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Title	Developing a legal framework for advance healthcare planning: Comparing England & Wales and Ireland
Authors	Donnelly, Mary
Publication date	2017-01
Original Citation	Donnelly, M. (2017) 'Developing a Legal Framework for Advance Healthcare Planning: Comparing England & Description of Health Law, 24(1), pp. 67-84. doi: 10.1163/15718093-12341412
Type of publication	Article (peer-reviewed)
Link to publisher's version	http://booksandjournals.brillonline.com/ content/journals/10.1163/15718093-12341412 - 10.1163/15718093-12341412
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Download date	2024-04-23 13:04:12
Item downloaded from	https://hdl.handle.net/10468/5687



This is a pre-review version of an article published in (2017) 1 European Journal of Health

Law 67-84

Developing a Legal Framework for Advance Healthcare Planning: Comparing England & Wales and Ireland

Mary Donnelly, Law School, University College Cork, Ireland

1. Introduction

The facilitation of advance planning is widely recognised as a key element in an appropriate legal response to capacity impairment and the adoption of legal measures in this regard is formally recommended by the Council of Europe.¹ A variety of legislative measures in respect of advance healthcare planning has emerged across Council of Europe Member States² and it has become clear that the choice to introduce legislation is only one aspect of the legislative choices to be made. The more interesting questions relate to the detail of the measures adopted. Choices made at this level reflect differing responses to the complex ethical and policy questions to which advance healthcare planning gives rise. In this respect, the Council of Europe Recommendation is largely non-directive, leaving the relevant choices to be made at member state level.³

This article explore the choices made in two Council of Europe member states with common law traditions, both of which have relatively recently introduced legislative frameworks for advance healthcare planning. In England and Wales, the relevant measure is the Mental Capacity Act 2005 (MCA) which came into effect on 1 October 2007 while, in Ireland, the legislation is the Assisted Decision-Making (Capacity) Act 2015 (ADMA), which was signed in law on 30 December 2015 and is expected to come into effect in 2016. Notwithstanding a number of similarities between the MCA and the ADMA, some

¹ Council of Europe, *Principles concerning continuing powers of attorney and advance directives for incapacity*, Recommendation CM/Rec(2009) 11.

See D. Veshi and G. Neitzke, 'Advance Directives in Some Western European Countries: A Legal and Ethical Comparison between Spain, France, Italy and Germany', *European Journal of Health Law* 22(4) (2015) 321-345; D. Veshi and G. Neitzke, 'Living Wills in Italy: Ethical and Comparative Law Approaches', *European Journal of Health Law* 22(1) (2015) 38-60; M. Navarro-Michel, 'Advance Directives: The Spanish Perspective', *Medical Law Review* 13(2)(2005) 137-169.

³ See Principle 15.1: 'States should decide to what extent advance directives should have binding effect'; Principle 16.2: 'States should consider what other provisions and mechanisms may be required to ensure the validity and effectiveness of those advance directives'.

interesting variations may be identified, reflecting differences in approach to the underlying principles of autonomy and protection. This article undertakes a comparative exploration of each measure, both in terms of background and also in terms of the detail of the approaches taken. The article begins with a contextual exploration, identifying the normative choices to be made in legislating for advance healthcare planning and looking at how the task of legislating was approached in the jurisdictions examined, as well as the available information on the efficacy of the MCA. It then looks at the detail of the two measures, arguing that in several respects, possibly because the drafters were able to absorb lessons from established legislation in other jurisdictions, the ADMA provides a more rounded and complete form of advance healthcare planning than that provided by the MCA.

2. Background and Context

Legislative provision for advance directives and continuing/enduring powers of attorney has been a feature of the law in some states in the United States since the 1970s, becoming national policy there from the early 1990s⁴ and in various Australian jurisdictions⁵ and New Zealand⁶ since the late 1990s. European developments have been somewhat more recent, typically taking place after 2000.

2.1 Identifying Ethical Complexities

The advantage of advance healthcare planning is that it allows a person whose capacity is unimpaired some degree of control over future decisions, notwithstanding a subsequent significant impairment in capacity. For this reason, within legal frameworks which prioritise the principles of autonomy/self-determination, the normative value of advance healthcare planning is clear. However, where the normative framework is extended to include other values (such as dignity or welfare), the position becomes more complex. In broad terms, tensions arise where there is an apparent conflict between an advance decision made by a person with unimpaired capacity and a contemporaneous preference or welfare interest of a person whose capacity is impaired. The question is especially contentious in the context of advance healthcare planning, where the choice may be of life-or-death significance.

The classic liberal view, espoused most famously by Ronald Dworkin, is that advance healthcare decisions made while a person's capacity is unimpaired should be respected notwithstanding subsequent harm to the person's interests (which Dworkin terms

Both forms of advance decision-making are a feature of the model law framework set out in the Uniform Health-Care Decisions Act 1994.

See e.g., Medical Treatment Act 1998 (Victoria) and Powers of Attorney Act 1998 (Queensland).

⁶ Code of Health and Disabilities Services Consumers' Rights 1996.

⁷ See the Preamble to CM/Rec(2009) 11.

See generally, A. Maclean, 'Advance Directives, Future Selves and Decision-Making', *Medical Law Review* 14(3) (2004) 291-230; P. Lewis, 'Medical Treatment of Dementia Patients at the End of Life: Can the Law Accommodate the Personal Identity and Welfare Problems', *European Journal of Health Law* 13(3) (2006) 219-234.

'experiential interests') when his or her capacity is impaired .9 Only in this way is the individual's autonomy (sometimes described as 'precedent autonomy') respected. The counter-argument is that advance and contemporaneous decisions cannot simply be equated in the manner Dworkin (and other supporters of this view¹0) assume. Allen Buchanan identifies three ethically significant differences between advance and contemporaneous decisions. First, even if the person is fully informed when making an advance decision, there may be subsequent developments in terms of treatment or prognosis which cannot be taken into account by the person at this time because they cannot be known. Secondly, the reasonable assumption that a person (without capacity impairment) is the best person to evaluate his or her own interests is less convincing where the evaluation relates to a radically changed situation (his or her life with significantly impaired capacity).¹¹ Thirdly, important safeguards against imprudent decisions (such as advice/discussion/counselling), which are present in a contemporaneous situation, may not be present in an advance situation.¹²

Clearly, the ethical significance of any of these factors will vary depending on context, e.g. a recent advance decision made in light of a specific conditions following careful thought and discussion with medical and other advisors will have considerably more ethical weight than an impulsive decision reached in a person's distant past. Thus, Buchanan's critique does not undermine the principle of advance decision-making. However, his argument (and those of other scholars with a broadly similar perspective¹³) is significant in drawing attention to the need for nuance in the legal framework around advance healthcare decision-making. The extent to which this is achieved depends on the detail of the framework employed and how the legislation balances values of autonomy/self determination on the one hand with values of welfare, dignity and life on the other.

2.2 Legislating for Advance Healthcare Planning in England and Wales

While the formal legislative framework for advance healthcare planning came into effect on 1 October 2007, the enforceability of advance treatment refusals had been firmly established through the courts well before this. ¹⁴ In terms of the balance between autonomy and other values, in the most detailed pre-MCA judicial consideration, Munby J.

⁹ Life's Dominion: An Argument about Abortion, Euthanasia and Individual Freedom (New York: Aldred A Knopf, 1993), pp. 201-2. Dworkin contrasts a person's experiential interests with his or her more morally significant 'critical interests' which relate to how s/he wishes to live his or her life.

See e.g. N. Rhoden, 'Litigating Life and Death', Harvard Law Review 102(2) (1988) 375-446.

A (more extreme) variant on this argument may be derived from Derek Parfit's work on memory and psychological continuity: D. Parfit, *Reasons and Persons* (Oxford: Clarendon, 1984). Parfit argues that once psychological continuity is lost (as for example where a person loses his or her memory whether through dementia or otherwise), the person becomes, in essence, a different person to that which s/he was before.

A. Buchanan, 'Advance Directives and the Personal Identity Problem', *Philosophy and Public Affairs* 17(4) (1988) 277-302.

See e.g. R. Dresser, 'Life, Death and Incompetent Patients: Conceptual Infirmities and Hidden Values in the Law', *Arizona Law Review* 28(3) (1986) 373-405; S. Holm, 'Autonomy, Authenticity or Best Interests: Everyday Decisionmaking and Persons with Dementia', *Medicine, Healthcare and Philosophy* 4(2) (2001) 153-159.

See e.g. Re C (Adult: Refusal of Medical Treatment) [1994] 1 WLR 290; Re AK (Medical Treatment: Consent) [2001] 1 FLR 129.

clearly favoured life over autonomy. In *HE* v. *A Hospital NHS Trust*, ¹⁵ Munby J. operated on the basis of a presumption in favour of life and found that this presumption meant that, where a person's life was at stake, clear and convincing proof must be provided that that advance refusal was valid and that it continued to apply in the circumstances arising. ¹⁶ The effect of the presumption, as noted by Sabine Michalowski, was that, in life-sustaining situations, advance refusals of treatment were inherently unreliable. ¹⁷

The MCA introduced two forms of advance healthcare planning, making provision for both advance refusals of treatment (referred to as 'advance decisions') and lasting powers of attorney (LPAs). Almost ten years after the commencement of the MCA, it is clear that there has been limited uptake on the measures provided for. In respect of advance decisions, data cited to the House of Lords Select Committee review suggested a take-up rate of only 3 per cent of the public. This was notwithstanding that 82 per cent of the public had indicated clear views about their end of life preferences. 18 Concerns were also expressed to the Select Committee about the low levels of awareness among professionals about the role and status of advance decisions. 19 Uptake on LPAs was somewhat higher but was still limited. Health and welfare LPAs made up a minority of registered LPAs, counting for only 20 per cent.²⁰ Given the low uptake, it is unsurprising that there has been limited case law. Judicial citations of the relevant measures have mostly been in a context in which they are of no relevance to the case in question either because such measures have not been put in place²¹ or because the patient was found to have lacked the capacity to make the advance decision.²² The House of Lords Select Committee make a number of recommendations to address the limited uptake, including increasing public awareness and improving professional understanding.²³ However, they did not address a more fundamental question regarding whether the underlying legislative approach is optimal. This question will be explored further as part of the comparative analysis below.

2.3 Legislating for Advance Healthcare Planning in Ireland

The Irish courts had also recognised the enforceability of advance refusals of treatment at a level of principle prior to the enactment of the ADMA.²⁴ However, jurisprudence was limited

¹⁵ [2003] EWHC 1017.

¹⁶ *Ibid.*, [24]

S. Michalowski, 'Advance Refusals of Life-Sustaining Medical Treatment: The Relativity of an Absolute Right', *Modern Law Review* 68(6) (2005) 958-982.

House of Lords Select Committee, *Mental Capacity Act 2005: Post Legislative Scrutiny* (London: The Stationary Office, 2014), para. 193: these data were cited in a submission made by the organisation Compassion in Dying.

¹⁹ *Ibid.*, para. 195.

²⁰ *Ibid.*, para. 179.

²¹ See eg. *W v. M and S and An NHS Primary Care Trust* [2011] EWHC 2443 (Fam); *Re D* [2012] EWCOP 885.

See *A Local Authority* v. *E* [2012] EWHC 1639; see R. Heywood, 'Revisiting Advance Decision Making under the Mental Capacity Act 2005: A Tale of Mixed Messages', *Medical Law Review*, 23(1) (2015) 81-102.

²³ Supra note 18, para. 200.

²⁴ See *JM* v. *St Vincent's Hospital* [2003] 1 IR 321.

and these was a good deal of uncertainty regarding the scope and limits of the common law position.²⁵ Moreover, although legislative provision had been made for enduring powers of attorney since the enactment of the Powers of Attorney Act 1996, the legislation did not extend to healthcare decisions. This was because it was felt at the time of enactment that it could be politically risky to include healthcare decisions within the ambit of the legislation because of possible public concerns that such measures might facilitate euthanasia.

The case for legislation addressing advance healthcare planning was made by the Irish Council for Bioethics²⁶ and the Law Reform Commission of Ireland²⁷ and public consultation in this regard was announced in February 2014.²⁸ The measures were developed on a standalone basis and then incorporated into the ADMA, which, like the MCA, provides the legal basis for most aspects of decision-making in circumstances of impaired capacity. The introduction of advance healthcare planning was largely uncontroversial; in fact, the most contentious aspect of the proposals was the fact that the advance planning provisions did not go far enough because they excluded certain treatments for a mental disorder.²⁹

3. Provision for Advance Directives

Advance directives (or 'living wills') are the quintessential mechanism for advance healthcare planning. Both the MCA and the ADMA make provision for advance directives and both Acts allow this facility only to a person aged over the age of 18 years who has capacity. The standard for capacity is largely similar in both Acts and both Acts also include a requirement that a person is not be considered unable to make a decision on the grounds of incapacity unless all practicable steps have been taken to help him or her to do so, without success. The ADMA also allows for two formal mechanisms for the provision of decision-making support in the forms of assisted decision-making and co-decision-making.

See M. Donnelly, 'Patient-centred Dying: The Role of Law', in: M. Donnelly and C. Murray (eds.) *Ethical and Legal Debates in Irish Healthcare: Confronting Complexities* (Manchester: Manchester University Press, 2016), pp. 222-235.

²⁶ Irish Council for Bioethics, *Is it Time for Advance Care Directives?* (Dublin: ICB, 2007).

Law Reform Commission, *Report on Bioethics: Advance Care Directives* (Dublin: LRC 94,2009). See C. Staunton, 'The Development of Healthcare Planning in Ireland', *Medico-Legal Journal of Ireland* 15(2) (2009) 74-81.

For summary of the 67 submissions made, see http://health.gov.ie/wp-content/uploads/2014/04/Overview-of-AHD-Public-Consultation-Submissions.pdf

See text to n. 60 *infra*. This omission was raised by several Senators in the debates: see Seanad Debates 10 November 2015.

MCA s. 24(1); ADMA s. 84(1).

In both measures, capacity requires the ability to understand the information relevant to the decision; to retain that information; to use and weigh the information and to communicate the decision: MCA s. 3(1); ADMA s. 3(2). On the application of the broadly similar common law standard for capacity to make an advance refusal, see *The NHS Trust* v. *T* [2004] EWHC 1279.

³² MCA s. 1(3); ADMA s. 8(3).

The development of measures for supported decision-making is a requirement under Art. 12(3) of the United Nations Convention on the Rights of Persons with Disabilities 2006, A/RES/61/106 (which has been ratified by the United Kingdom and signed but not yet ratified by Ireland, although there is a formal commitment to ratify).

Both mechanisms allow a person whose capacity is 'or may shortly be in question' to appoint someone to provide them with decision-making support to reach the standard for capacity.³⁴ Therefore, an advance directive made with the support of either a decision-making assistant or a co-decision maker would meet the capacity requirement.

3.1 Scope of Measures

The MCA applies to one type of decision only. This is an advance decision to refuse treatment.³⁵ Refusal may relate either to the carrying out or the continuation of treatment and may extend to 'life-sustaining' treatment, although designated formalities (discussed below) apply if it is to apply in this situation. No distinction is made between other types of treatment (other than treatment covered by the Mental Health Act 1983 discussed below). This leaves open the question of whether basic measures such as hygiene, warmth or other physical comforts would come within the definition of (refusable) treatment. It is probable that, if the matter were considered by the courts, basic care of this kind would not be considered to fall within the definition. Even leaving aside the question of whether a contemporaneous refusal of basic care should be permitted,³⁶ it may reasonably be argued that because of the ethically significant differences between contemporaneous and advance decisions discussed above,³⁷ advance refusals of basic care should not be permitted.

As under the MCA, under the ADMA a refusal of treatment must be complied with provided that the relevant conditions are met.³⁸ However, the ADMA avoids uncertainty in respect of basic care, by including a clear statement that an advance refusal does not apply to the administration of this.³⁹ 'Basic care' is defined as including (but not limited to) 'warmth, shelter, oral nutrition, oral hydration and hygiene measures'.⁴⁰ Crucially, it does not include artificial nutrition and hydration (ANH).⁴¹ The differential treatment of oral and artificial nutrition and hydration reflects established Irish⁴² case law and Irish professional ethics guidance.⁴³ It also reflects a broad ethical consensus that ANH is most appropriately

With assisted decision-making, the decision-making assistant assists the appointer in obtaining information and making a decision: ADMA s. 14; with co-decision-making, the co-decision-maker makes the decision jointly with the appointer: ADMA s. 19.

³⁵ MCA s. 24(1).

Even within a resolutely autonomy-focussed approach, a feasible argument could be made that harm to others (other patients, healthcare professionals) should prevent a right to refuse basic care in at least some circumstances: e.g. the circumstances identified (in the context of a refusal of hygiene care) in D. Dudzinski, S. Shannon and R. Tong, 'Competent Refusal of Nursing Care', *The Hastings Center Report* 36(2) (2006) 14-15.

See text preceding n. 12 supra.

³⁸ ADMA s. 84(2).

³⁹ ADMA s. 85(4)(a).

⁴⁰ ADMA s. 85(4)(b).

⁴¹ ADMA s. 85(4)(b).

In *Re a Ward of Court* [1996] 2 IR 79, the Supreme Court of Ireland treated the withdrawal of ANH no differently to the withdrawal of other forms of medical treatment.

Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Professionals* (2009) (available at https://www.medicalcouncil.ie/) para. 22.2 states that there is no obligation on a medical practitioner to start or continue ANH that is 'futile or disproportionately burdensome, even if such treatment may prolong life.'

categorised as a form of medical treatment⁴⁴ (although, as discussed below, medical treatment in respect of which particular ethical issues arise⁴⁵).

In focussing on refusal only, the MCA reflects the traditional 'thin' view of autonomy as simply a right to be left alone. He had be left alone. In this, it reflects the long-established position at common law that requests for treatment are treated differently to refusals of treatment. This position was affirmed by the England and Wales Court of Appeal in *R (Burke)* v. The General Medical Council and Others. Here, the Court dismissed the claimant's argument that he should be able to make an advance binding request that ANH would continue to be provided in the event that he should subsequently lose the ability to communicate his wishes (he suffered from spino-cerebellar ataxia and this was a realistic prospect). The Court was clear that a patient's right to choose treatment was 'in truth ... no more than a reflection of the fact that it is the doctor's duty to provide a treatment that he considers to be in the best interests of the patient and that the patient is prepared to accept'. Instead the Court relied on the doctor's duty of care, stating that, in respect of ANH, '[w]here ANH is necessary to keep the patient alive, the duty of care will normally require the doctors to supply ANH.'50

The ADMA adopts a different approach. Although it also distinguishes between refusal of treatment and requests for treatment, it allows greater scope for patient choice around requests. Requests for treatment are not legally binding under the ADMA. However, they must be 'taken into consideration' during any subsequent decision-making process 'if that specific treatment is relevant to the medical condition for which the directive-maker may require treatment'.⁵¹ If the request is not complied with, the healthcare professional concerned must record the reasons for not complying with the request in the directive-maker's notes and give a copy of these reasons to the person's designated healthcare representative⁵² (if such an appointment has been made).⁵³

The ADMA approach represents a more nuanced response to requests for treatment. On the one hand, it reflects an important ethical difference between refusals of, and requests for, treatment. As described by Jonathan Montgomery, the common law position is 'characterised by the assumption that judges and healthcare professionals have complementary roles in a single integrated system for ensuring that healthcare is governed

See M. Ashby and B. Stoffell, 'Artificial Hydration and Alimentation at the End of Life: A Reply to Craig', *Journal of Medical Ethics* 21 (1995) 135-140.

See H. Brody, L. Hermer, L. Scott, L. Grumbles, J. Kutac, S. McCammon, 'Artificial Nutrition and Hydration: The Evolution of Ethics, Evidence and Policy', *Journal of General Internal Medicine* 26(9) (2011) 1053-1058.

See O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002), p. 37.

See e.g. Re J (A Minor) (Child in Care: Medical Treatment) [1993] Fam 15.

⁴⁸ [2005] EWCA Civ 1003.

⁴⁹ [2005] EWCA Civ 1003, [51].

⁵⁰ [2005] EWCA Civ 1003, [32].

⁵¹ ADMA s. 84(3).

This role is an innovative aspect of the ADMA and is discussed in text to n. 74 *infra*.

ADMA s. 84(3)(b). The reasons must be provided as soon as practicable and no later than 7 working days after they have been recorded.

by sound moral principles.' ⁵⁴ Requiring a healthcare professional to provide medical treatment which is contrary to his or her clinical judgement would represent a very substantial legal invasion into the domain of professional ethics. ⁵⁵ However, the MCA position can be criticised for failing to afford any degree of recognition of patient choice. ⁵⁶ Particular issues arise around situations, such as in *Burke*, involving the removal of ANH. As had been recognised by Munby J. in the High Court in *Burke*, ⁵⁷ the removal of ANH raises specific issues under the European Convention on Human Rights. Munby J. had concluded that, during the period while the patient was aware of his surroundings, the withdrawal of ANH would leave him exposed to 'acute mental and physical suffering' and would implicate his rights under Art. 2 (right to life); Art. 3 (protection from inhuman and degrading treatment) and Art. 8 (right to personal autonomy). ⁵⁸ Reliance on the professional duty of care in such circumstances provides inadequate protection for patient rights, offering a patient no mechanism whatever to ensure that his or her views can continue to be heard once s/he can no longer communicate.

By affording patients the opportunity to record their views formally and requiring healthcare professionals to take account of these, the ADMA offers patients some degree of control (enhanced by the possibility of appointing a designated healthcare representative to whom the professional must account) without excessive intervention in clinical judgement regarding the appropriate delivery of care. It will, of course, only be possible to judge how effective the legislation is in this regard when it has become operational. Nonetheless, the approach taken in the ADMA offers potentially more substantive protection for patient autonomy and choice than the MCA/common law alternative.

Notwithstanding that, in some ways, it offers more substantive protection for patient autonomy, there are two important limitations to the ADMA, both of which derive from the interaction between this legislation and other legal frameworks. The first limitation is, in large part, shared with the MCA. Both Acts allow advance refusals of treatment for a mental disorder to be over-ridden where the person who made the refusal has been made subject to the applicable mental health legislation.⁵⁹ Under the ADMA, an advance healthcare directive must be complied with unless the Mental Health Act 2001 (or the Criminal Law (Insanity) Act 2006) applies.⁶⁰ The position under the MCA is largely similar except in respect of electro-convulsive therapy (ECT). Following amendments introduced by the Mental Health Act 2007, a person may make an advance refusal of ECT notwithstanding that s/he is subject to compulsion under the Mental Health Act 1983.⁶¹ As with a

J. Montgomery, 'Law and the Demoralisation of Medicine', Legal Studies 26(2) (2006) 185-210, at 204.

See K. Manson and G. Laurie, 'Personal Autonomy and the Right to Treatment', *Edinburgh Law Review* 9(1) (2004) 123-132.

See C. Lemmens, 'A New Style of End-of-Life Cases: A Patient's Right to Demand Treatment or A Physician's Right to Refuse Treatment? The Futility Debate Revisited', *European Journal of Health Law* 20(2) (2013) 167-183 at 181.

⁵⁷ R (Burke) v. The General Medical Council [2004] EWHC 1879 (Admin).

⁵⁸ *Ibid*, [171]. The position was different during the third stage (although Munby J. *Ibid*, [174] declined to reach a conclusion on the implications of this).

Mental Health Act 1983 (EW); Mental Health Act 2001 (Ireland).

⁶⁰ ADMA s. 85(7).

Mental Health Act 1983 s. 58A as inserted by Mental Health Act 2007 s. 27.

contemporaneous refusal of ECT, an advance refusal of ECT may be overridden where the treatment is immediately necessary to save the patient's life or is immediately necessary to prevent a serious deterioration in the patient's condition.⁶²

It is increasingly recognised that the provision of mechanisms for advance care planning around mental health is important both as protection for patient rights and as part of an effective recovery process. ⁶³ For jurisdictions which have separate mental health and mental capacity laws, such mechanisms are generally provided within the context of mental health laws, not least because of the need to ensure some degree of consistency between the legal treatment of advance and contemporaneous decisions. On this basis, the absence of provision for advance mental health care planning within the ADMA is not unexpected. However, there is a strong case for amendment of mental health legislation to afford greater recognition to the potential of advance planning in the mental health context.

The second limitation in the ADMA derives from the special protection afforded to the 'right to life of the unborn' under Art. 40.3.3 of the Constitution of Ireland. Given that the application of Art. 40.3.3 in the context of a contemporaneous refusal of treatment has not yet been resolved, the ADMA was limited in the choices it could make. Thus, the ADMA states that, where the directive-maker is pregnant, and the advance directive does not specifically whether or not she intended a refusal of treatment to apply in such circumstances and the healthcare professional involved in her care considers that the refusal of treatment would have a deleterious effect on the unborn, there is a presumption that the treatment should be provided or not withdrawn. Where the advance directive specifically states that the refusal is to apply in cases of pregnancy, and the healthcare professional involved in her care considers that the refusal of treatment would have a deleterious effect on the unborn, the matter must be referred to the High Court to determine if the refusal should be unheld. In determining the application, the Court must consider the potential impact of the refusal on the unborn; the invasiveness and duration of

Mental Health Act 1983 s. 62(1A).

See P. Weller, New Law and Ethics in Mental Health Advance Directives: The Convention on the Rights of Persons with Disabilities and the Right to Choose (Hove: Routledge, 2013); P. Weller, 'Psychiatric Advance Directives and Human Rights', Psychiatry, Psychology and Law, 17 (2010) 218-229; F. Morrissey, 'Advance Directives in Mental Health Care: Hearing the Voice of the Mentally Ill', Medico-Legal Journal of Ireland, 16(1)(2010) 21-33.

Although Art. 40.3.3 was intended to prevent the possibility of legalisation of abortion, either judicially or legislatively, the very broad wording has meant that the provision has had an impact well beyond the immediate matter of abortion e.g. the legal status of frozen embryos: *Roche* v. *Roche* [2010] IESC 10 and the withdrawal of life support from a brain-dead pregnant woman: *PP* v. *Health Service Executive* [2014] IEHC 622.

See K. Wade, 'Refusal of Emergency Caesarean Section in Ireland: A Relational Approach', *Medical Law Review*, 22(1) (2014) 1-25. In contrast, in England and Wales, it is clear that a contemporaneous (capacitous) refusal of treatment by a pregnant woman must be respected notwithstanding possible impact on the foetus: *St Georges Healthcare NHS Trust* v. *S* [1998] 3 WLR 936.

⁶⁶ ADMA s. 6(a).

⁶⁷ ADMA s. 6(b).

the treatment and risk of harm to the directive-maker; and, any other matters the Court considers appropriate.⁶⁸

The advance refusal of (some) treatments by pregnant women gives rise to legitimate ethical questions.⁶⁹ The ethically significant differences between contemporaneous and advance refusals discussed above are of particular relevance here. The possiblity of information deficit is accentuated in circumstances where a woman makes an advance refusal when she is not pregnant, unaware of how her views may be impacted upon by a subsequent pregnancy. However, it may be counterargued that this approach second-guesses the decisions of women of child-bearing age, and accords too little respect to their moral agency. Ultimately, in the unlikely event of a conflict between foetal interests/life and a woman's precedent autonomy, judicial consideration, as provided for in the ADMA, may be the most appropriate way of resolving the matter. The difficulty with the current constitutional position in Ireland is that any judicial consideration is inevitably weighted in favour of foetal interests rather than women's autonomy.

3.2 Giving Effect to the Advance Decision

One of the difficulties with the MCA identified by the House of Lords Select Committee Review was the lack of mechanisms to ensure that the instructions provided in an advance decision were actually given effect in practice. The Select Committee cited evidence that, where an advance directive was in place, there was no 'systematic process for the recording, storage and retrieval of this information' when a decision came to be made. The evidence also indicated that almost half of those who had made advance decisions has not shared this information with anyone else. The Select Committee also cited evidence from the England and Wales Law Society that, while medical professionals generally respected advance decisions which were valid and applicable, the difficulty usually arose in determining if this was the case. Delivery on advance directive has also been shown to be a problem in the United States where the extensive SUPPORT study carried out in the 1990s found that advance directives had almost no practical effect on the treatment which patients received towards the end of their lives.

⁶⁸ ADMA s. 6(c).

On ethical issues in contemporaneous refusals, see generally R. Scott, *Rights, Duties and the Body:* Law and Ethics of the Maternal-Fetal Conflict (Oxford: Hart Publishing, 2002).

Select Committee Report n. 18, para. 197. The Committee was citing the findings of the Advance Decision Evaluation (ADE) in Bipolar Disorder Study Team, Institute of Mental Health, University of Nottingham.

⁷¹ Ibid.

⁷² *Ibid.*, para. 198.

See J.M. Teno, S. Licks, J. Lynn, N. Wenger, A.F. Connors Jr, R.S. Phillips, M.A. O'Connor, D.P. Murphy, W.J. Fulkerson, N. Desbiens, W,A. Knaus, 'Do advance directives provide instructions that direct care? SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment', *The Journal of the American Geriatric Society* 45(4) (1997) 508–12; J.M. Teno, M. Stevens, S. Spernak, J. Lynn, 'Role of Written Advance Directives in Decision Making: Insights from Qualitative and Quantitative Data,' *Journal of General Internal Medicine* 13(7) (1998) 439–46.

In contrast to the MCA, which makes no attempt to deal with the matter, the ADMA includes several measures to help ensure that effective is given to an advance directive. The most significant of these is the provision made for the appointment of a designated healthcare representative (DHR). A directive-maker may designate a person to act as DHR in the advance directive⁷⁴ (subject to the agreement in writing of the DHR⁷⁵) and the appointed DHR has the power to ensure that the terms of the advance directive are complied with.⁷⁶ The directive may also confer on the DHR the power to advise and interpret the directive-maker's will and preferences about treatment, including life-sustaining treatment, based on the advance directive.⁷⁷ This potential to empower a trusted person to deal with issues which may subsequently arise offers a richer and more integrated approach to advance healthcare planning than the simple written instruction allowed for in the MCA.⁷⁸

Of course, empowering a DHR, especially with regard to decisions concerning life and death, raises issues of protection and accountability. In this regard, the ADMA requires that, where a DHR makes a decision in respect of the directive-maker, s/he must make and keep a record in writing and have this available for inspection by the Director of Decision Support Services (DDSS) ⁷⁹ or the decision-maker if s/he has regained capacity. ⁸⁰ Complaints about the way a DHR is exercising his or her powers may be made to the DDSS and, following investigation of the complaint, the DDSS may make an application to court for an order preventing the DHR from exercising his or her powers. ⁸¹ There is a risk that this level of formalisation of the process may make some people uncomfortable with agreeing to act as a DHR (particularly in a potentially fraught family situation). However, given the very significant powers afforded to a DHR, it is difficult to argue against the level of oversight employed.

ADMA s. 87(1)(a). The ADMA contains a list of persons who cannot be appointed as DHR: s. 87(2) and circumstances in which a person who has been appointed ceases to be permitted to exercise relevant powers: s. 87(3) and s. 87(5) and 87(6). In general, prohibitions relate to persons who have been convicted of a criminal offence in respect of the directive-maker/his or her children, or where a safety or barring order has been made in respect of the person, and to professional care-givers. A DHR also ceases to have the relevant powers where s/he was the spouse/civil partner of the directive-maker and the marriage/civil partnership has been annulled or dissolved or the parties have judicially separated or have separated and ceased to cohabit for a continuous period of more than 12 months (unless the directive specifically provides otherwise).

ADMA s. 87(1)(b). The designated person must sign the directive to confirm his or her willingness to act in accordance with the known will and preference of the directive maker as determined by reference to the directive.

ADMA s. 88(1)(a). As described above, in text to n. 51, this operates differently in the context of requests for treatment.

⁷⁷ ADMA s. 88(1)(b).

As discussed in the text to n. 109 *infra*, a person may appoint someone under an LPA who can make decisions for the appointer, including the giving or refusing of consent to the carrying out or continuation of life-sustaining treatment: MCA, s. 11(7)(c). However, there is no integration between the two processes and the LPA is subject to any advance decision: s. 11(7)(b).

The Office of DDSS is established under ADMA s. 94 and has a range of oversight functions in respect of the Act (s. 95).

ADMA s. 88(3). Note also that provision is made for the possible development of a Code of Practice applicable to DHRs: ADMA s. 91(3).

⁸¹ ADMA s. 88(5).

A second measure to ensure delivery on the advance directive is the provision made in the ADMA for the (possible) introduction of ministerial regulations requiring the directive-maker to inform the DDSS and other specified persons of the existence of the directive⁸² and the imposition of a requirement on the DDSS to maintain a register of notified directives.⁸³ This offers the potential for a formalised record and, presuming it is acted upon, should address some of the deficiencies identified by the House of Lords Select Committee in respect of the MCA.

4. Enforceability of Advance Directives

Conflicts between an advance directive and current preferences/best interests come to the fore in the context of questions regarding the enforceability of the advance directive. In striking an appropriate balance, the detail of two aspects of the legal framework are especially significant. These are the formalities and requirements for the creation of the advance directive and the statutory grounds on which the advance directive is deemed not to apply. Formalities provide a means to address ethical concerns regarding the absence of safeguards against imprudent decision-making at the time the advance directive is made.84 The imposition of a requirement for consultation with a medical advisor at the time the directive is made would ensure that the directive is, to some degree, at least informed.85 Thus, enhanced formalities/requirements may be seen to increase the ethical force of the advance directive and limit the grounds for subsequently invalidating the directive. Of course, more stringent formalities/requirements also make the creation of an advance directive be more onerous and may reduce the accessibility of this mechanism for advance healthcare planning. As will be seen below, the MCA adopted an approach based on fewer formalities but with significant potential for overriding the advance directive while the ADMA imposes more formalities but, correspondingly, allows the directive to be overridden in more limited circumstances.

4.1 Formalities

In terms of formalities required, the MCA differentiates on the basis of whether the advance decision concerns refusal of 'life-sustaining treatment'. For decisions that do not involving life-sustaining treatment, there are essentially no formalities. Thus, there is no requirement that an advance decision must be in writing.⁸⁶ Nor is there a need to use precise medical terminology: a decision may be regarded as specifying a treatment or circumstances even

⁸² ADMA s. 84(12)(a).

⁸³ ADMA s. 84(12)(b).

See text to n. 12 supra.

For a sceptical view of the value of the consultation in actually informing the patient, see A. Fagerlin and C. Schneider, 'Enough: The Failure of the Living Will', *Hastings Center Report*, 34(2)(2004) 30-42.

MCA s. 24(1). It is explicitly stated that neither a withdrawal nor an alteration of the decision need be in writing: MCA s. 24(4), (5).

though expressed in layman's terms.⁸⁷ For life-sustaining treatment, the refusal must be in writing; signed by the person making it or by another person at his or her direction; and signed and witnessed by one witness.⁸⁸ The decision must also contain an explicit statement that it is to apply to the treatment in question even if life is at risk.⁸⁹ One difficulty in this regard is that life-sustaining is defined as treatment which, in the view of a person providing healthcare for the person concerned, is necessary to sustain life.⁹⁰ Thus, an advance directive may subsequently be classified as involving life-sustaining treatment and fail because it does not meet the relevant formalities.

Clearly, the policy goal of the MCA was to make advance decisions accessible by minimising the formalities employed. However, as the very low uptake on the facility indicates, 91 this appears to have been largely ineffective. Moreover, as the decision in *A Local Authority* v. E^{92} shows, even with the greater formalities associated with an advance refusal of life-sustaining treatment, the lack of any requirement for formal capacity assessment at the time of making the decision leaves open the possibility of a subsequent finding that the person lacked capacity at this time. 93

In contrast to the MCA, the ADMA adopts a formalised approach to all advance directives. An advance directive must be in writing⁹⁴ and contain designated details.⁹⁵ It must also be signed by the directive-maker.⁹⁶ The directive-maker and the DHR (if any) must sign the advance directive in each other's presence and in the presence of two witnesses.⁹⁷ Each witness must be over the age of 18 years and at least one witness must not be an 'immediate family member' of the directive-maker.⁹⁸ Any revocations or alterations of the directive must be made in writing and the alternation must be witnessed in the same way as an original advance directive.⁹⁹ No additional formalities apply in respect of the refusal of life-sustaining treatment. However, the directive will not be applicable to such treatment unless it includes a statement that it is to apply to the treatment in question even if the directive-maker's life is at risk.¹⁰⁰ This level of formality represents a very different

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MCA s. 24(2).

⁸⁸ MCA s. 25(6).

⁸⁹ MCA s. 25(5).

⁹⁰ MCA s. 4(10).

⁹¹ See text to n. 18 *supra*.

⁹² [2012] EWHC 1639.

⁹³ See Heywood *supra* n. 22, 94.

⁹⁴ ADMA s. 84(4).

ADMA s. 84(5). These include the name, date of birth and contact details of the directive-maker and of the DHR (if any).

ADMA s. 84(5)(b). Someone may sign on behalf of the directive-maker but only if the directive-maker is unable to sign and the signature is completed in the presence of the directive-maker and at his or her direction.

⁹⁷ ADMA s. 84(6)

ADMA s. 84(6). This is defined in ADMA s. 84(13) and extends quite broadly, including in-laws, aunts and uncles, and nephews and nieces.

⁹⁹ ADMA s. 84(7).

¹⁰⁰ ADMA s. 86(3).

approach to the MCA, although it notably does not include any requirement for consultation with a medical advisor.

On the one hand, the more demanding approach in the ADMA risks creating obstacles to the creation of advance directives and may limit their adoption. On the other hand, the more robust procedures help to ensure that people do not make advance directives lightly and that they may receive some degree of support around choices made (although a case may be made that the express support of a healthcare professional should have been required). Thus, they lend a greater degree of ethical conviction to the advance directive than the MCA model. This, in turn, is reflected in the rather different statutory approaches to the circumstances in which an advance directive may found not to apply.

4.2 Grounds for Overriding

Under the MCA, in order for an advance decision to be effective, it must be valid and applicable to the treatment. 101 An advance decision is not valid if the person has withdrawn the decision while s/he had capacity to do so; if s/he has, under an LPA created after the advance decision, conferred authority on a donee to give/refuse consent in respect of treatment to which the advance decision relates; or, if s/he has done anything else clearly inconsistent with the advance decision remaining his or her fixed decision. 102 The last of these limitations is the most contentious because there is no requirement that, for it to apply, the person's capacity must be unimpaired. 103 Moreover, the vague way in which the provision is stated leaves a good deal of discretion in an individual case. An advance decision is not applicable if the person who made the decision has capacity to give or refuse consent at the time; the treatment in question is not the treatment specified in the advance decision; any circumstances specified in the advance decision are absent; or, there are reasonable grounds for believing that circumstances exist which the person making the decision did not anticipate at the time of the decision and which would have affected the decision if the person had anticipated them. ¹⁰⁴ This provision creates several difficulties. When combined with the lack of formalities required to make an advance decision, the requirement that treatment/circumstances must be specified may render an advance decision made in casual or informal circumstances unreliable and an oral advance directive close to pointless. In addition, the third limitation on applicability suggests a broad and open-ended potential for over-riding advance decisions. Overall, as described by Alasdair Maclean, the effect of the MCA requirements regarding validity and applicability means that advance directives are 'vulnerable to challenge' and this 'undermines their value as protection for precedent autonomy.'105

MCA s. 25(1). This is stated in negative terms: the advance decision does not affect the liability of a person carrying on the treatment unless the decision is valid and applicable to the treatment.

¹⁰² MCA s. 25(2).

See A. Maclean, 'Advance Directives and the Rocky Waters of Anticipatory Decision-Making', *Medical Law Review* 16(1) (2008) 1-22, at 20

¹⁰⁴ MCA s. 25(4).

¹⁰⁵ Supra n. 103, at 16.

The ADMA also requires that an advance directive be valid and applicable. However, the circumstances of invalidity/non-applicability are notably narrower than under the MCA. An advance directive is not valid if the directive-maker did not make the directive voluntarily; 106 or s/he has done something clearly inconsistent with the relevant decision outlined in the directive. However, unlike the MCA, this can only happen where the person has capacity. An advance directive is not applicable if, at the time in question, the directive-maker still has capacity to give or refuse consent to the treatment in question; the treatment in question is not materially the same as the specific treatment set out in the directive; or, at the time in question, the circumstances set out in the directive as to when the specific treatment is to be requested or refused are absent, or not materially the same. The concept of 'materially the same' allows more discretion to DHRs than the more constraining provision in the MCA. Thus, the ADMA allows for more reliable advance healthcare planning.

5 Powers of Attorney

The creation of an enduring or lasting power of attorney (EPA/LPA) provides an alternative form of advance healthcare planning, enabling the donor to hand over decision-making authority to a trusted donee with effect if and when the donor loses capacity. Although both the MCA and the ADMA allow for an EPA/LPA to be utilised for personal welfare decisions, ¹⁰⁹ which include some decisions about healthcare, these measures will more typically be utilised in respect of the donor's 'property and affairs'. For this reason, the requirements for the creation of an EPA/LPA are more detailed and legalistic than for other forms of advance healthcare planning ¹¹⁰ and these measures are unlikely to be used for healthcare planning alone.

Under the MCA, a donee of a personal welfare LPA has the power to give or refuse consent to the carrying out or continuation of treatment. However, this power does not apply to life-sustaining treatment unless the instrument contains an express provision to this effect. The power is also subject to any advance decisions to refuse treatment and to any conditions or restrictions in the instrument creating the power. Any decisions made by the donee of the LPA must be made in accordance with the best interests of the donor, as outlined in s. 4 of the MCA. This requires that, in making the decision, the donee must, insofar as is reasonably practicable, permit and encourage the person to participate as

Note also that it is a criminal offence to use fraud, coercion or undue influence to force another person to make, alter or revoke an advance healthcare directive: ADMA s. 90(1).

¹⁰⁷ ADMA s. 85(1).

¹⁰⁸ ADMA s. 85(2).

¹⁰⁹ MCA s. 9(1); ADMA s. 59(1).

See MCA ss. 9-14 and Sch. 1; ADMA ss. 58-81,

¹¹¹ MCA s. 11(7)(c).

¹¹² MCA s. 11(8)(a).

¹¹³ MCA s. 11(7)(b).

¹¹⁴ MCA s. 11(8)(b).

far as possible in any act done for him or her and any decision made for him or her.¹¹⁵ In addition, the donee must consider insofar as is reasonably ascertainable, the donor's past and present wishes and feelings and in particular any written statement made by the donor while s/he had capacity; the beliefs and values that would be likely to influence the donor if s/he had capacity; and the other factors that the donor would be likely to consider if s/he had capacity. ¹¹⁶ Jo Samantha argues that the requirement to act on the basis of best interests, rather than on the basis of substituted judgment (what the donor would have wanted), serves as an inappropriate limitation on the effectiveness of LPAs in a healthcare context. ¹¹⁷ This criticism does not recognise the extent to which the MCA best interests standard incorporates subjective elements into the traditional objective standard. ¹¹⁸ However, it is true that the effect of the application of the MCA best interests standard to LPAs means that the existence of an LPA does not absolutely guarantee that what the donor would have wanted will be done.

The MCA presents further difficulties in cases where the LPA decision relates to lifesustaining treatment. This is because of the MCA requirement that, in considering whether the treatment is in the person's best interests, the decision-maker must not be motivated by a desire to bring about the person's death. 119 As John Coggon has shown, this requirement is 'wholly unworkable' 120 because it focusses on motives for decisions rather than on the content of the decision itself. In the context of an LPA, a literal reading of the requirement would suggest that a donee, who had been given clear authority to refuse lifesustaining treatment and had been clearly told by the donor that he would wish to die in the circumstances arising would be prevented from making the decision to refuse if his motivation, based on an evaluation of the donor's best interests, was to bring about the death of the donor. Coggon argues that the requirement is a 'sorry compromise' with sanctity of life doctrine and that it 'cannot be expected to apply in practice'. 121 The requirement does not seem to have made an impact in judicial deliberations under the MCA. Nonetheless, the requirement creates unfortunate uncertainty regarding the operation of LPAs (as well other forms of best interest determinations) in respect of lifesustaining treatment.

The ADMA adopts a more extreme, albeit more certain, approach. While a donor of an EPA can authorise the donee to make healthcare decisions, s/he cannot include a decision relating to refusal of life-sustaining treatment or a decision which is the subject of an advance healthcare directive. Thus, the only way in which one person may give

¹¹⁵ MCA s. 4(4).

¹¹⁶ MCA s. 4(6).

J. Samantha, 'Lasting Powers of Attorney for Healthcare under the Mental Capacity Act 2005: Enhanced Prospective Self-Determination or a Simulacrum', *Medical Law Review* 17(3)(2009) 377-409 at 409.

See M. Donnelly, 'Best Interests, Patient Participation and the Mental Capacity Act 2005', *Medical*

Law Review 17(1)(2009) 1-29 at 29.

MCA s. 4(5).

J. Coggon, 'Ignoring the Moral and Intellectual Shape of the Law after *Bland*: The Unintended Side-Effect of a Sorry Compromise', *Legal Studies* 27(1)(2007) 110-125 at 119.

¹²¹ *Ibid.*, 125.

¹²² ADMA s. 62(5).

another the power to refuse life-sustaining treatment is through the DHR mechanism in an advance directive. While this adds an additional administrative burden for a person engaged in advance healthcare planning within a broader advance planning process, this burden should not be significant. There is nothing in the ADMA to prevent the same person being the donne of an EPA and a DHR. Thus, there would simply be one additional (and relatively straightforward) form to be completed. The advantage of the ADMA approach is that it provides much clearer grounding for the decision to remove life-sustaining treatment and, unlike the MCA, grounds this authority in the stated preferences of the person lacking capacity.

6 Conclusion

The development of an appropriate legal framework to address situations of significantly impaired capacity is a human rights imperative. ¹²⁴ Making legal provision for advance healthcare planning is a necessary component of such a framework although it is also important to recognise that it can only represent one part of an appropriate framework. Individuals' uptake on the option provided by advance healthcare planning is always likely to be limited. This may be seen in the United States, where advance healthcare legislation has been in place for over 20 years and there is a specific statutory obligation on most care facilities to draw attention to the mechanism. ¹²⁵ Although there are no definitive overall statistics, evidence from various studies suggests the uptake ranges from as low as 7 per cent of patients in general practice ¹²⁶ to a high of 88 per cent of patients discharged from a hospice. ¹²⁷ Studies indicate a range of reasons for the limited uptake among general patients. ¹²⁸ Some reasons, such as lack of knowledge among the public and healthcare providers or healthcare providers' reluctance to discuss the issue can be addressed ¹²⁹ (although, given the limited success of various US initiatives, evidently not easily). Other

See text to n. 74 *supra*.

In a Council of Europe context, the human rights imperative derives from the European Convention on Human Rights as well as from the United Nations Convention on the Rights of Persons with Disabilities (for those States which have ratified).

Under the Patient Self-Determination Act 1990.

L. Emanuel, M. Barry, J. Stoeckle, L. Ettelson, E. Emanuel, 'Advance Directives for Medical Care: A Care for Greater Use', *New England Journal of Medicine* 324(13) (1991) 889-895. See also SW Salmond and E. David, 'Attitudes towards Advance Directives and Advance Directive Completion Rates', *Orthop Nurs* 24(2) (2005) 117-127 found 25 per cent of people has completed advance directives; United States Department of Health and Human Services, 2008, *Advance Directives and Advance Care Planning: Report to Congress.* Retrieved 9 February 2016, https://aspe.hhs.gov/sites/default/files/pdf/75811/ADCongRpt.pdf reported an extensive range of studies showing that completion rates for advance directives among Americans were 18-36 per cent.

A. Jones, A. Moss, L. Harris-Kojetin, 2011, 'Use of Advance Directives in Long Term Care Populations', *United States National Centre for Health Statistics (NCHS) Data Brief* 54. Retrieved 9 February 2016, http://www.cdc.gov/nchs/data/databriefs/db54.pdf. This may be contrasted with 65 per cent of nursing home residents and 28 per cent of home healthcare patients.

See R. Johnson, Z. Yanfang, L. Kristin Newby, C. Granger, B. Granger, 'Reasons for Non-completion of Advance Directives in a Cardiac Intensive Care Unit', *American Journal of Critical Care* 21(5) (2012) 311-320.

For one proposal using a computer decision-aid, see B. Levi and M.Green, 'To Soon to Give Up? Reexamining the Value of Advance Directives', *American Journal of Bioethics* 10(4) (2010) 3-22.

reasons, however, are an inevitable part of human nature. Many people will not make advance plans, whether through a reluctance to confront their own mortality or because they do not consider this kind of planning to be appropriate¹³⁰. For some people too, the potential for advance healthcare planning may be limited because they have a cognitive or intellectual impairment which limits their capacity to make such plans (although developments in supported decision-making¹³¹ may expand the cohort of people for whom this kind of advance planning is possible). Acknowledging that advance healthcare planning may not be for everyone is important in developing a legal framework. It suggests that the aim of a legal framework should not be to achieve universal or even very extensive uptake but rather that the facility available to those who wish to utilise it should be robust.

The comparison undertaken in this articles indicates that, in most respects, the ADMA offers a more nuanced and defensible form of advance healthcare planning than that offered by the MCA. There is more protection for patient choice; the inclusion of the facility to appoint a DHR offers more potential for ensuring that healthcare providers actually deliver on the choices made; and the balance between formalities and enforceability delivers a more robust instrument. Of course, the analysis that has been undertaken of the ADMA is inevitably textual; it is only when the legislative model is actually given effect in practice that a comprehensive evaluation of the legislative choices made can be undertaken. More generally, the comparative analysis undertaken in this article makes clear that frameworks for advance healthcare planning must be evaluated at a level of detail because only in this context can the important choices made be identified. This kind of evaluation, and re-evaluation, is essential if this part of the important goal of providing appropriate legal frameworks for capacity impairment is to be realised.

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In this respect, there seem to be clear cultural and race differences, with United States studies showing much less enthusiasm for advance directives among African Americans and suggesting incompatibility with traditions and cultures of Hispanic, Asian and Native Americans: see US Department of Health and Human Services Report to Congress *supra* n. 126 at 15.

See text to n. 34 supra.