Governance Report for KAG, June 2017

There were 155 Incidents identified with the Key Word "Kidney in the 6 months November 2016-April 2017, a number consistent with previous totals
A detailed analysis was done of 50 Incidents in the first 2 months of this period. In addition, notable Incidents throughout the whole period are highlighted

Despite the inclusion of "Kidney", many of these Incidents were peripheral, or of minor interest; an example might be delayed dispatch of a blood specimen for malaria testing in multi-organ donor.
There were 29 out of the 50 with direct impact on the kidney

Of the Retrieval Incidents, in the two month period, there were six instances of reported retrieval damage. 4 of the kidneys could be transplanted, although one had to be switched from a paediatric to adult donor to allow arterial reconstruction.
There were two instances of bleeding from QUOD biopsy sites. One was picked up as an AV fistula on post-op ultrasound. In another, although bleeding was controlled in theatre, the renal pelvis had to be opened to evacuate clot
An overview of QUOD biopsy problems in kidneys is appended

There were a number of prolonged ischaemic times because of poor communication, both by SNODs and retrieval teams. One kidney was not transplanted because lost paperwork lead to a direct cross match being needed, following which the theatre was lost, and the CIT was by this stage very long

There were three sets of other delays because cross-matching material was either mislabeled or not identified at all.

Several Incidents were recorded around the reporting of positive transport fluid cultures – two were candida, but a number were relatively harmless organisms. The whole question of testing of transport fluid is being reviewed

Histopathology
Another problem area which is currently being examined is the pathology testing of worrisome lesions, and several examples occurred even in the two month period.

One kidney was removed post transplant, after differing opinions as to whether there were malignant cells in a lesion at the pelvis. From the notes of the Incident:
"At point of implant surgeon took a renal biopsy of kidney. There was no suspicious lesion present however due to the donor's history it was felt this may be of benefit. The results were provided post transplant and confirmed malignancy. Discussions were had and a decision made to explant.

The histopathology was reviewed by three separate centres and it was eventually confirmed that there was in fact no cancer present and the nodes were positive for benign mesothelial cells. This case provided significant learning:

- *Benign hyperplastic mesothelial cells can mimic a malignant process*
- *Rapid involvement of NHSBT aided the process.*

- *Early discussion with both patients at all stages was helpful despite an adverse outcome for one of the recipients.*

- *Wider sharing of the case to raise awareness*

In another case, a neuroendocrine tumor was identified after implant of a number of organs; Excerpts from the notes illustrate the problem:

"Small bowel polyp was removed at retrieval and sent for immunochemistry. The report showed a neuroendocrine tumour. All centres have been informed

Concerns raised around the communication with the laboratory, and the SNOD was unaware that the small bowel polyp had been taken for histopathology.

It was reported that during retrieval there were lesions found on the liver that were suspicious, therefore were biopsied and send for urgent frozen section; this subsequently excluded malignancy. However, because of the concerns relating to the liver lesions, the retrieval team performed a very thorough examination of the bowel, to exclude a possible bowel primary; this revealed a small polyp in the bowel. The retrieval surgeon did not think this at all likely to be malignant, but sent it for formal non-urgent histopathology.

All the centres were informed, and recipients are being monitored

The lead surgeon of the abdominal retrieval team acknowledges that what happened is less than ideal. For learning and wider sharing the he wanted to stress the following:

1. If a lesion is found that the team thinks warrants biopsy, this needs to be sent urgently - there is no point sending biopsies for routine histology.

2. The SNOD and implanting centres must be aware that this biopsy is being sent.

3. If there is a lesion found that the team believe to be almost certainly innocent, as was the case here, and that on balance does not require formal biopsy analysis, then that information still needs to relayed to the other implanting centres."

A working group is to come up with recommendations for the processes around biopsy of suspicious lesions

Note on Retrieval Incidents: Across the board, approximately 40% of all Incidents are ascribed to Retrieval. In recognition of this high proportion, detailed summaries of Retrieval Incidents are to be reported to the Clinical Retrieval Forum (CRF) and to the National Retrieval Group (NRG), which are more appropriate arenas for analysis and discussion.

Where, as in most cases, they affect individual NORS teams, they are also to be discussed at contract review visits. The forthcoming changes in NORS will include a more robust Governance process, with, for instance, retrieval timings

included in data by which teams are assessed, and an obligation to respond to Incidents with a complete report within 30 days.

Transplantation

Two recipients had inadvertent delayed listing by centres; the delay was only a few days and neither was disadvantaged

There were some minor delays related to decision making, but the previous examples of kidneys lost because different surgeons made different decisions were not seen in this period

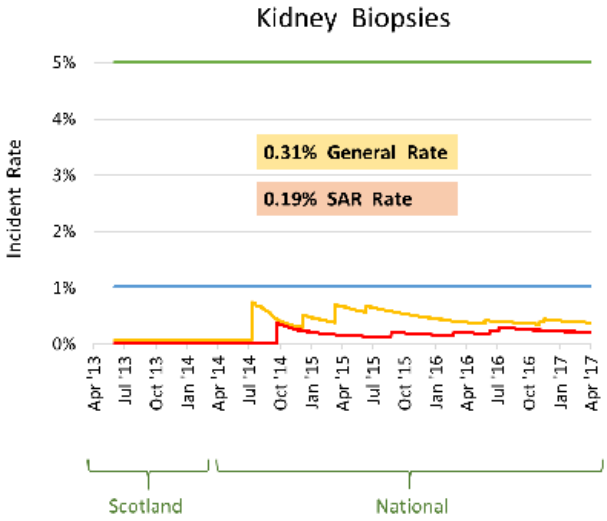
One delayed decision, with poor communication almost lead to a pointless retrieval in a very marginal DCD donor. In the end, no organs were retrieved.

Note on Future Reports

The Governance team has devised a method of real-time identification of Incidents worthy of reporting to Advisory Groups, identifying them on the database as they are resolved. This will lead to more complete and robust reporting to KAG from the second half of 2017 onwards

Appendix

QUOD Biopsy and Incident Metrics



Year	Gen	SAR	Bx
2013	0	0	71
2014	2	1	432
2015	3	1	819
2016	3	3	1009
2017	0	0	282
Total	**8**	**5**	**2613**

General Incidents:
Clinical incidents - no significant recipient consequences / or thought not to be attributable to QUOD biopsy

Serious Adverse Reactions:
Clinical incidents with recipient consequences – considered as most likely due to QUOD biopsy

Literature References:

- Cozens et al (1992). Br J Radiol. 65(775):594-7.
- Furness et al (2003). Transplantation. 76(6):969-73.
- Chunduri et al (2015). Semin Dial. 28(2):E11-4.
- Peters et al (2017). Acta Radiol. 58(2):240-8.