Harmonisation of reporting on study design, statistical methods, data analyses and results in the fields within EFSA's remit

Saghir Bashir
Scientific Assessment Support

EFSA Guidance on Statistical Reporting

Saghir Bashir
Scientific Assessment Support

Working Group Team

- Panel Experts
  - Jean-Louis Bresson (formerly NUTRI)
  - Mikolaj Gralak (FEED)
  - Matthias Greiner (formerly AHAW)
  - Andrew Hart (Former PPR)
  - David Makowski (PLH)
  - Joe Perry (GMO)
  - Hans-Hermann Thulke (AHAW)
- EFSA
  - Davide Arcella (DCM)
  - Saghir Bashir (SAS)
  - Andreia Carlos (SAS)
  - Laura Martino (SAS)

Outline

- Motivation
- Mandate
- Current Status
- Draft Structure
  - Key points
- Future Directions
  - Public Consultation
- Conclusions

Motivation

- EFSA receives various statistical “reports”
  - Often basic/key information is missing or partially reported
  - Objective assessment is difficult
  - Valuable time is lost when requesting additional information
- EFSA should also enhance the quality of reporting focusing on transparency and openness

Mandate: Background

- The risk assessment process often requires quantitative evaluation of scientific studies from different sources
  - E.g. dossiers, journal publications, technical reports
- The reporting of statistical methodology (including design), analysis and results varies considerably which can lead to delays in the review process whilst additional information is sought from the originating source.
- If the statistics were consistently reported in a harmonised and standardised way then this would benefit both EFSA and its stakeholders.

Mandate: ToRs

- The Guidance should be practical and applicable to the different areas covered by EFSA's remit.
- The EFSA Guidance should include:
  - how to ensure objective and accurate reporting of statistics
  - how to document and present the design, methodology, analysis and results to allow independent peer review.
  - a glossary of relevant terms.

Guidance Objectives

- A guidance document on Statistical Reporting
  - Covering all the steps including design, data collection and analysis (including statistical programming).
  - Generic reporting guidance with specific advice (e.g., on clinical trials, animal experiments, surveys) where necessary.
- Guidance aimed at
  - EFSA Panels, WGs & units
  - Stakeholders (including applicants)

Scope

- “Explain to the reader what was done”
  - To a level of detail that allows reproducibility
  - Has to be open and fully transparent
- The following are out of the scope:
  - What design to use
  - What methods to use
  - How to conduct studies/surveys/experiments/…

Tentative Timelines

- From first WG meeting (Feb 2013)
  - 12 months (Feb 2014)
    - Scientific Committee endorsement for public consultation
  - 14 months (April 2014)
    - Draft for public consultation
  - 16 months (June 2014)
    - End of public consultation
  - 19 months (September 2014)
    - Adoption by Scientific Committee
  - 20 months (October 2014)
    - Final version published
    - Public consultation report

Current Status

- Current high level structure
  - Reporting of objectives and scope
  - Reporting sources of information
  - Reporting of study design for data collection
  - Reporting conduct and quality of data collection
  - Reporting the methods of analysis
  - Reporting the principal results
  - Reporting the interpretation of the results
  - Detailed statistical outputs
  - Supplementary Study information
- This could change!

Objectives and Scope

- Background
- General objectives
  - In narrative form
- Specific objectives
  - Exploratory? Confirmatory? Estimation?
  - Statistical hypotheses (if any)

Sources of Information

- Existing sources of data
  - Provide all information to retrieve the data
    - e.g. time frame, geographical coverage, design, collection methdology
- Direct data collection
  - Document data collection methodology as part of the planned study design

Study Design

- Study Design
  - Design of Experimental Studies
  - Design of systematic reviews and meta-analyses
  - Design of observational studies/surveys
- Sampling
  - Sampling unit (e.g. 2 rats per cage)
  - Sample size/power calculation
  - Sample selection strategy
    - Representativeness

Data Collection: Conduct & Quality

- Data Management
  - Step to minimise bias and maximise precision
- Data Quality Assurance
  - Quality control
  - Operating procedures

Methods of Analysis

- Data processing (e.g. transformations, outliers)
- Statistical analysis
  - Complete specification of model and assumptions
  - Missing data and multiplicity
  - Model diagnostics, sensitivity analysis
  - …
- Software
  - Version, operating system,
  - To allow reproducibility of analysis

Principal Results

- Descriptive statistics
  - Quantitative Summaries
- Results of statistical analysis
  - Results of supporting analysis
  - In original units with interval estimates
    - for assessment of biological relevance
- Graphical summaries
  - To allow objective assessment

Interpretation

- Reporting results and their interpretation
  - Report all results regardless of statistical significance
  - Discuss biological relevance in parallel to the statistical significance
- Reporting Uncertainty
  - Assumption made
  - Magnitude and direction of potential bias
  - Level of precision
  - …

Statistical Outputs

- Essential results should be present in summary form in the body of the report
- Detailed results should be in this section:
  - Tables
  - Graphs
  - Listings

Supplementary Study Information

- Protocol and protocol amendments
- Sample information (data) collection form
- Statistical analysis plan and amendments
- Randomisation list
- Publications based on the study and/or analysis
- Unpublished references
- Quality assurance procedures
- Raw data in electronic format

Conclusions

- The quality of statistical reporting needs to improve:
  - Be open and transparent
  - Objective assessment
  - Reproducibile
- Statistical Reporting Guidance
  - Please give feedback during the public consultation
  - Any guidelines have to be workable for both EFSA and its stakeholders