Toward a sustainable and wise healthcare approach: potential contributions from hospital Internal Medicine Departments to reducing inappropriate medical spending

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ABSTRACT

All countries are facing the question of how to maintain quality of care with shrinking health budgets, in the presence of a persistent increase in life expectancy, and with a significant growing demand for health care from aging populations and chronically ill patients. Current implementation of legislative measures is largely presented as a cost-cutting policy. With this political approach, there is a risk of services and the number of hospital beds being drastically reduced, mainly to detriment of the most vulnerable groups of the population and without considering the results obtained by each regional healthcare organization according to explicit evaluation markers. In our Scientific Society of Internal Medicine (the Federation of Associations of Hospital Doctors on Internal Medicine, FADOI), we want to support good medical practice because *essential* medicine is still a goal to be achieved throughout medical hospital care. We are looking for original ways to implement a sustainable and frugal hospital Internal Medicine policy by searching for wise and efficient clinical methodology to be applied in the care of patients admitted to internal medicine wards according to their real needs. We firmly believe that reinforcing a common agenda between medicine and public health, and sharing a common vision among professionals and decision makers in the planning of care, may be the greatest opportunity for any every health care reform. The future of the health care system cannot be restricted to mere cost reduction, but should aim to deliver better health care in relation to the money spent. Even in this period of austerity, new opportunities can still be found and doctors must lead efforts to meet this challenge.

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Dr. House's prescription: more medicine is better (?)

Dr. House: *'Do an amylase, D-dimer, c-reactive protein, get a urine, and do a bronchial sputum while you're at it. You, check his… lab for radiation and toxins. And do a bone-marrow biopsy.'*

Younger doctor: *'All of that in twenty-four hours?'*

Dr. House: *'Nah, whatever you don't get done, you can finish at the autopsy.'*

from an episode of *Dr. House-Medical Division* that went out on air in 2006, http://www.kaiserhealthnews.org/stories/2009/september/01/doctor-house-and-health-costs.aspx

Introduction

According to the latest data from the Ministry of Health, in Italy, over the past ten years health spending has increased from 76 to slightly less than 113 billion euro, with a growth of approximately 37 billion euro. Government data for the year 2011[1] have shown that Italian public healthcare spending is equivalent to 7.1% of gross domestic product (GDP), and 1842 euro per capita per year. In a comparison between Italy and the European Union, the incidence of public health expenditure on GDP in the year 2009 was 7.3%, compared to 8.2% reported in Europe, highlighting the fact that on average, in Italy, we spend less on healthcare. All countries are facing the question of how to maintain the quality of care with shrinking health budgets, in the presence of a persistent increase in life expectancy, and with a significant growing demand for health care from aging populations and chronically ill patients.[2] For over a decade, in Italy and in the European Union, the health system has been undergoing reforms that are aimed at rationalizing resources and restraints on expenditure. Current implementation of legislative measures are presented largely as cutting and restricting costs. These automatic decreases in spending have also been called *sequestration*.[3] With a political approach, there is a risk of drastically reducing services and the number of hospital beds, without benchmarking comparisons between differences in availability of resources across all countries in Europe and worldwide. In Italy, too, without any specific consideration of the results obtained by each regional healthcare organization according to explicit markers, we risk moving towards reducing funds to hospitals, nursing homes and doctors, as seen in the US Medicaid System.[4] The relationship between health care cost and quality is still not fully understood, and further studies are needed to focus on what types of spending are most effective in improving quality and what types represent waste.[5]

Defensive medicine

In current medical practice, the most troubling and no less devastating aspect of surrendering professional liability for doctors to account for their actions is the use of *defensive medicine*. This means both work in hazardous clinical situations likely to have legal consequences and judicial aftermath, and the precautionary prescription of too many unnecessary, and even futile, diagnostic and therapeutic interventions.[6] Defensive medicine is defined as providing medical services that are not expected to benefit the patient but that are undertaken to minimize the risk of a subsequent lawsuit. Diagnostic defensive medicine practices have a much greater impact on costs than do therapeutic defensive practices. Defensive medicine is widely practiced. In a survey of physicians in 6 specialities at high risk of litigation (emergency medicine, general surgery, orthopedic surgery, neurosurgery, obstetrics/gynecology, and radiology), 9 of 10 respondents reported some defensive practices, with more than 90% of all respondents ordering tests unnecessarily.[7] In a Gallup poll, physicians attributed 34% of overall healthcare costs to defensive medicine and 21% of their practice as being defensive in nature. Specifically, 35% of diagnostic and 29% of laboratory tests, 19% of hospitalizations, 14% of prescriptions, and 8% of surgical interventions were performed to avoid lawsuits. This survey estimated that defensive medicine practices cost the US 650-850 billion dollars each year.[8] Many alternative strategies to contain national health spending have been proposed. As far as defensive medicine is concerned, the so-called *safe harbor* strategy might be useful. This is when physicians would be presumed to have no liability if using health-information-technology systems and adhering to evidence-based clinical practice guidelines.[9] Unfortunately, a similar strategy may not always be applicable in complex patients hospitalized on internal medicine wards, where uncertainty is often the order of the day. Most physicians believe that malpractice concerns result in unnecessary testing and procedures. They also believe the system should protect physicians from medical liability, suggesting that proposals to promote any cost-effective care, such as the promulgation of guidelines could be limited by physicians' fears of claims of malpractice unless such protections are ensured.[10] Many believe that any reasonable reform proposal to change the current situation would discourage unfounded claims, encouraging only the settlement of those found to be legitimate. These reforms would reduce the need for defensive medicine.[11]

Appropriateness in clinical medicine

Most physicians want to deliver appropriate care, most want to conduct ethical practice, but a substantial proportion of the health care delivered all over the word is inappropriate. Appropriateness, considered to be whatever is suitable, affordable, adequate, has been brought into common use in medicine in recent years to define features and quality of interventions. It has also often been mentioned in several legislative measures in Italy since the 2000s.[12] Appropriateness differs from performance, correctness, efficiency, efficacy, and effectiveness concepts (Table 1 and Figure 1).

In the same concept of appropriateness there are several interactions (Figure 1).[13]

Table 1. Appropriateness, performance, efficiency, effectiveness.

Appropriateness	Doing the right thing, to the right patient, at the right time, in the right setting, by the right professional, diagnostic and therapeutic clinical behavior		
	In relation to the objectives		**In relation to the execution**
	To do good things in a proper way		To do good things in a wrong way
	To do wrong things in a proper way		To do wrong things in a wrong way
Performance	The right way to do something, with reference to the clinical competence and skills required in the professional role		
Efficiency	**Technical efficiency**	Outputs cannot be produced with less of some input	Opportunity to reduce waste
	Efficient allocation of resources	Resources are optimally employed with respect to every available alternative	Opportunity to reduce waste
	Efficient production	Outputs cannot be produced at lower cost	Opportunity to save money
	Social efficiency	No person can be made better off without making someone else worse off	Opportunity to maximize ethical social values
Efficacy	The extent to which a specific intervention, procedure, or service produces the desired effect, under ideal conditions (controlled environment, laboratory/experimental circumstances)		
Effectiveness	The extent to which planned outcomes, goals or objectives are achieved as a result of an activity, strategy, intervention or initiative intended to achieve the desired effect, under ordinary circumstances (not controlled circumstances such as in the laboratory)		
Cost-effectiveness of health intervention	Benefits associated with an intervention and its relative costs		
	Average CE ratio=cost of intervention – costs averted by interventions/benefits of intervention		

CE, cost-effectiveness. Modified from The Agency for Healthcare Research and Quality and The Employer Health Care Alliance Cooperative. Highlights from a National Conference, Appendix A. Last update: of 11/06/2006. Available from: http://www.academyhealth.org/files/publications/EfficiencyReport.pdf

Correctness	If behaviors	*A priori* →	Comply with the rules
Effectiveness	If action	*A priori* → ← *A posteriori*	Achieves the purpose
Technical efficiency	If the tool	*A priori* → ← *A posteriori*	Is the most appropriate
Allocative efficiency	If resources	*A posteriori*	Are optimally employed with respect to every available alternatives

Figure 1. Interactions in appropriateness. *Adapted from Cislaghi, 2005.*[13]

Medical futility: not an unequivocal definition

Although doctors often recognize that the proposed interventions are, in many instances, unnecessary, they do, however, continue to prescribe, arguing a number of reasons for this: i) to maintain the goodwill of the patient; ii) to protect against any malpractice; iii) believing that the denial of that treatment may be inappropriate and immoral; iv) the primacy of patient welfare.[14] The concept of medical futility is empirical, without defined explicit *a priori* thresholds for its determination.[15] According to Scheinderman and colleagues, any time physicians conclude that a medical treatment has been useless in the last 100 cases (through personal and/or shared experience, or considerations reported in literature), such treatment should be considered as futile.[16] Most doctors had, have and will have to face dilemmas in decision-making and the reluctance to treat patients with poor prognosis. From a social point of view, the challenge to restrain health costs may induce debate to limit futile expensive treatments. Not everything that is technically possible is appropriate in a specific case: not everything that *could* be done *should* be done.[17] The problem should be addressed not just to whether a specific examination and/or treatment is useful or not, but according to a comprehensive assessment of the strength or weakness of the patient and his or her fitness to undergo treatment, if not upon an overall *gut feeling* of prognostic clinical judgment.[18]

Overdiagnosis and disease mongering

Overdiagnosis is the identification of clinically irrelevant cases (those that will not manifest within an individual's lifetime) at screening.[19] It occurs when people without symptoms are diagnosed with a disease that ultimately will not cause them to experience symptoms or lead to early death.[20] It refers to the related problems of over-medicalization and subsequent overtreatment, *diagnosis creep* (a phenomenon where a disorder is identified and doctors then begin to see it everywhere), shifting thresholds, and disease mongering, all processes helping to reclassify healthy people with mild problems or at low risk as sick.[21] Overdiagnosis inevitably means that many individuals are subjected to the potential harms of treatment while being afforded almost none of its benefits.[22] *Disease mongering*, defined as *widening boundaries of treatable illness in order to expand markets for those who profit from treatments*[23] is another wasteful threat to public health. Included among the *illnesses* identified in this connection are erectile dysfunction, female sexual dysfunction, bipolar disorder, attention deficit hyperactivity disorder, restless legs syndrome, osteoporosis, social shyness (also called social anxiety disorder and social phobia), irritable bowel syndrome, and balding.[24] Doctors should play a key role in combating disease mongering.

The (ab)use of hospital emergency services and unscheduled hospital readmissions

Departments of Internal Medicine in Italy take charge of most part of the admissions for complex and difficult patients.[25] Forty percent of walk-in patients to accident and emergency units could be seen and managed by the general practitioner.[26] According to the report of the Ministry of Health, the elderly population in Italy accounts for approximately 40% of ordinary hospital admissions and approximately 50% of days in hospital and estimated related costs.[27] The interaction between aging, the presence of chronic diseases and their exacerbations or intercurrent acute illnesses, together with socio-economic vulnerability defines a category of patients, mostly elderly, who are frequent hospital users. In a study carried out between 1990 and 2004, there was a 54% increase in the total number of patients with a disproportionate 198% increase in patients aged over 70 years, including a 671% increase in those aged over 90![28] Unscheduled hospital readmissions and post-discharge management are important issues in internal medicine departments. Readmissions are common and costly. Despite the fact that a reasonable fraction of them are preventable, evidence suggests that the primary drivers of variability in 30-day readmission rates are the composition of a hospital's complex patient population and the resources of the local community. None of these factors is connected with the organization or the professional behavior of the hospital staff, and are difficult for hospitals to change.[29]

Unnecessary procedures

We have spent the last twenty years introducing instruments of good clinical guidelines, diagnostic and therapeutic clinical pathways, and evidence-based medicine (EBM) practices. But much work is still needed to bridge the gap between what we have to do and what actually happens.[30] It is one thing to make an autonomous decision when evidence is lacking, another is to make decisions out of habit. Repeat testing following other examinations is common. Among Medicare beneficiaries undergoing echocardiography, 55% had a second test within three years (44% imaging, 49% pulmonary function tests, 46% chest computed tomography, 41% cystoscopies, and 35% upper endoscopies).[31] Some other examples of investigations with little or no additional value are the screening for cervical cancer in low-risk women aged 65 years or

older and in women who have had a total hysterectomy for benign disease, performing imaging studies (rather than a high-sensitivity D-dimer measurement) as the initial diagnostic test in patients with low pretest probability of venous thromboembolism and screening for chronic obstructive pulmonary disease with spirometry in individuals without respiratory symptoms.[32] In a representative national postal survey, 42% of US primary care physicians believe that patients in their own practice are receiving too much care. The most important factors identified as leading them to practice more aggressively were malpractice concerns (76%), clinical performance measurements (52%), and inadequate time to spend with patients (40%). Diagnostic testing would be reduced if it did not generate revenue for medical subspecialists (39% for primary care physicians).[33] Decision-making about the diagnostic investigations to perform cannot be based on merely putting at the bottom of the list the different tests proposed by different specialists in the shared management of complex patients. General practitioners in primary care and hospitalist internists have to select the real needs of their patients, testing their appropriateness before proceeding with any procedure and/or investigation (Figure 2).[34,35]

Laboratory testing

One of the fastest growing areas of health service spending is laboratory testing.[36] Overuse of laboratory resources is widely prevalent in hospital practice, mostly in emergency care. The reasons for excessive and inappropriate ordering of tests include defensive behavior and fear or uncertainty, lack of experience, the misuse of protocols and guidelines, *routine* and local attitudes, inadequate educational feedback, and the lack of awareness on behalf of the clinician about the cost of examinations and their related implications. This lack of attention to more detailed diagnostic issues, but rather to long-established or routine personal behavior, is mostly found in a context of diagnostic uncertainty, such as *defensive medicine*, mostly in critically ill patients.[37] More than 30% of tests, many of which are repeat tests, could be avoided. In most routine situations, tests requested in routine panels rarely add useful information to patient management. In some cases, it is better to *invest to disinvest*, *i.e.* the use of some tests may prevent further expensive investigations, as in the case of brain natriuretic peptide for the exclusion of heart failure and fecal calprotectin for the exclusion of inflammatory bowel disease,

Test ordering is spiraling[34]

Clinicians should address 3 questions before proceeding with tests, procedures, and investigations:

1. ***How likely is it to affect this patient's care?***
2. ***Was it already done in the past?***
3. ***What is the potential of adverse outcome or complications?***

When the answer to the first question is not strongly positive or when the other questions raise a red flag, a potential for a low Test Appropriateness Index exists and action had better be deferred[35]

Figure 2. Test appropriateness index.

which could reduce the need for costly echocardiography and colonoscopies.[38] Factors contributing to inappropriate ordering of tests are patient age (>65 years), hospitalization beyond seven days, and increased case difficulty (death or inability to establish a diagnosis).[39]

High technology diagnostic imaging investigations

Utilization of high technology and high-cost diagnostic imaging has increased substantially over the past decades. Several factors affect the criteria according to which the referring doctor request tests, including aging populations, advances in imaging technology and its availability, patients' expectations, professional uncertainty, time constraints, and defensive medicine. In a study asking radiologists to give their opinion as to what are the causes of the increasing and unnecessary use of radiological investigations, those rated highest were: implementation of new radiological technology, the demands of patients, clinicians' intolerance of uncertainty, expanded clinical indications and availability. Radiologists rated as causes of unnecessary investigations repeating investigations, situations in which anticipated results were unlikely to affect patient management, investigating too often, carrying out the wrong investigation, insufficient referral information, and overinvestigation.[40]

Quality of care

Potential bias risks in comparing econometric evaluations in different organizations/wards if these are not shared on explicit outcomes

Any econometric benchmarking between different wards and/or hospital settings should describe the patients involved. In our Internal Medicine typology of admitted patients (such as complex elderly old, *i.e.* somewhere between very old or very/very old), we have to define the basic comparative table regarding patients' complexity, such as number, age, gender, multimorbidities, polypharmacy, frailty, clinical instability, functional dependence, nutrition, affective state, social-economic context, etc. Before judging any positive or negative outcomes of care in *speciality-subspeciality departments versus Internal Medicine wards*, irrespective of the medical speciality concerned, we must describe the tools taken into consideration in defining the complexity of the patients' assessment and the resources available for their management. In aiming to avoid possible selection bias when comparing different populations, we should not confuse the intrinsic outcomes of speciality wards related to their mission (mostly orientated towards a problem concerning a single speciality) with the complexity of the patients hospitalized on internal medicine wards. Moreover, any hospital analysis based only on diagnosis-related groups, long-term stay, readmission rate and/or mortality (of very old-old/old patients), without comparing the real characteristics of the complexity of the patients admitted in different wards, runs a serious risk of selection bias. Many other factors can play a role in a comparison of the results of care: satisfactory quality of life, respect for an appropriate threshold of patient satisfaction, ensuring a proper care path also according to the expectations of the patients and their familes, palliative care goals, etc. Furthermore, other ways for an effective shared econometric assessment in the real world for the complex patient need to be proposed.

Quality of medication use: inappropriate prescriptions of drugs (but not only)

Many inappropriate prescribing detection criteria are described in the literature, exploring different ways to describe the inappropriateness according to domains of misprescribing, overprescribing and underprescribing (Table 2).[41]

One in 3 UK National Health Service (NHS) prescriptions is issued to a patient over the age of 65 years (90% of these prescriptions are for repeat medications). Elderly people are particularly susceptible to side-effects of drugs as a result of changes in both pharmacodynamic and pharmacokinetic factors. Polypharmacy as a result of multiple medical problems can result in poor concordance, multiple side-effects and drug interactions.[41] Therefore, we need to consider not only if we use the drugs in an appropriate way, but also the related implications.

There are other items that can affect health spending more than the inappropriate use of drugs. Programs to increase proper and safe use of drugs have to consider different quality markers of medication use, including too many prescribers in patient management, underuse of equivalent drugs, non-adherence to medication, interruptions of treatment, use of medications that are potentially inappropriate for older patients, home hoarding and storing of medicines, and adverse medical events. All these factors can influence, either directly or indirectly, healthcare costs[42] (Table 3).[43-54]

Some possible solutions

The primacy of effectiveness for attaining efficiency

Many inefficiencies are embedded in *the way things are done*. Cochrane's message is the primacy of effectiveness for attaining efficiency. Six essential

rules were proposed for a thrifty and effective health care system[55] (Table 4).

A need for only health care disinvestment and cuts?

The increasing burden of health care technologies, with medical costs increasing every year, has become a topic of discussion among all policymakers all over the word. The proposals to emerge are not based only on emphasizing the need for better care co-ordination, administrative efficiency, and elimination of useless interventions.[56] The impact of the spending review on health might have devastating effects, especially on the poorest and most vulnerable patient groups.[57] In this context, the feeling is that of a move on the part of politicians towards a *disinvestment* and a public healthcare approach suggestive of consequent reduced investments and diverting resources to other uses. This approach runs the risk of being associated only with cost reduction strategies rather than with a co-ordinated policy of maximizing the returns of investment in health care.[58] On the contrary, a key to a positive interpretation of disinvestment is needed, *i.e.* achieving results from the limited available resources.

Several ways in which disinvestment can be constructively promoted are represented in Table 5.[59]

In some instances, disinvestment means investing in order to avoid a negative outcome from investigations and/or treatment not timely performed or indeed not implemented.

Eliminating waste in health care expenditures

Some patients receive services that are redundant and of low value. *Clinical waste* was defined as *spending to produce services that provide marginal or no health benefit over less costly alternatives*.[59]

It is directly related to the concept of clinical uncertainly: *waste can result from uncertainty in the science of medicine, or when the diagnosis is unknown and each clinical interaction may result in different care decisions. This may lead to* treatment creep*, i.e. the provision of health care services that, though beneficial to some patients, are of low or no value to others*.[59] Wasteful services include those that have detrimental health effects or small positive health effects, compared with less costly alternatives. Clinical waste, or providing the wrong service, often overlaps with *operational waste*, *i.e.* the inefficient production of services.[59]

Eliminating waste, also in the context of uncertain and reduced funding of health care, should be provided in several ways:

i) carefully defining basic levels of public health care and selecting its related goals;
ii) defining the most suitable size of local health care organizations, such as expanded metropolitan areas, enlarged as much as possible in the health care services network according to the patients' real needs, and above questionable local managerial and operational functions;
iii) selecting the number of hospital/out of hospital beds, according to the real epidemiological requirements, considering the substantial increase in the aging population;
iv) defining any extensive clinical diagnostic-therapeutic pathway, consistent with substantial EBM problems, where possible;
v) predicting the summative patient characteristics that allow doctors and nurses to expect a certain trajectory of illness;
vi) tailoring a targeted treatment by defining clinical end points on a multidimensional comprehensive assessment of the complex patient;[60]
vii) targeting the *difficult* hospital discharge patients by assessing their complex needs (medical, functional, social, emotional, etc);
viii) providing optimal medical treatment, self-care education, integrated services, monitoring of progress, and early signs of problems to improve health outcomes and reduce costs;
ix) fighting against overtreatment, failures in execution of care processes, administrative complexity, pricing failures, fraud and abuse,[61] and any source of inefficiency[58,62] (Table 6);
x) reducing low-value services (use of services for which the harms likely exceed the benefits has been defined by the Institute of Medicine as *overuse*) intended as interventions, including those: i) for which the resultant harms likely exceed the benefits; ii) that may provide benefits, but with an undesirable trade off between health benefits and expenditures such as quantitative assessment

Table 2. Misprescribing, overprescribing and underprescribing.

Misprescribing	Prescription of a medication that significantly increases the risk of an adverse reaction. It includes: - Prescribing, that involves an incorrect dose, frequency, modality of administration or duration of treatment - The use of medications that are likely to cause clinically significant drug-drug or drug-disease interactions in which safer, equally efficacious alternatives should always be considered
Overprescribing	Prescription of medications for which no clear clinical indication exists
Underprescribing	Omission of potentially beneficial medications that are clinically indicated for treatment or prevention of a disease

Table 3. Some factors influencing cost of medication use.

Adhering to lifestyle changes	Convincing our patients to change lifestyle behaviors is the best way to achieve more benefits in health outcomes with a minimum social spending, *e.g.* the reduction in the incidence of type 2 diabetes by lifestyle interventions[43,44]
Concordance and non-adherence to medication*	- Complex drug regimens which entail the patient taking multiple tablets can be confusing and may result in poor concordance. Up to 50% of older patients may not be taking their medicines as intended[42,45,46] - Cost-related non-adherence to medication is an important quality marker because of its significant association with poor health outcomes and adverse medical events, including hospitalizations and nursing home admissions - Inappropriate formulations and packaging may contribute to low adherence, medication errors, and safety and efficacy problems - Additional considerations for a largely elderly population will include the need for easy administration, possible dose reduction, the effects of visual and motor impairment, and the likelihood of polypharmacy[47]
Underuse and misuse of generic drugs	- Despite compelling evidence and guidelines, generic drugs are still underused - The failure to explore new indications for new and existing generic drugs may result in a missed opportunity to further reduce health care costs.[48] It has been estimated that if in the year 2007 all potential users switched from brand-name drugs to regular generics, the potential savings would have been 115 US dollars (95% CI: 127-124 US dollars) per person/year, with total societal savings of 5.78 billion US dollars[49]
Generic/equivalent drugs, compliance and adherence	- Generic drugs are chemically equivalent to their brand-name counterparts in terms of active ingredients - They may differ in peripheral features, such as pill color or shape, inner binders and fillers, and the specific manufacturing process. The rules to check bioequivalence do not consider these pharmaceutical aspects.[50] These factors can negatively influence compliance and adherence to therapy, mostly in the elderly patient already taking many drugs
Improper treatment withdrawal	- The addition of new drugs that are not really necessary may result in the risk of elimination of some other essential ones (such as diuretics or anticoagulants), with possible detrimental effects on the underlying principal disease
ADRs	- ADRs are at the basis of hospital admission with a prevalence of 6.5%, median bed stay 8 days, accounting for 4% of the hospital bed capacity and projected annual cost of such admissions as 466m pounds sterling (706 million euros, 847 million US dollars)[51,52] - The most important determinant of risk for ADRs-related hospital admissions in older patients is the number of drugs being taken[53]
Too many prescribers	- A patient on multiple repeat medications at separate times may unintentionally receive the same medicine on separate prescriptions. The wastage that results from this inequivalence has been estimated to account for 6-10% of total prescribing cost[42] - The introduction of new drugs from other sub-specialists without the overall supervision of the general practitioner can lead to dangerous overlap or interference with other medications already being taken
Hoarded and stored drugs	- Especially if there have been recent changes in medication, it is common for elderly people and their families to have a back stock of drugs and continue taking their old drugs alongside new ones[40]
Medication reconciliation	- Intended as a formal process by which the complete and exact list of a patient's prior medication is assessed together with their pharmacotherapeutic prescription following any transition of care
***Me too* drugs**	- *Me too* drugs can be broadly defined as chemically related to the prototype, or other chemical compounds which have an identical mechanism of action[54] - *Me too* drugs (sometimes also called *follow-on* drugs) are products which largely duplicate the action of existing drugs. They show, however, some limitations: not documenting any added value *versus* the already available drugs, reducing the incentive to undertake further substantial innovations, showing an unacceptably low benefit/risk ratio with their relatively small incremental benefits and, finally, since they are more expensive, using up more resources than they are substantially worth

*Compliance: the extent describes the degree to which a patient correctly follows medical advice. Commonly, it refers to medication or drug compliance; Adherence: the extent to which the patient's behavior matches *agreed* recommendations from the prescriber. It has been adopted by many as an alternative to compliance, in an attempt to emphasize that the patient is free to decide whether to adhere to the doctor's recommendations and that failure to do so should not be a reason to blame the patient. Adherence develops the definition of compliance by emphasizing the need for agreement; Concordance: the process by which a patient and clinician make de-

by patients, clinicians and policymakers;[63] iii) those that exist for self-referential function which may work better when offered to the whole care system. The value-centric approach is indicated as a useful alternative to more traditional methods of containment of health costs by providing a global payment for healthcare services (cost-centric approach), on the assumption that global payments will lead to either a decrease in the number of services provided or a reduction in the price of services. On the contrary, it outlines the hypothesis that a payment system linked to the value of services may by providing more clinical value to patient's needs, potentially enhancing care and reducing costs.[64]

Bioethics has long addressed the issue of containing health care costs and how to allocate the scarce resources available, stressing the importance of maintaining a kind of distributive justice. But now the debate is shifting from a model of mere rationing costs to an ethical concept centered on avoiding waste. This shift in approach has significant consequences and implications for health policy and the organization of services.[65] There is a need for a substantial reorientation of the goals and priorities of our public health care system, and physicians have to negotiate the potential conflicts between quality care, patient's requests and socio-economic sustainability (Table 7).

Judicious prescribing

Prescribing tests

In the diagnostic phase of the clinical method, the contribution of evidence-based medicine is, in most cases, very limited and/or its usefulness is not always unequivocal. A better use of medical tests would reduce the growth rates of over-ordered and under-ordered tests, improve health professionals' knowledge about medical tests, and improve community awareness.[66] From this point of view, the introduction of health technology assessment is very useful. This is intended as a multidisciplinary activity that systematically examines the safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organizational implications, social consequences, and the legal and ethical considerations of the application of a health technology (usually a drug, medical device or clinical/surgical procedure). The focus has to be directed to evaluate both *clinical effectiveness* (how do the health outcomes of the technology compare with available treatment alternatives?) and *cost-effectiveness* (are these improvements in health outcomes commensurate with the additional costs of the technology?[67]

Therapy

Judicious prescription of therapy is a prerequisite for safe, appropriate and cost-effective medication use. Before deciding whether a prescribed medication is appropriate, and in particular if we are prescribing for the elderly, some fundamental principles have to be considered (Table 8).[68,42]

A quality use of drugs involves some fundamentals, such as those described in the four arms of the Australian National Medicines Policy-NPS MedicineWise:[67]

i) *judicious use* (selecting management options wisely): medicines, whether prescribed, recommended and/or self-selected, should be used only when appropriate, with non-medicinal alternatives considered as needed;
ii) *appropriate use* (choosing suitable medicines if a medicine is considered necessary): choosing the most appropriate medicine, taking into account factors such as the clinical condition being treated, the potential risks and benefits of treatment, dosage, length of treatment and costs;
iii) *safe use* (using medicines safely and effectively to get the best possible results): misuse, including overuse and underuse, should be minimized;
iv) *efficacious use*: the medicines must achieve the therapeutic goals by delivering beneficial changes in actual health outcomes.

Regarding the appropriate and optimal use of generic drugs, there is a need for a massive effort consisting of educational strategies aimed at health professionals and patients, specifically supported by those who pay for health care, the government and consumers.[69]

Chronic diseases: more transitional care and self-management, better early detection of deterioration of critically chronic ill patients to improve the quality of care

Transitional care programs, designed to ensure the co-ordination and continuity of health care, can reduce unnecessary use of health services and improve patient outcomes, particularly among patients transitioning from hospital to home, where the possibility of error and consequent costs are high, in improving functional outcomes, facilitating transfer of care from a hospital-based system to a community-based system, and preventing re-hospitalization and adverse events.[70] Programs teaching self-management skills for chronic diseases are more effective in improving clinical outcomes in primary care than only giving patients information.[71] Early recognition of warning symptoms and clinical deterioration, and subsequent timely intervention in chronic or severe illness, may reduce unsched-

Table 4. Cochrane's six rules for a thrifty and effective health care system.

1	Consider anything that works	- Compare alternative medical interventions and see whether a medical treatment does more harm than no intervention - Consider all the money spent on lower back problems with little evidence
2	Make effective treatments available to all	Be aware if effective treatments are available free to everyone who can benefit
3	Minimize ill-timed interventions	Effectiveness can be correlated to the time needed by examining all the diagnostic and treatment procedures, waiting times, waiting lists, referrals, length of stay, etc.
4	Treat patients in the most cost-effective place	Consider the best care setting for the best care and use of resources and beds
5	Prevent only what is preventable	Spend money only on preventive measures that are more effective than no treatment or alternative treatments, and screen only for treatable or preventable problems
6	Diagnose only if treatable	Doctors like to make diagnoses. Is this a sustainable approach if nothing can be done? (This is a growing and important ethical question)

Table 5. Some possible ways for the management of a constructive and wise health care (dis)investment.

Prevention as the way to sustain an effective health system
Better evidence-based clinical decision-making (when possible)
Better co-ordination of health services between primary and secondary care providers
Better continuity of care in chronic diseases
Reducing preventable hospitalizations by bolstering primary care
Early detection of deterioration and management of critically ill patients with chronic diseases
Better integration of the healthcare system with the social and community care systems
Critical analysis by the stakeholders and the ethical committees of the results of clinical studies and RCT not only based on their statistical significance, but also on their clinical relevance, useful to change prescriptive attitudes of professionals
Health technology assessment before implementing new technologies or changes in the organizational structure of the hospital
Allocating resources in homogeneous areas according to a principle of equity and workloads
Rationalizing the number and distribution of high-cost technologies according to the catchment area
Collaboration (rather than competition) between professionals, specialists and sub-specialists, managers, stakeholders and patients
Reducing any professional and/or corporative conflict of interests in the care of patients
The empowerment of patients in becoming active in their health care, particularly in implementing the self-management of chronic diseases
System of skill development and maintenance of clinical competence
Changes in working practice
Reductions in administrative costs
Implementing hospice/palliative chronic care models in the management of advanced chronic illness (not only for cancer patients) as an alternative to the hospital admissions

RCT, randomized clinical trials.

uled hospital readmissions, improve outcome, reduce length of stay, and thus should save beds and money in the long term. Any plan of integrated disease management has to be based on close co-operation between the hospital and primary carers, with a well-defined taxonomy to compare and evaluate the different program outcomes.[72] It is also important to pay careful attention to the use of care bundles and protocols.[38] In order to improve the quality of care for complex patients, we need to identify a range of relevant markers, supported by clear clinical evidence that can be applied to many patients. Scientific societies have a very important role to play in choosing the best set of markers to be proposed. Many patients are carriers of complex clinical problems and are also followed by many doctors. In their clinical assessment, it is necessary to adjust the prognostic risk when other associated factors are presented.[60] Electronic medical records of clinical data are useful to assess the quality of the doctor's work. The sooner we can activate and implement a network to also involve specialists, the more effectively we can improve the quality of care, especially of the more complex patients.[73]

Home-based, nurse-led health care for older people: reducing costs?

Home care programs for older people carried out by nurses and other health-care professionals positively affect functional status and may promote clinical benefits across a number of important health dimensions. However, in general, it is still not clear which components of this type of complex intervention contribute towards individual aspects of benefit for older people. Nor is it clear whether or not home-based health promotion interventions offer good value for money for the national health service.[74]

Professional inertia and health care costs

Inertia has been defined as the *failure of health care providers to initiate or intensify decision making or treatment when indicated.*[75] Clinical inertia may apply to all medical fields, with a lag time between advances in clinical understanding and incorporation into clinical guidelines. This may be due both to an overestimation of provided care, with an incorrect perception of clinical improvement in translating clinical trial results to individual patients, and a lack of understanding about achieving therapeutic goals.[76] Factors related to possible causes of an apparent inertia in decision-making can be attributed not only to the doctors directly responsible for the patients, but also to other decision makers (*i.e.* the specialists consulted). This inertia can also be due to the organizational environment of the care system and, mainly, the views of patients and/or their families/caregivers[77] (Table 9).[75,78-80]

Uncertainty, evidence-based medicine and decision-making in internal hospital healthcare: we really need a wise clinical judgment

Uncertainly and decision-making in hospital Internal Medicine patients require a critical assessment of the results of clinical trials, both in terms of selection of included/excluded cases and methodology in con-

Table 6. Ways to reduce waste in health care.

	Overtreatment	Failed care co-ordination	Failed care processes	Administrative complexity	Pricing failures	Fraud and abuse
Examples/ comment	Excessive use of antibiotics, use of surgery when watchful waiting is better, unwanted intensive care at the end of life for patients who prefer a hospice setting and homecare	Fragmented care, mostly in the chronically ill, leading to complications, hospital readmissions, increased functional dependency	Poor execution/ lack of adoption of effective known best care processes, patient safety systems and preventive care practices, with worse clinical outcomes or injuries to the patient	Failure to standardize efficient or misguided rules in management procedures, and administrative expenses	Absence of effective transparency and competitive markets	Such as fraudsters, professional misbehaviors of a very few people
Estimated wasteful spending (for 2011 in billion US dollars)	158-226	25-45	102-154	107-389	84-178	82-272

sidering the results, not only from a mere statistical point of view. Our patients need a comprehensive assessment in order to define the highest priorities. Evidence-based medicine has, in itself, some inherent limitations. In evaluating the results of randomized clinical trials, we need to consider not only the statistical significance of results, but also their clinical relevance, in accordance with the principle of Minimal Clinically Important Difference (MCID). In interpreting the results, we have to consider whether or not the MCID has been taken into account before applying the results of any trial to our therapeutic decisions, *e.g.* in the implementation of very expensive drugs, such as those for cancers. Moreover, current hospital organization tends to emphasize the improvement of care processes, as pre-ordained tools, mostly upon guideline-based clinical approaches and standards of care concerning a single disease. Unfortunately, the evidence of EBM is in many cases not well defined, not definitive and sometimes even contradictory. But the bedside decisions of the physician must be *black or white*. The internist usually takes decisions in situations of: i) certainty (the ideal decision is adopted and the corresponding strategy followed); ii) risk (the more suitable alternative selected can be the determination of the probable value or mathematical hope); and iii) uncertainty, in which decisions are linked to triple agents: beliefs and personal values of the doctors, their patients and society.[81] Uncertainty can be a strong barrier related to knowledge (uncertainty about ordering criteria), attitude (lack of self-efficacy due to lack of skills), behavior (fear of legal action), or feelings (anxiety about missing important findings). Internists have their own characteristics, *i.e.* mainly the ability of clinical judgment, that includes clinical reasoning and decision-making about the patient's real needs, critical thinking, and an overall grasp of the situation coupled with acquired skills. On the basis of a

Table 7. Fundamentals for a sustainable medicine.

Medical healthcare must be *economically sustainable*	It means there must be some attempt to control costs in a way commensurate with quality medical care
Sustainable medical healthcare requires a *sustainable doctor-patient relationship*	Enhancing a good doctor-patient relationship is a prerequisite to facilitate better and proper adhesion to care, and less recourse to other physicians and to emergency services
Sustainable medical healthcare must strive towards the *long-term* goal of maximizing health	Emphasizing goals on healthy nutrition, exercise, personal fulfilment, psycho-physical equilibrium and other lifestyle issues

Adapted from Kimberton Clinic, Sustainable Medicine. Available from: http://kimbertonclinic.com/what.htm

Table 8. Deciding whether a prescribed medication is appropriate.

Statements[68]	Questions[42]
- Think beyond drugs, considering non-drug therapy, treatable underlying causes, and prevention - Defer any non-urgent drug treatment - Be careful about unproven drug uses - Be careful and skeptical about new drugs - Be skeptical about surrogate rather than true clinical outcomes - Beware of possible publication bias - Start treatment with only one new drug at a time - Balance the potential risks of any drug against its benefits for that patient - In the elderly: start low, go slowly, check very carefully - Maintain heightened vigilance regarding adverse effects - Be aware of withdrawal syndromes - Educate patients to recognize reactions - Avoid stretching indications without evidence - Work with patients on a shared agenda - Consider non-adherence before adding drugs to regimen - Discontinue any unneeded drug after each reconciliation event - Listen and respect your patient's opinions about the use of drugs	- Is the drug really (still) necessary? - Are equivalent drugs available? - Are there overlapping drugs? - Are the daily dose, the frequency and interval of doses compatible with the technical sheet of the drugs? - Are the daily dose, the frequency and interval of doses compatible with the clinical picture of the patient, also considering comorbidities and potential interactions? - Are we prescribing an off-label therapy? - Is the prescription related to the existing guidelines of the international literature? - Is the prescription compatible with local policies of good clinical practice? - Is the prescribed drug the most advantageous from an economic point of view? - In the treatment of the patient, did we miss some medication that was really necessary? - Some new cancer drugs cost a lot of money per month for a single patient: is their use really related to clinically (not only statistically!) improved significant outcomes? Would it be better not to give chemotherapy to weaker patients who would not benefit from such additional treatment?

multidimensional assessment, we can decide what type of intervention to offer to our patients, such as intensive, interventional, conservative/frugal or palliative level of care. By exploring the real complexity of our patients and selecting their real needs, we can exercise holistic, anthropological, appropriate, but somehow also frugal individual healthcare, *i.e.* Internal Medicine.

Doctors have to share decisions with patients, also if not satisfying some of their unjustifiable requests

EBM requires consideration of the preferences of the patient in clinical decisions. Involving the patients in their own care is an important process, for example, in the definition of patient-reported outcomes. But it is a difficult process and not always applicable. Shared decision-making may promote the choice of less expensive (but equally effective) therapies in over 20% of cases. We could standardize the process of sharing by describing the therapeutic options, displaying them in an understandable language, providing an update of available knowledge and studies, describing the real possible clinical goals to be achieved, and illustrating potential side effects and complications.[82] With this objective in mind, there are several factors that interfere in this process, in addition to the underlying disease: emotions, cognitive dysfunction, depression, state of consciousness, social and economic factors, loneliness, etc. All these make *normal* patient involvement very difficult. Patients frequently express strong preferences for medical tests or treatments of their own choosing, even when physicians believe that those interventions are not beneficial.[83] Physicians often prescribe a brand-name drug to a patient when a generic is available because the patient wanted it. This practice, not always free from the influence of the pharmaceutical industry, leads to unnecessary associated costs and substantial increases in expenditure for the healthcare system.[84] Providing unconditional satisfaction to the patient does not always mean achieving better outcomes. Higher patient satisfaction was associated with fewer visits to the emergency department but greater inpatient use, higher overall healthcare and prescription drug expenditure, and increased mortality.[85] Strategies when refusing to satisfy some inappropriate patient's requests may be directed to communicating appropriate care plans, to reducing provision of medically inappropriate services, and to preserving the physician-patient relationship.[86] Transparency needs to be improved in all medical decision-making, with greater involvement of patients for a shared final decision.[87] An approach based upon shared decision-making with our patients promotes their sense of self-efficacy and improves their adherence to treatment recommendations.[88]

Clinical audit as a tool for improvement

Doctors can provide too little or too much care, giving both insufficient and unnecessary treatment, with a potential negative impact upon healthcare quality.[89] Audit and feedback seem to modestly improve

Table 9. Factors contributing to clinical inertia and prescribing.

Clinician	Patient	Health system
- Lack therapeutic skills, including drug and non-drug approaches to treatment - Lack of knowledge of current international guidelines - Failure to initiate treatment - Failure to measure treatment in relation to goal - Failure to set clear goals - Failure to identify and manage comorbid conditions - Failure to select priorities - Underestimation of patient needs - Overestimation of non-priority problems - Insufficient time - Insufficient emphasis on goal attainment - Reactive rather than proactive care - Fear of legal action, defensive medicine - Opportunistic behaviors induced by payment system (DRGs) in the hospital setting	- Adverse drug reactions - Polypharmacy - Adherence - Forgetfulness - Cost of medications - Denial of disease - Denial of disease severity - Absence of symptoms - Fear of consequences of diseases - Fatalistic approach - Poor communication with doctor - Cognitive impairment, depression, mental illness, substance abuse - Lifestyle - Pressure from patients on doctor's decision	- Influence of the pharmaceutical industry - Influence of colleagues and stakeholders - Influence of journals and the media - No clinical guidelines - No disease registry - No planning of medical follow-up - No active patient outreach - No decision support - No team approach - Too many doctors/subspecialists in the care of the same patient - Lack of care co-ordination - Poor communication between clinicians and office staff - Lack of other practice resources - Payment system (DRGs) in the hospital setting

DRGs, diagnosis-related groups.

quality of care, especially when performance is poor. They generally lead to small but potentially important improvements in professional practice. The effectiveness of audit and feedback seems to depend on baseline performance and how the feedback is provided. Feedback seems to be better and more effective when baseline performance is low, if the source is a supervisor or colleague, if it is provided more than once, if it is delivered in both verbal and written formats, and when it includes explicit targets and an action plan.[90]

The US National Physicians Alliance initiative: choosing wisely

The US National Physicians Alliance *Promoting Good Stewardship in Clinical Practice* project developed 5-item lists of evidence-based, quality-improving, resource-sparing activities in family medicine, internal medicine, and pediatrics. Each item is supported by appropriate evidence and benefits patients by improving treatment or decreasing risks and, where possible, reducing the healthcare costs.[91] Physicians cannot be innocent bystanders costs of healthcare increase. The model based upon the *top five list* (*i.e.* five diagnostic tests or treatments very commonly ordered by members of that speciality that are among the most expensive services provided) has the advantage of defining the most common causes of waste, demonstrating that doctors are genuinely protecting patients' interests and not simply *rationing* health care.[92,93]

Conclusions

Bioethics has long addressed the issue of containing healthcare costs and methods of allocation of the scarce resources available, emphasizing the importance of preserving a kind of distributive justice. But now the debate has to shift from a pattern of mere rationing costs to an ethical concept focused on avoiding waste, with important implications for health policy and the organization of services.[56,57,65,66] We firmly believe that reinforcing a common agenda for medicine and public health, and sharing a common vision among professionals and decision-makers in the planning of care, is perhaps the greatest opportunity for every health care reform.[94] The future of the health care system must not be restricted to mere cost reduction, but to delivering better health for the money spent. To meet this challenge, the physician's leadership in clinical judgment is essential[95] as a central element of the medical profession[96] (*...The clinician is the doctor at the sufferer's bedside, the doctor who accepts responsibility for the life entrusted to him by the patient, the doctor who plans the strategy and executes the tactics of therapeutic care*).[97]

Physicians have to go back to basics by making a clinical diagnosis based on history and physical examination.[98] It is possible to find new opportunities even at times of austerity.[94,95] Doctors are forced to reconsider their choices in the care of patients,[14,15] to gain some understanding of the costs of the services they provide and their potential relationship to care quality,[99] and remembering that less health care can result in better health.[100] It is not always true that *more is better*. On the contrary, in remembering the well-known report of the *Journal of the American Medical Association* (JAMA), we have to reinforce the concept that *less is more*,[101] by spreading the principle of *best care at lower cost* (as shared by the US Institute of Medicine).[102] In our Italian Scientific Society of Internal Medicine (the Federation of Associations of Hospital Doctors on Internal Medicine, FADOI), we want to support the view that essential medical healthcare is still a goal to be achieved throughout medical hospitals, not only in Italy, but all over the world. We are looking for original models of a sustainable hospital Internal Medicine approach, by searching for wise and efficient tools of clinical methodology for our patients. We would like to offer some possible ideas for action on a national level, aimed at a frugal and efficient hospital Internal Medicine approach. A practice that involves useful, selective, effective and wise medical interventions means being able to select priorities and identify the most important of the many complex problems, often overlapping with different sub-specialist situations.

We have to learn (or relearn) to practice a medicine that is not so dependent on technology. Our medical healthcare has to be tailored to the real needs of the person. In this way, it will be easier for us to remember that the diagnosis is based, in most cases, on history and physical examination, and that the last drug used is not necessarily the best.

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APPENDIX

The FADOI and their Friends in Appropriate decision making Project Group (FFA-PG) in hospital Internal Medicine wards: G. Ballardini (Rimini), G. Bajocchi (Reggio Emilia), M. Bassi (Bologna), G. Beltramello (Bassano del Grappa, VI), C. Campieri (Bologna), G. Chesi, (Scandiano, RE), G. Civardi (Firenzuola, PC), G. Corona (Bologna), M. Costantini (Genova), P. De Campora (Napoli), E. Degli Esposti (Bologna), L. Degli Esposti (Bologna), C. Descovich (Bologna), M. Errico (Acquaviva delle Fonti, BA), F. Fornari (Piacenza), P. Leandri (Bologna), G. Lelli (Ferrara), P. Iaccarino (Napoli), L. Luisiani (Castelfranco Veneto, TV), L. Magnani (Voghera, PV), M. Marvisi (Cremona), M. Masina (Bentivoglio, BO), M. Mazzetti (Bologna), M. Meschi (Borgo Val di Taro, PR), P. Montanari (Montecchio, RE), R. Motta (Bologna), A. Pasquale (Bologna), G. Pedretti (Fidenza, PC), C. Puoti (Marino, RM), M. Reta (Bologna), A. Sacchetta (Conegliano, TV), A. Salsi (Bologna), C. Salvarani (Reggio Emilia), F. Salvati (Ortona, CH), A. Santoro (Bologna), G. Scanelli (Ferrara), G. Stasi (Bologna), M. Stornello (Siracusa), G. Uomo (Napoli), M. Ventrucci (Bentivoglio, BO), F. Vescini (Gorizia), U. Volta (Bologna), A. Zuccalà (Imola, BO), P. Zuccheri (Bologna).