Digital Medicine & Therapeutics
Nuovi Modelli di Salute, medicina e Sanità nell'era post-covid

Springer Healthcare Communications

daVi DigitalMedicine

DIGITAL MEDICINE & THERAPEUTICS

NUOVI MODELLI DI SALUTE,
MEDICINA E SANITÀ
NELL'ERA POST-COVID

WORKSHOP ONLINE
Prima sessione: martedì 30 novembre 2021
Dalle 14:00 alle 17:00

ACCADEMIA DEL PAZIENTE ESPERTO EUPATI
CONOSCERE PER DECIDERE

Il paziente esperto in *digital therapeutics*

Sabrina Grigolo

Paziente Esperto EUPATI 3° Course Europe, 2018

Dottoranda presso il Dipartimento di Filosofia e di Scienze dell'Educazione in co-tutela con il Dipartimento di Scienza e Tecniche del Farmaco dell'Università di Torino

Ambasciatrice EPALE per l'Educazione degli Adulti

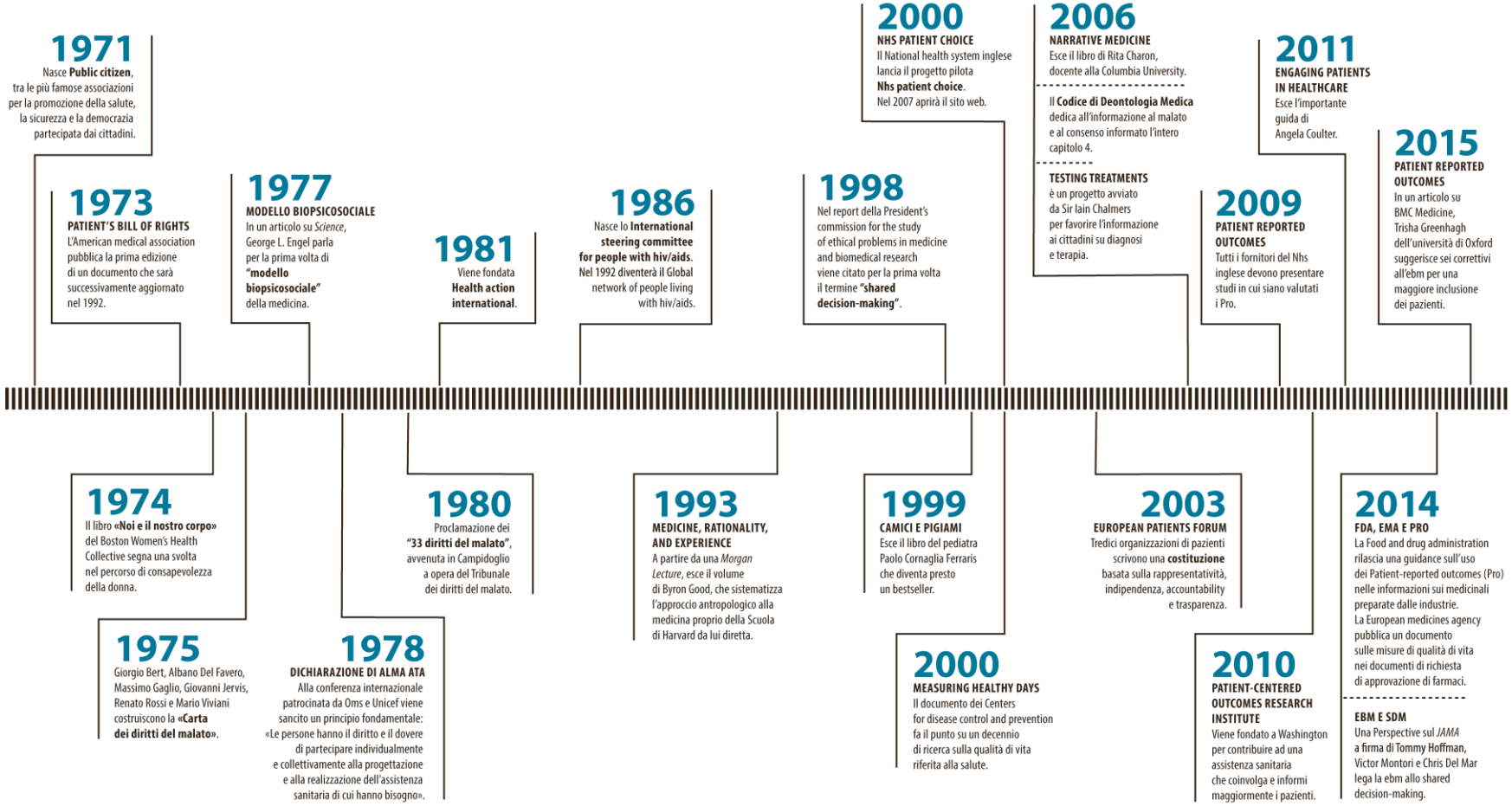
Membro del Tavolo di lavoro della Fondazione Smith Kline sulle Terapie digitali per l'Italia

https://www.fsk.it/gruppi-di-lavoro-fsk/i-gruppi-attivi/gruppi-di-lavoro-fsk-i-gruppi-attivi-progetto-terapie-digitali-italia-dtxita/

http://www.passonieditore.it/doi/tendenze/2021/numerospeciale/TerapieDigitaliTendenzeNuove.pdf

https://www.age-platform.eu/special-briefing/growing-old-digital-world

https://digital-seniors.eu/index.cfm/secid.265/lang.2



Perché «paziente esperto in DTx»?

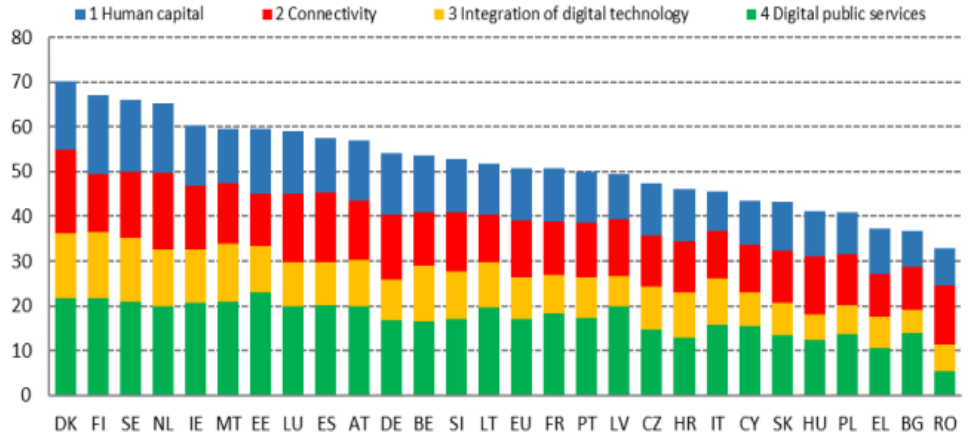


Figura 1 Digital Economy and Society Index, 2021. Source: DESI 2021, European Commission.

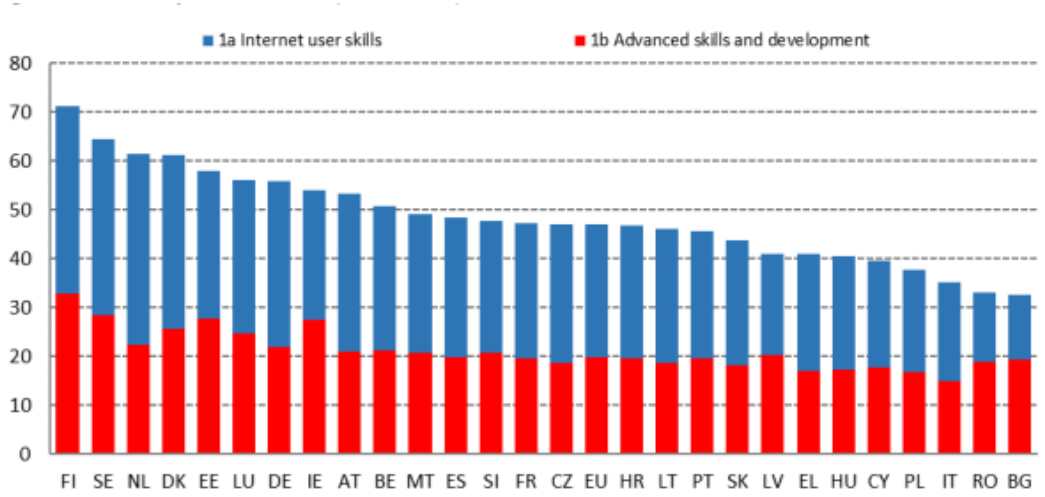


Figura 3 Human capital dimension (Score 0-100), 2021. Source: DESI 2021, European Commission.

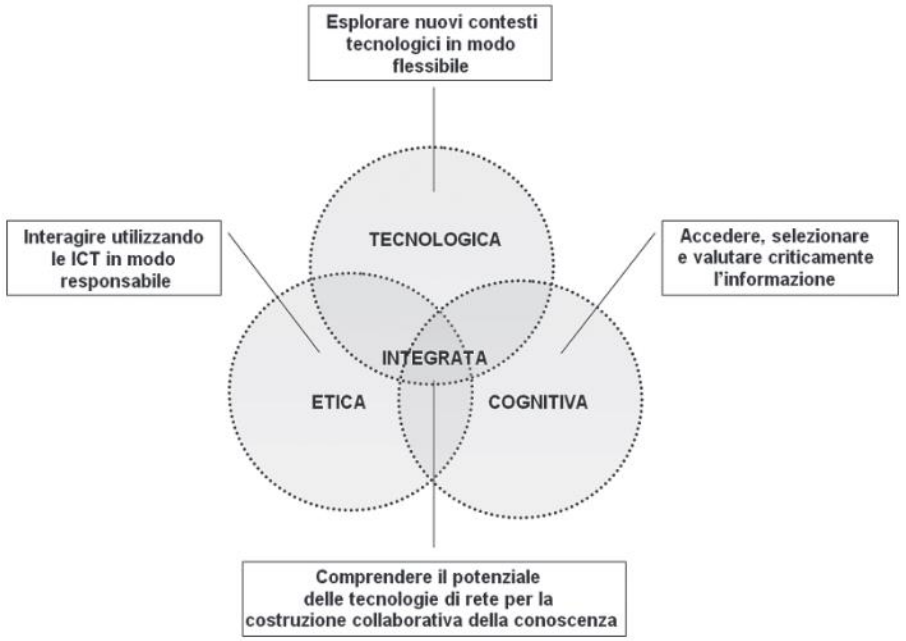


Figura 1. *Digital Competence Framework (Calvani, Fini, Ranieri, 2009)*

Connessione internet, Device, Knowledge, Digital skill

Non possono essere fattori causanti diseguaglianze in sanità e per la salute

Digital divide

Le aree di intervento per i pazienti nel processo di R&S dei farmaci

Dal *framework* EUPATI su R&S

Al *framework* nella sanità digitale per pazienti e caregiver esperti

Una proposta operativa

Corso di Formazione

Paziente Esperto in Tecnologie Digitali per la Salute

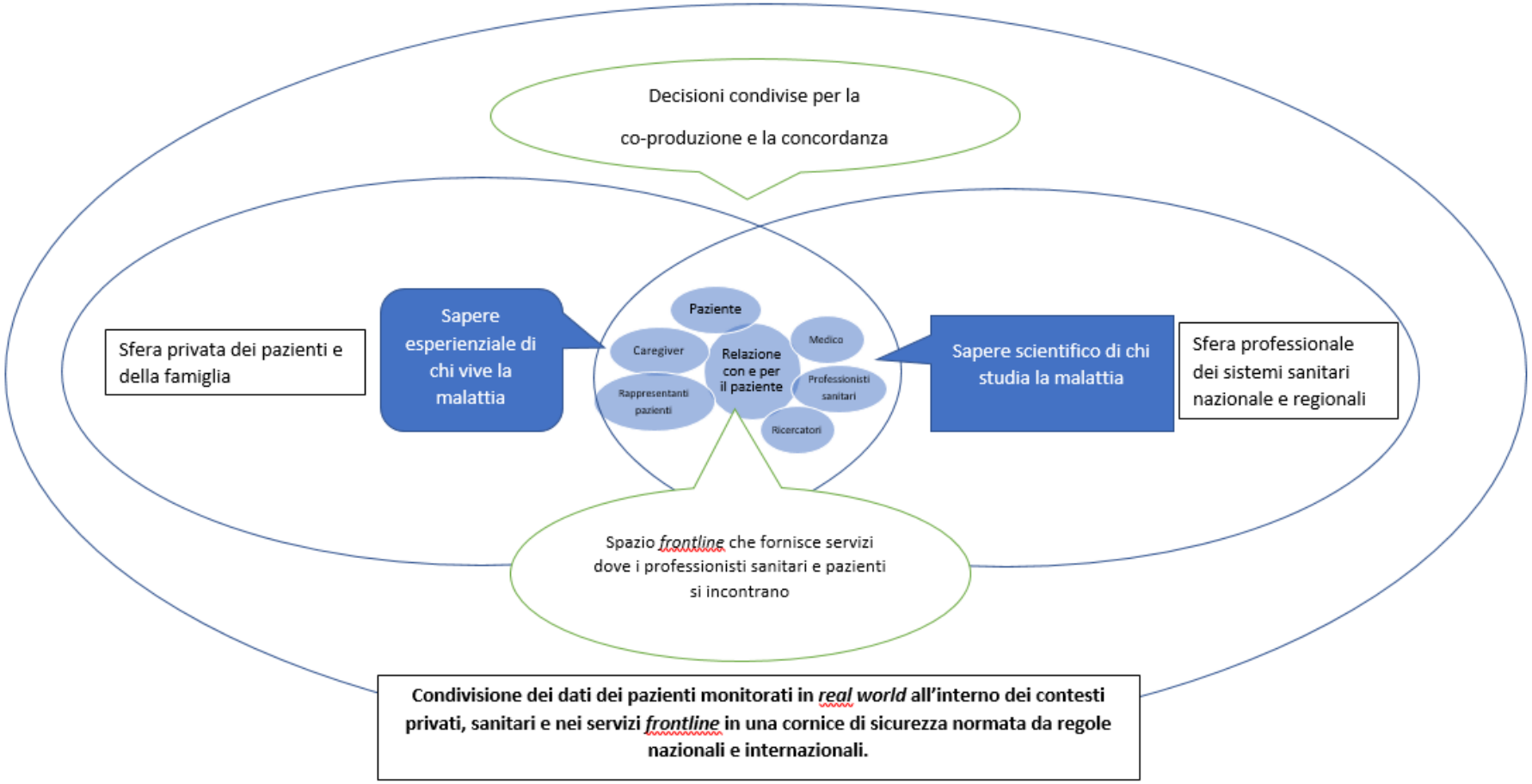
Coordinatori

Sabrina Grigolo e Giuseppe Recchia

in collaborazione con

Il setting di riferimento: un tentativo di rappresentazione

Co-produzione: input sono usati per produrre servizi che sono forniti da persone che non sono nella stessa organizzazioni (Hager et al, 2021)



Grigolo S., 2021

Background

TABLE 3 Participant Observations Regarding Types of Evidence Desired for Evaluating DTx and Determining Value

Type of Evidence	Desired Details and Questions to Consider
Required for market entry	
Information security	• Compliance with HIPAA data security requirements
Usability	• Is there a level of health/digital literacy that is required to receive benefit from the DTx? • Does the DTx operate as intended? For example, do all components of the software function as designed?
Required for evaluation of value	
Clinical effectiveness	• *Premarket:* Must demonstrate safety and efficacy using standard endpoints prior to market authorization by regulatory authority • What effect does the DTx have on clinically accepted, standard endpoints for the disease based on a measurable set of data? • What is a clinically meaningful benefit/result? • How do outcomes in the real world compare with those used for regulatory approval? • What is the effect on patient satisfaction and quality of life? • What level of evidence (e.g., RCT) is appropriate? o Will depend on the health condition/medical claim
Engagement (adherence)	• Do patients use the DTx as intended in the real world? • What "dosage" (level of sustained use over time) is required to achieve desired outcomes? • Patient acceptance of the user interface/satisfaction of using the therapeutic o Patient-reported outcomes can be used for assessment • Potential for product updates to alter the user interface and affect engagement
Safety	• What are the adverse events in clinical trials? • What are the adverse events in real-world use? • How do adverse events compare to standard of care? • What is the potential for harm? o For example, what is the effect if the patient discontinues another therapy as a result of using the DTx?
Comparative effectiveness	• How does the DTx compare with other available treatments for the condition? • The level of rigor required will depend on the potential for harm, availability of other therapies, and whether the DTx is considered an adjunct or a replacement (i.e., a standalone treatment)
Cost impact	• Can cost avoidance be demonstrated? • How does the DTx affect total cost of care?
Data access	• Who owns the data? • Who has access to the data? • How are the data used?
Ongoing evaluations	• How will product updates be assessed to provide ongoing assurances of efficacy, safety, and usability?

DTx = digital therapeutic; HIPAA = Health Insurance Portability and Accountability Act; RCT = randomized controlled trial.

Consensus Framework on the Digital Transformation of Healthcare

TABLE 3 Example of partnership-focused framework: the INVOLVE values and principles framework

Values	Summary principles	Example of measurable impact
1. Respect	Researchers, research organizations and the public respect one another's roles and perspectives	Public members' contributions are acknowledged, for example as co-applicants in research applications, as authors or co-authors of publications, or as presenters or co-presenters of research findings (1e)
2. Support	Researchers, research organizations and the public have access to practical and organizational support to involve and be involved	Public members' expenses are covered, and they are informed in advance if payment will be offered for their time (2d)
3. Transparency	Researchers, research organizations and the public are clear and open about the aims and scope of involvement in the research	Clear information is given about public members' role and what has been agreed; information is given about the time period and type of contribution (eg, partnership, advisory role, reviewer) (3b)
4. Responsiveness	Researchers and research organizations actively respond to the input of public members involved in research	Public members are listened to and changes are made to the research as a result of the insights, advice and guidance received; where changes are not made, reasons are explained (4b)
5. Fairness of opportunity	Researchers and research organizations ensure that public involvement in research is open to individuals and communities without discrimination	The diversity required for the research is considered and an effort is made to involve those who reflect that diversity (5a)
6. Accountability	Researchers, research organizations and the public are accountable for their involvement in research and to the people affected by the research	At the end of a research study, all those who have worked together actively reflect on the public involvement in the project and assess the learning and how it has gone; everyone is given an opportunity to feed back about their experience of involvement (6d)

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Greenhalgh T., Frameworks for supporting patient and public involvement in research: Systematic review and co-design pilot, Health Expectations. 2019;22:785–801.

The need for ethical guidance for the use of patient-reported outcomes in research and clinical practice

To the Editor—Patient-reported outcomes (PROs) are increasingly being used in clinical research to provide evidence of the benefits and risk of therapy from a patient perspective. PRO data from clinical trials can inform regulatory approvals and drug labeling, clinical guideline development and health policy[1]. Approximately one third of clinical trials include PROs collected through the use of patient questionnaires[2]. Beyond trials, PRO data are also increasingly captured in observational research and routine clinical care to provide information on the burden of disease and real-world evidence of treatment safety and effectiveness[3], for audit and benchmarking[4], and to monitor the status of patients and provide timely care tailored to individual needs. For instance, a study demonstrated that systematic web-based collection of information on symptoms led to improved health-related quality of life, survival and quality-adjusted survival, and fewer visits to the emergency room and hospitalization, among patients receiving chemotherapy for advanced solid tumors[5]. Patients value PRO trial results, as they can enhance clinician–patient communication about treatment options, which helps patients to feel more empowered in shared decision-making around their care[6].

Despite the benefits of incorporating PROs in research and routine practice, several ethical challenges can hinder the uptake and benefit to patients of PRO data. The PRO content of trial protocols and reporting of PRO results are often suboptimal, missing data rates are high, and delay of the publication of PRO data is commonplace. A recent study evaluating 228 studies from the National Institute of Health Research Cancer Portfolio demonstrated that 50,000 patients were involved in studies that failed to publish the PRO data collected, which is considered unethical[6].

PRO data collection is associated with a number of ethical considerations that must be addressed. An ethical consideration is defined as one that requires a choice based on moral considerations drawing on established principles, theories and values, that might have implications for the person's or society's welfare. The differing use of PROs in research and routine care settings, and review and/or use of data by clinical teams, may lead to uncertainties for patients about why data are being collected and data privacy—how their data are being viewed and used. Research indicates that in some instances, PRO measures may not reflect the perspectives of vulnerable groups or older people, which challenges bioethical principles and threatens the scientific validity of results[7]. The burden on patients associated with the completion of multiple questionnaires is also a concern. Of particular note is the lack of guidance on how staff should manage situations in which PRO data reveal 'concerning' levels of psychological distress or physical symptoms that may require an immediate response[8]. Evidence suggests research staff are handling such data inconsistently, which may lead to inequitable patient care, co-intervention bias and confusion.

Furthermore, PROs could be used for long-term follow-up to assess the impact of the coronavirus SARS-CoV-2 on patients' quality of life and alert clinicians of potential life-threating symptoms[9]. The increased use of telehealth will also heighten the use of PRO data to monitor patients' symptoms. Therefore, there is a need to ensure that this is done in an ethical way that protects patients' safety and data.

To address these challenges, the PRO Ethics Steering Group, composed of PRO methodologists, patient partners

About us

The EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network is an international initiative that seeks to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines.

It is the first coordinated attempt to tackle the problems of inadequate reporting systematically and on a global scale; it advances the work done by individual groups over the last 15 years.

- EQUATOR Network: what we do and how we are organised
- What is a reporting guideline?
- History of EQUATOR
- UK EQUATOR Centre
- Canadian EQUATOR Centre

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	

Grazie

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