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## Comment

Arthur L Caplan's recent piece in the *Lancet* raises an important issue about the ethical dilemmas that can face those involved in providing, "the simplest, mundane" aspects of health care.<sup>1</sup> In this case, a request from a bed-bound patient developing pressure ulcers that no one turn him over in his hospital bed. As the findings of the UK James Lind Alliance Pressure Ulcer Priority Setting Partnership (JLAPUP) confirm, the opening premise that this "simplest, mundane case" is in distant contrast to, "complicated medical decisions that are riddled with doubt and uncertainty" is false. Pressure ulcer prevention and treatment are areas of profound doubt and uncertainty. Nor is pressure ulcer care remote from issues about the promise of new medical technologies. Wound care management is one of the largest segments of the UK medical technology sector with a turnover exceeding £1bn in 2009.<sup>2</sup>

There are many unknowns about standard and basic care which can impact on patient wellbeing. The health care staff in Caplan's case study provided the patient with an air mattress and turned him regularly, but despite their efforts (turning and technology) he developed pressure ulcers. Once these ulcers had developed health care staff, "knew that Harold would die from infection without good pressure-sore management" and warned the patient that he was, "killing himself" by refusing to be turned. However, it is not clear to what extent his skin breakdown and infection is attributable solely to not being turned. Caplan focuses in on only this one aspect of pressure ulcer management, turning, and does not describe any other course of treatment. For example, is the patient also refusing to have the wound dressed? These things matter in considering the ethical implications of the patients' decision not to be turned.

There are perhaps also wider ethical issues to consider that also have relevance for debates about patient autonomy and patient safety, for example the problematics of acknowledging and resolving uncertainty about the effects of health care interventions. It is important to note that pressure relieving mattresses and wound dressings are classified as devices rather than medicinal products. The European regulatory focus (CE marking) is on safety assessment, viability, and competitiveness of devices rather than population effectiveness. This leaves clinical uncertainty about outcomes in clinical practice.<sup>3</sup> Devices used in pressure ulcer management that have not been tested for efficacy may not be actively dangerous but neither might they produce the effects promised by their marketing, meaning that although health professionals are busy using them, their patients may not be receiving effective treatment. Wound care remains something of an evidence wilderness with systematic reviews of evidence revealing a predominance of small, underpowered, and methodologically flawed trials.<sup>4 5 6</sup> It is a sector in which practice is reliant on custom, opinion and marketing and where systematic reviews are being portrayed as a means of rationing access and reducing choice.<sup>7</sup>

The ethics of patient involvement in treatment decisions includes involving patients in discussions of treatment uncertainty. Direct patient involvement in deciding what research to fund and what outcomes to measure is absent in the wound care sector. Between January and May 2012 JLAPUP asked patients, carers and clinicians where they would like to see further research or where they thought there was uncertainty about the best medical and nursing care in pressure ulcer prevention and treatment. Nearly 1,000 questions were gathered, including questions about the effectiveness of regular turning of patients and the

best means of engaging patients in their own care. All intervention questions for which existing research does not provide a reliable or complete answer will be published on NHS Evidence in the UK Database of Uncertainties about the Effects of Treatments (DUETs) <http://www.library.nhs.uk/duets/> . UK patients, carers and clinicians are also being asked to judge the importance of the most frequently asked questions for which there are no reliable answers. Further details at <http://www.ilapressureulcerpartnership.co.uk/>

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<sup>1</sup> Caplan AL. Not my turn. *Lancet* 2012; **380**: 968–969.

<sup>2</sup> BIS (Department of Business Innovation and Skills). Strength and opportunity: The landscape of the medical technology, medical biotechnology and industrial biotechnology sectors in the UK. HM Government, London, 2010. <http://www.bis.gov.uk/assets/biscore/business-sectors/docs/s/10-p90-strength-and-opportunity-bioscience-and-health-technology-sectors> (accessed 25 September 2012).

<sup>3</sup> Cohen D, Billingsley M. Europeans are left to their own devices. *BrMed J.* 2012; **342**: d2748.

<sup>4</sup> Beitz JM, van Rijswijk L. Developing Evidence-Based Algorithms for Negative Pressure Wound Therapy in Adults with Acute and Chronic Wounds: Literature and Expert-based Face Validation Results. *Ostomy Wound Manage.* 2012; **58**(4):50–69.

<sup>5</sup> Dumville JC, Soares MO, O'Meara S, Cullum N. Systematic review and mixed treatment comparison: dressings to heal diabetic foot ulcers. *Diabetologia.* 2012 Jul; **55**(7):1902–10.

<sup>6</sup> Brölmann FE, Ubbink DT, Nelson EA, Munte K, van der Horst CMAM, Vermeulen H. Evidence-based decisions for local and systemic wound care. *Br J Surg.* 2012 Sep; **99**(9):1172–83.

<sup>7</sup> Madden M. Alienating evidence based medicine vs. innovative medical device marketing: a report on the evidence debate at a Wounds conference. *Soc Sci Med.* 2012 Jun; **74**(12):2046–52.