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EDITORIAL

The potential impact of PNNR on the management of patients with epilepsy

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In recent years, public health in Italy has changed significantly: scientific progress, continuously evolving research, the development of new technologies and innovative drugs have remarkably improved the quality and life expectancy of patients.

Inevitably, as in all sectors of economy, there still is the need to ensure a trade-off between innovation, sustainability and resource allocation.

In this scenario, some key health policy principles should be adhered to in planning medium- and long-term investments, and to allow for a rational allocation of resources, which must be in line with real needs. A critical element for building a 'mutually sustainable' system is to ensure, as far as possible, a solid and stable planning and financial framework.

The value of technologies, connected to the economic and social 'weight' of diseases, represents one of the most important elements in this scenario, especially if it refers to the concept of innovation. Epilepsy appears to fit within this context.

Epilepsy is a chronic condition affecting people worldwide. It is identified by recurring, uncontrolled phenomena called seizures, often leading to neurobiological, cognitive, psychological and social consequences. Seizures, usually of short duration (from a few seconds to a few minutes) are classified according to the awareness level of the patient (integral or impaired awareness) and to the presence of involuntary movements (motor and non-motor seizures). Based on their onset, we can identify focal or partial seizures (which arise in one cerebral hemisphere) and generalized seizures (involving both hemispheres) (1).

In Italy alone, there are over 500,000 people with active epilepsy and more than 36,000 new cases are expected every year. Epilepsy incidence appears to be higher in the first year of life, decreasing during adolescence, remaining low in adulthood and rising after the age of 75. People living with epilepsy experience reduced access to educational opportunities and barriers to enter certain occupations. Uncontrolled epilepsy is often associated with significant psychological dysfunction and impaired quality of life and carries the risk of premature death. Furthermore, stigma and discrimination still surround epilepsy across the world. The economic impact of epilepsy varies significantly depending on the disease duration and severity, response to treatment and the healthcare setting. Out-of-pocket costs and productivity losses inflict substantial burdens on households (2).

Epilepsy proves to be a condition which, if inadequately addressed in terms of organizational model and management approach to diagnosis and patient care, risks generating significant disabilities leading to remarkable economic and social impact (direct healthcare costs, direct non-healthcare costs, indirect and social costs).

It is necessary to allocate adequate investments aimed at improving disease management. Unfortunately, healthcare is generally, and erroneously, perceived as a cost. Only recently has the concept of healthcare cost been evolving in the concept of healthcare investment, despite some barriers still needing to be overcome.

Even if innovative, efficient technologies represent the main driver for improving health and attracting investments in healthcare, their return on investment is more in the long and medium term than in the short term. How is it possible, then, to foster innovative technologies? Which approach may allow decision-makers to match spending limits while ensuring access to effective innovative technologies (drugs, devices, prevention and vaccination campaigns)?

In major industrial countries, including Italy, health technology assessment (HTA) and economic evaluation are the most valuable tools to assess the real value of new technologies. However, it is not sufficient to demonstrate that a technology (health intervention, drug, etc.) is cost-effective: it is necessary to develop approaches based on HTA results, which allow to evaluate/calculate the willingness to pay of the system. In this respect, one of the most important organizational and managerial barriers in our health system is represented by the 'budget silos' approach, at the central, regional and local levels.

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The assessment of the impact of technologies, particularly drugs, takes into consideration their impact only within their sector (i.e. direct costs). This means that more complex technologies are deemed too expensive (as only their price is taken into consideration), without considering their impact on related expenses, such as loss of productivity (days of absence from work; loss of work), social costs sustained by the National Health System (NHS), for example, disability pensions or caregiver benefits, social spending and impact on employment. Applying the logic of silos, the focus has been on the expenditure for drugs without taking into consideration its possible positive effects in the comprehensive patient healthcare plan. The most impactful technologies would benefit from a broader perspective (from the point of view of both price and effectiveness), considering not only health expenditure (at general, regional and local levels) but also social and social security expenditures (direct and indirect costs). Many diseases have a dramatic impact of indirect and social costs which significantly influence the value of a given therapeutic option within an economic evaluation.

When we discuss disease costs, we often resort to the metaphor of the iceberg: the tip shows only direct costs; indirect costs, representing the most consistent part in most diseases or health interventions, are below the surface and therefore invisible.

An accurate estimate of all costs generated by an integrated care approach must therefore take into account all costs (3). With this in mind, when evaluating the use of certain technologies within a health programme (e.g. third-generation anti-seizure medication [ASM] epilepsy drugs), it is necessary to evaluate, along with the technology cost, the impact on indirect and social costs. In other words, it is necessary to evaluate the potential of technologies to reduce these cost items within a comprehensive healthcare plan, as well as their potential to improve efficacy and tolerability. Additionally, a cost assessment including indirect costs is a valid tool for efficient business and regional planning (4,5) and for a better allocation of resources.

However, we are currently experiencing significant inefficiencies between access regulations and actual access, especially for innovative drugs: budget impact, regional heterogeneity, clinical re-evaluation, etc., contribute to reimbursement delays and longer access times to drugs. It is not necessary, therefore, to reduce spending or to approve further cuts, but to identify those areas which allow for improved spending and, above all, to standardize organizational and management models.

The treatment of epilepsy should be managed by highly qualified clinicians, involved in specific contexts, taking into consideration the number of patients, the personnel required and the organizational complexity. On the Italian territory, reference centres with highly qualified personnel, defined on the basis of regional needs and the population, should be accessible to every person suffering from epilepsy. To avoid discrepancies in care and to overcome the 'health system regionalization', the central government should guarantee homogeneity in the qualification of centres dedicated to epilepsy, their medical personnel and the specific equipment (6).

To reach these goals, along with the remarkable effort of the Ministry of Health in securing important resources (increased resources for the health system, increase in pharmaceutical spending limits) the National Recovery and Resilience Plan (PNRR) could ensure a significant upgrade of the NHS, addressing the real needs of citizens. These assumptions are forcing both scholars and decision-makers to make an important evaluation. In my view, a once in a lifetime scenario for our NHS, and welfare as a whole, is taking shape. We see the real possibility of being able to plan a complete reorganization of our NHS and structure it to shape future challenges, with important benefits for the entire country's economic system. The PNRR represents – if well addressed – a unique opportunity for the future sustainability of the NHS. This option is identified not only by financing in itself but also by procedures which can facilitate important reforms in management and organizational models. This means innovative health technologies (drugs, devices, goods and services), new healthcare structures and the 'renovation' of a territory-based care model. With regard to health technologies (drugs and medical devices) we could finally see a rethinking of their role within the NHS and, above all, aligning resources to real needs (abolishing outdated limits and the silos approach). Health technologies are no longer considered a 'mere cost' but as the cornerstone of an investment strategy aimed at guaranteeing patients' timely access to novel and well-studied technologies, which ensure the improvement of patients' health (partial or even total recovery) as well as a significant reduction in costs in the medium- to long term, both direct and indirect (i.e. drugs and effective devices ensure a reduction in hospitalizations, in visits, in comorbidities and in a reduction of disabilities and inabilities).

In conclusion, the PNRR can represent the tool to guarantee sustainability to the NHS, but how resources will be allocated becomes crucial. There are two options available: a distribution of resources without controls or a targeted allocation based on 'robust' models, benefiting from HTA stakeholder involvement. Today more than ever, politics is called upon to make decisions that will determine the life of our country and the organizational, managerial and economic structure of our welfare system in years to come.

State intervention must be imperative both to respond to the critical situation today and also to avert future crises and to build the foundations which, in the long term, will guarantee the trade-off between innovation and sustainability, contributing to a bright future for our welfare system.

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