IDEAL Orthopaedic Surgery

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&
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Disclosures

- Institutional Research Grants – Zimmer Biomet
- Committees - Arthritis Research UK, Finnish Academy
- Institutional support - ZB
- PRO-MAPP Ltd – Director – Oxford U Spin Out

- No conflicts with content of this session
Table 1: Brief description of the IDEAL stages and proposals for modifications to develop IDEAL-D

| IDEAL-D | IDEAL-D innovations
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<tr>
<td>Main IDEAL recommendations (procedures/operations)</td>
<td>IDEAL-D recommendations (devices)</td>
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<td>Stage 0 (preclinical)</td>
<td>Silent but recognized: no recommendations for study design or reporting.</td>
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<td>Stage 1 (first in human)</td>
<td>Compulsory reporting all new innovations to accessible international registry.</td>
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<td>Confidentiality allowed to encourage reporting of failed innovations.</td>
<td>Reporting of first-in-human use integrated into a process by which devices are patented and regulated. May use existing channels—for example, ClinicalTrials.gov—but must conform to a basic standard of evidence presentation to allow learning. Confidential reporting allowed if manufacturer might still be liable.</td>
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<td>Stage 2 (prospective developmental studies exploratory studies)</td>
<td>Device iterations mostly occur in stages 0-1, but products with device insertion/thrombolysis may require iteration. No clinical studies (investigational device exemption in US) will be conducted where multiple manufacturers produce trial devices. Stages 2a and 2b may be combined if rationale for separation seems weak. Quality control and learning curve estimation remain important, and studies should be conducted in experienced centres to minimize risk of harm. Regulatory guidance on study designs.</td>
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<td>Procedure now gaining wide acceptance and considered as a possible replacement for current standard. Definitive clinical comparison (preferably randomized controlled trials) against current best practice should occur since learning curves are ever present and consensus is achieved over definition of interventions, indications, and quality control measures.</td>
<td>Trials might follow stages 2a and 2b or proceed immediately after stage 1 (stages 2a, 2b, and 2) where insertion/thrombolysis is simple, meaning that learning, quality control, and intervention definition are not major issues. Regulators should reach consensus on an international set of principles for deciding when a randomized controlled trial is needed.</td>
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<td>Stage 3 (assessment via randomized controlled trial or alternatives)</td>
<td>Registries for monitoring rare problems and changes in use (indication creep).</td>
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<td>Registries valuable but may begin much earlier, particularly for “med-ted” products that enter practice after stage 0. For novel devices, registries should ensure controlled introduction.</td>
<td>Registries allows for monitoring rare problems and changes in use (indication creep)</td>
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<td>Stage 4 (long-term study)</td>
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<td>1. 1st in man – bio shoulder</td>
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<td>2. Innovation to market – spine</td>
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<td>3. Registries and surveillance - hip</td>
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The IDEAL Collaboration
Idea, Development, Exploration, Assessment, Long-term follow-up
Faculty

- Prof. Stephen Graves – Ortho Surgeon – Aust. Joint Registry
- Prof. Andrew Carr – Ortho Surgeon – innovator/academic/triallist
- Mr. Jeff Dunkel – VP Titan Spine – Health Strategist

- Mr. Blair Fraser – VP Smith & Nephew – Scientific affairs / Registries
- Dr. Pamela Plouhar – VP DePuy/J&J – Clinical Research/NIHR
- Dr. Liz Walton-Paxton – Dir. Kaiser Permanente – Surveill/Registry/FDA

- General discussion around area
- IDEAL specific
Objective

- Explore and outline best ways of;

Safe efficient evaluation of surgical devices
W I T H O U T
suffocating innovation
First in man – Andrew Carr/Pam Plouhar

- Lots of needs - IDEAL has “a lot to cope with”
- Fast moving - no standards/template
- Sometimes difficult to set requirements (n=?)
- How to deal with pauses in development
- Clear aims critical
- Patent – confidentiality
- How detailed for reporting
- Just safety?
- Commercial interest/conflict/bias?
Innovation testing: Jeff Dunkel/Liz Paxton

- “Accidental” discovery of new nanatexture process to help spinal integration.
- FDA requirements
- Tough scientific demands – agreed was correct
- Dependence on retrospective “costing” data
- Costly process
- Needed tenacity to overcome
- IRB to publication ratio is a useful metric
- More structure and knowledge (esp IDEAL) likely helpful in process – echoed by LP
Registries: Steven Graves/Blair Fraser

- Registries
  - Definition of a registry
  - Safety or outcome or both?
  - Good compliance
  - Good for simple questions
  - Choice of outcome measures critical
    - Survival? Revision or PROM
  - Mimic products (me too’s)
  - A priori tailored risk assessment could be a better way?
  - Who pays?
  - Definite place for IDEAL (stage 4)
- Orthopaedics first in man, any differences compared with other specialities? Risk lower?
- What is safe? How many needed? Confidentiality?
- Innovation journey – where are the gaps - how do we get standardisation?
- Spine special issues? Failure v success?
- Registries – comparators – confounders – grandfather new similar products
- When should we start a registry – is it from first implantation