

The impact of consent on observational research

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National Patient Safety Agency

National Research Ethics Service

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Applicants



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*The National Research Ethics Service was launched on 1 April 2007 superseding
the Central Office of Research Ethics Committees.*



Ethical principles underpinning the research ethics process

- Autonomy, beneficence, non-malficence, justice
- Autonomy often considered the most important in issues of conflict between these principles
- Raises issue of consent for research
- And use of body parts / data etc for purposes for which consent was not explicitly given



Potential problem

- In the past clinical data have been used to address questions of importance
- A strength of this has been the degree of completeness of the data
- Electronic records (after being anonymised) can sometimes contribute
- Concern about the use of patient data without explicit concern



The Academy of
Medical Sciences



Personal data for public good:
using health information
in medical research

January 2006



Methods

- Re-analysis of data collected from medical records using only the sample who later consented by completing a questionnaire study

Do affluent women get a better deal from the NHS than deprived women?

Study population

Women in Greater Glasgow Health Board area

Diagnosed with breast cancer in 1992 and 1993

Deprivation categories

1 and 2 (affluent)	37.7%
6 and 7 (deprived)	62.3%

Methods

- 1. Hospital records data collection**
- 2. GP record data collection**
- 3. Postal questionnaire**
- 4. Interviews**

Main findings from hospital records data collection

- **No differences found between affluent and deprived women with respect to:**
 - **Access to hospital**
 - **Pathological prognostic factors in women with operable cancers**
 - **Surgery, radiotherapy, chemotherapy and endocrine treatment**

However:

- **More locally advanced and metastatic presentations in deprived women**
and
- **Evidence of the presence of co-morbidity in deprived women**

Macleod U, Ross S, Twelves C, George WD, Gillis C, Watt GCM. Primary and secondary care management of women with early breast cancer from affluent and deprived areas: a retrospective review of hospital and general practice records. *BMJ* 2000; 320: 1442-45.

Association between deprivation grouping and stage at presentation

Stage at presentation	AFFLUENT n = 156	DEPRIVED n = 260
Early	146 (93.6%)	220 (84.6%)
Locally advanced or metastatic	10 (6.4%)	40 (15.4%)

$$X^2 = 7.42, \quad DF = 1, \quad p = 0.006$$

Macleod U, Ross S, Gillis C, McConnachie A, Twelves C, Watt GCM. Socio-economic deprivation and stage of disease at presentation in women with breast cancer. *Annals of Oncology* 2000; 11: 105–107.

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Surgical treatment, radiotherapy and adjuvant therapy for women living in affluent and deprived areas (whole sample and questionnaire respondents)

	AFFLUENT n (%)		DEPRIVED n (%)		P-value (chi square)	
	WHOLE SAMPLE	CONSENTED SAMPLE	WHOLE SAMPLE	CONSENTED SAMPLE	WHOLE SAMPLE	CONSENTED SAMPLE
BREAST SURGERY	n = 142	n = 75	n = 215	n = 97		
Mastectomy	64 (45.1%)	37 (49.3%)	104 (48.4%)	43 (44.3%)	0.54	0.54
Conservation	78 (54.9%)	38 (50.7%)	111 (51.6%)	54 (55.7%)		
AXILLA SURGERY	n = 129	n = 70	n = 196	n = 94		
Clearance	123 (95.3%)	68 (97.1%)	146 (74.5%)	69 (73.4%)	0.000	0.000
Sampling	6 (4.7%)	2 (2.9%)	50 (25.5%)	25 (36.6%)		
RADIOTHERAPY	n = 146	n = 72	n = 220	n = 98		
	54 (37.0%)	22 (30.6%)	90 (40.9%)	50 (51.0%)	0.45	0.018
CHEMOTHERAPY	n = 146	n = 75	n = 220	n = 100		
	29 (19.9%)	13 (16.9%)	30 (13.6%)	15 (15%)	0.11	0.84
Endocrine therapy	n = 146	n = 77	n = 220	n = 100		
	128 (87.7%)	71 (92.2%)	196 (89.1%)	92 (92.0%)	0.67	1.0


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Personal data for public good: main findings and recommendations

- The law allows for identifiable patient data to be used without consent
- The regulatory process needs improved
- Good Practice Guidance should be developed
- The opportunities of the NHS National IT programme should be harnessed
- The public should be engaged





Robling MR, Hood K, Houston H, Pill R, Fay J, Evans HM. Public attitudes toward the use of primary care patient record data in medical research without consent: a qualitative study. *J Med Ethics* 2004;**30**: 104-109.

- Focus group study about general practice records
 - Being reviewed by GP
 - GP transferring names and addresses to external research team
 - Transfer of patient data to external disease register



Conclusions

- We need a debate about the role of consent
- If we agree to go with principle of *no consent = no use of data* we have to understand the potential implications
- We have a duty to communicate these to the public



With thanks...

- To Cancer Research UK who funded the original study
- Prof Charles Gillis for comment