Understanding the procurement process

Ophthalmology unit or directorate staff, whether clinical professionals or managers, may need to be involved in procurement processes and these can be complex and difficult to understand. This document aims to be an informal simple guide and provide useful information for those not familiar with procurement, particularly clinical staff.

Procurement – what do we mean?

Procurement in the NHS is the act of obtaining goods or services, typically for our business or department purposes, to meet the needs of our staff and patients and will generally be from within a revenue or capital budget.

What might NHS staff be involved in buying?

- Capital projects and/or new or replacement medical equipment involving such things as:
    - Buildings and facilities
    - Medical devices or equipment e.g. outpatient OCT, retinal cameras, slit lamps, lasers, phaco machines, microscopes
    - Smaller equipment such as surgical instrument sets
- Consumables: smaller things that get replaced more often - “revenue” or recurring costs
    - Outpatient – tonometer heads, tissues etc.
    - Theatres – procedure packs, IOLs, gloves, disposable instruments, sutures etc.
- Bundled or amortised agreement: where, due to capital funding constraints, a contract is agreed with a vendor which may include a free on loan or free of charge piece of capital equipment which is subsequently funded by a slightly higher consumable cost over a given contract period
- Maintenance service contracts to service equipment
- Contracts to provide agency cover or insourced services.

Why does good procurement matter?

This matters to you because

- As soon as we become a consultant or a senior non-medical clinician, everyone expects us to know how to buy and procure
- We all ought to understand what products and equipment we use on our patients and why that is the best choice

- We need to understand how procurement operates, and how we can collaborate with local or national procurement staff to obtain new products, understand what needs to happen when contract is due to end, a piece of equipment comes to the end of its life or breaks down, or we want something new, or there is a problem or safety issue with existing products or equipment.
- Most of us rarely think about or consider changing what products and equipment we use routinely unless we have to, and that is not good for providing best care or best value. It's worth proactively reassessing what we use even when we do not "have to".
- Many of us will be asked to contribute to CIPs (cost improvement programmes) and you may struggle to achieve your CIP if you do not understand procurement.

Why does this matter to the whole NHS?

There is a lot of evidence, e.g. from the Carter Report and GIRFT programme, that currently there is a lot of waste, and a huge amount of unwarranted (unjustified) variation in both quality and the cost of products and equipment across the NHS. Issues with commercial confidentiality and accurate data collection on products and cost detail inhibit transparency and comparisons of costs between different units. There have also been safety issues from devices which could be better managed or avoided with excellent national procurement systems and combined analysis of purchase and outcome data. NHS Improvement / NHS England and NHS bodies for all the four nations are working hard to address this through national procurement strategies to drive down costs, improve data collection and analysis, and improve quality and safety. This helps to ensure the NHS can save enough money to be sustainable and prevent safety issues for patients.

Currently there is an annual spend on ophthalmology supplies of £160million and it is estimated that, with simple improvements nationally and locally, the opportunity for savings is around 5% which could be invested in services and staff going forward.

Key principles

- If we change what we use/buy:
  - There is a long list of people to involve early
  - There are different routes to buying things and things are changing to be more centralised
  - Don't just buy more of the same without thinking through and considering small or even radical change
- Prices are affected primarily by:
  - Volume
  - Source e.g. supplier vs NHS Supply Chain vs local arrangement, different suppliers

    - Bundled deals (e.g. IOLs purchased more cheaply because you also buy the same company's packs or phaco machines).
- There are laws and rules you must not break.

Keeping it legal

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government organisation responsible for ensuring medicines and medical devices work and are safe. The MHRA is the Competent Authority that regulates medical devices. It issues various Directives to enhance and improve patient and public health and safety. It ensures that European directives are incorporated into UK law and places obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose (The Medical Devices Regulations 2002). However they do not govern procurement processes.

How you conduct making decisions on what products and services to buy and how this is then taken forward to the actual purchase is governed by a long list of guidance and rules such as:

- Your own local Trust Standing Financial Instructions (SFI's)
- NHS terms and conditions for the supply of goods and provision of services
- The Public Contracts Regulations 2015 for goods, works and services NOT governed by the NHS (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (where the commissioner is NHS England or a CCG)
- Department of Health and Social Care guidelines
- NHS England / Wales / Scotland ~~etc~~etc. guidelines
- Cabinet Office guidelines
- Crown Commercial Service Guidance

It is currently subject also to EU rules although these may change with Brexit:

- OJEU* tender cut off – under European law we have to conduct a formal tender for anything worth >£181,302 (the whole future contract value), unless it is purchased under an already tendered and compliant national Framework Agreement
- Lesser amounts require depending on value:
    - Verbal quotations
    - Written quotations
    - Smaller tender or mini-competition processes.
- There are also:
    - Specific timing requirements for the various steps
    - Rules on how many bids you may need as a minimum

- Fair and transparent detailed specifications for the desired products are required
- Must be explicit criteria for awarding the contract (making the choice) including price, quality, function, delivery, maintenance etc.
- Reasons for rejection usually need to be formally recorded
- May be a challenge period in which suppliers can challenge the decision you have come to through an objection to the way the process has been conducted or impartiality in scoring.

The number of steps and demands for the level of detail and effort involved increase as the value of the purchase increases.

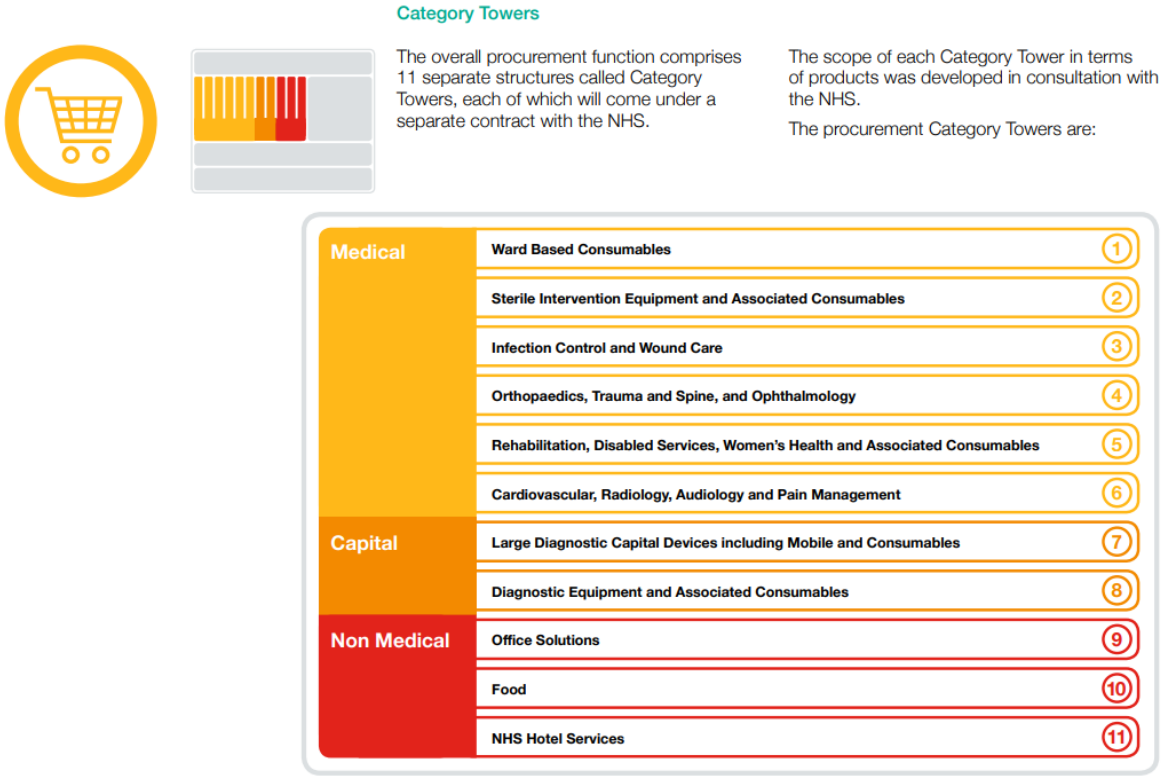
*OEJU is the Official Journal of the European Union, not a scientific journal but the name of legislation covering the actions of organisations and projects that receive public money such as local authorities, NHS trusts, Ministry of Defence, central government departments and educational establishments.

If you don't respect these rules:

- You might break the law
- Challenge can be mounted by unsuccessful suppliers or even those who were not invited to submit a bid or were not informed about the process
- You might not get what you want
- You might end up losing money
- The whole process might take a very long time to complete or get stuck in limbo.

What is the external structure for procurement?

In England, there has been a major reconfiguration over the last couple of years to try and create a national structure to support and rationalise NHS procurement. Trusts still retain their local procurement staff and have support from various regional procurement companies but we now have the so-called "Future Operating Model". In this, a number of procurement companies have come together to form the "Category Towers" which each have a different area of product responsibility and together are known as NHS Supply Chain.



There are 6 “Category Towers” which, between them, have divided up the various specialties of NHS Supply Chain with each ‘Tower’ specialising in a small number of areas. The Category Tower Service Provider (CTSP) is a commercial company which has won the contract to be responsible for the procurement and category management of all products and services relating to that specialism or area. Category Tower 4 covers Orthopaedics, Trauma and Spine, and Ophthalmology. Tower 4 covers spend of approximately £460 million in orthopaedics and £160 million in ophthalmology, a total of over £620 million per annum.

Tower 4 provides procurement expertise in both orthopaedics and ophthalmology and have a team experienced in procurement and industry work. The team actively engage with industry, trusts and clinicians, to help trusts purchase in accordance with the Carter Report and GIRFT principles of delivering best practice and improved patient outcomes, whilst delivering savings to the NHS and reducing unwarranted variation. They can supply all ophthalmology products but also provide advice and benchmarking for purchases via other routes. They aim to help trusts and clinicians make the best choices for them whilst ensuring optimal use of resources at local and national levels through their 3 year category strategy.

They have a requirement to move from the original 20% of products purchased via NHS Supply Chain to 80% over 3 years (by May 2021). Scotland, Wales and Northern Ireland are pursuing their own national programmes and for more information see the relevant NHS Scotland, NHS Wales etc. websites.

Routes to purchase

The main routes to obtain products and equipment are:

- Suppliers sell direct to trusts
- Through the NHS Supply Chain national framework agreements i.e. procurement category towers
- Through collaborative purchasing arrangements i.e. regional procurement teams

There are also:

- Other national framework collaborations and contracts for very large things like buildings
- Government tenders and contracts.

A procurement "framework agreement" is where the framework owner offers suppliers already compliant with the many procurement regulations and this provides easily availability for a range of products with high volume discounts to buy direct or using a mini-tender with ready-made contracts. The framework owner has already done most of the hard work required to be compliant with the regulations to save the trust the effort. NHS Supply Chain and Tower 4 have several framework agreements for ophthalmology which cover the majority of consumables and equipment used across ophthalmology, covering as follows:

Complete Ophthalmology Solutions:

- Lot 1 Intraocular lenses
- Lot 2 Surgical instruments
  - 2.1 Single use
  - 2.2 Re-usable
- Lot 3 Procedure packs
- Lot 4 Solutions and gases
- Lot 5 General accessories and consumables
- Lot 6 Ophthalmic equipment
  - 6.1 phacoemulsification
  - 6.2 vitreoretinal machines
  - 6.3 ophthalmic microscopes
  - 6.4 diagnostic equipment
  - 6.5 ophthalmic lenses
  - 6.6 additional ophthalmic equipment
- Lot 7 Combination specific lots
- Lot 8 Managed services.

Who do you need to be involved in your procurement of ophthalmic products?

Very early on you should consult your trust standing financial instructions (SFI's), your local procurement policy and your medical equipment and devices policy, and involve or speak to the following people in your organisation:

- Procurement staff
- Devices/equipment staff (EBME, electrical and biomedical engineering)
- Pharmacy if medicines involved
- Clinical lead / subspecialty ophthalmologist expert (e.g. medical retinal consultant for intravitreal injection products)
- Ophthalmic service managers
- Theatre managers if surgical product
- Clinical users
- Theatre / outpatient senior nursing
- Finance
- +/- as relevant:
    - Infection control, risk team, estates and facilities, information governance etc.

Trust procurement staff and devices/equipment staff (EBME i.e. electrical and biomedical engineering) are expert in this area and need to be involved from the very beginning of any process to ensure you are compliant with the rules and get the best equipment for the best price. In addition, your trust may have device standardisation rules (e.g. only certain equipment models and specifications allowed) you need to adhere to.

What do you need and what are the options out there?

You need to consider the following:

- What do you want? Why?
- What are the key choices – undertake a market survey i.e. investigate what's out there. Things may have changed since you last looked.
- What are the constraints e.g. has to fit with existing systems
- Your trust may have device standardisation rules (e.g. only certain equipment models and specifications allowed)
- Is it worth combining this with anything else? E.g. if you are looking for a new IOL should you combine this with packs, phaco machine, microscope purchases or rental? Remember in bundled deals suppliers will usually still get their capital investment return over time.
- Could you do things differently and use different products: disposable vs reusable; new supplier; different staff models; contents in your procedure pack; what do others do? ~~any~~Any advances in technology or practice now or to get ready for?

- What are the risks and benefits for each option?

Funding

A common pitfall is to fail to undertake a truly comprehensive financial assessment for potential purchases.
When calculating how much this will cost or developing your business case for the trust, consider:

- Indicative costs – work out approximate costs to decide how to pursue the options; you may discard some options immediately as way too expensive.
- Costs are both one off (capital) and also ongoing (revenue) costs and those making the decisions will be looking at **all** costs and the **whole life** costs including:
    - Installation
    - Training (user & technical)
    - Consumables
    - Decontamination
    - Servicing /maintenance
    - Compatibility with existing systems of all sorts (equipment, processes, IT etc.)
    - Warranty
    - Final disposal.

The costs may be offset by income gained or cost savings from more efficient equipment or processes with the new equipment.
Remember, this has to be affordable for the trust. The cost may be affordable within existing budget, it may need a short business case or it may need a full and detailed business case, justifying the issues, the reason for change, risks and benefits and finances (costs and income) at some point.

Gaining approval

This can be a long process with various stages for a large value or high risk purchase with presentations and discussions at a number of meetings:

- Business case may first need to be approved at various levels
- May need an awards panel to oversee the procurement process and undertake decision making of the desired product
- After the decision of preferred product is made, it may again need unit, directorate/divisional, finance, medical devices, IT, DTC or even Board meeting approval at various stages including before you finally place the order.

Specification and choosing your supplies

You will need to define exactly what you need in great detail – the level of detail required can be quite a surprise to clinicians. Functional requirements should be defined in detail with

references. Include any requirements to comply with legislation, standards and guidelines. This is for all involved. There may be a trust template for this and previously completed forms for similar purchases will remind you of any detail forgotten.

- Selection is made in close consultation with all the involved staff
- Need to identify decision making strategy including scoring and weighting of the scores (e.g. scores in safety may be considered more important than usability)
- Take into account relevant clinical, safety, technical and financial information (lifetime costs including all the hidden costs above), warranty provision and the availability of technical support or replacements, service manuals, and compatibility with current systems, delivery systems and reliability of supply, response to issues or equipment failure.
- You may need to trial your equipment and will then need to generate scoring forms for users for all aspects of use and performance with scoring, weighting etc. Arrangements will then need to be made to trial the equipment when the right staff re there, staff will need to complete the forms and return them for analysis.

Standardisation & maintainability

Trusts will generally want to standardise equipment where possible although clinicians can sometimes find this frustrating when their preferred product does not fit with this. Standardisation helps with:

- getting more use of the equipment;
- safety
- improve efficiency and productivity
- consumable costs
- purchasing power through volume discounts (bulk buy)
- staff training
- service personnel training
- spares costs
- maintenance costs
- Interoperability of equipment.

.

If you are considering non-standard equipment this will need to be justified and there will be more checks to ensure any loss of the advantages above are worth it or can be overcome.

Safety and risks

Although there is a formal process for assessing this **(**the Pre-acquisition Questionnaire) before purchase, it is worth considering early on what the risks and potential safety issues from supply interruptions through to clinical risk profile is for what you are considering purchasing. This should inform the selection process.

Before an order is placed, suppliers are required to demonstrate that their equipment is safe and suitable for its intended purpose and that it can be cleaned and decontaminated, maintained and fulfils technical and legislation requirements, through completion of the Pre-acquisition Questionnaire (PAQ) to be approved by EBME and other stakeholders covering:

- Estimated lifespan of the product under consideration
- Regulatory product information
- Provision of user & service manuals,
- Warranty period,
- Technical support and availability of spare parts
- Information regarding patient data
- Cost of consumable items,
- Decontamination method
- User & technical training information.

CE Mark – For now, in all but highly unusual situations, only CE (European Community) marked devices should be purchased which guarantees the meets the requirements of all relevant European Directives. It is Trust Policy that under normal circumstances no medical device will be procured unless it is "CE" marked.

The last hurdle

Don't forget, once your new device arrives there may be more steps until you can use it e.g.

- EBME will oversee for acceptance tests and registration on device database giving it an asset number
- Provision of user and technical staff training
- Secure supply of any consumables for a device
- Risk assessment of device or product/new treatment
- Arrange availability of any instructions for device

Further information:

Getting it Right First Time (Ophthalmology) 2019. https://gettingitrightfirsttime.co.uk/girft-reports/
Operational productivity and performance in English NHS acute hospitals: Unwarranted variations. An independent report for the Department of Health (the Carter Report). 2015. https://www.gov.uk/government/publications/productivity-in-nhs-hospitalsNHS Standard Contract 2019/20. https://www.england.nhs.uk/nhs-standard-contract/
Model Hospital. NHS Improvement. https://improvement.nhs.uk/resources/model-hospital/
DHSC. NHS Procurement. https://www.gov.uk/government/collections/nhs-procurement
NHS Supply Chain. https://www.supplychain.nhs.uk/

Medicines and Healthcare Regulatory Agency (MHRA. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Melanie Hingorani, Chair UKOA December 2019

With grateful thanks to: Alex Lines, Category Manager, Partners Procurement Services; Mick Corti, Director, Partners Procurement Service; and Steve Vandyken, Category Tower Director, NHS Supply Chain.