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**Credit Author Statement**

Charlotte Davies: Conceptualization, Methodology, Software, Validation, Formal analysis, Resources, Writing original draft and review and editing

Stephen Davies: Methodology, Supervision, Draft writing – review and editing,

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## **Assessing competition in the hip implant industry in the light of recent policy guidance**

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## Key words

Competition, Total hip replacement surgery, procurement, implant, NHS, concentration, innovation

## Abstract

NHS procurement is a highly topical area, attracting a great deal of recent policy focus. The pivotal report by Lord Carter of Coles, 2016 highlighted unwarranted variation, estimating it to be worth approximately £5bn in efficiency savings. In relation to hip replacement surgery, recent procurement policy guidance has recommended the use of cemented hip implants for all patients aged 68 years and over in England and Wales. Previous work established that the hip implant supplying market was very concentrated, with only a few large suppliers, especially for cemented implants. The advocated major shift towards cemented implants would almost certainly increase further the market share of the dominant manufacturer of cemented sector thus raising potential competition and welfare issues.

We carry out a market study to establish whether there might be a potential competition concern, using data from the National Joint Registry (2005 to 2018, 37 suppliers, 672 models). We first establish the structure of the industry with a specific focus on seller concentration. Secondly we evaluate the dynamics underlying concentration in the market, assessing the innovative performance of the sector using a novel statistical analysis of the dynamics of market shares. We then look to three comparable but alternative markets for similarities or differences to the THR implant industry.

We find a high and increasingly concentrated oligopolistic and static market structure, largely devoid of dynamics and with no real sign of innovation. These findings are further emphasized when compared with the three close alternative markets.

Although this stability could just be a mature market where technical advances have already taken place, our findings highlight the potential welfare and policy implications of

concentrating on cemented fixation. Given the current emphasis on efficiency in procurement, it is essential that there should also be scrutiny of the firms dealing with public procurement.

Lord Carter of Coles, *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations*, Department of Health, Editor. 2016.

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## 1. Introduction

The overall objective of this paper is to assess the potential impact of recent policy guidance on NHS procurement, bearing in mind the state of competition between suppliers of the cemented implants used for Total Hip Replacement (THR) Surgery in England and Wales.

### 1.1 Policy perspectives

The NICE guidance of 2014[1] on THR, noted that there was considerable variation in the prices of the implants used. This was followed by two pivotal reports by Lord Carter of Coles, 2016[2] and the 'Getting it Right First Time', 2015[3] (GIRFT) initiative for which the pilot project focussed on Orthopaedics. Both reports highlighted unwarranted variations in prices paid across resource areas in the NHS. Focussing on THR, the GIRFT report suggested (amongst other things) that hospitals should specialise in implanting only a small number of brands and use cemented rather than uncemented implants for patients aged 68 years plus (this has since been supported by further studies[4, 5]). The Carter report also cited GIRFT guidance that if "75% of patients aged over 65 years received a cemented implant this would lead to an increase in 11,000 cemented implants per annum, generating a saving of £16 million per annum". A recent cost-effectiveness analysis by Fawcitt et al [5] reinforces these recommendations, finding that cemented implants are the most cost effective, and this result is generally robust across age groups and gender. A major reason is the lower cost of the cemented implants themselves (typically about £1300 cheaper than uncemented implants.) While the authors acknowledge that uncemented implants entail shorter surgery times (approximately 20 minutes), they argue that this is insufficient to offset the cost differential between implants. An earlier study, Griffiths et al [6] had also come to a similar conclusion, estimating NHS savings of at least £18.5 million per year by switching exclusively to cemented implants. However, they also acknowledge shorter surgery times achieved for uncemented implants, which are nevertheless insufficient to offset their higher cost.

While these reports all point in the same direction, by their nature, they all focus exclusively on the buying side of the market (NHS procurement). In the current paper we argue that the selling side is also important, and that a wholesale switch to cemented implants, driven by short-term cost savings, may have unintended adverse consequences.

Our starting point is previous work[7] which showed that, by 2010, the hip implant supplying industry was very concentrated, with only a few large suppliers, especially for cemented implants. Therefore, any major shift towards cemented implants would almost certainly increase further the market share of the already dominant manufacturer of cemented, Stryker Howmedica, raising potential concerns that competition on the supply side may be damaged - ultimately to the detriment of consumers. Competition theory tells us that increased concentration can have a variety of adverse consequences – not only increased prices, but also reduced incentives to develop and introduce new products.

In the present context of hip implants, this raises the possibility of two types of potential welfare trade-offs. First, for the NHS, there are indisputably short run cost savings to be gained from increased switching to cemented, but these might be gradually eroded over time if competition declines and an increasingly dominant supplier is able to raise future prices. Second, there is the possibility that the interests of hospital and patient might not be perfectly aligned. In a world of NHS tariffs, choosing the cheaper cemented, rather than uncemented implant earns the hospital a larger “profit” per patient, but as recognised by Griffiths et al [6, p. 1034], it might mean that surgeons can only undertake fewer operations (because of the shorter uncemented surgery times described earlier). If so, from the patient’s perspective, this may mean longer waiting times. Beyond this, if by concentrating its purchases on cemented implants, the NHS reduces the availability of product variety and, in due course, future innovation, this may be to the detriment of patients, both current and future.

## 1.2 Study Aims

This paper is analogous to a market study which might be undertaken by a Competition Authority (CA) – in the UK context, this is the Competition and Markets Authority (CMA). The overall objective is to establish whether there might be a potential competition concern, but without making any initial presumption that there necessarily is. The first specific objective is to establish how far the structure of the industry has changed over the last decade. We assess the state of competition in the market for cemented hip implants, first from a structural perspective paying particular attention to seller concentration in the market, which is widely believed to be a key variable impacting on product price, quality, productivity and innovation.

To anticipate, we do indeed find that concentration is high and rising, especially in the cemented segment, and this leads to our second objective, which is to explore whether this market dominance and high concentration necessarily signal adverse outcomes for consumers. We do this by evaluating the market dynamics underlying the high concentration: is it an inevitable outcome of vibrant competition between firms such that it is possible for different firms to gain market share rapidly by being more efficient and innovative than their rivals? While there may be only one or two firms that are dominant at any point in time, the identity of those firms may change. We explore this line of argument partly by evaluating the innovative performance of the sector, and partly with a novel statistical analysis of the dynamics of market shares.

The latter analysis is unusual, even in the investigations of CAs. A recent, highly influential example of a similar approach is Philippon[8], who distinguishes between “bad” concentration and “good” concentration, where “bad” reflects harmful market power, while “good” reflects the outcome of vibrant, beneficial competition, in which the dominant firms are only dominant because they are more efficient. Empirically, we explore which type it may be in this case by conducting regression analysis of the evolution of the firms’ market shares.



The third objective is to confront the possibility that high concentration is in some sense inevitable in this industry, given its technology and the nature of the market. We do this by looking to three comparable, but alternative, markets for similarities or differences: the uncemented segment in England and Wales, the THR industry in other countries, and the Knee Implant Industry in England and Wales.

### **1.3 Previous literatures**

This paper will contribute to a number of different literatures. The first is the broad area of NHS procurement. Here, although there has been extensive research and policy implementation, with regards to both the buyer and seller sides in the pharmaceutical sector, less is known about medical devices in the UK[9]. This is beginning to be addressed on the buyer side with the recent policy developments mentioned above - recommending a less disaggregated approach to procurement for example, by the introduction of procurement hubs in local geographical areas to exploit economies of scale.

Much more work on this has occurred in the USA with significant research into the impact of centralised procurement on competition in the health care sector[10, 11]. The USA market for health care is very different to other geographical markets in that there is a very limited use of government buyer power. Rising health care costs have led to calls for the federal government to make greater use of this buyer power, referred to as aggregation strategies. The theory is that these strategies can have positive effects over the competitive process, generating competition, lowering prices, generating operational economies of scale and reducing public expenditure. However, these benefits will only be felt if competition as a process is properly preserved. By aggregating purchasing or pooling purchasing, the buyer is able to exert buyer power in the form of monopsony and bargaining power. Advocates of this approach argue that aggregated purchasing which facilitates non-abusive bargaining power is justified, but not one where it generates monopsony effects as this may lead to inefficiencies. It should also be borne in mind that the supply side needs to retain sufficient power to charge a price above cut-throat levels.

There is also an expanding literature on competition issues in health [12-15] using THR as a clinical example. Baier et al[16] compare rates of surgery across districts in Germany, whereas Roos et al[17] use THR to explore the price effects of a hospital merger in The Netherlands. In the UK, Beckert and Kelly[18] use THR as a common elective procedure to investigate patient choice of provider following the introduction of for-profit providers; and, still in the area of competition and providers, Beckert [19] examines GPs pre-selected choice-set of provider for elective THR on behalf of their patient using Hospital Episode Statistics (HES) data.

However, to date, the only previous research on competition between implant suppliers and their interaction with the health provider is a preliminary analysis of the evolution of the market structure based on the first 5 years of NJR data (2003 to 2008)[7]. This established an emerging picture of the industry's structure revealing a very concentrated market in England and Wales with just two main suppliers (Stryker and Johnson & Johnson (J&J)) holding 65% of the market. The research also showed variability in the choice of implant according to the geographical location of the hospital and the hospital type. The current paper extends this earlier research by including data from 2009 to 2018, deepening the scope of the analysis, and focussing particularly on the cemented sector and the implications of GIRFT and Carter.

Finally, one other potential source of competition lies with generics where there is now an emerging literature on their use in THR surgery. As many of the established brands have come off patent, there is scope for entry of new generics which are similar to the originals by the process of reverse engineering. These implants would be cheaper to produce and for the hospital to purchase, even more so because they would potentially exclude the sales and marketing component of the cost, estimated to be approximately 40%[20]. Here a possible comparator is the Pharmaceutical sector, in which, generics are fully established, facilitating competition in many parts of that sector. In pharmaceuticals, the drug is defined as identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of

administration, quality, performance characteristics and intended use, thus genuine replication of the product is possible. The process of regulation in medical devices is much less stringent than for the pharmaceutical market, for example in Europe a supplier of a new device need only demonstrate 'equivalence data' whereby they have demonstrated that the implant is similar enough in design to an existing implant in order for it be provided with a CE mark and approved for use in clinical practice[21].

Nonetheless, there has been considerable resistance from some surgeons to the use of generics, specifically with regards to the testing of the processes of production and the tolerances of replicas. There is also resistance to the withdrawal of sales and marketing i.e. supplier presence (a member of the sales and marketing team for the manufacturer) in the Operating Theatre which would be implied by switching to generic implants. One interpretation of this is that the less rigorous standards is leading to less trust by surgeons, which in turn leads to them sticking to tried and tested standards. Some of this may have arisen from the metal on metal (MoM) scandal of 2010 where resurfacing surgery with MoM bearing surfaces were found to have significantly high revision rates than those with metal on polyethylene (MoP). This was thought to be due to adverse reactions to metal debris which was released from the bearing surface as the implant starts to wear[22, 23]. This scandal may well have made surgeons more risk averse to trying new innovations and therefore resistant to generic implants especially when (as some suggest) rigorous clinical evidence on effectiveness is lacking[24].

## **2. Methods and rationale**

### **2.1 Study design**

There are two stages to our analysis: first to evaluate various indicators of competition in the cemented hip implant segment; and second to assess these relative to three comparators: the uncemented segment, the knee implant industry, and hip replacement elsewhere in Europe.

Since our purpose is to investigate the extent of competition between suppliers in this market, we frame our analysis along the lines conventionally used by a competition authority (CA) when carrying out its investigations (into anti-competitive behaviour, significant proposed merger or market studies). In academic terms, many of the basics of competition law derive from the study of Industrial Organisation (IO) and Competition Economics. One of the key objectives of IO is to define and measure market power because this can lead to any, or all, of the following: lower product quality, restricted choice, slow innovation, barriers to entry as well as higher prices. This is reflected, in the UK policy context, by the CMA [25] which explains that “Competition is good for consumers and businesses. It means that people get better products at lower prices, and it helps ensure the most consumer-focused and innovative businesses are the ones that succeed.”

The typical approach adopted by CAs [26] when investigating a case involves three steps. They first define the market in an economically meaningful way so as to include all competing firms. Second, various aspects of the market’s structure are evaluated, notably concentration and the leading firms’ market shares, as measures of the degree of oligopoly; this may also address various dynamic features of the market structure, including how much new entry and exit occurs, and whether concentration is persistently high. Third, the CA then goes on to assess the impact of that structure on various aspects of market performance. (profits, price, quantity, quality, innovation and productivity etc.)

We apply this approach to the hip implant supplying industry, but with special emphasis on the dynamic aspects of structure and performance. Regarding industry structure, we employ a novel statistical methodology to examine what turbulence, if any, lies beneath the headline result of high concentration. This recognises that high concentration may be harmful in dampening competition, but it may also be the result of healthy competition, whereby the most innovative and competitive firms rise to the top. Regarding performance, we place the emphasis on innovation because product quality is arguably the most important feature of the product for the ultimate consumer – the patient.

In the second stage to our analysis, we step back and undertake three comparisons. These are designed to assess how our findings for the cemented sector are paralleled in other markets which should be broadly comparable in terms of technology and supply: the uncemented segment of the industry, the supply of knee implants, and the market for hip implants in other major European countries.

## 2.2 Data Source

Throughout this paper, we use publicly available data from the National Joint Registry (NJR). These data are derived from their online annual and subsidiary reports [27-37], which allow us to construct a panel database for 2005-2018 of the market shares of all firms and all implants used in the market. The strength of this database is the richness in its information on the sales of different individual brands and suppliers of implants. Not only does this allow us to construct a panel database of the sales of each supplier on an annual basis for a reasonably long time period, but also we can plot the ebb and flow of new models/brands over time. In turn, this gives us the information needed to measure the churn in firm market shares, and also new product innovation.

On the other hand, the database has no comparable data on the prices of the individual prostheses and suppliers. Since access to sufficient price data from other sources have so far proved elusive, this has dictated that the emphasis of this paper is on quantities, market shares and innovation, rather than prices. We discuss this further in the final section.

## 2.3 Key Variables

### *Market shares and the HHI concentration index*

Our assessment of the extent of competition in the market follows the approach used by CAs; in the UK, as set out, for example, in the Merger Assessment Guidelines[38] section 5. The conventional way of summarising market shares is to employ measures of the concentration of sellers. The most common measure is the Hirschmann-Herfindahl Index (HHI)[26, 39] which is defined as the sum of squared market shares of all firms[26, 39]. HHI

will vary between 0 and 1: a low value reflects a market with a large number of small firms while a higher value reflect a small number of very large firms – tending to 1 as the market tends to monopoly. A useful yardstick to bear in mind is the one used by CAs in the UK, EU and USA: a market is deemed to be highly concentrated if  $HHI > 0.2$ .

#### *Stability in market shares*

A competitive market is one in which firms are continually striving to increase profits and market share, and innovation and efficiency are rewarded by firms gaining (or losing) market share rapidly as a consequence of outperforming (or lagging behind) their rivals. As such, we should look for evidence of dynamic activity within the market, manifested either as significant entry of new firms and/or instability in market shares amongst existing firms. Levels or changes in aggregate market concentration will not necessarily capture that instability - in any given year, there will be some gainers and some losers, so the identity of the leaders may change, but the level of concentration might not.

In spite of relatively older research in the 1990s ([40, 41]), such turbulence of market shares amongst firms already in the market has often been overlooked. However, very recently in the academic literature, highly influential work, by Philippon and co-authors[8, 42], has employed such measures to show how competition in the US economy has seriously declined in recent decades[40, 41]. The international agencies are also becoming interested in a more dynamic approach, see for example a recent report by the OECD, 2020[43]. To capture the extent of instability – the ebb and flow in market shares - we also follow this route and go further than the typical competition authority by employing a quantitative approach which is novel in this area. This uses the stability of market shares amongst incumbent suppliers as a measure of the instability of competition (as described in section 2.4).

#### *Innovation: the number of new models including generics*

As a measure of how structure impacts on how firms behave and the performance of the market, we focus on innovation. There is a general presumption, and a balance of evidence, that competition has a positive impact on the innovative performance of firms in a market (for summaries of the evidence, see Gilbert [44]) or Cabral [39]. In this paper we examine (i) the number of new models (or ‘brands’) introduced on to the market and (ii) their success in penetrating the market. Fortunately, the raw data available in the NJR allows us to document both features very accurately. For this purpose, we define a potential entrant brand as one which had achieved a market share of at least 1% in its segment by 2018, but not having featured in 2005. We also look for evidence that entry (and/or) exit of generic brands of implants has occurred bearing in mind the emerging literature on the feasibility of such generic entry into the market for hip implants[20, 45].

## 2.4 Comparators

Having established a picture of competition in the market for cemented implants, an obvious question to ask is whether what we find might be expected, given the nature of the technology, and the nature of demand and supply for this sort of product. To answer this, we identify three other markets which should provide reasonable comparators (i) the other segment of the market itself, but using a different technology – uncemented implants, (ii) the same market, for THR implants, but in different countries, European Union, (iii) using a similar technology but a different medical application, Total Knee Replacement (TKR). Interestingly, all three involve essentially the same set of firms.

### *Uncemented*

The two main components of a hip implant are the cup and the stem, with a key distinction being made by the method of fixation used i.e. cemented or uncemented. Traditionally, implants are fixed to the bone with cement, however, as an alternative, the surfaces of the implants can be roughened or specifically treated to encourage bone to grow into them,

known as uncemented. Sometimes an implant might be a hybrid, where only one part of the implant is fixed with cement.

A key issue is whether cemented and uncemented implants compete in the same market. This was precisely the judgement that the European Commission had to make when defining the market in its investigations of mergers between implant suppliers (notably Zimmer and Biomet[46]). It judged that they were, recognising that cemented and uncemented implants are seen as substitutes on the demand side, and all main firms supply both cemented and uncemented components. Note however that this does not necessarily mean they are very close substitutes: surgeons may have a strong preference for uncemented over cemented implants for certain types of patients, and some suppliers may be stronger in cemented while others are stronger in uncemented. It is also worth noting that surgeons also need to make a choice between which bearings surface to use, where the bearing surface refers to the area of contact between the two objects. Traditionally, a hard-on-soft (metal or ceramic femoral head with a polyethylene cup) has been the preferred choice. However, more recently, hard-on-hard surfaces have been used (replacing the polyethylene cup with a metal or ceramic one) to improve the wearing over time which takes place with polyethylene. Although choice of bearings surface warrants further investigation too, it is beyond the scope of the work at this stage.

#### *THR in Europe*

International comparisons are often used when assessing potential interventions in competition economics, especially, as here, when demand and cost conditions are likely to be similar across countries. While there is no central repository for comparable international data, fortunately we are able to draw upon data published by the European Commission (EC) in its decision report on the 2014 merger between Zimmer and Biomet [46]. The Commission judged that the merger would have no anti-competitive concerns in the UK - the two firms were ranked 3<sup>rd</sup> and 5<sup>th</sup> largest with combined shares of only one-sixth of the UK market - although it had some relatively minor concerns in other member states in which the



two firms had more significant market shares, and these were remedied by minor divestments. For present purposes, however, our main interest is not so much with the EC's decision, but more with the data it reports on the market structure in the other European countries. As will be seen, these provide a striking contrast with England and Wales. We were unable to identify any information on implant prices aggregated or disaggregated or time series at the European level.

### *Total Knee Replacement (TKR)*

TKR is a surgical procedure where both sides of the knee are replaced usually due to some form of arthritic disease having taken place. It is the closest orthopaedic surgical procedure to hip surgery with both surgeries requiring an implant, many of each which are produced by the same manufacturers. The NJR also reports implantation rates yearly by brand and manufacturer for TKR to enable comparisons to take place. We were unable to identify any information on implant prices aggregated or disaggregated or time series for TKR.

## **2.5 Statistical Analysis**

Much of the statistical analysis in this paper employs straightforward graphical and tabular descriptive devices and the HHI index. However, the analysis of the dynamics of market shares (section 3.2) is more specialist and requires some explanation. We use panel data to look at year on year changes in supplier market shares over the 14-year period within each segment. Thus, we regress each supplier's market share against its market shares for the previous year:

$$x_{it} = \alpha + \beta x_{it-1} + \varepsilon_{it} \quad (1)$$

Where  $\alpha$  and  $\beta$  are coefficients and  $x_{it}$  is the market share for supplier  $i$  in year  $t$  (2005-2018) and  $x_{it-1}$  is the market share for supplier  $i$  in the previous year  $t-1$ .  $\varepsilon_{it}$  is the error term[8]. Philippon et al[8] use an AR(1) model of this type to estimate market share volatility across all sectors of the US economy.

In this model, there are two key indicators of the strength of the competitive process.  $\beta$ , the slope on lagged market share reveals whether there is any underlying tendency for the larger suppliers to grow at the expense of the smaller ones ( $\beta > 1$ ), or whether smaller suppliers are able to catch up to some extent ( $\beta < 1$ ). The second is the variance of the disturbance term. Relative to the variance of the market share, this is reflected by the R-squared of the equation: where the R-squared is near to unity, this indicates that all that matters in determining a firm's current market share is its share last year, But where R-squared is small, this suggests that there is much more scope for suppliers to grow or decline due to other non-size-related factors.

We fit the model to a truncated form of the data set, which excludes those smaller suppliers which have only very low shares of less than 0.5% and appear only intermittently in the NJR. This provides a balanced sample. The model is estimated in logged form, which is the convention in this context as it provides a test of the law of proportional effects i.e. whether the proportionate growth of the firm is related to its initial market share.

It is estimated in two forms - first as a standard panel regression model with random effects, second, as an Arellano-Bond model which manages the potential issues raised by using a lagged dependent variable as a repressor. This violates strict exogeneity due to its correlation with the error term; and in the Arellano-Bond method, first differences of the regression equation are taken to eliminate the fixed effects. Then, deeper lags of the dependent variable are used as instruments for differenced lags of the dependent variable (which are endogenous[47])

### 3. Results

Figure 1 shows the time series for the market shares of cemented and uncemented implants (at this stage not distinguishing between different suppliers). Two distinct phases are apparent: an initial strong penetration of uncemented at the expense of cemented, 2005-

2010, followed by broad stability 2013-19. This reveals no evidence yet, as at 2019, of the switch to cemented recommended by GIRFT.

### 3.1 Market structure and concentration

Table 1 establishes the supplier market shares, 2006-2018 for cemented and uncemented implants. The two largest, Stryker Osteonics (Stryker) and Johnson & Johnson (J&J) currently supply approximately 69% of the market; the only other sizeable player is Zimmer Biomet with 17%. The next three largest, Smith & Nephew, Joint Replacement Instrumentation (JRI) and Corin account for only 11% between them.

This shows a change from findings from previous data from 2011[7], Stryker have in fact increased their share over the 13 year period by 6 percentage points, at the expense of J&J and amongst the smaller players (JRI has lost 6%, while Corin has gained 2%).

In 2018, the aggregate HHI is 0.27, unquestionably very highly concentrated by CA standards (far exceeding 0.2). The Table also reveals that concentration has increased over the time period, partly fuelled by the effects of merger between Biomet and Zimmer in 2014.

However, arguably more important for present purposes are the market shares in the cemented sector, as shown in Table 2 (we return to the uncemented in section 3.4). This reveals an ever-increasing dominance for Stryker whose market share grew significantly from 43% to 57% over the period. Similarly, the HHI rose dramatically from 0.31 in 2006 to 0.41 in 2014, and although it has declined marginally recently, an HHI of 0.39 and a market share for the leader of 57% places this market firmly in the bracket of “highly concentrated, with a dominant leader.”

### 3.2 Market Dynamics

The results of estimating equation (1) using the panel model with random effects are reported in table 4. Focusing, for the moment, only on the cemented results, these point to a market with very little dynamics, the  $\beta$  coefficient is significantly greater than 1 for cemented

cup and not significantly different from 1 for cemented stem. This indicates a systematic tendency for the larger firms to grow proportionately faster in cups, with very little change in stems. Magnitudes of the statistics are robust to using the Arellano-Bond model (not shown in the table but available from the authors). The within R squared in both models is close to 1 for cemented cups, meaning that what matters most in determining a supplier's current market share is what it was in the previous period – perhaps reflecting surgeon-loyalty leading to a tendency to opt for no change in their implant preferences.

### **3.3 Innovation**

From trawls of the NJR annual reports, we have identified 59 new brands of hip implant (cemented and uncemented) over this period. However, of these, 12 appear to have been merely re-branding of existing implants, with the new named brand replacing an old, immediately discontinued. Therefore 47 new potential implants were identified. Interestingly, while Stryker and J&J were responsible for just under half of the re-brands, they accounted for only 6 of the 47 new implants. This suggests that Stryker and J&J were focussing on largely fine-tuning their existing dominant brands, while the smaller players were the main source of genuine product innovation.

In order to assess the success of the new brands as significant innovations, an obvious measure is the share of the market they gained. Focusing for the moment only on the cemented components, we find that while new brands of cups emerging between 2005 and 2018 had secured 45% of the cemented cup market by 2018, virtually all of this was due to rebranding, with only 2% from genuinely new brands. For stems too, genuinely new brands gained only 2% of the market. Overall much of the rebranding was accounted for by the renaming of the Charnley as the Marathon cup (J&J) and the Exeter X3 as the Duration cup (Stryker). Putting this rebranding to one side, the penetration of new brands - gaining just a joint 2% market share for both cups and stems - is strikingly low for a 14 year period.

Against this backcloth of scarcely no real innovation within the cemented segment, we next turn to another possible form of innovation - the generic implants. In fact, we could identify only one generic supplier within our NJR data-set: Orthimo, who manufactured the OPTISTEM XTR and OPTIHEAD XTR/Opticup. According to 'Beyond Compliance'[48], the date of their first use was 2014, where they were given an 'unclassified' rating. The number of their implants rose from 2 (cup and stem) in 2014, to 83 and 101 cup and stem respectively by 2016. However, by 2017, Orthimo had gone into liquidation with no specific reason specified. Since then, there appears to have been no generic companies entering the market, although we cannot completely rule out the possibility of "branded generic" entry, whereby some of the newer implants supplied by the established companies were 'direct copies' of, and sold alongside, their existing well established brands.

### 3.4 Comparators

#### *Uncemented*

Returning now to the results in Tables 3 and 4 for the uncemented segment, a very different picture emerges. The market shares and HHI in Table 3 now show a different market leader (J&J in place of Stryker). Although this market can also be classified as "concentrated" according to the CMA yardstick, with an HHI of around 0.23, having risen from 0.19 in 2005, it is far less concentrated than the cemented segment, with four firms in this case having market shares of 10%+ and two others each with 4%. Moreover the market leader's share (38%) would probably not qualify for the term 'dominant' in most jurisdictions.

Returning to the results of the regression analysis for market churn in Table 4 but now for the uncemented segment, the  $\beta$  coefficient is significantly less than 1 for both cup and stems in both the random effects and Arellano-Bond models. This indicates a significant tendency for small firms to make some inroads into the leaders' market shares.

As seen earlier, innovation has had very little impact in the cemented segment (new brands accounting for only 2% in both cups and stems). In the uncemented segment on the other

hand, while J&J's Pinnacle cup and Corail stem continued to hold leading positions, there is some evidence of entrant brands' success: a combined share in both uncemented cups and stems of 10%.

#### *Other European THR markets*

Table 5 provides an international comparison, drawn from the EC report on the Zimmer-Biomet merger. This reveals that market structure is typically oligopolistic in all countries, and that the same 4 firms as in the UK, are prominent. On the other hand, England and Wales stands out as an outlier in one obvious respect: the dominant position of Stryker. As can be seen, Stryker's market share is less than 20% in all other countries, as opposed to 37% in England and Wales. The obvious question is why Stryker should command a market share in England and Wales at least twice as large in any other country. The big 4 firms are all large multinational firms presumably offering similar portfolios of implants in all countries, and perhaps the most likely explanation lies in differences in surgeons preferences and practices between Europe and the UK. If so, why do these differences exist? These questions lie outside the scope of the current paper, but they do confirm that Stryker holds an unusually dominant position, especially, as we have seen, in the cemented segment.

#### *Knee Replacement Implants*

Table 6 reports market shares and the HHI's for TKR, 2006-18. This industry exhibits distinct similarities with the hip implant industry: high concentration, with the same four multinational firms supplying most of the market. Given that it employs a broadly similar technology and sells predominantly to the NHS, it is an appropriate comparator to Hip implants. It is notable that there are structural differences here: (i) market concentration is lower and has been declining over the 12 year period, with the HHI falling from 0.26 to 0.23, (ii) all four leaders have market shares of at least 10% and none dominates to the same extent as Stryker in hip implants, (iii) there is also a degree of market churn taking place, even more pronounced when the market shares are disaggregated down to the brand level to show the entrant and exit of a number of brands (available upon request).

Taking the results of all three comparisons together, a clear picture emerges. Like cemented THR, all three exhibit high concentration, with the same four large multinationals involved. However, in cemented THR, the level of concentration in England and Wales is particularly high, and it has steadily grown, unlike in uncemented and TKR. But most striking of all, Stryker's market dominance in cemented THR in England and Wales is unparalleled relative to the three comparators.

## **4. Discussion**

### **4.1 Summary**

We have reviewed the structure of the market for cemented hip implants bearing in mind the likely impact of two key policy guidances from 2016. We have found a high and increasingly concentrated oligopolistic and static market structure. The value of the HHI index of concentration is considerably in excess of the yardstick used by CAs to identify potentially problematic markets; and Stryker, the market leader, has a market share well in excess of 50% - a level usually identified with "market dominance". The market also seems largely devoid of dynamics: there has been very little entry or exit, and the market shares of the incumbents show scarcely no change over time. The large firms remain large, and small firms remain small, without any evidence of thriving competition where efficient firms can gain at the expense of the inefficient. There is also no real sign of significant innovation. These findings are not necessarily evidence of a weakly performing uncompetitive market, for example, stability may merely reflect a mature market, in which the major technical advances have all been made. On the other hand, our comparisons reveal a market which is out of line with natural comparators: Stryker has a share at least twice as high in England and Wales as elsewhere in Europe; concentration is significantly lower, and market share

mobility and innovation noticeably higher, in the uncemented segment of the industry; and the Knee Implants industry is less concentrated and market shares more fluid than in cemented hip implants.

## 4.2 Policy Implications

There are potentially important welfare and policy implications, for health policy and competition policy. The former relates to the prevailing guidance to surgeons that they should concentrate on employing cemented fixations[2- 6]. This was intended to help the NHS secure a better deal in its purchasing and procurement (amongst other things). However, these deals should aim for achieving similar but also lower prices for all hospitals. Advice to specialise increasingly on cemented implants increases the likelihood that the main supplier of cemented stems (Stryker) will further consolidate its already dominant position. This raises the risk of less price competition and reduced choice for patients and their agents. Suppliers with more of a focus on the uncemented market might thereby suffer from these recommendations, and this might explain why companies are already looking to expand in the Asian markets. This also assumes that cost saving on the surgical intervention is the only issue of concern to the patient/NHS. As previous literature has shown, cemented implants are undoubtedly cheaper than uncemented [5-6] regardless of whether concentration levels go up. However, there may be unintended consequences of focussing purely on these implants. If the welfare objective is to make cost savings, then using cemented implants would be the preferred option. However, if the objective is to maximise the number of patients treated (and thus reduce waiting times) then fitting uncemented implants would be the preferred option as more operations can be carried out per day. If the objective is to maximise the quality of the implant, then the conclusion is ambiguous as there is no clear evidence to support the use of a specific type of component for younger patients. As figure 1 implies, there are still a significant number of surgeons implanting uncemented types in the UK, a trend even more evident in the wider international community. The purpose of this paper is to alert the reader to the wide reaching impact of a



more general guidance based solely on cost. There could also be a potential danger in focussing on cemented implants as patient demographics may change over time with people living longer and younger more active people potentially requiring more hip replacements earlier (i.e. the gold standard implant might not work for them). Moreover, even if innovation in the cemented segment of the market has reached saturation then a complete switch to cemented from uncemented runs the risk of losing the potential to return to its use at a future date if needed (lost surgeon skill in implanting uncemented and procurement contracts).

Turning to competition policy, viewed through the eyes of a competition economist, the market structure we have identified in this case would raise concerns of potentially weak competition, and, at the very least, definitely merit further investigation. More generally, the medical devices supplying industries have attracted far less attention from CAs, both in the UK and worldwide, than the other major supplying health sector, pharmaceuticals. Given the, thoroughly appropriate, current emphasis on efficiency in procurement, it is essential that there should also be scrutiny of the firms dealing with public procurement.

### **4.3 Limitations**

There are a number of limitations on the scope of the paper. Our research would ideally have had access to implant price data, disaggregated to the manufacturer and brand level, to explore the impact of policy guidance on price variation. This would then allow for a panel data set to be produced which would include information on hospital trust type and geographical location. Data for the post policy guidance years, i.e from 2017/18 onwards, would enable a formal 'before and after' analysis of the impact of the Carter/GIRFT reports on innovation. It would also provide the opportunity to assess whether this has led to increased market concentration, both across and within hospital trusts. This would then allow a comparison with our previous work[7] where we identified variability across and within the system as whole.

Our current research also lacks more in depth analysis on the current state of innovative activity in this sector. There is some evidence that suppliers are beginning to focus attention on other aspects of innovation beyond just the implant such as establishing contracts with the hospitals themselves to provide procurement and after sales services. Such initiatives although still in relatively early stages, could be seen as commercial strategies designed to establish or protect manufacturer market share with the hospital. Suppliers already have an intermittent presence in hospital operating theatres, providing a unique opportunity to develop a relationship with the orthopaedic surgeon and discuss current and new products. This is in direct contrast to the more 'off the peg' approach for some other medical devices.

As suggested by Deere et al [49], one approach would be to conduct a mixed methods survey of decision making by surgeons, procurement departments and suppliers, to better understand **who** is making the decisions about implant choice and on **what basis** the choice is made. Conducting such qualitative work, alongside implantation rates, could enable greater understanding of how recent policy recommendations might impact on competition in what is already a highly concentrated market.

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Further disaggregations of the data such as market shares and HHI by the 4 segments and market share of individual new brands, are available on request.

## **Declaration of interest**

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**Table 1- Market Shares (%) of leading suppliers of THR**

	2006	2008	2010	2012	2014	2016	2018
<b>Stryker</b>	33	33	32	34	35	36	38
<b>J&amp;J</b>	32	32	34	32	32	31	31
<b>Zimmer Biomet*</b>	17	16	18	18	18	19	17
<b>Smith &amp; Nephew</b>	6	7	5	4	5	4	6
<b>Others</b>	12	12	11	12	10	10	8
<b>HHI</b>	0.24	0.24	0.24	0.24	0.24	0.27	0.27

The HHI is an index of concentration as defined and described in section 2.5.

Here and in the following tables, shares are reported biannually; full annual data available upon request from the authors.

\* There was a merger between Zimmer and Biomet in 2014, the table shows their combined market shares for previous years.

**Table 2- Market shares (%) of leading suppliers of cemented**

	2006	2008	2010	2012	2014	2016	2018
<b>Stryker</b>	43	51	55	59	60	58	57
<b>J&amp;J</b>	33	24	22	21	20	20	22
<b>Zimmer Biomet</b>	16	16	16	14	17	17	16
<b>Others</b>	8	8	8	8	7	7	9
<b>HHI</b>	0.31	0.33	0.36	0.4	0.41	0.4	0.39

**Table 3 – Market shares (%) of leading suppliers of uncemented**

	2006	2008	2010	2012	2014	2016	2018
<b>J&amp;J</b>	32	40	42	40	41	41	38
<b>Stryker</b>	18	16	16	15	15	17	22
<b>Zimmer Biomet</b>	19	17	18	19	19	20	18
<b>JRI</b>	18	12	11	9	9	6	4
<b>Smith &amp; Nephew</b>	9	8	6	5	7	7	10
<b>Others</b>	22	19	18	21	18	15	12
<b>HHI</b>	0.20	0.22	0.24	0.22	0.22	0.23	0.23

**Table 4 Stability of market shares, panel model with random effects**

	$\beta$	95% confidence interval for $\beta$	R <sup>2</sup>	Observations
<b>Cemented Cup</b>	1.11	1.05-1.17	0.858	90
<b>Cemented Stem</b>	0.97	0.91-1.03	0.656	78
<b>Uncemented Cup</b>	0.94	0.88-0.99	0.779	104
<b>Uncemented Stem</b>	0.9	0.84-0.96	0.800	91

The table reports the results for estimation equation (1) using a panel model with random effects. Results for a parallel regression estimated using the Arellano-Bond method are very similar and available on request from the authors.

**Table 5 Market shares (%) of leading suppliers of hip implants in Europe, 2013**

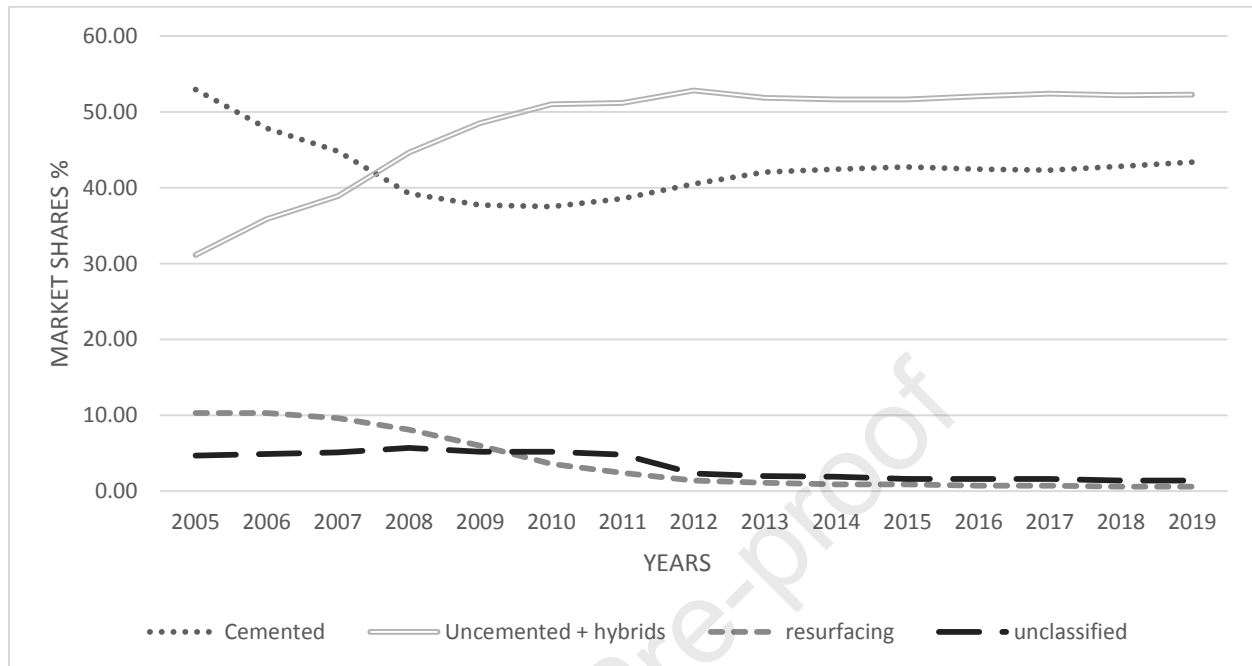
	Stryker	Zimmer Biomet	J&J	Smith & Nephew
<b>England and Wales</b>	35	18	32	5
<b>EEA</b>	10-20	30-40	10-20	10-20
<b>Denmark</b>	10-20	50-60	20-30	5-10
<b>Finland</b>	10-20	40-50	30-40	5-10
<b>Lithuania</b>	10-20	50-60	20-30	5-10
<b>Netherlands</b>	10-20	50-60	10-20	10-20
<b>Portugal</b>	10-20	30-40	20-30	10-20
<b>Spain</b>	10-20	30-40	10-20	10-20
<b>Romania</b>	5-10	70-80	20-30	5-10
<b>Slovenia</b>	5-10	40-50	20-30	5-10
<b>Germany</b>		30-40	10-20	10-20

Sources: England and Wales Table 1 above; for all other countries, EC merger report [45], in which statistics are reported as ranges for confidentiality reasons.



**Table 6 Market shares (%) of leading suppliers of Total Knee Replacement (TKR)**

	<b>2006</b>	<b>2008</b>	<b>2010</b>	<b>2012</b>	<b>2014</b>	<b>2016</b>	<b>2018</b>
<b>J&amp;J</b>	39	39	40	39	36	36	33
<b>Zimmer Biomet</b>	27	28	29	30	31	35	26
<b>Stryker</b>	13	14	14	14	13	16	20
<b>Smith &amp; Nephew</b>	12	11	11	10	8	9	10
<b>Others*</b>	10	12	10	9	10	11	10
<b>HHI</b>	0.26	0.26	0.28	0.28	0.26	0.29	0.23

**Figure 1 Market shares of cemented and uncemented implants (%), 2005-2019**

The source for this figure and all Tables except Table 5, is the raw NJR data for England and Wales, collated and manipulated by the authors. While the data for this figure is up to 2019, all other tables are only reported up to 2018 because the 2020 NJR annual report does not include any of the disaggregations available in the reports for previous years.

## Highlights

- Recent guidance recommended the use of cemented hip implants for patients aged 68 years and over.
- The supplying industry of cemented implants is very highly concentrated.
- There are no signs of dynamics in market shares or real innovation.
- The results are further underlined when compared with three similar markets.
- Potential adverse welfare implications of recent guidance may warrant further scrutiny.