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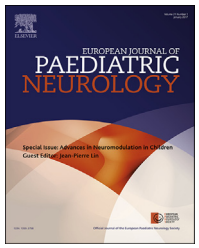

Original article

Securing a future for responsible neuromodulation in children: The importance of maintaining a broad clinical gaze

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ABSTRACT

Aim: This perspective paper provides an overview of several key tensions and challenges within the social context of neuromodulation, and it suggests a means of securing the future of paediatric neuromodulation in light of these.
Results: Tensions and challenges relate to: the considerable clinical and economic need for new therapies to manage neurological diseases; significant commercial involvement in the field; funding pressures; public perceptions (particularly unrealistic expectations); and the emerging Responsible Research and Innovation initiative. This paper argues that managing these challenges and tensions requires that clinicians working within the field adopt what could be called *a broad clinical gaze*. This paper will define the broad clinical gaze, and it will propose several ways in which a broad clinical gaze can be – and indeed is being – operationalised in recent advances in neuromodulation in children. These include the use of multidisciplinary and interdisciplinary clinical team structures, the adoption of clinical assessment tools that capture day-to-day functionality, and the use of patient registries.
Conclusion: By adopting a broad clinical gaze, clinicians and investigators can ensure that the field as a whole can responsibly and ethically deliver on its significant clinical potential.

1. Introduction

The emerging area of paediatric neuromodulation represents an exciting and highly promising set of developments in the management of neurological illness in children. However as with many emerging, innovative clinical developments, its potential may be hindered by challenges in the wider social and political context of healthcare research and provision. It is therefore necessary that clinicians and investigators within the area of paediatric neuromodulation are attentive to such challenges, and that they collaboratively establish a set of responsible practices for mitigating them. The work of the Irving Cooper (1922–1985) serves as a useful introductory

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illustration as to why this is important. Cooper was a pioneer in functional neurosurgery, developing several novel techniques for managing movement disorders and epilepsy: a cryosurgical probe to conduct thalamectomy,[1] cerebellum stimulation to manage spasticity and cerebral palsy,[2–4] and deep brain stimulation (DBS) of the thalamus or internal capsule to manage tremor, spasticity, and dystonia.[3,5,6] These techniques, Cooper claimed, delivered meaningful improvements to patients. Yet during his time and until this day, his work has been treated with a mixture of admiration and scepticism. He clearly made important contributions to understandings of movement disorders and neuromodulation, but because of what has been described as his poor research technique and his inclination for working within his own, isolated "investigative domain", the true clinical implications of his techniques cannot be elucidated.[7] At that time, many of the standard movement disorder clinical assessment tools did not exist, and Cooper tended to rely on his own subjective measures for capturing clinical outcomes. Much of his work was published in the form of anecdotal reports rather than as part of a scientific series. Because of this, a valuable opportunity to produce a useful body of data on neuromodulation was missed, and the field as a whole was deprived of some much needed-direction.

Since Cooper's time the field of neuromodulation has been assisted by various technological developments (most markedly in imaging technology) accompanied by major advancements in understandings of neuro-networks, particularly in basal ganglia function (e.g.[8]). Clinicians now also have access to standardised, validated tools for rating disease severity and assessing clinical outcomes that enable a common language between clinical centres and the pooling of data. The field, then, is on much firmer ground that it was in Cooper's time. It is important, however, not to become complacent about these scientific and technical developments and assume they will assure that neuromodulation will live up to its considerable potential. Now more than ever it is vital that clinicians and investigators collaboratively establish a set of responsible practices for the field. There are, as this paper will explain, various contextual social, economic, and institutional factors that could hinder the field, and which pose significant challenges for biomedical innovation more generally. These relate to the commercial climate and public perceptions, pressure on national healthcare budgets, and the European Commission's call for Responsible Research and Innovation (RRI). These factors should not be considered secondary to the scientific and clinical challenges of translational medicine – they are challenges that need to be addressed and managed at all stages of the innovation process.

This paper will provide an overview of these challenges, and in doing so, it will suggest that managing these challenges will require that investigators and clinicians perceive disease as biopsychosocial phenomenon, and it will require capturing and evaluating the social impact of disease, and of the intervention. It will require, in other words, that investigators and clinicians deploy what could be called *a broad clinical gaze*. Drawing on the French philosopher Michel Foucault's notion of the Medical gaze, this paper will define the broad clinical gaze, and it will propose several ways in which a broad clinical gaze can be – and indeed is being – operationalised in recent advances in neuromodulation (some of which feature in this special issue). These include the use of multidisciplinary and interdisciplinary clinical team structures, the adoption of clinical assessment tools that capture day-to-day functionality, and the use of patient registries. Such measures, it is argued, can help with the production of a pool of valuable evidence on the clinical effectiveness and social impact of neuromodulation, and they can help ensure that innovation within the field is directed towards genuine social and clinical need. This paper will also highlight some of the institutional constraints that can hinder the ability to operationalise a broad clinical gaze. Overcoming such constraints will require coordinated action within field, and this paper will conclude by suggesting that such coordinated action can be seen as moulding an institutional context that embodies responsible research and innovation and will enable neuromodulation to deliver on its considerable clinical potential.

2. The social context of neuromodulation: key challenges and tensions

First and foremost, the social context of the field is characterised by a considerable and urgent need for therapies for managing neurological diseases in children. Neurological disease is a cause of great suffering for patients, and is often a huge burden for families and carers. For this reason, the Nuffield Council on Bioethics (an influential 'think tank' in the UK) has stated that society has a moral obligation – in accordance with the ethical principle of beneficence – to explore and develop new therapeutic interventions, and they explicitly identify neuromodulation as a promising field in this regard.[9] Additionally, neurological illness also constitutes a huge economic burden for nation-states. According to one estimate, the total economic cost of brain disorders (which includes both mental and neurological disorders) in Europe for 2010 was 798 billion EUR; a figure which takes into account both direct costs and indirect costs (such as lost participation in workforce).[10] This is an average cost per inhabitant of around five and a half thousand euros. More specifically, neuromuscular disorders (excluding multiple sclerosis and Parkinson's) have an economic cost of around 7.7 billion EUR and epilepsy (both adult and paediatric) has a cost of around 13.8 billion EUR.[10] As we see further on in this section, such economic considerations are increasingly shaping health and research policies in the EU. Together, the economic implications and unmet clinical need necessitate urgent research into, and development of, neuromodulation therapies, and thus provide an important moral justification for advancing the field of paediatric neuromodulation as a whole.

This great need has of course attracted considerable commercial interest, and some therapeutic areas in the field now represent lucrative markets for device manufacturers; this is another important aspect of the social context of neuromodulation. In 2014, the total net sales of neuromodulation technology of the top three manufacturers (Medtronic, Boston Scientific, and St Jude Medical) was just under three billion USD, and generally the field is characterised by a high rate of innovation.[11] One reason manufacturers have been so interested in the field is that the same technology platform can be