider (over a lifetime) are probably unique
- Can be used to re-identify you if someone has both de-identified data and other data that link to identifiers
- Genetics makes this immensely more problematic
  - Think Gattaca

# Danger of Re-identification

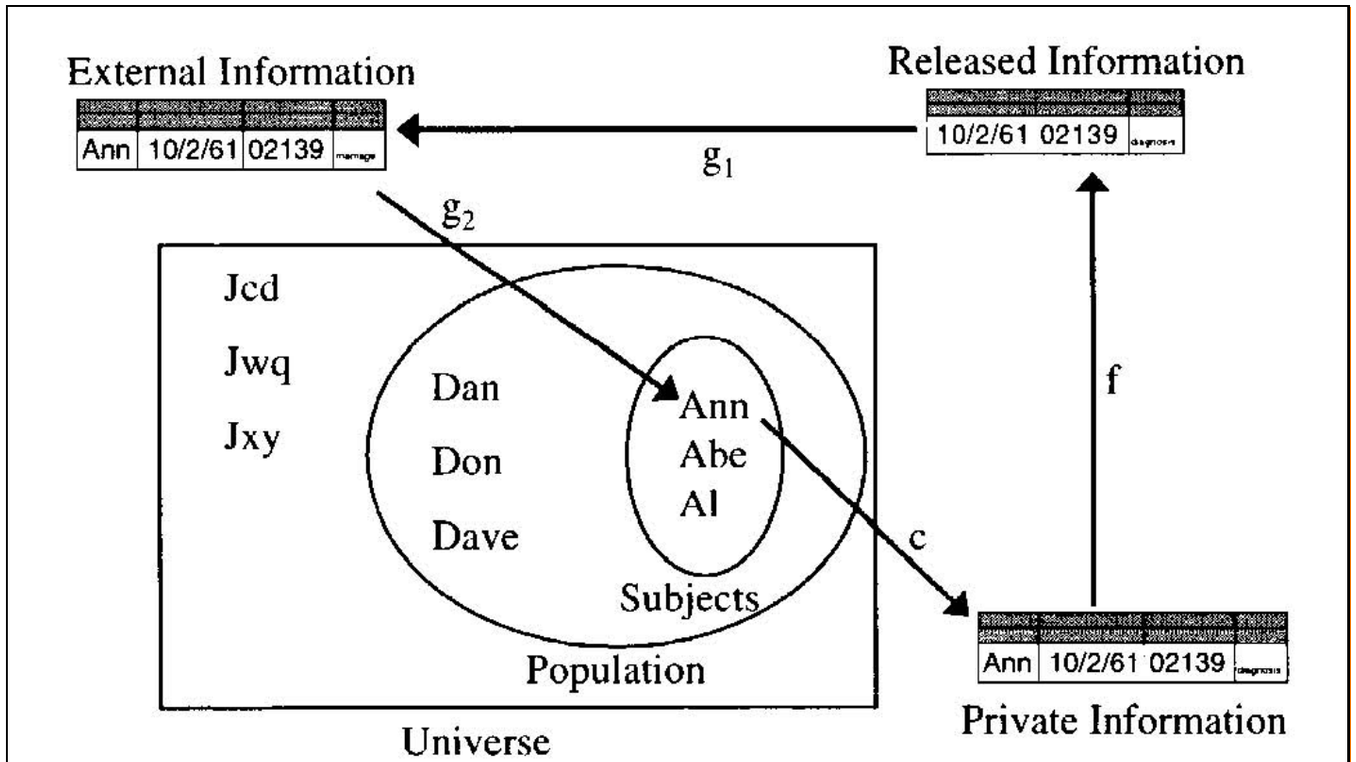



**Figure 18 Release using de-identification**

Figure by Sweeney, Latanya. "Computational disclosure control: A primer on data privacy protection." *Massachusetts Institute of Technology*, 2001.

# Protection via generalization

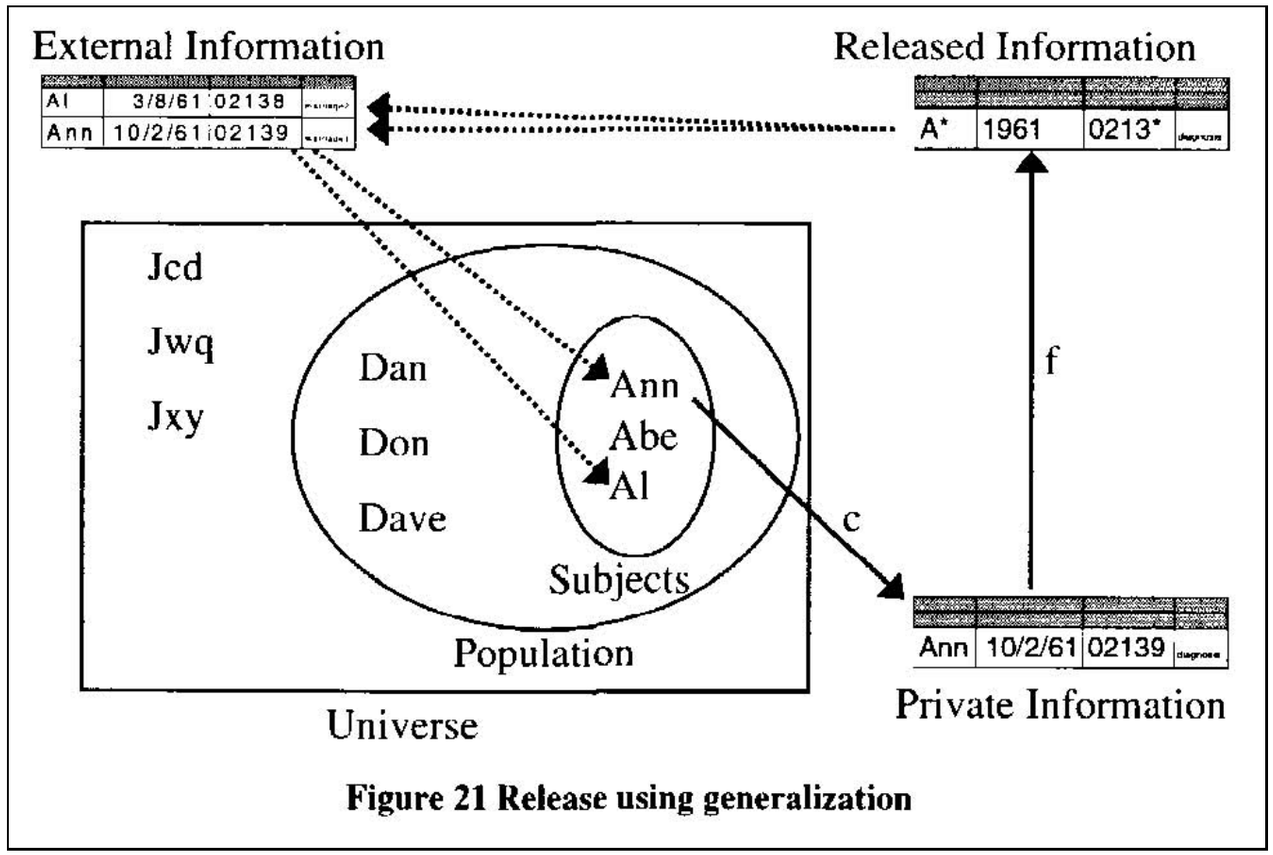



**Figure 21 Release using generalization**

Figure by Sweeney, Latanya. "Computational disclosure control: A primer on data privacy protection." *Massachusetts Institute of Technology*, 2001.

# Computational Disclosure Control

- Make sure data cannot be traced back to a set of size < n
  - Generalization
  - Suppression of unique combinations
  - Account for leakage from what has been suppressed; e.g., back-calculating from aggregate statistics
- How to estimate "external information"?
- **Every** release becomes more external info.

# Methods of Generalization/ Suppression

- Underlying problem (find minimal generalization/suppression to achieve a level of anonymity) is NP-hard (Vinterbo)
- Mainly heuristic search over space of possible generalizations/suppressions
  - Scrub, Datafly, μ-Argus (Netherlands), k-Similar
- Lasko: spectral anonymization
  - Build a model of data that captures the n-th order statistics of the distribution
  - Synthesize "fake" patients from that distribution

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