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Letter to the Editor

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The "Embrace Project": facilitating the health care professionals in diagnosis, clinical reasoning and virtuous co-management of chronic patients before, during and after the COVID-19 pandemic in Italy

https://doi.org/10.1515/dx-2020-0101 Received July 15, 2020; accepted September 17, 2020; published online October 9, 2020

Keywords: chronic disease; digital healthcare; Embrace Project; patient journey.

To the Editor,

According to the World Health Organization, 70-80% of world healthcare resources are allocated to the management of chronic diseases [1]. About 55% of contacts with General Practitioners (GPs) in Italy are generated by chronic patients [2] and 48.7% of subjects aged 65-74 are affected by at least two chronic diseases [1]. The Italian National Health Service was born in 1978, establishing a universal and unlimited system of care. In 1992 the healthcare system was reformed: the State determines the essential levels of assistance whilst the Regions have exclusive competence in the regulation, organization and financing of local health services. The National Chronicity Plan (NCP) was born in 2016 from the need to harmonize activities and provide a common strategic direction in this field [1]. Compatibly with the availability of economic, human and structural resources, the chronic patient

should be ideally followed mainly at home, creating individualized care paths integrating hospital and primary care. The coexistence of multiple diseases may require the intervention of several professional figures, with high risk of fragmented interventions, lack of integration of the care services and absence of a single point of reference and coordination. As a consequence, the patient involvement in the care process and adherence to interventions might be difficult, triggering severe delays in diagnosis, sub-optimal disease management with progression and onset of additional comorbidities and disabilities, having a great impact not only on the individual but on the whole society, due to the associated incremental costs. Hence, within the current organization of the Italian National Health Service (NHS), the GP may take a key role with full ownership of the patient journey. In the past, the GP was considered first as a "gatekeeper", mainly responsible for controlling healthcare expenditure and compliance with drug use, and then as a "case manager", as patient services coordinator with more managerial than clinical skills. There is a great need to evolve the GP to become a generalist for "low risk" diseases and a specialist for some chronic diseases, with proper medical education and equipped with modern tools, including digital innovation. This has become dramatically evident in the days of the COVID-19 emergent pandemic, when the primary care was essential not only in managing patients infected with SARS-Cov2 but also chronic patients not infected but unable to get assistance from hospitals entirely switched to manage severe COVID-19 patients [3]. In light of this scenario, there is therefore even a greater need to optimize the chronic patient's care path to improve health outcomes and use the available resources efficiently. Below we want to describe the "Embrace Project" that, operating in full

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alignment with the spirit and principles of the NCP, aims to facilitate the management of chronic patients by integrating the diagnostic, therapeutic and monitoring processes implemented by specialists in the hospital setting with those put in place by GPs in the primary care setting. The expected outcomes are reducing the time necessary for a correct diagnosis and promoting optimal adherence to therapeutic interventions of any nature under the ownership of the GP. A team of 80 millennials, expert in digital and with a solid scientific background ("Embrace Advisors", EA) was recruited through an innovative selection process. Leveraging on its wide scientific expertise, Novartis trained the EAs with up-to-dated scientific information on chronic diseases such as allergic asthma, heart failure, migraine, psoriasis, spondyloarthritis and spontaneous chronic urticaria. The training included epidemiology, pathophysiology, signs and symptoms, differential diagnosis, clinical management, with reference to the official guidelines, and the existing local care paths to refer the chronic patient to specialized hospital reference centers. The team was deployed throughout the country in May 2019. Each EA acted as "disease consultant", providing GPs with up-to-dated science, and as "referral navigator", providing GPs with up-to-dated information on local procedures. Referral of patients had to be compliant with the local procedures, preserving patient privacy as individual medical records are not shared by GPs. Not being a clinical study, no ethical approval was required. No drug-related promotional activity was in scope of the interaction. Numbers of GPs contacted, contacts and patients referred to hospitals were collected and considered as quantitative key performance indicators (KPI).

In the period June 2019-June 2020 the EAs contacted about 20,000 GPs representing 55% of the GPs active in Italy. Of those, 12,000 were interested in being involved in the project Embrace, and each of them was contacted on average every month. The first contact was focused on explaining the rationale of the project and selecting the topic of interest for the GP. GPs were mostly interested in heart failure and psoriasis, followed by migraine, chronic spontaneous urticaria, allergic asthma and ankylosing spondylitis. The next contacts were dedicated to identify profiles of patients who might have benefitted from a clinical re-assessment based on proper criteria, and finally GPs in autonomy selected among their patients those who may have fitted with such criteria. Overall, about 4,000 patients were identified and referred to hospital specialists for further evaluation: an intervention of any kind was instituted to improve their clinical conditions (Figure 1) as well as a co-management plan. Although the number of referrals is significant, it represents around 3% of to the potential patients who may benefit from such an approach, estimated in approx. 150,000 for diseases in scope. The number of referrals was growing exponentially up to February 2020, demonstrating a progressive impressive impact of the Embrace Project. The dramatic and fast spread of the SARS-Cov2 pandemic had a profound impact on the project: GPs were completely focused on identifying and managing properly SARS-Cov2 infected patients. During the "lockdown" period imposed by the authorities to limit the viral transmission the access to GPs offices was restricted only to urgent cases, and out-patients visits in hospitals were mostly either canceled or postponed. The referral still took place but only in a minority of hospitals, mainly in the part of Italy less impacted by COVID-19. In this context implementation of digital tools such as tele-diagnosis,

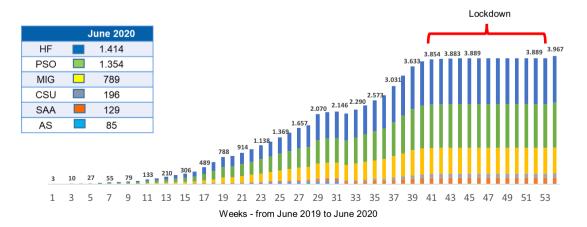


Figure 1: Number of chronic patients for each disease reassessed by GPs, referred to hospital, and included in a co-management plan between primary and hospital care.

HF, heart failure; PSO, psoriasis; MIG, migraine; CSU, chronic spontaneous urticaria; SAA, severe allergic asthma; AS, ankylosing spondylitis.

tele-consultations, remote assistance to quarantined individuals, digital repetition of medical prescriptions, was essential to manage emergent COVID-19 patients as well as to continue managing chronic patients. Similarly, vast majority of interactions between EAs and GPs switched from traditional face-to face contacts to remote modes (i.e., video-calls, webinars). Although initially perceived as surrogate, it became soon evident how such digital interactions might represent valid alternative options and becoming part of the standard practice in the post-COVID-19 era. Although the identification of patients was quicker than expected, in most of the cases the recall was based on manual screening of clinical records. A digital approach applying artificial intelligence to GPs clinical databases would represent a formidable accelerator. Hence, the Embrace Project is evolving as well by implementing digital initiatives based on the IBM Watson platform to connect all stakeholders and move together towards a proactive partnership with the patient, transforming the unpleasant journey in a new opportunity for enjoying life. Such initiatives may allow measuring the impact of the Embrace project on the efficiency of the health system with more sophisticated qualitative endpoints, in the light of a value based approach that should become the standard approach in the hard times we are going to face in the post-COVID-19 era. Results will be shared in future communications.

Research funding: None declared.

Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Competing interests: Authors state no conflict of interest. **Ethical approval**: No ethical approval was required.

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