BOA Professional Guidance to Implement Getting it Right First Time in England

February 2016

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Contents

Foreword

The GIRFT Report, by Professor Tim Briggs, gives Trauma and Orthopaedic (T&O) departments information on the features of the best performing units that demonstrably provide high quality care. These are listed in the report's appendices and include dedicated theatres, clean air delivery, skilled T&O support staff in theatre and ring fenced beds. These could usefully be discussed within several hospital trusts to facilitate improved care.

Following the report, the GIRFT Programme has been adopted by the Department of Health and NHS England. Its solutions will now be implemented, enabled by the provision of performance dashboards for each unit, and may require us to alter the way that we practice. The process will also be supported by surgeons sharing their NJR data with unit colleagues.

So far GIRFT has concentrated on elective orthopaedics and arthroplasty but is now being applied to trauma, spine and nearly all surgical specialties. The recommendations are not prescriptive and will require pragmatic interpretation within units. The purpose of this process is to encourage constructive contemplation of the practice of units and surgeons rather than to dictate to them how they should practice.

The aim of this guidance is to help T&O Surgeons and departments assess their practice and ensure that they are compliant with GIRFT principles. We believe that this will facilitate high quality local governance, aid effective appraisal and optimise local care delivery.

In the modern health service in the UK, individual T&O surgeons should probably *not* be performing all, or nearly all, elective and some trauma procedures – the distribution of particular procedures needs to be carefully optimised to allow all our patients to get the best care available. Implant selection should be patient appropriate and should also be considered in the context of the needs and limitations of a department. If you need to hire in equipment and instruments to perform a procedure, then consideration should be given as to whether the procedure could be performed more effectively elsewhere.

The BOA believes that changes to practice must be carefully considered, and implemented at a scale and pace which is manageable and in the best interests of improving patient care. We also understand that achieving this may require further advice and support, which we are, of course, happy to provide.

Our sincerest thanks go to all who have contributed comments and advice during the development of this guidance. Production of this guidance has benefited tremendously as a result of advice from various BOA committees, the BOA Council and specialist societies.

Yours,

Tim Wilton
BOA President

Executive Summary

The GIRFT programme in T&O has been adopted by the Department of Health and NHS England. The report identified both variation and scope for quality improvement in terms of procedure volumes, implant selection and infection rates. It will now be implemented, enabled by the provision of performance dashboards to each unit, and may require us to alter the way that we practice. Other broader resource management issues raised in the GIRFT report, for example the need – strongly supported by the BOA – for ring fenced beds for orthopaedic patients, the cost per orthopaedic spell of litigation, and the paucity of rehabilitation facilities, will be addressed separately by the National Director for Clinical Quality and Efficiency via the DH and NHS England. While we will continue to use our influence to promote ring fenced beds in particular, the associated levers of delivery lie outside the direct ambit of the BOA.

The BOA recognises that it may not necessarily be apparent to surgeons how GIRFT will affect or be implemented in their practice. This document aims to provide appropriate clarity. All recommendations in this guidance should be considered with the caveat that it is essential to maintain a comprehensive T&O service comprising both urgent and elective care.

GIRFT, and therefore this guidance, concentrates to a large extent on planned, or elective, orthopaedics in a number of high volume areas such as hip and knee replacement. The GIRFT dashboards will reflect this and provide a useful starting point, in conjunction with parallel consideration by individuals of their own registry data, for evaluating practice at unit level. This should form the basis for a departmental discussion about the relevant aspects of unit practice on a regular basis.

In relation to procedure volumes, we do not prescribe a simple minimum figure – it is for units to determine their own optimum volumes. However, the BOA's view is that it is good practice for surgeons who are performing low volumes of a specific procedure to examine their practice with particular care.

For implant selection, the BOA is clear that some variation is acceptable – provided it is not detrimental to patient outcomes or Trust finances. However, in some units change will be necessary. In such cases, any decision to change implants must have clinical support and any discussion to alter implant selection should consider the potential adverse consequences of doing so.

For infection, the GIRFT recommendations should be implemented in full if the data provided, once validated, highlights an infection problem within a unit.

1. Scope of this Guidance

1.1. The GIRFT programme has been adopted by the Department of Health and NHS England. Implementation of the report recommendations is now going ahead and will require feedback from units, and may require us to alter the way that we practice.

1.2. Initially GIRFT concentrated to a large extent on elective (planned) orthopaedics in a number of high volume areas (e.g. hip and knee replacement) where the majority of treatment is carried out well in hospitals of varying sizes. Similar attention and scrutiny in other areas (e.g. spinal surgery and trauma care) will be equally important. Detailed guidance on those areas will be developed as and when suitable comparative data are available from around the country. This guidance should be considered with the caveat that it is essential to maintain a comprehensive T&O service comprising both elective and urgent care. In some areas pragmatism may be required.

1.3. The BOA recognises that it may not necessarily be apparent to surgeons how GIRFT will affect or be implemented in their practice. This document aims to provide appropriate clarity: it offers a framework for units and surgeons, individually and collectively, to examine their own practice, respond to and address any issues that might arise. This should form a routine element of clinical governance, as well as appraisal. The objective should be for all units to reach consensus on their pattern of healthcare delivery and on optimum procedure volumes.

1.4. Designed to facilitate discussion between T&O surgeons on issues of clinical practice, this guidance may well inform broader decision making processes, although this should only be done on the basis of clear clinical judgement. In cases of any doubt about the application of this guidance the T&O Clinical Director should contact the BOA Professional Practice Committee via policy@boa.ac.uk. For complimentary guidance on any wider decision-making related to T&O, please see the 2015 report by Monitor, *Helping NHS providers improve productivity in elective care.* This report was co-badged by the BOA and Royal College of Ophthalmologists and contains a number of options for improving efficiency.

1.5. The guidance is applicable to all surgeons undertaking independent operative practice, including SAS surgeons and senior trainees. It is designed to:

- **Support** both units and individual surgeons in arriving at an optimum volume of procedures;
- **Provide a framework** with which to arrive at **rational implant selection**;
- **Provide suggestions to avoid adverse events, with particular reference to infection rates**.

1.6. Just as revision/complex arthroplasty and spinal services require that the serving orthopaedic community has the appropriate, comprehensive skill set and volume of work to produce good outcomes, a similar comprehensive skill set in fracture management is essential to providing a satisfactory trauma service. Whether the complex orthopaedic trauma is dealt with at a major trauma centre or at another unit, the necessary skill set needs to be made available and utilised, for example through intra- or even inter-departmental referral patterns. Clearly the most effective and appropriate treatment could sometimes involve referral from a smaller centre to a larger one, but may also involve referral in the other direction.

2. How to use this Guidance

2.1. This guidance and any resulting change to surgical practice should be implemented through discussion within, and where necessary between units. The aim will be to achieve a consensus. Further guidance on achieving consensus by using data is provided in Appendix 1. If you need support in implementing any of the suggested steps below, or encounter any issues with Trust management, advice and practical assistance is available from the BOA via policy@boa.ac.uk.

2.2. The data provided by the GIRFT dashboards constitute a useful starting point. They should form the basis for a departmental discussion about the relevant aspects of unit practice on a regular basis. Refreshed dashboards will initially be published every six months and there is an ambition to publish data on a quarterly basis in due course. NJR data will also be available, though there may continue to be some temporal inconsistency between the two data sets as they currently cover overlapping time periods.

2.3. Units are strongly recommended to use existing divisional meetings as the forum for formal, in-depth, discussion of the data. At the same time, individual surgeons are strongly encouraged to review their own registry data and share their results and reflections with unit colleagues. Given the frequency with which the data will be published, we recommend that units plan for discussions to be held on a six-monthly basis initially. Discussion can then be held on quarterly basis when GIRFT and NJR data flows allow.

2.4. We invite Clinical Directors to call for a meeting in April/May 2016 for an initial discussion of GIRFT and NJR data. This will coincide with publication of a new PDF formatted GIRFT dashboard in April 2016, and updated NJR reports. In addition to this meeting, we encourage surgeons to review their NJR data, and share it with unit colleagues.

2.5. Each meeting need not necessarily cover every aspect of the dashboard. We anticipate that in many units the data will take a full session to discuss adequately in order to identify a suitable action plan where that is required.

2.6. There may be circumstances when no action is required if the whole department is entirely content with all the data presented, the position of each surgeon and that of the whole unit against the national benchmark.

2.7. All discussion of data within the implementation framework of GIRFT is consistent with the principles of the BOA's position statement on outcome data, T&O surgeons and units. Specifically, this guidance embodies the ethos that: "all individuals or units that are highlighted as having variance issues… must act upon this information to review their data, consider the reasons for variation and whether any further action or alteration to practice is required". [1]

[1] British Orthopaedic Association (2016) *Outcome data, T&O surgeons and units: a background and position statement from the BOA*

3. Optimising Procedure Volumes in Planned Care

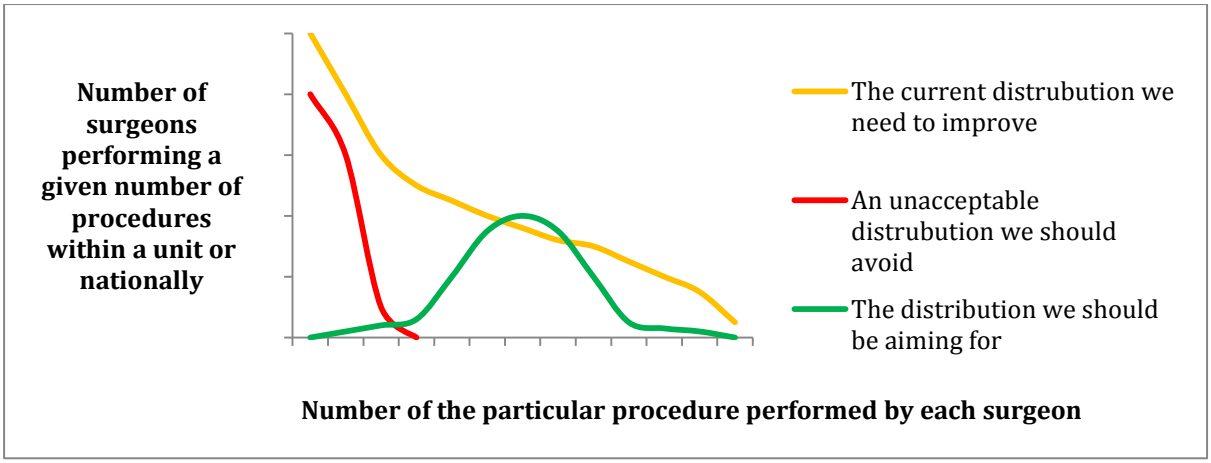
3.1. A unit's or surgeon's experience of a given procedure can affect the quality of the outcome for that procedure. Performing low numbers of cases may often be, but is not invariably (e.g. for rare conditions that present infrequently), associated with less good outcomes in many studies of surgery. In addition, most surgeons would choose the surgeon to whom they might refer a patient based on the volumes of procedures performed by that surgeon, as well as their experience.

3.2. The BOA's view is that it is good practice for surgeons who are performing low volumes of a specific procedure to examine their practice with care, reflect on the potential patient safety consequences, and actively consider whether continuing to perform the procedure is professionally appropriate. Clearly there will be situations, for example unusual conditions in which the surgeon may have an established expertise and where they have as good outcomes as can reasonably be expected, when the surgeon may be felt quite justified in performing low numbers of cases. Low volume surgeons should nevertheless consider whether they should undertake complex cases within their normal practice, in particular those cases involving unfamiliar techniques or technologies. In these cases, surgeons should consider onwards referral either internally or externally.

3.3. Accordingly, we suggest that with the arrival of each GIRFT dashboard, it should be standard practice for the unit to examine the numbers performed by each surgeon and the unit as a whole, and to compare these with the benchmark of the numbers performed by surgeons across the country. NJR data should also be used as part of this process, and it will be important that surgeons share their data with unit colleagues.

3.4. We recognise that surgeons in some units may feel that these discussions cannot be held with all their colleagues for one reason or another. While it may be reasonable in some cases to limit the discussion about a surgeon's results to their own appraiser, the Clinical Director, or even a trusted senior colleague, this should be considered exceptional. In these circumstances we believe it would also be appropriate for that whole department to reflect on whether these difficulties are a sign of more fundamental inter-personal issues, which need to be addressed in the interests of proper professional functioning.

3.5. The diagram on page six illustrates a comparison of procedure volume distributions, illustrating the hypothetical numbers of surgeons performing different volumes of a procedure. The yellow line indicates the unsatisfactory current distribution of numbers by surgeon for many procedures in the country, which this process seeks to improve. The green line shows an acceptable, broadly normal, distribution which the BOA considers T&O surgeons should be aiming to achieve in time. It shows surgeons mainly performing a reasonable number and few (if any) in any unit performing very small numbers. The red line shows what might reasonably be described as an unacceptable distribution, that T&O surgeons should aim to avoid. Several surgeons in the unit are performing very small numbers and no surgeon performing more significant numbers. To assess your unit for low numbers, compare the distribution in your unit to the distribution illustrated by the green line in the diagram.



3.6. It is clear that a simple minimum number would be inappropriate since this would depend upon the nature of the procedure. If the unit or individual surgeon routinely performs numbers at the lower end of the distribution discussion should occur at the meeting, or with the Clinical Director or his/her clinical appraiser, about whether the outcomes of those cases are better or worse than average. Reoperation rates and revision data will be one outcome; others may be used where suitable comparative data are available.

3.7. Bear in mind that, due to the wide confidence intervals of the data where low numbers are done, while a better than average revision rate provides some reassurance, it is certainly not a definitive confirmation that the surgeon's performance in that procedure meets the standard required. Indeed, for surgeons performing very low numbers it is probably necessary for them to be at the bottom of the funnel plot (i.e. showing no revisions/failures) for it to be reasonable that they continue performing the procedure if higher volume colleagues, with good outcomes, are available. We should consider every patient who experiences an untoward result to be important.

3.8. The purpose of this process is to optimise patient care, which may involve reducing low-volume operating by surgeons and units. It is guided and modified by outcomes such that a low volume surgeon who has good outcomes (perhaps being senior but with a high life-time experience) would not be penalised by the process. There is some evidence, though, that surgeons starting their career and those approaching the later part of their career may be more prone to errors and unsatisfactory performance. It is important, therefore, that those surgeons remain especially alert to this potential problem.

3.9. After assessing the data it is likely that each unit and individual surgeon will fall into one of four categories; these situations would need to be addressed in various ways as outlined in the flow chart on page eight. The categories are:

- High volume and good outcomes;
- Low volume but good outcomes;
- Low volume and poor/doubtful outcomes;
- High volume and poor/doubtful outcomes.

3.10. The BOA anticipates that if surgeons with very low volumes for a procedure refer to higher volume surgeons, there will be only a modest, and therefore containable, impact on the distribution of trauma procedures.

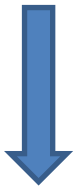
3.11. Although there may be exceptions, it is not normally good practice for there to be only one surgeon performing a given procedure in a unit. Accordingly we anticipate that, for low volume procedures, two-surgeon operating will be necessary to maintain good practice whilst improving the distribution of procedure numbers. If this were to have a potential impact on 18 week referral-to-treat targets, trusts should be encouraged to acknowledge the need for justifiable under-achievement against RTT in order to facilitate improvements in patient care.

Flow Chart for Optimising Procedure Volumes

Assessment

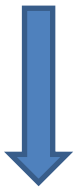
Consider:

- **Are volumes low at unit or surgeon level?**
- **Is the performance of the unit/surgeon against relevant indicators satisfactory?**
- **Are complex cases being completed at low volume?**



Category

- **Category 1**: High volume and good outcomes
- **Category 2**: Low volume but good outcomes
- **Category 3**: Low volume and poor/doubtful outcomes
- **Category 4**: High volume and poor/doubtful outcomes



Next steps for each Category

- **Category 1**: No further action required. Continue routine monitoring.
- **Category 2**: Where applicable, discussion should be held with surgeons in unit performing low numbers (i.e. at the unit specialty meeting). This should assess their results and procedure volumes and address whether they should refer procedures to a higher volume surgeon in the unit. If whole unit numbers are low, it would be logical to discuss with nearby units about whether cases should be referred onwards.
- **Category 3**: Further whole unit discussion is needed to assess causes of poor results, referring to all relevant data and the provisions of this guidance pertaining to infection rates and implant selection. The unit should consider contacting the BOA Professional Practice Committee (PPC) for further advice and consider referring cases to a high volume unit with good results.
- **Category 4**: Further whole unit discussion is needed to assess causes of poor results, referring to all relevant data and the provisions of this guidance pertaining to infection rates and implant selection. The unit should contact the BOA PPC for further advice and consider referring cases to a high volume unit with good results.

4. Rationalisation of Implant Selection

4.1. The GIRFT Report highlighted large variations in implant selection. As a result there is clearly scope for financial savings and especially so in more elderly patients where the more expensive implants may have little or no potential advantage. With multiple varieties of implant available, staff may remain unfamiliar with the different sets of equipment and inventory increasing the possibility of error. T&O units should therefore undertake regular reviews of their implant use and the associated costs. GIRFT has undertaken a review of implant costs and a letter has now been issued to all Trusts indicating those that should reasonably be incurred for use of primary cemented and cementless TKR and THR implants[2]. Many units may have been paying very substantially more than the indicative prices. This should be addressed through the tendering process and, if need be, by instituting a change in implants and rationalisation to an appropriate number of different manufacturers' devices.

4.2. Lower cost devices with good long-term provenance and high ODEP ratings should be used where possible. The ODEP ratings of implants used by each department will be a feature of the GIRFT dashboards.

4.3. The guiding principles should be:

- Any unit decision to change implants must have clinical support. There should be a clear, evidence-based, rationale for using a device which is not at the cheaper end of the scale and which has less than a 10A ODEP rating;

- It follows therefore that while variation in implant use is acceptable, it should not adversely affect the patient outcomes or the Trust's finances;

- Before a decision to change implants is taken jointly by clinicians and managers, the potential impact on patients due to the expected learning curve, the training costs, and other disruptions to patient flow should all be taken into account and discussed with the surgeons concerned. These factors will be important in determining the optimum way forward that best meets the needs of patients, surgeons and the unit.

4.4. The use of loan kits is expensive. While on occasion it may be necessary to call for special equipment, if this occurs regularly it adds both cost and risk to the procedure. On each occasion consideration should be given to whether it is correct to continue or perhaps send to a unit where the equipment is available and in regular use. When equipment is regularly ordered in, consideration should be given to arranging a formal contract of supply or sending the complex case to a centre which has the equipment available. Given the expense of loan kits, the number of cases in which loan kit is used should be seen as a key performance indicator for the cost-effectiveness of the unit.

4.5. Please note that the BOA is able to provide advice where implant selection proves contentious within units. An example of such advice is provided in Appendix 3.

4.6. The chart on page 10 summarises the steps we recommend to discuss possible rationalisation of implant selection.

[2] The text of the letter is provided in Appendix 2.

Rationalising Implant Selection Chart

1

Based on available information, Is the unit or surgeon using implants that:

- **Are more costly than alternatives**

and/or

- **Have an ODEP rating of less than 10A?**

2

- **If no**: no further action is required
- **If yes**: no further action is required *if there is a clear, evidence-based rationale justifying implant selection (eg. The use of an implant with an ODEP rating of 5A or 7A with very low revision rates).* ***Otherwise move to step 3***

3

- No further action is required *if changing implant would create unjustifiable training costs or disruptions to patient flow, or involve a learning curve which would threaten patient safety.* ***Otherwise move to step 4***

4

- Change implants selection if all relevant surgeons are in agreement. ***Otherwise move to step 5***.

5

- Review performance of surgeon(s) not in agreement and discuss in detail their concerns, ***then move to step 6.***

6

- Change implants selection if there is now consensus amongst all relevant surgeons.

OR

- Allow variation *if there is still disagreement and variation would not adversely affect patient outcomes or Trust finances*.

5. Avoiding Infection

5.1. GIRFT has shown that there is unacceptable variation in surgical site infection between units which could amount to as much as a 20-fold difference. GIRFT has also identified a number of potential solutions for both professionals and provider units to improve this infection problem, which are provided in Appendix 4.

5.2. On receipt of the dashboards, units should first ensure that the data are verified against their other sources of infection monitoring. If this is not the case they should feedback any discrepancies urgently to the GIRFT data team via jamie.day@nhs.net with a full justification for their comments.

5.3. If the problem is confirmed they should assess whether the GIRFT data indicate any scope for reduction of the infection rate and whether the problem relates to deep infection or superficial wound infection.

5.4. If it is clear from this discussion that a potential problem exists, the unit should:

- Determine immediately whether the GIRFT recommendations for reducing infection are currently being implemented in the unit;
- Develop a plan to implement those recommendations within the constraints of their unit;
- Highlight the concern to the Trust's Medical Director, insisting that a Trust-wide plan to implement the recommendations be implemented as urgently as possible;
- Notify the BOA PPC in any case and request assistance if needed.

5.5. The chart on page 12 explains the steps we recommend to discuss and, if necessary, address infection rates.

Reducing Infection Rates Chart

1	Check if GIRFT dashboard data is accurate using your own infection monitoring. If GIRFT data is inaccurate, report this to GIRFT team and explain the inaccuracy.
2	If GIRFT data is accurate, assess whether a possible problem with infection, especially deep infection exists.
3	If a potential problem with infection exists, assess whether GIRFT recommendations for professionals and providers are in place.
4	If GIRFT Recommendations are not in place: 1. Develop a plan to implement the recommendations within the constraints of unit 2. Insist a Trust-wide plan to implement the recommendations is adopted as urgently as possible.

Appendix 1: Reaching clinical consensus using data

1. The GIRFT dashboards can be used to identify variation in issues such as infection rates, implant selection, procedure volumes and many others. Unit investigation will necessitate inter-clinician discussion, in order to identify and agree any changes that may be needed to bring the variation under control. Investigating variation in this way allows suitably rigorous application of professional judgement. This is critical given the complexity of the issues involved, especially when there is:

    - A lack of any definitive causal evidence for significant variations. In this scenario applied clinical judgement will be essential;
    - An urgent requirement to develop a properly validated approach to remedy those variations.

2. Unit level discussion of data aimed at reaching consensus on an optimum T&O health care pattern will require a structured approach. When the GIRFT dashboard data identify variation, the causes will warrant further constructive investigation. The objective here is to bring unhelpful variation under control.

3. The variation to be discussed will be specific, non-random and indicated by the unit or surgeon being a statistical outlier. This is known as special cause variation.

4. Given the richness of information available on the dashboards and from other sources, discussion of special cause variation on any measure will necessarily involve cross referencing with other data , such as local infection monitoring, to:

    - Consider and assess the accuracy of the measurement in question;
    - Establish possible causes of the variation and the resultant options to improve patient care.

5. For example, if the GIRFT dashboard indicates that your unit has a high revision rate, a reasonable investigation of the apparent special cause variation may consider:

    - Any internal records of revisions to verify the accuracy of the data;
    - Procedure volumes, individual surgeon outcomes and implant selection to identify the possible causes of the high revision rate and the potential quality improvement options available.

6. It follows that this is continuous improvement activity aimed at incremental yet appropriately rapid care quality enhancement whenever the circumstances so warrant.

Appendix 2: Text of Royal National Orthopaedic Hospital letter entitled "Raising Transparency of Pricing for Total Hip and Total Knee Replacements: A National Pilot on Value for Money for the NHS in Orthopaedic Procurement" (11th June, 2015)

"Dear Colleague,

Raising Transparency of Pricing for Total Hip and Total Knee Replacements: A National Pilot on Value for Money for the NHS in Orthopaedic Procurement

I write on behalf of The Royal National Orthopaedic NHS Trust who have been commissioned to deliver the Getting It Right First Time Orthopaedics Clinical Delivery Programme by and on behalf of the Department of Health.

As past President of the British Orthopaedic Association I have visited over 120 Trusts (incorporating 205 Hospitals) as part of the Getting it Right First Time pilot. During the visits initial conversations highlighted to me that there is, potentially, a significant variation in the cost of Hip and Knee replacement Implants between Trusts. As a consequence I have been liaising with NHS providers, the National Joint Registry, NHS Supply Chain and a number of member organisations serving different groups within orthopaedics in order to seek greater transparency on the subject.

Furthermore, in August 2013 the Department of Health published Better Procurement, Better Value, and Better Care and established a National NHS Procurement Efficiency Programme to deliver it. Dr Dan Poulter MP emphasised the need for improved data, information and transparency to highlight significant price variations, and how the development of clinical partnerships could help to tackle this whilst ensuring quality is continuously improved. Orthopaedics was identified as one of the areas which could benefit from this approach.

We are therefore working together to look at how we might drive better procurement by establishing clinical partnerships.

As part of this work we believe that the starting point would be to bring about transparency, and have been working with NHS Supply Chain and the Business Services Authority to look at NHS Supply Chain data to identify the price range paid for the prostheses and equipment for three different orthopaedic procedures[3] namely:

- Cemented Primary Total Hip Replacement
- Uncemented Primary Total Hip Replacement
- Cemented Primary Total Knee Replacement

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[3] The price range variation illustrated in this letter is based upon the most widely used implants as identified from data within the National Joint Registry (2013), with pricing information provided by NHS Supply Chain from mini-competitions for the systems detailed. All mini-competitions included a standard supplier representative service, consigned implant and instrument stock provided by the manufacturer, and commitment to volume over 12 months. It should be noted that for many systems the standard price covers a core range of stems and that pricing may increase significantly for non-core range items. Whilst all efforts have been made to obtain up-to-date and complete pricing, for the avoidance of doubt neither the Department of Health (or any of its officials, agents or advisers), The Royal National Orthopaedic NHS Trust nor myself makes any warranty or representation (whether express or implied) concerning the pricing data referred to in this letter, or the accuracy or completeness of such pricing data."

It is important that the consultant orthopaedic workforce, senior managers and clinical directors within providers, as well as procurement staff, are aware of the existence of variation in pricing, and understand the variables which contribute to this.

The information for price range uses the most widely used implants (by NJR reported volume 2013) to provide the maximum and minimum pricing, with the lowest price that was made available for the NHS to use. There may well be other Trusts who are achieving still lower prices than those we have identified here and by improving transparency we hope to understand the true scale of variance.

It is important to realise that this process is ***not*** designed to pin every Trust down to using the cheapest implant on the market; quality outcomes are critical in the selection of particular implants in order to achieve a balanced view in terms of cost.

The prices shown are for a widely used range of implants of that type and are ***not*** for the cheapest implant available. However, given that this price is available for a commonly used implant we feel it represents a reasonable indication of what can be achieved.

In each Trust there may well be legitimate reasons why pricing is higher than at another Trust for the same implant, for example rebates may be attributed to the arrangement, the ability to accurately manage inventory or the procurement route may not be yielding the best pricing.

It is important to understand what variables in your Trust are contributing to the pricing you achieve. We therefore hope that the pricing we have provided will initially allow you to consider whether you are buying in the minimum or maximum ranges, and prompt you to question these variables and work with your clinical colleagues, procurement staff and suppliers to firstly understand these variables and secondly determine how these may be minimised.

Primary Cemented Total Hip Replacement

• The price range variation for the most widely used implants for **primary cemented hip with an acetabulum, femoral stem, and metal femoral head** is £595 to £854 (exc. VAT) *.

• The prices of the **cement restrictor and the mixes of antibiotic loaded cement (including the mixing system)** are not included in the prices shown, as these are frequently supplied separately. The price range variation for a cement restrictor is £36.70 to £72.37 (Exc. VAT)* and the price range variation for **three** mixes of bone cement is £123 to £270 (exc. VAT)*.

Caution should also be exercised if using implants indicated for use in revision procedures as primary implants, as this can increase the procedure cost significantly[4].

Primary Uncemented Total Hip Replacement

• The price range variation for the most widely used implants for a **primary uncemented hip with an acetabulum, polyethylene liner, femoral stem and metal femoral head** is £1,266 to £1,977 (exc. VAT)*.

• The price range variation for the most widely used implants for **primary uncemented hip with an acetabulum, polyethylene liner, femoral stem and ceramic femoral head** is £1,457 to £2,219 (exc. VAT)*.

[4] Note provided by BOA not in original text : It should also be borne in mind that use of such a revision implant as a primary would probably constitute an 'off-label' use of the device

• The price range variation for the most widely used implants **for primary uncemented hip with an acetabulum, ceramic liner, femoral stem and ceramic femoral head** is £1,636 to £2,420 (exc. VAT)*.

• Given the cost of ceramic bearings, we would urge clinicians to consider all of the available evidence when deciding whether this bearing combination is the most appropriate on an individual patient by patient basis.

• **Primary hybrid Cemented / Uncemented combination Total Hip Replacement**

• The price range variation for the most widely used implants for a **hybrid primary hip with a cemented femoral stem, uncemented cup with a polyethylene liner, and a metal femoral head** is £1,097.49 (exc. VAT) and the highest sell price is £1,399.68 (exc. VAT)*.

• The price range variation for the most widely used implants for a **hybrid primary hip with a cemented femoral stem, uncemented cup with a polyethylene liner, and a ceramic femoral head** is £1,288.45 (exc. VAT) and the highest sell price is £1,641.58 (exc. VAT)*.

Please note that this "hybrid" is taking a cemented stem product and combining it with uncemented cup, liner and head products.

• The prices of the **cement restrictor and the mixes of antibiotic loaded cement (including the mixing system)** are not included in the prices shown, as these are frequently supplied separately. The price range variation for a cement restrictor is £36.70 to £72.37 (exc. VAT)* and the price range variation for **two** mixes of bone cement is £82 to £180 (exc. VAT)*.

Cemented Total Knee Replacement

• The price range variation for the most widely used implants for **primary knee replacement** is £943 to £1,674 (exc. VAT)*.

• This excludes one mix of antibiotic loaded cement (with the mixing system), the price range variation for this is £41 to £90 (exc. VAT)*.

It is also important to note that all prices stated exclude VAT. VAT is chargeable at 20% so the more expensive the Prosthesis the greater the cost of the VAT attributed to it.

As you may already be aware the National Joint Registry is now also incorporating pricing data from all Trusts into the registry. With the inclusion of this data we will shortly be exploring the pricing of hybrid solutions and will provide an overview of this information in a follow up letter. You can however, obtain a report for your specific Trust from the National Joint Registry which will provide you with your current pricing versus the national averages.

I would caution any provider wishing to impose the lowest price as a ceiling price. This approach could be clinically restrictive and have unfortunate consequences in terms of impairing well established high quality practice, and negatively affect surgeon morale. I would advise that a shared decision making process with the clinical orthopaedic team should be entered into prior to procurement for prostheses above any minimum threshold that a Trust might wish to establish.

The National Joint Registry Pilot consisting of data from 35 NHS Trusts and Local Health Boards across England and Wales identified that in some instances the prices paid do not always have any correlation to the volumes used. This will be reviewed further when the NJR gathers greater volumes of data. Furthermore, whilst I recognise that there may be situations when a more expensive prostheses may be the best choice, I am keen to encourage a level of scrutiny of the decision making process to ensure that the cost is justified.

We have a duty to make the best clinical choices for our patients but we also have a moral responsibility, during this time of financial austerity, to ensure that our choices allow for the less expensive of two equally good options to be our standard preference on all occasions. It is also vital, considering that the average age for patients undergoing lower limb arthroplasty is still 68 years (*NJR annual report 2013/14*), that we follow the evidence of the many registries available when making decisions about implant choice. With tariff deflation with us for a number of years, implant costs will become an ever more important issue.

It is my hope that this letter will assist in triggering greater debate amongst clinicians and managers and to seek a way forward that provides best outcomes for patients and best value for the taxpayer.

For the avoidance of doubt, nothing in this letter should be regarded as a representation on the part of the Department of Health, The Royal National Orthopaedic NHS Trust or I (or any other person) that a particular implant should be purchased.

Next steps

The Royal National Orthopaedic NHS Trust will be working with NHS Supply Chain, the Department of Health's orthopaedic procurement QIPP team and the National Joint Registry to provide a greater level of transparency and detail on prosthesis pricing. The aim is to empower clinicians in revaluating their prosthesis selection.

In pursuance of the Getting It Right First Time Orthopaedics Clinical Delivery Programme, the Royal National Orthopaedic NHS Trust are especially interested to hear from Trusts achieving very low prices or those paying the highest ones in order to share best practice and provide support**. I have also included a link to the Better Procurement, Better Value, Better Care document and the Getting it Right First Time Report for your information:**

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226835/procurement_development_programme_for_NHS.pdf

https://www.boa.ac.uk/wp-content/uploads/2015/03/GIRFT-Executive-Summary-Mar15.pdf

Yours sincerely
Professor Tim Briggs
Immediate Past President of the BOA
Chair of the National Clinical Reference Group in Specialist Orthopaedics
Chair of the Federation of Specialist Hospitals
Consultant Orthopaedic Surgeon Royal National Orthopaedic Hospital NHS Trust
For and on behalf of The Royal National Orthopaedic Hospital NHS Trust
The Royal National Orthopaedic NHS Trust is delivering the Getting it Right First Time (GIRFT) Orthopaedics Clinical Delivery Programme on behalf of the Department of Health

Appendix 3: Text of Letter Concerning Rationalising Knee Implant Use

Dear

Thank you for contacting the Professional Practice Committee regarding the difficulties that you have had in encouraging surgeons in your Trust to accept change to the prostheses used for knee replacements. The BOA cannot comment on individual surgeon's behaviour, but we are happy to clarify the principles that should be followed when asking surgeons to change prostheses and how these apply to knee replacement.

Orthopaedic departments should be encouraged to rationalise their prosthesis usage to deliver savings that can be reinvested elsewhere. As you will know, this is in line with the recommendations of the *Getting it Right First Time* (GIRFT) report.

Furthermore attempts to rationalise prosthesis use in knee replacement are well supported by evidence suggesting that all major systems produce similar outcomes. NJR data show that crude revision rates are broadly comparable across all major manufacturers for the most commonly implanted knee replacement systems. Combined with the reality of surgeon's preferences for systems varying, it is untenable to believe that one is inherently significantly "better" than all the others. To substantiate this point, the figures below show the all-cause risk of requiring a revision at ten years (unless stated) for six of the most common systems[5]:

- DePuy PFC 2.66% for 213,264 implantations
- Zimmer Nexgen 3.61% for 87,273
- Biomet AGC 3.43% for 57,603
- S&N Genesis 2 2.74% for 36,619
- Stryker Triathlon 2.40% **at 7 years** for 40,170
- Stryker Scorpio 3.72% for 24,978

It also follows from this evidence that, for the majority of surgeons, dependence on a particular instrument is not a sine-qua-non for the procedure in general, as good results can, in principle, is achieved with other systems.

However, decisions to rationalise prosthesis use should recognise that switching systems might not be straightforward for an individual surgeon. Partly this relates to the considerable familiarity with instruments, jigs, sizings and so forth built up over years, all of which have to be relearned. It is a well established principle that the introduction of any new system is associated with a learning curve. Inevitably the risks here could compromise patient outcomes in the absence of appropriate training. Positive engagement of the surgeons concerned is vital as they are unlikely to adapt well to a new system if under any sense of coercion or obligation.

Any decision to rationalise prosthesis use should also recognise that it might be more difficult for a specialist surgeon to adapt to a new system. For specialist knee surgeons systems need to have a range of options to extend the indications from the straightforward cruciate retaining or PS

[5] as reported in the 2014 NJR report

replacement (on which the data above will largely be based) to the more complex degrees of constraint, including the use of stems, wedges and hinges. Paradoxically, therefore, it might be more difficult for a specialist surgeon to become familiar with this range of options within a new system than it might be for a non-specialist knee surgeon, who simply needs to adapt to the technique used to deal with the more routine cases.

Despite these qualifications, a number of Trusts have been able successfully to rationalise their implant systems. This has been achieved through strong clinical leadership and full engagement of the department concerned.

If a surgeon feels strongly that they do not wish to change to a new system, we suggest that the Clinical Director carefully scrutinise the surgeon's results with their preferred system, as evidenced by NJR and any other data available. If the results are good and the costs of retaining the old system are not significantly greater than the costs of the new system, it would be reasonable to accept the variation and retain both systems for use.

This does not negate the obligation of surgeons to behave professionally and consider carefully whether being asked to change is appropriate or reasonable. Nor does it negate a surgeon's responsibility to declare any conflicts of interest that they might have with any of the companies concerned which, if declared, should not preclude their views being taken fully into consideration.

Yours sincerely

Mr. Tim Wilton
Vice President, British Orthopaedic Association
Chair, British Orthopaedic Association Professional Practice Committee

Appendix 4: GIRFT recommendations to reduce infection rates for Professionals and Providers

Audience	Recommendation
Professionals	• Discipline in theatres needs to be improved in some trusts and issues such as 'walk through' and too many people in the theatre need to be addressed. • Dedicated experienced specialist orthopaedic scrub nurses should be mandatory, and any new trainee should be adequately supervised by an experienced scrub nurse (as would be expected of a surgeon or pilot). • Dedicated orthopaedic theatres with laminar flow. • The whole theatre nursing team must know the procedure, be experienced in elective orthopaedic procedures (especially joint replacement), and work regularly in teams with the orthopaedic clinicians to maintain productivity and reduce complications.
Providers	• The creation of a 'cold' elective orthopaedic centre, either within an existing hospital environment e.g. Leicester (General site) or separate on the same site e.g. Princess Elizabeth Orthopaedic Centre in a dedicated unit. • Another model exists, for example, the Elective Orthopaedic Centre in Epsom or the RNOH at Stanmore. These units bring together groups of surgeons undertaking significant volumes of routine and complex cases. • All of these models can work well, but must have available the co-adjacencies that allow high quality safe care. This includes the appropriate medical care of the complex patient. Infection rates remain very low in these units and staff morale is high from both clinicians and managers proud of their results and outcomes.