



Research and scientists, the media and the disabled, politicians and judges, actual real treatments and possible false hopes: a PRM perspective on the Italian Stamina Foundation case

S. NEGRINI^{1, 2}

One may wonder why, at the current stage of research and clinical knowledge, a physical and rehabilitation medicine (PRM) journal would look at stem cell therapy. The main reason is that PRM physicians may learn something from the current controversies around the clinical application of stem cells by the Stamina Foundation.

The Stamina Foundation case: a short synthesis

Davide Vannoni, a psychology professor, through the Stamina Foundation, has advocated the use of stem cell injections for treating disabled patients with end-stage neurological diseases. In certain circumstances, Italian law permits so-called “compassionate” treatments when no other therapies are available.

The case began some months ago when, because of lack of required documentation, Italian regulatory agencies ordered the discontinuation of stem cell therapy. This led to protests by single patients and patient associations. Seizing a media occasion, a popular television program launched a campaign in favor of the so-called “Stamina Method”, interviewing the parents of the children involved. The case rapidly gained wider media attention, with editorials appearing also in various scientific journals. Some judges have ruled that the treatment could continue in individual cases, while others ruled against it.

Corresponding author: S. Negrini, Department of Clinical and Experimental Sciences, University of Brescia, Brescia, Italy.
E-mail: stefano.negrini@med.unibs.it

¹Department of Clinical and Experimental Sciences
University of Brescia, Brescia, Italy
²IRCCS Fondazione Don Gnocchi, Milan, Italy

Under pressure from public opinion, the Italian Parliament and Government allocated 3 million Euros to finance a research protocol to test the method. The scientific commission concluded that, due to lack of safety information in the protocol, patients would not be involved. In early December administrative judges decided that, because of (scientific?) bias, the commission was flawed, and the ruling was overturned. But the case is not over yet.

Methods in PRM

The current case evokes memories of previous instances in PRM where treatments are proposed by people who have never performed proper clinical research. Many of us will remember the Doman-Delacato method and the clinics for intensive “restoration” of paraplegics and tetraplegics. And many of us battle daily against questionable methods in neurologic or orthopedic domains of PRM. What we all witness is PRM patients turning to so-called “treatments” that more often than not engender “false hopes”. Such methods share the fact of being based on “ideas”, perhaps theoretically very good, perhaps effective, but NOT (yet?) PROVEN effective and NOT STUDIED scientifically. Common to many of these methods is a rejection of the scientific approach, or the fight against scientific regulatory agencies.

In this respect, many scientists were initially criticized at start but, like Galileo, their concepts and methods were ultimately vindicated through experimentation. Herein lies the difference with the methods mentioned above. Simply, scientists strictly follow rigorous methodological pathways: they experiment; they evaluate their results scientifically; and from their results they infer hypotheses, some of which are rejected and others proved by facts. "The great tragedy of science - the slaying of a beautiful hypothesis by an ugly fact" (Thomas Huxley). Moreover, clinicians inform their patients of the potential risks and benefits of these experiments. Exercising prudence and rigor, they seek methods that meet ethical standards, thus respecting medical deontology. Such cannot be claimed for unproven treatments, and not only in PRM.

The psychology of disability and chronicity

Another problem is patient-related factors, specifically, chronicity and disability. As PRM physicians, we are all aware of what disability and chronicity means for both patients and their parents and caregivers. In dealing with sudden health changes and supporting our patients as they maneuver through the unknown world of disability, we are acutely aware of the fine balance between motivation and false hopes. We address these issues while trying to rehabilitate our patients: there is no rehabilitation without motivation, just as psychological denial will defeat activation of the compensating mechanisms needed to improve activity and participation. In this context, caregivers are crucial: they help the patient and bear the burden of living with a person with disability. And though this burden may be minimized, it continues to remain such.

Generally, sons more easily accept their parents' new health conditions; the opposite is not only rare but almost impossible: parents never totally accept their child's disability, they suffer, and hold out in the hope something can be done. Even if they outwardly accept the situation, they are often prone to having false hopes raised.

What would you say to someone *telling* you that he could improve your disabled child's condition, and perhaps also *showed* you something that could seem a result? Oftentimes, we put faith in blind hope, seeking something that doesn't exist. While an im-

mediate physiological response to specific stimulation can be obtained in certain health conditions, this does not necessarily produce a positive change (sometimes can even generate a negative one). This apparent effect is what allows methods devoid of evidence to survive and makes people think that the effect is something real.

When medicine is unable to provide hope, it should at least help build a good physician-patient relationship and a basis for care. In this perspective, discovering new therapies it is not only possible but also essential. This must be done only after acquiring preliminary safety data; it must be done only after formal ethical committee approval; it must be based on informed consent of parents and patients. Any other approach acts against the patient's interest, though this point is sometimes not appreciated.

The social factor: journalists, judges, and politicians

The general situation is complicated by social factors (this sounds like the International Classification of Functioning, Disability and Health, doesn't it?).

Journalists need news: what attracts more readers' and viewers' attention? The apparent negation of a suffering child's rights or a scientific position? The problem increases when clinicians are depicted as not fighting for their patients (ensuring safety is fighting for patients, demanding reliable research results means siding with patients, but this is not always easily understood) but instead appears to be acting to defend their rules and ideas (which have been developed precisely in the patient's interest). On the surface, it's very easy to choose. Journalists have a responsibility to the public, but we must be aware that their work and competence are grounded in neither science nor medicine.

Judges decide according to principles that are not necessarily based on scientific evidence: judges have to respect laws not science. Where there are no certainties, what are the limits of the rights of an individual? Must we wait for positive scientific results before we can consider offering a treatment (which is the only possible choice in modern medicine) or record negative reactions before negating possible therapies that could be false hopes, when not even dangerous (this can be another choice, apparently perceived by some judges as being more important for individual

rights according to the law). Judges have responsibilities to society, but their work and competence too are grounded in neither science nor medicine.

Some politicians aim for enhancing their visibility and garnering votes above all else. Navigating between legal interpretation and scientific knowledge, they follow the winds of public opinion. And this doesn't necessarily make for rational judgments and actions. Their responsibilities are the highest but, again, their work and competence are grounded in neither science nor medicine.

Conclusions

First, the Hippocratic Oath: "do no harm".

Second, science: see if it works, through a formal

research project, with all its ethical implications. If it works, it must be done.

Third, the disabled and their needs: find possible solutions, preparing them against unrealistic expectations and "false hopes", supporting them when we can no longer provide a cure but only care. Without sound advice and support, patients with chronic disability will be more easily swayed by purveyors of false hopes.

Fourth, as professionals engaged in our society, with expertise in evidence-based medicine and research, and particularly in dealing with chronic conditions, the disabled and their families, we need to inform politicians, but also the public, so that they can take responsible decisions, without succumbing to populism, sensationalism, and incompetence.

MINERVA MEDICAL®
COPYRIGHT®