An Roinn Sláinte
Department of Health

Health Research – Some further policy considerations

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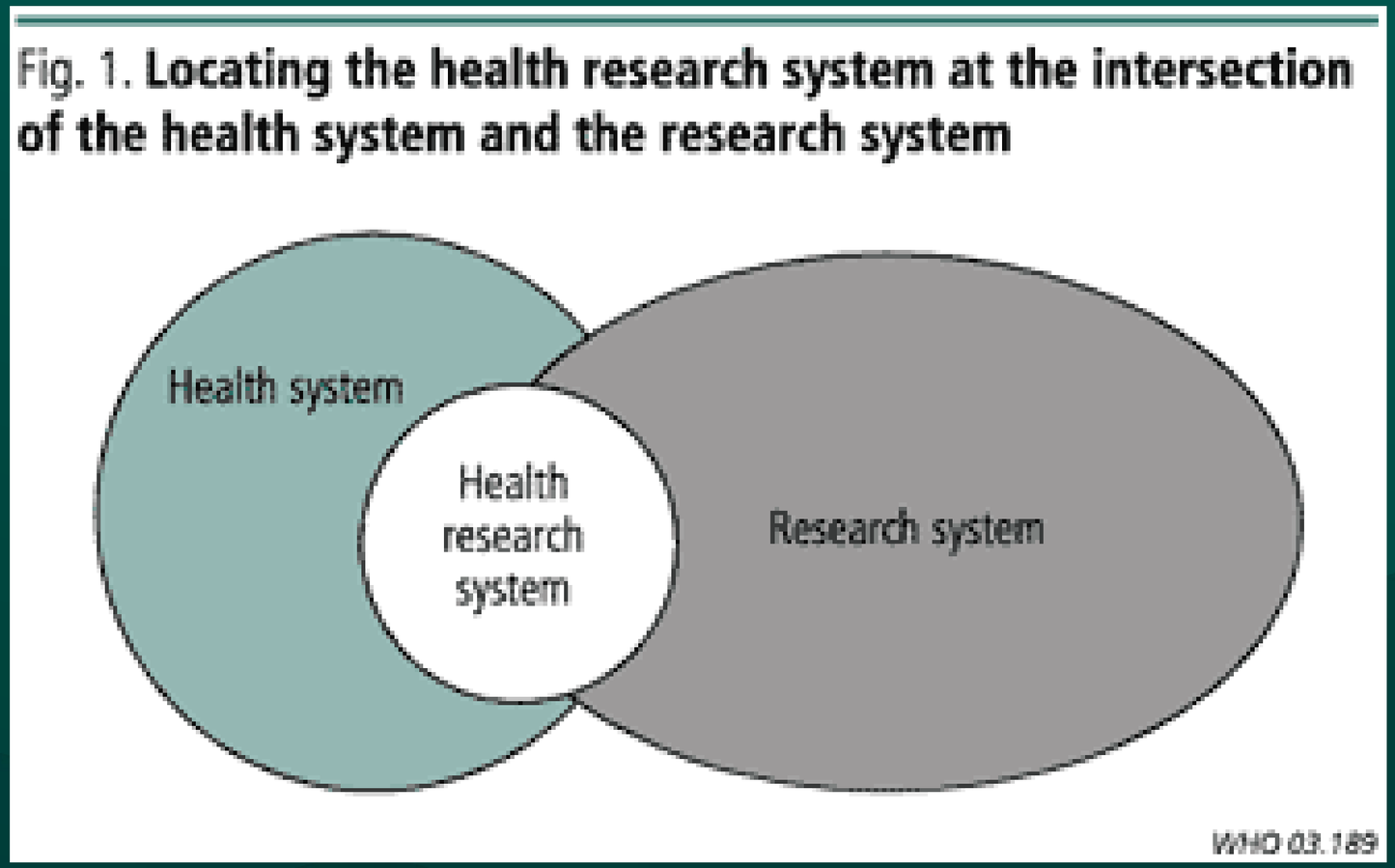
The importance of Government and public policy in enabling the research enterprise



- Define and articulate vision for a national health research system (HRS)
- Identify appropriate health research priorities and coodinate adherence to them
- Set and monitor ethical standards for health research and research partnerships
- Monitor and evaluate the HRS

- Produce scientifically valid research outputs
- Translateand communicate research to inform health policy, strategies, practices, and public opinion
- Promote the use of research to develop new tools (drugs, vaccines, devices, etc) to improve health

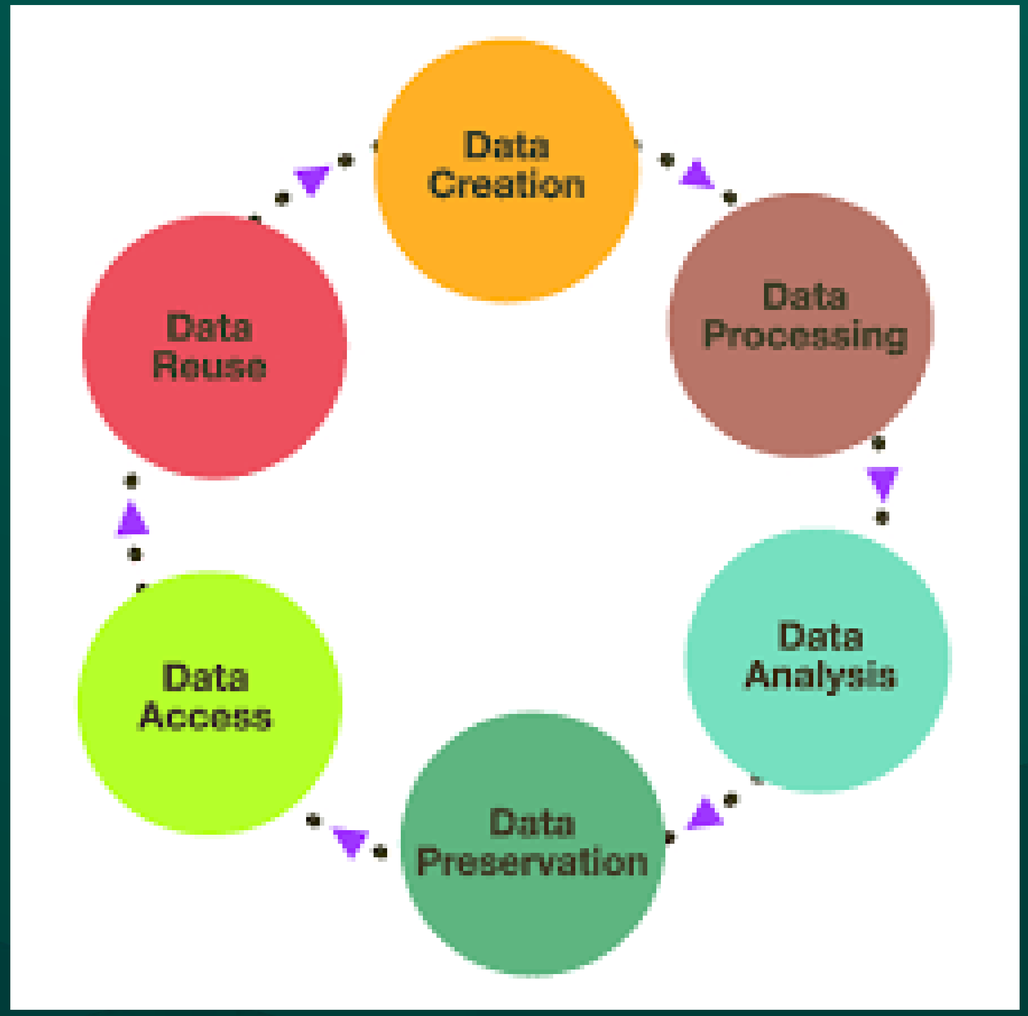
- Build, strengthen, and sustain the human and physical capacity to conduct, absorb, and utilize health research

- Secure research funds and allocate them accountably

Public understanding, support and engagement is critical to the success of the health research enterprise

Consent, Privacy, Legal and Ethical considerations

RESEARCH DATA LIFECYCLE



Circumstances where consent cannot be obtained

- These situations are exceptional and need case-by-case review
- There are many considerations, both legal and ethical, which need to be viewed in context before a decision can be made as to whether it is reasonable not to seek consent for the use of identifiable information in health research
- The rights of the individual with respect to privacy need to be balanced against the public interest in the outcomes of health research

• Countries differ in the mechanisms through which this review is conducted

- England and Wales, the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA) - under Section 251 of the NHS Act 2006
- Privacy Advisory Committee (PAC) in Northern Ireland
- Public Benefit and Privacy Panel for Health and Social Care in Scotland
- NHMRC produced enforceable guidelines under Section 95 and 95A of the Privacy Act, reviewed by National RECS in Australia
- In British Columbia in Canada, changed from N-RECS reviewing privacy considerations to new Data Stewardship Committees

Health Research- Consent Declaration Committee

- To provide a way of ensuring that important health research can be undertaken in circumstances where the data subject's expectations around consent cannot be met.
- To provide a sound framework of accountability and oversight of the handling of health information without consent.
- To provide robust, transparent, consistent, appropriate information governance scrutiny of such requests
- To provide leadership and act as a centre of excellence for privacy, confidentiality, and research
- To support the direct involvement of members of the public in the scrutiny process, and decision making

REPORT INTO THE GENERAL PUBLIC'S ATTITUDES TOWARDS CLINICAL RESEARCH- IPPOSI (2009)

- The public has a low level of understanding of the term "clinical research" over and above a general recognition that it relates to "medical research".
- Very supportive of the contribution such research makes to society
- However a key finding of the research was how the presentation of basic information about the purpose of clinical research and the degrees of participation serve to encourage an attitudinal change amongst the public.
- Information regarding patient consent, confidentiality and the presence and role of an independent ethics committee served to reassure the public about the strict protocols employed.
- 65% claimed they "would be willing to supply personal information to be used for clinical research if it is done in a confidential manner".

Public attitudes to the use in research of personal health information from general practitioners' records: a survey of the Irish general public

Buckley BS, Murphy AW, MacFarlane AE (2011)

- Assessed attitudes to research access to personal health information and factors that influence these.
- Completed questionnaires were returned by 1575 (40.6%).
- Among the respondents, 67.5% were unwilling to allow GPs to decide when researchers could access identifiable personal health information.
- However, 89.5% said they would agree to ongoing consent arrangements, allowing the sharing by GPs of anonymous personal health information with researchers without the need for consent on a study-by-study basis.
- At the same time, whilst the ‘greater good’ of research was recognized across groups, most participants stated that they would still prefer to know if, and when, their information was being used

Public views on health research and consent

Public views on data sharing and data linkage for health research (Scotland 2018)
- shows support is not unconditional

Factors which were important for shaping public acceptability

- Purpose of the research
- What type of data is being linked
- Who the researchers are
- Whether private/commercial interest, to what extent and how profits are managed and shared
- How the research will benefit the public
- Who is overseeing the process

Consent declarations/waivers/exemptions

CAG (England)- research applications

- What, when, why, who?
- Public Interest
- Practicable alternatives (to disclosure of identifiable data without consent)
- Justification for data required
- Data Flows
- Security Assurances
- Use of anonymised/pseudonymised data
- REC opinion
- PPI inputs/views
- Exit Strategy (seek consent or remove identifiable information once completed)

CAG (England)- research applications

Participant Identification Applications (to identify a cohort of patients and subsequently seek their consent)-

- only where you argue that it not feasible for member of the direct care team to seek consent, or to seek consent to pass on their contact details to the researcher, or to send on details of the study so they can contact the research themselves

CAG (England)- research applications

Where seeking access to data on-site to extract anonymised data

- Applications should only be made if you have explored all alternatives (the direct care team; sitting in with the care team who provide only the required information; funding the care team to carry out the search)

CAG (England)- research applications

- Applications for time-limited access to data to undertake record linkage and then anonymise the data–

Example #1

- Hereditary non-polyposis colorectal cancer (HNPCC) syndrome accounts for 0.3%–3.0% of colorectal cancer cases, a preliminary screening process is necessary to ascertain families at likely high risk of an MMR gene mutation
- In light of epidemiological data on the prevalence of HNPCC, the anecdotal evidence suggested that few at-risk families were being referred to the state's only familial cancer program run by Genetic Services of Western Australia (GSWA)
- Request for approval to conduct a study to estimate the ascertainment of HNPCC families by GSWA at the population level (tissue microarrays comprising 1050 consecutive colorectal cancers diagnosed in Western Australia over 10 years)

Case made for a consent waiver

- individuals would have been unnecessarily presented with the prospect of a potentially worrying medical condition that the statistics indicated they would almost certainly not have.
- study would be conducted by health care workers within a public system bound by confidentiality requirements
- the identity of patients was not going to be made public
- 313 patients had died by the time the study would be initiated, so identifying and contacting their next of kin would have been a major undertaking, and introduced potential bias into the study if they had to be excluded
- a prospective study requiring informed consent would take several years to accrue a statistically significant sample. In the meantime, many patients who could potentially benefit from a simple screening method would not have their cancers detected under current practice.
- obtaining informed consent from each of the 1050 individuals whose tumours were screened would have required significant counselling resources.

Reasons given for granting a consent waiver

- The clear pathway established for contacting, counselling and managing at-risk individuals satisfied the Committee that there was potential benefit to those identified as being at risk and their families.
- They were convinced because the organisation involved in the study (GSWA) was also committed to managing the at-risk individuals, as they provided the only state familial cancer genetic counselling and testing service.

Results

- Found 24 individuals at risk of HNPC, of whom only four were known to the Familial Cancer Program. Eighteen of the remaining 20 at-risk individuals, or their next of kin, were successfully contacted and offered an appointment for consultation. Of these, 17 agreed to attend the clinic for further discussion

Example # 2

- Study to determine whether some specific blood chemistry values change in people undergoing clinically indicated abdominal surgery, and if there is a correlation of changes with increased incidence of complications after surgery.
- Involves review of medical records of all patients who have undergone abdominal surgery in the past two years (about 10,000 surgeries), collecting limited data that will be double-coded so link is known only to researchers.
- **Would not adversely affect rights and welfare of subject:** Surgery and associated blood chemistry values are clinically indicated, therefore would be done regardless of the research. No study results would affect clinical decisions about the individual's care.
- **Research could not be practicably carried out without the waiver:** Identifying and contacting thousands of potential subjects, while not impossible, would not be feasible for a medical record review where results would not change care the individuals already would have received. (Note: In smaller studies, it may be harder to argue that obtaining consent is not feasible, especially if subjects have not yet been treated or are still being seen.)

Example # 3

- CTIMP to assess a new cholesterol lowering treatment, which if shown to be effective, could have major impact on number of strokes, heart attacks and deaths
- Applied for waiver to access medical records to identify participants (estimated that need to review 400,000 to get sample size of 12,000)
- Once identified, could be contacted and asked for informed consent
- Committee granted waiver for the identification and recruitment stages only. Assured that it was not feasible for the direct care teams to undertake this process due to such large numbers

Studies of already collected data (Secondary Use)

- Typically, there is no consent process to collect these data, under which future uses of the data have been defined and permission for those uses has been obtained; and even when data are collected in research studies under REC-approved consents, those consents are often lacking in information about, and permission for, future use in other studies
- For this reason, any researcher considering a real world or big data study must consider the terms of consent gained for the primary acquisition of data that are to be used for the big data aggregation and study – or whether there was no such consent gained at all.
- (any request for a waiver of consent would likely be disapproved if the original consent had expressly promised, for example, that other than the primary study, there would be no later research uses of the data.

Cluster randomised studies

The central defining feature of a cluster randomized trial (CRT) is that randomization occurs on a group level rather than an individual level

- a large-scale community health trial for the prevention of cardiovascular disease involving television, radio and billboards
- interventions that involve changing the environment, such as fluoridation of community water supplies

- Retrospective Chart Reviews
- Quality Improvement (QI) Activities (clinical audit, quality assurance, service evaluation)
- Distinguishing between public health practice and public health research (and protocols that combine elements of both)

Special Considerations for Genome Research

- Broad Consent
- The continuing nature of consent
- Re-contact to request new or updated consent
- Considerations for Families
- Considerations for Identifiable Populations
- Data and Sample Sharing Through Data Repositories and Biobanks
- Transfers of samples or data across borders
- Use of samples or data by commercial researchers
- Return of Results and Incidental Findings to Participants
- Open access and Open data considerations

Further considerations (for research policy)

- National REC system (HIPS/CTIMPS)
- Build on existing PPI work
- Health Information Policy
- Safe Haven (HRB DASSL Model)
- Genomic Research, Genomic Medicine & Biobanks
- Big Data
- Capacity Building
- Stay connected in European discussions/activities

HRCDC

Health Research Consent Declaration Committee

Transparency | Confidence | Trust

- Securing and confirming HR-CDC members
- Recruitment of the HR-CDC Secretariat staff
- Dedicated HR-CDC Website
- Application forms and guidelines
- Continue to collect queries and provide guidance, where possible

HRCDC

Health Research Consent Declaration Committee

Transparency | Confidence | Trust

- Immediate meeting with RECs
- Ongoing engagement, as appropriate with DPC
- Meeting with the recently appointed DPOs

  Continued engagement on specific issues
- Application process open in November
- Committee convenes in December
- First decisions published in Jan 2019