

Summary of research course to date

Research can be considered to be the generation of new knowledge. To gain new knowledge, we need to gather data that we can analyse.

TWO BROAD TYPES OF RESEARCH

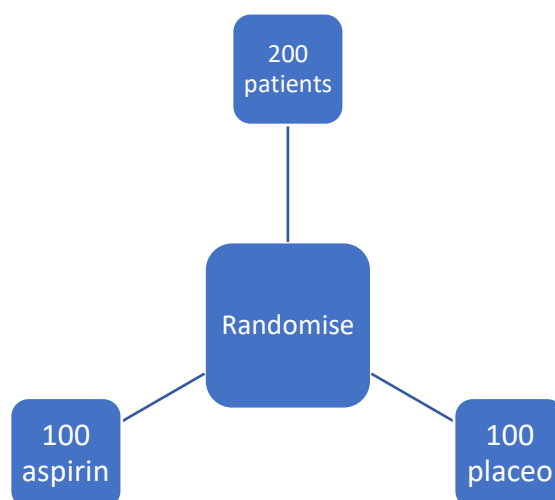
There are two broad types of research. There is quantitative research and as the name suggests, this looks at a quantity or number. The second type of research is qualitative, for example asking patient their views about a service. This is often written as text quoting the patient.

QUANTITATIVE RESEARCH

There are several ways to undertake quantitative research. One is an experimental approach, such as the 'gold standard' randomised controlled trial. This is sometimes abbreviated to the letters RCT.

In a RCT, a group of patients are randomly allocated to receive a new treatment. This might be via a simple method such as a toss of coin. This study is controlled so we give the active medicine versus placebo. Trial suggests that we do not know what the study outcome will be.

Suppose we have 200 patients who had a heart attack. We would randomly give 100 patients a new treatment and 100 patients the placebo. 50 years ago the first trial of aspirin was conducted in Wales.



We follow up the patients and measure their subsequent heart attacks. Suppose 10 patients taking aspirin have a heart attack and 15 patients taking placebo have a heart attack. We can work out the %.

A % is simply a number shown in comparison to 100. So if 10 patients out of 100 have a heart attack taking aspirin then this is 10%. For placebo this is 15%. So we see aspirin gives a lower risk of heart attack.

Medical regulators, such as the National Institute for Health and Social Care (NICE), will often use RCT to advise on treatments for the National Health Service. Cost of treatment will also be important.

Observational quantitative research

This can be used to describe a situation. For example, if we wanted to know the number of people who were drinking too much alcohol, we could do a survey. This is important for planning healthcare service.

Suppose we have 500 people living in a village. We could survey them about their alcohol intake. Let's assume everyone agreed to be involved and gave accurate answers. We might find the following.

People drinking too much	People drinking moderately	Total
100 (20%)	400 (80%)	500 (100%)

We can calculate the %. For people who drink too much, the numerator 100 and the denominator is the total village size, 500. So we calculate 100 divided by 500 multiplied by 100 (%) or as below.

% of people drinking too much is $100 / 500 * 100 (\%) = 20\%$.

We can calculate people who drinking moderately as follows.

% people drinking moderately = $400 / 500 * 100 (\%) = 80\%$

Importantly, we account for everyone in the sample. So 100 plus 400 = 500. And 20% plus 80% is 100%. This is important for research.

QUALITATIVE RESEARCH

This can be used to understand the reasons that something is occurring. For example, we might want to ask the 100 people who are drinking too much about their reasons for drinking. For those that agree to participate in this research, we could design a qualitative research study. We could ask many questions – why do you drink to excess? Are there any barriers to you reducing your alcohol intake?

In qualitative research, there are usually many ways to conduct the study. This might include an anonymous survey or a face to face meeting or a telephone call. Each has strengths and weaknesses so the situation itself will help guide which method will be most helpful.

Interpretation of findings can sometimes be difficult as there may be many reasons. It is therefore important to consider how the results will be analysed, for example trying to identify different themes. In the case of alcohol use, people may drink too much to reduce stress.

MIXED METHODS APPROACH

Quantitative and qualitative research can also be used together. So we could undertake a lifestyle survey of a community so that we can understand the factors, such as alcohol, smoking and exercise, that help people keep healthy or increase their risk of developing illness.

If we take smoking as an example, suppose we survey a town of 10,000 people and that we find that 20% are smokers. We can calculate that this is 2,000 people as shown below. We can also ask people what are their barriers to giving up smoking. This might show that people are not sure how to access a smoking cessation service. So we can then put in place a service that has the required level of resource and is also well advertised so that people know how to get in touch if they wish.

20% of the town are smokers and the population is 10,000. What is the number who smoke. We can reverse our previous calculations.

$20\% = 20 \text{ in } 100 \text{ people. So } 20/100 * 10,000 = 2,000 \text{ people.}$

In class exercise

1. Why is research important?
 - i) Generate new knowledge
 - ii) Help advance treatments
 - iii) Both of the above

2. What is a medical regulator?
 - i) Approves medicine
 - ii) Provides treatment
 - iii) None of the above

3. What are the two broad types of research?
 - i) Randomised controlled trial and qualitative
 - ii) Quantitative and qualitative methods
 - iii) Observational and randomised controlled trial

4. We have 50 patients in an eye clinic. Smoking levels are 10% or 1 in 10. How many patients in the eye clinic smoke?
 - i) 5 patients smoke
 - ii) 10 patients smoke
 - iii) 50 patients smoke

5. We want to seek views of patients about their experience of receiving stroke care. What could be the best method?
 - i) Ask them in person
 - ii) Questionnaire survey
 - iii) Combination of both

CONVERSION TABLES

In research, sometimes data is present in different forms. This sheet sets out some conversions that may help understand different data.

Fraction : This has two parts. The first is the numerator, which is the top number. The second is the denominator, which is the bottom one.

Some fractions might be easy to recognise. So $\frac{1}{2}$ is a half. $\frac{5}{10}$ is also a half. $\frac{3}{4}$ is three quarters. So if we have 10 patients in a clinic for physiotherapy and 5 smoke, then we know half of the patients smoke.

Percentage : This shows the data as a fraction of 100. The symbol is %. So if half of our physiotherapy patients smoke, then we can calculate this as 50%. As a calculation this is $\frac{1}{2} * 100 (\%) = 50\%$.

Or we could do this in reverse. Suppose we know half the physiotherapy patients smoke. And if we have a clinic list of 10 patients then we can calculate $50\% * 10 / 100 = 500 / 100 = 5$ patients

Decimal point : This shows a value in comparison to the number 1. So if 1.0 is the same as 100%, then 0.5 is the same as 50%. Or we can increase the value higher than 1 so that 2.0 is the same as 200%.

Word	Fraction	Percentage	Decimal
One-tenth	$\frac{1}{10}$	10%	0.1
Two-tenths	$\frac{2}{10}$	20%	0.2
One-third	$\frac{1}{3}$	33.3%	0.33
Half	$\frac{1}{2}$	50%	0.5
Two-thirds	$\frac{2}{3}$	66.6%	0.66
Three-quarters	$\frac{3}{4}$	75%	0.75
Whole	1 or $\frac{1}{1}$	100%	1
Double	2 or $\frac{2}{1}$	200%	2

OTOOIN in the treatment of childhood asthma

Introduction : Childhood asthma is a respiratory illness which affects the ability to breath. Treatments for childhood asthma include medications that can relax the lungs and therefore prevent bronchospasm. In this relevant clinical test (RCT), we tested the medicine OTOOIN to see whether it could help reduce the risk of asthma attacks in 200 children in a clinic.

Methods : 100 children with asthma were allocated to standard treatment whilst 100 children received OTOOIN. This was done via a flip of a coin to ensure equal chance of receiving standard treatment or OTOOIN. Children were followed up for 6 months and medical records used to determine if they had an asthma attack. OTOOIN is associated with skin rashes and we used medical records to measure if this occurred using NHS computers.

Results : We summarise the results in Tables 1 and 2. We found a 30% reduction in children having asthma attacks and a 50% increase risk of children experiencing skin rashes. We further validated our results by again cross referencing medical records to ensure there was no errors.

Conclusion : Based on our study, we conclude that the benefit versus risk of OTOOIN does not justify it being used in standard treatment in children.

Table 1 : RCT of OTOOIN results in childhood asthma

	OTOOIN	Placebo	Total
No further asthma	90	85	175
Asthma attack	10	15	25
Total	100	100	200

Risk of asthma attack on OTOOIN = $10/15$ or 66%. Reduction of one-third

Table 2 : OTOOIN skin rash results in childhood asthma

	OTOOIN	Placebo	Total
Skin rash	6	4	10
No skin rash	94	96	190
Total	100	100	200

Risk of skin rash on OTOOIN = $6/4$ or 150%. Increase of 50%.

Questions

1. Do the authors correctly use the term RCT?
2. Are all the cases accounted of 200 children?
3. Complete the following table.

	OTOOIN	Placebo	Fewer on OTOOIN?
Asthma attack	10	15	

4. Divide 100, which is the number of children on OTOOIN, by number of fewer asthma attacks in the above table. This is called the number needed to treat (NNT). Which is correct?
 - i) 20
 - ii) 5
 - iii) 100

5. Complete the following table

	OTOOIN	Placebo	More on OTOOIN?
Skin rash	6	4	

6. Divide 100, which is the number of children on OTOOIN, by number of extra skin rashes in the above table. This is called the number needed to harm (NNH). Which is correct?
 - a) 10
 - b) 50
 - c) 100

7. Complete the following table

	NNT to prevent asthma	NNH to cause skin rash
OTOOIN		

8. Do you agree with their conclusions? Explain your answer.

QUALITATIVE STUDY ON OTOOIN

Design a questionnaire that seeks the views of key stakeholders who receive OTOOIN. You might include the children who receive it and their carers, for example parents or another person if appropriate.

You might want to ask about how they feel while taking the medicine and this could be an unstructured or semi-structured questionnaire.

For those who experience the skin rashes, you might ask how this has affected them and if they have managed to deal with this effect.

You might want to think about how you will obtain this information. For example, via an interview in the clinic or telephone appointment.

You could also think about how you will present the results. Will you do this by quoting what was said or try to group views into themes?

How will you handle conflicting views? Suppose some responses suggest OTOOIN makes children feel well and others feel unwell?

Work-based research

Work-based research has two main drivers. Firstly, to provide 'real time and real world' answers to a situation. Secondly, to utilise readily available data – so called 'natural evidence' – in the research in order to justify why it is collected. If data that is collected has no obvious use then why is it being collected?

There is a circular relationship between research and practice. We want research to be converted into practice where possible. We also want practice converted into research where possible. Let's consider an example of each.

Research into practice : In 2019, there was a major outbreak of the bacterial lung infection, tuberculosis (TB), in a small village in Llywnhendy. Outbreak control has many elements to it. One of these is TIME, PERSON, PLACE. So we can ask question – when did people contract the infection? Using routinely collected healthcare data, we could look at the cases diagnosed with TB and draw inferences about when they caught the illness. As regards person, was the illness affecting particular individuals such as adults rather than children? And is so, was particular individuals particularly at risk, such as heavy smokers?

Regarding place, the starting point was the village of Llwynhendy. Were there particular locations that had the highest incidence of TB? Or was there a working hypothesis about the 'index case'? In this situation, the centre of the outbreak was the local pub / restaurant where spread of the disease occurred.

How would we bring research into practice? Firstly, in terms of identifying people with TB the research evidence was that two tests are appropriate to confirm or eliminate disease. A blood test will show TB exposure and a chest x-ray (CXR) will show active disease. The evidence base, derived from research, also shows the following interventions are effective for TB as a framework:

1. Negative for TB – vaccinate and this is called primary prevention
2. Latent positive for TB – offer a course of curative antibiotics (Rx)
3. Active TB – several months treatment as appropriate to the patient

The prevention framework, which offers a theoretical underpinning to infection control outbreak, is primary prevention which reduces the level of new or first infections to keep the incidence low. Secondary prevention looks at reducing the prevalence of existing infections that have not become active disease. Tertiary prevention is the treatment of active TB to reduce complications.

Exercise : Think about the COVID-19 pandemic and discuss research ideas.

Practice into research : Elderly residents in care homes may experience minor injuries, such as accidentally grazing their shin against a chair. If treated effectively, such minor skin injuries can heal and require little or no follow up.

In such cases, the District Nurse could be asked to look at the wound and recommend the appropriate treatment. An alternative was considered and a care home was identified in Llanelli to pilot test a new method where the care assistant staff were upskilled to manage non-complex skin wound care. A research project was to be embedded into this new practice collecting data.

Number of skin wounds	Collected in care plans
Number of District Nurse calls	Rota information
Time spent in the care home	Timesheet record
Care assistant staff upskilled	Training records
Wounds Rx by DN and CA	Various sources

From this routinely collected data, it was demonstrated that the amount of time that District Nurses spend treating non-complex wounds in the care home fell by 50%. As part of the evaluation of the project, care assistant staff were interviewed and enjoyed the additional duties which did not significantly take up time as most treatments were simple of cleaning the wound and applying a dressing if required. In addition, it was possible to undertake a health economic analysis of this. By costing District Nurse time by the hour, the financial savings were calculated albeit there were costs of care assistant staff time and the training that they received. The particular health economic technique used was a 'Return on Investment' study where a time interval was calculated in which the investment would be balanced by the return. The service became cost neutral after 6 months and then saved resources from that point forward.

This practice has there generated an innovation which led to a peer-reviewed publication and it was also given Bevan exemplar status in recognition of this.

POST-SESSION EXERCISE : DEFINIING NATURAL EVIDENCE

Think about a situation, either in a work setting or from another situation, where there is access to natural evidence. For example, how many people are admitted to a hospital ward with long-COVID? Or source data from nationally collected information, such as the census or surveys. What other data can be readily sourced and combined with this? What can be done with this data? Can this data be analysed in another secondary way, for example bringing in costs?

PRIMARY AND SECONDARY RESEARCH

Primary research can be considered the generation of new knowledge by a robust methodology. Randomised controlled trials are often considered 'gold standard' evidence. Suppose we generated the following data from a trial:

Table 1 : Illustrative data on aspirin and subsequent myocardial infarction

	Aspirin	Placebo	Total
No further heart attack	90	85	175
Second or third attack	10	15	25
Total	100	100	200

90% of aspirin users had no heart attack compared with 85% in non-aspirin users did. Now suppose there were 4 other studies of equal size and the data gave the following results: 87% & 82%, 75% & 70%, 77% & 80% and 95% and 90%. Suppose we undertook a systematic review of the literature to find these studies and that we then did a meta-analysis to combine all of the results into one.

% with no further heart attack	ASPIRIN (% Heart attack)	PLACEBO (% Heart attack)
TRIAL ONE	90 (10)	85 (15)
TRIAL TWO	87 (13)	82 (18)
TRIAL THREE	75 (25)	70 (30)
TRIAL FOUR	77 (23)	80 (20)
TRIAL FIVE	95 (5)	90 (10)
Total and average %	424 / 5 = 84.8%	407 / 5 = 81.4%
% with a further heart attack	15.2%	18.6%

Discuss the data and what can be inferred for clinical practice. Are there any outliers? If so, what could be the explanation for this? What further research?

PRIMARY VERSUS SECONDARY RESEARCH

Randomised controlled trials are often considered primary research whilst a meta-analysis is often considered secondary research. This illustrates the point that primary research and secondary research both have validity and mutual dependence, rather than being considered hierarchical. It also shows the point that individual trials may not always provide definitive answers. Medical regulators such as NICE may sometimes wait for multiple trials before granting a licence for a new medication and this is also dependent on the affordability.

QUALITATIVE RESEARCH : PRIMARY AND SECONDARY

One of the errors in conducting qualitative research is the assumption that it needs to be of a quality and robustness to be published in a peer-reviewed academic journal. In fact, there may be a lot of 'grey literature' that is available in the public domain, for example Health Boards often make available papers from Executive meetings and this may include qualitative research. These may be called consultations, stakeholder panels, patient surveys or focus groups yet they will generate subjective information that will be useful in service delivery.

Suppose we wanted to ensure that mental health services were accessible to the D/deaf community. How might we engage with the D/deaf community? Attendance at D/deaf clubs? Discussions with D/deaf charities? Anything else?

We could collect views – ?? unstructured or semi-structured ?? – and undertake a thematic analysis. Suppose we found that barriers D/deaf people experienced included concerns about lack of communication support, such as British Sign Language. One response to this qualitative data would be the provision of a trained mental health practitioner who can deliver British Sign Language.

It is also possible to undertake secondary qualitative research. Suppose we wanted to identify the factors that determine the delivery of evidence-informed policy. We could undertake a systematic literature search and bring together the body of knowledge from around the world. Let's suppose we found papers from Mexico, Australia, Europe and South America. How could we extract the key factors? One method is to use the 'realist review' which is driven by the question : What works and in what setting? After critically appraising each paper, we could then undertake an analysis where we group the key issues together and we might find the factors include multi-disciplinary teams, broad range of stakeholders, circular relationship between evidence-base and policy.

We can then go a step further to test and develop these factors in a situation, such as a national care project in Wales for people over 50 years of age.

Morgan G. Policy development and implementation : The National Service Framework for Older People in Wales. *Eurohealth* 2010;15(4):23-25.

POST-SESSION EXERCISE

Consider a setting of your choice. What primary research could be undertaken using quantitative and qualitative methods? What would be the driver for undertaking such research e.g service improvement? How about secondary?

In class exercise

Research proposal

You will be allocated to a small in class research team. The anticipation is that everyone will make a contribution to preparing the final assignment and making a short presentation summarising it.

The final assignment will be a paper of upto 4 pages covering:

Background

Introduction

Methods

Results

You can use the pages in any way you choose although it is recommended that one page each will be written for each section.

Background : What is the topic of the research you are going to look at? And why are you going to look at this? So for example, a research proposal looking at the sustained impact of COVID-19 infection, so called long-COVID, might be good because the knowledge base is limited at present. On this example, the background might include a general outline of COVID-19, including some recent research papers.

Introduction : This is where the paper starts to become more specific. If we continue with the example of long-COVID, then what specific aspect will be explored. For example, will it be the impact of long-COVID on future hospital admissions? Or the impact of long-COVID on mental health? Again, it will be important to establish what is known and how this research will generate new knowledge on the situation.

Methods : Describe what methods you will use to undertake the research. For example, if we wanted to look at the impact of long-COVID on mental health, we could undertake a mixed methods approach. We could use healthcare records to quantitatively measure prescriptions for mental health conditions like anxiety and depression. We could also qualitatively survey patients on lived experience.

Results : Explain how you are going to analyse your data. So with long-COVID and mental health, we could measure changes since 'lockdown' and plot a graph showing trends. For the qualitative data, we could undertake a thematic analysis, grouping the information according to sub-headings. Explain any limitations to the data and if helpful, create some fictional data to illustrate how you might undertake the analysis.

GENERAL ADVICE

The word count is fixed as a maximum of 4 pages although you can use other forms of illustrations, such as figures and tables. Please also ensure that you provide references as appropriate within the paper.

Within the group of people, there is going to be different ideas. Keeping a log of the discussions and a record of the ideas maybe helpful. They may not be in the final report but are part of the process.

PREPERATION

Time will be set aside during the course for you to work on this assignment. We will have regular 'peer-review' by in class discussions and sharing progress. The final report needs to be typed and printed.

SUBMISSION

The reports need to be sent to Dr Gareth Morgan and then a short presentation will be given at a future session. There will be a few questions. Every member of the research team will be expected to make some contribution either to the report writing or presentation. This is because in research, working together is an essential element.