The Life of a TJR
The stages of regulating and monitoring a total joint replacement

Now and the future

Amie Smirthwaite
&
Keith Tucker
WHAT WE ARE DISCUSSING TODAY....... 

WHAT WILL A MANUFACTURER HAVE TO DO IN THE FUTURE TO OBTAIN A CE MARK?
DECLARATION OF INTERESTS
KEITH TUCKER

Consultant Orthopaedic Surgeon. President BHS 2007-8

Chair Beyond Compliance advisory group and ODEP

Past Member NJR Steering Committee.
Member NJR Implant performance committee,

In the past I received monies from J&J for being a co-designer of 4 hip replacement implants.
All royalties were paid into a research fund

I hold stock in Accentus Medical
I do not receive any financial reward for NJR,MHRA BEYOND COMPLIANCE or ODEP work. My travel expenses are reimbursed.

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WHERE I STARTED

• BOA REPRESENTATIVE TO MDA 1986

• JUST AFTER CE MARKS WERE INTRODUCED
• MDA HAD JUST BECOME THE COMPETENT AUTHORITY

• WHAT ABOUT PMS I ASKED

• YOU WILL HAVE TO CHANGE EU LAW IF YOU WANT THAT!!
WHY AM I HERE

• I AM A SURGEON AND HAVE SEEN THE RESULTS OF BAD IMPLANTS

• SURGEONS DO NOT WANT TO USE BAD IMPLANTS

• SURGEONS WANT TO BE SURE THAT THE REGULATIONS ARE THE BEST THEY CAN BE

• MANY SURGEONS ARE PREPARED TO HELP WITH THE INTRODUCTION OF NEW IMPLANTS

• MOST OF US ARE PASSIONATE ABOUT THESE ISSUES
WHERE WE ARE

• POST CE

• POST MOVING TJRS FROM 2b to 3

• WE HAVE AN OPPORTUNITY OF GETTING IT RIGHT THIS TIME

• THE NEW REGULATIONS

• THERE ARE NOW > 2 MILLION TJRS INSERTED THROUGHOUT THE WORLD pa

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THE LIFE OF A TJR

Developing the idea assessment

Pre CE testing

CE mark & Pre CE mark evaluation

Immediate Post market surveillance

Long term

Developer ISO Standards

Notified Body (NB) Notified Body

“Beyond Compliance”

ODEP and Joint Registries

The Regulator / Competent Authority
A NEW JOINT REPLACEMENT

• THE THOUGHTS ARE PUT DOWN ON PAPER

• A MANUFACTURER IS INVOLVED

• ALL ASPECTS OF THE DESIGN ARE DISCUSSED

• EQUIVALENCES ARE LISTED

• ISO STANDARDS ARE OBSERVED
A NEW JOINT REPLACEMENT
ISO STANDARDS

• INTERNATIONAL ORGANISATION FOR STANDARDIZATION

• www.iso.org/home.htm

• ISO creates documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

• We've published 22041 International Standards, which you can buy from our members or the ISO Store.

• Bringing real and measurable benefits to almost every sector imagineable, standards underpin the technology that we rely on and ensure the quality that we expect.
A NEW JOINT REPLACEMENT

ISO STANDARDS

• INTERNATIONAL ORGANISATION FOR STANDARDIZATION

AMIE...

• HOW GOOD ARE THEY FOR JOINT REPLACEMENT?

• ARE THEY UP TO DATE AND RELIABLE

• DOES THE EU HAVE INPUT INTO THEIR DEVELOPMENT

• WHO VALIDATES THEM?
A NEW JOINT REPLACEMENT
THE NEXT STEP

• DISCUSSION WITHIN THE COMPANY

• ADVICE AS TO HOW THEY PROCEED

• WHERE CAN THEY GET ADVICE?
A NEW JOINT REPLACEMENT

THE NEXT STEP

At present

• SUBMISSION TO A NOTIFIED BODY
• ARE ALL NBS THE SAME?
• WHAT ARE THE RULES?

• WHERE DOES “EQUIVALENCE” FIT INTO THE PRESENT REGULATIONS?
A NEW JOINT REPLACEMENT
THE NEXT STEP

• WHEN WILL THEY HAVE TO UNDERTAKE A CLINICAL EVALUATION

  *Do we know?*

• WHERE DOES THE NEW EU PANEL FIT IN? WHO TRIGGERS IT

  *Do we know?*
A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

• I HAVE NEVER SEEN A UNVALIDATED PUBLICATION WHICH HAS INCLUDED A PMS STUDY LET ALONE A VALIDATED ONE

• WHY NOT?

• WHAT IS ASKED FOR AT PRESENT?

• WHAT WILL BE ASKED FOR IN THE FUTURE?

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SUFFICIENT CLINICAL DATA
A DEBATE IN ITSELF!

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

WHAT MANY WOULD LIKE TO KNOW!
NOW AND IN THE FUTURE

• HOW RIGOROUS SHOULD IT BE?
• WHAT SIZE OF COHORT
• FOR HOW LONG
• WHAT METRICS SHOULD BE USED
• HOW IS IT VALIDATED

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

THE TOOLS WE HAVE
NOW AND IN THE FUTURE

• CLINICAL TRIALS
• RCTs ARE EXPENSIVE AND OFTEN NOT COMPLETED
• REGISTRIES ARE USUALLY MANDATORY

• EARLY REGISTRY DATA IS UNRELIABLE
• NOT ALL REGISTRY DATA HAS THE SAME RELIABILITY

• RSA STUDIES HAVE BEEN SHOWN TO ACCURATELY PREDICT EARLY FAILURE

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

THE TOOLS WE HAVE
NOW AND IN THE FUTURE

• REGISTRIES CAN BE USED AS CONDUITS
• THEY CAN GENERATE QUESTIONS
• THEY CAN STORE ANSWERS
A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

THE TOOLS WE HAVE
NOW AND IN THE FUTURE

• RSA STUDIES HAVE BEEN SHOWN TO ACCURATELY PREDICT EARLY FAILURE

• WHAT DOES IT INVOLVE?

• WE HAVE ONE OF THE WORLD’S EXPERTS HERE.... ROB, PLEASE GIVE US A MINUTE!

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

SHOULD RIGOR OF PMS DEPEND ON PERCEIVED RISK
NOW AND IN THE FUTURE

• EVALUATE RISK
• ? STEP BY STEP
• ? QUICK BLAST THEN STOP
• WHO DOES THE MONITORING?

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

SHOULD RIGOR OF PMS DEPEND ON PERCEIVED RISK
NOW AND IN THE FUTURE

• IS BENCHMARKING AN OPTION?

• BENCHMARKING IMPLIES SETTING A STANDARD ACROSS ALL PRODUCTS

• BENCHMARKING USUALLY IMPLIES THE USE OF “NON INFERIORITY” CONCEPT
A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

WHERE DO THE RESPONSIBILITIES LIE AND FOR HOW LONG?
A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

• WHAT HAPPENS IF AN IMPLANT IS NOT DOING WELL IN ONE COUNTRY?

• WE SHOULD BE ABLE TO INTERROGATE ACROSS ALL EU COUNTRIES
A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

NIMAC

NORE IMPLANT MONITORING ADVISORY COMMITTEE

IS THIS A GOOD IDEA?

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A NEW JOINT REPLACEMENT
HOW SHOULD IT BE INTRODUCED

SURGEONS NEED TO KNOW
MANUFACTURERS NEED TO KNOW

ANSWERS PLEASE!

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Developing the idea → Pre CE testing assessment → CE mark & Pre CE mark evaluation → Immediate Post market surveillance → Long term

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