UKIVAS Steering Group Meeting Minutes
Thursday 22nd June 2017
Liverpool Medical Institution, 9am – 12 noon

Present:

Mark Little (ML, Co-Chair), Neil Basu (NBa, Co Chair), Peter Lanyon (PL), Stephen McAdoo (SM), Janice Harper (JH), Sarah Hardy (SH), Andrea Craven (AC), Nina Brown (NBr), Fiona Pearce (FP), Rachel Jones (RJ), Lynn Laidlaw (LL), Ann Morgan (AM), Jackie Andrews (JA), John Mills (JM), Joanna (student at Addenbrookes)

Apologies: Jo Robson, Lorraine Harper, Raashid Luqmani, Richard Watts, Sian Griffin, Michael Robson, Matthew Morgan

1 – UKIVAS registry update; Anthea Craven

- New website went live 26/05/2017.

- Current recruitment to June 2017 >3900 patients at 56 active sites; 22 sites awaiting approval. RaDaR has additional 1250 patients, at 27 additional active sites excluding known duplicates. Commissioning document for rituximab had been a driver to recruitment.

- Planning to link RaDaR to UKIVAS; will require encrypted NHS number, introduced in the new UKIVAS database. UKIVAS consent allows for this. RaDaR currently reworking ethics to include consent for linkage. Also aim for linkage to RUDY (patient reported outcomes).

- 30-50% overlap with DCVAS, which has permission to share

- Benefits of recruiting patients to both: funding; UKIVAS has detailed vasculitis specific fields; RaDaR has link to longitudinal lab data and medication.

- Data management concerns raised by GST following recent ethics amendment – issue of identifiable data. Meeting planned in near future with Dipak Kalra – from iHD, an EU organization with expertise in Data Protection Regulations. Vasculitis UK a potential source of funding to support this. AM suggested early involvement of NHS Digital to ensure legality of data sharing.

- Recruitment by diagnosis – additional categories included in new database. Some existing patients have been re-assigned; some still missing. Aiming to have no 'other' field!

- Website includes SOPs for data entry and for site set up and study procedures (those for data management planned Autumn 2017).

- RIVAS (Rituximab Surveillance Study) modules launched June 2017, Cambridge only at present before potential roll-out to other sites. Illustrates potential for subsidiary modules accessed by specific sites in the future.

- Similarly, Irish patients have separate consent to data storage in Oxford. No Hospital IDs or NHS numbers in Ireland – Irish recruitment to a separate module.

- Biosimilars– new commissioning guidance on switching to biosimilars is due; will emphasize enrolling patients in existing registries (PL).

- Inclusion of postcode data discussed – difficulties with data anonymisation, though useful data to have. Could convert to a Lower Layer Super Output Area, ONS standard (FP); would be useful for future linkage (e.g. with Census data). Dipak Kalra may advise.

- Discussion ensued on long-term ambitions for the registry – purpose primarily for research, or for service development and audit (similar to the UK Renal Registry model; JH). Consensus to articulate a 'mission statement' for UKIVAS, highlighting benefits for users and commissioners; ?with timelines for planned analyses and data interrogation. Using Leeds model; should be aligned with RITA aims and objectives (JA).

2 – Committee Restructure, Neil Basu

- Co-Chairs: Mark Little, Neil Basu
- Treasurer: Steve McAdoo
- Registry: Rashid Luqmani
- Governance: Anthea Craven
- Specialist representation:
    - Alan Salama (Renal)
    - Paul Brogan (Paeds)
    - Jo Robson (Rheum)
    - none (yet) for Neurology, Dermatology, ENT
- NHS Engagement: Peter Lanyon
- Patients: John Mills, Lynn Laidlaw
- ERN: Jackie Andrews
- EUVAS: David Jayne
- Research: Paul Lyons (SVV), Ann Morgan (LVV)
- Comms: Nina Brown (Website); Sian Griffin (Social Media & Twitter)
- Trainees: Fiona Pearce
- Industry: Lars Erwig
- RaDaR: Mike Robson
- Secretariat: Hugh Cahill
- ANP Lead: Sarah Hardy (introduced at the meeting)

- ERN: European Centres of excellence for rare diseases. Vasculitis falls within RITA (primary immunodeficiency, autoinflammatory and rare autoimmune diseases). Leeds is the sole adult Vasculitis centre in UK. Role in defining international standards and benchmarking; teaching and training will be a priority; clinically (not science) driven. Likely affiliate role (at least) for the UK post-Brexit. Likely that future ERN-badged centres will need to interact with RITA via UKIVAS (virtual network).

- Discussed trainee needs and supporting future clinicians and researchers. Concern regarding lack of exposure to sufficient cases with restructuring of UK medical training. UKIVAS may have a role in delivering mentorship, co-ordinating/signposting to fellowships at specialist centres, including post-CCT fellowships. FP will survey Rheum and Renal trainees to assess unmet needs with current training.

- Noted that UKIVAS does not have oversight to decree these specialist centres, but can signpost to those already designated by NHSE (i.e. The CRGs) or ERN (PL); and highlight top recruiting centres to the registry as an indicator of expertise (RJ). ML to circulate ERN information.

- To include reference to supporting trainees in proposed Mission Statement (JA).

3. 'EGVAS', Rachel Jones

- UKIVAS-linked EGPA study. Mepolizumab now licensed for severe eosinophilic asthma. Phase III trials in EGPA positive; GSK likely to pursue regulatory approval in EGPA. In the meantime, many EPGA patients will fulfil prescribing criteria for severe asthma. Proposal to use UKIVAS to collect prospective data on these patients. GSK supportive (may provide additional data to support their licensing applications) though could be seen as 'off-label' use. Potential role for Lars Erwig to liaise. Possible PK/Biomarker study in parallel. Separate consent application will be required. Potential for a UKIVAS fellow project.

- Next steps: Oxford and GSK have already discussed contracts (Judith Brown, Jonathan Steinfield), currently halted do to change in personnel at GSK ?how far advanced. AC will follow up with Raashid Luqmani.

    - Addendum: ML/NBa subsequently discussed with RL. Oxford proposal is more around use of the software technology / UKIVAS engine than clinical data, so there is additional potential to develop a protocol along the lines of RIVAS. Will need to discuss further with LE.

4. BSR Clinical Reference Group Update, Peter Lanyon

- Clinical Reference Groups an outcome of Specialist Commissioning. Alan Salama represents RA, and PL the BSR, to the Rheumatology CRG. Two key strands to work so far: to produce commissioning policies for access to high-cost drugs (e.g.

rituximab for AAV, IgG4, or myositis); and to create commissioning process and networks that ensure outcomes are the same regardless of geography.

- Also highlighted new alliance between BSR, Lupus UK, Scleroderma UK, Vasculitis UK: Rare Autoimmune Rheumatic Disease Alliance (RARDA); to lobby and raise awareness for rare autoimmune diseases. E.g. invited to join UK Rare Disease Forum (perhaps focused previously on rare genetic disease).

- National Confidential Disease Enquiry: RA, BSR, BTS, BAD, Vasculitis UK – made joint application to NCEPOD for enquiring in Vasculitis last year. Got to second round (8 areas), but not final selection (2 selected). Encouraged to apply again. Could have additional support of UKIVAS in next application. UKIVAS may be able to assist with identification of cases or assessors for the enquiry if successful.

- Pan-Midlands and East of England Audit: hosted by HQIP-funded unit in Dudley. Report under preparation at present. Key audit template was based on BSR guidelines and national commissioning policies. Focused mainly on process (e.g. timing of treatment). Included 213 incident patients in cohort. Found differences in compliance with standards between tertiary and non-tertiary centres; e.g. adherence to guidelines for cyclophosphamide prescription. BSR could make template available for similar audits locally, or is there a way to do it nationally without going through the HQIP process of national audit procurement (which takes about 3 years)? Could we include an audit 'module' in UKIVAS along these lines? Outcome of potential NCEPOD may be an important driver for conducting national audit.

5. Communications and Website, Nina Brown

- Redesigned website has been launched. Includes links to published guidelines (e.g. EULAR, BSR) for professionals and Vasculitis UK for patients.

- Discussed potential for sharing protocols and patient information leaflets (would require local governance approval at individual Trusts). Desire to upload and link to presentations from UKIVAS meetings.

- Should aim to align with RA guidelines; formal endorsement by RA (and BSR) would strengthen UKIVAS recommendations. ML to discuss with Mike Robson (who is currently Chair of RA Guidelines Group).

- Current email list has developed 'organically', and not all centres or contributors to registry are well represented (FP). Aim to broaden email distribution list – use contact UKIVAS recruiting centre contact list as starting point (Hugh Cahill to liaise with AC).

6. Next Meeting

- Hosted by Alan Salama, Royal Free Hospital, London Dec 17/Jan 18.