Emerging Health Policy Research Conference 2017

Abstract Submission

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Presenters Details

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Short Biography of presenter (maximum 50 words):
Jessica Pace is a pharmacist and PhD candidate at Sydney Health Ethics (formerly Centre for Values, Ethics and the Law in Medicine) at the University of Sydney. She has undergraduate degrees in biochemistry, law and pharmacy. Her doctoral research is examining the ethics of debates surrounding accelerated access to medicines.

Presentation Details

Presentation Title (up to 10 Words):
Debates about accelerated access to medicines: reality or rhetoric?

Keywords: (up to 5 to assist organisers in streaming papers):
- Pharmaceutical regulation
- Pharmaceutical funding
- Qualitative research
- Cancer
- Rare diseases

Research Details (250 word limit)

Introduction/Background:
In recent years, there has been an increasing emphasis on initiatives that allow patients to access therapies outside of traditional regulatory and reimbursement processes (termed "accelerated access" to medicines). However, we know little about the beliefs and values driving demands for accelerated access. This is an important lacuna because accelerated access has both risks and benefits, and acceding to demands that are based on unsound reasoning may have adverse impacts on patients and health systems.

Research Question:

We explored the discourse surrounding accelerated access to medicines in order to determine the arguments that stakeholders make and the techniques they use to advance these.

Methodology:
We analysed published discourse on three different forms of accelerated access-managed entry and coverage with evidence development, the UK cancer drugs fund and drugs used to treat rare diseases. Relevant materials for the first two case studies were identified by searching the databases Google, Google Scholar and Factiva in September 2016; submissions to the Australian government reviews of the Orphan and Life Saving Drugs programs were used for the third case study. Material was analysed using Fairclough and Fairclough's framework for analysing practical argumentation.

Findings:
We analysed 40 published materials. Stakeholders emphasised the importance of timely access to new therapies and the barriers that current regulatory and reimbursement systems pose. Issues such as uncertainty surrounding the safety, efficacy and cost-effectiveness of new therapies, the opportunity costs of funding these and the impact of this on the sustainability of healthcare systems were rarely mentioned. The use of techniques such as emotive language, personal stories from patients, metaphors of war and battle, slippery slope arguments and arguments to pity, the people, authority and against the man give these arguments significant rhetorical force.

Policy Implications:
The current discourse surrounding accelerated access to medicines is an emotive one that is placing increased pressure on policy makers to both register and fund medicines even when there are significant questions about their safety, efficacy and cost-effectiveness. Policy makers need to offer alternative messages (such as community solidarity or non-exploitation) and, more importantly, alternative forms of access (such as publically-funded clinical trials) that address stakeholder concerns about current regulatory and reimbursement processes while protecting the interests of both current and future patients and the broader community.

N.B. All presenters will be asked to include a final slide in their presentations that summarises the policy recommendations and/or implications that can be drawn from the research presented.