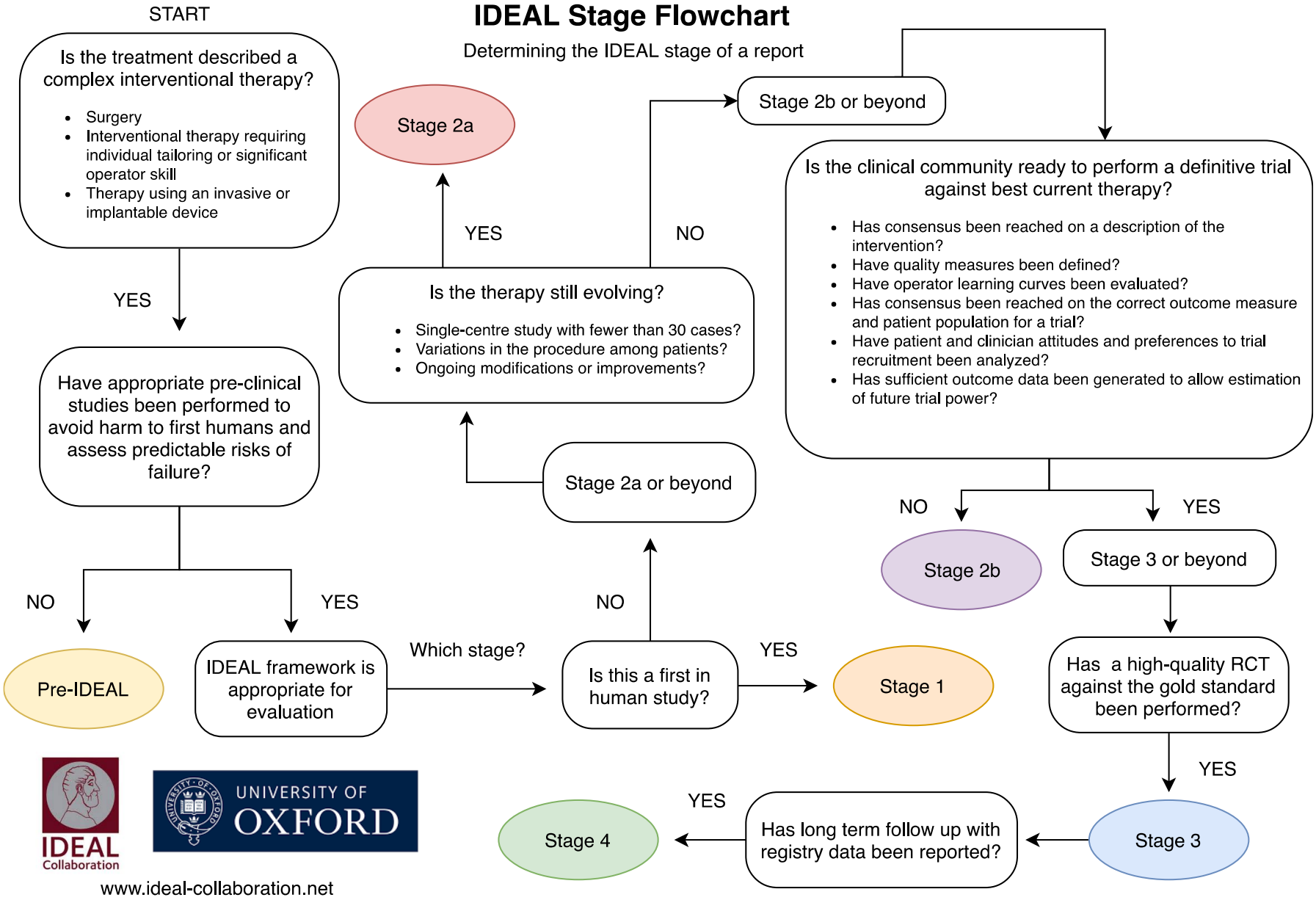
IDEAL Stage Flowchart

Determining the IDEAL stage of a report



IDEAL Collaboration

UNIVERSITY OF OXFORD

www.ideal-collaboration.net

Authors: Nicole Bilbro MD, MPH, Allison Hirst BA, MSc, Prof Peter McCulloch

IDEAL Stages Defined

Each IDEAL stage is defined by key research questions:

- **IDEA—STAGE 1**: What is the new treatment concept/why is it needed?
- **DEVELOPMENT—STAGE 2a**: Has the new intervention reached a state of stability sufficient to allow replication by others?
- **EXPLORATION—STAGE 2b**: Have the questions that might compromise the chance of conducting a successful RCT been addressed?
- **ASSESSMENT—STAGE 3**: How does the new intervention compare with current practice?
- **LONG-TERM STUDY—STAGE 4**: Are there any long-term or rare adverse effects or changes in indications or delivery quality over time?

General issues that should be reported at all stages:

- Reference to IDEAL stages before (in previous publications) and after (planned)
- Ethics – details of approvals obtained and Informed Consent (full and accurate information for the patient including the stage of development of, and experience with the procedure, and where appropriate the likelihood that not all risks are yet known)
- Funding sources
- Reference to an available protocol for the intended study
- Use of reporting guidelines (see EQUATOR network www.equator-network.org)
- A review of existing relevant scientific literature
- A transparent account of patient inclusion and exclusion criteria and decisions
- Use of standardised, validated, widely accepted and where possible objective measures for outcomes, (see COMET initiative http://www.comet-initiative.org/) potential confounders and patient characteristics

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IDEAL Stage 1 Important Questions

1. Does the report clearly state why the new technique was needed? Was any pre-clinical development of the technique referenced?
2. Was it clear what the new procedure was? Was it sufficiently described so that a skilled clinician reading the paper could reproduce the technique?
3. Does the report discuss any risks or uncertainties relating to the technique?
4. Do the authors provide full details of reasons why this patient was a good candidate for the procedure? Were there details of patients not selected?
5. Do the authors indicate whether this procedure is ready to be evaluated in a Stage 2a study?

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IDEAL Stage 2a Important Questions

1. Does the report describe the technical details of the procedure?
2. Does it say whether the technique or indications were modified at any point? If so, does it explain when and why? How is this information displayed?
3. Does the report give outcome data sequentially for all patients in the series?
4. Do the authors indicate any plans to take the technique forward into a prospective multi-centre evaluation study? If so what type of study?

IDEAL Stage 2b Important Questions

1. Does the report clearly state that the study is collaborative, multi-centre with co-operative data collection?
2. Are subgroups of patients identified for which the applicability of the technique is considered uncertain?
3. Does the report give a clear description of or reference to the technique, including any variants which are accepted?
4. Are quality standards for performance of the procedure defined and used?
5. Does the study attempt to collect data on operator learning curves?
6. Does the study include attempts to gather information on patient and clinician preferences and values relevant to their willingness to participate in an RCT?
7. Is progression to a Stage 3 RCT desirable and feasible? Do the authors refer to planning an RCT?

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IDEAL Stage 3 Important Questions

1. Does the report give a satisfactory explanation of how learning curves have been accounted for? Does the report make clear how clinician preferences were excluded from the informed consent process?
2. Does the report include quality measures to demonstrate the fidelity with which the procedure was conducted as intended?
3. Do the authors identify issues requiring long term monitoring?

IDEAL Stage 4 Important Questions

1. Is the report based on a population who have all had a single condition or one who have all had the same treatment?
    a) If the latter, is there any information on which patients with the same conditions have had alternative treatments, and what their outcomes were?
2. Is it clear who designed the dataset and for what purpose? Was it a group with expert knowledge of the procedure, device, and condition? Are there any questions around conflict of interest?
3. Is it clear who CURATES (i.e. manages) the dataset and who FUNDS the dataset, and what the relationship is between the two?
4. Does the dataset contain the most important outcome measures and measures that account for known risk factors or confounders?
5. Does the report clarify the extent of missing data fields in the dataset?

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