7

Conducting research investigations and analysing findings

7.1. Planning for implementation

Having acquired the resources required to undertake your research investigation you are now at the implementation stage. There is a temptation to 'dive in' and start conducting experiments. However, time spent planning proper investigations is time well spent since planning will help to design an investigation that will have the best chance of completion without error and of producing data that can be analysed in a meaningful way to deliver firm conclusions that will be accepted by peers.
There are four components in planning to implement a research investigation:

1. Listing requirements

Making a list of what you require for an investigation is an obvious step. Every investigation will have different requirements but they are all likely to include:

- Material for investigation: patients, blood specimens; animals, cell lines etc.
- Equipment: preparatory, analytical, computing, storage etc.
- Consumables: reagents, laboratory ware, disposal etc.
- Facilities and staff: access to facilities and availability of staff when needed etc.

There is no point in commencing the investigation until everything is to hand.

2. Planning for data acquisition and recording

The investigation will generate data. As part of planning it is necessary to define the nature of that data, how it will be acquired and stored.

- Nature of data required: measurements; quantity; units etc.
- Method of data acquisition: manual; automatic; quantitative; qualitative etc.
- Data storage: data store; format; accessibility; flexibility; security etc.

3. Planning for the analysis of results, including statistics

Having planned to acquire and store the correct data you should also plan how you are going to analyse it and display the results of the analysis.

- Preparation: table; database, spreadsheet; etc.
- Statistical test; see Table 7.1
- Statistics package
- Presentation: table; figure; chart; plot etc.

4. Conducting pilot investigations

Pilot investigations are a useful way to test that the planning has been comprehensive. Pilot investigations also help to confirm that equipment is working and to clarify timing and logistics.

7.2. Methods and equipment

The choice of methods will have been planned at the research proposal stage. The suitability and availability of the equipment required to undertake the investigations will have been confirmed as part of planning for the investigation. If possible a pilot investigation will have been performed to assess timing and logistics. The final step before starting the investigation is checking the performance characteristics of the equipment.

Most equipment requires to be calibrated. This means that its performance needs to be compared with an independent standard. A simple example is the calibration of a micro-pipette where the volume of water dispensed can be weighed on a suitable balance, which itself has been calibrated. Other examples of calibration relate to standards of time, temperature, mass, electrical conductivity etc. Calibration is the basis of ensuring an accurate result when the equipment is applied to the test investigation.

In addition to accuracy it is necessary to know the imprecision (uncertainty) of measurement of the equipment used. Using the example of the micro-pipette the imprecision can be calculated by weighing the water dispensed from repeated use of the same pipette. Clearly, the imprecision of measurement should be as small as possible in order to reduce its impact on the difference between test and control.
Data from the calibration and assessment of all the equipment to be used in the investigation should be recorded and dated. It is the responsibility of the researcher to obtain this data since it will underpin the results obtained and the conclusions drawn from the investigation.

7.3. Conducting research investigations

After all the preparation the time has finally arrived to conduct the research investigation. It is at this stage that the value of that preparation becomes apparent. You have already selected and tested your methods and equipment and you may have been able to conduct a pilot investigation to optimise the test investigation. Therefore, the researcher can proceed with confidence knowing that risks have been minimised. This is important because precious material (e.g. patients or samples) will now be committed to the investigation.

Many research investigations involve repeated measurement, which may only be possible in batches. In such circumstances every effort should be made to reduce inter-batch variability. This can be achieved by meticulous attention to every detail of the procedure. In particular the balance between control and test samples should be the same in every batch. The inclusion of identical control samples in each batch provide the opportunity for objective quality assessment.

7.4. Recording research investigations

The recording of a research investigation is a critical part of research governance because this record contains the data that is the evidence arising from the investigation. Record keeping should be timely, systematic and comprehensive because it is possible that an external source may ask to audit the research or examine a specific data set.

The classical way to record investigations is to create a research book. There is an entry for each day of the project in which contains:

- Date and name of researcher
- Detailed study performed
- Raw data from study, including print-out from equipment
- Summary arising from raw data
- Comments
- Signature of researcher

Such a record cannot easily be changed at a later date.

Today most research records are kept in an electronic format, often in a series of files or folders. The same approach should be adopted as for the research book. The advantages of electronic records lie in convenience, the ability to perform data analysis directly from the record, and the ability to back-up the record in the interests of data security. From a research governance perspective the disadvantage of electronic records may lie in capturing raw data and in the ease with which changes can be made at a later date.

There is no excuse for the researcher who does not keep detailed records. Without the evidence from the investigations there is always the risk that the researcher may be accused of unprofessional practice or even fraud.

7.5. Analysing data

Data analysis is a structured process of inspecting, cleaning, and transforming data with the goal of discovering useful information. In effect, this information represents a result from the investigation.

Prior to analysis the required data has been collected and recorded. The next stage is data processing, which may involve transferring the raw data into groups, rows or columns as part of a database or spreadsheet. It may become apparent that the data is incomplete, contain duplicates or errors. The data should be cleaned to remove all invalid data and a record should be kept of the data that was removed and the reasons for removal.

Data transformation entails converting the cleaned data into a form where it can be examined using statistical or other objective methodology. A simple example of data transformation is to convert individual data points from a group study into a mean or median, with confidence limits.

Different analytical techniques may be applied to the transformed data. In medical research the transformed data is usually numeric, lending itself to formal statistical analysis. However, the data from a survey or case study may be qualitative rather than quantitative in which case data analysis may involve pattern identification. Further consideration of the techniques used for data analysis are beyond the scope of this text.

The methodology used to display analysed data is part of the reporting process and is considered in more detail in Chapter 8. It is usual to display the transformed data, together with a confidence limit and the level of statistical significance. Display can be in tables or in a range of figures that include plots and charts.

The timing of data analysis depends on the research methodology. In a clinical trial, especially one that is 'blind' to the researcher no data analysis is possible until the research investigation is complete. Conversely, in basic research it may be possible to perform exploratory data analysis at an earlier stage in order to seek reassurance about the quality of the data collected or the detailed research methodology.

7.6. Statistics

A detailed consideration of the use of statistics in medical research is beyond the scope of this short booklet. There are inexpensive specialist texts on medical statistics; most researchers will have access to a statistician for advice or practical assistance; and many academic institutions run courses on statistics for research. Different research questions require different statistical tests and so it is important that the choice of the correct statistical test is made at the planning stage of conducting a research investigation. Planning for statistical analysis will help the researcher to determine both the nature of data to be collected and the quantity of data required to give power to the study so that the statistical analysis may produce a clear outcome.

The importance of statistics becomes apparent when the researcher presents his/her findings to peers or submits a manuscript for publication. The use of inappropriate or invalid statistical methods is easily spotted and can result in dismissal of the research findings.

A simple way to classify statistical tests is shown in Table 7.1. This is based on the text recommended in the References section at then of this chapter.

Table 7.1. | Simple classification of statistical tests

Nature of statistical test	Example of statistical test
Describing data	Percentage; mean; median; standard deviation; coefficient of variation. Parametric or non-parametric
Testing confidence	Confidence intervals; p values
Testing difference	Parametric: t test Non-parametric. Mann-Whitney test Chi-squared test
Comparing risk	Risk; Odds ratio; risk ratio; risk reduction; number needed to treat
Analysing relationships	Correlation; regression
Analysing survival	Kaplan-Meier plots
Analysing clinical investigations	Sensitivity; specificity; predictive value; level of agreement

7.7. Drawing conclusions

Once the results of the investigation have been analysed it is time to draw conclusions. This process will be considerably easier if the investigation was planned to include adequate sample size, a suitable control and the testing of a single variable. In such circumstances the results are likely to demonstrate whether there is a statistically significant difference between the test and the control arms of the investigation.
If there is a 'positive' outcome to the investigation it is possible to conclude that there is a significant difference between test and control. However, by itself that finding may not be sufficient to justify the hypothesis that was tested in the investigation. This is because there may be more than one explanation for the positive result. Researchers are often quick to reach conclusions that are beyond their results, especially if the results are in line with their original hypothesis.
To illustrate this dilemma one has only to look to recent literature to find many studies that have demonstrated statistically significant vitamin D deficiency in a range of common chronic diseases. It is possible to conclude that there is a difference but it is not possible to conclude that vitamin D deficiency is the cause of the chronic disease. Indeed it may be that the chronic disease is responsible for the vitamin D deficiency. This cause or effect phenomenon is common in medical research and may prompt the valid conclusion that further research is required to differentiate between the possible explanations for the observed results.
The over-interpretation of results can lead to a high quality investigation being disregarded by peers. The inexperienced researcher would do well to follow a systematic approach to drawing conclusions from his/her results:

- Record the result of the investigation performed
- List all possible explanations for the observed result
- Use scientific knowledge to reduce the number of possible explanations
- Reach a conclusion based on the number of valid explanations that remain
- Discuss the process used to reach the conclusion with your research supervisor or mentor

7.8. References

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