



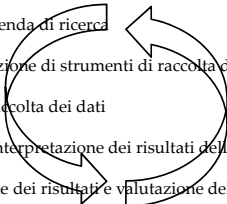
Definire le priorità della ricerca coinvolgendo cittadini e pazienti

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Cosa si intende per coinvolgimento ...

È un **processo-percorso** attraverso il quale cittadini & pazienti *non sono solo soggetti* della ricerca ma intervengono:

- nel fissare l'agenda di ricerca
- nella progettazione di strumenti di raccolta dei dati
- nella fase di raccolta dei dati
- nell'analisi e interpretazione dei risultati della ricerca
- nella diffusione dei risultati e valutazione della ricerca



Chi rappresenta chi?

Cittadini e pazienti, utenti attuali o futuri di servizi sanitari
con riferimento anche ai membri della famiglia, alle persone che si prendono cura degli altri e ai membri della collettività

con riferimento anche al variegato mondo dell'associazionismo organizzato

The Autonomous Patient
Ending Paternalism in Medical Care
by Angela Coulter
Published in September 2002, Stationary Office

The modern patient – Threat or promise?: Physicians' perspectives on patients' changing attributes

The resourceful patient.
JA Muir Gray. (173 pages, £14.50) eRosetta Press Ltd, 2002. ISBN 1-904262-00-4.

Volume 35:72534-2535 December 20, 2007 Number 25

The Good Patient
J. Galen Buckwalter, Ph.D.

Partecipasalute
Il cittadino esperto

J Am Coll Cardiol. 2008; 51:1955-1958. doi:10.1016/j.jacc.2008.03.013 © 2008 by the American College of Cardiology Foundation

EDITOR'S PAGE
The Informed Patient

Quali sono i vantaggi del coinvolgimento?

Vedere il mondo in una **prospettiva multidisciplinare** di condivisione delle scelte e quindi

- ◆ garantire che i temi di ricerca importanti e rilevanti per la comunità siano identificati e abbiano priorità
- ◆ garantire che la ricerca non si limiti a misurare i risultati che vengono identificati e considerati importanti per i professionisti o per il mercato
- ◆ garantire che i fondi pubblici non siano sprecati per la ricerca che ha poca o nessuna rilevanza, partecipando alle decisioni sul finanziamento
- ◆ migliorare progettazione e adesione, sostenere la diffusione dei risultati della ricerca, assicurare che i risultati siano trasferiti nella pratica
- ◆ discutere sull'etica della ricerca clinica, anche migliorando il processo di consenso

La ricerca clinica risponde ai bisogni dei pazienti?

Le ricerche cliniche degli ultimi 5 anni hanno risposto ai bisogni dei pazienti che rappresentate, in termini di rilevanza quesito clinico? (n58)

No	44%
Non risponde	22%

Non abbiamo avuto ricerche cliniche, non possiamo rispondere (o non siamo a conoscenza) *Sindrome Ehlers Danlos*

L'associazione non è in grado di rispondere perché non è a conoscenza delle ricerche cliniche in corso nell'area *Diabete*

Non siamo in grado di rispondere alle domande perché non siamo mai state coinvolte in ricerche cliniche né informate sugli esiti di eventuali ricerche effettuate nella nostra *USL Tumore del seno*

Le ricerche cliniche necessitano ormai di studi multicentrici, di casistiche molto ampie e di fondi rilevanti. Tutto ciò esula dalle capacità di risposta della nostra associazione che inoltre essendo una onlus, è limitata ad attività che abbiano un'immediata utilità nei confronti dei pazienti *Urologia*

Mosconi, Ricerca & Pratica 2007

La ricerca clinica risponde ai bisogni dei pazienti?

Attualmente ritenete fattibile definire le priorità della ricerca clinica con clinici e ricercatori specialisti nel vostro settore di interesse?

No	13
Sì	41 71%
Non risponde	4

Portatori di quelli che sono i reali bisogni dei pazienti per stabilire un miglioramento della qualità della vita con ricadute anche a carico del care giver
I bisogni dei pazienti spesso non coincidono con gli interessi/necessità dei clinici
I bisogni dei pazienti non sono solo farmacologici ma riguardano anche gli ausili e andrebbero valutati anche gli aspetti della qualità della vita

Mosconi, Ricerca & Pratica 2007

Le esperienze

The James Lind Alliance: patients and clinicians should jointly identify their priorities for clinical trials

Dec 1 sees the launch of the James Lind Alliance at the Clinical Excellence conference in Birmingham, UK. Convened jointly by INVOLVE, the Royal Society of Medicine, and the James Lind Library, the James Lind Alliance aims to bring patients and practising clinicians together in a new way to identify and address the most important uncertainties they face about the effects of care and treatments.¹

In many areas over the past 10 years, involving patients, and to a lesser extent the public, in research has moved from a radical concept to an accepted and valued part of the research cycle. However, the past 10 years have also seen a decline in the number of non-commercial clinical trials,² and the needs of patients and practising clinicians are still rarely discussed when deciding research priorities. Rather, the needs of industry and academia take precedence.

Clinicians might not always face important uncertainties about treatments and discuss them openly with patients, for understandable reasons.³ Yet discussion of well-informed uncertainties about treatments is essential to fully understand the real priorities of patients and to set the agenda for future trials of treatment.⁴

The James Lind Alliance is named after an 18th-century Scottish naval surgeon who, faced with uncertainty about how best to treat scurvy, did a controlled trial to find the

How do we do it?

The priority setting process:

- Set up steering group
- Invite partners
- Gather uncertainties
- Prioritise uncertainties
- Promote priorities to researchers and funders

www.thelja.com Vol 364 November 27, 2004

CONVERSATIONAL TOPIC

Prioritizing Research: Patients, Carers, and Clinicians Working Together to Identify and Prioritize Important Clinical Uncertainties in Urinary Incontinence

Fig. 1. The JLA priority setting partnership on UR process.

INVOLVE

National Institute for Health Research

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Home Resource centre Publications by INVOLVE Publications Exploring the impact of public involvement on the quality of research

POPpy

Parents of Premature babies Project

The impact of public involvement on the research questions, the development of methods and the analysis of data were important areas where parents influenced the study. Parents tested the utility, relevance and applicability of the systematic review, and were involved in analysing and reviewing the qualitative data (Staniszewska, 2007; Brett, 2012). Perhaps their most significant impact was in the development of the model of care where the involvement of parents brought about a realignment in the philosophy of care, putting the family at the centre of care in neonatal units (Staniszewska 2012).

With the power of experience behind them, the parents took part in presentations at conferences and in the National Institute for Health and Care Excellence (NICE)¹⁰ consultations. POPpy is referenced in a Department of Health neonatal toolkit and the United Nations Children's Fund (UNICEF) has included it in their quality standards for neonatal units.

Involve is a national advisory group which is funded by the National Institute for Health Research in the UK which was established to promote consumer involvement in all stages of the research process.

The rationale for the group is the belief that research which has consumer input is more likely to produce practical results that can be used to improve practice in health care. They advocate for an active partnership between the public and researchers in the research process.

Consumer Involvement in Dementia Research: Alzheimer's Australia's Consumer Dementia Research Network

Consumer Involvement in Dementia Research Alzheimer's Australia 17

CONCLUSIONS

There is support for greater consumer involvement in research in Australia but there has been no objective evaluation of this involvement which is often considered too difficult or costly to support. The UK Alzheimer's Society's approach to consumer involvement has a model for actively engaging consumers in dementia research. The Alzheimer's Australia Consumer Dementia Research Network has been developed from this model, and aims to enable people with dementia and their carers to have a more active role in dementia research and knowledge translation. This network represents a sharp advance on the more traditional means of involving consumers through steering committees or simply as subjects of research.

An Australian Government Initiative The Wicking Centre for Ageing Research DCRC

Journal of Clinical Epidemiology

Effective stakeholder participation in setting research priorities using a Global Evidence Mapping approach

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Abstract

Objective: We present a multistep process for identifying priority research areas in rehabilitation in injured (TRI) patients. In particular, we aimed to (1) identify which stakeholders should be involved, (2) create a list of research questions, and (3) examine different criteria for the generation of research priority areas, and (4) test the feasibility of the process, decision makers, and other potential users of the research.

Study Design and Setting: Potential research questions were identified and developed using an iterative search, followed by a facilitated mapping workshop and an online survey. Identified areas were then ranked against specific criteria (clinical importance, novelty, and consensus). Existing evidence was then used to inform the search, screening, and selection. A broad range of stakeholders were then invited to provide research themes for future research investment. Using clinical and research leaders, online surveys were used to generate research projects for each of the identified themes.

Results: Twenty-six specific questions about TRI rehabilitation were generated, 14 of which were high-priority questions. Methods that relied solely on the views of clinicians and researchers identified paired with methods that used broader stakeholder engagement. Evidence maps of these high-priority questions, priority questions and evidence maps were then used to inform research focus, which identified 11 research questions. Our research demonstrates the value of a multistep and multithemed process involved in prioritising research to improve the rehabilitation outcomes of people who have suffered a traumatic injury. This process can be augmented using a combination of methods and a process of linkage and exchange. This prioritisation of research areas. © 2013 Elsevier Inc. All rights reserved.

Keywords: Prioritisation; Trauma; Brain injury; Research funding; Evidence mapping; Research gaps; Rehabilitation

Box 1 Defining research gaps

Research gaps exist when:

1. There is insufficient research to answer a question (and primary research is needed);
2. There is research that addresses the question, but it is of insufficient quality to be able to rely on the findings (and better quality research is needed);
3. There is research, but the patients, interventions, comparators, or outcomes differ from that which is most relevant in my setting, or the context in which the research is done is different in important ways (and research examining applicability and generalizability is needed);
4. There are multiple research studies, but they have not been synthesized in a meaningful way (and a systematic review is needed).

The Patient-Centered Outcomes Research Institute (PCORI) National Priorities for Research and Initial Research Agenda

Joe Y. Sacks, MD, MPH
Anne C. Boal, MD, MPH
Lori Frank, PhD

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT of 2010 created the Patient-Centered Outcomes Research Institute (PCORI) to fund and promote comparative clinical effectiveness research (CER) that will "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can be effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis."¹ CER is not a new concept,^{2,3} but appreciation of its potential for providing patients and their clinicians with uniquely valuable information on what works, tailored to the clinical situation and to patient priorities, has increased rapidly in recent years.

The research institute founded by this legislation was named to emphasize the critical importance of a patient-centered perspective in conducting this research.⁴ The PCORI CER evidence agenda, which is the national research agenda, was developed by the Board of Governors determined early on that taking this name seriously, placing patients at the center of CER and actively engaging clinicians and other stakeholders was an ideal strategy to ensure that the PCORI research agenda was focused on practical questions, relevant outcomes and study populations, and the possibility that treatment effects may

participating in the merit reviews. A total of 48 individuals were subsequently recruited, trained by the NIH, and included as voting members of the 10-study sections (1 per section). Second, proposed scoring criteria included an additional criterion—extent of patient engagement.

The legislation required PCORI to develop national priorities for research and a research agenda, and to post both for a 45- to 60-day public comment period before major funding for research could begin. The development process extended from July to December 2011. It included examination of other recent prioritization efforts^{5,6} and consideration of 9 criteria cited in the statute (Box),⁷ and of input received through discussions with stakeholder groups, participating clinicians, industry, clinicians, hospital systems, industry, and consumers produced 1 agenda, which is the national research agenda, which is the national research agenda, which is the national research agenda.

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Segnali dall'Europa

The screenshot shows the ECRAN website interface. At the top, there's a navigation bar with 'Home', 'Chi siamo', 'Mappa del sito', 'Indice', 'Ricerca avanzata', and 'Accessi'. Below this, there are several news items with titles like 'Alzheimer e EMA: consultazione pubblica' and 'Partecipasalute'. A search bar is visible on the right side of the page.

Segnali dall'Europa

The cover of the EMA's Annual Report 2013. It features the EMA logo at the top, which includes a stylized 'E' and 'A' with a globe. Below the logo, the text reads 'EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH'. The date '2 October 2014' and 'EMA/103410/2014 Stakeholders and Communication Division' are listed. The main title is 'Annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations (2013)'. At the bottom, it says 'Latest Blog Entries'.

Priorità e coinvolgimento "passivo"

The screenshot shows the Partecipasalute website. The header includes the logo and the tagline 'Il portale sulla salute per partecipare e decidere consapevolmente'. There are navigation links for 'Home', 'Chi siamo', 'Mappa del sito', 'Indice', 'Ricerca avanzata', and 'Accessi'. The main content area features a section titled 'Alzheimer e EMA: consultazione pubblica' with a sub-section 'Il progetto'. There are also search bars and social media icons.

Priorità e coinvolgimento "passivo"


The screenshot shows the Fondazione Paracelso website. The header includes the logo and the tagline 'Per l'emilia e le patologie affini'. There are navigation links for 'Home', 'Chi siamo', 'Mappa del sito', 'Indice', 'Ricerca avanzata', and 'Accessi'. The main content area features a section titled 'Fondazione Paracelso' with a sub-section 'Il progetto'. There are also search bars and social media icons.

Cittadini e pazienti: alleati vulnerabili?

The screenshot shows a news article from Reuters. The headline is 'Patient Organizations' Funding from Pharmaceutical Companies: Is Disclosure Clear, Complete and Accessible to the Public? An Italian Survey'. The article is dated 09 September 2014. The main text discusses the funding of patient organizations by pharmaceutical companies and the need for transparency. A quote from Chris Mahony, a freelance journalist, is included: 'The 342 Trust did not respond when asked whether greater transparency would be better. It said it was satisfied that the trust's independence and integrity was protected by its policy on raising funds from the drug industry, which is to be welcomed.' The article also mentions that 17 drug companies were considered, with 13% providing funding to 130 patient and consumer groups.

Cittadini e pazienti: alleati vulnerabili?

The screenshot shows a BMJ article. The headline is 'LET THE PATIENT REVOLUTION BEGIN'. The article is dated 09 September 2014. The main text discusses the funding of patient organizations by pharmaceutical companies and the need for transparency. A quote from Chris Mahony, a freelance journalist, is included: 'The 342 Trust did not respond when asked whether greater transparency would be better. It said it was satisfied that the trust's independence and integrity was protected by its policy on raising funds from the drug industry, which is to be welcomed.' The article also mentions that 17 drug companies were considered, with 13% providing funding to 130 patient and consumer groups.



- * **Superare** le difficoltà ad accettare Citt e Paz come interlocutori privilegiati riconoscendone esperienza e capacità
- * **Organizzare** l'attiva partecipazione di Citt e Paz secondo i principi di "evidence based advocacy", quindi promuovere formazione indipendente
- * **Il panorama dell'associazionismo** che rappresenta Citt e Paz è molto forte, radicato e frammentato, molto focalizzato sui bisogni
- * **Essere trasparenti** sulle modalità di coinvolgimento
- * **Contare** su finanziamenti della ricerca indipendente

Aree per implementare il coinvolgimento

Scopo e contesto

Identificare lo scopo di coinvolgere i consumatori
 Individuare in quale fase si vuole coinvolgere i consumatori (es. definizione di domande di ricerca, la progettazione di strumenti di raccolta dati, raccolta di dati, risultati delle analisi, la diffusione dei risultati)
 Identificare le caratteristiche dei consumatori di essere coinvolti
 Identificare i problemi per ottenere contributi da parte dei consumatori

Preparare per coinvolgere i consumatori

Determinare come verranno reclutati e impegnati consumatori
 Identificare le strategie per coinvolgere i consumatori (es. Membro del gruppo di ricerca, nel gruppo consultivo)
 Identificare il supporto adatto per aiutare i consumatori a partecipare in modo efficace (es. supporto amministrativo, trasporti, parcheggi, persona da contattare)
 Determinare i tipi di informazioni e di orientamento da fornire ai consumatori
 Determinare strategie per chiarire e comunicare i ruoli dei consumatori
 Identificare i requisiti di personale
 Identificare i costi connessi col coinvolgimento dei consumatori

Monitorare e valutare i processi di coinvolgimento

Identificare i processi di monitoraggio e valutazione