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SYMPOSIUM – “Give me five”: “Choosing Wisely” in Italy. Five things not to be done

Looking for waste and inappropriateness: if not now, when?

Gianfranco Domenighetti • Sandra Vernero

Abstract A look at the international medical literature shows the importance of waste and inappropriateness defined as futile and inadequate services that may not be beneficial for patients but rather expose them to additional risks, to over-diagnosis and over-treatments. A 2010 WHO report estimates that the amount of services providing no benefit to patients accounts for approximately 20-40% of healthcare spending. The main drivers of the inappropriateness and waste in clinical practice are the economic incentives, the uncertainty that characterizes the medical practice, conflicts of interests and defensive medicine. Although Italy ranked below the OECD (Organisation for Economic Co-operation and Development) average in terms of health spending per capita in 2011, this evidence does not mean that the Italian Health System is characterized by an underuse of medical services or by a low level of prescriptions inappropriateness. In reality, the low Italian spending seems to be due of a huge shortage of nurses and hospital and nursing home beds for long-term care for the elderly. This framework collides with the general exuberance of availability of high technological devices and departments of highly specialized medicine. In Italy, at the end of 2012, the movement “Slow Medicine” launched a project named “Doing more does not mean doing better”, similar to “Choosing Wisely” initiative in the USA. The focus of the project is fighting against overuse of medical services, which is not only a leading factor in the high level of healthcare expenditures but also places patients at risk of harm. To date, 7 Italian national medical specialty societies and associations have already created their lists of tests and treatments at risk of inappropriateness and other 12 also joined the project and are creating their lists. One list has been created by Italian Specialty Societies of Nurses too, and others will follow. The project is also promoted by FNOMCeO (National Federation of Medical Doctors’ and Dentists’ Colleges), IPASVI (National Federation of Nurses’ Colleges), and other patients and consumers associations. In addition to the Italian medical specialty societies and associations, some hospitals also started to identify tests and treatments whose necessity should be questioned and discussed. Until now the project “Doing more does not mean doing better” has aroused the enthusiasm of physicians and of other health professionals, as it is based on their own responsibility in the appropriate use of resources. We believe that the success of the project will, to a large extent, depend on the sense of responsibility and on the ethical involvement of the participating physicians in particular. The active involvement of patients, in fact, is likely to remain a mythical desire for the vast majority of them and for many years to come.

Riassunto *Uno sguardo alla recente letteratura medica internazionale mostra come i sistemi sanitari siano caratterizzati anche dall’importanza degli sprechi e dell’inappropriatezza, definiti come servizi e prestazioni futili che non danno in generale nessun beneficio ai pazienti sottoponendoli invece a rischi addizionali, a sovra-diagnosi e sovra-trattamento. Un rapporto dell’OMS del 2010 stimava tra il 20 e il 40% della spesa sanitaria la prevalenza delle prestazioni e dei servizi che non danno nessun beneficio ai pazienti. I principali fattori che promuovono l’inappropriatezza e gli sprechi sono gli incentivi economici sia individuali che aziendali, l’incertezza che caratterizza la pratica medica, i conflitti di interesse e la pratica della medicina difensiva. Benché il sistema sanitario italiano abbia un costo per abitante inferiore a quello medio dei paesi dell’OCSE (Organizzazione per la Cooperazione e lo Sviluppo Economico), ciò non significa che esso sia caratterizzato da un sotto-utilizzo dei servizi oppure da un livello inferiore di inappropriatezza prescrittiva. In realtà il*

G. Domenighetti (✉)
Slow Medicine and Università della Svizzera Italiana,
Lugano, Switzerland
Email: gianfranco.domenighetti@usi.ch

S. Vernero
Slow Medicine and Azienda USL di Bologna, Italy.

confronto con gli altri paesi indica che il basso livello di spesa pro-capite in Italia è soprattutto dovuto a una importante carenza di infermieri e di posti letto in ospedali e in strutture per l'assistenza a lungo termine degli anziani. Quest'ultimo quadro collide con la generale esuberanza e sovra-dotazione di tecnologie di punta e di reparti di alta specializzazione medica. Per promuovere una miglior appropriatezza delle cure in Italia, alla fine del 2012 il movimento Slow Medicine ha promosso e implementato un progetto denominato "Fare di più non significa fare meglio" simile all'iniziativa "Choosing Wisely" negli USA. Scopo del progetto è lottare contro l'uso non appropriato di tecnologie e prestazioni sanitarie, che rappresenta non solo uno spreco economico di risorse ma sottopone i pazienti a rischi addizionali non giustificati. A tutt'oggi 7 società medico-scientifiche nazionali hanno già elaborato le loro liste di prestazioni a rischio di inappropriatezza e altre 12 hanno aderito al progetto e stanno procedendo nell'elaborazione delle rispettive liste. È stata anche definita una lista da parte di società scientifiche infermieristiche e altre seguiranno. Il progetto è pure sostenuto dalla FNOMCeO, dall'IPASVI nonché da altre associazioni di pazienti e consumatori. Inoltre alcuni ospedali stanno identificando al loro interno tali pratiche a rischio. Fino a ora il progetto "Fare di più non vuol dire fare meglio" ha suscitato l'entusiasmo dei medici e degli altri professionisti della salute, probabilmente perché esso si fonda sulla loro responsabilità verso un utilizzo appropriato delle risorse. Infatti il successo del progetto dipenderà in larga misura dal senso di responsabilità e dal coinvolgimento etico dei professionisti partecipanti, mentre il coinvolgimento attivo dei pazienti è probabilmente destinato a rimanere un "augurio" la cui concretizzazione, per la stragrande maggioranza di loro, non sarà possibile che tra molti anni a venire.

Background

According to the Research ANd Development (RAND) Corporation, clinical "inappropriateness" in medical care is defined as "*…services for which the expected risks or negative effects significantly exceed the expected benefits for the average patient with a specific clinical scenario"* [1]. According to Brody, "waste" can be defined as "*spending for interventions that do not benefit patients",* actually amounting to at least 30% of the US healthcare budget [2]. A 2010 WHO report estimates that the amount of services providing no benefit to patients accounts for approximately 20-40% of healthcare spending. It is important to point out that another important source of waste and inappropriateness at macro-, meso- and micro-levels is to be found in the way healthcare services are organized and managed. The waste of resources in healthcare, especially when these are limited, may hamper the possibility for society to guarantee a fair access to its citizens to the highest level of health and well-being.

A simple look at the international medical literature shows the importance of waste defined as futile and inadequate services that are not beneficial for patients but rather expose them to additional risks, to over-diagnosis and over-treatments. About half of angioplasties in patients with stable angina is inappropriate [3], as both the 23.4% of colonoscopies [4] and the 55.7% of magnetic resonance imaging (MRIs) at the lumbar spine [5] are. Eighty percent of "new" drugs on the market is copy of existing ones and only 2.5% represents a major therapeutic advance [6]. Also variations in healthcare utilization, among regions and socio-economic groups, raise fundamental questions about misuse, over- and underuse, effectiveness, efficiency, equity and appropriateness of professional decision-making [7]. For instance outpatient antibiotic prescription between European countries varies by a factor of 4 [8] as do among regions in Italy [9].

The four main drivers of the inappropriateness and waste in clinical practice are:

- the individual economic incentives (in particular a fee-for-service remuneration) and the need to achieve corporate or business goals that lead to a multiplication of diagnostic and therapeutic services;
- the uncertainty that characterizes the medical practice and, consequently, the more or less strict compliance with "evidence-based" guidelines;
- conflicts of interest, and
- defensive medicine.

"Choosing Wisely" and the "Top Five" list

Although the Institute of Medicine invited physicians to avoid overuse, underuse and misuse since many years [10], the main focus has been directed towards the problems of underdiagnosis and undertreatment, while neglecting overtesting, overdiagnosis and overtreatment.

"Medical Professionalism in the New Millennium: A Physician Charter" [11], published in 2002 and authored by the American Board of Internal Medicine (ABIM) Foundation, the American College of Physicians Foundation, and the European Federation of Internal Medicine, was a first call for physicians to lead the effort against overuse of medical practices. The charter, having as its fundamental principles the primacy of patient welfare, patient autonomy, and social justice, specifically called on physicians to be responsible for the appropriate allocation of resources and to avoid unnecessary tests and procedures.

In the same year, the British Medical Journal published the

issue "Too Much Medicine?" [12] with articles on the medicalization of many aspects of ordinary life.

More recently, in 2010, the "Less Is More" series of articles [13] published in the Archives of Internal Medicine, focused on the need to counter the belief that "if some medical care is good, more care is better".

Still, in 2010, Howard Brody [14] proposed, as a concrete action, to have each specialty society to prepare a specific specialty-related "Top Five" list. "*The Top Five list would consist of five diagnostic tests or treatments that are very commonly ordered by members of that specialty, that are among the most expensive services provided, and that have been shown by the currently available evidence not to provide any meaningful benefit to at least some major categories of patients for whom they are commonly ordered*".

The US National Physicians Alliance (NPA) was the first to put Brody's concept into practice with a set of three top 5 lists in internal medicine, family medicine and pediatrics [15].

In April 2012, the ABIM Foundation, together with Consumer Reports, launched the "Choosing Wisely" [16] campaign. After asking leading physician specialty societies to create a "Top 5" list of medical services that provide no overall benefit to patients in most situations, they published lists from nine specialty societies [17]. The outcome was, for each society, to develop lists entitled "Five Things Physicians and Patients Should Question" [18]. These lists were aimed at stimulating discussion between clinicians and patients about the need – or lack thereof – for many frequently ordered tests or treatments.

Additional societies and consumer groups joined the effort in the following months. In April 2014, 52 specialty specific lists and 290 tests and treatments were released overall. Most of them are tests and more than a third (98) concerns imaging.

Waste and inappropriateness in Italy

Although Italy ranked below the OECD average in terms of health spending per capita in 2011, this evidence does not mean that the Italian Health System is characterized by an underuse of medical services or by a low level of prescriptions inappropriateness. In reality, the low Italian per capita health spending seems to be due: 1) to the low ratio of practicing nurses compared to other OECD countries (Italy 6.3 per 1000 population/average OECD 8.8/Denmark and Belgium 15.4) who earn relatively low wages, and 2) to the worst ratio of hospital and nursing home beds for long-term care for the elderly (Italy 18.6 beds for 1000 population aged 65 and over/average OECD 49.1/France 59.5/UK 51.7/Sweden 73.4) [19]. This framework of huge shortage of essential resources for care and for a fair technical assistance, relationship and emotional support to patients, collides with the general exuberance of availability of high technological devices and departments of highly specialized medicine although often under employed.

Some examples: in the years 2011-2013 Italy ranks first in Europe for computed tomography (CT) scan with a ratio to one million population of 32.11 devices (France 12.52/UK 8.92/Netherland 12.5), for MRI the ratio was of 26.68 (France 7.5/UK 5.9/Netherland 12.9) [19] and for robotic surgery devices Da Vinci of 1.1 (France 1.05/Germany 0.75/UK 0.56) [20]. In Italy, heart transplants are carried out in 17 centers but only one of them has reached, in the 2012-2013 period, the average minimum standard of 25 transplants per year, as decided by the State-Regions conference [21]. Seven of the 12 cardiac catheterization laboratories of the metropolitan area of Milan perform less than 400 angioplasties per year (minimum caseload criterion according to Italian Society of Invasive Cardiology-GISE) treating in this way from 0.4 to 0.9 patients per day [22].

Research on healthcare variations probably represents the best way to address the question of misuse, over- and underuse in the utilization and prescription of medical services at the macro level. They raise fundamental questions about effectiveness, efficiency, equity and appropriateness of professional decision-making. Some examples: at international level, Italy ranks first in Europe for CRT (cardiac resynchronization therapy) implantations (168 per million population/Germany 115/France 84/UK 77) and for implantable cardioverter-defibrillator (Italy 310 per million population/Germany 262/France 128/UK 74) and second for pacemaker implantations (Italy 1064 per million population/Germany 1193/France 983/UK 632) [23]. The same is true for caesarean section rates per 100 live births (Italy 38.4/France 20/Germany 30.3/UK 23.7/Netherland 14.3) and for antibiotic consumption (Italy 30.2 DDD per 1000 population-die/France 30/UK 17.7/Netherland 10.4) [19]. Also, the variability of some interventions among the Italian regions should put the issue of over- and underuse of medical services as a public health priority. As an example, the hospitalization rates for angioplasty vary 13.5 folds among Italian regions (from 8 per 100,000 inhabitants to 108) [24]. It is important to point out that the medical profession has always been uncritical to practice variations. Nevertheless it had to take responsibility for the question: "Which rate is right?" Otherwise, in the current cost-containment context, the theory of "The lowest is always the best" will dominate by default.

Some Italian studies deal specifically with the theme of the appropriateness of some medical services.

According to Cristofaro et al. [25], only 56% of outpatient radiology requests would be appropriate, and the Italian Society of Medical Radiology has estimated that 33% of all

radiological examinations is inappropriate [26]. A list of possible waste in clinical decision making in Italy is reported by Alberto Donzelli [27] and concerns pharmaceutical prescription, angioplasty for stable coronary disease, spirometry to motivate smokers to quit, PSA screening in asymptomatic men with no risk factors and no hereditary family history.

We performed a Medline search of papers relating to medical practices carried out in Italy in the past 10 years published by an Italian medical author or coming from an Italian Institution. We found that the number of papers reaches the 167,296 units. Among the latter, 141 concerned clinical inappropriateness (0.084%) and 47 organizational inappropriateness (0.03%). Hence, according to the scientific literature published over the past 10 years, the Italian Healthcare System does not seem to identify major problems regarding «misuse» and «appropriateness» in the clinical activity and as well in organizational field.

The findings presented here suggest that:
- medical overuse and underuse are well implemented in the Italian Healthcare System even if it is not possible to quantify them precisely;
- medical practices are often based on "personal guidelines" rather than on "evidence based" ones, and finally that
- other factors (i.e. economic incentives, conflicts of interest, availability of technology, medical and hospital supply density, habits) seem to influence the appropriateness of medical practice.

Taking into account the scarcity of published scientific literature from Italian medical authors or Institutions on medical misuse, appropriateness, adequacy and variation in healthcare utilization, one must conclude that these issues are not of great interest to the medical community in Italy. Times are ripe to change this trend.

The Italian project "Doing more does not mean doing better"

In Italy, at the end of 2012, "Slow Medicine" [28] (an Italian movement founded in 2011, opened to health professionals, patients and citizens and aimed at the promotion of a Measured, Respectful and Equitable Medicine) launched a project named "Doing more does not mean doing better" [29], similar to "Choosing Wisely" in the USA.

The focus of the ongoing project is overuse of medical resources, which is not only a leading factor in the high level of healthcare expenditures but also places patients at risk of harm.

The Italian project involves physicians as well as other health professionals in the responsibility for the appropriate use of medical resources.

The project is also promoted by:
- The National Federation of Medical Doctors' and Dentists' Colleges (FNOMCeO);
- The National Federation of Nurses' Colleges (IPASVI);
- The Italian Society for Quality in Healthcare (SIQuAS VRQ);
- Change Institut – a training agency in communication and systemic counseling in Turin;
- Partecipa Salute – a project established by IRCCS-Mario Negri, Italian Cochrane Centre and Zadig Srl. aimed at participation of patients and citizens in healthcare;
- InversaOnlus – the Italian association of patients with hidradenitis suppurativa;
- Altroconsumo – an Italian consumers' association which counts 345,000 members;
- Slow Food Italy – founder of and component of Slow Food International (100,000 members in 150 countries).

A steering group of the project with representatives of these associations was created in March 2013.

According to Brody, each specialty society engaged in the project must develop a list of the top 5 field-specific tests and treatments that are commonly ordered in Italy, but the necessity of which should be questioned and discussed. This is mainly because:
- they have been shown by the currently available evidence not to provide any meaningful benefit to at least some major categories of patients for whom they are commonly ordered;
- they may cause harm to patients.

The cost of tests and treatments was not included among the criteria of choice.

To date, the following national specialty societies and associations are involved in the project and created their lists of tests and treatments at risk of inappropriateness:
- Italian Society of Medical Radiology – SIRM
- Italian Association of Radiation Oncology – AIRO
- Italian Board of Medical Oncology Directors – CIPOMO
- Cochrane Neurological Field in Italy – CNF
- Italian Association of Dietetics and Clinical Nutrition – ADI
- Italian Society of General Practitioners – SIMG
- Italian Specialty Societies of Nurses of: Operating Theater, Stomacare, Skin Ulcers, Hospital Medicine – AICO, AIOSS, AIUC, ANIMO
- Italian Association of Hospital Cardiologists – ANMCO.

The first seven Italian lists were released in March 2014 [30]. The total number of practices was 32 (11 tests and 21 treatments), as 3 of them were chosen by two specialty societies.

Among them, 13 (6 tests and 7 treatments) were equal or similar to practices in "Choosing Wisely", while 19 (5 of tests and 14 treatments) were different.

The following national specialty societies and associations also joined the project and are creating their lists:
- Italian Association of Neuroradiology – AINR
- Italian Association of Psicogeriatrics – AIP
- Italian Association of Medical Diabetologists – AMD
- Italian Association of Hospital Dermatologists – ADOI
- Italian Federation of Associations of Hospital Internal Medicine – FADOI
- Italian Society of Human Genetics – SIGU
- Italian Society of Allergy, Asthma and Clinical Immunology – SIAAIC
- Italian Association for the Promotion of appropriate care in Obstetrics, Ginecology and Perinatal Medicine – ANDRIA
- Italian Association of Nuclear Medicine – AIMN
- Italian College of Chief Vascular Surgeons – COLLPRIM-VASC
- Italian Federation of Pediatricians – FIMP
- Italian Society of Palliative Care – SICP
- Other Italian Specialty Societies of Nurses.

As in "Choosing Wisely", physicians and patients should have conversations and discuss the use of these tests and treatments, in view of wise and shared choices taking into account patients' values, expectations and desires.

The societies and associations promoting the project or involved in the creation of the lists, will play a key role for informing health professionals about the project and about the tests and the treatments whose necessity should be questioned and discussed in Italy. They will also promote physicians and other health professionals education and training on Evidence Based Medicine, on Medical Humanities and on practices to improve the interaction and the relationship with patients.

Patients and citizens will have an active role in the project. They will collaborate with health professionals for the development of patient-friendly material about overused tests and treatments as well as in widely disseminating the culture that "Doing more does not mean doing better" and that less healthcare can often result in better health.

The project aims at promoting links among the various medical professionals on the one hand, and between medical professionals and "citizen-patients" on the other, with the objective of building up joint or consensual actions and choices for the future.

It is very important for everyone to understand that the goal of the project is to protect patients' interests and not to "ration" healthcare for cost-cutting purposes. Treatments and diagnostic tests that are inappropriate for patients may not only be harmful but may also produce false positive results and overdiagnosis, that in turn lead to more tests, treatments and complications [2].

"*Primum non nocere*" becomes the strongest argument for eliminating non beneficial medicine [31], towards the Measured, Respectful and Equitable approach promoted by Slow Medicine.

A first practical application of the project will be carried out in Turin, with the collaboration of the local section of the Italian Society of General Practitioners (SIMG). Starting from the practices already chosen by the SIMG, other actions will follow, namely:
- a specific training of physicians focusing on the acquisition of communication and of counseling skills;
- the development of patient-friendly material about the overused tests and treatments identified;
- a specific communication campaign to patients and citizens;
- a quantitative and qualitative assessment of the impact of the initiative.

The project also arrives at the hospital setting

In addition to the Italian specialty societies and associations, some hospitals also started to identify tests and treatments whose necessity should be questioned and discussed. The first were the hospitals in Cuneo (Italy) and in Locarno (Switzerland).

In Cuneo, the CeO of the hospital launched a project in September 2013, asking the medical directors of each ward to create a "Top 3" list of medical services that provide no overall benefit to patients in most situations.

All the 33 wards participated in the project and 96 practices (63 tests and 33 treatments) were identified. Out of the 96 practices, 37 were either equal or similar to those in "Choosing Wisely" and some were equal or similar to practices identified by the Italian specialty societies and associations.

In Locarno, the following topics were identified:
- patient blood sampling and x-rays for each day of hospitalization;
- antibiotic consumption;
- proton pump inhibitor consumption;
- benzodiazepine/zolpidem consumption.

Again, these topics were similar to those in "Choosing Wisely" and in the Italian Project (chosen by specialty societies and by the Cuneo hospital). Attention will be given to the training of physicians and to the measurement of the chosen practices through specific indicators and a clinical database.

Other Italian hospitals and health organizations (Reggio Emilia, Alessandria, Ferrara, Trento, Verona…) are expected to plan similar projects in the next future.

Which could be the main obstacles to be overcome for achieving the goals of the project "Doing more does not mean doing better"?

The main obstacles regarding the implementation of the project are to be found on the demand side (patients) and on the supply as well (service providers).

Problems on the demand side

As "Choosing Wisely" did, the Italian project postulates the active involvement of patients (alliance between doctors and citizen-patients) to promote discussion with their clinicians about the need – or lack of it – to perform this or that test or treatment. Such "alliance" requires a "minimum" of clinical education on the patient's side, in order to allow him (or her) to express preferences and to interact with physician about the utility or futility of the proposed diagnostic and/or therapeutic service. This condition cannot be easily met today even if no specific survey on health literacy skills has been carried out in Italy. Nevertheless, in the last OECD survey on adult literacy and numeracy skills, Italy reaches the worst rank among 24 countries [32].

Consequently, the dominant physician-patient relationship will still remain "paternalistic", where the patient, not having technical knowledge, slavishly follows, without interaction, the suggestions of his (or her) doctor. Last, but not least, it is worth asking to what extent citizen-patients will perceive the "inappropriateness" of a medical service as an implicit rationing or the prelude to an explicit one.

Problems on the supply side

The project and the list of services at risk of inappropriateness should not be a "fig leaf" for the participating scientific societies [33].

To avoid this adverse event it seems mandatory for every society to implement 1) a monitoring system able to inform to what extent individual physicians will actively join the project and 2) an evaluation program to follow the trend of the prevalence of practices – identified as being at high risk of inappropriateness – over time. This could be very easily implemented at a hospital level, while it would require both an investment and an innovative organizational framework at the territorial level.

In reporting the most common overused medical services in the US "Choosing Wisely" campaign (as in the "Doing more does not mean doing better" project), it was highlighted that the majority of listed items targeted "imaging" [34]. This fact points out the need to promote strong links and to build up consensual actions between radiologists and other medical professionals who prescribe radiological images.

It would be highly desirable to enhance the radiologists' role in order to reduce the overuse of imaging tests prescribed by other medical specialists. Should radiologists play more a role of gatekeeper rather than of service provider [35]? Or, at least, should they become more involved in decisions regarding the appropriate use of their services thus supporting other clinicians in the decision-making process beyond the economic incentives to overuse?

Last, but not least, more numerous and more courageous lists having a real impact on clinical practice should be developed and published.

Two other questions could be seriously taken into account to avoid the suggested "fig leaf" effect.

To what extent the propensity to avoid medical practices at a high risk of inappropriateness will be "honored" when that choice collides with economic individual or corporate incentives? To what extent the fear of litigation (defensive medicine) will influence the appropriateness of prescribing behavior?

Conclusions

The project "Doing more does not mean doing better" has aroused the enthusiasm of physicians and of other health professionals, as it is based on their responsibility in the appropriate use of resources.

At this moment, it is not perceived as a top down initiative (or as an "administrative directive"), as it was launched by a movement of health professionals and of citizens and not by institutional bodies. Above all, they appreciate that the main goal of the project is to improve the quality and appropriateness of care and to ensure the safety of patients. It is most likely for these reasons that a lot of specialty societies of physicians and nurses, as well as hospitals, are joining the project. Also, consumers' association as Altroconsumo are supporting it.

We believe that the success of the project will, to a large extent, depend on the sense of responsibility and on the ethical involvement of the participant, physicians in particular. The active involvement of patients, in fact, is likely to remain a mythical desire for the vast majority of them and for many years to come. However, the project can be a powerful tool for the community health education. In order for this to happen, though, it should be supported by an intense and intelligent communication campaign addressed to the general public and not only to elitist groups of consumers. In fact, the physician-patient encounter may not be sufficient to change habits and behaviors that are already deeply entrenched [34].

Finally, it seems inescapable to implement a program to assess and monitor the impact of the project.

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