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OVERTCOMING ENTRENCHED DISAGREEMENTS. THE CASE OF MISOPROSTOL FOR POST-PARTUM HAEMORRHAGE

Ghinea N, Lipworth W, Little M, Kerridge I, Day R. (2013)

ABSTRACT

The debate about whether misoprostol should be distributed to low resource communities to prevent post-partum haemorrhage (PPH), recognised as a major cause of maternal mortality, is deeply polarised. This is in spite of stakeholders having access to the same evidence about the risks and benefits of misoprostol. To understand the disagreement, we conducted a qualitative analysis of the values underpinning debates surrounding community distribution of misoprostol. We found that different moral priorities, epistemic values, and attitudes towards uncertainty were the main factors sustaining the debate. With this understanding, we present a model for ethical discourse that might overcome the current impasse.

INTRODUCTION

Almost all maternal deaths occur in the developing world¹, of which the major causes are known to be post-partum haemorrhage (PPH), infection, eclampsia and unsafe abortion. The majority of these deaths (87%) occur in Sub-Saharan Africa and Southern Asia². In these contexts, PPH is the leading cause of maternal mortality, being responsible for approximately one-third of all maternal deaths. In Latin America and the Caribbean, PPH is the second

¹ N.M. Nour. An Introduction to Maternal Mortality. *Reviews in Obstetrics and Gynecology* 2008; 1: 77-81; World Health Organisation. 2012. *Maternal Mortality Fact Sheet No: 348*. Available at: <http://www.who.int/mediacentre/factsheets/fs348/en/index.html#> [Accessed 18 April 2013].

² United Nations. 2010. *Millenium Development Goals Report 2010*.

leading cause of maternal death after hypertensive disorders³. In contrast, maternal deaths in the developed world are most commonly due to ‘other direct causes’ (such as complications related to caesarean section and anaesthesia), hypertensive disorders, and embolism respectively⁴.

PPH is treatable with the use of uterotonic drugs and other conservative interventions, with surgery being a last resort, but most women in Africa and Southern Asia usually give birth at home without skilled care⁵ and access to effective care within a reasonable time is not possible for many women in the developing world⁶. The problem, therefore, is not that PPH is untreatable, but that women cannot access the care they need.

In response to the massive global inequity in maternal health, the United Nations set a target in 2000 to reduce maternal mortality by 75% between 1990 and 2015 (Millennium Development Goal (MDG) 5). In the 20 years to 2010, the rate of maternal mortality in developing countries has reduced by 47%⁷, which although significant, falls far short of the United Nations’ targets.

Many believe that the drug misoprostol is a key tool in the struggle to reduce maternal mortality in the developing world. Misoprostol is a prostaglandin E1 analogue that was developed by Searle in 1973 and approved in the late 1980’s for the treatment of gastric ulcers due to its ability to inhibit gastric acid secretions. It is also widely used ‘off-label’ for many other purposes including labour induction⁸, abortion⁹, PPH¹⁰, and as a general cervical ripening agent

³ K.S. Khan, et al. WHO analysis of causes of maternal death: a systematic review. *The Lancet* 2006; 367: 1066-1074.

⁴ World Health Organisation. *Maternal and Perinatal Health*. Available at: http://www.who.int/reproductivehealth/topics/maternal_perinatal/epidemiology/en/ [Accessed 18 April 13].

⁵ United Nations, *op. cit.* note 2.

⁶ S. Naicker, et al. Shortage of Healthcare Workers in Developing Countries - Africa. *Ethnicity and Disease* 2009; 19: S1.60-64; UNFPA. 2003. *Maternal Mortality Update 2002: A Focus on Emergency Obstetric Care*.

⁷ World Health Organisation. 2012. *Trends in Maternal Mortality: 1990 to 2010*. WHO, UNICEF, UNFPA and The World Bank estimates.

⁸ Z. Alfirevic & A. Weeks. Oral misoprostol for induction of labour. *Cochrane Database of Systematic Reviews* 2010; G.J. Hofmeyr, A.M. Gulmezoglu & C. Pileggi. Vaginal misoprostol for cervical ripening and induction of labour. *Cochrane Database of Systematic Reviews* 2010; E. Krause, et al. Off-label use of misoprostol for labor induction: a nation-wide survey in Switzerland. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2011; 159: 324-328.

⁹ H. von Hertzen, et al. Comparison of vaginal and sublingual misoprostol for second trimester abortion: randomized controlled equivalence trial. *Human Reproduction* 2009; 34: 106-112; J. Chai, et al. A randomized trial to compare two dosing intervals of misoprostol following mifepristone administration in second trimester medical abortion. *Human Reproduction* 2009; 24: 320-324.

¹⁰ G.J. Hofmeyr, et al. Misoprostol to prevent and treat postpartum haemorrhage: a systematic review and meta-analysis of maternal deaths and dose-related effects. *Bull World*

to ease other obstetric and gynaecological interventions¹¹. Importantly, misoprostol is cheap, stable at ambient temperature and therefore requires no special storage, and is easy to administer because it comes in an oral tablet form. In 2006 the International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives argued that distributing misoprostol to communities may be the only realistic way to manage PPH in low-resource communities¹².

While convincing evidence exists that misoprostol is efficacious in management of PPH¹³, it is less clear how to deliver the drug safely to those who need it most. In particular, very little is known about the benefits and risks associated with community distribution of misoprostol in low resource settings. In 2012 both a Cochrane review and systematic review published by Chu and colleagues reported that there is no definitive evidence to support distribution of misoprostol in low resource settings¹⁴. The Cochrane review identified only three relevant studies of which none met the inclusion criteria, while Chu's review identified 176 studies of which only 6 met the inclusion criteria.

In the face of this evidentiary uncertainty, people have expressed widely divergent views as to how widely, if at all, misoprostol should be distributed in the developing world. Some have argued that community distribution of misoprostol is a poor option for addressing PPH in low resource communities, while others have strongly advocated for its use¹⁵. WHO and FIGO have been circumspect in their recommendations regarding community distribution,

Health Organ 2009; 87: 666-677; J. Blum, et al. Treatment of post-partum haemorrhage with sublingual misoprostol versus oxytocin in women receiving prophylactic oxytocin: a double-blind, randomised, non-inferiority trial. *The Lancet* 2010; 375: 217-223; B. Winikoff, et al. Treatment of post-partum haemorrhage with sublingual misoprostol versus oxytocin in women not exposed to oxytocin during labour: a double-blind, randomised, non-inferiority trial. *The Lancet* 2010; 375: 210-216.

¹¹ W.L. Cowman, et al. Vaginal misoprostol aids in difficult intrauterine contraceptive removal: a report of three cases. *Contraception* 2012; 83: 281-284; K. Cepni, et al. Randomised trial of oral misoprostol treatment for cervical ripening before tandem application in cervix cancer. *International Journal of Radiation Oncology, Biology and Physics* 2011; 81: 778-781;

N.P. Polyzos, et al. Misoprostol prior to hysteroscopy in premenopausal and postmenopausal women. A systematic review and meta-analysis. *Human Reproduction Update* 2012; 18: 393-404.

¹² M. Potts, N. Prata & N.N. Sahin-Hodoglugil. Maternal mortality: one death every 7 min. *The Lancet* 2010; 375: 1762-1763.

¹³ Winikoff, et al. *op. cit.* note 10.

¹⁴ O.T. Oladapo, et al. Advance misoprostol distribution for preventing and treating postpartum haemorrhage. *Cochrane Database of Systematic Reviews* 2012; C.S. Chu, P. Brhlikova & A.M. Pollock. Rethinking WHO guidance: a review of evidence for misoprostol use in the prevention of postpartum haemorrhage. *Journal of the Royal Society of Medicine* 2012; 105: 336-347.

¹⁵ C. Ronsmans & W. Huang. Community based interventions to reduce maternal mortality. *The Lancet* 2010; 375: 457; M. Potts, et al. Empowering women to control post-partum haemorrhage. *The Lancet* 2010; 375: 459-450.

settling to support its use in circumstances where alternative pharmacotherapy is not available¹⁶. WHO in particular is concerned about lingering safety concerns and uncertainties associated with widespread community distribution of misoprostol¹⁷, and has recommended that rigorous research is needed¹⁸.

With the inclusion of misoprostol in the 2011 WHO Essential Medicines List for the ‘prevention of postpartum haemorrhage where oxytocin is not available or cannot be safely used’ a consensus of sorts seemed to have been reached between stakeholders. However, as of March 2013, two contradictory applications to review the approved indications of misoprostol in the Essential Medicines List had been submitted¹⁹. One sought to expand misoprostol’s use in management of PPH, and another sought to delete misoprostol for prevention of PPH under any circumstances.

This raises the question: why do some people support community distribution of misoprostol, while others are opposed to this course of action, whether absolutely or conditionally, when both groups face the same level of evidentiary uncertainty? It seems that, as might be expected in any complex policy arena, deeply held convictions of governments, researchers, the medical establishment, and not-for-profits, in addition to evidence, are contributing to, and even dictating, the terms of the debate.

In this article we attempt to deconstruct the debate around community distribution of misoprostol for PPH in the developing world, and characterise its main conceptual features and tensions. We do not seek to provide a normative analysis as to whether or not the evidence supports the case for misoprostol’s distribution. Nor do we try to provide a historical analysis of how attitudes have adapted as the evidence base has evolved. Rather, we seek to make visible the values underpinning stakeholders’ published opinions, and to demonstrate that these can be just as important as (and sometimes more important than) the evidence with which they are presented.

METHOD

¹⁶ A.M. Gulmezoglu, et al. Misoprostol use in the community to reduce maternal deaths. *The Lancet* 2010; 376: 955; FIGO. 2012. *Misoprostol for PPH in low resource settings initiative*. Available at: <http://www.who.int/reproductivehealth/topics/misoprostol/post-partum-haemorrhage-low-resource-settings-initiative> [Accessed 18 April 2013].

¹⁷ Ibid.

¹⁸ World Health Organisation. 2010. *Clarifying WHO position on misoprostol use in the community to reduce maternal death*. Available at:

http://whqlibdoc.who.int/hq/2010/WHO_RHR_10.11_eng.pdf [Accessed 18 April 2012].

¹⁹ World Health Organisation. 2013. *Essential Medicines Selection*. Available at: http://www.who.int/selection_medicines/committees/expert/19/applications/en/ [Accessed 18 April 2013].

We performed a qualitative analysis of the debate surrounding the community distribution of misoprostol for PPH in low resource settings, as evident in opinion pieces (editorials, commentaries and letters) in medical journals, using concepts derived empirically from the broader debate around the off-label use of misoprostol in maternal health.

In this study health and medical journals were the main source of evidence. Our sampling frame was kept as general as possible to capture a broad understanding of the issues surrounding misoprostol for maternal health. Since our research was concerned with the subjective views of stakeholders rather than the evidence for or against misoprostol's use for various indications, we searched Google Scholar for editorials, comments, correspondences and letters in journal articles using the search term 'misoprostol'. Although no timeline was pre-selected, it emerged that the most appropriate starting year for the analysis was 2000 as it coincided with the establishment of the Millennium Development Goals, which are of particular importance to the maternal health debate, and therefore the misoprostol debate. The final month for collecting data coincided with the beginning of our analysis in June 2012.

In keeping with the principles of qualitative research, we began to analyse the materials immediately using Morse's outline of the cognitive basis of qualitative research²⁰, and Charmaz's outline of data analysis in grounded theory²¹. We entered all articles into an Excel spreadsheet paragraph by paragraph and began to identify themes. Articles were collected until it was clear that thematic saturation was reached – that is, until we reached a point at which no new themes were emerging in our analysis. To ensure that no critical issues were overlooked we searched the Lancet, British Medical Journal, New England Journal of Medicine, the Journal of the American Medical Association, PLOS Medicine, and the Annals of Internal Medicine using their advanced search utilities using the search term 'misoprostol' and filtering by editorials, correspondences, comments, or letters. In total approximately 50 articles were reviewed as part of this research.

Themes were collated into the following categories by the first author: the nature, purpose and context of evidence; safety and clinical uncertainty; ethical concerns; regulatory concerns; and health service delivery. With these categories in mind, several cycles of immersion in the data and crystallisation of insights were undertaken to identify the fundamental differences in values

²⁰ J.M. Morse. 1994. 'Emerging from the data': The cognitive processes of analysis in qualitative inquiry. In *Critical issues in qualitative research methods*. J.M. Morse, ed. Thousand Oaks: Sage.

²¹ K. Charmaz. 2006. *Constructing grounded theory: a practical guide through qualitative analysis*. London: Sage.

essential to the apparent disagreements²². A theoretical framework was developed that the authors agreed had explanatory power with regards to understanding the nature of the debate. The theoretical framework was then applied to the more focused debate around community distribution of misoprostol for PPH in low-resource settings.

RESULTS

Arguments against misoprostol distribution

Those against community distribution of misoprostol for PPH in the developing world were concerned primarily with the fact that it has been associated with adverse side effects, some serious, and that these complications may increase in number or become even more serious if misoprostol were distributed widely in low-resource settings. This was seen to be partly because adequate monitoring and controls in these settings are unavailable, therefore increasing the likelihood of harm.

Others focused their attention on the fact that the evidence base for community distribution of misoprostol continues to be disputed, or is weak. When Pagel and colleagues developed a model to assess the effectiveness of potential strategies to improve maternal health, for example, they were criticised by some for using unjustified estimates of misoprostol's effectiveness in reducing mortality from PPH. It was argued that a Cochrane Review published in 2007 had indicated that there was no evidence of misoprostol's effectiveness on maternal mortality reduction and 'substantial heterogeneity of effect on severe postpartum haemorrhage'²³. While WHO included misoprostol in the Essential Medicines List for PPH, they have never recommended its distribution, stating that:

'...WHO does not recommend such practices [community distribution of misoprostol] with unknown benefits and harms.'²⁴

Contributing to the uncertainty of evidence claims was the argument that blood loss is notoriously difficult to measure accurately and that this has compromised comparative studies²⁵. Some, therefore, have argued that the only reliable way to generate data about maternal mortality from PPH would

²² S.L. Schensul, J.J. Schensul & M.D. LeCompte. 1999. *Essential Ethnographic Methods*. Oxford: Altamira Press.

²³ Ronmans & Huang , *op. cit.* note 15.

²⁴ Gulmezoglu, et al. *op. cit.* note 16, p. 955.

²⁵ R. Khan & S. Sharma. Use of misoprostol in third stage of labour. *The Lancet* 2002; 359: 708-709.

be direct observation of deaths, which would require large and complex trials²⁶.

The fact that misoprostol has not been subject to regulatory approval for management of PPH (that is, is used off-label for this indication) was seen to add further uncertainty because it meant that there was insufficient official guidance on the most effective and safest dosage regimens²⁷.

Those against community distribution of misoprostol for PPH in low resource settings therefore preferred to wait for certainty, on the basis of further high-grade evidence, to ensure that the intervention was safe before promoting widespread distribution of misoprostol.

Arguments in favour of misoprostol distribution

Those in favour of community distribution of misoprostol for PPH in the developing world were primarily motivated by what they saw as the unconscionable inequity in maternal mortality. PPH was framed as a 'scourge' that needed to be eliminated, and the women most at risk were seen as vulnerable and powerless, requiring protection²⁸.

Advocates of community distribution of misoprostol did not deny the fact that gaps in the evidence base existed, but they claimed that the use of lower standards of evidence was legitimate because it would be difficult, if not impossible, to generate high-grade evidence for logistical, ethical and financial reasons²⁹. Great need, combined with a low prospect of generating high-grade evidence, was seen as an adequate (if not ideal) basis for action³⁰.

Some advocates of community distribution of misoprostol also sought to strengthen the case for using weaker evidence by challenging the sacrosanct nature of high-grade evidence. They claimed that even the best research is only informative about the settings in which it is conducted. For instance Potts and colleagues described how two studies examining the comparative effectiveness of misoprostol and oxytocin, one conducted in well-resourced hospitals and the other in Egyptian hospitals, reported contradictory results³¹. By suggesting that even high-grade evidence would not resolve the dispute

²⁶ A. Weeks. Oral misoprostol for postpartum haemorrhage. *The Lancet* 2006; 368: 2123.

²⁷ Blum, et al. *op. cit.* note 10; N. Deole & A. Weeks. Knowledge of correct dosages of misoprostol in reproductive health. *International Journal of Gynecology and Obstetrics* 2010; 109: 71-77.

²⁸ M. Potts, et al. *op. cit.* note 15; P.D. Darney. Misoprostol: a book to safe motherhood...or not? *The Lancet* 2001; 358: 682.

²⁹ M. Potts, et al. *op. cit.* note 12.

³⁰ M. Potts, N. Prata & N.N. Sahin-Hodoglugil. Misoprostol use in the community to reduce maternal death. *The Lancet* 2010; 376: 955-956.

³¹ M. Potts, et al. *op. cit.* note 12.

about using misoprostol for management of PPH, the use of other forms of justification could be more easily legitimised.

Advocates of misoprostol distribution also questioned claims about the side effects of misoprostol. For instance, in response to safety concerns highlighted by critics, Potts and colleagues argued that since its introduction, misoprostol has been used by millions of people for many indications, in high doses and for extended periods of time, including self-administration of misoprostol in the developing world. They therefore asked:

‘Are deaths occurring and going unregistered, or is misoprostol not only a highly effective drug but also a remarkably safe one?’³²

Whatever risks did remain were seen by proponents to be insignificant ‘in comparison to the very real danger of post-partum haemorrhage after home births where skilled attention is inaccessible’³³.

DISCUSSION

Conflicting ‘prudences’

In deconstructing the values underpinning the debate about community distribution of misoprostol it became evident that there was one key question implicitly shaping the arguments of both ‘sides’: at what point is it ethical to take action? In other words, the co-existence of scientific, clinical, and ethical uncertainty, combined with conflicting moral priorities, have created a tension that has split the professional community between those who maintain a ‘conservative’ risk-averse position and those who seek a more ‘progressive’ solution to the misoprostol dilemma.

More specifically, these two groups differ with respect to 1) their tendency to focus on harm, or on benefit and justice, 2) their willingness to act in the face of uncertainty, and 3) their views about the need for ‘strong’ scientific evidence.

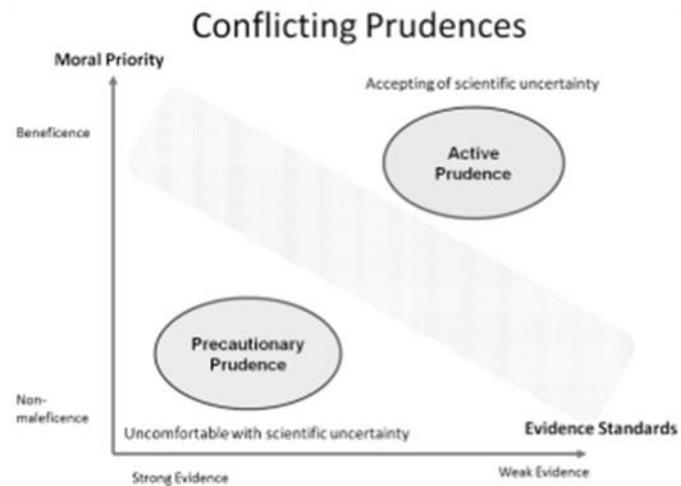
Those against community distribution of misoprostol in low resource settings were ‘conservative’ in that they were concerned about the potential for causing harm, found the degree of scientific and clinical uncertainty unacceptable, and were the strongest supporters of the need for generating robust scientific evidence before acting. On the other hand, proponents of distributing misoprostol wanted to challenge the status-quo. They focused more on the potential benefits of distributing misoprostol, and were willing to act on higher levels of uncertainty and accept lower standards of evidence to support their case. In other words there was a strong correlation between

³² Ibid: 1763

³³ M. Potts, et al. *op. cit.* note 15.

epistemic and moral values. Those who emphasised the ethical principle of non-maleficence most strongly were most strict about evidence requirements and least tolerant of uncertainty, whereas those who emphasised beneficence tended to be more lenient about epistemic standards. We defined these two positions as variants of ‘prudence’—precautionary prudence and active prudence respectively (Figure 1).

Figure 1: Mapping of prudential commitments observed in the misoprostol debate in terms of the correlation between moral priorities and epistemic standards



As well as being implicit in the pro- and anti-distribution arguments, these two versions of prudence can be seen explicitly in the discourse of prominent spokespeople. In a commentary about the difficulties associated with generating definitive evidence about harms, Luis Cuervo, former Clinical Editor of BMJ, and Mike Clarke, former Co-Chair of the Cochrane Collaboration Steering Group (the group responsible for overseeing the development and implementation of policy affecting the Cochrane Collaboration) expressed a position consistent with active prudence in reference to misoprostol:

‘When insufficient data are available to ascertain the size of the problem for an intervention and for any alternatives, people may end up worse off. They might be deprived of an intervention that is on balance more beneficial than harmful ...’³⁴

On the other hand, WHO, in defence of their conservative position on misoprostol, drew upon a statement by Sir Iain Chalmers, one of the founders of the Cochrane collaboration, which expresses the precautionary prudential principle:

³⁴ L.G. Cuervo & M. Clarke. Balancing benefits and harms in health care: we need to get better evidence about harms. *British Medical Journal* 2003; 327: 65-66: 66.

'Because professionals sometimes do more harm than good when they intervene in the lives of other people, their policies and practices should be informed by rigorous, transparent, up-to-date evaluations.'³⁵

WHO interpreted 'rigorous, transparent, up-to-date evaluations' to mean randomised controlled trials, systematic reviews, and evidence based clinical and public health practice guidelines.

Our notion of 'prudence' is consistent with that of Aristotle, for whom 'prudence' involved the application of intuitive reason to scientific knowledge. Prudence therefore has a subjective aspect that makes it difficult, if not impossible, to quantify³⁶. Aristotle did not describe how to define a prudent decision, but instead argued that prudence was best manifested by 'virtuous' people who possessed the capacity to reason in particular ways. For the purposes of our paper we understand prudence as the conflation of knowledge and values in the selection of a preferred option, and we assume that conflicting 'prudences' will inevitably be manifest when stakeholders committed to different value systems participate in a debate.

It is not surprising that different stakeholders should take up different versions of prudence in the misoprostol debate. Regulators and intergovernmental organisations have good reason to be risk-averse due to their responsibility for large numbers of people and the potential far reaching impacts that their decisions can have. Professional bodies and individual clinicians are understandably driven by their immediate desire to help patients, whether by avoiding harm or maximising benefits. And the pharmaceutical industry's views will necessarily be shaped, at least in part, by commercial considerations. These political, clinical and commercial commitments lead, in turn, to differing conceptions of prudence in the face of a particular body of evidence (or lack thereof).

Practical implications

This in turn raises the question of how we can move past intractable moral and political disputes about community distribution of misoprostol. We believe that it is possible for those engaged in these debates to make progress, and we will explain this assertion with reference to Gallie's notion of 'essentially contested concepts', and theories of public discourse.

³⁵ World Health Organisation, *op. cit.* note 18, p. 2.

³⁶ Aristotle. 1980. Book VI. In *Nicomachean Ethics*. Oxford University Press.

According to Gallie³⁷, a philosopher who explored the nature of disputes, apparently intractable disagreements of the kind we have presented here are a natural consequence of ‘essentially contested concepts’ embedded in the debate. Gallie outlined several conditions that might suggest that a concept is essentially contested (of which we will describe the two most relevant for our purposes). First, the concept must be appraisive, in the sense that it assigns a value to some outcome that is not measurable in any objective sense. For instance, the concept ‘beneficial’ can be applied by many different people in different ways. To label something beneficial is to give it a value, but this doesn’t mean that all will agree that it is. In the misoprostol debate, control of PPH is seen as benefit enough by one side, but not by the other, which sees evidence of reduced mortality as the only acceptable indication of benefit.

Second, an essentially contested concept must be complex, in the sense that its meaning is derived from other concepts, while at the same time not being reducible to them. Therefore contesting parties can construct different opinions based on the relative value they give to the sub-concepts. For instance, a ‘good’ health policy intervention may depend on differing judgements about cost-effectiveness, sustainability of the intervention, and the most important clinical or public health end-point. In the case of reducing maternal mortality, some see community distribution of misoprostol as an excessively simplistic and reductionist option, arguing that it is a ‘seductively cheap’ short-term solution, and that the real need is for long-term commitment to health facility strengthening³⁸. Importantly, Gallie described how both parties in a debate containing an essentially contested concept may have perfectly legitimate and rational arguments to support their differing positions, yet no objective principle can be found to determine which position is better.

Prudence fulfils the criteria for being an essentially contested concept. It is a qualitative concept open to different interpretations, as we have demonstrated, and is also complex, requiring ‘virtuous’ judgements about (at the very least) morality, epistemic standards, and uncertainty.

The implication of this is that if prudence is accepted as essentially contested, then there will be no decisive ‘technical-scientific’ solution to the misoprostol debate. Indeed it seems the issue at hand is so complex and so ridden with value judgements that further research, even though important, may never lead to universal agreement about the best course of action. With this in mind, it is clear that new ways of thinking are needed³⁹.

³⁷ W.B. Gallie. Essentially Contested Concepts. *Proceedings of the Aristotelian Society, New Series* 1956; 56: 167-198.

³⁸ Ronsmans & Huang, *op. cit.* note 15.

³⁹ K. Kastenhofer. Risk assessment of emerging technologies and post-normal science. *Science, Technology & Human Values* 2011; 36: 307-333.

We believe that in order to move forward with the misoprostol debate, it needs to be recognised that the debate is an example of a ‘public discourse’. Public discourse is essential to democracy as it represents a form of speech that helps to form public opinion, and allows society to ponder what it believes and thinks⁴⁰. However, public discourses are not free from the expression of power in various guises, with those who have more power influencing the discourse in their favour. Habermas believed that the liberal ideology had failed as it allowed for the concentration of power in private hands, such that ‘society... [had] to relinquish even the flimsiest pretence of being a sphere in which the influence of power was suspended’⁴¹. More recently, the late health economist Gavin Mooney commented on the influence of the neoliberal ideology in perpetrating disparities of power, resulting in private and institutional interests taking priority over ‘communitarian claims’, and ultimately leading to poorer health outcomes⁴².

Habermas suggested that the way to diffuse disparities in power was through ‘discourse ethics’⁴³. This approach was based on the premise that moral norms can only claim validity if they meet with the consent of all parties that would be affected by its introduction. He argued for a structured discourse where agreement must be reached through moral argumentation governed by rationality and due consideration of the concerns of all participants in the discourse. Mooney, on the other hand, believed that the power for allocating health care resources should rest firmly with communities, and suggested that the best way of identifying their preferences was to use ‘citizens’ juries’ comprised of a representative cross-section of the community. Experts provide relevant information to the jury, and the jury has the opportunity to question the experts, after which the jury deliberates and decides on their preferred course of action.

Within the context of the misoprostol debate, we disagree with Habermas’ premise that all parties affected by a decision must consent to it in order for it to be morally valid, because not all parties are equally affected by a decision. It is also not clear how one would go about defining all of those ‘affected’ and how one could ever reach a situation of universal consent. Instead we believe that an approach similar to Mooney’s could help achieve local resolution of the misoprostol debate. While people in low resource settings might not be familiar with the latest scientific evidence about misoprostol, they will have a

⁴⁰ J. Blocher. Public Discourse, Expert Knowledge, and the Press. *Washington Law Review* 2012; 97: 409-443; E. Volokh. The Trouble With "Public Discourse" as a Limitation on Free Speech Rights. *Virginia Law Review* 2011; 97: 567-594.

⁴¹ J. Habermas. 1991. *The Structural Transformation of the Public Sphere*. Cambridge, Massachusetts: The MIT Press: 144.

⁴² G. Mooney. 2012. *The Health of Nations: Towards A New Political Economy*. London: Zed Books.

⁴³ J. Habermas. 1990. *Moral Consciousness and Communicative Action*. Cambridge: Polity Press.

particular appetite for uncertainty, a particular set of desires and fears, and a particular willingness to trade off risks for benefits. By synthesising the technical knowledge provided by experts and the views of communities about their moral priorities, attitudes towards uncertainty, and beliefs about the value of different types of evidence, the essentially contested concepts at the heart of the misoprostol debate might be revised. Importantly, given the inherently contested nature of debates such as the one we have presented, communities would need to be given the opportunity to revise their position as the consequences of their decision becomes apparent, and as significant new information becomes available.

Of course, it must be kept in mind that this method is an analogy for the jury system in Western legal practice. Other practical analogies may be more appropriate to the decision-making frameworks that exist in different cultures. We therefore propose that as far as possible communities should be engaged through social processes already embedded in their culture.

Importantly, if this approach was taken, stakeholders such as WHO would need to also accept that not all communities will share the same epistemic and moral standards, and therefore that seeking a ‘global’ solution may be counterproductive.

Although the discourse ethic described in this paper would be difficult to govern and implement, we believe it is the necessary price for making decisions under uncertainty and sustained disagreement. It is difficult to see how under such circumstances any other approach could ensure that community values are not sidelined by power and global thinking.

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