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## Safeguarding NICE from patient groups' conflicts of interest

Patient groups are essential to understanding the value of medicines, but NICE must improve its disclosure practices for conflicts of interest to ensure credibility and impartiality, write Iva Parvanova, Arianna Gentilini, and colleagues

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Since its creation, the National Institute for Health and Care Excellence (NICE) has committed to including patient and public perspectives to fully capture the value of medicines.<sup>1</sup> For example, in their appraisals, which inform funding recommendations for the English NHS, patient groups and their nominated experts provide testimonies of first hand experiences on how a disease affects them and those around them.<sup>2</sup> All contributing parties are required to declare any direct or indirect interests. NICE defines an interest as a situation where there is, or could be perceived to be, an opportunity for a person involved with NICE's work, or their third party associates, to benefit from NICE's decisions.<sup>3</sup> Relevant interests may be constituted by payments received up to 12 months prior to their involvement with NICE from any commercial organisation that might be affected by NICE's decisions.<sup>3</sup>

Reliance on industry funding can undermine the credibility of patient groups and align their agendas with their funders.<sup>4,5</sup> Given the important role played by these groups in NICE, the potential lack of transparency and impartiality warrants further scrutiny of their ties to industry.

An investigation by *The Guardian* reported on the financial connections between Novo Nordisk and UK based patient and medical experts who supported the funding of the company's new obesity drug, semaglutide (Wegovy).<sup>6</sup> Payments from the manufacturer were declared in accordance with NICE's conflict of interest (COI) policies; however, these may be insufficient to prevent industry sponsorship bias in patient contributions.<sup>6</sup> A separate investigation regarding serious breaches of the Association of British Pharmaceutical Industry code of conduct in connection with a weight management programme culminated in Novo Nordisk's suspension from the association for two years.<sup>7</sup>

Two UK based charities supporting people with obesity, the Association for the Study of Obesity and Obesity UK, and their nominated patient experts and representatives, provided submissions and comments to NICE's appraisal of semaglutide in favour of the drug's expanded access and long term use.<sup>8</sup> In accordance with NICE's rules, both patient groups' representatives declared payments from Novo Nordisk in the year leading to their involvement.<sup>3,8</sup> Nevertheless, NICE considered these not to be grounds for their complete or partial exclusion.

The semaglutide case calls into question whether NICE's current approach to the declaration of COIs is sufficient to uncover and manage the ties between

industry and patient experts and ensure unbiased patient expert contributions in NICE appraisals and reimbursement decisions. It also highlights concerns about the extent of NICE's efforts to select experts with no financial ties to industry.<sup>3</sup> While this may not be feasible for conditions where knowledge is concentrated in a few experts, such as in rare diseases, it is unlikely to be the case for a widespread condition like obesity.

To tackle the concerns raised, NICE should consider enhancing its approach to defining and managing COIs in the following ways.

Firstly, COI disclosures should be comprehensive about the financial reliance of patient groups on industry. A 2019 study showed that NICE's decision-making committees were aware of less than a quarter of patient groups' direct financial interests with pharmaceutical companies.<sup>9</sup> Timely, accurate, and detailed charity income data need to be juxtaposed with these disclosures to maintain transparency and ensure credibility. Financial reliance on industry can affect the agenda of patient groups' contributions to NICE appraisals and therefore it is imperative to examine the precise extent to which they are dependent on industry funding.<sup>4</sup>

Secondly, arguably any payment by industry leads to COIs and potential biases.<sup>10</sup> However, patient groups often resort to commercial sources for funding because of a lack of alternatives.<sup>11</sup> Transparency is a step in the right direction, but it does not always lead to independence. Until governmental funding fills existing resource gaps among patient groups, NICE should increase its timeframe of COI disclosure to more than 12 months to avoid overlooking more historical commercial ties.

Thirdly, many patient groups lack resources to represent themselves. Additionally, participation in NICE appraisals creates an opportunity cost for their representatives. This increases the risk of over-representation of a small number of well endowed organisations.<sup>12</sup> In 2017, Haute Autorité de Santé—the French assessment body—launched an online platform for systematic collection of data about contributions to patient groups.<sup>13</sup> NICE should consider implementing a similar strategy with a view to enabling participation from a broader range of patient groups and experts. This would help to circumvent concerns around over-representation and to reduce industry sponsorship bias.

Contributions from patient groups and experts are important to capturing the lived experience of a

condition that cannot always be gleaned from clinical trials. But strong financial ties with industry pose the risk of undermining their credibility and impartiality. To safeguard reimbursement recommendations from vested interests, NICE should revise its COI disclosure and management policies.

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- 1 Norburn LA-O, Thomas LA-O. Expertise, experience, and excellence. Twenty years of patient involvement in health technology assessment at NICE: an evolving story. *Int J Technol Assess Health Care* 2020;37:e15doi: 10.1017/S0266462320000860.
- 2 National Institute for Health and Care Excellence. *Public Involvement Programme—Overview of technology appraisals: a factsheet for patient and carer organisations*. National Institute for Health and Care Excellence, 2014.
- 3 National Institute for Health and Care Excellence. Policy on declaring and managing interests for NICE advisory committees, 2018.
- 4 Lin DH, Lucas E, Murimi IB, et al. Financial conflicts of interest and the Centers for Disease Control and Prevention's 2016 Guideline for prescribing opioids for chronic pain. *JAMA Intern Med* 2017;177:8doi: 10.1001/jamainternmed.2016.8471.
- 5 Herxheimer A. Relationships between the pharmaceutical industry and patients' organisations. *BMJ* 2003;326:doi: 10.1136/bmj.326.7400.1208.
- 6 Das S, Ungood-Thomas J. Revealed: experts who praised new 'skinny jab' received payments from drug maker. *Guardian* 12 March 2023. <https://www.theguardian.com/business/2023/mar/12/revealed-experts-who-praised-new-skinny-jab-received-payments-from-drug-maker>
- 7 Association of the British Pharmaceutical Industry. Novo Nordisk is suspended from ABPI membership 2023. <https://www.abpi.org.uk/media/news/2023/march/novo-nordisk-is-suspended-from-abpi-membership/>.
- 8 National Institute for Health and Care Excellence. Semaglutide for managing overweight and obesity. 2023. <https://www.nice.org.uk/guidance/ta875/evidence/appraisal-consultation-committee-papers-pdf-11381311261>.
- 9 Mandeville KL, Barker R, Packham A, et al. Financial interests of patient organisations contributing to technology assessment at England's National Institute for Health and Care Excellence: policy review. *BMJ* 2019;364:doi: 10.1136/bmj.k5300.
- 10 McCoy MS, Emanuel EJ. Why there are no "potential" conflicts of interest. *JAMA* 2017;317:2doi: 10.1001/jama.2017.2308.
- 11 Baggott R, Jones K. The Big Society in an age of austerity: threats and opportunities for health consumer and patients' organizations in England. *Health Expect* 2015;18:73doi: 10.1111/hex.12185.
- 12 Menon D, Stafinski T, Dunn A, et al. Involving patients in reducing decision uncertainties around orphan and ultra-orphan drugs: a rare opportunity? *Patient* 2015;8:39doi: 10.1007/s40271-014-0106-8.
- 13 Gesbert C, André-Vert J, Guerrier M, et al. The contribution of French patient and consumer groups to health technology assessments over a 2-year period: an observational retrospective study. *Int J Technol Assess Health Care* 2021;37:e48doi: 10.1017/S0266462321000180.