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COMMENTARY

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The Scientific (but Also Logical) Basis for Integrated Medicine

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Introduction

The concept of Integrated Medicine (IM) has been clearly defined for the first time in Italy on 3rd December 2011, when SIOMI presented its manifesto for IM, containing the conceptual and functional definitions of this discipline as agreed with the Italian leading health institution. The event has been celebrated with a monographic edition of HIMed (Homeopathy and Integrated Medicine, SIOMI's official journal)¹ in which the individual assertions written in the manifesto have been accompanied by the thorough scientific, clinical, ethical, and epistemological analysis habitually required to allow a complex discipline to interact transparently and safely with patients, doctors, and the medical world.

There is a great confusion in the international literature over the terminology, conceptualization and even the definition of the health model of IM, which only increases the skepticism of many—albeit poorly informed—members of the scientific community. From this perspective, it should be stressed that IM has no intention of rejecting the use of everything

that comes under the umbrella of *academic* medicine, but instead it aims, as its own name suggests, to integrate it with therapeutic practices currently defined as unorthodox, and now generally known as Traditional Medicine (TM) or Complementary Medicine (CM). Another important discussion is about the use of the term “integrated” or “integrative” medicine that are behind the same acronym IM, both indicating the concept of a medical approach with CM together with conventional medicine in a same therapeutic prescription. It has never officially stated but the term “integrated,” should mean the use of “shared protocols,” in which the intervention of complementary medicine is intended to complete a therapeutic protocol already in use in CM in a standardized schedule. In the case of “Integrative Medicine” there are more people involved in putting together conventional medicine and CM and creating new approaches. When a model of care is yet existing, in our opinion is better to complete the existing one (integrated); however, as described in our scientific papers, as CM are finalized to personalization, to do this we should add in the

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standard protocol an homeopathic medicine or an acupuncture treatment based on a peculiar patients' aspect as result of a personal evaluation by the CM' doctor. In our opinion, this process is necessary because the evidence coming from the ever-growing number of scientific publications, together with the positive clinical experiences of doctors and patients alike, comprise a solid basis for the further exploration of disciplines that could integrate (or even in some cases replace) the practices of academic medicine and lead to improvements where the methods of biomedicine have produced disappointing results.

After the clarification of these important points, we need to take a few steps back to understand the history that has led to this situation. Everything started in 1992, when the evidence-based medicine (EBM) workgroup published the results of an in-depth review of medical attitudes in JAMA,² the first of this kind. The group was coordinated by David Sackett, who later has written a book³ that has been, for many years, considered the final statement on EBM. Sackett's perspective can be approximately summarized as follows: "The practice of Evidence Based Medicine means integrating individual clinical expertise with the best available external clinical evidence coming from a systematic research... [including] *the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care*"⁴ (our italics).

While EBM has led to the objective verification of most clinical practices, the individual patients' "*predicaments, rights, and preferences*" are still now largely ignored. The reason is surprisingly clear, if interpreted considering the current model of chronic disease, which consider a given medical disorder as having an environmental trigger that could act on a constitutional predisposition, that may be considered the cause of the host individual's response and, ultimately, of the chronic disease itself.

EBM has always aimed to improve the efficiency of clinical studies by eliminating, as far as possible, all confounding factors (*biases*) that might alter the results' interpretation. This methodology is undoubtedly the best approach when studying any therapeutic treatments for acute disorders—those areas of medicine where the declared aim is to eradicate any interference generated by the patient's response, to avoid "contaminating" results and making it unreliable. For

this reason, the study population must be as homogeneous as possible, with minimal differences between the participants' various characteristics. All this, it should be stressed, is ideal when applied to a disease with a short latency period that is consequently easy to recognize and diagnose. In brief, in an "acute" case we could or indeed should focus on the disease, whose identified features can be found in all affected patients, while ignoring the constitutional prevalence of the patient where it occurs. In this context, it is very easy to extrapolate the results obtained in the study group to a larger population, as suggested by Sackett.

The problem arises when the same system is applied to a chronic disease. This is a dramatically different situation, as the definition of chronicity includes several factors that make more complicated to "measure" the disease, its intensity, and its evolution. The ways in which individual patients have learned to adapt to their own condition make it very difficult, for example, to put together a homogeneous study group in which to investigate all these factors. Furthermore, the many complexities of the patient's response mean that its adaptation process often succeeds in "compensating" for the clinical imbalances caused by the disease, thus generating periods of relative well-being alternating with periods of relapse. It should also be considered that patients often present other comorbidities alongside their main disease, and that the complexity of everyone can lead to different responses even in similar conditions. It becomes evident that the simplification and verification process proposed by EBM is difficult to apply in such contexts.

The undeniable results achieved by EBM have led to a growing disregard for individual clinical experience and a greater reliance on clinical trials, to the point that the latter have become the solo identifying element of a method applied even in the absence of the specific factors that require its use, such as in the case of lifelong diseases. Sackett himself recognized the excessive "extremism" conferred upon his work, and indeed published an article⁵ in the *British Medical Journal* in which he attempted to redress the balance. This revision of EBM has, in recent years, led to the individual clinical expertise theorized by Sackett being identified with patient reported outcomes,⁶ which offer the patient's perspective on a disease or treatment which cannot be measured with any clinical



test, but that could be just as important for the patients themselves as the determination of any given parameter. In brief, individuals with the same state of health, diagnosis, or disease can have different perceptions of their own feelings and their own health status because they have different abilities to deal with their own limitations and disabilities, and this finally leads to a different perception of their quality of life (QoL).

In this way, more suited factors to measuring the clinical variables typical of chronic diseases have gradually come in and play a role in the complex equilibrium of clinical research: QoL, the patients' satisfaction about the results of the treatment, their psychological condition, their limitations of working or social life, and also the adherence to treatment.⁷ All these factors, as noted by Jeff Sloan's group in Explore,⁸ comprise an integral part of the investigational methodology in most procedures characterized as TM/CM, and above all in homeopathy. It is therefore legitimate to ask if randomized controlled trials (RCTs) are always the most reliable way to generate clinical evidence in medicine, given the complexity of the therapeutic regimens (especially in chronically ill patients with many comorbidities), the demographic and clinical variability of the patients, the continuation of many therapies and, finally, the questionable adherence of prescribers to the guidelines. As a result, RCTs without additional information on the patient's experiences and chronicity are insufficient to guide the clinical-decisional process, due to the controlled (but false!) environment for which they are designed, which often makes it impossible to generalize their results to the so-called *real world*.

The same conclusions⁹ were reached by a network of scientific societies¹⁰ involved, for the main part, in the study of chronic diseases. There is now an adequate body of scientific evidence to begin challenging the monopoly of EBM in clinical research in favor of a growing area known as real-world evidence, which also includes the patients' experiences and that can produce evidence on the best way to improve the prescribed treatments, especially in the case of chronic diseases. These were the premises on which Edward Wagner based an editorial in effective clinical practice,¹¹ back in 1998, which laid the foundations for what is now known as the chronic care model (CCM): his discussion of the results of a four-year clinical trial on more than 4000 patients with diabetes, decompensated heart disease, anxiety, and depression confirmed the validity of a

model that has had a significant effect on morbidity and complications. Later developments of the CCM in different clinical sectors¹²⁻¹⁴ offered an inevitable source of inspiration for the Italian Ministry of Health's 2016 National Chronic Disease Plan, in which the integration of EBM and RWM was totally re-evaluated and the much-needed distinction between acute and chronic states of disease has been done.

In 2011, Tuscany Region, moving in the direction to evaluate the real efficacy of CMs in patients' cares, has realized the first Integrated Medicine hospital in Pitigliano, within the public Italian health care system, with these goals: (1) to potentially establish a clinical setting between orthodox medicine and CM practitioners, based on mutual agreement and close cooperation in terms of therapy and treatment; (2) to test the interdisciplinary approach among inpatients; (3) to verify the beneficial effects deriving from the approach regarding the improvement of life quality in patients suffering from chronic diseases as well as the decrease of side-effects triggered by the conventional therapy; (4) to verify potential advantages coming from the integrated medicine in terms of costs management regarding the regional health care system.

CMs, as homeopathy and acupuncture have been offered both to inpatients and outpatients, and in ten years of integrated cares the model of integrated cares has been described and the results of the integrated protocols have been published in scientific papers regarding allergic patients,^{15,16} oncologic patients,¹⁷ rehabilitation patients (neurological and orthopedic patients)¹⁸ and palliative cares' patients;¹⁹ here we report some highlights from our experience in the Neurological and Orthopedic Centre of Manciano (Grosseto, Italy): in the article mentioned above, examining a group of 383 patients, with a mean age of 70.28 years old for neurological patients (stroke suffering) and of 70.13 years old for orthopedic patients (knee or hip replacement), we have evaluated (treated vs. control) the change in two parameters: activities of daily living performance for the first group (Barthel index) and the second group (Barthel index and Trunk Control Test) and number of days with analgesic drug treatment for the second group. The results were that the application of IM have changed positively the observed values, indicating that IM treatment increases the performance in activities of daily living in both groups, with *p*-values in Fisher's exact tests of 0.008 for stroke patients for the Barthel Index and of 0.046 for the Trunk Control Test. The



treatment also reduced the duration of analgesic treatment by 2.8 days (Fisher *p*-value: 0.0015).

The model of care in which CM could be included in a mode of integration already exists and is the Chronic Care Model, devised in 1999 and suitable for including the various professional figures and nonprofessionals who take care of the chronically ill patient in his pathway. The Chronic Care Model was presented for shared evaluation at the ECH (European Committee of Homeopathy)

meeting in Lisbon in July 2015 and a scheme (see Fig. 1) was shown which, taking the Chronic Care Model as a model, included the possible areas of intervention by CM, shared with other professionals. The Region of Tuscany has also created several integrated pathways including homeopathy, phytotherapy, and acupuncture, some of which have recently been approved, such as the diagnostic and therapeutic care pathways for gynecological cancers, breast cancer and colon cancer.

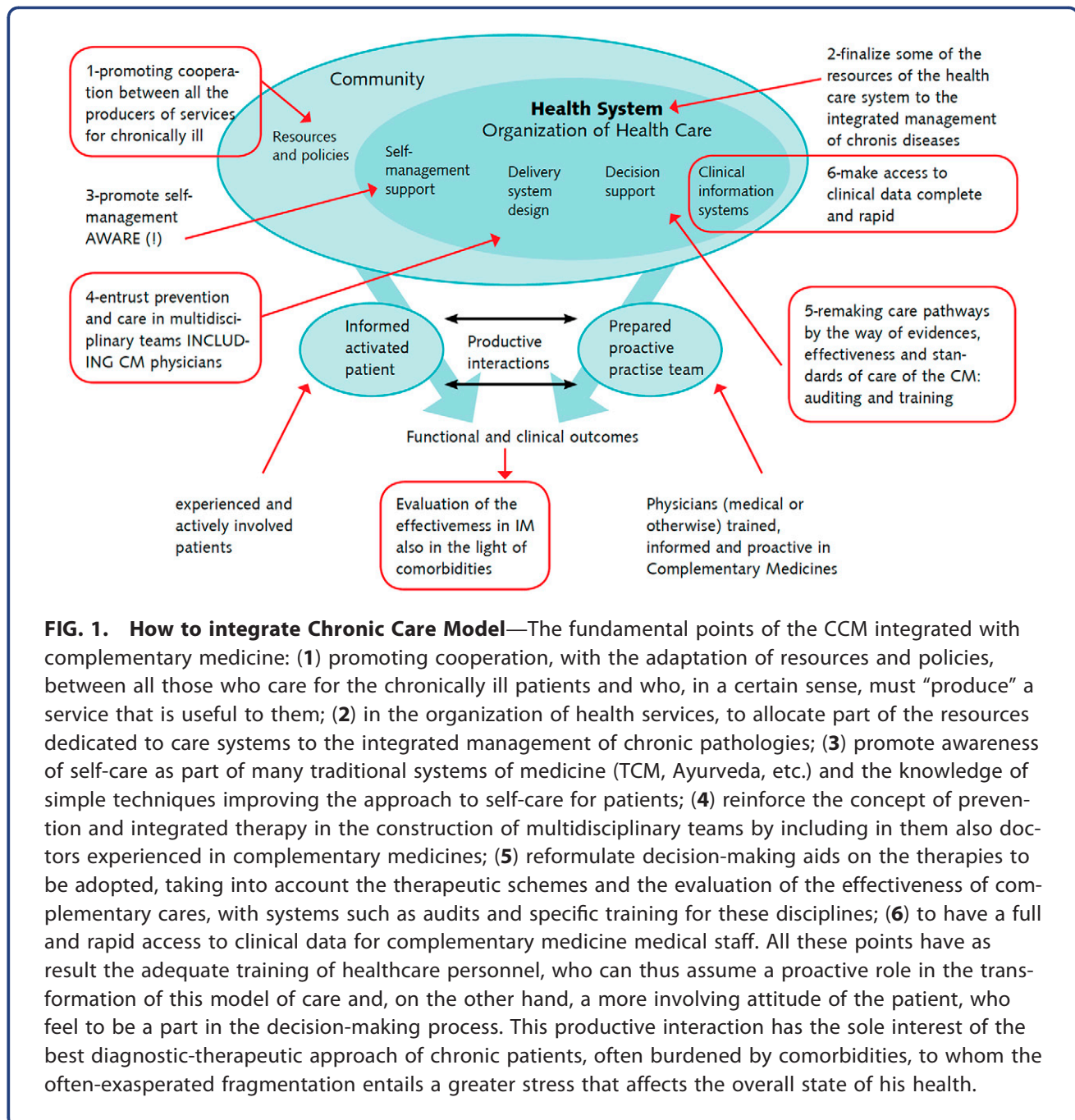


FIG. 1. How to integrate Chronic Care Model—The fundamental points of the CCM integrated with complementary medicine: (1) promoting cooperation, with the adaptation of resources and policies, between all those who care for the chronically ill patients and who, in a certain sense, must “produce” a service that is useful to them; (2) in the organization of health services, to allocate part of the resources dedicated to care systems to the integrated management of chronic pathologies; (3) promote awareness of self-care as part of many traditional systems of medicine (TCM, Ayurveda, etc.) and the knowledge of simple techniques improving the approach to self-care for patients; (4) reinforce the concept of prevention and integrated therapy in the construction of multidisciplinary teams by including in them also doctors experienced in complementary medicines; (5) reformulate decision-making aids on the therapies to be adopted, taking into account the therapeutic schemes and the evaluation of the effectiveness of complementary cares, with systems such as audits and specific training for these disciplines; (6) to have a full and rapid access to clinical data for complementary medicine medical staff. All these points have as result the adequate training of healthcare personnel, who can thus assume a proactive role in the transformation of this model of care and, on the other hand, a more involving attitude of the patient, who feel to be a part in the decision-making process. This productive interaction has the sole interest of the best diagnostic-therapeutic approach of chronic patients, often burdened by comorbidities, to whom the often-exasperated fragmentation entails a greater stress that affects the overall state of his health.



In conclusion, notwithstanding the issues caused by the complexity of the patients, different ways of thinking, differences in legal regulations, and objective difficulties caused by the health directives of individual governments, the time is now right to develop a proposal for Integrated Medicine in a European context. Despite the continued problem of hard-line academic positions (probably caused by a lack of the cultural foundations needed to understand this development), Integrated Medicine could lead to a growth in the art of healing in all areas of human life: not only patients' health, but also their relationship with themselves and with society.

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Author Disclosure Statement

The authors declare no competing interest.

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- di Reumatologia (SIR) [Italian Rheumatology Society], Società Italiana per l'ipertensione Arteriosa [Italian Arterial Hypertension Society], Lega Italiana contro l'ipertensione Arteriosa (SIIA) [Italian League against Arterial Hypertension], Società Italiana di Health Technology Assessment (SIHTA) [Italian Health Technology Assessment Society].
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Abbreviation Used

CCM	=	Chronic Care Model
CM	=	Complementary Medicine
EBM	=	Evidence Based Medicine
ECH	=	European Committee for Homeopathy
HIMed	=	Homeopathy and Integrated Medicine
IM	=	Integrated Medicine
ISMO	=	Institute of Homeopathic Medicine Studies
PRO	=	Patient Reported Outcomes
QoL	=	Quality of Life
RCT	=	Randomized Controlled Trial
RWM	=	Real World Medicine
SIOMI	=	Italian Society of Homeopathy and Integrated Medicine
TCM	=	Traditional Chinese Medicine
TM	=	Traditional Medicine

