KAG short-term working group on issues arising from the deceased donor kidney offer scrutiny schemes

Background and terms of reference

At the last KAG meeting, early experiences of the following deceased donor kidney offer scrutiny schemes were presented:

- 'ideal' donor offer decline

- 'ideal' donor organ discard

- standard criteria donor offer decline for a high priority patient (waiting time >7 years, cRF>85%, 0-0-0 mismatch), where the organ was eventually implanted

Early experiences of responses to letters sent out through these schemes suggested that there are recurrent themes regarding logistical issues and concerns about clinical decision-making in some units. However, KAG questioned about how best to take these issues forward.

KAG agreed that a short-term working group (STWG) would be set up to examine the following:

1) how to categorise responses from centres to letters querying organ utilisation decisions
2) defining a 'trigger' to take the next step in the process
3) deciding what the next step in the process should be, if there were recurrent concerns about organ utilisation decisions in some units
4) oversight for any process
5) 'duty of candour' issues for units, i.e. the need to retrospectively inform patients if there were concerns about organ utilisation decisions

This submission reports the recommendations of the STWG. KAG is asked for its comments and approval.

STWG members and meetings

The STWG consisted of Chris Callaghan (chair), Anusha Edwards, Nick Inston, Gareth Jones, Lisa Mumford, Kathleen Preston, and Julia Mackisack. Two teleconferences were held.

Recommendations

1) Categorising unit responses to letters generated through the three schemes

Options were discussed, including that of having no categories. It was agreed that categorisation would be useful, and, after further discussion, the following categories are recommended, using a RAG approach:

a) major concerns raised by the unit response (RED)

- after further discussions on how this might be defined, it was felt that a definition would need to be suitably broad, and that a set of specific definitions would be difficult to identify. It was suggested that 'a fundamental breach of the service specification leading to major concerns about the unit' would suffice. It is noted that the NHS England contract does not deal specifically with utilisation issues, so, alternatively, a 'code of practice' could be developed that units would be expected to adhere to. Breach of this could be an alternative trigger.

- the presence of a major concern would be expected to lead to a trigger of NHSBT-level review processes, e.g. immediate notification to the Associate Medical Director

b) some concerns, i.e. residual concerns about utilisation practices and/or unit infrastructure, that, if accumulated over time and at a certain threshold, would warrant further investigation (AMBER)

c) no concerns at the response, i.e. a reasonable explanation from the unit for an organ utilisation decision (GREEN)

It is expected that the overwhelming majority of responses would fall into the GREEN or AMBER categories.

2) Defining a 'trigger' for the next step in the process

The STWG agreed that an accumulation of AMBER issues would be significant, depending on the appropriate denominator and time frame. Therefore some way of tracking AMBER responses, and standardising event rates according to number of offers would be desirable.

Statistical advice was that it would be both feasible and valid to use a CUSUM-style approach to provide a denominator for the process. 'Events' would be defined as a letter response categorised as AMBER. 'Non-events' would be GREEN letter responses combined with all other 'ideal' donor offers defined by NHSBT criteria (either accepted, or declined but with no letters generated). It was agreed that a significant proportion of these 'ideal' donor offers defined by NHSBT criteria would not actually be 'ideal' donors defined by clinical criteria (i.e. not all 'ideal' donor offers are scrutinised to determine if they fit clinical criteria). As there is no good clinical reason to suspect centre variation in

the ratio of actual to suspected 'ideal' donor offers, this approach was felt to be acceptable. Further models would need to be generated by NHSBT statistics teams.

The STWG recommend that the trigger point be set to the national average of AMBER letter response rates, rather than a centre-specific historical baseline. In addition, there is no clinical need to accept centre variation in decline of such offers, as they represent the best quality organ offers.

The STWG also noted:

- the need to avoid counting AMBER responses multiply, as one offer decline might be captured in more than one of the scrutiny schemes

- the need to exclude 'ideal' DCD kidney offers from donors that didn't proceed to asystole

- that the 'ideal' donor schemes and the SCD-high priority recipient schemes have slightly different inclusion criteria. This will need to be taken into account when a denominator group is identified.

The NHSBT statistics team would need to advise on how often the analysis would run and report.

3) Next steps in any system

The STWG agreed that the current governance pathway for event triggers through existing CUSUM analyses (i.e. graft failures, patient deaths) should be followed. This involves a letter from the Associate Medical Director to the unit lead asking for an internal investigation of specific issues, with the unit given time to respond formally. If the AMD had on-going concerns about any responses, options might include a centre visit. The STWG felt that this pathway was widely accepted and respected and advised that it should be followed for offer scrutiny CUSUM processes.

4) Oversight of this process

The decision to stratify unit responses into RAG categories was agreed to be subjective. The STWG felt that these decisions would best be made by a small group of expert clinicians, e.g. drawn from KAG members and including the organ utilisation lead. When unit responses are discussed, the centre should be anonymised. How this group might be selected, and the make-up of the group could include:

- three individuals (e.g. OU Lead + one other surgeon + a nephrologist), with majority decisions to decide categorisations

- a larger group, e.g. 5-7 clinicians, in order to take account of instances where there might be apparent conflicts of interest, e.g. a unit represented by the one of the oversight group was being investigated.

Any CUSUM triggers and outcomes should be noted during KAG meetings, as per current CUSUM reports.

5) 'Duty of candour' issues (Appendix 1)

The STWG noted that informing patients of declined offers after responses to letters through utilisation scrutiny schemes are a separate proposal than that discussed at the last KAG, which focussed on whether patients should be informed of every offer at the time of offering by the declining centre. The issue before the STWG was to offer an opinion on whether or not NHSBT could / should retrospectively ask centres to inform patients of a declined offer that was brought to light through an AMBER or RED response.

The STWG agreed that patients should be informed if a high quality organ offer was declined for them and a group of clinicians had concerns about the reasons for offer decline (i.e. AMBER or RED).

The STWG noted that the term 'duty of candour' might not be helpful, as it implies following well-defined NHS processes after a notifiable safety incident, i.e. apologising to the patient, documenting this in a clinical record, informing the patient of details of enquiries, and informing them of outcomes of enquiries.

It is unclear if the definition of a notifiable safety incident that is required to trigger a duty of candour discussion would, for example, be applicable if an 'ideal' organ offer was declined for a pre-dialysis patient who successfully received a kidney transplant from another donor a few weeks later.

After further discussion the group suggested that the term 'duty of candour' not be required for AMBER or RED responses, but that NHSBT should recommend discussions with the relevant patient(s) to the individual unit.

Chris Callaghan

National Abdominal Organ Utilisation Lead

On behalf of Gareth Jones, Julia Mackisack, Anusha Edwards, Kathleen Preston, Lisa Mumford, Nick Inston

Appendix 1 – Informing patients of a declined offer identified through an offer scrutiny scheme: case study

A kidney was offered to centre for a patient aged 50-60 years with a cRF of >85% and a waiting time of more than 4 years. The kidney was from a DBD donor of a similar age with an intracerebral bleed, a creatinine of 88 micromol/L at retrieval, and no other significant past medical history. The offer was declined by the unit; the reason for offer decline was recorded as 'past medical history' and 'unable to locate surgeon or surgical team and unable to make decision'. A letter was written to the unit from NHSBT via the 'standard criteria donor / high priority recipient' offer scrutiny scheme, asking for further information.

The unit responded, saying that there was a technical issue with the mobile phone of the on-call consultant transplant surgeon, and therefore the on-call consultant nephrologist (who received the offer) felt unable to accept the kidney. After further discussions within the unit, it transpired that the on-call surgeon was not called on their landline, and no other consultant surgeon was called. The unit reassured NHSBT that the incident was without precedent in the unit. A formal internal analysis was performed within the unit, and an incident form was submitted to the Trust's Medical Director.

NHSBT has asked the unit whether or not the waiting list patient has been informed of the incident. The unit has referred this matter to their Medical Director for consideration.

This case is included to provide an actual example of a 'duty of candour' issue identified through an offer scrutiny scheme, and to highlight the complexity of these issues.