NHS
Queen Victoria Hospital
NHS Foundation Trust

EYE BANK
Practical considerations

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Eye Bank Services at QVH

- Eye donation – referrals, consent and retrieval
- Corneal storage evaluation and screening
- Graft preparation – PK / EK / ALK
- DSAEK pre-cutting for internal and external users
- Clinical cell culture - Limbal, COMET cells
- Autologous Plasma eye drop preparation
- Importation of corneas from US
- Store Amniotic membrane + other corneal products e.g. Keranatural
- R&D activities – New product imports / distribution for clinical trials
- Education and Training

Set up considerations

Policy – laws – Opt in vs Opt out (deemed) consent

Socio cultural - messaging / perceptions / education public and professional

Financial constraints payment for products / funding for services – Ongoing and sustainable

Quality standards and regulation

Tissue supply – donation

Tissue retrieval

Tissue processing facilities

Tissue distribution

Workforce

Establishment of an Eye Bank service?

Utilise conventional project planning /management processes

Establish what is desired, what is required and what is feasible – in context of the scope of the service

Perform a Gap analysis - looking at what needed vs what is currently in place or available

Instigate and implement everything through are formalised change control process and document decisions + conversations with stakeholders

Before implementation the proposed processes and equipment should be risk assessed. If risks to high then review.

Eye Bank requirements – Laws, standards and regulation

Regulation – Current vs Future (+ any anticipated changes)

Laws allowing donation – UK required a law change. Prior to this Eye Donation was illegal – Legal authorisation must be in place

Meaningful Codes of Practice / Standards / laws strong standards needs expert input for creation and ongoing review. They drive improvement and will constantly evolve.

UK - HTA, MHRA, JPAC, SABTO, Royal College of Ophthalmologists
EU - EBAA, EU GMP, EDQM
US - EBAA, FDA
India - EBAI, NPCBVI
Asia - AEBA
Aus & NZ - EBAANZ

Ideally the standards should have statutory force and there should be a single independent regulator auditing establishments

Disease factor differences

Screening requirements some regions do not require NAT testing or Hep B core – increased risk.

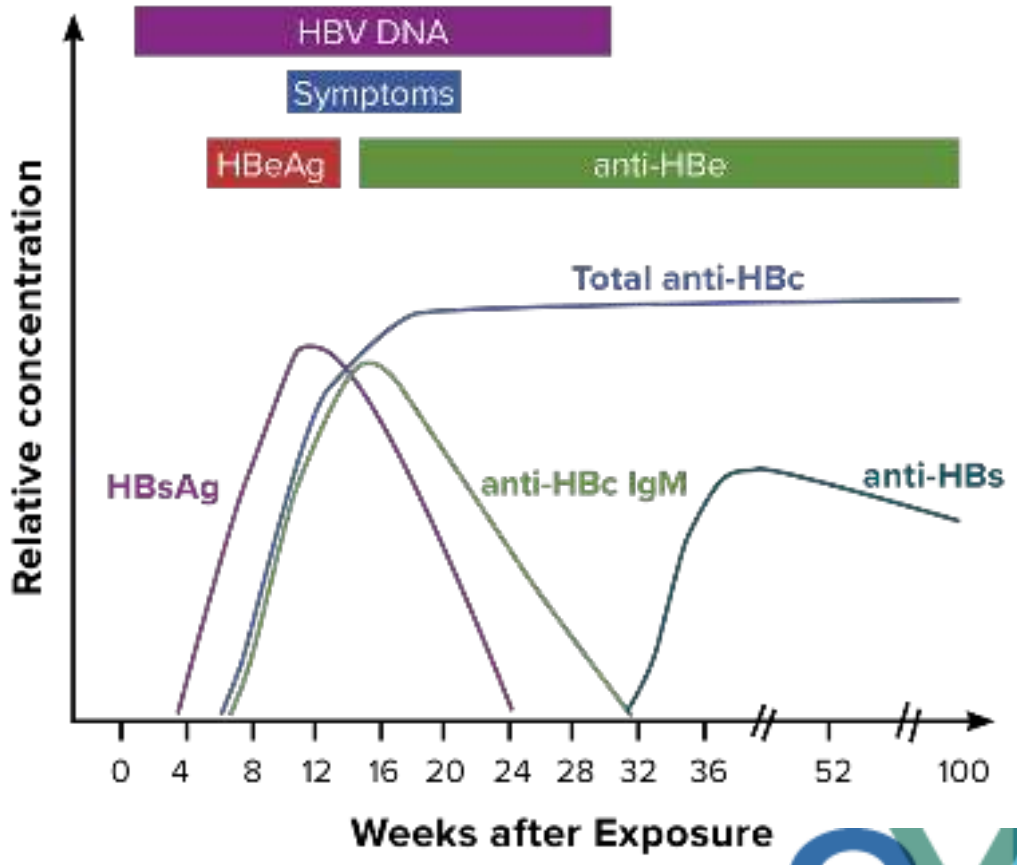
Steroid / chemotherapy use – NAT testing more sensitive – these donors can then be accepted

Requirement that screening tests must be validated for deceased donor samples?

Active bacterial infection – if the corneas are to be stored by organ culture, accept

HTLV testing mandatory in UK – not always elsewhere

Differences in donors with history of malignancies



US CDC on line

Eye Bank requirements – Donation

Donor Consent Opt in / Opt out - Deemed

Voluntary / mandatory referral pathways – legal decisions

Resourcing / staffing implications

Centralised 24hr referral / consent

Donor locations UK – can be from hospitals, hospices, funeral directors

Strong links between donation centres and eye banks – local large hospitals preferable – large number of potential donors

Retrieval teams – at donor sites – or mobile

All of these may have an impact on the type of excision process and corneal storage type

Retrieval - In situ vs whole globe enucleation

In situ pros and cons

Possible shorter death to storage times – may improve outcomes? Depends on media type etc.

May be more accepted by donor families

Can be placed directly into cold storage media reducing need for cleanrooms / laminar flow

Should be a sterile procedure – more equipment – more donor preparation

May limit donation location type (subject to risk assessment) – depends on cleanliness - Less decontamination possible

More training for retrieval staff required to prevent endothelial damage

Retrieval - In situ vs whole globe enucleation

Whole globe pros and cons

Additional decontamination possible – whole globes fully immersed in povidone iodine in Eye Bank

Cleanroom facilities /laminar flow required for excision – (classification depends on country specific regulations)

Wider range of donation centres possible due to environment
Retrieval sterility requirements slightly less onerous

Potentially longer death to storage times – cooling more difficult during transport back to Eye Bank – may be exacerbated in warmer regions

Cultural / relative's concerns about removing whole eyes

However, there are numerous published articles indicating little difference in outcomes

Organ culture vs cold storage

Warm Storage / Organ culture

Warm – Cornea Max, Cornea Jet, Tissue-C, In house media, 28-37°C up to 4 weeks

Both can be used with in-situ or whole globe excision

Hyperthermic storage more complex – de-swelling required

Longer storage period – greater flexibility

- Less issues about serology / virology TATs
- More flexible in terms of planning tissue use

More flexible delivery temperatures. Ambient delivery in UK

Cleanroom / laminar flow will be required - Further processing possible with cleanroom – DSAEK/DMEK, Stem cell culture. etc.

More expensive equipment – heating /cooling incubators

Inverted light microscopy needed - Specular will not work.

Better contamination detection with Hyperthermic storage – widens donor pool – allows donors with active bacterial infections

Cold storage

Hypothermic – Optisol GS, Eusol – C, Kerasave - up to 14 days at 2-8°C

Simpler process – less steps – no de-swelling

Shorter storage times – less flexibility

Greater need for faster serology / virology TAT

Fridge storage - needs to be delivered on ice

No requirement for cleanroom / laminar flow if enucleated in situ – this limits further processing

Once cleared – ready to go – no de-swelling required

Specular microscope required

More restrictions on donor contraindications e.g. bacterial infections

Eye Bank Pre Release Sterility Tests

Not undertaken pre-release for cold stored corneas

Required for Organ Culture Storage

Final sterility test taken 3 days before issuing
48 Hr incubation period

Delays in transport / processing culture bottles will delay release

Corneas 4 days in de-swelling medium commonly for 4 days

Sterility testing in house saves time

Access to microbiology services for species ID – if required by standards / regulations

Eye Bank Processing / Clean room GMP requirements

Staff – multiple grades from cleaning to technical & regulatory and clinical - Training varies considerably around the world US CEBT – India training centres - EU / Australia online courses – Others UK – in house How is this to be provided?

Information / records / quality

Database at the centre of activities – this will not change easily so plan ahead – data storage requirements continue to expand – list of data / types increases with regulatory vigor

Avoid if possible paper based solutions / use of spreadsheets / multiple data storage locations

Use an Electronic Quality Management System if possible

One of the main challenges for us in recent years has been the greatly increased regulatory requirement for audits – processes against standards and records - to be undertaken by staff independent from production. Requirement for a dedicated Quality Manager.

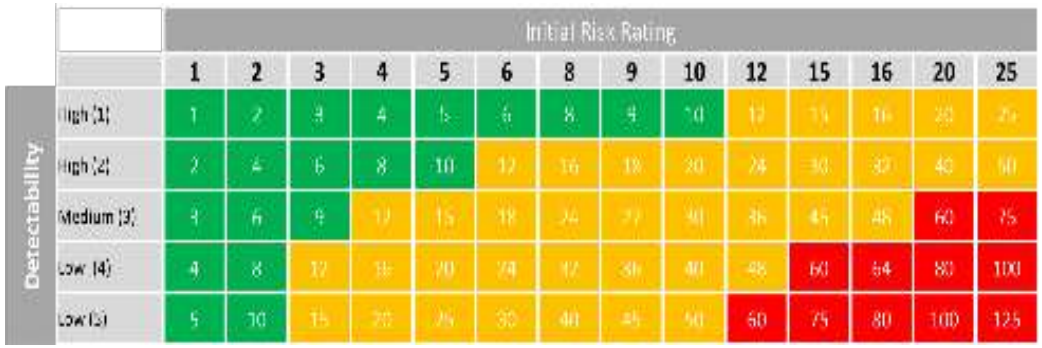
Risk Assessment

When processes and equipment have been decided on then there should be a risk assessment. If risk is to high then a review of the process should be made

Alongside the European Directorate for the Quality of Medicines and Healthcare (EDQM) there are 2 tools

EURO GTP II
1 Assess Novelty
2 Assess the risk
3 Determine follow up required to assure safety and efficacy

MiRCA Tool Microbiological Risk of Contamination Assessment
1 Help users identify contaminatio risks in new, existing or changed processes
2 Alert users to the degree of risk of introducing contamination during procurment or processing
3 Support decisions and changes to mitigate risks during aseptic processes



Summary

Deliverable and sustainable

There is a wealth of data and resources to draw on

Great opportunity! – with sufficient ambition, investment, expertise and effort all things can be achieved