

1. Do you think your members have sufficient knowledge of and confidence in using the Mental Capacity Act 2005?

In 2005 the Department of Health funded a programme of work on implementing the Mental Capacity Act 2005 in intensive care units. This resulted in the development of specific guidance on implementation of the Act in ICU settings. This guidance has been endorsed by the Intensive Care Society (UK) and is available on the Intensive Care Society website (<http://www.ics.ac.uk/ics-homepage/guidelines-standards/>).

Assessment of knowledge about the Mental Capacity Act was undertaken via a questionnaire sent to 284 ICUs in England and Wales on two occasions. The first was after the passage of the MCA in Spring 2007 (Phase 1: Pre-MCA Guidance, abbreviated to Pre-MCA), and before specific guidance on implementation of the MCA in ICUs was available (Phase 2: Post MCA Guidance, abbreviated to Post-MCA in 2011). Responses were obtained from 104 (37%) and 70 (25%) ICUs on the two occasions.

Overall, we found that high proportions of responders were aware of issues surrounding clinical care, and that this did not change over the two phases of the study. The proportion aware of Clinical Trials legislation was smaller, but showed no significant change over the two phases of the study. However, most units did not have policies in place regarding the MCA at the first audit (29%), but had plans for developing such policies (76%). Gratifyingly, assessment following provision of ICU-specific guidance showed that the vast majority of units (76%; $p < 0.001$ for change from baseline) had policies in place relating to the MCA. In addition, although overall knowledge about the roles of the Independent Mental Capacity Advocate (IMCA) increased between the two phases of the audit (from 16% to 41%; $p < 0.001$), even in the second phase knowledge was only moderately good.

Given the low rate of knowledge about IMCAs, a subsequent ongoing audit (REC 12/WA/0240) is being undertaken to address this issue, and seek an independent opinion about knowledge of the MCA in ICUs. We have sent questionnaires to 130 organisations across England and Wales, to collect data from individual IMCAs on how many instructions they had received in their organisation, how many individual cases they have worked on and the nature of the cases. The form also asked IMCAs to rate how knowledgeable about the Mental Capacity Act staff are at the critical care units where they have worked. Information about the study and the benefits of taking part was sent to IMCA providers. The collection of data from IMCAs is ongoing, but early findings suggest that:

- The number of instructions to IMCA for patients in ICU varies across IMCA providers although mostly the numbers are very low.
- Feedback from IMCAs is that most have had cases in ICU where family members are involved.
- IMCAs judge the MCA knowledge of the ICUs where they have worked as mostly average or poor, but some are described as having excellent or good knowledge.
- The nature of the IMCAs involvement is mainly end of life care/decisions

2. What aspects of the Mental Capacity Act you believe currently work well, and why?

- Perhaps the most effective consequence of the MCA has been to make people think about capacity, and undertake decision making within the framework of capacity assessment. The development of the guidance for ICUs on the MCA referred to above is

a direct consequence of this awareness. While the document has not been exposed to external scrutiny by governmental bodies, it is the consequence of rigorous discussion between well informed experts from a whole range of backgrounds, and has been subjected to a period of consultation, and trial by usage.

- Many units have policies and procedures in place which are compliant with the MCA code of practice which is relatively straightforward and training and information are available both face to face and electronically for staff and they can access advice 24/7 if required. There are leads for safeguarding and vulnerable adults and have recently established a cross site committee for 'Mental health and safe guarding adults' to ensure that the organisation is compliant and carrying out its responsibilities satisfactorily. Many capacity issues relate to consent.
- An additional benefit has been the creation of a clear pathway for research recruitment for diseases that cause impairment of capacity in the ICU. This was, in the initial phases after passage of the MCA, confounded by lack of clarity regarding how the Data Protection Act (DPA) and the EU Clinical Trials Directive (CTD) interdigitated with the MCA and affected research in incapacitated subjects,¹ but these problems were sorted out through constructive discussions with the Department of Constitutional Affairs (in the case of the CTD), and with the Office of the Information Commissioner (in the case of the DPA).

Reference

1. Reid CL, Menon DK. *Researching incapacity: Time to get our acts together.* *BMJ* 2007; 335(7617):415.

3. What aspects of the Mental Capacity Act you believe don't currently work well & why?

- Despite the availability of national guidance and ICU specific guidance, there is still some uncertainty in individual Units about how the nuts and bolts of the MCA should be applied to patient care. There is no clear pattern to the type of Unit in which this is a particular problem, but we have some preliminary evidence that research active units seem to have thought these issues through a bit more thoroughly, although this requires confirmation.
- A second problem, which probably relates to the first, is the variability in knowledge about and application of the Act between staff in a given Unit. Preliminary data from small numbers in our audit suggests that the takeup of information in this area may be more rapid amongst medical staff than nurses, and slowest amongst other clinical disciplines, though this requires confirmation. This points to a greater need to reintensify dissemination of knowledge in these latter two categories of clinical staff.
- Third, the IMCA service seems to be used very variably. In many instances, clinicians are not clear what the IMCA service can provide, and conversely, it is difficult to use a service that is only available Monday to Friday between 08.00 and 17.00 hours (at best), for a service that has to make critical decisions 24 hours a day, 7 days a week. Ideally, the IMCA would substitute for family members and act as advocates for the incapacitated patient, but this aspiration is difficult to fulfill when the service is not available nearly 75% of the time. There is substantial scepticism amongst many

clinicians that a person who does not know the patient can make a useful contribution to decision making on a *de novo* basis. It may be that IMCAs can only provide a benefit in very restricted and specific settings, but exploration of the opportunities available and better refinement of their role would benefit from more formal evaluation.

- The provision of advance directives would greatly facilitate decision making in many patients, but this option is greatly underutilised at present. There would be substantial benefit in publicising this generally, and also ensuring that admitting clinicians consider this when undertaking high risk operations or treating high risk diseases in high risk individuals. Currently, there is a reluctance for admitting clinicians to bring this up for fear of seeming inappropriate, but we need to work hard to remove this apparent stigma, so that critical management choices can be made in the light of full knowledge about patients wishes.
- A major area of concern is restraint of those who lack capacity and deprivation of liberty safeguards- there are very practical issues here in terms of what NHS staff can actually do and we are in discussion with our in house security teams to ensure they know how to handle these challenging situations.

4. Any other supporting comments you may have, for example changes or additions you would like to see?

The Medicines and Healthcare products Agency (MHRA) is consulting on the European Commission's proposal for a Clinical Trials Regulation. They state "The Government is committed to ensuring that the European Union (EU) regulatory framework for clinical trials does not create unnecessary burdens on researchers, and makes the EU an attractive place to conduct clinical trials." However, the proposed harmonization of the EU CTD has raised substantial fresh concerns, which the FICM and ICS have responded to.² These are not directly relevant to the MCA, but the responses from the ICM community are available if needed. The proposal and the Commission's impact assessment are available at: [Revision of the Clinical trials Directive](#). While the FICM welcomes some of the proposals in the revised Directive, the regulations taken as they stand without further clarification will create major obstacles to performing research in time-critical emergencies where the patient lacks capacity.

Reference

2. Matei M, Kompanje EJ, Maas AI, Menon DK, Lemaire F. *Clinical research into the ICU: clouds at the horizon, once again. Intensive Care Med* 2013; 39(8):1479-80.