# Informed consent to record linkage: A systematic review

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# Background

Record linkage can be a powerful tool in health research[1].

Exact matching (deterministic or probabilistic) aim to link records that are believed to refer to the same individual[2].

Record linkage demands the use of personal identifiers available in the databases to be linked[1,2].

Despite the potential benefits of applying record linkage in public health research, its use raises the discussion of privacy issues, such as whether a written informed consent for access to health records and linkage should be obtained[3].

# Purpose

To systematically review studies which address informed consent and record linkage.

# Methods

A computer-assisted search of the PubMed electronic database up to November 2008 was performed using the following strategy:

*consent[All Fields] AND (("records as topic"[MeSH Terms] OR ("records"[All Fields] AND "topic"[All Fields]) OR "records as topic"[All Fields] OR "record"[All Fields]) AND linkage[All Fields])*

We included articles published in the following languages: Portuguese, Spanish, English and French.

We included original articles, comments and reviews and excluded editorials and letters.

Study selection and data extraction was conducted independently by two reviewers. Disagreements between reviewers were resolved by a third independent reviewer.

# Methods

Studies were classified according to:

*(1) publication year – year and period (before and after 2000)*

*(2) journal area - public health, medicine, computer science and law*

*(3) country of first author's institutional affiliation*

*(4) study aim - empirical study concerning consent rates; theoretical discussion; other - consent is mentioned without being the main issue explored in the study).*

Differences in the aim of the study by journal area were determined by chi-square tests.

References were managed using ProCite (version 5) and Zotero (version 2.0b7.4).

Analyses were performed using Stata 8.0/SE.

# Results

A total of 42 studies were selected for inclusion in the review. Flow diagram is depicted in Figure 1.

The search of PubMed provided a total of 52 citations. After reviewing the abstracts, three studies were discarded due to: language (n= 2) and study aim (n=1). One additional study was discarded because its full text was not available.

We reviewed the full text of the 48 remaining studies and discarded six of them because: study aim (n= 4); type of publication (n=2).

Searching PubMed, we observed an exponential increment of the number of articles that address record linkage in general, but the number of articles which address consent are markedly lower and the increment is only observed after 2000 (Figure 2).

# Results

Tables 1 to 3 depict the studies included in the review according to the aim of the study: empirical study concerning consent rates (n= 5; 11.9%; Table 1); theoretical discussion (n= 18; 42.9%; Table 2); consent is mentioned without being the main issue explored in the study (n=19; 55.2%;Table 3)

Articles were published in Medical (n= 20; 47.6%), Public Health (n=12; 28.6); Law (n=5; 11.9%) and Computer Science (n=5; 11.9%) journals.

A significant difference in the study aim by journal area was observed (Figure 3).

Regarding the country of the first author's institutional affiliation, there is a predominance of UK (n= 11; 26.2%), Australia (n=11; 26.2%), USA (n= 10; 47.6%) and Canada (n= 6; 14.3%).

# Conclusions

The majority of articles were published after 2000, coinciding with the introduction of laws addressing privacy of health information in different countries.

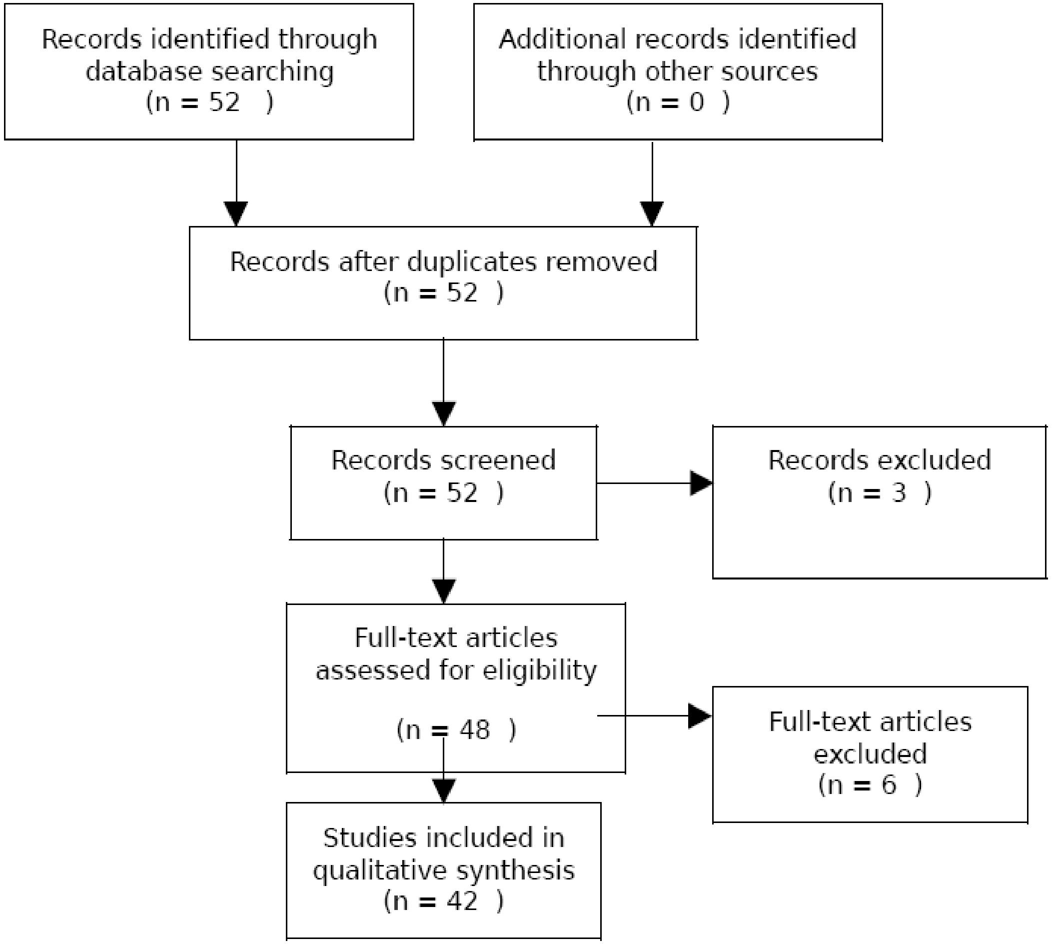
There is a predominance of studies conducted in research institutions located in countries with longer running traditions in using record linkage techniques and where the oldest integrated health record registries using such methods are located.

The majority of the studies did not present empirical data about the actual proportion of participant consent.

Despite the increasing utilization of record linkage techniques in research, the issues related to participant consent are not yet adequately addressed.

# Figure 1

## Flowchart of the record linkage and consent review*



Records identified through database searching
(n = 52 )

Additional records identified through other sources
(n = 0 )

Records after duplicates removed
(n = 52 )

Records screened
(n = 52 )

Records excluded
(n = 3 )

Full-text articles assessed for eligibility
(n = 48 )

Full-text articles excluded
(n = 6 )

Studies included in qualitative synthesis
(n = 42 )

* Adapted from PRISMA (http://www.prisma-statement.org/)

# Figure 2

Time series of number of articles in PubMed concerning record linkage (total and consent)

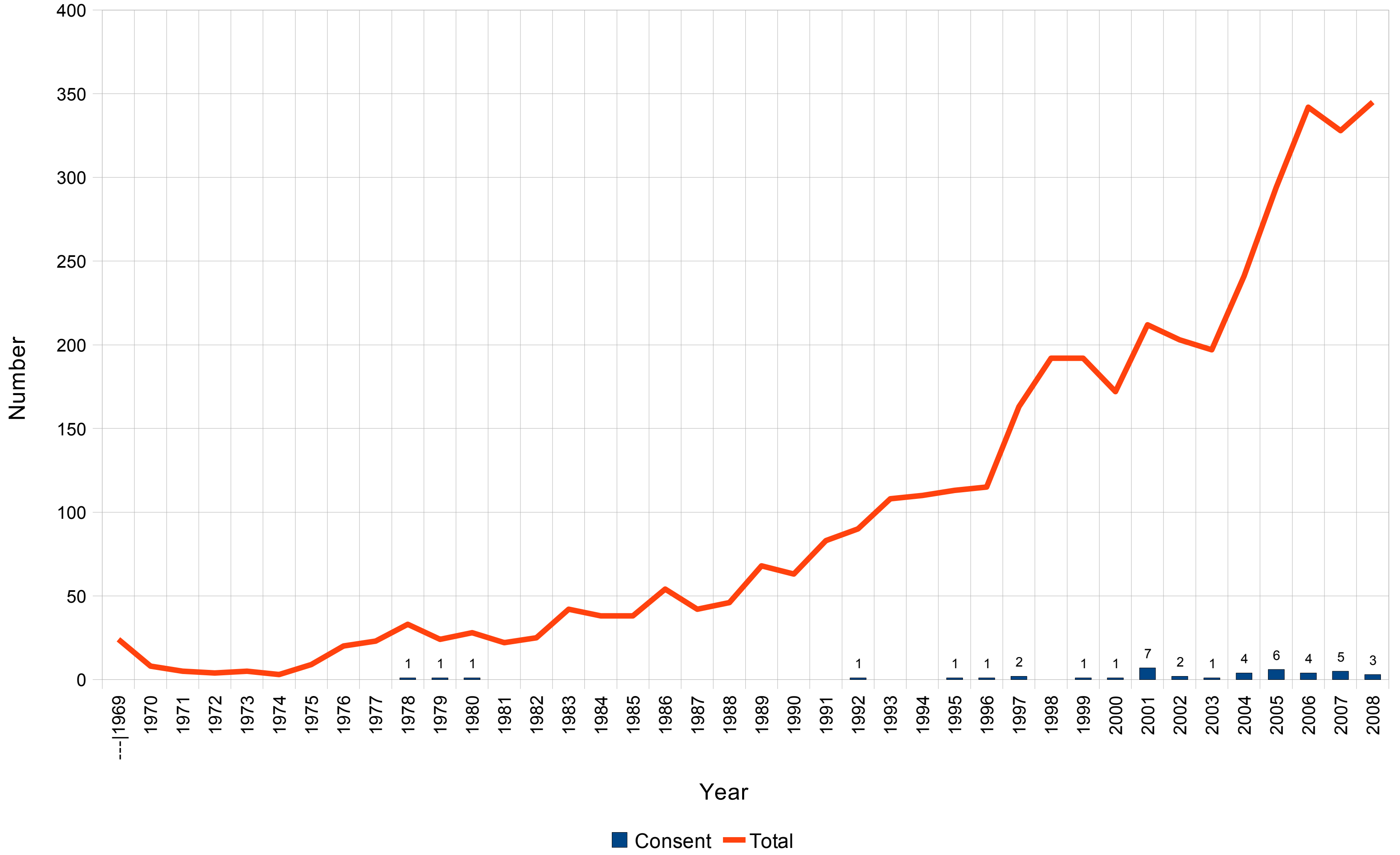
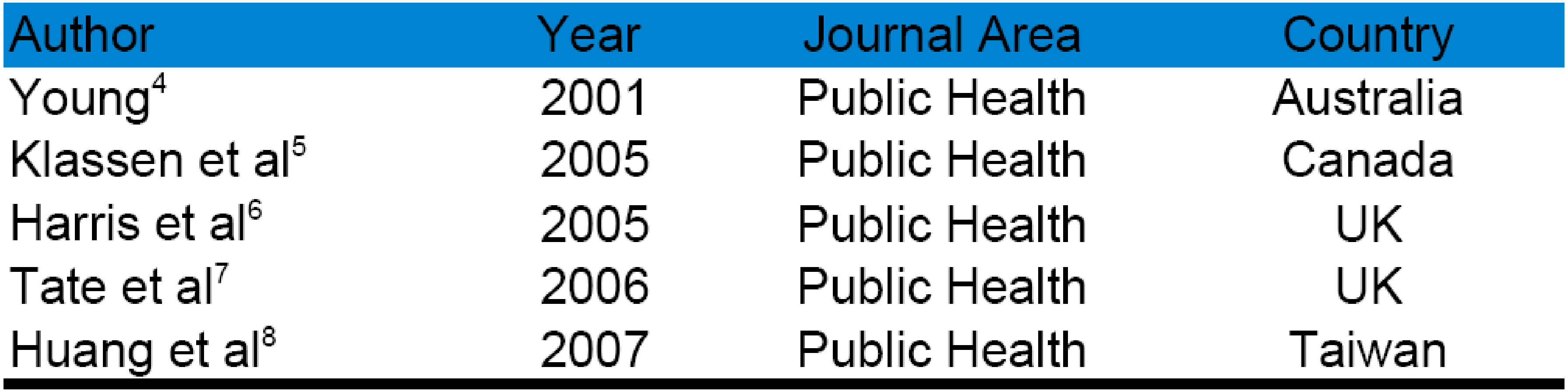


**Table 1**

Empirical studies concerning informed consent rates for record linkage.



| Author | Year | Journal Area | Country |
|---|---|---|---|
| Young[4] | 2001 | Public Health | Australia |
| Klassen et al[5] | 2005 | Public Health | Canada |
| Harris et al[6] | 2005 | Public Health | UK |
| Tate et al[7] | 2006 | Public Health | UK |
| Huang et al[8] | 2007 | Public Health | Taiwan |

# Table 2

Theoretical studies concerning informed consent for record linkage.

| Author | Year | Journal Area | Country |
|---|---|---|---|
| Rosen[9] | 1978 | Medicine | USA |
| Acheson[10] | 1979 | Medicine | UK |
| Lanman[11] | 1980 | Medicine | USA |
| Bang[12] | 1992 | Medicine | Denmark |
| Sibthorpe[13] | 1995 | Public Health | Australia |
| Lyttle[14] | 1997 | Medicine | Canada |
| Breen[15] | 2001 | Public Health | Australia |
| Montgomery[16] | 2001 | Medicine | USA |
| Holman[17] | 2001 | Public Health | Australia |
| Rothstein[18] | 2002 | Law | USA |
| Magnusson[19] | 2002 | Law | Australia |
| Iacovino[20] | 2004 | Law | Australia |
| Paterson[21] | 2004 | Law | Australia |
| McSherry[22] | 2004 | Law | Australia |
| Hetzel[23] | 2005 | Public Health | Australia |
| Mills[24] | 2006 | Computer Science | USA |
| Boyd[25] | 2007 | Public Health | UK |
| Safran et al[26] | 2007 | Computer Science | USA |

# Table 3

Studies concerning record linkage in which informed consent is mentioned.

| Author | Year | Journal Area | Country |
|---|---|---|---|
| Pilotto et al[27] | 1996 | Medicine | Australia |
| McLeod et al[28] | 1997 | Medicine | Canada |
| Kalman[29] | 1999 | Public Health | UK |
| Weber et al[30] | 2000 | Medicine | Canada |
| Shah et al[31] | 2001 | Medicine | UK |
| Sargent[32] | 2001 | Medicine | USA |
| Yip[33] | 2001 | Medicine | Canada |
| Berman[34] | 2003 | Medicine | USA |
| Harris et al[35] | 2004 | Medicine | UK |
| Soon, J. A. et al[36] | 2005 | Medicine | USA |
| Grobbee et al[37] | 2005 | Public Health | Netherlands |
| Kerlikowske et al[38] | 2005 | Medicine | USA |
| Powell et al[39] | 2006 | Computer Science | UK |
| Boutin[40] | 2006 | Medicine | Canada |
| Quigley et al[41] | 2007 | Medicine | UK |
| Moo & Fletcher[42] | 2007 | Computer Science | Australia |
| Greenhalgh et al[43] | 2008 | Medicine | UK |
| Heimly[44] | 2008 | Computer Science | Norway |
| Hockley et al[45] | 2008 | Medicine | UK |

# Table 4

Study aim according to journal area.

| Study Aim | Journal Area (%) | | | |
|---|---|---|---|---|
| Study Aim | Medicine | Public Health | Law | Computer Science |
| Consent Rate | 30.0 | 41.6 | 0.0 | 0 |
| Theoretical | 0.0 | 41.7 | 100.0 | 40 |
| Mentioned informed consent | 70.0 | 16.7 | 0.0 | 60 |
| Total | 20 | 12 | 5 | 5 |

P= 0.00

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