Chapter 7

Cognitive Vulnerability and Consent to Biomedical Research in England and Wales

Until recently, the status of first person contemporaneous legal competence (FPCLC) to consent to medical research in England and Wales was in considerable disarray. The absence of a legislative measure combined with ambiguous ethical guidelines and confusing terminology, created a situation fraught with uncertainty. To a considerable extent, this confusion persists despite efforts to systematize the law. Whilst competence and capacity are two of the most widely used concepts in relation to English medical law, they are also two of the least understood and most poorly employed. In part, this has arisen due to inadequate attention paid to assessments and judgments of decisional competence.

This confusion is starkly apparent amongst medical practitioners. In a survey published in 2002 regarding knowledge of consent and capacity in the medical profession,[829] only a small proportion were aware of the legal position relation to consent and research. Two out of sixteen junior doctors (13%), three out of ten non-career-grade doctors (30%), seven out of nineteen specialist registrars (37%), five out of fifteen consultants (33%) and four out thirty-five general practitioners (11%) gave correct answers.[830] For every grade, this was lower than the figures for consent to treatment. These alarming figures represent a dearth of knowledge on behalf of the medical profession about the current law. As such, it is difficult to imagine that these practitioners would be in a position to apply the existing law accurately, let alone evaluate its shortcomings.

The purpose of this chapter is to survey the legal position in England and Wales and selected ethical guidelines issued by professional bodies in the UK. It will also consider the significance of European regulation in generating norms of decisional competence judgment that have influenced the English legal position or may do so in time. Throughout, we will assess the prospects for compatibility between the regulatory position and precautionary task or decisional competence judgment (PTDCJ). In particular, we will consider the differences that exist between 'mental capacity' and 'legal capacity', the current legal status of decisional competence to

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[829] Jackson and Warner (2002).

[830] Jackson and Warner (2002: 602).

P. Bielby, *Competence and Vulnerability in Biomedical Research,*

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consent to medical research in England and Wales and ethical guidance on decisional competence to consent to medical research. As our focus is on FPCLC, we will not consider the position of decisionally incompetent individuals (frequently known as 'mentally incapacitated' or 'mentally incompetent' individuals) as they will in all probability lack FPCLC.

Three Approaches to Determining FPCLC

It is helpful to begin by drawing a distinction. A legal judgment of FPCLC can be made upon three possible grounds – on a functional, outcome or status based test.[831] Functional tests involve an assessment of the task or decisional competence of an individual in respect of a particular task or decision. A functional test of capacity involves ascertaining the task or decisional abilities of an individual in terms of the nature, purpose and effect of the activity in question at the time of the assessment. Functional tests of capacity therefore establish a clear link between decisional competence and FPCLC, so that the latter is typically explained mostly, if not wholly, in terms of the former.

Functional tests are particularly useful where an individual is associated with a cognitively vulnerable group who usually may not be considered to have task or decisional competence in respect of that activity. This is because such tests have the advantage of recognising both specific contexts in which the individual can be judged to have FPCLC and areas where she can be judged to lack capacity in this regard. Functional tests of capacity are analogous to demonstrable task or decisional competences given the demonstration of ability at the task or decision needed in order to convince the assessor of the presence of the ability and the specificity of the test to the task or decision involved.

Outcome tests of FPCLC are concerned with the content of the choice that the individual reaches. As such, they can be utilized only in decisional contexts. According to this test, a decision that is inconsistent with accepted values, clinical advice or with the judgment of the assessor represents sufficient grounds for declaring the individual to lack capacity in that respect. Outcome tests of FPCLC are closely related to asymmetrical or risk-relative models of competence we examined in Chapter 1. If applied, outcome tests potentially give rise to a situation whereby an individual is considered to have FPCLC if she chooses one way, but lacks FPCLC if she chooses another within the same decisional scenario. This approach to determining FPCLC is premised on values which tend towards paternalism rather than the promotion of individual autonomy and in extreme cases engineer conformity to received opinion. The nature of such a test in the context of determining consent to

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[831] See Freedman (1981) for a theoretical discussion and Law Commission of England and Wales (1993, Part II, pp. 10–24) for a discussion in relation to English law.

participation in biomedical research could be open to exploitative misuse, as it is possible that the values of the competence assessor could surreptitiously determine the existence of FPCLC, disguised as an attempt to support decision-making.

Status tests confer FPCLC upon the grounds of the possession of a certain characteristic, such as age, achieved universally. It excludes all individuals who do not fall within this group as lacking this capacity. A status approach grounds the enfranchisement of individuals once they reach the age of eighteen years, and determines other decisional competences, such as contractual capacity and consent to sexual intercourse. Status approaches are less appropriate in healthcare contexts where the moral imperative of giving effect to decisional competence is high and the cost of assessing competence on a case-by-case basis is comparatively low. They also can give rise to, as the Law Commission noted, the presumption of an absence of FPCLC in *all* areas, where this is not the case.[832] However, status approaches may be necessary where adopting a functional approach would be administratively unworkable (such as a functional test for adolescents to attain the right to vote). In this sense, status approaches are analogous to presumed competences insofar as they require a universally attainable quality and the absence of a test of individual capability.

A functional test to determine FPCLC is most consistent with PTDCJ. This is because it ensures that the grounds upon which competence is judged are specific to the nature of the decision at hand, and do not account for the possession or absence of other task or decisional competences or instances of FPCLC that are irrelevant to the abilities being assessed. Status approaches tend to frustrate a PTDCJ approach to FPCLC as they rely upon blanket presumptions of decisional competence, unless the adoption of a status test is the only way FPCLC can be ascribed without undermining more important rights of other agents. Outcome tests accord an unwise amount of discretion to those responsible for assessing competence in ways that could allow inappropriate factors such as the values and wishes of the competence assessor to influence a determination of FPCLC.

The Meaning of FPCLC Consent in England and Wales

English law has originally formulated standards of FPCLC in relation to medical treatment rather than research. This is the case in the context of adults and children. These standards warrant consideration, as they inform the basis of the standard of FPCLC to consent to research, and would provide a legal background to any attempt in English law to develop specific principles in relation to making judgments of decisional competence.

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[832] Law Commission of England and Wales (1995, para. 3.3).

Adults

Following the judgment of Lord Donaldson in *Re T,*[833] every adult in English law is presumed to have FPCLC consent to treatment, but this is a presumption that can be rebutted if the existence of capacity is brought into doubt.[834] The level of understanding required for a legally valid consent to treatment must be commensurate with the gravity of the decision to be taken, with more serious decisions requiring greater capacity.[835] This appears on the face of it to be an example of risk-relative competence. However, it is compatible with a decision-relative theory of competence, as the decisional abilities required are related to the complexity of the decision to be taken, not simply the choice made, and 'seriousness' is a measure of this complexity, rather than merely a measure of the risk.

The most authoritative English case law definition of FPCLC in adults is provided in *Re C (adult: refusal of medical treatment),* a case in which a schizophrenic patient in a psychiatric hospital refused consent for an operation to amputate his gangrenous leg.[836] Thorpe J held that in order to have FPCLC, to consent, the patient must understand "the nature, purpose and effect"[837] of the procedure. This involves the ability to comprehend and retain information about treatment, to believe this information and to weigh the information in order to evince a choice.[838] When we evaluate this test against non-legal criteria of decisional competence, it yields fundamental similarities with the conceptual definition of decision-relative decisional competence examined in Chapter 1.

More importantly, *Re C* firmly establishes that the quality of internal reasoning expressed by the decision-maker should solely determine FPCLC in adults, and not the view of the competence assessor about the reasonableness of the choice or the rationality of the reasoning process. This is again analogous to decision-relative competence, in that the consistency of the decision-maker's reasoning in terms of her own established values is interpreted as a indicator of decisional competence rather than how well the value judgments expressed in that reasoning process correspond with those health care professionals believe the patient ought to hold. This principle has been affirmed in England and Wales subsequently, in *Re MB (an adult: medical treatment)*,[839] which concerned a pregnant woman refusing venepuncture for a caesarean section, and perhaps most notably in *Re B (adult: refusal of medical treatment)*,[840] where a quadriplegic adult's refusal of life-sustaining treatment was granted.

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[833] *Re T (adult: refusal of medical treatment)* [1992] 4 All ER 649.

[834] *Ibid.*, Lord Donaldson MR, p. 661.

[835] *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175 (CA).

[836] [1994] 1 All ER 819.

[837] *Ibid.* Thorpe J, p. 824.

[838] *Ibid.* Thorpe J, p. 824.

[839] (1997) 38 BMLR 175 (CA).

[840] [2002] EWHC 429 (Fam).

Re C symbolizes a clear recognition of the acceptance of a functional test towards determining adult FPCLC in English law, as opposed to a status test. Accordingly, the test turns upon the decisional abilities of the individual and not upon any concomitant mental disorder or intellectual disability, provided that the existence of the disorder or disability does not affect the integrity of the decision-making. The existence of these important parallels between standards of decisional competence and tests of FPCLC in adults indicates how in English law, 'competence' is frequently understood as a synonym for 'capacity'. Indeed, it is true to say of the *Re C* test that it defines FPCLC wholly in terms of decisional competence.

The burden of proof in any dispute about FPCLC is placed upon those who are alleging that someone lacks FPCLC, or alternatively that someone who previously was judged to lack FPCLC now possesses FPCLC.[841] This meshes with the position under PTDCJ, as the basis for a judgment under precaution has to be that whatever is being alleged can be given a compelling explanation under conditions of uncertainty,[842] and that the consequences for the generic rights of the individual(s) concerned in believing one way are less harmful than the consequences in believing another. The standard of proof that a judgment of FPCLC requires is the civil law standard of the balance of probabilities rather than the higher criminal law standard of beyond all reasonable doubt.[843] Given the administrative difficulties that may follow from operationalizing a standard of beyond all reasonable doubt (that could, as we saw in Chapter 5, compromise the state's ability to fulfil its obligations to other agents), a balance of proof on the civil law standard appears appropriate from the perspective of PTDCJ.

Tan and McMillan argue that there is a disparity between the standard of legal capacity articulated in the *Re C* test and that which is embodied in the BMA and Law Society's guidance document, *Assessment of Mental Capacity*, the second edition of which was published in 2004.[844] This arises because the guidance couches FPCLC in terms of understanding and retention of information (concentrating on the first strand of the *Re C* test), while failing to elaborate on believing and weighing the information (the second and third elements of the *Re C* test).[845] The BMA and the Law Society also appear to add to the *Re C* test by including the freedom to make a choice, which is usually part of the definition of consent rather than competence or capacity.[846]

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[841] Mental Capacity Act 2005, s. 1(2). See also the Mental Capacity Act 2005 Code of Practice, para. 4.10, p. 44 and the British Medical Association and the Law Society (2004: 28).

[842] Remembering that in matters of judging decisional competence, just as in matters of agency ascription, all that can be known with certainty is that I myself am an agent.

[843] Mental Capacity Act 2005, s. 2(4). See also the Mental Capacity Act 2005 Code of Practice, para. 4.10, p. 44 and the British Medical Association and the Law Society (2004: 29–30).

[844] Tan and McMillan (2004), British Medical Association and the Law Society (2004).

[845] Tan and McMillan (2004: 428).

[846] Tan and McMillan (2004: 427–428).

Tan and McMillan directed their criticism towards the first edition of the guidance, published in 1995. Although the second edition now includes reference to weighing the information in reaching a choice, and freedom of choice is now related explicitly to the validity of the consent, there is still no reference to believing the information.[847] It remains an important omission, since believing the information presented is as central to making a judgment of decisional competence as understanding the information – even if the decision-maker subsequently goes on to reject the importance of the information. Moreover, it is likely that healthcare professionals, one of the target audiences of the guidance, will come to interpret the *Re C* test in the more restrictive terms in which the BMA and the Law Society have construed it.[848]

The connection between FPCLC and decisional competence is strengthened the recent introduction of 'mental capacity' as a statutory legal concept by the Mental Capacity Act 2005 (hereafter MCA 2005).[849] Until recently, attempts have been made to maintain the separation of the concepts of legal and mental capacity.[850] Since then, there has been a retreat from this position to the point where the new statutory definition of legal capacity in English law is framed in terms of mental capacity. The Act provides a clear presumption in favour of FPCLC grounded in decisional competence[851] and applies to individuals above the age of sixteen years. Section 2(1–2) of the MCA 2005 provides:

> s. 2 People who lack capacity
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> (1) For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.
> (2) It does not matter whether the impairment or disturbance is permanent or temporary.

Inability to make a decision is defined in s. 3(1)(a–d) of the Act as an inability to understand, retain, use and weigh the information relevant to the decision and an inability to communicate the decision (belief is not included as a criterion).[852] This tracks very closely the structure of decision-relative decisional competence to consent discussed in Chapter 1. By implication, mental incapacity in English law must be defined as the absence of those abilities. This posits a *prima facie*

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[847] British Medical Association and the Law Society (2004: 120).

[848] Tan and McMillan (2004: 428).

[849] The MCA 2005 received Royal Assent on 7 April 2005 and came into force in two phases during 2007.

[850] Law Commission of England and Wales (1991: 19).

[851] MCA 2005, s. 1(2).

[852] A similar definition of capacity has been issued previously by the Department of Health in their *Good Practice in Consent Implementation Guide*: "A patient will lack capacity to consent to a particular intervention if he or she is … unable to comprehend or retain information material to the decision, especially as to the consequences of having, or not having, the intervention in question, and/or …unable to use and weigh this information in the decision-making process" (2001b: 46).

conceptual link between decisional competence and mental capacity and, by extension, to FPCLC as mental capacity provides the criteria for having FPCLC.

The Explanatory Notes to the MCA 2005 stipulate that the Act's definition of capacity "focuses on the particular time when a decision has to be made and on the particular matter to which the decision relates, not on any theoretical ability to make decisions generally".[853] In other words, a person's inability to manage their financial affairs, for example, should not influence judgments about their decisional competence in relation to consent to medical treatment. It follows from this that FPCLC strongly pertains to the ability of the individual to make a decision for him or herself that is decision-relative, and therefore constitutes a legal instantiation of decision-relative competence. Thus, FPCLC would appear to approximate to a statutory definition of mental capacity that is itself informed by decision-relative notions of decisional competence.

The MCA 2005 goes on to make provisions in relation to research with individuals who lack mental capacity that do not involve clinical trials, although these do not give rise to a separate test of FPCLC consent.[854] FPCLC to consent to medical research is therefore determined by the provisions of s. 3. Similarly, the Human Tissue Act 2004 makes provisions for "appropriate consent" but construes capacity in terms of its meaning under the MCA 2005.[855] We can gather from this that in terms of FPCLC to research, the test of capacity elaborated in s. 3 of the MCA 2005 along with the case law discussed above will remain the principal reference point.

The Medicines for Human Use (Clinical Trials) Regulations 2004 (hereafter 'the Clinical Trial Regulations') is a piece of delegated legislation (made under the authority of the relevant Secretary of State) which implements Directive 2001/20/EC into English law.[856] Schedule 1 Parts 1–5 of the Clinical Trial Regulations outline legal protections for adults, incapacitated adults and children involved in clinical trials. "Adult" is defined as an individual above the age of sixteen years.[857] Again, there is no explicit discussion of the principles underpinning decisional competence or FPCLC and no guidance on what approach should be taken if decisional competence is questionable or how to support decisional competence. However, the EU Directive, which was responsible for the British Government enacting the Clinical Trials Regulations, makes elliptical reference to FPCLC by presuming its absence in certain cognitively vulnerable participants. Paragraph 4 of Directive 2001/20/EC (hereafter 'the Clinical Trials Directive') discusses the participation of the mentally impaired:

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[853] Department of Constitutional Affairs and Department of Health (2005: 4).

[854] MCA 2005, s. 30–34.

[855] Human Tissue Act 2004, s. 1–3 and Explanatory Notes, Part 1, Section 6.

[856] SI 2004/1031, s. 28–31 and Schedule 1. There is no general exclusion of tissue-based research in either the MCA 2005 or the Clinical Trial Regulations; however, the Human Tissue Act 2004 more comprehensively regulates the removal, storage and use of human tissue samples.

[857] Clinical Trials Regulations 2004, s. 2(1).

> In the case of persons incapable of giving their consent, such as persons with dementia, psychiatric patients etc., inclusion in clinical trials in such cases should be on an even more restrictive basis. Medicinal products for trial may be administered to all such individuals only when there are grounds for assuming that the direct benefit to the patient outweighs the risks. Moreover, in such cases, the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial.[858]

The reference to the written consent of the participant's legal representative entrenches the assumption that all such participants would lack FPCLC and instead be entered into clinical trials though provisions for proxy consent.[859] This assumption links decisional incompetence to the presence of a mental disorder and returns us to the status based tests outlined above. This is a retrograde step, especially at a time when the general tenor of English case law and the MCA 2005 represents a significant departure from this trend.

In England, academic commentators and judges frequently use competence as a synonym for FPCLC.[860] Given the affinity between decisional competence and FPCLC, underscored through the advent of the MCA 2005, this is not surprising. Competence, however, is not a legal concept in English law.[861] This means that in current English law, FPCLC *can* be defined in terms of decisional competence *but this need not necessarily be the case*. It follows that it cannot be known with absolute certainty whether competence is being used to express a non-legal judgment about the decisional competence of the individual, or as a substitute for FPCLC. This militates against clarity and consistency in legal reasoning.

To illustrate this, consider the use of competence in the following excerpt from the judgment of Butler-Sloss LJ in *Re MB*[862]: "The graver the consequences of the decision, the commensurately greater the level of *competence* [emphasis added] is required to take the decision."[863] This claim, considered alone, is perfectly reasonable. However, in the next paragraph, Butler-Sloss LJ expounds the criteria for an individual to lack *capacity*.[864] It is unclear from this whether the use of 'competence'

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[858] Directive 2001/20/EC, OJ L 121, 1.5.2001, p. 35.

[859] Additionally, the emphasis placed upon "direct benefit to the patient" means the Directive would permit only therapeutic research upon those participants incapable of consenting.

[860] See, for example, Brazier and Lobjoit (1991: 34–51), Kennedy and Grubb (2000, Chapter 5) and Mason and Laurie (2006, Chapter 10).

[861] This is antithetical to the position in the US, where 'capacity' denotes *mental* capacity only, and competence is a legal concept. See Berg et al. (1996: 348–349).

[862] (1997) 38 BMLR 175 (CA).

[863] Butler-Sloss LJ, p. 198.

[864] "A person lacks capacity if some impairment or disturbance of mental functioning renders the person unable to make a decision whether to consent to, or to refuse, treatment. That inability to make a decision will occur when: (a) the patient is unable to comprehend and retain the information which is material to the decision, especially as to the likely consequences of having, or not having, the treatment in question; (b) the patient is unable to use the information and weigh it in the balance as part of the process of arriving at the decision" *ibid.*, Butler-Sloss LJ.

is a reference to the psychological decisional abilities of MB, and the use of 'capacity' a reference to the legal factors that would render any individual to be without FPCLC to treatment.

A judge may, of course, disclaim any such difference between the two terms and rely upon the resemblance between non-legal criteria for decisional competence and FPCLC outlined above. However, closer analysis of the reasoning here suggests Butler-Sloss LJ is referring to the FPCLC of MB throughout, but substituting capacity for competence at various intervals on the understanding that competence is *necessarily* the same as FPCLC, with no obvious rationale for doing so. The consequence is that Butler-Sloss LJ is invoking a psychological and philosophical notion when she is actually applying a legal concept.

Why is this problematic? One may reasonably object that this is not unprecedented and that it may well be desirable for a judge to approach the issue of FPCLC by having regard to a theory of decisional competence. But this is not what Butler-Sloss LJ is seeking to do. She is not presenting an argument in the judgment as to *why* FPCLC should be defined in terms of decisional competence but is instead articulating the legal principle (i.e. FPCLC), which is then applied to the facts of the case. Moreover, to articulate FPCLC in terms of a generic notion of legal capacity (which Butler-Sloss LJ does) is to fail to distinguish the three different forms of legal capacity that exist, only one of which (FPCLC) can correlate to decisional competence.

Children

The common law position in relation to the FPCLC of children under 16 to consent to medical treatment, set out in the landmark case of *Gillick*,[865] has become a quintessential part of English medical law. Although the principle has been subjected to controversial judicial qualification in the intervening years,[866] the basis of the ruling still stands – a child under the age of sixteen has FPCLC to consent to medical treatment "if and when the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed".[867] The ruling has become known as the test of *Gillick* competence. As Beyleveld and Brownsword observe, the concept of *Gillick* competence is therefore not a measurement of ostensible agency, but an attempt to articulate a standard of decisional competence.[868] Section 43(8) of the Children Act 1989 reflects and extends the *Gillick* principle in statutory form by permitting a child to refuse a medical or psychiatric

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[865] *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] A.C. 112.

[866] In particular, see *Re R (A Minor) (Wardship: Consent to Treatment)* [1992] Fam. 11 and *Re W (a minor: medical treatment)* [1992] 4 All ER 627.

[867] *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] A.C. 112, p. 188–189 (Lord Scarman).

[868] Beyleveld and Brownsword (2001: 133, n. 24).

examination as part of a child assessment order provided she is of "sufficient understanding".[869]

Gillick represents a departure from the status-based approach to ascertaining FPCLC in favour of the functional approach. The judgment in *Gillick* delivered by Lord Scarman implicitly reveals a willingness to allow standards of FPCLC in relation to children to be influenced by the same kind of understandings of the decisional abilities of children that we considered in Chapters 5 and 6. It follows that FPCLC to consent to treatment in relation to children is also partly informed by a decision-relative account of decisional competence. However, this rejection of the status test is only partial. Despite espousing of the autonomy of mature children, *Gillick* nonetheless represents a risk-relative standard of decisional competence and an outcome test of FPCLC. This is because it still permits the consent of a parent or the decision of the courts to override any refusal of treatment given by the child. Although the English courts have acknowledged the tension between, on the one hand, the logical symmetry of a decision and, on the other, employing a risk-relative theory of decisional competence with young people,[870] this remains so far unresolved.

In *Re R*, Lord Donaldson considered that the parental right to consent to treatment that *Gillick* circumscribed was to determine the legal approach to a mature minor, but that a parental consent could still be valid in the light of the child's refusal, where it was in the best interests of the child to have that treatment.[871] The decision in *Re R* also precludes fluctuating competence. The court ruled that a determination of FPCLC to consent should be made only after having regard to the general condition of the young person, rather than as a result of an assessment of decisional competence at a point when she was competent.[872] This is because any judgment of decisional competence that may follow would be unrepresentative of her usual level of decisional incompetence.[873] The court's reasoning is compatible with PTDCJ

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[869] s. 44(7) reiterates the principle, which deals with orders for emergency protection of children and in Schedule 3, which deals with supervision orders. In the former case, the child may refuse to submit to a psychiatric examination or other assessment if she possesses "sufficient understanding". In the latter case, a supervision order is not required if the child has "sufficient understanding" to consent to co-operation. We should note however, that this scope for FPCLC for refusal is circumscribed by the conditions set out in the legislation and does not extend to normal treatment situations, where FPCLC is ascribed to mature children for consent and not refusal.

[870] As acknowledged by Lord Balcombe in *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1993] Fam. 64 at p. 88.

[871] *Re R (A Minor) (Wardship: Consent to Treatment)* [1992] Fam. 11, p. 24.

[872] *Re R (A Minor) (Wardship: Consent to Treatment)* [1992] Fam. 11, p. 24 (Lord Donaldson).

[873] Referring to the facts of the case, Lord Donaldson said: "Even if she [R] was capable on a good day of a sufficient degree of understanding to meet the *Gillick* criteria, her mental disability … was such that on other days she was not only '*Gillick* incompetent', but actually sectionable" (*ibid.*: 26). Assuming that he is correct about this, then under Gewirthian precautionary reasoning, R should be considered a societally incompetent agent, for whom the treatment is necessary in order to protect her from causing unintended harm to herself or others.

insofar as it requires that a test of decisional competence reflects whether the decisional competence in question is a consistent feature of the individual, but is incompatible in the sense that it operates within the context of a risk-relative theory of competence.

The position of FPCLC in respect of 16–17 year-olds to consent to treatment is found in s. 8(1) of the Family Law Reform Act 1969. The section provides that consent to surgical, medical or dental treatment on behalf of the young person should be given effect and supplementary consent need not be sought from the young person's parents.[874] This statutory presumption of FPCLC is indicative of a legal presumption of decisional competence, but one which is subject to the qualification that it is still possible for someone with parental responsibility or the court to override refusal.[875] Since the MCA 2005 came into force, however, the test of capacity set out in s. 3 will apply to young people above the age of sixteen to consent to treatment and research that is covered by the Clinical Trials Regulations. Moreover, as we acknowledged earlier, an adult for the purposes of the Clinical Trials Regulations is defined as someone aged sixteen and above. This may create a tension with the existing case law, as s. 2(3) of the Act states that age cannot be determinative of capacity.[876] It also gives rise to a bizarre current situation whereby a sixteen year-old cannot refuse treatment on her own behalf but can consent to research.

In one sense, s. 8(1) is an extension of risk-relative *Gillick* competence. However, there is an important difference. Whereas we can describe the effect of *Gillick* more accurately as a partial instantiation of a demonstrable risk-relative competence, insofar as the competence must be proved to the satisfaction of the assessor, both the FPCLC of 16–17 year olds to consent to treatment and FPCLC of adults for the same are instances of a presumed decisional competence. In both cases, this is defeasible when the individual in question is found through subsequent examination to lack the cognitive requirements for decisional competence in that regard. The difference between the FPCLC of adults and the FPCLC of 16–17 years olds is that the latter do not also have a rebuttable presumption to refuse. Therefore, the theory of decisional competence that informs the FPCLC of sixteen and seventeen years olds is as asymmetrical as that which informs the FPCLC of young people under sixteen.

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[874] s. 8(2) states: "The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to the person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian."

[875] *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1993] Fam. 64, p. 84 (Lord Donaldson).

[876] Pattinson (2006: 159) also makes this observation.

This view is endorsed in respect of 16–17 year olds in *Re W (a minor) (medical treatment: court's jurisdiction)*,[877] where it was held that the court could exercise extensive powers of wardship to act in the best interests of the young person. Lord Donaldson held unequivocally that it is not possible for the refusal of any person under the age of eighteen to override the consent of someone with parental responsibility or the court.[878] Similarly, Lord Balcombe looked at the wording of s. 8(3) of the Act and concluded that it was not possible to construct an interpretation to provide for an absolute right of refusal.[879] However, Lord Donaldson intriguingly supposed a difference between medical law and medical ethics, which he took to mean that an abortion performed on a sixteen or seventeen year old without her consent but with the consent of the parents would be unlikely to go ahead, unless it was in the young person's best interests.[880] This suggests that positive law is not the only factor which judges are prepared to consider when a tension arises between FPCLC and decisional competence.

Of course, given our earlier recognition that FPCLC need not be construed in terms of decisional competence, it is theoretically possible to frame a test of FPCLC in asymmetrical terms without incurring internal incoherence. There is nothing inherent in the definition of legal capacity that requires FPCLC to attach to all possible options in a given decision making context. The absence of a necessary connection between FPCLC and decisional competence in English law emphasizes this. However, this is a much less compelling explanation for *Gillick*, because of the ubiquitous association of the word 'competence' in academic debate as well as by the judiciary with the *Gillick* standard. If one takes the view argued for in Chapter 1 that risk-relative decisional competence is incoherent, then the ruling in *Gillick* and s. 8(1) of the Family Law Reform Act 1969 are not tests of decisional competence at all but rather choice-relative ascriptions of FPCLC which follow an outcome test approach. Both are tests of FPCLC which draw upon notions of decisional competence but whose conceptual structures ultimately defy the nature of decision-making. Indeed, it would have been more accurate had the *Gillick* test instead been named '*Gillick* capacity'.

Problems Surrounding the Use of Capacity

One might object that the British Government's choice to frame legal capacity in the language of mental capacity through the MCA 2005 is confusing. If one recalls the previous distinction, whereby legal capacity was restricted to legal discourse and mental capacity was restricted to medicine and psychiatry, this objection is

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[877] [1993] Fam. 64.

[878] *Ibid.* at p. 84.

[879] *Ibid.* at p. 86.

[880] *Ibid.* at p. 79.

underscored.[881] However, given the appreciable extent to which FPCLC is defined in terms of decisional competence in English law, then using mental capacity as a synonym for FPCLC might be construed as simply describing the same relationship by using different terminology.[882] Understood in these terms, this is merely an innocuous substitution.

This would be a hasty conclusion to reach. Let us first consider the prospects of mental capacity as a new legal concept. Clearly, from the nomenclature of the Act, mental capacity is used in preference to legal capacity. This may have been as a result of a deliberate political choice to emphasise that the Act is seeking to legislate for the position of those who are commonly referred to outside of legal circles as lacking mental capacity. It is clear from the Act that all persons without mental capacity will not have FPCLC under the Act and that some of these persons with mental incapacity, by virtue of having created an LPA before the onset of their incompetence, will have legal capacity exercised on their behalf through their surrogate (the second sense of legal capacity elaborated in Chapter 1).[883]

However, this is not the same as claiming that all persons without FPCLC will also lack mental capacity, on which the Act is silent. Since mental incapacity is defined in s. 2 and 3 of the Act in terms of criteria for decisional incompetence, it is highly foreseeable that there will be groups of individuals who would meet the standard of decisional competence, but who, due to countervailing legal principles in statute and common law, do not have the relevant FPCLC to come within its ambit. Examples would be decisionally competent fourteen or fifteen year olds who wish to consent to medical research on their own behalf or sixteen and seventeen year olds who wish to refuse medical treatment without the risk of that refusal being overruled by their parent/guardian or by the courts.[884] Thus, the presumption in favour of mental capacity set out in s. 1(2) of the MCA 2005 does not cover all individuals who are capable of making decisions and will be circumscribed by other legal principles. Moreover, as the British Medical Association and the Law Society have observed, mental capacity can mean something different to each

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[881] Law Commission of England and Wales (1991: 19).

[882] This convergence of terminology has had a long history in the proposals for law reform that led up to the passing of the Act (Law Commission, 1993, 1995; Lord Chancellor's Department, 1997, 1999; Department of Constitutional Affairs, 2003).

[883] 'LPA' refers to Lasting Power of Attorney, an expanded class of legally authorised surrogate decision-makers created by the MCA 2005 (replacing the old 'enduring power of attorney'). Section 11(7)(c) of the Act allows an LPA to give or refuse consent to the continuation or carrying out of treatment by a person providing health care for a decisionally incompetent individual. In respect of medical research, Schedule 1 Part 5 of The Medicines for Human Use (Clinical Trials) Regulations 2004 already allows for a legal representative to consent to research participation on behalf of a decisionally incompetent individual where the research is being conducted into a "life-threatening or debilitating condition from which the subject suffers" (Part 5, s. 11).

[884] Levine (1988: 261) identifies this distinction by employing the terms 'de jure' and 'de facto' incompetence, where 'de jure' incompetence is an absence of FPCLC to decide (even though the person may in fact have decisional competence) and 'de facto' incompetence is an absence of decisional competence, which will usually be accompanied by an absence of FPCLC.

profession involved in assessing it.[885] There is, then, the potential for mental capacity and legal capacity to be in practice informed by different standards, even though the Act suggests otherwise.

Towards Supported Decision-Making?

A principal advantage of supported decision-making is that it maximizes the extent to which cognitively vulnerable individuals both possess and exercise legal capacity, as opposed to having legal capacity exercised through a surrogate decision-maker. In the Joint Committee Report on the Draft Mental Incapacity Bill (the precursor to the MCA 2005), the Making Decisions Alliance (a lobbying organisation which represents a variety of support groups) pointed out that the then Draft Mental Incapacity Bill perceived decisional competence as either fully present or fully absent. It would be preferable, they insisted, that steps should be taken to ensure that decision-making is supported through accessible information and communication.[886] This parallels the argument I have made earlier in this book.

There is a requirement in s. 1(3) of the MCA 2005 that an individual should not be treated as incapable of making a decision "unless all practicable steps to enable him to do so have been taken without success". No case law has yet considered the question of what constitutes 'practicable steps' due to the Act only recently having fully come into force. Similarly, the Human Tissue Act 2004 makes provisions relating to "appropriate consent" for the removal and storage of tissue from adults and children who are decisionally competent, although nowhere in this Act is there reference to steps that must be followed to preserve or enhance decisional competence. However, the MCA 2005 Code of Practice does provide some suggestions, such as establishing how the individual usually communicates, using a qualified interpreter, employing 'mechanical devices' (such as a voice synthesizer), engaging in non-verbal communication or offering speech or language therapy as examples of assistance in relation to maximizing decisional competence.[887] The core objectives of supported decision-making could fall within a broad interpretation of any of these examples of assistance.

By way of comparison, s. 1(6) of the equivalent Scottish provision, the Adults with Incapacity (Scotland) Act 2000 stipulates that:

> a person shall not fall within this definition [the definition of incapability of making a decision] by reason only of a lack or deficiency in a faculty of communication if that lack or deficiency can be made good by human or mechanical aid (whether of an interpretative nature or otherwise).

Although s. 1(6) does not suggest that the Scottish legislation is premised necessarily on a concept of supported decision-making, the wording of this section strongly indicates that supportive interventions are of utmost importance when a determination

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[885] British Medical Association and the Law Society (2004: 4).

[886] Joint Committee on the Draft Mental Incapacity Bill (2003: 24, para. 73).

[887] Department of Constitutional Affairs (2007, para. 3.11 and para. 2.7).

of mental capacity is at stake. Indeed, the emphasis upon remedying shortcomings of communication by an unspecified range of interpretative devices would seem to catalyse such supportive interventions. If a permissive interpretation of the duties upon physicians and researchers is adopted in relation to the MCA 2005 – and the Scottish legislation may prove a persuasive referent for the English courts – then there is greater potential for a legal accommodation of supported decision-making in English law.

It is important to emphasise that the MCA 2005 could not accommodate supported decision-making by way of the role of the Independent Mental Capacity Advocate (IMCA).[888] The function of the IMCA is qualitatively different in two respects from the concept of supported decision-making. First, the IMCA pertains only to individuals who have already been found to be incompetent to make decisions of that particular type. It does not encompass individuals with questionable capacity who may still be able to make decisions of that type. The use of IMCAs is restricted to scenarios where the person for whom the intervention is designed to benefit does not have a Lasting Power of Attorney or a Deputy appointed. Unlike the supported decision-making approach, then, the Advocate becomes operative only where an individual already has been found to lack decisional competence and where no other authorised surrogate exists.

Second, the role of the Independent Mental Capacity Advocate is limited to certain specified scenarios: provision of serious treatment by an NHS body and provision of accommodation by an NHS body or by a local authority.[889] This adds weight to the terminological preference for 'supported decision-making' in favour of 'advocacy', which has a distinct legal meaning as a result of the implementation of the MCA 2005. The former more easily accommodates the idea of provision of information and advice to an adult who is still competent, in spite of experiencing cognitive vulnerability.[890]

The Significance of European Regulation of Capacity

Recommendation No. R (99) 4 (1999) of the Committee of Ministers to Member States on Principles Concerning the Legal Protection of Incapable Adults[891] emphasises the preservation of decisional competence as the central value that should underpin

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[888] Set out in s. 35–41 of the MCA 2005.

[889] s. 37–39.

[890] In the *Consultation on the Independent Mental Capacity Advocate Service* (UK Department of Health, 2005), the Government signalled their willingness to consider expanding the service to include individuals who are not suffering from mental incapacity for the purposes of the Act and intimated that the service could expand to include research (*ibid*.: 38). However, the significant costs associated with expanding this service and the lack of enthusiasm for it in the consultation means that this was not carried forward in the Department of Health's 2006 response to the consultation or in The Mental Capacity Act 2005 (Independent Mental Capacity Advocates) (Expansion of Role) Regulations 2006. It is also worth noting that research does not fall within the remit of independent mental health advocates recently created by s. 30 of the Mental Health Act 2007 (but not yet in force at the time of writing).

[891] Council of Europe Committee of Ministers (1999).

any approach to dealing with individuals with mental impairment. It was devised by a group of specialists on Incapable Adults (CJ-S-MI) set up by the Council of Europe in 1995.[892] As a Recommendation, it has no binding force within EU law, but it embodies nonetheless a clear articulation of decisional competence and its relationship with FPCLC:

> *"Principle 3 – Maximum preservation of capacity:*
>
> 1. The legislative framework should, so far as possible, recognise that different degrees of incapacity may exist and that incapacity may vary from time to time. Accordingly, a measure of protection should not necessarily result automatically in a complete removal of legal capacity. However, a restriction of legal capacity should be possible where it is shown to be necessary for the protection of the person concerned.
> 2. In particular, a measure of protection should not automatically deprive the person concerned of the right to … consent or refuse consent to any intervention in the health field, or to make other decisions of a personal character at a time when his or her capacity permits him or her to do so."[893]

These principles are close in nature and application to the MCA 2005 and to PTDCJ. Paragraph 1 defines 'incapacity' as a task specific or decision-relative quality rather than as a lack of agency competence. This paragraph also attempts to distinguish mental capacity from legal capacity. This is welcome as it seeks to avoid the potential for conflation that stems from the unqualified use of 'capacity'. Since there appears to be a strong connection between the decision-relative use of 'capacity' and 'legal capacity' (understood as FPCLC), a lack of FPCLC can be taken to amount to a legal recognition of the absence of a task specific or decision-relative competence rather than as an inability to exercise any FPCLC at all.

From the perspective of PTDCJ, this is a justifiable interpretation of FPCLC, as it is only withheld in spheres of activity where decisional competence is not apparent. Furthermore, the measures of protection that are proposed appear to be proportionate to the task and decisional inabilities that a person may possess. This is very similar to how we must treat societally incompetent agents under the PGC. Although there may be grounds for additional protections (the words "not *automatically*" in paragraph 2 suggests there is some scope for depriving an individual of FPCLC if on the evidence, the individual lacks decisional competence in this respect), the overriding consideration appears to be respect for individual autonomy.

In paragraph 2, there is an explicit recognition that the protection owed to an individual with an unrelated specific task or decisional incompetence need not render the individual incapable of being able to make decisions about medical interventions, providing that she does possess decisional competence in this respect. We do not need to speculate as to the meaning of "interventions in the health field", as earlier in the Recommendation, the definition is framed to include both treatment

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[892] Jansen (2000: 333).

[893] Part 2, Principle, 3, s. 1–2.

and research.[894] The inclusion of the phrase "consent or refuse" substantiates our earlier claim that the use of 'capacity' in the Recommendation is grounded upon a decision-relative concept of competence. It also provides support for the view that we should as far as possible respect the competences of individuals at the time they are exhibited, even if at previous or subsequent times they are absent.

Later in the Recommendation, Principle 22 states that provided an adult is capable of giving informed consent, even where an adult is the recipient of protective measures, the intervention may only be carried out with his or her consent.[895] But how can we know, under the Recommendation, whether or not an individual is indeed decisionally competent to give or withhold consent? Principle 12 stipulates, "[T]here should be adequate procedures for the investigation and assessment of the adult's personal faculties,"[896] although no reference is made to the form or substance that the competence assessment would take or the standards to which it should have recourse. This devolves responsibility for devising or choosing a competence assessment measure to an unnamed authority and appears not to require consistency in approach. Without any elaboration of the test which may be used to assess competence, the Recommendation's aim to preserve capacity as long as possible is compromised.

Other instruments offer much less scope for furthering our understanding of the regulatory meaning of 'capacity'. The two principal instruments that seek to regulate research on human participants in the EU, the European Convention on Human Rights and Biomedicine (ECHRB),[897] along with its Additional Protocol on Biomedical Research[898] and the Clinical Trials Directive (Directive 2001/20/EC),[899] emphasise special protections owed toward the participation of adults with mental disorder and children. However, none discuss the issue of the assessment or preservation of decisional competence or FPCLC. Indeed, the phrasing of the ECHRB and the Clinical Trials Directive suggests that both approach the issue of the participation of adults with mental disorder *not* from a standpoint that requires decisional competence be assessed before the issue of surrogate decision-making arises, but from one that assumes surrogate decision-making as the appropriate starting point in relation to their participation. Where brief reference is made to cases of doubtful competence in Article 14(3) of the Additional Protocol to the ECHRB on Biomedical Research, there is simply a statement that "arrangements shall be in place to verify whether or not the person has such capacity". There is no attempt to expand upon what form these arrangements might take or to what criteria these arrangements must adhere.

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[894] Principles – Part 1 – Scope of application, para. 5.

[895] Part 5, Principle 22, s. 1.

[896] Part 3, Principle 12, s. 1.

[897] Council of Europe (1997). As of 1 March 2008, the UK still has not signed up to the European Convention on Human Rights and Biomedicine.

[898] Council of Europe (2005).

[899] Directive 2001/20/EC, OJ L 121, 1.5.2001.

On other occasions, we can witness internal incoherence within the same guidance on capacity. In the 2000 Council of Europe White Paper on the protection of the human rights and dignity of people suffering from mental disorder, especially those placed as involuntary patients in a psychiatric establishment,[900] it was suggested that the concept of mental capacity in Europe was inadequately articulated and needed development. Interestingly, the Council of Europe thought such mentally disordered persons should be protected from involvement in non-therapeutic clinical trials even if they consent to them.[901] It would appear that the White Paper saw scope for development of FPCLC more in terms of constraint, in which paternalistic considerations could trump the moral authority of a decisionally competent consent. This is redolent of the status test of FPCLC outlined at the beginning of the chapter, which if used, would circumscribe the autonomy of decisionally competent patients, re-conceptualizing the best interests test as one which applies to competent cognitively vulnerable research participants as well as incompetent individuals. This would be incompatible with the approach taken under PTDCJ, because unless the research had not been subjected to ethical review, had failed such review or was ethically deficient in some other way (according to standards consistent with the PGC), decisional competence to consent should otherwise be a sufficient condition for participation.[902]

The emphasis that the Convention and the Directive place upon research relating to a condition experienced by the individual concerned is clearly motivated by an intention not to exploit their vulnerability. On the face of it, this is laudable. Nonetheless, there is a pervasive shortcoming which follows from the failure to distinguish research participants into individuals capable and incapable of giving consent without first addressing the issue of competence assessment. Equally, there is no reference to why preserving capacity should be valuable and how it should be undertaken in the context of medical research. Due to a silence on the issue of assessing and judging competence found in all these instruments surveyed, along with any meaningful reference to supported decision-making, the status of decisional competence to consent and its ability to inform ascriptions of FPCLC is frustrated.

Ethical Guidance on Decisional Competence in Biomedical Research in the UK

The ethical guidelines that have emerged on the protection of human participants in clinical research in the UK since the beginning of the 1990s have preceded legal discussion of these issues. Typically, there are three forms of ethical guidance in

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[900] Council of Europe (2000).

[901] p. 34 paragraph 32. This reiterates Article 5, paragraph 3 of Recommendation No. R 83(2) (1983) concerning the legal protection of persons suffering from mental disorder placed as involuntary patients, without any discernible justification.

[902] That is, assuming the existence of no public wrong. See Beyleveld and Brownsword (2007a: 356–357).

research, that which covers good practice in research generally, that which pertains to adults and that which pertains to children.

One of the first guidelines issued during this period was *The Ethical Conduct of Research on the Mentally Incapacitated*, published by the Medical Research Council (MRC) in 1991.[903] The MRC revised this guidance as *Medical research involving adults who cannot consent* in 2007, to reflect the legal developments brought about by the MCA 2005 and the Clinical Trials Regulations 2004.[904] In the 1991 version, the MRC concluded in paragraph 8.1 that, "Many people with mental impairment or disorder are able to consent to their inclusion in research provided care is taken to explain it to them".[905] This represented a progressive attitude towards the participation of adults with mentally disorder or intellectual disability in medical research, pre-empting the ethos of the 1999 Council of Europe Recommendation. The same statement does not appear in the 2007 guidance, although echoing the endorsement of capacity preservation in the MCA 2005, the revised guidance states: "Capacity is present if the person only has a difficulty with communication that can be overcome with human or mechanical assistance".[906] The guidance goes on to address approaches to supported decision-making in the context of vignettes, recognising the importance of eliciting the decisional competence of potential participants with mental disorder and intellectual disabilities as far as possible.[907]

In 2001, the UK Department of Health published its guidance on informed consent to medical examinations or treatment.[908] This also includes discussion of consent to research. It stipulates:

> 2.6. Care should also be taken not to underestimate the capacity of a patient with a learning disability to understand. Many people with learning disabilities have the capacity to consent if time is spent explaining to the individual the issues in simple language, using visual aids and signing if necessary.[909]
> [.…]
> 15. … when seeking consent from patients for research purposes … "particular care" should be taken to ensure that possible research subjects have the fullest possible information about the proposed study and sufficient time to absorb it. Patients should never feel pressurised to take part, and advice must be given that they can withdraw from the research project at any time, without their care being affected. If patients are being offered the opportunity to participate in a clinical trial, they should have clear information on the nature of the trial.[910]

This guidance reflects a belief in the maximization of FPCLC to consent through the role of education and information provision. The specific reference to the assessment

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[903] Medical Research Council (1991).

[904] Medical Research Council (2007).

[905] Medical Research Council (1991: 22).

[906] Medical Research Council (2007: 9).

[907] Medical Research Council (2007: 12–13).

[908] UK Department of Health (2001a).

[909] UK Department of Health (2001a: 5).

[910] UK Department of Health (2001a: 9).

of decision-relative decisional competence supports PTDCJ and the tenor of the 1999 Recommendation, and shares affinities with the MCA 2005. Furthermore, the emphasis placed upon learning disabilities or factors that may lead to temporary decisional incompetence as constituting no necessary impediment to FPCLC reinforces the possible coexistence between the two. There is also a clear recognition that these principles should be applied with even greater care to research as to treatment. This reflects the common lack of personal benefit in the case of research, and the greater level of comprehension required in order to consent.

Specifically in relation to research, the General Medical Council in its 2001 draft guidance entitled *Medical Research: The Role and Responsibilities of Doctors*[911] explicitly states, “most adults with mental illness or disorders are competent to decide whether or not to participate in research”.[912] The final version of the guidance, published in 2002, goes on to refer to assessing decisional competence to consent with vulnerable adult research participants. According to paragraph 43, vulnerable adults include those experiencing mental disorder or intellectual disabilities, along with institutionalized adults and frail elderly persons. The GMC acknowledge that consent sought under the pressures from the health care professionals or institutions with which they have contact might compromise the validity of that consent. However, these adults can be “competent but vulnerable” and that to omit research with vulnerable groups simply because of the ethical issues to which it gives rise may engender discrimination.[913] They go on, in paragraphs 44 and 46 to recommend approaches to dealing with members of these groups sensitively:

> 44. Careful consideration should therefore be given to involving vulnerable adults in research, and particular attention should be given to the consent process, ensuring that they have sufficient information provided in a suitable format, and enough time to consider the issues. You should give consideration to their vulnerability and difficulties they may have in understanding or retaining information. You may need to encourage them to seek the help of a relative/close friend, support worker/advocate. You should proceed with the research only if you believe that the participant’s consent is voluntary and based on an understanding of the information they have been given.[914]
>
> [….]
>
> 46. Where participants have difficulty retaining information, or are only intermittently competent to make a decision, you should provide any assistance they might need to reach an informed decision. You should record any decision made while they were competent, including the key elements of the consultation. You should review any decision made whilst they were competent at appropriate intervals before the research starts, and at intervals during the study, to establish that their views are consistently held and can be relied on.[915]

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[911] General Medical Council (2001).

[913] General Medical Council (2001, para. 30). Curiously, this statement was not adopted in the final version of the guidance (General Medical Council, 2002), but there is nothing in the final version that would contradict this statement.

[913] General Medical Council (2002, para. 43).

[914] General Medical Council (2002, para. 44).

[915] General Medical Council (2002, para. 46).

The GMC guidance indicates that grounds exist for treating cognitively vulnerable adults as decision-makers in their own right, by virtue of consistency in their decision-making capabilities and the effects of assistance on their understanding, which tacitly endorses the methods we examined in Chapter 6. However, this approach towards adults is at odds with the legal position of children under sixteen who are "intermittently competent to make a decision", since, as we saw earlier, they are not considered to possess decisional competence for a sufficient length of time to be considered *Gillick* competent.[916]

This anomaly raises the issue of what could justify the participation of adults with fluctuating decisional competence to consent but not children. A plausible response is the need for a consistent set of values to underpin decision-making, emphasised in the competence theories of Wicclair, Grisso and Appelbaum considered in Chapter 1. Whereas adults with intermittent decisional competence are more probably in possession of these values, an older child or adolescent with fluctuating capacity is less probably in possession of them. This is broadly reflective of the evidence for task and decisional competences that typically differentiates adults and older children, with the adult more probably having a wider range of task and decisional competences and to a greater degree, and the older child more probably having fewer task and decisional competences, and to a lesser degree.

The Medical Research Council issued guidance in 2004, entitled *Medical Research Involving Children*, which replaced its earlier guidance on the same issue.[917] It recommends:

> Seeking consent is not a single response but a *process*. The child should be provided with information appropriate to his or her increasing ability to make decisions about complex and serious issues. It is helpful for researchers to produce child-friendly information in a form appropriate for the relevant age groups – this could make use of pictures or videos. More than one version may need to be produced if research covers a wide age range, such as eight-18 years.[918]

These recommendations present potentially effective solutions with which to elicit a young person's understanding. Unlike the previous guidance we have examined, they suggest examples as well as general strategies for achieving this. The MRC's recommendation is predicated on a belief that young people can and should become involved in making decisions about themselves, and thus meshes with a number of approaches that seek to encourage young people to develop their own autonomy, without simply being abandoned to it. Unlike the previous edition of the guidance, there is also an explicit recognition that the decisional abilities of children change vastly from early childhood to adolescence and that forms of supported decision-making need to be tailored to the needs of the age group. One hopes that the empowering and supportive model of developing decisional competence proposed here will find widespread acceptance.

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[916] *Re R (A Minor) (Wardship: Consent to Treatment)* [1992] Fam. 11.

[917] Medical Research Council (2004).

[918] Medical Research Council (2004: 34).

Summary

Decisional competence has no legal status in English law. Although British judges and legal academics frequently invoke the term ‘competence’ in discussions of cases involving ‘capacity to consent’, it would appear to be no more than as a synonym for a poorly defined notion of legal capacity. It is poorly defined because there is no attempt to distinguish between the three types of legal capacity which we introduced in Chapter 1. This has given rise to a conflation of competence and capacity in English law, as we cannot ultimately know in what sense competence is being invoked by the unqualified term ‘capacity’. This risks jeopardizing legal clarity and consistency.

The emergence of ‘mental capacity’ as a new legal concept does suggest a close link between a notion of FPCLC defined in terms of mental capacity (which the MCA 2005 embodies) and decisional competence. However, there is no necessary connection between the two. There remains a possibility for FPCLC and mental capacity to be assessed by different standards in spite of the correspondence between s. 2(a–d) of the MCA 2005 and decision-relative decisional competence. This, along with the silence surrounding whether those persons without FPCLC should therefore be considered as not having mental capacity suggests that mental capacity cannot be read entirely as a synonym for decisional competence.

Whilst the definition of mental capacity in the Act maintains internal coherence, when applied to these broader questions raised by factors outside of the Act, questions arise about its external coherence. If one is seeking clarity and consistency in the law, it would have been wiser to have renamed mental capacity in the Act as FPCLC, which would minimize ambiguity and also admit more clearly and consistently of the distinction between FPCLC, delegable legal capacity and fiduciary legal capacity. Insofar as individuals could still have decisional competence to consent when they lack FPCLC to do so, FPCLC should be formulated so that there is a necessary conceptual relationship between the two. A second legal category, delegable legal capacity, should be created to accommodate surrogate decision-making, and the third, fiduciary legal capacity, to refer to decision making by parents or legal guardians on behalf of young children.

Legislating for decisional competence to consent to medical research is a first step towards clarity and consistency in the law. But this needs to be accompanied by a higher profile for supported decision-making than is currently accorded in the MCA 2005 to ensure that it is seen as a mandatory part of the consent seeking process in medical research, rather than a more nebulous form of ‘good practice’. In this chapter, we have witnessed the beginning of moves in this direction, within the MCA 2005 Code of Practice, the 1999 Council of Europe Recommendation and in ethical guidance from the MRC and the GMC. Ultimately, however, success in meeting these aims depends also upon maintaining and cultivating attitudes of compassion, ethical integrity, fairness and diligence amongst those responsible for making judgments of competence and supporting decision-making in both the medical and legal fields. Legislating for this is much more problematic.