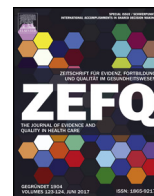




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## Shared decision making in Italy: An updated revision of the current situation



### Partizipative Entscheidungsfindung in Italien: die aktuelle Situation im Überblick

Alessandro Bottacini<sup>1,\*</sup>, Peter Scalia<sup>2</sup>, Claudia Goss<sup>1</sup><sup>1</sup> Department of Neurosciences, Biomedicine and Movement Sciences, Section of Clinical Psychology, University of Verona, Verona, Italy<sup>2</sup> The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College, 1 Medical Center Drive, Lebanon, USA

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#### ABSTRACT

The aim of this paper is to update the previous review on the state of patient and public participation in healthcare in Italy.

Policymakers consider patient involvement an important aspect in health care decisions and encourage patients to actively participate in the clinical interaction. Nevertheless, the term shared decision making (SDM) is still not clearly defined. Patient associations promote patient participation in health care decisions. Several experts attended the latest consensus conference about patient engagement to reach a consensus on the definition of SDM.

Research regarding SDM in Italy continues to increase with 17 articles published between 2012 and 2017. Researchers have assessed the variables associated with patient involvement and explored the use of the SDM approach in different medical settings.

Despite the dedicated SDM initiative, researchers in Italy recognize room for improvement. Work is needed to reach a common language regarding SDM and its mechanisms to implement this approach at the clinical level.

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#### ZUSAMMENFASSUNG

Der vorliegende Beitrag stellt die Aktualisierung eines früheren Reviews zum Stand der Partizipation von Patienten und der Öffentlichkeit am italienischen Gesundheitswesen dar. Politische Entscheidungsträger sehen die aktive Beteiligung von Patienten an gesundheitsbezogenen Entscheidungen als wichtig an, auch wenn der Begriff „partizipative Entscheidungsfindung“ (PEF), so wie er uns geläufig ist, noch nicht ausdrücklich erwähnt oder beschrieben worden ist. Von den Patientenverbänden wird die Partizipation der Patienten und Bürger an gesundheitsbezogenen Entscheidungen aktiv gefördert. Mehrere Experten nahmen an der letzten Konsensuskonferenz zur Patientenbeteiligung teil, um zu einer gemeinsamen Definition von PEF zu gelangen.

Die Forschungstätigkeit zum Thema PEF hat in Italien zugenommen. So wurden von 2012 bis 2017 17 Beiträge publiziert, in denen verschiedene mit Patiententeilhabe verbundene Parameter sowie der Einsatz von PEF in unterschiedlichen medizinischen Bereichen untersucht wurden.

Trotz der Initiative zur Förderung von PEF sehen Wissenschaftler in Italien noch Raum für Verbesserungen. So sollten weitere Anstrengungen unternommen werden, um zu einem einheitlichen Verständnis bezüglich PEF und der Mechanismen zu gelangen, mit deren Hilfe PEF im klinischen Bereich implementiert werden kann.

#### Introduction

Since the previous report published in 2011 [1], there has not been considerable progress towards wider implementation of shared decision making (SDM) in Italy. Patients are invited to actively participate in their healthcare decisions and advocate for

\* Corresponding author: Alessandro Bottacini, PhD, Psychologist, Department of Neurosciences, Biomedicine and Movement Sciences, Section of Clinical Psychology, University of Verona, Policlinico G.B. Rossi, Piazzale L.A. Scuro 10, 37134 Verona, Italy.

E-mail: [alessandro.bottacini@univr.it](mailto:alessandro.bottacini@univr.it) (A. Bottacini).

SDM policies in their community [2]. Based on scientific evidence, we are aware of the process and principles underpinning medical decision-making. Decision-making in healthcare has different levels [3]: a) the *macro* level - decisions on resource allocation and utilization; b) the *meso* level - clinical decisions on optimal treatment policies for groups of patients with the same disease or similar clinical characteristics, e.g. development of guidelines; c) the *micro* level - refers to SDM for the individual patient. In recent years, the public has advocated for support at all three levels.

The aim of this paper is to update the current state of patient and public participation in healthcare in Italy. This paper provides a description of: i) the Italian National Health Service organization; ii) the latest governmental and institutional initiatives regarding patient participation; iii) the current associations and initiatives promoting patient participation; iv) the latest research projects on patient participation published in peer-reviewed journals; and v) the training initiatives to promote patient participation.

We searched the official websites of the *Italian Ministry of Health* to retrieve relevant documents, and identify individuals working in the area of shared decision making [4]. We also conducted a literature review using the PubMed and Cochrane databases to identify research articles on patient participation and shared decision-making (SDM) in Italy since 2011 using the following key words: patient participation, patient involvement, empowerment, shared decision-making and Italy. We also searched Google, using the same key words, to find Italian sites discussing initiatives related to patient participation in health care and SDM.

The following paragraphs aim to give a general overview of the current initiatives in Italy regarding SDM and patient participation in healthcare, and is not meant to be exhaustive.

### Brief description of the Italian National Health Service

The *Italian National Health Service (Servizio Sanitario Nazionale/SSN)* was established with the aim of providing efficient, universal healthcare to all Italians, regardless of socioeconomic status, employment status, or pre-existing health conditions. The organization functions at three levels: national, regional and local. The institution at the national level is the *Ministry of Health (Ministero della Salute)* [4]. It is responsible for setting the overall objectives of the SSN (through the National Health Plan), controlling the drug market and its related research (in conjunction with the Italian drug agency: *Agenzia Italiana del Farmaco - AIFA*), national prevention programs (e.g., information on vaccinations) and veterinary medicine. It also coordinates a cooperation of 40 public and private hospitals (*Istituti di Ricovero e Cura a Carattere Scientifico - IRCCS*) which are dedicated to research. The regional government is responsible for planning, financing, controlling, and supervising the efficacy, quality and the provision of services through public and private health organizations at the regional level. On the local level, more than 200 local health authorities (*Azienda Sanitaria Locale/ASL*) administer the SSN.

### Governmental and institutional initiatives regarding patients' and citizens' participation

The 2010-2012 *National Health Plan*, yet to be updated by policymakers, recognizes the importance of patient participation in decision-making processes, and highlights the paradigm of patient-centered medicine oriented towards a "shared and active health promotion" [5]. In this context, doctor-patient communication and patients' involvement in treatment decisions are essential. Patients are considered "empowered" if they have the "knowledge, awareness and ability necessary for influencing their own and

others' behaviors, in order to improve their quality of life". Policymakers acknowledge that people need to play an active role in planning, controlling and evaluating the health and social services both at regional and local health authority level.

A more recent plan is the *Prevention Plan (2014-2018)* [6] that stresses the importance of preventative medicine in health, but does not explicitly mention shared decision making or patient involvement. However, it underlines the vision of creating a patient-centered culture where citizens (both healthy and ill), with their expectations and needs, are the focal point.

The shared decision making community has yet to reach a consensus on a clear definition of shared decision making. The lack of 'common language' is reflected in the Plan, and makes it difficult to compare the Italian situation with other European countries. Moreover, we recognize the lack of tools for evaluating SDM processes at macro and meso levels. The Italian version of the *OPTION scale* [7] and the *Shared Decision Making-Questionnaire (SDM-Q-9)* [8] remain the only validated scales used at the micro level for evaluating SDM in terms of the doctors' abilities and the patients' perspective.

### Examples of associations and initiatives promoting patient participation at the meso and macro level

In recent years, few projects aimed at organizing and promoting patient participation in healthcare have been endorsed by public and private institutions.

In 2016, a conference titled: "*Promoting patient engagement in care processes with evidence-based and impact measures*" took place in Milan, Italy [9]. The workshops included different representatives involved in the promotion of patient engagement and participation (eg. researchers, clinicians, patient associations, experts of new technology). The conference was part of a larger research program promoted by the Lombardy region, called "*Open Innovation project* [10]". The project aimed at reaching an agreement among experts on the most effective tools and strategies to promote patient engagement. Several experts from various sectors of the medical, business, and academic communities attended the event with the objective of setting evidence-based recommendations for the patient's active involvement in the healthcare process. Throughout the conference, experts highlighted the change in perception of patient's role as "an epochal transformation". They stressed the importance of the patient's active involvement in prevention and treatment phases, since the aging of the population is directly proportional to the increase in chronic diseases. Unfortunately, the growing attention to patient engagement by researchers is not correlated with an increase in concrete initiatives to promote the patient's active involvement.

"*Partecipa salute*" (*Participate in health care*) [11] remains an active project promoted by *The Mario Negri Research Institute* (Milan) aimed at fostering a strategic alliance between patients (or groups) and professionals (institutions and/or societies), with the common goal of promoting better health care and patients' involvement.

The non-profit organization "*Cittadinanza attiva*" (*Active Citizenship*) [12] remains very active on the national front with the primary aim of promoting civic participation for the care of the common good, particularly healthcare, and the defense of citizens' rights.

Another example of associations working to promote and protect patient's rights is "*Difesa del Malato*" (*Ill Person Defense*) [13]. It raises awareness, through social media, of elements that could jeopardize the health of individuals. In addition, it promotes cultural activities to increase participation and commitment in Italian communities.

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