NICE National Institute for Health and Care Excellence

Surveillance report 2016 – Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (2011) NICE guideline CG135

Surveillance report

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Contents

Surveillance decision

We will not update the guideline at this time.

We will amend the guideline to include a footnote to recommendation 1.1.2 for early identification of patients who are potentially suitable donors. This footnote is to make reference to guidance on diagnosis of brain stem death in infants between 37 weeks' gestation and 2 months (post-term) published by the Royal College of Paediatrics and Child Health (RCPCH) in 2015. The footnote will also include a link to the guidance.

We will also include a footnote to recommendation 1.1.9 for seeking consent to organ donation when a patient lacks capacity to consent. This footnote is to make reference to the modification of the NHS Organ Donor Register which is now allowing anyone to register a decision to donate, not to donate or to nominate a representative to make a decision after their death. The footnote will also include a link to the NHS Organ Donor Register where these options can be seen.

Reason for the decision

We considered the impact of 38 new studies through surveillance of this guideline. We found 118 additional studies but these were conducted in other countries outside the UK and not used to inform the surveillance decision.

This included new evidence that supports current recommendations:

- Identifying patients who are potential donors.
- Patients who have capacity.
- Assessing best interests.
- Seeking consent to organ donation.
- Approach to those close to the patient.
- Discussions in all cases.
- Organisation of the identification, referral and consent processes.

We also identified evidence on potential of neonatal organ donation and guidance on diagnosis of brain stem death in infants between 37 weeks' gestation and 2 months (post-term). We asked topic experts whether this new evidence would affect current recommendations on organ donation for transplantation: improving donor identification and consent rates for deceased organ donation. Generally, the topic experts' opinion whether or not an update was needed was mixed. Two topic experts thought that an update of the guideline was needed, regarding the potential of neonatal donation, with the publication of the guidance on diagnosis of brain stem death in infants between 37 weeks' gestation and 2 months (post-term) by RCPCH.

None of the new evidence considered in surveillance of this guideline was thought to have an effect on current recommendations.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the new evidence and views of topic experts, we decided not to update this guideline.

See how we made the decision for further information.

Commentary on selected new evidence

With advice from topic experts we selected 3 studies for further commentary.

Seeking consent to organ donation

We selected the panel study by Shepherd et al. (2014) for a full commentary because this study reports a comparison of deceased and living organ donation between opt-in and opt-out consent systems. Wales changed to a deemed consent in December 2015 (also called 'soft opt-out system') and this has required a change to the NHS Organ Donor Register, which now allows anyone in the UK to register a wish NOT to donate after death (as well as to register a wish to be a donor).

What the guideline recommends

NICE guideline CG135 recommends the following (recommendation 1.1.9):

If a patient lacks the capacity to consent to organ donation seek to establish the patient's prior consent by:

- referring to an advance statement if available
- establishing whether the patient has registered and recorded their consent to donate on the NHS organ donor register and
- exploring with those close to the patient whether the patient had expressed any views about organ donation.

Methods

Shepherd et al. (2014) reported a panel study in 48 countries (n=23 opt-in consent, n=25 opt-out consent) to compare organ donation and transplant rates between opt-in and opt-out organ donation consent systems. Countries were included if they had published their organ donation and transplantation statistics on the Transplant Procurement Management's International Registry of Organ Donation and Transplantation (IRODaT) and if they had 3 or more years of deceased and living organ donor data

between 2000 and 2012. Countries were excluded if: they had a population below 2 million in 2000; had inconsistent organ donation legislation across the nation; had changed their consent system in the 13-year period under investigation; had paid organ-donor programs; or high levels of organ transplants occurring abroad. Countries were also excluded if they were reported as having high levels of organ trafficking and if they had a mixture of civil and common law. The outcome variables were organ donation and transplantation rates. Instrumental variables analysis was used to control for covariates and to estimate causal effect of consent system on organ donation to transplantation rates.

Results

Deceased organ donation rates (per million population) were significantly higher in opt-out than opt-in consent systems (mean [M] 14.24, standard error [SE] 1.28; M 9.98, SE 1.30; p=0.029). However, living organ donation rates were significantly lower in opt-out than opt-in consent systems (M 5.49, SE 0.94; M 9.36, SE 0.95; p=0.006).

Deceased organ transplant rates (per million population) were significantly higher in opt-out than opt-in consent systems for kidney and liver and also higher but no significant for heart and lungs transplants:

- kidney (M 23.07, SE 1.80; M 14.27, SE 1.84; p=0.002)
- liver (M 8.88, SE 0.95; M 5.51, SE 0.96; p=0.022)
- heart (M 3.32, SE 0.37; M 2.40, SE 0.39; p=0.111)
- lungs (M 1.22, SE 0.31; M 0.79, SE 0.28; p=0.343).

Living organ transplant rates (per million population) were significantly lower in opt-out than opt-in consent systems for kidney transplants, and also lower, but not significantly so, for liver transplants:

- kidney (M 5.13, SE 0.98; M 8.01, SE 0.99; p=0.049)
- liver (M 1.02, SE 0.39; M 1.27, SE 0.37; p=0.590).

Strengths and limitations

Strengths

Strengths of the evidence included a well-described study, deceased organ donor data of at least 3 years for each country, and the use of instrumental variables analysis for controlling covariates.

Limitations

Limitations of the evidence included that the study could not account for the variability in the application of opt-out legislation because some countries applied either 'soft' opt-out (permission of family members is necessary for donation) or 'hard' opt-out consent (family members do not need to be consulted) legislation. Another limitation was that organ consent legislation was taken from previous research for most of the included countries apart from for 4 countries, where it was taken directly from their governments or professional organisations. Bias in measurement of organ consent legislation was likely to be present but the effect might have been small.

Impact on guideline

This study is relevant to NICE guideline CG135 because the UK is classified as having an opt-in consent system and Wales recently changed to an opt-out consent system. Topic experts mentioned that the change in Wales has required a change to the NHS Organ Donor Register, which now allows anyone in the UK to register a wish NOT to donate after death (as well as register a wish to be a donor). Recommendation 1.1.9 only refers to consent to donation and does not refer to the new change to the NHS Organ Donor Register about a decision not to donate or the nomination of another person to make the decision. The recommendation might need to add the establishment of the patient's decision either to donate, not to donate or the nomination of another person to make the decision.

Approach to those close to the patient

We selected the cohort study by Hulme et al. (2016) for a full commentary because the results of this study strengthen recommendations 1.1.11 and 1.1.12 of NICE guideline CG135 which highlight the importance of the specialist nurse in organ donation during the

approach of the family for consent to organ donation.

What the guideline recommends

NICE guideline CG135 recommends that a multidisciplinary team (MDT) should be responsible for planning the approach and discussing organ donation with those close to the patient (recommendation 1.1.11).

NICE guideline CG135 also recommends that the MDT should include:

- the medical and nursing staff involved in the care of the patient, led throughout the process by an identifiable consultant
- the specialist nurse for organ donation
- local faith representative(s) where relevant (recommendation 1.1.12).

Methods

Hulme et al. (2016) reported a cohort study to identify factors associated with family consent for deceased organ donation (n=4,703 approaches to families of eligible organ donor patients). This study only included patients who were referred as potential donors. The analysis was restricted to patients who met the donation eligibility criteria, and whose family were approached for consent. The analysis was reported separately for donation after brain death (DBD) and donation after circulatory death (DCD). Data was collected from a national database.

Results

There were 4,703 approaches to families of eligible organ donor patients (n=1,741 approaches for DBD; n=2,962 approaches for DCD). Overall consent rate was 58%:

- 68.9% for DBD
- 56.5% for DCD.

The following factors were significantly associated with consent for DBD donation:

- Ethnicity
  - white (reference group)
  - Asian (odds ratio [OR] 0.20, 95% confidence interval [CI] 0.12 to 0.34, p<0.0001)
  - black (OR 0.31, 95% CI 0.18 to 0.53, p<0.0001)
  - other (OR 0.51, 95% CI 0.26 to 1.01, p=0.0549).
- Nature of patient's prior donation wish
  - no donation wish (reference group)
  - expressed to family only (OR 49.12, 95% CI 6.71 to 359.60, p=0.0001)
  - expressed via organ donor register (ODR)/donor card only (OR 5.52, 95% CI 3.48 to 8.75, p<0.0001)
  - expressed via ODR/donor card and family (OR 35.38, 95% CI 15.44 to 81.08, p<0.0001)
  - unknown at time of approach (OR 1.47, 95% CI 0.89 to 2.43, p=0.1366).
- Timing of formal approach to family
  - before first set of neurological tests (reference group)
  - between first and second set of neurological tests (OR 0.48, 95% CI 0.32 to 0.72, p=0.0004)
  - after neurological death confirmation (OR 0.44, 95% CI 0.31 to 0.63, p<0.0001).
- Donation mentioned pre-formal approach
  - no (reference group)
  - yes, by family (OR 3.28, 95% CI 2.05 to 5.25, p<0.0001)
  - yes, by nursing/medical staff (OR 1.27, 95% CI 0.97 to 1.67, p=0.0822)
  - unknown (OR 0.72, 95% CI 0.21 to 2.50, p=0.6081).

- Nature of approach to the family
  - specialists nurses in organ donation (SNOD) only approach (reference group)
  - collaborative, SNOD asked for a response (OR 1.03, 95% CI 0.76 to 1.39, p=0.8644)
  - collaborative, SNOD did not ask for a response (OR 0.36, 95% CI 0.23 to 0.58, p<0.0001)
  - SNOD not involved (OR 0.35, 95% CI 0.24 to 0.52, p<0.0001).

The following factors were significantly associated with consent for DCD donation:

- Ethnicity
  - white (reference group)
  - Asian (OR 0.33, 95% CI 0.21 to 0.52, p<0.0001)
  - black (OR 0.33, 95% CI 0.15 to 0.72, p=0.0055)
  - other (OR 0.74, 95% CI 0.36 to 1.53, p=0.4197).
- Cause of death
  - neurological (reference group)
  - non-neurological (OR 0.63, 95% CI 0.50 to 0.79, p<0.0001).
- Nature of patient's prior donation wish
  - no donation wish (reference group)
  - expressed to family only (OR 8.85, 95% CI 5.25 to 14.90, p=0.0001)
  - expressed via ODR/donor card only (OR 4.01, 95% CI 3.08 to 5.20, p<0.0001)
  - expressed via ODR/donor card and family (OR 21.00, 95% CI 13.70 to 32.20, p<0.0001)
  - unknown at time of approach (OR 1.84, 95% CI 1.34 to 2.53, p=0.0002).

- SNOD present during withdrawal conversation
  - no (reference group)
  - yes (OR 1.30, 95% CI 1.04 to 1.63, p=0.0213).
- Donation mentioned pre-formal approach
  - no (reference group)
  - yes, by family (OR 2.64, 95% CI 1.91 to 3.65, p<0.0001)
  - yes, by nursing/medical staff (OR 1.74, 95% CI 1.43 to 2.11, p<0.0001)
  - unknown (OR 0.87, 95% CI 0.44 to 1.71, p=0.6875).
- Nature of approach to the family
  - SNOD only approach (reference group)
  - collaborative, SNOD asked for a response (OR 0.93, 95% CI 0.74 to 1.17, p=0.5393)
  - collaborative, SNOD did not ask for a response (OR 0.60, 95% CI 0.42 to 0.87, p=0.0070)
  - SNOD not involved (OR 0.32, 95% CI 0.26 to 0.42, p<0.0001).

Strengths and limitations

Strengths

Strengths of the evidence included that data was taken from a national database and the population matches the groups covered by NICE guideline CG135.

Limitations

There were some limitations in this study. The authors concluded that a possible source of bias was the exclusion of family approaches made before referral because referral was very unlikely in families that had already refused to give consent for donation. Regarding the factors associated with consent for DBD or DCD donation, the odds ratios and the confidence intervals were imprecise for the factor of 'nature of patient's prior donation wish'. For example, only 1 approached family did not consent to DBD donation in the group

of patients who expressed their wish to donate to their family only. This is why the odds ratio was high and the confidence interval too wide. A bigger sample size might be needed to have a more precise result.

Impact on guideline

Topic experts highlighted that the most easily modifiable factor that increased donation rate in this study was the involvement of the SNOD in the family approach which was significant for both DBD and DCD. Topic experts concluded that the findings strongly support NICE guideline CG135 regarding the importance of the SNOD.

Organisation of the identification, referral and consent processes

We selected the National Institute for Health Research (NIHR) report by Morgan et al. (2016) for a full commentary because the results are relevant to NICE guideline CG135 regarding UK deceased organ donation among minority ethnic groups. This was a 3-phase programme. The report includes 2 systematic reviews (1: barriers to organ donor registration, 2: effective interventions); 4 qualitative studies (1: community focus group, 2: ethics discussion groups with staff, 3: intensive care unit [ICU] observation and interview, 4: interviews with bereaved families); and an intervention study training ICU staff to increase their confidence and skills in communicating with patients and families from different cultural groups. The intervention study is the final aim of the NIHR study, therefore, this commentary is focused on the intervention study.

What the guideline recommends

NICE guideline CG135 recommends that the skills and competencies required of the individual members of the team will depend on their role in the process. However, all healthcare professionals involved in identification, referral to specialist nurse for organ donation, and consent processes should:

- have knowledge of the basic principles and the relative benefits of donation after circulatory death (DCD) versus donation after brainstem death (DBD)
- understand the principles of the diagnosis of death using neurological or cardiorespiratory criteria and how this relates to the organ donation process

- be able to explain neurological death clearly to families
- understand the use of clinical triggers to identify patients who may be potential organ donors
- understand the processes, policies and protocols relating to donor management
- adhere to relevant professional standards of practice regarding organ donation and end-of-life care (recommendation 1.1.31).

NICE guideline CG135 also recommends that consultant staff should have specific knowledge and skills in:

- the law surrounding organ donation
- medical ethics as applied to organ donation
- the diagnosis and confirmation of death using neurological or cardiorespiratory criteria
- the greater potential for transplantation of organs retrieved from DBD donors compared with organs from DCD donors
- legally and ethically appropriate clinical techniques to secure physiological optimisation in patients who are potential organ donors
- communication skills and knowledge necessary to improve consent ratios for organ donation (recommendation 1.1.32).

Methods

Morgan et al. (2016) reported the development and pilot evaluation of a training package to enhance cultural competence among ICU staff (n=99 staff [n=19 SNODs, n=58 nurses, n=22 doctors]). The training package was structured around 5 key social aspects of interactions during deceased organ donation consent among minority ethnic groups (termed the Donation, Transplantation and Ethnicity [DonaTE] dimensions):

- emotional expression
- faith, religion and cultural beliefs
- extended family and visitors

- language and communication
- knowledge and anxieties about organ donation.

The training package had three components:

- a core factual programme (30-minute digital versatile disc [DVD]) addressing issues of ethnicity and needs for transplantation, followed by discussion relating to each of the 5 DonaTE dimensions
- a 3-part structured drama (10-minute DVD) aiming to reinforce the 5 dimensions and providing a more detailed understanding of families' experiences by dipping in and out of a longer-term narrative
- a workbook for self-learning containing background information about organ donation that depicts the potential outcome as worthwhile in terms of increased organs for transplant, thus justifying a positive attitude.

This was a before-and-after evaluation which measured changes in theory of planned behaviour constructs (attitudes towards organ donation, subjective norms, perceived behavioural change, and behavioural intentions) with a Likert scale. Rates of family consent from the potential audit donor (PDA) were also reported.

Results

A total of 99 ICU staff responded the pre-intervention questionnaire and 21 of these participants responded the 3-month post-intervention questionnaire (questionnaire scores ranged from −3 to +3). No SNODs completed the follow-up questionnaire. Pre-intervention and post-intervention median scores were reported separately for nurses and doctors.

Pre-intervention and post-intervention median scores for nurses (n=12) were:

- Attitudes towards organ donation (pre-intervention median 0.80; post-intervention median 1.55; p=0.04)
- Subjective norms – normative beliefs about subjective norms (pre-intervention median 1.20; post-intervention median 1.40; p=0.72)
- Subjective norms – motivation to comply with subjective norms (pre-intervention median 2.62; post-intervention median 2.75; p=0.95)

- Perceived behavioural change – control beliefs (pre-intervention median 1.00; post-intervention median 1.00; p=0.33)
- Perceived behavioural change – influence of beliefs (pre-intervention median 0.13; post-intervention median 0.84; p=0.11.)
- Behavioural intentions (pre-intervention median 1.95; post-intervention median 1.69; p=0.45).

Pre-intervention and post-intervention median scores for doctors (n=9) were:

- Attitudes towards organ donation (pre-intervention median 1.10; post-intervention median 1.70; p=0.04)
- Subjective norms – normative beliefs about subjective norms (pre-intervention median 2.00; post-intervention median 2.00; p=0.91)
- Subjective norms – motivation to comply with subjective norms (pre-intervention median 0.80; post-intervention median 1.20; p=0.20)
- Perceived behavioural change – control beliefs (pre-intervention median 0.25; post-intervention median 0.25; p=0.50)
- Perceived behavioural change – influence of beliefs (pre-intervention median 0.75; post-intervention median 0.63; p=0.60)
- Behavioural intentions (pre-intervention median 1.00; post-intervention median 0.80; p=0.87).

A multivariable analysis showed that consent rates increased by 7.2% post-intervention but the increase was not significant (95% CI –4.0% to 18.5%, p=0.21).

Strengths and limitations

Strengths

Strengths of the evidence included that it was an important programme of work on black, Asian and minority ethnic groups which developed and evaluated a novel DVD/workbook intervention.

Limitations

Limitations of the evidence included that it was a before-and-after study, the methods were not fully described, most of the participants did not respond to the post-intervention questionnaire (79%). The authors mentioned that there was contamination of control sites because the specialist nurses for organ donation moved between sites and the project was presented during regional meetings. Topic experts highlighted that the authors used the theory of planned behaviour to guide their intervention, and referred to one of the key components as 'perceived behavioural change'. However, the original model by Ajzen (1991) referred to this component as 'perceived behavioural control'.

Impact on guideline

The results of this study strengthen recommendations 1.1.31 and 1.1.32 of NICE guideline CG135 which emphasises the importance of knowledge and skills of health professionals involved in the identification, referral and consent processes during deceased organ donation.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 4 years after the publication of organ donation for transplantation (2011) NICE guideline CG135.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

Previous surveillance update decisions for the guideline are on our website.

New evidence

We found 23 new studies in a search for all publication types published between 14 August 2013 and 19 July 2016. We also considered 4 additional studies identified by members of the guideline committee who originally worked on this guideline.

Evidence identified in the previous evidence update 2 years after publication of the guideline was also considered. This included 11 studies identified by search.

From all sources, 38 studies were considered to be relevant to the guideline. We found 118 additional studies but these were conducted in other countries outside the UK and not used to inform the surveillance decision.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: summary of new evidence from surveillance and references for all new evidence considered.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline.

Views of stakeholders

Stakeholders commented on the decision not to update the guideline. Overall, 4 stakeholders commented. See appendix B for stakeholders' comments and our responses.

Four stakeholders commented on the proposal to not update the guideline: 1 agreed with the decision and 3 disagreed with the decision. Most of the comments were related to the guidance on diagnosis of brain stem death in infants between 37 weeks' gestation and 2 months (post-term) published by the RCPCH in 2015. Therefore, it was decided to include a footnote to recommendation 1.1.2. This footnote is to make reference to the guidance. The footnote will also include a link to the guidance.

This surveillance review also proposed to remove 5 research recommendations from the NICE version of NICE guideline CG135 and the NICE research recommendations database. All four consultees answered the proposal. Consultees disagreed with the proposal of removing the research recommendations. It was decided to retain four of these research recommendations based on the feedback on their importance.

See ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual' for more details on our consultation processes.

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