MENTORS IN ORTHOPEDICS

REGISTRIES....WHAT HAVE WE ALL LEARNED AND WHAT OF THE FUTURE? OUR EXPERIENCES WITH NJR

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SUMMARY

Background: Arthroplasty registries have transitioned from experimental initiatives to essential components of orthopedic practice. Historically, significant implant failures, such as the 3M Capital Hip and metal-on-metal bearing surfaces, underscored the necessity for systematic longitudinal surveillance to identify poor-performing designs and ensure patient safety through evidence-based decision-making.

Objective: This article reviews the evolution of national joint registries, examines the technical requirements for robust data collection, and discusses the role of surveillance systems in monitoring implant performance, surgeon outcomes, and hospital standards.

Key Points: Effective registries integrate patient demographics, hospital data, and implant-specific attributes via Universal Device Identification barcodes. High granularity in database architecture is critical to prevent "camouflaging," where the aggregate performance of a large cohort masks the failure of specific implant variants. The National Joint Registry utilizes Patient Time Incident Rates and funnel plots to identify outliers among implants and clinicians. Collaborative initiatives like the Orthopaedic Data Evaluation Panel and "Beyond Compliance" provide independent benchmarking and early-stage monitoring of new technologies. Furthermore, the integration of Patient-Reported Outcome Measures addresses the limitations of revision rates as a solitary metric for success. International cooperation through organizations such as the International Society of Arthroplasty Registries facilitates the standardization of data quality and global surveillance of orthopedic devices.

Conclusion: Arthroplasty registries are vital for maintaining clinical standards and enhancing patient safety. Future developments will involve the integration of mobile applications for data collection and the application of machine learning to analyze increasingly complex datasets, ensuring that orthopedic practice remains rooted in objective clinical evidence.

KEYWORDS

Registries; Arthroplasty, Replacement, Hip; Arthroplasty, Replacement, Knee; Product Surveillance, Postmarketing; Prosthesis Failure

INTRODUCTION

Nowadays joint registries are accepted as part of everyday orthopaedic practice. Not only do we have registries for total joint replacement but there are now registries of one type or another in many other orthopaedic specialities. Arguably it was the joint registries, particularly the National Joint registries that led the way. They have given orthopaedics a massive profile and many other specialities are now trying to emulate us. They have initiated the whole concept of "Observational Studies" and completely changed the mind set of most orthopaedic surgeons and given us "EVIDENCED BASED DECISION MAKING". It was not that long ago they started and like so many culture changing initiatives it took quite a while to get them started and before their use fully appreciated.

The theme for this EFORT meeting is Registries and it is an opportunity for us to celebrate the contribution that all registries have brought to orthopaedics, particularly joint replacement, over the past few years. Europe has led the world with the development of registries and we have shown how the data collected in registries can influence practice for the benefit of all or patients. We have both the oldest and the biggest registries, the Swedish and the NJR. I hope you find my views on registries and allied systems interesting and that you enjoy EFORT 2019.

DISASTERS GIVE REGISTRIES A KISK START

We all know that the two men, the original pioneers of joint replacement, were Sir John Charnley from Wrightington and Ken McKee from Norwich. There is no doubt they were competitors but were also friends and both kept impeccable records of their cases (Fig 1).

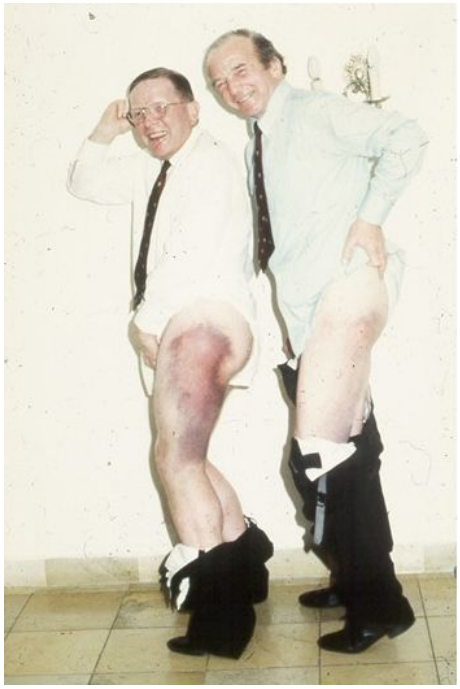


Fig 1 - Sir John Charnley and Ken McKee after, they had both fallen on their left hip whilst skiing! (Photo attributed to the late Alan Apley)

Perceptively, Sir John wrote in 1972: “Serious consideration should be given to establishing a Central Register to keep a finger on the pulse of total implant surgery on a nation-wide basis” (JC Internal Publication No. 39 July 1972). The late Robin Ling, whose Exeter unit are renowned for their record keeping, also made the case for a registry in the early 1990s.

In the UK, it took the 3M capital hip disaster (1) to mobilize the British government of the time, to support the British Orthopaedic Association (BOA) in their case for a National Joint Registry (NJR). The 3M Capital Hip was a “look-a-like” Charnley in appearance but not in performance (Fig 2). They were cheaper than the Charnley and the NHS encouraged surgeons to use them. Perhaps it was the fact that the government held the smoking gun and that they had to “do” something that we at last got our registry!

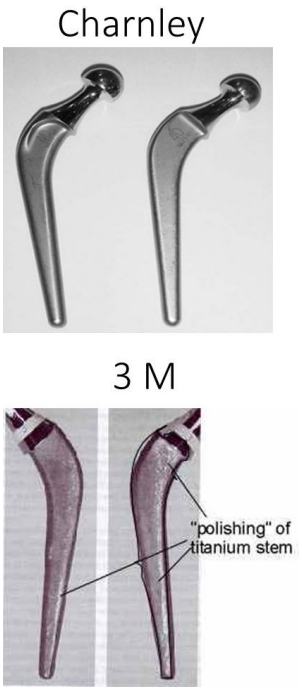


Fig 2 - Spot the difference! Most of the 3 M capital hips made of titanium

LESSON! AN APPARENTLY MINOR MODIFICATION CAN LEAD TO A MASSIVE CHANGE IN PERFORMANCE

The 3 M Capital hip disaster brought to light several other failings besides the uptake of a poor design. In the UK, we had little idea of which patients had received these hips and no easy way of contacting them. The 3 M capital hip was the trigger for the NJR and ODEP for hips, but we all were aware of several types of joint replacement that not lived up to expectation and as surgeons there were many of us who had been demanding a registry for a considerable time (Fig 3).

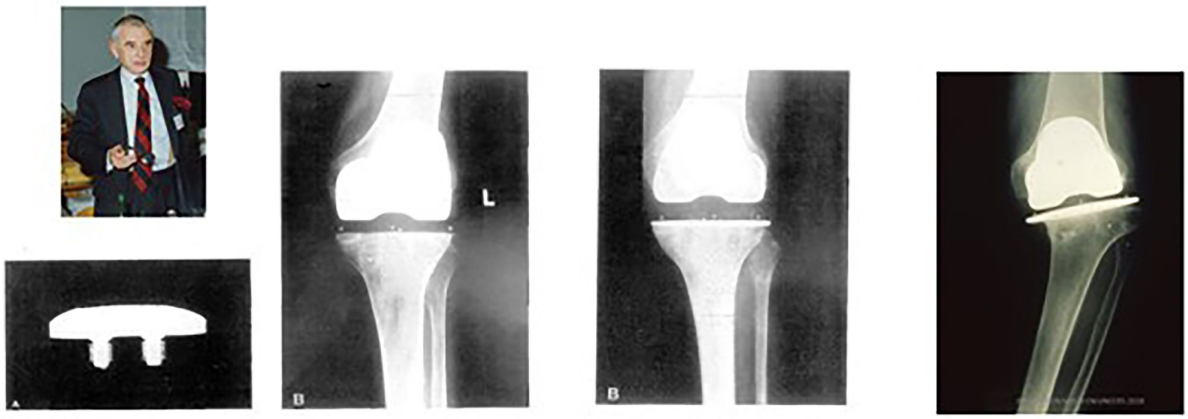


Fig 3 - The late Mike Freeman's mark 1 knee worked well. The addition of a metal plate underneath the HDP Tibial component showed the unexpected consequence at 1 year.

The late Mike Freeman's mark 1 knee worked well. The addition of a metal plate underneath the HDP Tibial component showed the unexpected consequence at 1 year.

In England, before NJR we had the Trent Regional Artroplasty Register which was pioneered by Prof Paul Gregg in Leicester. Paul's vision and experience was pivotal in commissioning, promoting and developing the NJR. Tim Wilton has recently become the Medical Director of the NJR, having succeeded Mr Martyn Porter. Tim previously served on the Steering Committee besides having been President of BASK and the British Orthopaedic Association besides being Chairman of the Bone and Joint Journal (BJJ). Tim is a member of ODEP and Beyond Compliance (Fig 4).

Fig 4 - Prof Paul Gregg & Tim Wilton

Other registries have not needed such a sad reason for getting under way; the father of them all, the Swedish Knee Registry (SKAR) was started by Goran Bauer in 1975 who is quoted as saying that Total Knee Replacement was an experiment (2). He also reported a case where a patient received a sided TKR in the wrong leg. He felt that careful records should be kept of all joint replacements (Fig 5, 6).

Fig 5 - Goran Bauer

Fig 6 - Otto Robertsson who has maintained SKAR since Gorran's retirement

The Swedish Hip Registry (SHAR) was next 1979, started by Peter Herberts and Lennart Ahnfelt. For many years, and to this day Henrik Malchau and Göran Garellick have had a massive and positive influence on all our registries (Fig 7-9).

Fig 7 - Peter Herberts

Fig 8 - Henrik Malchau

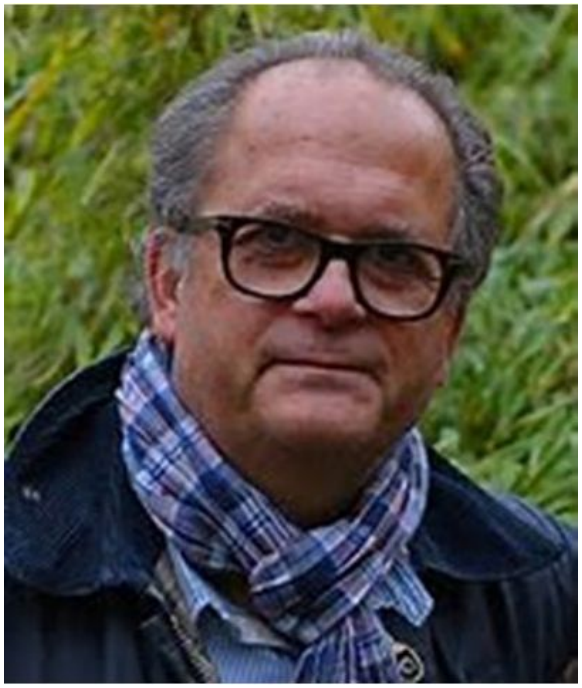


Fig 9 - Göran Gallerick

Many other registries have started because the local surgeons had heard what problems had occurred in another country and wanted to make sure it was not repeated in theirs. The Australian registry has been pre-eminent. Steve Graves' name will be forever associated with it and he kindly wrote to describe its origins: The instigation of the AOANJRR commenced in 1993 when the AOA Arthroplasty Society asked the AOA to look at establishing a National Registry. The reason for this was there was uncertainty of the outcomes and it was not even clear how many joint replacement procedures where being done. It was also based on the success of the Swedish registries which had been demonstrated to improve the outcomes of joint replacement. There was no concern over a particular device but it was thought likely that there was variability of results based on the type of prosthesis used. I was first approached by the AOA to look at implementing the registry in 1996. I lead a pilot study to determine the feasibility and the success of this led to federal Government funding being provided in 1998. The AOANJRR commenced data collection in 1999 (hips and knees) with complete national implementation being completed by mid 2002. Other joints shoulders elbows wrists, ankles and spinal discs commenced in 2007 and osteotomies 2015.

WHAT IS NEEDED FOR A REGISTRY TO FUNCTION PROPERLY ?

The best and easiest way to produce a registry is where an implant is used. The data collection can be built around the event, using the bar code on the device.

PATIENT DATA + HOSPITAL DATA + IMPLANT BARCODE = REGISTER

REGISTER + FILTERS = REGISTRY

REGISTRY + INTELLIGENCE = PATIENT SAFETY

In these days of patients having electronic hospital records their dated demographic data, the surgeon's name and the barcode can easily be put together by a data clerk and uploaded into a computer and exported to a registry. In the UK a patient's signed consent is needed for this system to work most effectively (Fig 10).

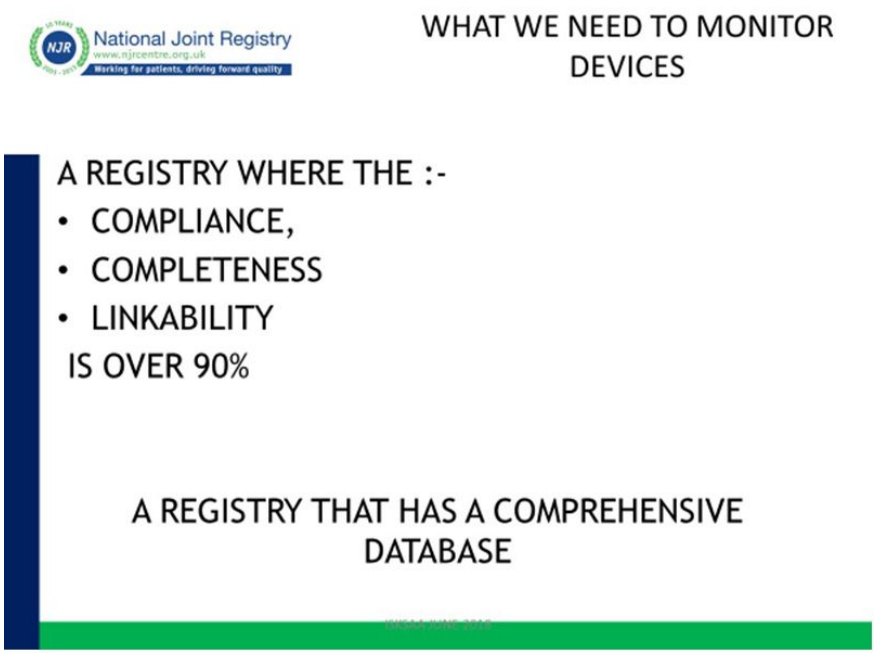


Fig 10

The barcode usually contains the UDI (Unique Device Identification) and the product code. Some barcodes include the Global Medical Device Nomenclature (GMDN). Behind the product code are details of the implant. Nowadays all the major registries are computer based and all this data is collected in their main frame. For the registries, like NJR who are set up to evaluate implant performance, manufacturers will inform the registries of the attributes associated with an individual product code. The registries will have a library of attributes that a manufacturer will be asked to ascribe to a product. AN ATTIBUTE IS JUST ONE FEATURE OF AN IMPLANT such as size, shape, substrate material, bone facing surface, bearing surface, etc. The example below just relates to a femoral component of a knee replacement. You will notice that this classification is common to both NJR and EPRD. In the combined NJR / EPRD registry there are >560 Hip and Knee Attributes (Fig 11).

National Joint Registry
www.njrcentre.org.uk
Working for patients, driving forward quality

EPRD
Endoprothesenregister Deutschland

Knees

K1.1		Femoral Component		Business Rules
		Articulating Surface Modification	Titanium Nitride(TiN) Titanium Niobium Nitride (TiNbN) Zirconium Nitride Treated Other Other description None	Single selection 'Other description' is free text and must be completed if 'Other' selected. Option only available if 'Other' is selected If 'None' selected then no other option allowed
		Bone Facing Coating	Titanium/titanium alloy Cobalt-Chrome Calcium Phosphate Hydroxyapatite (HA) Antimicrobial - silver based Antimicrobial - copper based Antimicrobial - antibiotics Antimicrobial - other Titanium Nitride (TiN) Silane/Silicate PMMA Zirconium Nitride Other Other description None	Multiple selection 'Other description' is free text and must be completed if 'Other' selected. Option only available if 'Other' is selected If 'None' selected then no other options allowed
	Fixa	**Primary Fixation Method**	Cemented Cementless No bone fixation (i.e. total bone replacement)	Single selection 'No bone fixation' option only for Type = Total (inc bicondylar)

Fig 11 - Granularity of a sound data collecting system

THE ARCHITECTURE OF THE DATABASE / LIBRARY... "CAMOUFLAGING"

A few years ago, NJR realised that their database architecture had not kept pace with our aspiration of detecting outlier implant performance. The small beginnings of the NJR had steadily developed into “BIG DATA” and we were running into the problems of Big Data camouflaging poor performance of a variant of a brand. The first example of camouflaging that we eventually identified was a very painful one for all of us at NJR. We failed to pick the early failures of “Stemmed Metal on Metal” hips which lead to so many patients being severely damaged. Until then we had been collecting cemented hips, uncemented hips, hybrids (cemented stems and uncemented cups) and resurfacings.

By the time of large head stemmed MoM THRs both the hybrid and uncemented silos were very large (> 10,000 hips). These silos were mainly made up from a large number of metal on HDP hips with modular uncemented acetabular components. The PTIR (Patient Time Incident Rate) for the whole “Hybrid Group” was extremely low and (initially) the small number of failed MoM hips were not enough to trigger outlier status for the group although the PTIR for the MoM subset was grossly raised. It was reports to the MHRA (Medicines and Healthcare products Regulatory Agency, the UK’s Competent Authority) that triggered us looking at the MoM group where to our horror we found the truth. We also found extensive use of “Mix and Match” where a surgeon had used components from more than one manufacturer (3).

THE ANSWER

What we needed was more granularity, ie many more attributes in the database and a new architecture. Before we risked “redesigning the wheel” we looked around other registries and decided the layout and granularity of the EPRD (Endoprothesen Register Deutschland) was what we needed to at least emulate. We needed to have database that would evolve and which we could modify with the introduction of new attributes be major ones (a completely new material) or ones which were a lot more minor. For an attribute to be accepted into the database we had to think it was relevant. The test we applied to all the attributes before they were adopted was “Could a modification to this attribute possibly lead to an increase in risk?” The database has also been designed so that an investigation could be conducted vertically down through one brand or “horizontally” across a certain attribute that is common to several implant brands.

It was important that manufacturers were continuously involved in its design; there are two representatives from the implant industry on the NJR steering committee and we hold regular meetings with Industry several times a year. Recently we dropped 3 relatively unimportant attributes from the list on account of the difficulties industry was having with them and their rather doubtful use (Fig 12).

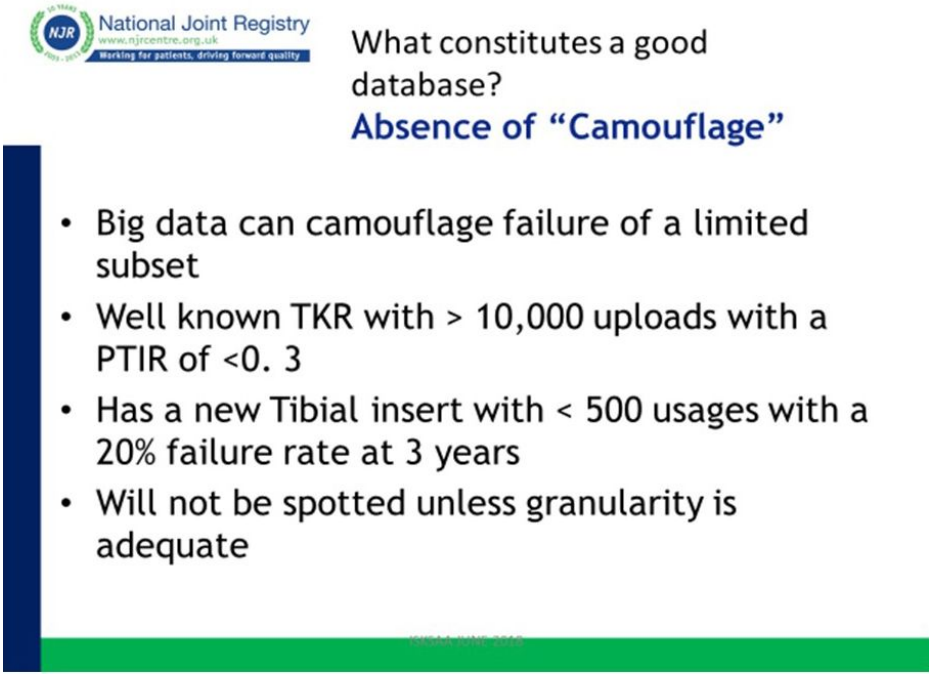


Fig 12

Thus, NJR and EPRD have a common database which is regularly reviewed. RIAP (Registro Italiano di Artro Protesi) are also adopting the data base and there has been considerable interest from other registries. This linkage will increasingly give us the ability to simultaneously check on the performance of an implant or an attribute in one very large registry (NJR) and one that will be eventually be much bigger (EPRD) in the future. It is anticipated that "Beyond Compliance" (vide infra) will extend to Germany at some stage.

OTHERS HAVE ASKED NJR ASSISTANCE

Enthusiasts from several other counties / registries have come to NJR for advice, to set up their joint replacement registry on the basis of NJR experience. They include Japan, Singapore, India, the Republic of Ireland, Zimbabwe, Brazil and several others. We have always been pleased to help.

Several non-arthroplasty registries have built on our experience and we are or have been working with Spine Tango, the British Spine Registry, the Brain pacemaker registry and several others besides TORUS (Trauma & Orthopaedic Registries Unifying Structure) Registries that do not have an implant around which data collection can be built have other challenges, particularly if "Revision" is not a reliable metric. Enquiries are always welcome. We believe in what we do and are always delighted to help others.

A REGISTRY CANNOT SIMPLY BE A MASS OF COLLECTED DATA..... IT IS A WHOLE VITAL, EVOLVING ORGANISATION WHICH ADDS INTELLIGENCE TO THE DATA

What makes up NJR?

1. A very advanced IT company (Northgate Public Services) who are responsible for the data collection from hospitals, data housing and making data available to industry (Supplier feedback) and the analysts....IT is critical to the success of any registry.

2. The Analysts, "The University of Bristol" who are responsible for making sense of the data principally for

3. The Implant Performance Committee

4. The Surgeon Performance Committee

5. Research Committee

6. The organisation behind it all, HQIP (Healthcare Quality Improvement Partnership) with the Steering committee and the medical advisory committee.

In my view, Registries must be “inclusive” if they have any chance of succeeding. On the main committee of the NJR, the “Steering committee” all our stakeholders are fully represented. It is chaired by a lay person, at present Laurel Powers-Freeling . There are surgeon representatives, patient representatives, representatives from the joint manufacturers, procurement, NHS management, allied professions and of course its own management, headed by Elaine Young, the Director of Operations, on behalf of HQIP. There are several committees most of which are attended by the Medical Director, Mr. Tim Wilton who is a highly respected orthopaedic surgeon. The previous medical director was Martyn Porter who was in at the beginning of NJR.

WORKING WITH OTHERS

NJR, works closely with the MHRA (The Medicines and Healthcare products Regulatory Agency), ODEP (The Orthopaedic Data Evaluation Panel) and Beyond Compliance besides EPRD and other registries and organisations. All the world’s major registries link up with ISAR (International Society of Arthroplasty Registries). ISAR had its 3 day 8th Annual International Congress last weekend in Leiden. Some of the member registries are National Registries and those who play a big part, include the Scandinavian Registries, the Australian and New Zealand Registries, the Netherlands and the German Registries besides the relatively small but very important American Registry. Other registries are regional such as some of the Italian Registries (who come together under RIAP), the Kaiser Permanente Registry and many registries in the USA. And then there are local registries such as the very excellent Geneva Registry. They all play their part.

COMPLETENESS, COMPLIANCE AND LINKABILITY

ISAR has drawn up guidelines for the quality assessment of Registries. In NJR we have well over 99% coverage and 97% compliance. Compliance is the ratio of operations performed and records being uploaded to NJR. The link between the index operation and a revision is critical and this is what is meant by linkability. Linkability is pivotal to the monitoring of surgeons, hospitals and implants with any reliability.(Fig 13-14)

Fig 13

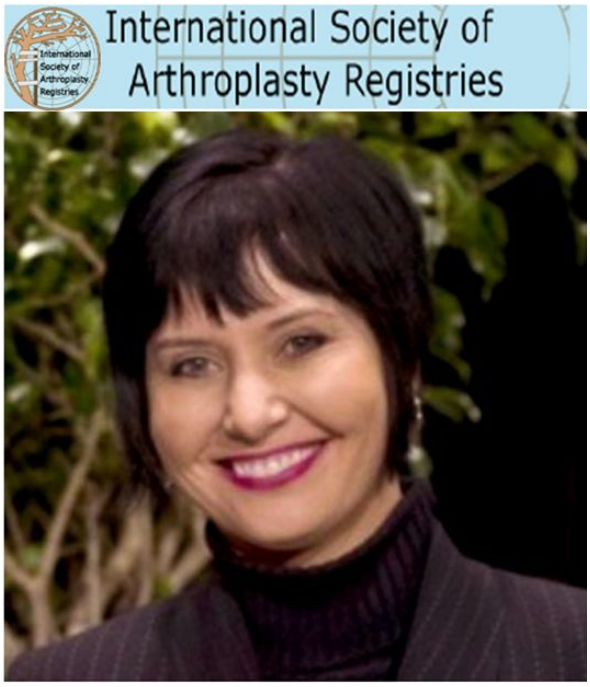


Fig 14 - Liz Paxton, current President of ISAR

Whilst ISAR is an international organisation, the Network of Registries of Europe (NORE) was formed about 4 years ago to be a forum for European Registries and is chaired by Prof Rob Nelissen. NORE advises EFORT on Registry matters and importantly is available to advice the European Commission should the commission require advice on joint replacement. It is also a forum for members of registries to communicate and also to produce joint papers such as the recent publication on the Surveillance of Metal on metal hip replacements in Europe (Fig 15).

Fig 15 - Prof Rob Nelissen from Leiden

THE MOST IMPORTANT QUESTION!

WHAT DO WE USE REGISTY DATA FOR?

THE ANSWER "FEEDBACK"

TO DISCRIMINATE BETWEEN THE GOOD AND THE BAD

THERE IS NO POINT IN COLLECTING DATA IF IT IS NOT FED BACK!

THERE ARE LIMITATIONS TO "REVISION"

Revision can be a rather "blunt tool" and it is important to understand its limitations (Table 1).

• Waiting lists can delay admissions and leading to a delay on the revisions triggering outlier status.
• Comorbidities may dictate that a revision was unsafe which means a "failure" is not going to be registered.
• Patients being reluctant to undergo revision
Therefore, we have all looked for parallel metrics to assess success or failure of a procedure and one of them is PROMS (Patient reported outcome measure)
PROMS CAN BE USED TO TRY AND ASSESS THE PATIENT'S VIEWS ABOUT THEIR NEW JOINT
• QUALITY OF LIFE
• QUALITY OF JOINT FUNCTION

Table 1

An example of where we hope PROMS data will be particularly useful in benchmarking shoulder replacements where revision can be a very week metric. Unless a shoulder prosthesis is infected or very painful it might not be removed (which would trigger the revision word) if it was thought that surgery would not be helpful. The implant is not revised but is pretty useless. (Fig 16)

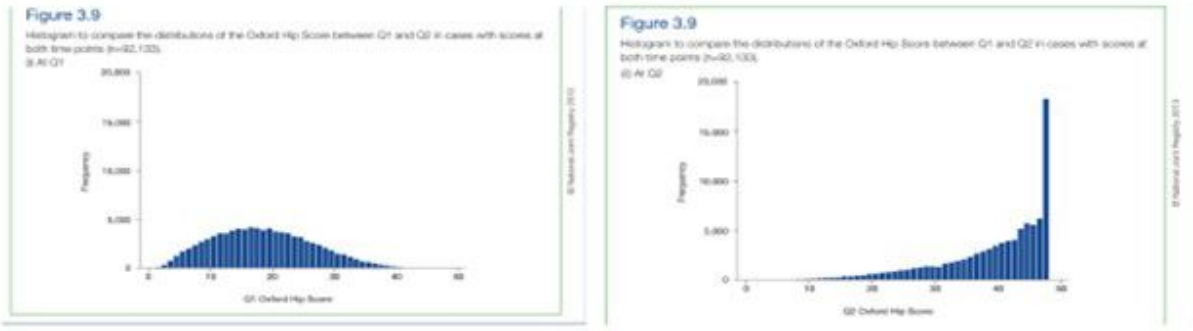


Fig 16 - Pre-op and Post-op Oxford hip prom

In the NJR, the Oxford Hip, Knee and shoulder PROMS together with WOMAC, are collected by NJR pre operatively and then postoperatively at 3 & 5 years. PROMS mean a patient has to fill in a form and in the NJR, the post-operative PROMS scores are completed by between 60-80% of patients. These are linked to the pre-operative PROMS score collected pre-operatively. Paper PROMS are extremely costly and when patients give us an e mail address it is very much cheaper.

EXAMPLE OF USES OF REGISTRY DATA

1. RECALL

It goes without saying the most important function of registry is to be able to contact patients if something has been noticed to go wrong with their implant. Within 2 weeks of the recall notice for the ASR NJR had contacted all patients who were recorded in the registry with this implant.

2. INFORMATION FOR REFLECTION AND AUDIT

Nowadays, in the Annual reports of all the major registries there are excellent data showing usage, trends and outcomes associated with total joint replacements. The NJR Annual report focuses very much on outcomes. (Fig. 17)

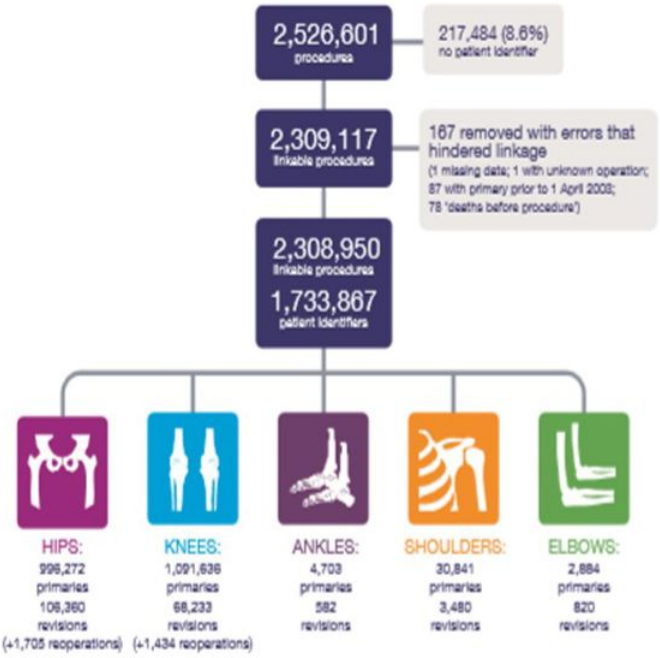


Fig 17 - The NRJ has over 2.5 million joint replacement to assess

The steady improvement in completeness, compliance and linkability since the start of NJR.

A reassuring message to any registry that has a period of despondency in its early days! (Fig. 18)

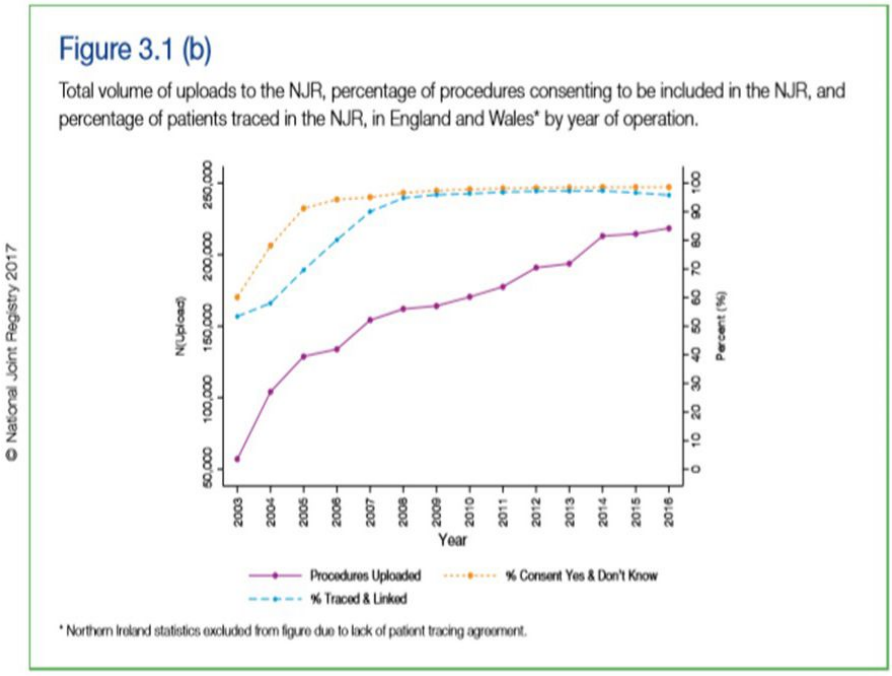


Fig 18

3. TRENDS

NJR has reported annually for 15 years and many observations have been made. Trends have been followed such as the trend in the use of different types of THR. (Fig. 19)

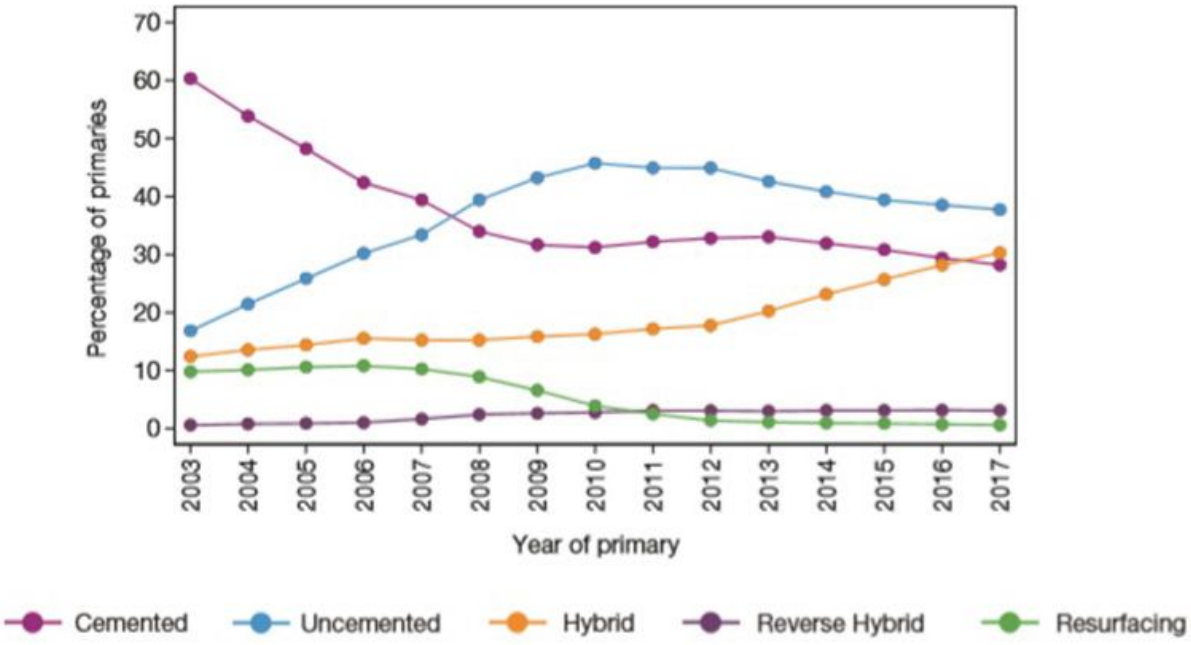
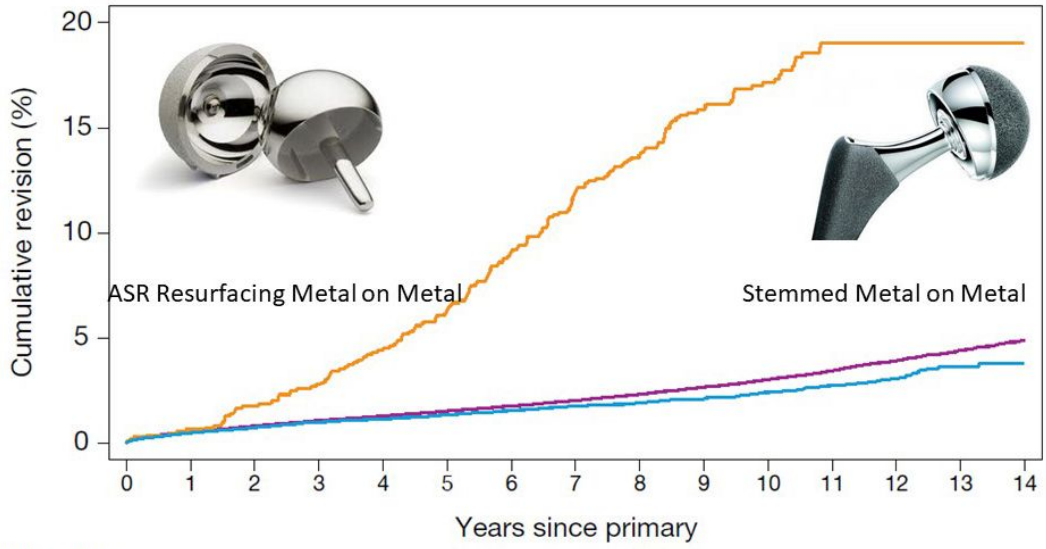


Fig 19

One of the most startling outcomes we have come across was with Metal on Metal (MoM) particularly in respect of the ASR and Stemmed Metal on Metal (Fig 20).



Number at risk

MoP	293,839	265,287	237,235	208,951	180,428	153,720	128,564	106,303	86,347	67,944	50,547	34,395	21,847	11,229	3,832
MoM	1,108	1,087	1,057	1,026	982	940	884	823	759	654	472	306	169	73	13
CoP	38,128	33,002	28,230	23,692	19,532	15,896	12,697	10,084	7,839	5,978	4,337	2,998	1,835	887	250

Fig 20

4. REVISIONS

Fig 20. The graph for revision hip shows a steady improvement rate in hip revision over the years except 2007 -9 when the results were compromised with MoM (Fig 21)

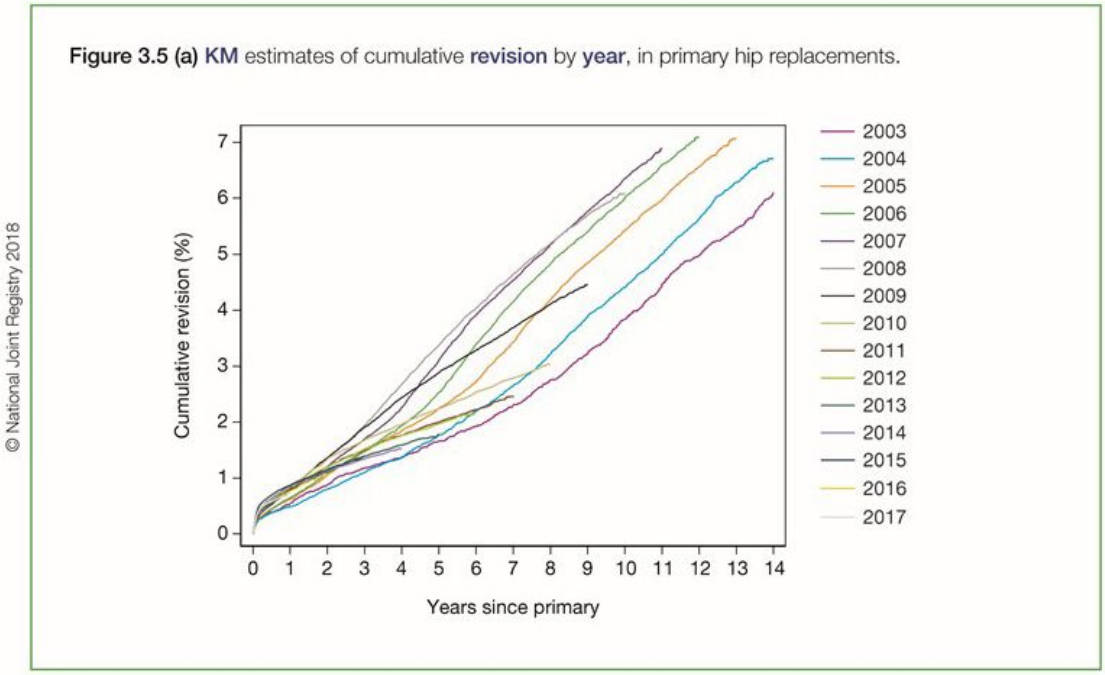


Fig 21a, b - This next graph shows how the revision rate for primary TKR has steadily improved with time

More recently NJR has been tracking Total Shoulder Replacement. Interestingly this graph shows how the performance of TSR in trauma is tracking the performance of TSR in elective patients. (The time frame is very short)(Fig 22)

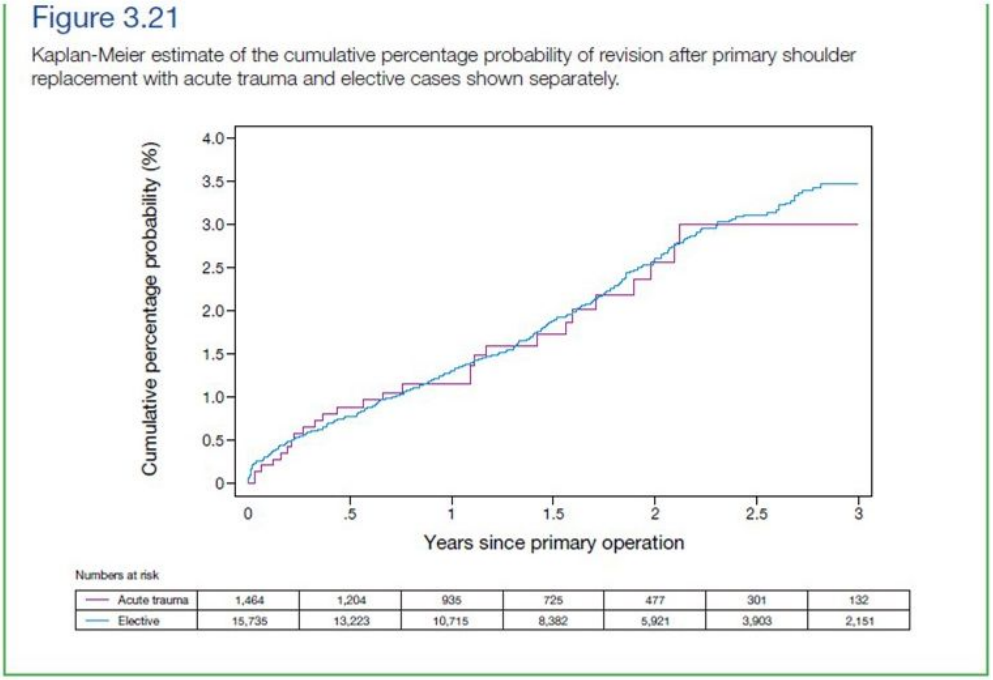


Fig 22

5. FEEDBACK

Feedback is THE KEY TO "BUY IN" AND SUCCESS FOR A REGISTRY.

a) NJR CLINICIAN FEEDBACK

NJR clinician feedback is a resource available to all orthopaedic surgeons in England, Wales, Northern Ireland and Isle of Man who undertake hip, knee, ankle, elbow and shoulder replacement surgery and are registered with the National Joint Registry (NJR). It gives them all the data about any operation that NJR has recorded against their name and also includes details of procedures undertaken by other members of their team. Their data will also include their funnel plots, arranged in such a way that they will be able to detect any trend that is developing in their practice".

www.clinicianfeedback.org.uk is therefore the route all our surgeons take to check on their practice and many of them will use the data for their annual appraisal. Best practice is to share their results with colleagues at a 6 monthly department meeting. Below is the home page for my clinician feedback. (Fig. 23)

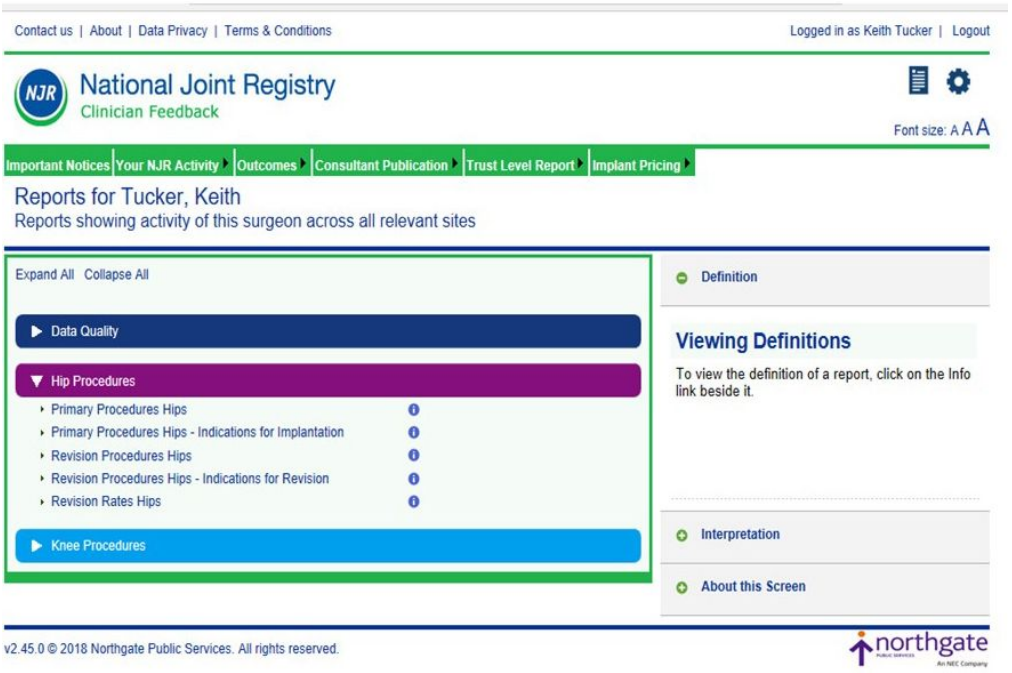


Fig 23

b) SUPPLIER FEEDBACK

Supplier feedback is very popular with manufacturers and is unique to NJR. (Fig. 24, 25)

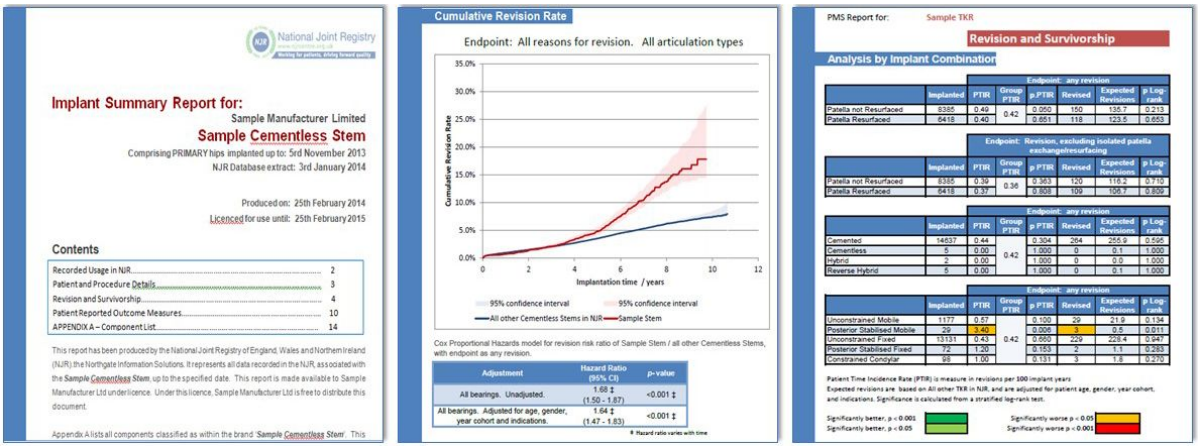


Fig 24 - Is an example of how a report will look to the manufacturer.

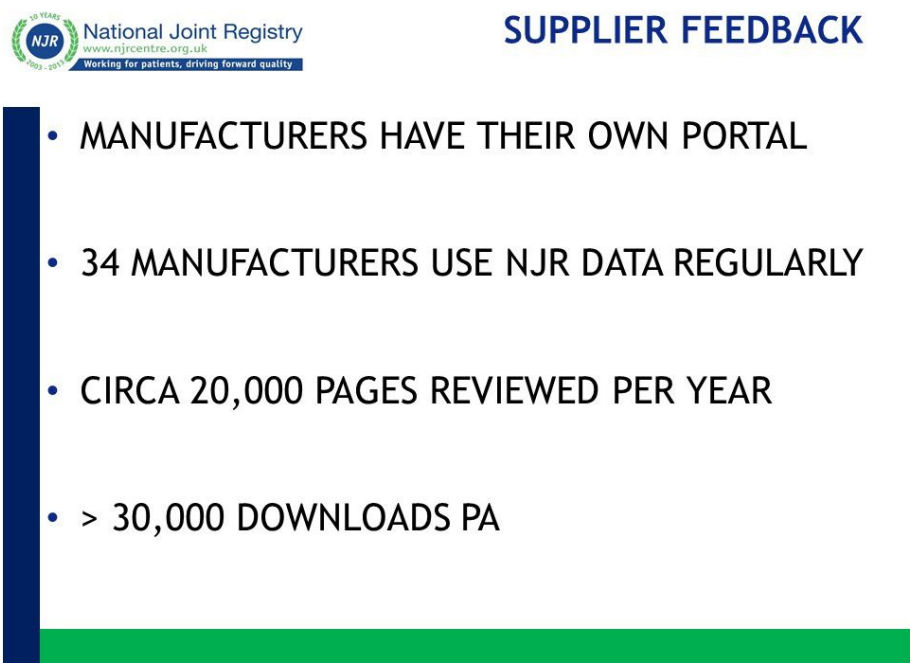


Fig 25 - http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2015th%20Annual%20Report%202018.pdf

- access to non-identifiable record level data, tracking usage and outcomes of their products

• data for post market surveillance purposes only.

• data for submission to ODEP and to MHRA.

6. NJR VIGILANCE

The NJR monitors the performance of

- All Surgeons

• All Implants

• All Hospitals

SURGEON PEFORMANCE COMMITTEE

Since 2008, when NJR had reached a degree if maturity, the surgeon performance committee, chaired by Peter Howard (Derby) meets twice yearly to review all the NJR listed surgeon's performance. Their performance is measured against the norm using the SRR (Surgeon Revision Rate) as the metric. When a surgeon's position on the funnel plot crosses the 95% control limit (alert level), they are contacted to advise them of this, and recommending they examine their data and practice. When they cross the 99.8% line (alarm level, or "outlier") they are contacted again, and the Medical Director of their institute is notified. Should they wish to discuss their status with an NJR surgeon (with or without declaring their name) they can.

The performance of hospitals/Trusts/units is similarly monitored and reported upon. Units with persistently poor performance are recommended for an external review process with the British Orthopaedic Association. (Fig. 26, 27)

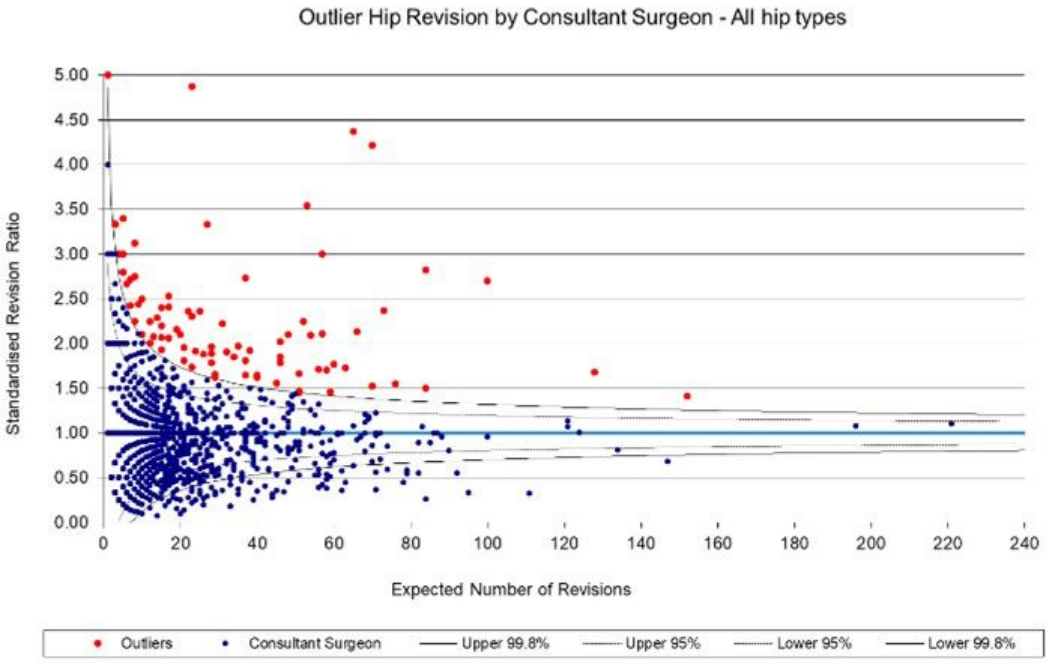


Fig 26 Shows the funnel plot for all hip surgeons. The red dots are surgeons who fall outside the accepted standard.

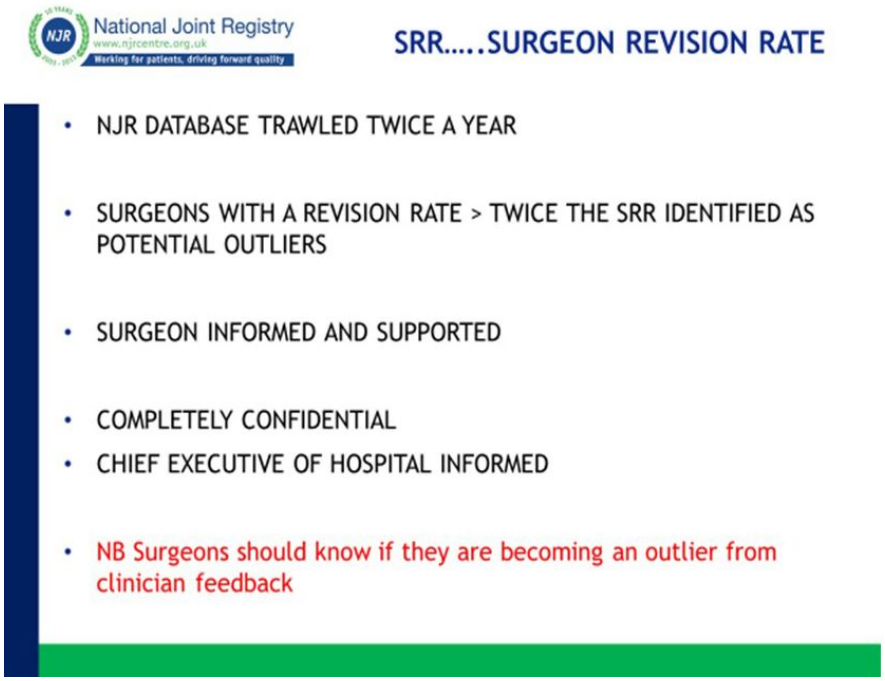


Fig 27

Peter Howard has spent a lot of time looking at the data that is typically associated with outlier surgeons and has come up with some very interesting generalisations which he has presented in numerous meetings: (Fig. 28)

Fig 28

THE IMPLANT PERFORMANCE COMMITTEE

In NJR, implants are monitored in a similar way by surgeons. Since 2009, the Implant Performance Committee meets twice yearly and reviews the performance of all implants in the registry. Electronic filters are applied to the raw data by the team at Bristol. PTIR (Patient Time Incident Rate) is used as the main detector of poor performance. An implant with a PTIR of more than twice the group average and has > 100 usages are described as a potential outlier and the MHRA is informed together with the manufacturer. If the PTIR is between 1.5 and 2 times the group average or > 2 but in a cohort < 100 usages, the manufacturer is informed. We also use "Word on the street" as a trigger for a drill down and we look to see if other registries have identified a particular implant that is performing poorly. "Word on the Street" comes from surgeons at meetings and other informal gatherings. It can be a pointer to more serious findings.

As of January 2019, 163 brands of knee implant, have been monitored with the identification of 4 Level 1 outliers and 12 Level 2 outliers. Some 2,806 different combinations of hip stem/cup implants have been monitored with 17 Level 1 outliers and 40 Level 2 outliers.

7) NJR RESEARCH

The massive amount of data that is stored in a mature registry lends itself to research and audits. NJR research is conducted through the research committee chaired by Prof Mark Wilkinson (Sheffield). Some of the research is undertaken "Internally" by the NJR department in the University of Bristol (UOB) under the supervision of Prof. Ashley Blom or his senior lecturer, Mike Whitehouse whilst many other papers have been written externally.

To date, 91 papers have been published using NJR data.

RESEARCH FELLOWS

The NJR has on its staff one or two research fellows. To date these have always been "out of programme" senior trainees (senior residents) who take a year out from their adopted training programme and undertake audits or research under the direction of a UK academic orthopaedic unit. They are appointed by the Royal college of Surgeons of England through open competition. Their work usually leads to a MD or occasionally a PhD. NJR research fellows have had 28 peer reviewed papers accepted over the past 8 years.

Registries have given Orthopaedic Surgeons, for the first time, the ability to do observational studies using "Big Data". Orthopaedic is way ahead of all other specialities, certainly in the UK, in collecting large quantities of data to assess the value of a product or any of its attributes. (Table 2)(Fig. 29)

• CANCER AND METAL ON METAL HIPS…….. NO LINKAGE FOUND
Published in the British Medical Journal April 2012, Risk of Cancer in the first seven years after metal on metal hip replacement compared with other bearings and general population: linkage study between the NJR and HES (Hospital Episode Statistics) Smith. A, Dieppe. P, Porter. M, Blom A.W
• CARDIAC TOXICITY FROM METAL HIP IMPLANTS ……NO LINKAGE FOUND
In response to concerns about metal on metal hip replacements possible causing heart disease that had been expressed internationally NJR linked with the cardiac databases to establish if there was a link in the UK R Berber1, A Abdel-Gadir2, L Palla3, J Moon2, C Manisty2, J Skinner1, A Hart1
• THROMBOEMBOLIC DISEASE…… Asprin and Heparin
The effect of Asprin and low-molecular-weight heparin on venous thromboembolism after Hip replacement: a non-randomised comparison from information in the National Joint Registry
JBJS Br. 2011:93 (11) p 1465-70 Jameson SS; Charman SC; Gregg PJ; Reed MR; van der Meulen JH
• IMPLANT RELATED
• Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. Lancet (March 2012): Smith, A.J; Dieppe, P; Vernon, K; Porter, M; Blom, A.W.
• Failure rates of metal-on-metal hip resurfacings: analysis of data from the National Joint Registry for England and Wales. Lancet (October 2012): Smith, A.J; Dieppe, P; Howard, P; Blom, A.W.
• No functional benefit of larger femoral heads and alternative bearings at six months following THR. Acta Orthop.2015 Jameson SS, Mason JM, Baker PN, Gregg PJ, Deehan DJ, Reed MR.
• Have cementless and resurfacing components improved the medium-term results of hip replacement for patients under 60 years of age? Acta Orthop 2015 Jameson SS, Mason J, Baker P, Gregg PJ, Porter M, Deehan DJ, Reed MR
• Mixing components from different manufacturers in total hip arthroplasty: prevalence and comparative outcomes in the National Joint Registry for England and Wales Keith Tucker Martin Pickford, Claire Newell, Peter Howard, Linda Hunt, Ashley Blom Acta Orthopaedica 2015; 86 (6): We showed that mixing and matching "hard on soft" was often better that average and that all "Hard on Hard" metal on metal were bad whether there was mixing and matching or not.

Table 2

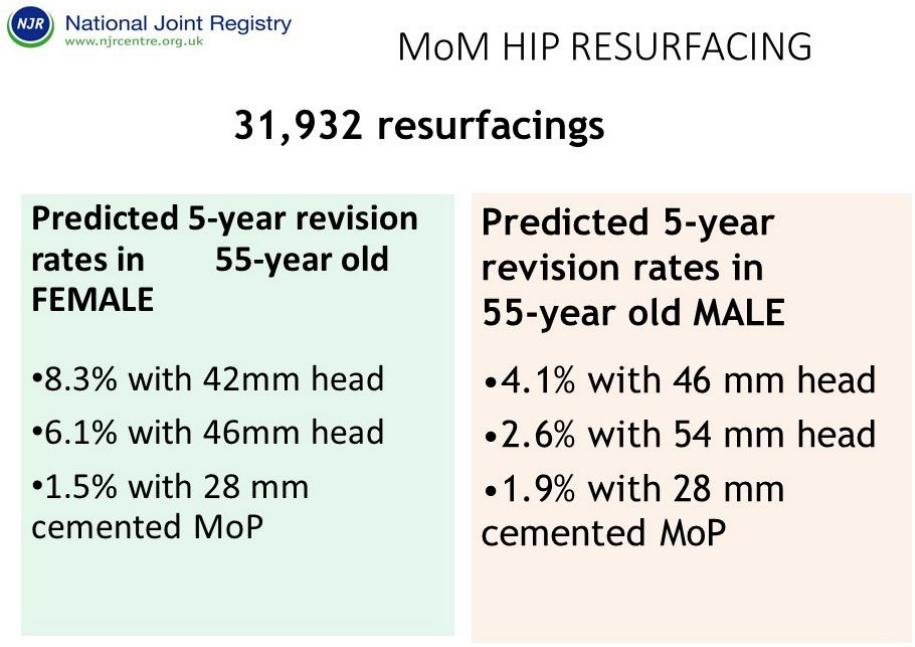


Fig 29

8) REPORTING

Most Registries report annually electronically or on paper or both. Some annual reports tend to look like a large telephone directory! (Fig. 30)

Fig 30 - The NJR limits the amount it prints in the paper version and interested parties should go on line (www.njrreports .org.uk) to view

ACTA Scandinavia

It has been a great boost for all registries that the editors of ACTA have recognised that research papers using registry data need a home. Most journals have now come round to accpeting articles quoting registry data and have got their heads around “Observational Studies”. There was a time when several articles were pushed back by reviewers because some of the patients in a cohort had only follow up of a year or so. The reviewers failed to understand that a cohort from a registry will always have patients in who the joint has been in place for say 10 years and some patients will have only reccently had their operation. The fact that surgeons are still using that prosthesis is information in itself.

9) BENCHMARKING

Quite rightly, Patients, Surgeons and hospital mangers like to know that an implant has been independently assessed as being fit for purpose. Benchmarking is an accepted method for achieving this end. Three countries provide a benchmarking service for joint replacements, Australia, the Netherlands and the UK. ODEP, the Orthopaedic Data Evaluation Panel is based in the UK and has an international profile.

REGISTY DATA NOW FORMS THE BASIS FOR BENCHMARKING FOR ODEP.

ORTHOPEDIC DATA EVALUATION PANEL (ODEP)

ODEP for Hips was introduced in 2003 and at that time there was a paucity of registry data. Only the Scandinavian registries had any maturity; the NJR had not started and for most implants there was little data outside often very limited clinical trials etc. Nowadays, although validated data from RCTs and other trials is welcome by ODEP, the majority of data that manufacturers use in their ODEP submissions is derived from registries. ODEP accepts data from registries where there is close linkability between primary and revision surgery.

ODEP for knees was introduced in 2014 and since 2016 there has been a staged introduction for ODEP for shoulders.

The panel consists of experienced orthopaedic surgeons from the UK and the Netherlands. The Netherlands merged their own benchmarking system with that of the UK about 3 years ago. (Fig. 31, 32)

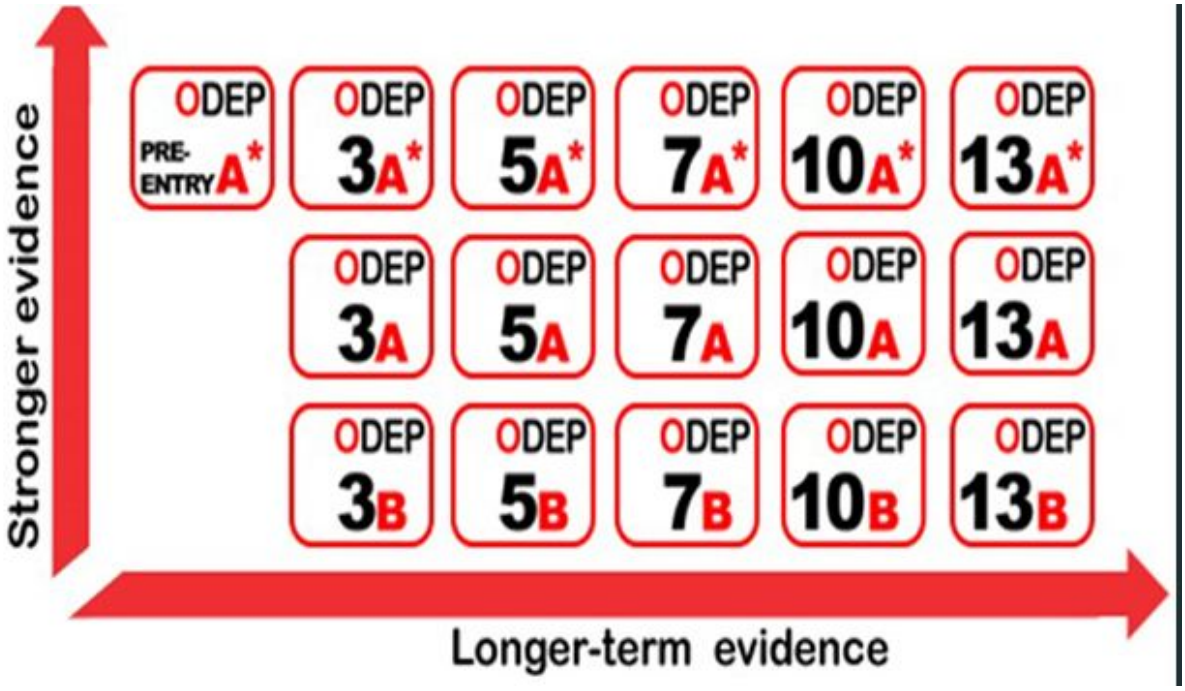


Fig 31

Fig 32

ODEP has become an international brand. We benchmark implants from all around the world. ODEP seems to be very popular. Manufacturers use their ratings in their advertising. ODEP promotes good implants whilst making it difficult for poor implants to be marketed. (Fig. 33, 34)

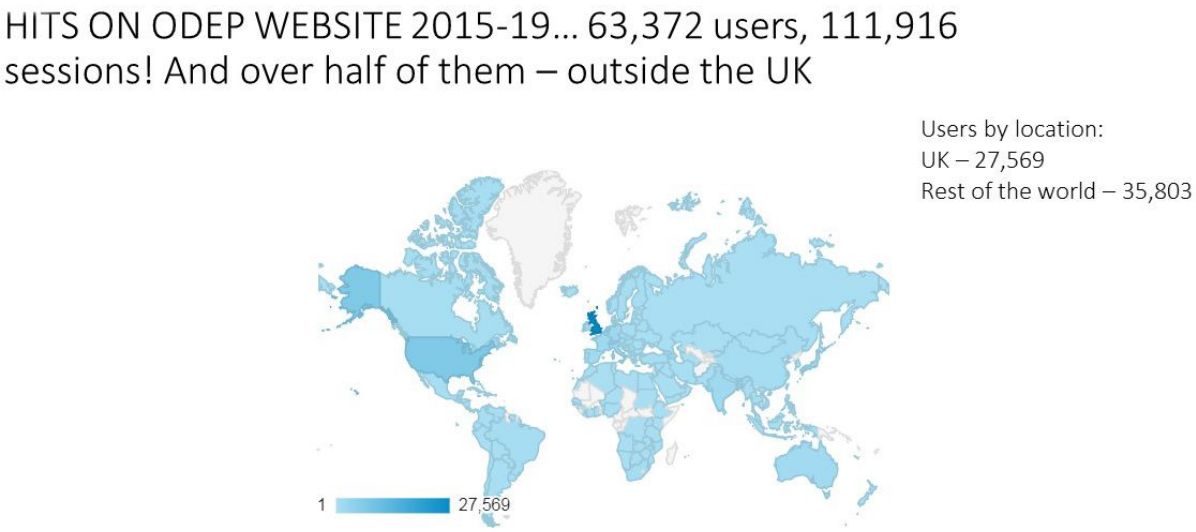


Fig 33 - HITS ON ODEP WEBSITE 2015-19... 63,372 users, 111,916 sessions, UK – 27,569 Rest of the world – 35,803

Criteria - Total Hip Replacement					
Criteria - A* Ratings	**3A***	**5A***	**7A***	**10A***	**13A***
Minimum number of centres outside development centre(s)	3	3	3	3	3
Minium number of surgeons outside of development centre(s)	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	150	225	300	400	400
Maximum revision rate ‡	3.0%	3.5%	4.0%	5.0%	6.5%
Criteria - A Ratings	**3A**	**5A**	**7A**	**10A**	**13A**
Minimum number of centres and surgeons	3	3	3	3	3
Minimum total cohort	150	250	350	500	500
Minimum at risk at benchmark time	72	66	60	51	42
Maximum revision rate ‡	5.0%	5.5%	6.0%	7.0%	8.5%
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level					
Criteria - B Ratings	**3B**	**5B**	**7B**	**10B**	**13B**
Minimum number of centres and surgeons	1	1	1	1	1
Minimum total cohort	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.0%	3.5%	4.0%	5.0%	6.5%
Criteria - Pre-Entry A*					
Product launched under Beyond Compliance					
Pre-Entry					
Products registered with NJR. All primaries and revisions monitored via supplier feedback.					

Fig 34 - The ODEP grid.

"BEYOND COPLIANCE"..... the gap between the CE mark and ODEP 3

NJR was the registry that confirmed that the ASR surface replacement was doing very poorly and that “Stemmed Metal on Metal” was running into serious trouble. The Australian Registry had picked up the poor results from ASR before NJR data was statistically sufficiently strong to make the final call which lead to the MHRA field safety alert. A lot of us felt that we should have picked up these problems earlier. All these implants were “COMPLIANT”, they had a CE mark and had passed the FDA 510K assessment. We felt that there had not been nearly enough emphasis on diligent post market surveillance.

What all this meant was that unless we changed the CE mark rules, which was clearly impossible, we would continue to have implants in the British market which were not adequately monitored.

So, provided it was voluntary and did not break the rules around the CE mark, why could we not go “BEYOND COMPLIANCE” (fig. 35)

Fig 35

With NJR, we were in an excellent position to introduce such a system. Manufacturers would meet with the Beyond Compliance Advisory group so that a risk assessment could be performed which would lead to a discussion as to the rate of introduction for that particular implant and then it would be very carefully monitored. This system has been working since 2012 and the figure below give an idea as to where we are now. Manufacturers have to confirm that any surgeon using one of these new implants has been appropriately trained.

The upload into the NJR is as for any upload but when the data hits the NJR main frame the product is recognised by its bar code details and all the data is copied into a separate dedicated electronic file prepared for that implant as in the figure below. You will see how other information is added to this separate repository to generate a rich information profile for the implant. (Fig. 36)

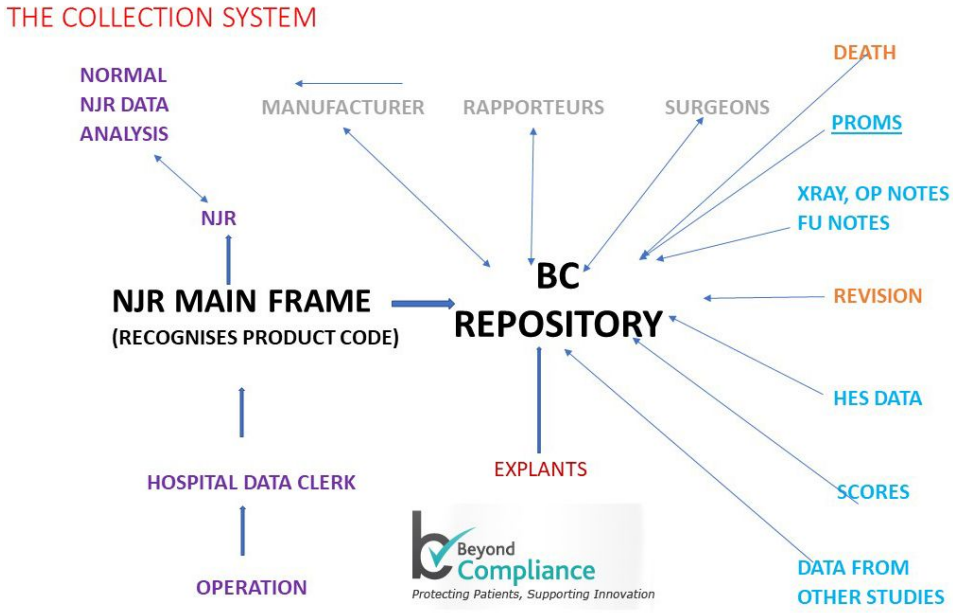


Fig 36

At present there are about 43 implants at various stages in “Beyond Compliance” and 1,353 are registered as having been trained in the use of one or more BC products. Several implants have moved on into “Safeguard” which is a less stringent system but means that the implant is still kept under review.

After the initial assessment there are BC review meetings and “User Group meetings” when we share the data we have with surgeons using the implant and the manufacturer, whilst at the same time taking note of any problems that users might have experienced, whilst using the new implant.

ODEP and Beyond Compliance are developing an App so that we can develop a personal link with the patient and we are working closely with the company “My Recovery”.

We have no doubt that Apps are the way forward in data collection, particularly improved PROMS. We are investigating how machine learning might help us analyse all the data that will be produced in the future. (Fig. 37)

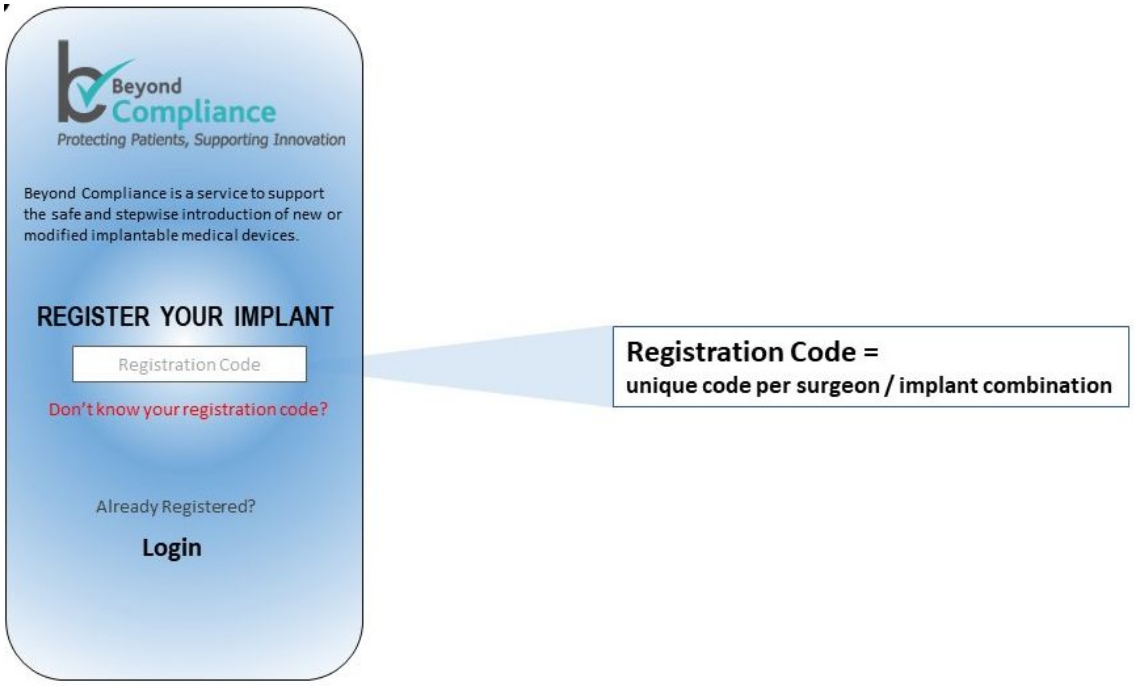


Fig 37 - Prototype of the BC App

9) VALIDATION OF REGISTRY DATA

This means validation of compliance and particularly compliance with uploading revisions. It has been suggested that surgeons and hospitals might be reluctant to upload their revisions for what some would say were obvious reasons. Maybe patients going through emergency operating theatres could get missed out by a local system based on ORs dedicated to joint replacement. NJR takes validation of its data very seriously. In 2014, the NJR started a review of its current understanding of data quality in the registry and how to increase data completeness, timely submission and data accuracy further. This work is summarised in the NJR's Supporting data quality strategy document and covers all of the areas that affect the quality of data including existing activities and new initiatives that was implemented over the subsequent years. NJR are confident that the data they issue is extremely reliable, particularly since 2012.

10) ACCEPTABILITY..... The Attitude of Surgeons in the UK

This figure demonstrates my view about the change of attitude of surgeons to the NJR since 2003. (Table 3)

2003	2019
MANY HOSTILE	A VERY FEW HOSTILE
WORRIED ABOUT CONFIDENTIALITY	USE THEIR DATA FOR APPRAISALS
COULD NOT SEE ADVANTAGES	WANT MORE INFORMATION!
COMPLIANCE LOW	> 95% COMPLIANT
LITTLE VALUE	SUPPORT RESEARCH
MDS "TOO BIG"	MDS "NOT BIG ENOUGH" !
SUSPICION	A LOT OF PRIDE

Table 3

Surgeons do get very concerned when they think that their data could be made public when doubtless the press would pick up on it but basically it is "Not Cool" not to co-operate with NJR.

COSTS

The NJR is funded in two ways. Firstly, there is a levy of circa £13 attached to each joint replacement and then manufacturers pay for the NJR data they require for assessing the performance of their implants, ODEP submissions and regulatory reasons etc. The annual cost of running NJR amounts to about £2 million.

REGISTIES AND THE NEW MDR (MEDICAL DEVICE REGULATIONS)

To obtain a CE mark with the new MDR, manufacturers are going to have to undertake a clinical investigation for any of their new implants, unless they have convincing evidence that they have a closely equivalent implant in their portfolio. No longer will they be able to cite "Equivalence" to a product from another manufacturer with the new rules. Obviously, supporting systems such as "Beyond Compliance" could be very helpful in this respect. Likewise, with legacy products, clinical investigations are going to be needed for manufacturers to support their continuing use of their CE mark. ODEP would provide externally validated clinical data for this purpose. It looks certain that surgeons will need to realise they will have to co-operate with manufacturers to produce clinical evidence to satisfy the Notified bodies so that their favourite joint replacement can stay in the market.

WHAT JOINT REGISTRIES HAVE WE ACHIEVED

Many would argue that our joint replacement registries have set a new standard for information backed decision making across the whole of medicine. (Table 4)

ADVICE TO ANYONE STARTING A REGISTRY!
1) MAKE SURE IT IS MANDATORY.
2) MAKE SURE YOU HAVE "BUY IN" FROM ALL STAKEHOLDERS.
Registries are beholden to the suppliers and users and not the other way round!
3) FEEDBACK
There is no point in having a glitzy registry if it does not "Feedback" the data that manufacturers, surgeons, hospitals, regulators need in a way they can use. The raw data supplied back to manufacturers through supplier feedback is an excellent example of this.
4) MAKE SURE YOU HAVE A GOOD TEAM
You will need good leaders, massive IT support, dedicated analysts and statisticians and it will be best if they have a good sense of humour! NJR has been fortunate in this respect

Table 4

THE FUTURE

For us the future is exciting. Bigger and bigger data will probably generate some unexpected issues. It seems that Artificial Intelligence (AI) or at least machine learning will have a part to play in data analysis if the experts are proved correct. Apps for patients so that we really do know how they are performing will be the norm and that will certainly need some very smart analytic systems if only for the massive volume of data traffic. There can be little doubt that patients and surgeons will only want to undertake treatments that are evidenced based. To all those who are interested in this work now and in the future, I send my very best wishes.

ACKNOWLEDGMENTS

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All our thanks goes to all the patients who allow their data to be recorded in registries

I would like to record a special thanks to Prof Siegfried Hoffmann for his editing and encouragement

The views expressed in this article are those of the author, based on his experience which includes, helping to set up NJR, serving on the steering committee, chairing the Implant Performance committee and being a member of several other NJR committees. He continues to be involved with the Implant Performance committee and the linkage with EPRD and other registries.

REFERENCES

1) An Investigation into the Performance of the 3M Capital Hip. Royal College of Surgeons of England Report 2001

2) Kaj Knutson, Otto Robertsson **ACTA 2010** 81(1)5-7

3) K. Tucker, M.Pickford, Claire Newell, P.W.Howard, Linda Hunt, **A Blomeith on behalf of the National Joint Registry for England, Wales, and Northern Ireland Acta Orthopaedica 2015**; 86 (6):