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Drugs, cancer and end-of-life care: A case study of pharmaceuticalization?

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ABSTRACT

There is evidence from some countries of a trend towards increasingly aggressive pharmacological treatment of patients with advanced, incurable cancer. To what extent should this be understood as a progressive development in which technological innovations address previously unmet needs, or is a significant amount of this expansion explained by futile or even harmful treatment? In this article it is argued that while some of this growth may be consistent with a progressive account of medicines consumption, part of the expansion is constituted by the inappropriate and overly aggressive use of drugs. Such use is often explained in terms of individual patient consumerism and/or factors to do with physician behaviour. Whilst acknowledging the role of physicians and patients' expectations, this paper, drawing on empirical research conducted in the US, the EU and the UK, examines the extent to which upstream factors shape expectations and drive pharmaceuticalisation, and explores the value of this concept as an analytical tool.

1. Introduction

Since the mid-1990s, a number of studies have focused attention on the growing importance of pharmaceuticals in our day-to-day lives. This work has been reviewed by Abraham (2009, 2010) and by Williams et al. (2011), and recent articles by these scholars and by Busfield (2010) from the United Kingdom (UK) have provided broad overviews of the rapid expansion in medicines use over recent decades, and suggested conceptual and heuristic frameworks for the development of future sociological analyses. Abraham and Williams et al. suggest that processes of 'pharmaceuticalization' – '[t]he transformation of human conditions, capacities or capabilities into opportunities for pharmaceutical intervention' (Williams et al., 2011, 711) – have driven this expansion, and all authors agree that the trend cannot be adequately explained by 'progressive' accounts of techno-scientific progress meeting population health needs – what Abraham calls the 'biomedicalism thesis' (2010, 606).

As Abraham argues, addressing the validity of biomedical explanations is crucial to any analysis since it is directly relevant to sociological understanding and evaluation of the impacts of pharmaceuticalisation, including 'the implications of pharmaceuticalization for health' (Abraham, 2010, 606). Of the three overviews, only Abraham attempts in any substantive way to address the plausibility of what he calls the biomedicalism thesis as an explanation for *overall* pharmaceutical expansion, arguing that, given an overall decline in therapeutic innovation since the late 1990s, 'biomedicalism … cannot be an explanation for the *growth* in overall pharmaceutical markets or *expanded* pharmaceuticalization in some therapeutic areas, because no such growth or expansion of drug innovation offering significant therapeutic advance has occurred in the last 15–20 years' (2010, 616). However, this argument is problematic in that it fails to recognise that increased rates of medicines prescribing can also be explained by increased utilisation of *existing* drugs to meet the *established* health needs of a growing patient population, despite declining rates of therapeutic innovation. Patient populations may expand due to demographic factors, higher incidence rates of disease, and/or improved diagnosis or access to healthcare. In such cases, biomedical explanations *may* provide a sufficient explanation for higher rates of medicines utilisation. More detailed analyses of patterns of use, the plausibility of different explanatory factors, and the impacts of increased medicines consumption within specific disease areas is needed to test 'progressive' explanations and shed further light on the usefulness of 'pharmaceuticalization' as a conceptual tool.

This article explores the drivers and impacts of expanding medicines use in the treatment of patients with advanced,

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metastatic solid tumour cancers in the US and the EU. The analysis draws on research, undertaken between 2008 and 2013, investigating the dynamics of patient advocacy and the regulation of new anticancer drugs. This research involved extensive documentary data collection and analysis, including review of the scientific, social scientific and 'grey' literature. Fieldwork was undertaken in the United States (US), the UK and throughout the European Union (EU), and a total of 60 semi-structured interviews were conducted with a purposive sample of: US cancer patient advocates and advocates acting at the level of the supranational EU (representing 41 separate patient groups and 13 tumour types); medicines regulators; cancer specialists; journalists and other stakeholders. Ethics approval was obtained for the research and participants gave informed consent before taking part. In-depth interview guides covered a range of topics including respondents' perceptions of the therapeutic value of new drugs, patients' interests and needs, attitudes towards regulatory science and standards, the balance between evidence development and access to new medicines, patient and public participation in medicines regulation and new drug development, and the nature of relationships between the different stakeholders. Data was analysed against an initial coding frame reflecting the central research questions of the project and relevant data falling outside the initial frame was used to modify the coding iteratively, until no more useful information could be extracted.

To interrogate the plausibility of progressive accounts of medicines expansion in the treatment of patients with advanced metastatic solid tumours, this paper begins with a review of the scientific literature, including recent assessments of the clinical benefits offered by new anticancer drugs, an evaluation of these benefits in the context of studies of patient expectations and preferences, and a review of research investigating the impacts of chemotherapeutic expansion towards the end-of-life. I argue that, taken as a whole, this evidence raises significant doubts about the credibility of biomedical explanations for the increased utilisation of chemotherapy in patients with end-stage disease. I then utilise William et al.'s (2011) concept of a 'pharmaceutical regime' – and the shifting configuration of relationships between key actors and institutions – to explore alternative explanations for this chemotherapeutic expansion. Finally, I consider the usefulness of 'pharmaceuticalisation' as a lens through which to view these dynamics.

2. Chemotherapeutic expansion: a model of progress?

There is a lack of comprehensive and publicly accessible data on long-term, national-level trends in oncology drug prescribing. However, available data indicates that utilisation has indeed increased. According to US pharmacy benefits data analysed by Express Scripts there was a 3.4% increase in utilisation of cancer drugs between 2011 and 2012, and a 10.5% increase between 2012 and 2013 (Express Scripts, 2013, 2014). In the UK, data from one large cancer network show that between 2003/04 and 2009/10 there was a 67% increase in the number of chemotherapy courses given to cancer patients with solid tumours (Roche et al., 2010) and comprehensive, national-level data from France also demonstrates expanding utilisation of chemotherapy. Between 2005 and 2010, the number of patients receiving chemotherapy grew by 20% – faster than the growth in the number of new cancer patients diagnosed (INCa, 2012, 10). Finally, large population-based studies provide evidence of a temporal trend of increasing use of chemotherapy towards the end-of-life in North America (Earle et al., 2004, 2008; Ho et al., 2011), and the Netherlands (Bernards et al., 2013).

On first inspection, the plausibility of the biomedical thesis in accounting for this growth appears high. Globally, both the incidence and prevalence of cancer are increasing (WHO, 2013). In addition, many cancers continue to carry a poor prognosis and almost 50% of cancer patients will eventually develop metastatic disease (Koedoot et al., 2003), hence there is a desperate need for more effective treatments. Has this growing demand been matched by increased availability of effective new therapies? Here again, the indicators appear to support a progressive account of chemotherapeutic expansion. Oncology has become a major area for R&D investment by the biopharmaceutical industry over the last two decades, and this has resulted in a 70% increase in the number of drugs available to treat cancer in 2005 compared with 1995 (Analysis Group, 2013; Jonsson and Wilking, 2007). Furthermore, evaluations by medicines regulators in the US and EU indicate that between a third and one half of all new approved cancer indications offer important therapeutic advances over existing treatment options (Davis and Abraham, 2013, 155–157; Sherman et al., 2013). This would have the effect of both expanding the 'treatable' patient population *and* of increasing the number of drugs prescribed per patient, since new drugs are often used *in combination* with established therapies for various stages of the disease (Niraula et al., 2012; INCa, 2012, 10).

For patients with metastatic cancer, the current clinical research paradigm means that most new drugs are first tested and approved for use in patients with advanced disease who have exhausted existing treatment options (Goss et al., 2012). This may have resulted in expanded utilisation, and increased duration of chemotherapy use towards the end-of-life (Martoni et al., 2007, 420; Murillo and Koeller, 2006; Temel et al., 2008, 830; see also below). According to the industry, regulatory agencies and some research scientists and patient advocates, this 'pharmaceuticalisation' in the treatment of advanced cancer represents a gain for individuals and society as more patients are able to benefit from the therapeutic advances offered by these new treatments in terms of life-extension and improved quality of life (Goss et al., 2012). Yet there is accumulating evidence that whilst increasing numbers of patients with advanced disease receive drug treatment, the benefits offered by new drugs may not match patients' expectations or informed preferences and that aggressive use of chemotherapy towards the end-of-life is associated with poorer quality of life and death, regret, financial hardship and possibly shorter survival. This evidence and related issues are considered below.

3. What patients need and want (and what they get)

Since most metastatic solid tumours are incurable, the goal of chemotherapy for patients must be 'palliative' – that is, drug treatment should relieve disease-related symptoms, improve quality of life or prolong life *without* an unacceptable impact on quality (Braga, 2011; Doyle et al., 2001). Clinicians refer to care as 'futile' when patients are administered burdensome, toxic and potentially life threatening therapies that will not achieve any of these goals (von Gruenigen and Daly, 2005). A decision to forgo 'disease-directed' chemotherapy – that is, chemotherapy aimed at shrinking or stabilising the tumour – does not entail 'doing nothing' for patients. Instead, 'palliative' or hospice care focuses on relief of pain and other symptoms, and on enhancing patients' general physical, psychosocial and spiritual wellbeing (Rocque and Cleary, 2013). Whilst anticancer drugs *may* have a role to play in treating patients near the end-of-life, by definition, palliative care should not include anticancer drugs that could negatively impact on quality-of-life. The more marginal or uncertain the degree of benefit offered by drug therapy, the less likely it will be that the risk-benefit balance of drug treatment will be positive since all pharmaceutical use carries some risk.

Given evidence of chemotherapeutic expansion amongst patients with advanced disease, it is therefore particularly concerning that a number of recent, independent reviews indicate that the