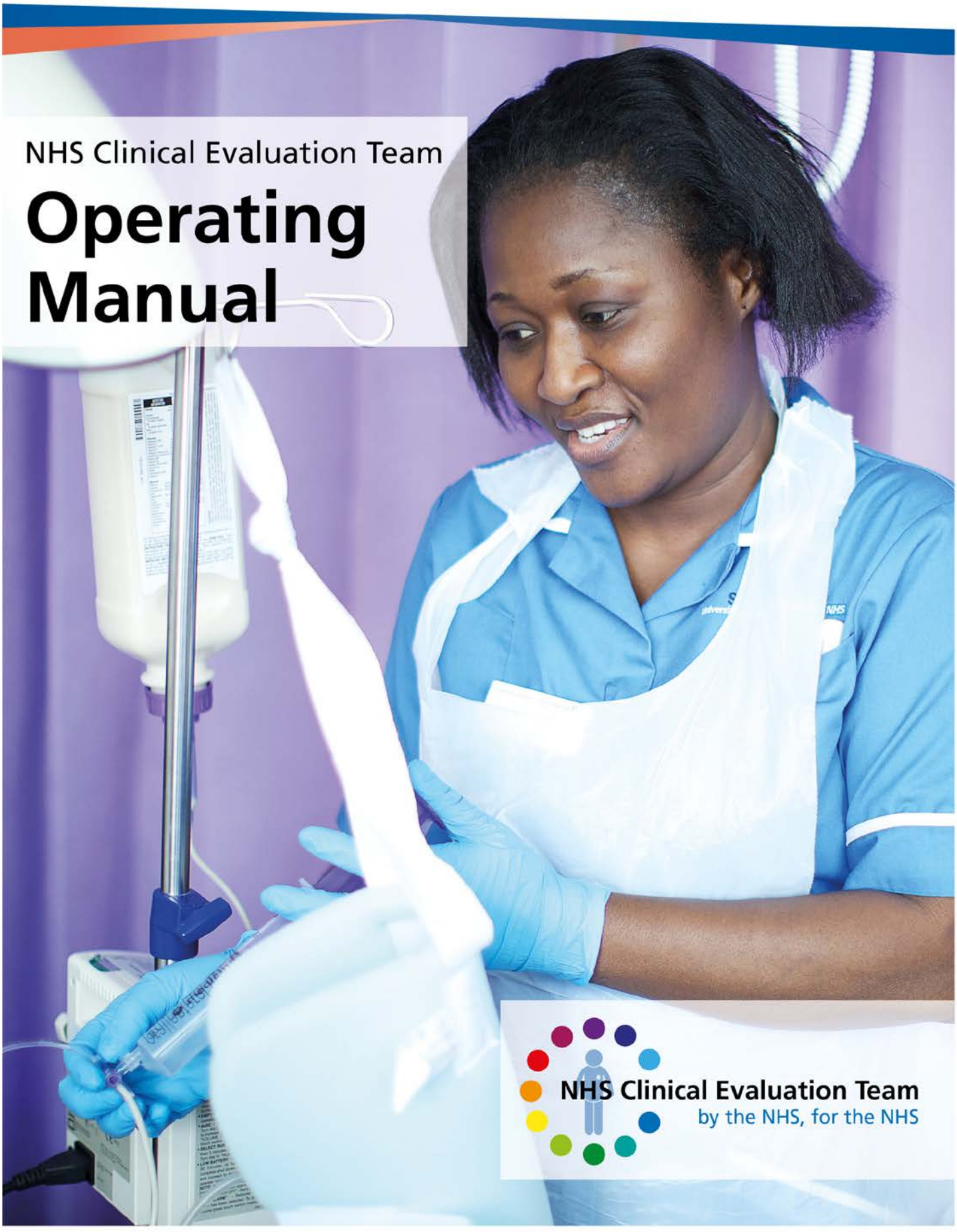
NHS
Business Services Authority

NHS Clinical Evaluation Team

Operating Manual



NHS Clinical Evaluation Team
by the NHS, for the NHS

NHS Clinical Evaluation Team Operating Manual

‘Quality, safety and value are at the heart of our work’

Contents

Introduction

The NHS Clinical Evaluation Team (CET) came into place in April 2016. Funded by the DH and hosted by the NHSBSA, the team is accountable to the Clinical Reference Board (and through them to the NHS Customer Board). The team's remit is to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

The formation of this team was driven by the recognition that within the process of clinical product selection, there were no NHS clinical standards for products, and a lack of independent clinical review on a national basis. A clinical evaluation review will add to the information available to both clinicians and procurement specialists when they are securing the best clinical quality product at the best price.

All defined terms used in this operating manual shall have the meaning set out in the Glossary (Appendix 4)

Background

The team came into place in the context of two key drivers:

- Mandie Sunderland, Chief Nurse and Chair of the Clinical Reference Board, saw the opportunity for nurses and clinicians to contribute to the efficient use of resources and subsequent quality and value improvements which could be made by understanding the quality of items commonly bought across the NHS.

- At a similar time, the Lord Carter Review highlighted the wide variation in both what was purchased across the range of NHS organisations, and the wide variation in price at which they were sold. He made recommendations to reduce these unwarranted variations, including the need to create an independent, clinically-driven, product testing and evaluation capability. This would ensure a high quality national catalogue of goods was delivered for the NHS, where NHS organisations would have the confidence in both the range of products and the price at which they are purchasing.

Purpose

The purpose of the team is to add independent clinical review to 'everyday healthcare products' ensuring that the clinician's voice is heard. Initially their focus is on products currently available to the NHS through the NHS Supply Chain catalogue and their frameworks.

Planned outputs

The team's outputs will be focused around the production of an independent, clinical review which will be accessible to the public detailing NHS clinical criteria (the process for which are set out below) and product assessment evaluation. To achieve this:

- The team has developed and will follow a transparent five-stage process to define NHS clinical criteria and to test each product (see Appendix 1).

- The team will act and plan cohesively through the NHSBSA to align with DH and NHSI priorities and any other initiatives in order to add timely information into the procurement cycle where possible.

- The team's outputs will be freely available for use, aimed primarily at the NHS and all those working to support patient care. If further information is required on how reports can be used in your clinical setting, the team can be contacted by emailing clinical.evaluationteam@nhs.net.

- The team's outputs will represent a clinical view in partnership with NHS colleagues. Their assessments will be based on products identified within each project as being available to the NHS from the national provider, and it should be noted that the team cannot delist products from the NHS Supply Chain catalogue which were all validly procured.

Reports disclaimer

Reports published by the CET represent general guidance and the team's opinions on products are based on the clinical evaluations undertaken, using the information and clinical criteria generated from extensive stakeholder engagement in line with the team's requirements and evaluation pathway. The procedure for updating and reviewing the reports is set out below.

Trusts are entitled to purchase any of the products on the NHS supply chain catalogue as they have all been EU-compliantly procured and are available for purchase notwithstanding the contents of the team's reports. No directions will be made to Trusts to mandate or recommend the purchase of any particular product as a result of the reports. In the absence of the CET's reports, Trusts already have the ability to apply whatever criteria they see fit to assess their needs and place an order for products listed on the NHS supply chain catalogue. Given the large range of choice on the catalogue, the CET's reports are aimed at providing an additional tool to help Trusts act efficiently and effectively as well as comply with quality, safety and value requirements.

As the CET reports act as a guidance tool only, you should make your own assessment and not take or rely on the opinions expressed by the CET as contained in the reports as recommendations or advice to buy or not buy (as the case may be) particular products.

The CET is not responsible for any errors or omissions, or for the results obtained from the use of the information contained in the reports. The reports are provided "as is", with no guarantee of completeness, accuracy or timeliness and without representation, warranty, assurance or undertaking of any kind, express or implied, including, but not limited to fitness for a particular purpose.

The CET shall not be liable to you or anyone else for any decision made or action taken in reliance on the information contained in the reports or for any consequential, special and / or indirect loss.

Background – the role of clinical evaluation in procurement and the Lord Carter Review

The Lord Carter Review acknowledged that the NHS was the best value healthcare system in the world. However, it also acknowledged that within the NHS there are variations in the resources used and inequity across the country for the cost of these items per unit of issue. Putting that into the current context, whereby the NHS is expected to deliver efficiencies of 10-15% in real terms by 2021, there is a need to achieve quality at the best price for all.

The Lord Carter Review also stated that procurement needed to transform with national category strategies. This proposal highlighted that all product areas being developed should have a robust independent, clinically driven, product testing and evaluation capability. This led to the proposal and establishment of the CET.

Prior to this report, in 2012, the NHS Customer Board approached the Royal College of Nursing (RCN) seeking senior nurse representation. In response to this request, Mandie Sunderland, Director of Nursing at Nottingham University Hospitals NHS Trust, took up a place on the NHS Customer Board. Seeing the contribution that clinicians and initially nurses, can make to the approach of quality at the best price, Mandie was asked to establish and chair the Clinical Reference Board which she continues to lead.

Small Changes, Big Differences

One of the first initiatives led by Mandie Sunderland and the CRB was collaboration with an RCN campaign, entitled ‘Small Changes, Big Differences’. In this work, a group of NHS organisations working with their nurse clinicians led the way in making small changes to what they bought and how they used everyday healthcare consumables, reducing variation of comparable products, making clinical practice easier and, in many cases, improving patient safety. This also led to significant financial savings and indirect savings through reductions in bed days in some projects. Separately, this work also highlighted the enormous potential for the impact of nurses within procurement.

Some of the reductions in variation and associated direct financial savings were significant and demonstrated a clear opportunity where local initiatives could be replicated at a national level (see http://www2.rcn.org.uk/newsevents/campaigns/small-changes-big-differences/success-stories).

A business case for the creation of a national group of independent clinicians to provide clinical review of everyday healthcare consumables was submitted by Mandie Sunderland and colleagues at the DH. The CET, which included a number of seconded clinical specialists from a range of NHS and nursing organisations, was established in April 2016.

NHS Customer Board

The purpose of the NHS Customer Board is to influence and lead procurement strategy through engagement with senior stakeholders who understand the challenges currently faced by the NHS, with particular attention to the NHS Supply Chain contract.

The NHS Supply Chain Customer Board was originally established in 2011. The group was renamed to become the NHS Customer Board when its management was transferred to the NHSBSA on 1 March 2016, with Sir Ian Carruthers continuing in his position as Chair.

More information can be found at the NHSBSA website:
http://www.nhsbsa.nhs.uk/CommercialServices/4945.aspx

Clinical Reference Board

Role of the Clinical Reference Board

The Clinical Reference Board reports to the NHS Customer Board for procurement and supply and has several roles. Its principal remit is to agree clinical procurement priorities and to work with the national and regional Customer Boards to implement changes which deliver high clinical quality whilst making efficiency savings for the NHS. The main objectives to achieve this remit are to:

- raise awareness of the role clinicians play in achieving best value from clinical products
- facilitate interaction with trusts at a local level to support change and delivery of significant savings
- identify areas for savings, rationalisation and standardisation, linked to the original NHS £300m savings challenge, and other national programmes such as the Nationally Contracted Products activity to ensure high quality is maintained
- support and drive the existing good practice of clinical engagement in procurement
- publicise the work of the group and seek opportunities to engage the wider clinical workforce in the challenge
- work collaboratively with all the Local Boards to support clinical engagement across their key priorities
- support the development of CET to develop clinical product reviews for quality and clinical use at a national level
- provide governance and direction to the team, through the team's Clinical programme lead.

Membership of the Clinical Reference Board

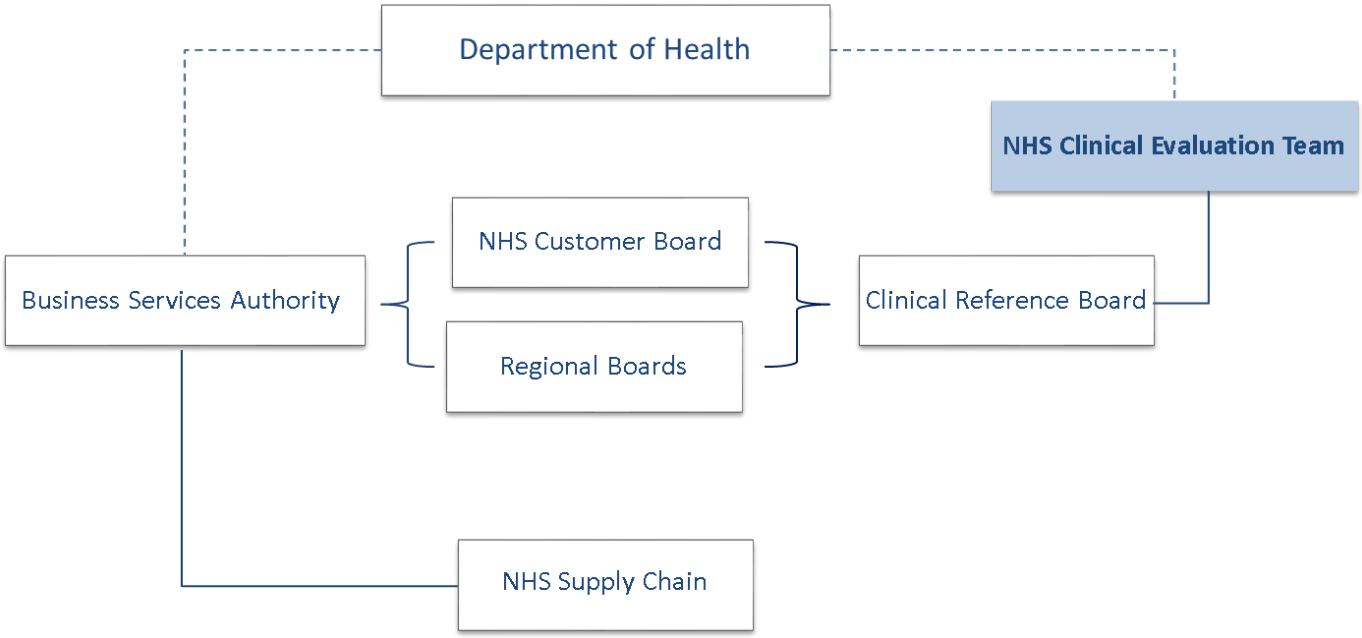
Membership of the CRB (1st May 2017) is comprised of senior nurse leaders from NHS Trusts and other clinical organisations. Members are listed below:

- Mandie Sunderland (Chair), Chief Nurse, Nottingham University Hospitals NHS Trust
- Greg Dix (Vice Chair), Director of Nursing, Plymouth Hospitals NHS Trust
- Sandy Brown, Director of Nursing and Clinical Quality, East of England Ambulance Service NHS Trust
- Dr Naomi Chapman, Clinical Programme Lead, NHS Clinical Evaluation Team
- Geraldine Cunningham, Associate Director of Cultural Change, Barts Health NHS Trust
- Rose Gallagher MBE, Interim Head of Standards, Knowledge and Innovation, Royal College of Nursing
- Siobhan Heafield, Regional Nurse Director Midlands and East, NHS Improvement
- Professor Suzanne Hinchliffe, Chief Nurse/Deputy Chief Executive, Leeds Teaching Hospitals NHS Trust
- Michelle Norton, Director of Nursing, George Eliot Hospital NHS Trust
- Christine Perry, Director of Nursing, Weston Area Health NHS Trust
- Dee Roach, Executive Director of Nursing and Quality Lancashire Care NHS Foundation Trust
- Shelley Dolan, Chief Nurse, The Royal Marsden NHS Foundation Trust
- Suzanne Banks, Chief Nurse, St George's University Hospitals NHS Foundation Trust

Formation of the CET

Structure

The below illustrates where the CET sits in relation to the Department of Health, NHSBSA and its stakeholder boards:



Members

Team members were drawn through the DH recruitment process and were selected for their specific clinical skills and specialist knowledge. Members are from a wide range of NHS organisations including Acute Trusts and Primary Care, covering the patient pathway from Paramedic to District Nurse. In creating the team, it was essential that they should be working on behalf of the NHS, for the NHS. Team member biographies are available at: www.nhsbsa.nhs.uk/CET

Team charter

A team charter (Appendix 2) was created to unite the team under a common purpose and goal. This included a mission statement to provide clarity for the scope of the team and skill set and expectations of its members.

Tenure and DH support

Clinical team members were seconded into the DH from the NHS with support and guidance from DH colleagues as part of the Procurement Transformation Programme. Funding is available, subject to bi-annual reviews until the Future Operating Model (FOM) comes into force.

Working with the NHSBSA

The team are hosted by the NHSBSA's Supplier Management team, who are based in Mansfield. The NHSBSA provides the team with work space, communications support, a conduit to NHS Supply Chain and the opportunity to work with teams on other initiatives, such as the Trusted Customer programme.

Working with NHS Improvement

The team's clinical evaluation review reports will be available to NHS Improvement to inform their procurement strategy and as part of the Nationally Contracted Products Programme (NCPP).

Critical Friends

In order to ensure that the team's work has rigour and integrity in the wider health landscape, a network of Critical Friends was established. These form two groups, National Critical Friends and Clinical Critical Friends.

National Critical Friends

The remit of these national colleagues was to overview the team process and strategy to ensure they have rigour, independence and value to the NHS.

Members include:

- National Institute of Healthcare Research
- The Queen's Nursing Institute
- The Patients Association
- National Institute for Health and Clinical Excellence
- Society of Chiropodists and Podiatrists
- Rapid Review panel
- Chair – Clinical Reference Board
- Association of United Kingdom University Hospitals (AUKUH)
- Department of Health – Director of Supply Chain
- National Director of Clinical Quality and Efficiency – GIRFT (Get It Right First Time)
- National Director of Clinical Productivity – GIRFT (Get It Right First Time)

Clinical Critical Friends

The remit of these clinical networks was to overview the relevance of the work plan and output for our clinical colleagues in practice.

These clinicians will work in a virtual way to review and contribute to the clinical outputs as required, providing reasoning and clinical opinion to ensure report formats are pragmatic and useable in clinical practice.

Governance

The team reports to the Clinical Reference Board as its steering group, who in turn reports into the NHS Customer Board. Additional external reference points exist through the Critical Friends groups, with further scrutiny from the DH Programme Lead.

Work plan and CET toolkit

The Work Plan (Appendix 3) has been developed independently by the team members. The approach to the Work Plan prioritisation was:

- Is the product an everyday clinical product?
- Does the product have clinical impact?
- Does the product have patient impact?

If the answer to these questions is yes, then consideration of the volume usage of the product was used to prioritise the potential benefit for clinicians conducting a review and all findings are recorded in the internal CET toolkit.

The order of proposed products to be reviewed was made in the first instance for the initial six months with on-going reviews thereafter.

The order of the product reviews will be responsive to DH priorities and will inform on-going procurement cycles as well as suit the needs of the clinical community, and therefore proposed plans may be adjusted accordingly.

Communications

The CET is committed to openness and transparency. It has worked to ensure that all interested parties have access to the work plan, processes and this operating manual. The NHSBSA Communications Team has supported the team with communication tools such as banner stands, webpages, name badges etc. and active support for the team's stakeholder events.

The team has delivered a range of external presentations to offer insight into their process and outputs, with additional external and internal communications being published online at www.nhsbsa.nhs.uk/CET. A DH intranet portal with additional detailed information supporting the NHS Clinical conversations can also be accessed by invitation.

All external communications are signed off at team level, DH level and NHSBSA level.

Engagement

The team is comprised of practicing clinicians seconded from NHS organisations and wider healthcare organisations. As such, they are all passionate about the team's evaluation work being driven by clinicians.

Built into the review process, NHS clinicians are invited to share their clinical knowledge in order to ensure the team has a concise message regarding what they need from each product, what (in some instances) enhancements they may need, and the level of performance each product delivers.

To ensure this clinical “opinion” is as robust as possible and encompasses all needs, the team engages with several key national networks including, but not limited to the Association of United Kingdom University Hospitals, the Clinical Procurement Specialist Network, Tissue Viability Society, Infection Prevention Society, National Infusion and vascular access society, Trusted Customers and the NHS regional Customer Boards.

The Work Plan, process and future events are available at: www.nhsbsa.nhs.uk/CET. The Clinical Specialist Leads within the team are actively supported to keep their professional networks engaged with this work.

Clinical Review Pathway – Stages 1-5

Stage 1: Product range assessment

Stage 1 of the process is centred on consideration of products for inclusion in the work plan.

The team starts by considering products available from the main national provider (currently NHS Supply Chain).

Each product range must meet the team definition of 'everyday healthcare consumable' – the types of products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags. They are products that are generally used across a multitude of healthcare settings.

Additional clinical products may be evaluated by the team, which are used in high volume and have significant patient impact although not found in the majority of clinical environments. These activities will only be undertaken if agreed by the Clinical Reference Board.

Step 1 – Decision making

The purpose of stage 1 is to determine if the product being considered for evaluation meets the agreed definition and criteria of an everyday healthcare consumable. To determine this, the stage 1 toolkit must be completed:

- Does the product have clinical impact?
- Does the product impact on patients?
- Is the product used at high volume in the NHS?

1. **Defining the product**

   Consider the product and identify the key features. Consider the features that are inclusion criteria and features that are exclusion criteria. Clearly state which product features are to be evaluated and those features that are to be excluded.

Example definition: Examination Gloves
Gloves that are non-sterile and available in multi-unit packaging for easy access in clinical settings (including acute, community, primary care and domiciliary settings). To include gloves that are worn during patient contact where there is a risk of exposure to body fluid and gloves worn during procedures where there may be contact with a substance that has a COSHH implication e.g. preparation of medications, use of cleaning products. To exclude all sterile gloves and domestic, heavy-duty gloves.

Text highlighted in yellow- key product feature
Text highlighted in green- included features
Text highlighted in red- excluded features

2. **Consider the purpose and objective of the evaluations**

   This includes the key objectives of:

   a. Defining the clinical requirement(s) for the product under evaluation
   b. Identification and evaluation of the range of consumables meeting the definition available to the NHS on the national framework
   c. Define and publish a product assessment results matrix

   In addition to these core objectives, consideration of any additional objectives related specifically to the product under evaluation to be listed in the stage 1 toolkit.

3. **Consider the clinical priority and rate as low/medium/high**

   The defined questions enable the clinical specialist lead to establish the clinical priority of reviewing the proposed product group:

   a. Is the product used during the majority of patient contact?
   b. Is the product single use/reusable?
   c. Is the product essential to comply with local/national policy?

   Positive answers to all questions would rank the product as high clinical priority.

4. **Consider the patient impact of this product and rate as low/medium/high**

   Questions to establish this impact were determined around:
   a. Frequency of use
   b. Patient safety impact
   c. Risk and impact on removal of product lines

   As previous, higher scores against the defined questions increase the patient impact and urge the need for clinical review.

5. **Recommendation and approvals from stakeholder groups**

   Priority will always be given to the CRB and latterly the NHS Improvement Nationally Contracted Products Programme. A product being considered through another evaluation programme also raises priority, to provide clinical opinion to evaluations, and avoid re-working/duplication of work.

6. **Market change/stability**

   A stable market for the product to be evaluated with no changes imminent would also encourage evaluation, whereas a market prone/subject to change had lower weighting; as the clinical opinion may have limited value should the available market of products change. It was recognised that there may be circumstances where a significant market change is underway which would also score positively. Where this is the case, the impact of this market change must be discussed with the team and consensus gained from the group on the scoring.

7. **Usage**

   A review of the volume purchased through NHS Supply Chain should always be undertaken. The team will identify the % market share held by NHS Supply Chain if this information is available.

   High volume promotes early clinical review.

8. **Innovation**

   Where the team is notified of, or uncovers through engagement, innovative and new products, the relevant Clinical Specialist Lead will endeavour to include and undertake evaluation as quickly as possible, in order that the NHS has clear, independent review and can make decisions accordingly.

9. **Resilience and stability concerns**

   Where the team is notified of, or uncovers through engagement, any issue regarding resilience, sustainability and stability, of either product or supplier, the Clinical Specialist Lead will endeavour to include and undertake evaluation as quickly as possible, in order that the NHS has clear, independent review and can make decisions accordingly.

10. **Clinical best practice**

    Changes in clinical practice, whether driven through legislation or enforcement and inspection regimes experienced by Trusts from the Health and Safety Executive, will be referenced in all clinical reviews.

Step 2 - Risk register

A risk register and action log for the programme is required. The proposed format for assessing risk includes:

1. Risk/action
2. Impact
3. Impact on delivery score
4. Likelihood score
5. Mitigating actions
6. Owner
7. Last review date
8. Next review date
9. Updates

The risk register/action log remains a live document for the duration of the programme; it is to be reviewed and updated regularly and as a minimum, at the end of each stage, prior to approval/validation to close the stage for each product being evaluated.

Step 3 – Assigning the type of product and timelines

Evolution of the clinical pathway has identified a clear differentiation of product testing requirements, and validation groups. This has led to predicted timescales being developed with products now classified into type A, B and C products.

- **Type A:** Product groups, where the choice of the product used has a limited impact on patient experience and outcome (24 weeks)
- **Type B**: Product groups where there is a requirement for generalist and specialist clinical alignment for product choice, but where there is a low level of patient advocacy (28 weeks)
- **Type C:** Product groups where the choice of product is co-owned by generalist and specialist clinicians. There is a high level of patient advocacy required, which needs to be reflected in a clinician's provision of care (33 weeks)

Review and approval

Once the decision making matrix has been completed and the risk register made a live document, the information must be presented to the CET panel for approval. Secondary approval from the Clinical Reference Board must also be sought.

Stage 2 – Intelligence gathering

The purpose of stage 2 is to identify key information about the product under review. This is to determine, what type and depth of clinical evaluation, if any, has been completed previously. This will allow the team's evaluation to build on previous work, if available.

This evidence is then used as a basis to help form initial ideas around suitable clinically based statements, to understand better what clinical staff require of a product and how it should best perform in order to satisfy those identified and confirmed clinical requirements.

The following data sources should be consulted as a minimum:

Supporting information from NHS Supply Chain

NHS Supply Chain information is key to confirming that the product meets the criteria set out in stage 1. For each product, the project lead should liaise with the procurement delivery manager at the NHSBSA to obtain the following information from NHS Supply Chain:

a. Existing specification
b. Framework details and timelines
c. Suppliers – current/proposed
d. Suppliers data sheets/technical information/literature regarding product (this may be accessed through supplier website)
e. Lines/range and catalogue descriptions
f. Volumes
g. Sample range required

The relevant Clinical Specialist Lead for that product range should ensure they are acting for the NHS, by the NHS with independence maintained at all times. A summary of the information gathered (as listed previously) garners whether the product is suitable for evaluation by the CET.

The Clinical Specialist Lead within the team confirms relevance to the project and highlights any information that requires further follow-up including a plan and timeframe to complete this. If further follow up is required, the overarching project plan will be reviewed to adjust timescales if necessary and highlight any changes on the live risk register.

Academic literature search

A literature search is undertaken by each Clinical Specialist Lead to establish what current academic knowledge exists on the product for evaluation. It should be noted that the team are not conducting a comprehensive or systematic review of literature. However, CET will be interrogating the information to look for common themes which will support the development of their clinical criteria.

Healthcare databases and nationally respected services such as NICE may be used to gather this information, at the discretion of the Clinical Specialist Lead.

All databases and search terms/terminology are to be recorded to provide a clear methodology and record of the information gathered.

Search results and sources should be downloaded and retained for a reasonable amount of time. It may not be necessary to include this information in the final report; however, a record must be kept for reference.

Literature that has been obtained should be reviewed to assess the relevance to the project and suitability to inform outcomes. Literature that is deemed relevant should be summarised in the toolkit. The source of all literature will also be documented to provide protection against bias and challenge on information. Titles of literature that is deemed not relevant should be noted in the toolkit for reference.

Findings should be presented as a summary of the relevant literature. This will be used to inform stakeholder engagement during stage 3. The summary should also identify if any aspect identified as important by the team/CRB/NHSBSA is not adequately covered in the literature.

National guidance/professional guidance

Clinical Specialist Leads will search relevant DH arm's length body literature to identify any relevant national guidance, policy or legislation. As a minimum, this search should include central DH, NICE, MHRA, PHE and other relevant professional bodies' resources.

The team will record which organisations have been searched and any findings in the toolkit. Where information has been identified, the team will summarise the relevant areas to the project and include the reference to the full document.

National and international standards – BSI, ISO, etc.

All equipment used in the NHS is required to be CE (Conformité Européene) marked. The CE mark is the manufacturer declaration that the product complies with the relevant European legislation, which, in practice, includes European technical specifications. Standards for medical equipment are voluntary and are led by manufacturers with input from other stakeholders. They are developed at national (British Standards Institute, BSI), European (European Committee for Standardisation, CEN) and International (International Standards Organisation, ISO) levels.

Team members will search the relevant organisations to identify any relevant standards and how they apply to products.

Other national health bodies – Wales, Scotland and Northern Ireland

The Clinical Specialist Lead should contact their counterpart in other UK nations to identify if any information (relating to evaluation or review projects that have been carried out in any other UK nation) is available. The specialist lead may review information that has been provided from national procurement in Wales, Scotland and Northern Ireland. All additional information will be logged, together with source, as outlined with intelligence gathering.

Independent laboratory testing

Where supplier information, literature or national guidelines indicate that technical testing has been carried out previously, the Clinical Specialist Leads should obtain a copy of this for summary and inclusion. The sources for these may be:

- NHS Supply Chain (via the NHSBSA)
- Manufacturers
- Independent testing laboratories
- DH arm's length bodies that are producing relevant national guidance
- Other countries' health teams who have carried out work independently

The team members will note all contacts with the above sources in the toolkit and the outcome. If no previous laboratory testing has occurred, they will document this as not applicable.

Supplier engagement and call for action – information/data/research

When engaging with suppliers and appropriate trade bodies the CET will decide, acting reasonably and taking account of any requests by them, whether an initial introductory meeting is required as the project commences, to allow product suppliers an opportunity to hear from the Clinical Specialist Leads about the process for clinical review and how they can contribute by providing their product information.

This will be followed (if required, the CET acting reasonably and taking account of any requests by suppliers) by specific supplier meetings or call for action letters, using agreed templates to request any information that has not been received through the NHSBSA and the national provider. Contact should only be made with the nominated framework lead for the company as provided by NHSBSA or as directed by a supplier. Details of who was contacted and when should be noted in the toolkit. Any follow up or responses received must also be noted in the toolkit.

When information is received from a supplier, team members will summarise in the toolkit and insert a link to the full document. They will acknowledge that this is supplier provided.

The CET will endeavour to copy in the relevant Trade bodies and NHS Supplier Board where appropriate.

Summary of intelligence gathered

A review and summary of the information gathered will be used as a toolkit for gathering clinical opinion. This intelligence summary will also form part of the final product report.

Sample requests and products ordered

The CET will use its reasonable endeavours to make sure that it orders all products in a particular category from NHS Supply Chain through the NHSBSA in time for its clinical evaluations. To that end, written requests for product samples to be clinically reviewed will be made to the NHSBSA, who will source the products from NHS Supply Chain following a process agreed between the two organisations.

Products are requested as ward-ready / clinician ready. Points considered when requesting samples include:

- Unit of issue
- Size range
- Alternative source
- Lead time for sample delivery

Risk register

A review and update of the risk register will be undertaken on completion of each stage in the evaluation process.

Validation

The summary of intelligence and updated risk register for each product will be presented to the CET panel for validation, prior to moving to stage 3.

All of the data is then summarised into an evidence table which will also include any areas of missing data identified and used by the team members to inform the further planning of that product evaluation. Technical testing and adherence to standards is not retested.

Stage 3 – Stakeholder engagement

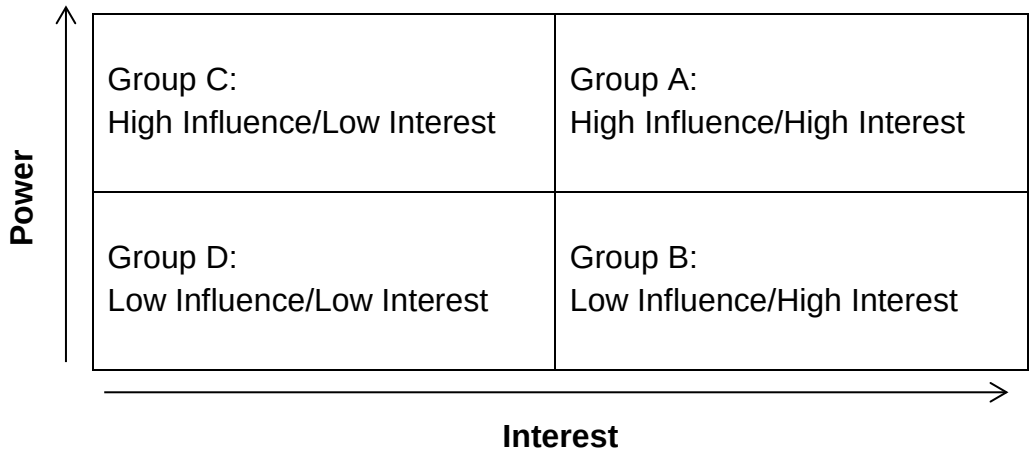
The purpose of stage 3 is to gain the clinical opinion and experience of the NHS to determine the clinical quality requirements of everyday healthcare consumables. This information, along with the intelligence gathered in stage 2, will form the basis of a clinical quality requirement for the everyday healthcare consumable under review.

The definition of a stakeholder in this context is a Clinician or Patient with an interest in the CET programme of work.

Stakeholder engagement is a two-stage process, namely: (i) the identification of stakeholders through mapping and; (ii) active engagement, from which additional stakeholders may be identified. The following sections discuss both of these stages.

Stakeholder identification and analysis

Stakeholder analysis identifies every stakeholder that could be impacted by the programme, and/or impact the team's evaluation process. Before engagement can take place, the level of influence and interest they have over the products for evaluation aids identification of the method and significance of their engagement. They should be mapped using the power interest grid shown below.



There are four defined groups of stakeholders depending on their level of interest and influence.

- Group A: High Influence/High Interest – this represents the dominant group relevant to the specific product evaluation. Support of this group must be gained for project success. This requires effective engagement and consultation through multifaceted involvement.
- Group B: Low Influence/High Interest – this group represents stakeholders that may be subject to marginalisation and advocacy of their interests is necessary. This requires effective engagement and consultation.
- Group C: High Influence/Low Interest – this group contains stakeholders that have a high level of power over the programme and could cause delays to decision

making, yet have relatively low interest. This group requires cooperative management and close oversight.
- Group D: Low influence/Low Interest – This group requires low scrutiny as they will have little concern regarding the programmes outputs.

Stakeholder analysis will identify all relevant stakeholders who can impact the programme both positively and negatively. Engagement with different groups of stakeholders should be planned based on where in the matrix they sit.

Stakeholder engagement

Engagement should be planned to ensure that the CET remains independent and uninfluenced by industry and other stakeholders such as NHS procurement organisations. It is therefore likely that a number of stakeholder events will be necessary for different stakeholder groups. It is anticipated that for all projects, NHS colleagues will be Group A stakeholders and events should be planned to support this.

Engagement methods

Multimodal engagement methods should be considered. It is important to ensure that as many individuals in the NHS have access to the product evaluation as soon as possible, so the following methods must be considered for each project:

- regional and national face-to-face events with NHS stakeholders
- website subscription, dedicated workspace discussions and/or WebEx sessions
- attendance at specialist network events
- attendance at NHSBSA events
- visits to NHS colleagues.

One, several, or all of these methods should be employed, depending on the group to be engaged with.

Group A engagement – high influence/high interest

The team aims to achieve the highest level of engagement as possible, so the priority for this group is to ensure that accessible face-to-face engagement events are available for them to attend. The purpose of these events is to gather information from frontline clinicians using these products to aid the identification of the clinical requirements for the everyday healthcare consumables under review.

Communication to this group is done, as a minimum through the CRB representatives. Invitations will be circulated to all CRB members with a request for nominations to attend the session and a clear description of what will be involved. Each representative is asked to confirm their attendance to assure that a broad range of clinical expertise will be available for discussions.

Group B engagement – low influence/high interest

This group contains stakeholders from a variety of backgrounds. The NHS stakeholders who fall into this group are likely to be NHS employees who have little influence within their organisations, or little clinical knowledge of the products. When requesting attendees for face to face events, individuals who fall into this group should be considered as participants.

Engagement with NHS Supply Chain will be done in collaboration with the NHSBSA.

Engagement with industry should be done in a controlled manner with single requests for all information sent from the team. Supplier engagement event(s) may be required depending on the project.

Group C engagement – high influence/low interest

Organisations that have a high influence must have regular updates on the team's progress. Engagement with these stakeholders will take the form of the clinical and operational programme leads meeting with their counterparts in these organisations to provide updates and assurance of progress.

Group D engagement – low influence/low interest

This will take the form of project updates posted on the team's webpages, through subscriptions to the DH Exchange portal and newsletters. Reviews of the individuals and organisations in this group will be performed regularly to ensure that this method of engagement remains appropriate.

Plan for face to face events

Face to face NHS events will have a focused agenda in order to achieve the aim of gathering clinical opinion and knowledge around what makes quality from the everyday healthcare consumables being evaluated. Initially engagement days were co-ordinated with booklets for the delegates to complete with regard to the product type being consulted upon. The booklets contained questions and aided discussions, providing opportunities to comment about the key features and benefits that were needed. Future development of the clinical pathway aims to capture this electronically in real time, to reduce time and potential errors in re-interpreting raw data. Through any chosen medium it is essential that any outputs are collected and collated to inform the evaluation criteria for the next stages of determining the clinical evaluation methodology. The CET aims to ensure equality of access to clinical conversations regardless of where you live.

Key requirements/considerations:

- Regional locations
- Ideal delegate number of 35 - 40
- Mix of clinical skills with knowledge of the range of products

- Large room with tables that encourage discussion
- IT facilities and support
- Refreshments
- In healthcare environment
- Live data capture and recording of feedback e.g. booklets, minutes, WebEx sessions and the DH Exchange Portal.

Feedback from stakeholder engagement events

Feedback from events is collated and circulated to all participants within a reasonable time frame of the final event within this phase of the programme. This feedback will be documented in the programme to complete stage 3 of the evaluation process.

Feedback from individual meetings will also be collated and documented in the project toolkit.

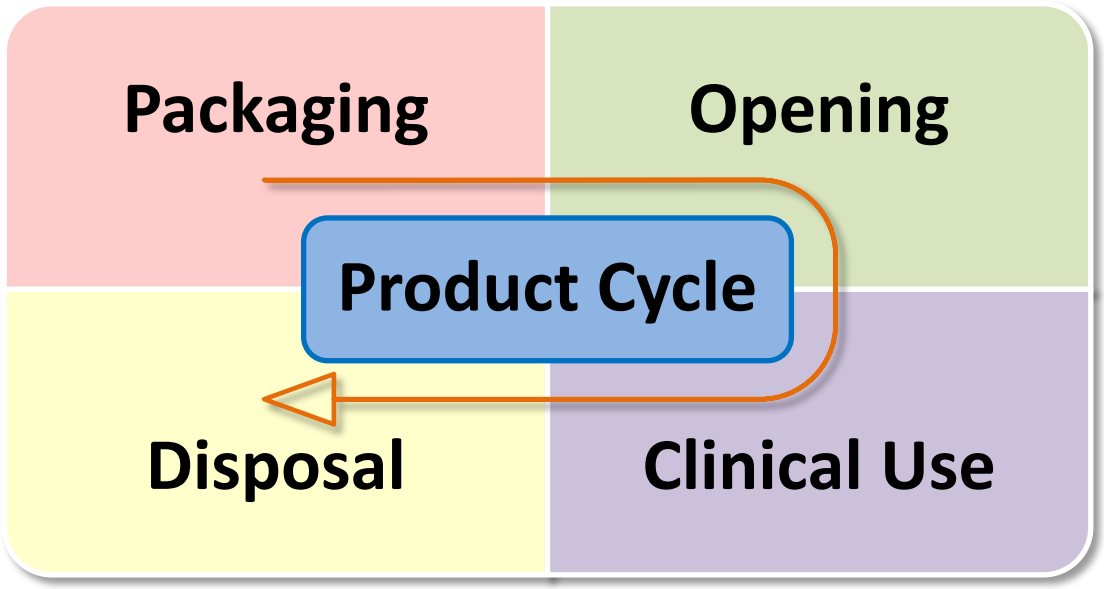
Stage 4: Clinical product requirements/criteria

The purpose of stages 4 and 5 of the pathway process is to develop defined clinical quality criteria for the product group.

These stages of the pathway constitute a process by which clinicians can communicate the clinical criteria that are important to them in practice. The clinicians are those that are using the products on a daily basis and it is one of the principal purposes of the CET that their opinion acts as the basis for the clinical quality criteria. The team considers that to allow suppliers to set the criteria or influence them may not always be consistent with this rationale. However, suppliers have the opportunity to demonstrate how their products meet the specified criteria against which their products will be clinically assessed.

A clinical criterion is defined as a principle or standard by which products may be evaluated. It is an objective statement which describes the clinician's requirements for the product.

The team takes into account the entire product lifecycle (shown below), reviewing products currently on the national framework against this criterion, and ultimately developing the product assessment results matrix, which will be captured in the final report and clinical review for the given product(s).



Developing a draft clinical quality criteria

Information from stakeholders is critical to this stage. Along with all intelligence gathered in stage 2, the Clinical Specialist Lead will develop clinical quality criteria using the stage 4 toolkit. Key inclusions to frame these initial criteria will consider:

- purpose of the product
- patient need/expectation

- clinical need
- clinical use – consider all possible functions for this product
- packaging – presentation, information and requirements (including shelf life/use by dates)
- user information/user guide
- understanding of relevant standards

CET's reports are aimed at providing an additional tool to help NHS Trusts who are responsible for using clinically appropriate products to act efficiently, effectively as well as comply with value for money and quality requirements. CET acknowledges that this may also include service and support, education and training should they be required at a local level.

Determining evaluation mode and methodology

The purpose of evaluation is to determine whether and, to what degree, each product meets the NHS defined clinical criteria statement. This may include in-situ testing or observations in clinical use, simulated clinical use, technical laboratory testing, case studies and other modes that are identified as appropriate at this stage.

Validating criteria and evaluation methods

The proposed clinical criteria and evaluation methodology will be shared with the CET for peer review and comment. Team members are required to return comments to the relevant Clinical Specialist Lead within five working days of receiving the proposal.

This may lead to amendments, alterations and adaptations to the criteria, which will be shared with NHS Colleagues. The process of peer review and approval from the team will be required with each amendment to the previous proposed criteria, before requesting formal sign off from the Clinical Reference Board.

Publication of evaluation criteria

After the clinical criteria have been developed by the CET, they will be made available to the suppliers whose products are being clinically evaluated. Those suppliers will then be given the opportunity to provide any additional information within a reasonable time period to the CET to demonstrate that their products can meet the criteria against which their product(s) will be clinically assessed. The CET will consider any relevant information that it receives when carrying out its clinical evaluations.

Stage 5: Product evaluation and final review

The extent of product evaluation required will depend on the NHS defined clinical criteria statement, taking into account the product classification type A, B and C products:

- **Type A:** Product groups, where the choice of the product used has a limited impact on patient experience and outcome.
- **Type B**: Product groups where there is a requirement for generalist and specialist clinical alignment for product choice, but where there is a low level of patient advocacy.
- **Type C:** Product groups where the choice of product is co-owned by generalist and specialist clinicians. There is a high level of patient advocacy required, which needs to be reflected in a clinician's provision of care.

Product evaluation is a stepwise process. The CET panel will review all products. If additional modes of evaluation are identified and required to be undertaken, a concise method and process of meeting those evaluation needs will be developed and agreed at this time. This may include further observation in clinical use, technical laboratory testing, cases studies and other modes that are identified as appropriate at this stage.

CET panel evaluation

Simulated clinical use will be undertaken by a quorate panel which will include CET members, a facilitator, a coordinator, and a product appropriate number of clinical specialists.

The purpose of the evaluation panel is to gain clinical opinion on whether, and to what degree, products available on the national framework, meet the defined clinical quality criteria.

The team will assess each product against the criteria and give an opinion which may be in a defined format i.e. yes/no, or subjective giving a star rating against performance against proposed test.

In-situ evaluations and observations in clinical use

If beneficial, the team will undertake additional in-situ evaluations or request to observe products in use in a clinical area. A list of the NHS trusts using the product brand in question will be provided by the NHSBSA. This will allow the project lead to identify users of the product in order to address any questions about clinical use.

To facilitate this, the CRB and Customer Board members may be approached as a point of access. Where a trust with a member of the CRB or Customer Board uses the product in question, the CET's programme lead may make contact with the Nurse Director to make them aware of the request for access. Following this, the relevant Clinical Specialist Lead may contact their speciality counterpart in the trust to arrange an observation visit. Criteria for observation will be developed by the team to ensure consistency.

Technical testing

If products' actual performance against defined tests is required, the Clinical Specialist Lead will seek funding for laboratory testing to establish product performance against the defined test.

Managing concerns

Following assessment and evaluation by one or all of the methods above, any concerns identified will be escalated to the CET programme lead. If necessary, a stakeholder viewpoint should be sought, either from the Clinical Specialist Lead's parent Trust or the appropriate clinical specialist network. This interaction and its outcomes will be documented in the project toolkit.

Data sense check and committee decision making

The Clinical Specialist Lead will review all the evaluation data following the agreed evaluation process. All incongruence, or lack of a clear result, will be discussed and either ratified by the group as a committee decision, or a decision will be made to seek further external advice (e.g. from an external clinician specialist in the area) or where appropriate, retest of the product.

Final review report and product assessment results

The final report summarises all information gathered and documented throughout each stage of the project. It will include a full clinical review to include, where appropriate, clinical definition, product technical design, product properties and intended clinical use, along with any details of clinical practice or impact.

Details of the intelligence gathering undertaken, and the NHS clinical engagement to determine the NHS clinical criteria is included, together with the scope of evaluation undertaken.

Product assessment results

Each product evaluation will be produced within a results assessment matrix of similar products.

The evaluation will include a photograph of the product, its catalogue reference, and the score awarded from the clinical evaluation against each of the defined criteria. Star rated scoring provides, unless the criterion being clinically assessed falls into the category listed below, a maximum of three stars for each element of the evaluation based on the scoring regime of:

- 0 stars – Does not meet criteria
- 1 star – Partially meets criteria
- 2 stars – Fully meets criteria
- 3 stars– Exceeds criteria

The above scoring mechanism will not be followed where the criterion identified by the CET cannot reasonably exceed expectations. For example, if the clinical criterion was whether the removal of an adhesive dressing was atraumatic and with the individual patient reporting no pain or skin damage then it cannot reasonably be expected that a product could exceed that criteria. Therefore, in such circumstances, the relevant criteria will be based on the scoring regime of:

- 0 stars – Does not meet the criteria
- 1 star – Partially meets the criteria
- 2 stars – Meets the criteria

The reports will make it clear when the maximum number of stars that can be awarded by the CET for any single criterion is 2 or in certain instances where the criteria generated may have a defined answer i.e. Yes/No

The scores provided should be read in conjunction with the following notes:

Yes/No Criteria with a defined answer

In certain instances the criteria generated may have a defined answer i.e. Yes/No and this will be represented with a √ / X

Y = Yes √

N = No X

N/A = not applicable

Yes/No Criteria which may be subjective

Where Yes/No answers may be subjective, such Yes/No answers will be converted into aggregate percentage scores and then converted into star ratings as follows:

Percentages	Star value
0% to 16.66%	**0 stars**
16.67% to 33.33%	**1 star**
33.34% to 49.99%	**1.5 stars**
50% to 66.66%	**2 stars**
66.67% to 83.33%	**2.5 stars**
83.34% to 100%	**3 stars**

Illustrative example – By way of example only, where there is a clinical criterion which evaluates whether a particular product leaves a sticky residue after application, 5 clinical evaluators return with 4 "Yes" responses and 1 "No" response. In this illustrative example, the Yes/No responses will be converted into an aggregate percentage of 80%. Such percentage will then be converted into a star rating of 2.5 stars.

Other subjective criteria

For other criteria a subjective score may be given against the defined criteria and these will range from 0-3 (0 – This does not meet the criteria; 1 – this partially meets the criteria; 2 – this meets the criteria; and 3 – this exceeds the criteria).

These numerical scores from all evaluators will be totalled and a mean score determined. This mean score will be converted into a star rating as follows:

Point scored	Star value
0 to 0.99	0 stars
1 to 1.24	1 star
1.25 to 1.74	1.5 stars
1.75 to 2.24	2 stars
2.25 to 2.74	2.5 stars
2.75 to 3	3 stars

Illustrative example: By way of example only, where there is a clinical criterion which evaluates whether the instructions for application of a particular product are easy to follow, evaluators are directed to provide scores ranging from of 0 to 3 (based on the above) and the response from five clinical evaluators are scores of 3, 2, 3, 3 and 3. In this illustrative

example, the mean score of the responses is 2.8, which is then converted to a star rating of 3 stars.

Criteria that cannot reasonably exceed expectations

The above scoring mechanisms will not be followed where the criterion identified by the CET cannot reasonably exceed expectations. In such circumstances, the relevant criteria will be based on a scoring regime of:

a. If the criterion is a Yes/No response, the responses will be converted into aggregate percentages and then star ratings as follows:

Percentages	Star value
0% to 24.99%	**0 stars**
25% to 49.99%	**1 star**
50% to 74.99%	**1.5 stars**
75% to 100%	**2 stars**

b. For other subjective criteria (i.e. ones which do not require a Yes/No response), the responses will be converted into mean scores and then star ratings as follows:

Point scored	Star value
0 to 0.49	**0 stars**
0.5 to 0.99	**1 star**
1 to 1.49	**1.5 stars**
1.5 to 2	**2 stars**

On the basis that clinical evaluators will be providing scores of 0 – 2 (0 – does not meet the criteria; 1 – partially meets the criteria; 2 – meets the criteria).

The draft report then goes through a process of communications and final checks to ensure accuracy of all information.

Supplier links

Prior to publication of each report, product suppliers will be given sight of their individual product evaluation matrix for a minimum period of 72 hours to allow them the opportunity to comment on any factual and material error or mistake that may have been made against their product reviews. The CET considers that a minimum period of 72 hours ahead of publication is reasonable for suppliers to alert the team to any such factual and material errors or mistakes bearing in mind: (i) the earlier opportunity given to suppliers to provide information to demonstrate that their products meet the clinical evaluation criteria; and (ii) that the reports are based on the views of expert clinicians applying the evaluation criteria. The minimum period is a starting point for suppliers and the team may give suppliers more time if in the circumstances it is reasonable to do so, taking account of, amongst other things, product type and complexity.

In the event of any queries being raised by a supplier in relation to the clinical evaluation of their product on the basis of the above, a response by the team will be provided before the report is published and should be documented using the following template to ensure a consistent format and record is kept of both questions and answers.

	Supplier comment	**CET response**
1.		
2.		
3.		
4.		

Final sign off will be by the Clinical Reference Board, which generally meets every two months, as the team's governing body. This must happen prior to publication.

Updates to the team's reports

The CET recognises that suppliers may release new products to the market and make changes to their products as time progresses. Therefore, the team intends to update its reports fairly and consistently in accordance with the following process:

- At each Clinical Reference Board meeting, the team will review and discuss each of the reports that it has published.

- Where, in the time that has passed between the publication of a relevant report:

  (a) a supplier has alerted the CET that it has made a change to its product which, in the reasonable opinion of the CET, would make a material change to the results of its clinical evaluation of that product; and/or

  (b) a new product or products have been procured in accordance with the relevant procurement law and added to the NHS supply chain catalogue,

  the CET will update its reports, using the methodology set out in its clinical pathway in respect of such revised or new products.

Impact evaluation

Focus and further background

The CET has been established with the focus of providing clinical review of everyday healthcare consumables used by the NHS. There have been a range of outputs and process developments to support and aid evaluation flow from the team. In order to represent these outputs and impacts, a balanced scorecard approach has been taken to represent them in their activity.

Team

The initial team consisted of:

- Clinical Programme Lead
- Clinical Specialist Leads x 6 seconded from NHS organisations
- Supported by a DH Programme Lead and DH Delivery Lead

The team (with six Clinical Specialist Leads) came into post over the April/May period of 2016 and included senior clinical staff who were seconded from NHS organisations. The numbers of Clinical Specialist Leads in the team at any one time will vary as secondments end and new team members are appointed.

Biographies and further information on the key members of the CET can be found on the CET's website, details of which are set out in the "Useful links" section to this operating manual.

Infrastructure

CET Shared work spaces

The team established an internal web-based platform hosted by DH in which the team would share documents and have common team workspace. This enables a team working at distance with united and real time access to guidance, standard templates and other team documentation as required.

External infrastructure

With the support of the NHSBSA's communications and stakeholder teams, the team established its brand identity, logo and a shared email address for correspondence clinical.evaluationteam@nhs.net. A stakeholder portal site was also created within the DH Exchange system allowing clinicians access to the clinical conversations

Communications collateral has been designed and produced by the NHSBSA communications team, including branded event materials, document templates, business

cards and an external website www.nhsbsa.nhs.uk/CET to promote the activity and outputs of the team.

Process and sign off

The critical criteria and evaluation pathway process is the core of the team's work process and is shown in full at Appendix 1. This pathway also details governance and sign off, with the process defined as part of the pathway toolkit.

Sign off for the CET strategy, work plan and outputs sits with the Clinical Reference Board.

All external communications are signed off by the team and/or Clinical Programme Lead, then DH and finally by the NHSBSA's stakeholder and communications teams prior to external exposure.

Added value

During the course of team member tenure, several key areas of unanticipated 'added value' into the system have been realised.

Clinical input for procurement colleagues within the NHSBSA

Informal clinical clarification, viewpoint and discussions been held with NHSBSA colleagues resulting in informal input e.g. retention of a 2l urine bag with tap option through NHS main provider.

Product hierarchies, sub-categories and descriptions for the national provider's catalogue have been improved.

Future Operating Model

The team's respective programme leads are part of the DH's Future Operating Model working group, which is working toward a new model of procurement provider(s) in 2018. This will ensure clinical engagement is embedded into the procurement transformation programme.

Influencing behaviour change

As practising specialist clinicians, team members represent the needs and requirements of frontline clinical staff and health provider organisations. The detail of the evaluations and defined criteria are aimed at enabling informed choice for product purchasing and use based on clear impartial clinical opinion and testing. This process does not remove clinical choice but reduces time and effort in selecting everyday healthcare consumables. This enables increased clinical face to face time with patients, and allows transparency to enable challenge or defence of the product choice being used in any given clinical area.

Dissemination and influence within clinical networks

The team members are well established within a range of clinical and regional networks. They will use these networks to acquire clinical views and engagement, with a view to informing the wider clinical movement of informed change.

Networks represented in the first phase of activity include:

- Clinical Procurement Specialist Network
- Association of UK University Hospitals - Deputies
- NHSBSA national road-shows
- Tissue Viability Network Conference
- Nursing Times Director of Nursing Conference
- London Procurement Partnership
- NHSBSA Regional Customer Boards
- NHSBSA Trusted Customer first national event

Useful links

- MHRA: www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- Patients Association: www.patients-association.org.uk/
- NICE: www.nice.org.uk/
- National Institute for Health Research: www.nihr.ac.uk/
- The Queen's Nursing Institute: www.qni.org.uk/
- Royal College of Nursing: www.rcn.org.uk
- Department of Health (2016) – Operational productivity and performance in English NHS acute hospitals: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf
- The CET's website: https://www.nhsbsa.nhs.uk/CET

Appendix 1 – CET Work Plan 2016-18

NHS Clinical Evaluation Team Work Plan 2016 to 2018

NHS Clinical Evaluation Team
by the NHS, for the NHS

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags. They are products that are generally used across a multitude of healthcare settings.

Type A: Product groups where the choice of the product used has a limited impact on patient experience and outcome.
Type B: Product groups where there is a requirement for generalist and specialist clinical alignment for product choice, but where there is a low level of patient advocacy.
Type C: Product groups where the choice of product is co-owned by generalist and specialist clinicians. There is a high level of patient advocacy required, which needs to be reflected in a clinician's provision of care.

Objective: To define a work plan, based on an objective, clinical, customer/patient approach, using the definition for 'everyday healthcare consumables'.

Step 1: Clinical expertise employed to identify every day healthcare consumable product groups.
Step 2: Apply time lines, based on complexity - product, user, clinical and sensitivity - market, user, clinical.
Step 3: Cross-reference with NHS Supply Chain / NHSBSA initiatives + NHS Improvement Nationally Contracted Products programme. Identify opportunities to harmonise our timings to maximum effect.

Phase 1 - 14 projects	
Wave 1: Report December 2016	
IV therapy consumables	Syringes - hypodermic luer slip **A**
IV therapy consumables	Blunt drawing up devices - no filter **A**
IV therapy consumables	Blunt drawing up devices - with filter **A**
Oxygen therapy	Open suction catheters **A**
Oxygen therapy	Open suction tubing **A**
Gloves	Examination gloves non sterile **A**
Gloves	Examination gloves sterile. **A**
Wave 2: Report January 2017	
Wound care & dressings	No sting skin barrier film **C**
Wound care & dressings	Gelling fibre dressings **C**
Wound care & dressings	Film & film island dressings **C**
Wound care & dressings	Medical adhesive tape **C**
Wave 3: Report February 2017	
Blood Collection	Single use tourniquets **B**
Urology consumables	Urine drainage bags – sterile **B**
Urology consumables	Urine drainage bags non sterile **B**

Phase 2 - 15 projects	
Diagnostic consumables	ECG electrodes – diagnostic **B**
Diagnostic consumables	ECG electrodes – monitoring **B**
Bed/Chair protection	Procedure under pads **C**
Wipes	Patient skin cleansing - dry **C**
Wound care and dressings	Bandages - compression not included **C**
Wound care & dressings	Hydrocolloids **C**
Wound care and dressings	Foam **C**
Wound care & dressings	Non-woven Island **C**
IV therapy consumables	IV Line fixation devices (peripheral & central) **C**
IV therapy consumables	Gravity admin sets – blood, **A**
IV therapy consumables	Gravity admin sets – solution **A**
IV therapy consumables	Safety hypodermic needles **B**
IV therapy consumables	Needle free extension sets **B**
IV therapy consumables	Extension lines **A**
IV therapy consumables	Needle free connectors **B**

Phase 3 & 4 and beyond – 40 projects			
Oxygen therapy	Yankauer suction tubes	Infection Control	Wipes – Skin: skin prep, wet
Oxygen therapy	Bag valve masks	Infection Control	Wipes - Environment
Oxygen therapy	Nebuliser	Infection Control	Wipes - Instrument
Oxygen therapy	Oxygen masks – Venturi	Infection control	Hand hygiene
Oxygen therapy	Oxygen masks–non re-breath	Medical packs	Cannula
Oxygen therapy	Oxygen tubing	Medical packs	Catheter
IV therapy consumables	Pre-filled syringes	Medical packs	Wound care
IV therapy consumables	Cannula peripheral non-ported	Diagnostic consumables	Thermometry
IV therapy consumables	Cannula peripheral ported	Diagnostic consumables	Safety lancets (blood collection)
Wound care & dressings	Medical swabs	Diagnostic consumables	Specimen pots: faeces, sputum, urine
Wound care & dressings	Tissue adhesives	Diagnostic consumables	Blood pressure cuffs - disposable
Wound care & dressings	Wound closure strips	Diagnostic consumables	Blood pressure cuffs - re-usable
Wound care & dressings	Dressing pads	Diagnostic consumables	Gels - ultrasound (electrodes)
Wound care & dressings	Hydrogel	Diagnostic consumables	Gels - lubricant (electrodes)
Wound care & dressing	Super absorbents	Continence care	Body worn pads and pants
Clinical waste products	Clinical waste containers	Dietetic / Enteral feeding	Syringes single patient use
Urology consumables	urinary catheters – short term	Dietetic/ Enteral feeding	Syringes single use
Urology consumables	urinary catheters – long term		
Urology consumables	urinary catheters – intermittent		
Urology consumables	Urine meters		

*NB: This work plan is correct at December 2016 and may be subject to change.

Appendix 2 – NHS Clinical Evaluation Team Charter

*'**Quality, safety** and **value** are at the heart of our work and it's important that we use our clinical experience to deliver high standards of care while **reducing cost and waste** in the NHS. The financial strain on the NHS is considerable, and I am confident that the NHS Clinical Evaluation Team is uniquely placed to address this by effectively evaluating product ranges. I believe the team's work will have a huge impact'.*

Mandie Sunderland

Purpose

A national team to support the delivery of quality clinical products to frontline staff:

- To work for the NHS to independently define criteria and evaluate everyday healthcare consumables, identifying product ranges important to delivering high quality patient care, particularly where use is high and where there is a wide range of products available.
- Credibility through a transparent, evidence based clinical criteria and evaluations with an emphasis on quality, provided through an independent process undertaken for the NHS, by the NHS.
- A consensus on quality and safety focusing on NHS requirements, engaging widely and collaboratively with all stakeholders.

The Nursing Midwifery Council code states:
6.1 'Nurses and midwives must make sure that any information or advice given is evidence based, including information relating to using any healthcare products or services'.
The Health and Care Professions Council (HCPC) standard of conduct and proficiency states:
6.1 You must take all reasonable steps to reduce the risk of harm to service users, carers and colleagues as far as possible.

Outcomes and objectives:

- To support efforts to deliver to the NHS high quality everyday healthcare products that meets NHS defined requirements, clinical confidence, sourced on a national scale securing best value for the NHS, improving patient experience and confidence trough a transparent process, enhancing continuity of care, removing unnecessary variation with NHS volume compressing market prices.
- To make it as easy as possible for frontline NHS staff to pick the right product for safe, effective patient care every time they need to.
- To work together to ensure that all NHS clinical staff have the voice in determining product choice, maximising and optimising opportunities to make savings for the NHS in places other than the frontline.

Outputs:

- To report project outputs and findings through the publication of clinical review report, including a full product assessment results matrix, validated by the team members (and, where appropriate, Critical Friends) and approved by the Clinical Reference Board.
- To make all output and reports freely available – local, regional, national.
- To define a process, clinical pathway, toolkit with appropriate stakeholder engagement and governance.
- To define and deliver a product work plan, with clear timelines, identifying product ranges.
- To apply our critical path and toolkit, in the first six months, to NHS Supply Chain products.

Background and context:

Lord Carter's report on unwarranted variations makes reference to a single NHS catalogue, which provides a high quality, national catalogue of goods where **Trusts can have confidence** both in the range, quality and price at which they are procuring.

National category strategies are being developed that involve range rationalisation and price re-competition in a number of key product areas. This will require independent, clinically driven, product testing and evaluation capability to be established. This will ensure the NHS can confidently adopt the outcomes of these processes and switch products where appropriate, unless a clinically agreed exception exists.

Team members, roles and responsibilities

Sponsor: Mandie Sunderland – Chair of the Clinical Reference Board

Clinical Programme Lead – Dr Naomi Chapman

- To lead the clinical specialist team, supporting the team to manage the specific clinical specification and evaluation projects and work plan, taking into account existing national guidelines (e.g. NICE) and best practice, involving the product users (including patients) at every stage.
- To advocate clinical involvement, developing 'Critical Friend' stakeholder network and linking with professional organisations, as appropriate, RCN and the 'Small Changes, Big Differences'
- To be the team's representative on the Clinical Reference Board, to co-ordinate and present for discussion recommendations by the NHS Clinical Evaluation Team for approval.
- To act as an ambassador for the programme, giving talks and presentations, responding to requests for information, managing the communications delivered by the team.

Clinical Specialist Leads – Simon Hall, Liam Horkan, Sian Fumarola, Stephanie McCarthy, David Newton, Clare Johnstone, Jillian Best, Marc Naughton

- To manage (and act as the main point of contact) specific clinical product specification and evaluation projects, taking into account existing national guidelines (e.g. NICE) and best practice, involving clinicians and patients and to deliver their work plan on time.
- To utilise established communities of practice/professional organisations and other networks to understand NHS requirements, support product specification and evaluations.
- To review relevant product information and effectiveness data as required, undertake appropriate clinical evaluations and provide written reports including data analysis within required timescales.
- To remain independent of commercial interest with reference to the NMC Code of Practice.

DH Programme Lead – Liz Wright

- To act as the DH programme lead interfacing with the DH Future Operating Model (FOM) team to ensure the team's independence and adherence to ongoing strategies.
- To establish DH governance and approval, ensuring robust and transparent procedures for the programme are developed and adhered to.
- To work with the team and NHS Business Services Authority (NHSBSA) to develop a communications strategy, including a brand identity which builds confidence in the programme.
- To embed the team's role and process into current activity and to future proof, ensuring the programme evolves in line with business strategies and in preparation of transition to FOM.

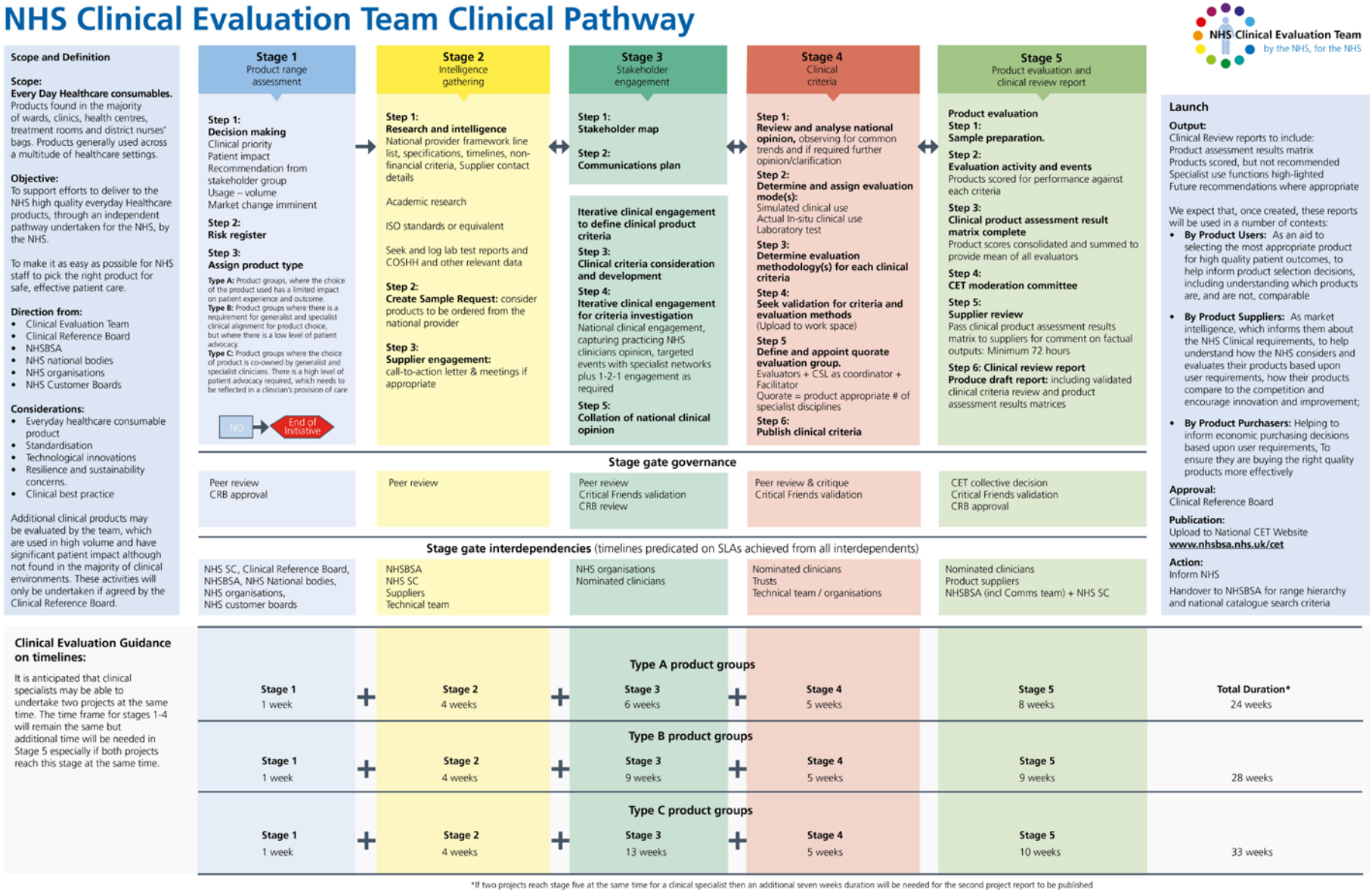
DH Operational Delivery Lead / Procurement Specialist – Sally Fenwick

- To act as lead on engagement with the NHSBSA, managing expectations and procurement deliverables
- To work with the NHSBSA and NHS procurement provider for action.
- To define and develop programme structures, templates, process, critical path, risk register, SOPs and audit trail, ensuring rigorous, disciplined, consistent methodologies.
- To work with team to develop work plan, with timings and commercials and programme structures.
- To develop programme plan with RACI and timelines.
- To embed the team's role and process into current activity and to future proof, ensuring the programme evolves in line with business strategies and in preparation of transition to FOM.

NHSBSA Stakeholder Lead – Ros Burkinshaw

- To ensure alignment with Customer Board strategies and ways of working, including all central messaging.
- To facilitate NHS Clinical Evaluation Team and Clinical Reference Board activity.
- To be central point of contact for communications, events matrix and expressions of interest.

Appendix 3 – NHS Clinical Evaluation Team Pathway



Appendix 4 – Glossary of Terms

“CET” or “team”	the NHS Clinical Evaluation Team;
“Clinical Reference Board” or “CRB”	the Clinical Reference Board established and maintained by NHSBSA, about which more information can be found at https://www.nhsbsa.nhs.uk/nhs-procurement-stakeholder-boards;
“Clinical Specialist Leads”	the team’s clinical specialist leads from time to time;
“DH”	the Secretary of State for Health, otherwise known as the Department for Health;
“FOM”	the future operating model for the national procurement of consumables;
“Lord Carter Review”	the report entitled “Operational productivity and performance in English NHS acute hospitals (DH 2016)”, led by Lord Carter;
“NHSBSA”	the NHS Business Services Authority;
“NHS Supply Chain”	DHL Supply Chain Limited;
“NHS Customer Board”	the NHS Customer Board for Procurement and Supply established and maintained by NHSBSA about which more information can be found at http://www.nhsbsa.nhs.uk/CommercialServices/4945.aspx
“Trusted Customer Programmes”	the trusted customer programmes established and maintained by NHSBSA;
“Work Plan”	the team’s work plan as set out in Appendix 3.