Research:
How does it affect Practice?

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The importance of research: past, present and future

Types of Research

Clinical Trials

Using research findings in practice
1798 First Successful Vaccine developed by Edward Jenner and introduced to combat Smallpox.

WHO certified the eradication of Small in 1979. Today many vaccines are now available including MMR, BCG, Meningitis, HPV, Hep B & Flu.

1928 Discovery of Antibiotics
Alexander Fleming was the first to suggest that the Penicillium mould must secrete an antibacterial substance, and the first to concentrate the active substance which he named penicillin.

300 million prescriptions for antibiotics issued in the US. Over 100 different antibiotics available to cure minor, as well as life threatening infections.

1978 IVF
The pioneers of this historical landmark were two British doctors, Dr. Robert Edwards and Patrick Steptoe who materialised the test tube baby after ten years of hard research.

Over 5 million IVF babies born worldwide.

Adapted from Dooley and Ritzema 2014
Importance of Research: Past, Present & Future

QUESTIONS raised about research?

What is research?
Who does research?

Why do research?
When should you do research?

Is it hard to do?
How long does it take?

Will it make a difference?
Where can I find out more about research?
Types of Research & EBP

Definition:

“Research is the systematic and rigorous process of enquiry which aims to describe phenomena and to develop and test explanatory concepts and theories. Ultimately it aims to contribute to a scientific body of knowledge. More specifically... it aims to improve health, health outcomes and health services.”

Bowling (2009, p.1)

Evidence Based Practice

Clinical Trials  Qualitative research study  Cohort Studies
Systematic Reviews  Case Control Studies
Meta-analysis  Editorials  Expert Opinion
Case Reports  RCT’s – Randomised Control Trials
Types of Research & EBP

The Evidence Base Hierarchy

High Quality

- Systematic Reviews
- Randomized Controlled Trials
- Cohort Studies
- Case-Control Studies
- Case Series, Case Reports
- Editorials, Expert Opinion
An Example of Qualitative Research

Types of Research & EBP

Inter-Professional Learning in Adult Critical Care

Vikki Park

Research title

An ethnographic study of the Inter-Professional Learning culture of NHS staff within the adult critical care clinical setting.

Background

Critical care is acknowledged as a complex and fast-paced care environment (Rothschild et al. 2005). The intensive level of patient care results in frequent interactions between different professional groups, therefore potentially increasing opportunity for collaborative practice and Inter-Professional Learning (IPL) to occur in this particular clinical setting. A body of evidence is accumulating to support the potential benefits to patients, staff and organisations as a result of Inter-Professional Learning through Interprofessional education and collaborative practice (Reeves et al. 2009). However, research into Inter-Professional Learning within the specific area of critical care is limited. My research aims to explore this further.

For the purpose of this study IPL is defined as:
- Learning which happens between different occupational groups through the collaborative sharing of expertise, knowledge and experience.

Research Design

A naturalistic qualitative approach will be adopted using ethnography to observe the interprofessional interactions of NHS critical care staff which may present learning opportunities within their natural setting, and in their “natural state” (Hammersley and Atkinson 1997).

“Ethnographic research aims to provide rich, holistic insights into people’s views and actions as well as the nature of the location they inhabit through the collection of detailed observations and interviews (Reeves et al. 2008 p.512).”

Focused ethnography has been chosen, also known as micro-ethnography, to focus upon one distinct issue within a culture in specific settings (Cruz and Higginbottom 2013). Using focused ethnography the distinct issue of IPL will therefore be explored specifically in adult critical care settings.

Method

- Stage 1: Part–participant observation
  - Sample: Three adult NHS critical care units
  - All professionals within the environment
  - Duration: Observations spanning 4 months per unit

- Stage 2: Interviews
  - Sample: n = 4–12 per critical care department
  - 4 occupational groups: Nurse, Doctor, Health Care Assistant, Physiotherapist

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Types of Research & EBP

The Evidence Base Hierarchy

High Quality

1. Systematic Reviews
2. Randomized Controlled Trials
3. Cohort Studies
4. Case-Control Studies
5. Case Series, Case Reports
6. Editorials, Expert Opinion
Research in Critical Care?

Many Current trials occur in Critical Care

Below: Trial data taken from the CRN portfolio on the 1st May 2015

<table>
<thead>
<tr>
<th>Subtopic</th>
<th>Study Status</th>
<th></th>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>CriticalCare</td>
<td>In set-up</td>
<td>9</td>
<td>52</td>
<td>139</td>
<td>200</td>
</tr>
</tbody>
</table>

The grid above shows current activity in the portfolio and may not list every Subtopic.

Examples from practice:
- Current
  - VAP2 – Rapid detection and treatment of Ventilator-AssOCIated Pneumonia towards antibiotic stewardship.

Previous
- Oscar: Oscillation ventilation in ARDS
- SPOT(light): Sepsis Pathophysiological & Organisational Timing
- ProMISe: Protocolised Management in Sepsis
- GRiP: Does GM-CSF restore neutrophil function in critically ill patients?
What is ProMISE?

A multi-centre, randomised controlled trial of the clinical and cost-effectiveness of early, goal-directed, protocolised resuscitation for emerging septic shock.

An important, collaborative, NIHR-funded research effort between emergency, acute and critical care medicine.

Primary objectives:

- To estimate the effect of early, goal-directed, protocolised resuscitation compared with usual resuscitation on mortality at 90-days.
- To compare the incremental cost-effectiveness, at one year of early, goal-directed, protocolised resuscitation versus usual resuscitation.
“International Clinical Trials Day is celebrated around the world on or near the 20 May each year, to commemorate the day that James Lind started his famous trial on the deadly disease scurvy. It provides a focal point to raise awareness of the importance of research to health care, and highlights how partnerships between patients and healthcare practitioners are vital to high-quality, relevant research.”

NIHR (2014)
<table>
<thead>
<tr>
<th>Stage</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolment</td>
<td>• Would you like to volunteer for the chocolate trial?</td>
</tr>
<tr>
<td></td>
<td>• n= 6-10</td>
</tr>
<tr>
<td></td>
<td>• Review the “Participant Information Sheet”</td>
</tr>
<tr>
<td></td>
<td>• Are you eligible to take part in the study?</td>
</tr>
<tr>
<td></td>
<td>• Do you consent to take part?</td>
</tr>
</tbody>
</table>
The Chocolate Trial

Participant Information Sheet

We would like to invite you to take part in our research study, “Chocolate”.
Before you decide to take part we would like you to understand why the research is being done and what it would involve for you.

What is the purpose of the study?
Chocolate is delicious treat to enjoy and satisfy hunger at any time, but it could be that the addition of a little flavour will make it even more satisfying.
We are holding a trial today to see if participants find the new chocolate and flavour more satisfying compared to the standard chocolate flavour.

Eligibility
To be eligible to take part in the trial you will need to be willing to eat the piece of chocolate and provide feedback. You will not be able to take part if you don’t like chocolate, are lactose intolerant, or suffer from any food allergies.
N.B. THE INGREDIENT LISTS FOR BOTH PRODUCTS ARE AVAILABLE ON REQUEST.

What will happen to me if I take part?
If you have agreed to take part:
You will be randomly allocated to receive either a piece of standard chocolate or new chocolate. You have an equal chance of getting either.
You will be asked to eat your chocolate straight away and not save it for later.
You will then be asked to provide feedback on the chocolate eaten.

Do I have to take part?
Taking part in the trial is entirely voluntary and you may withdraw your consent at any point without giving a reason.

Thank you for taking the time to read this sheet.
The Chocolate Trial

<table>
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</table>
| Allocation | • Participants are randomised to one of two arms of the trial.  
              • **Pick a piece of paper from the bag**  
              • You will be given either chocolate 1 or chocolate 2 corresponding to the number drawn. |

**Key points for discussion**

- Randomisation is important to this study.
- The experimental arm is the treatment being tested, and the control arm is either a placebo or the best current treatment for the condition (as in this case).
- In a real trial blinding is important. If possible neither the participant or the study team should know who has been given the experimental treatment and who is in the control/placebo arm.
- In emergencies the study can be un-blinded.
The Chocolate Trial

Follow-Up
Once you have eaten your chocolate (taken your treatment) please feedback.

Chocolate Trial Feedback Sheet

Please put a circle round the statement that best applies to you today.

Which chocolate did you eat today?  Option One  Option Two

Now that you have eaten your chocolate – do you feel hungry?
Very Hungry  A Bit Hungry  Ok  Not Hungry At All

Have you learnt more about taking part in a clinical trial?
Not At All  A Little Bit  Quite A Lot  A Lot

Thank you for taking part in the Chocolate Trial
## The Chocolate Trial

### Analysis

- Data will now be analysed.
- Results will be published and disseminated.
- ....?

<table>
<thead>
<tr>
<th>Quantitative</th>
<th>Qualitative</th>
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Mixed Methods
A Randomised Control Trial

Eligibility
- Volunteers invited to take part in the study
- Do they meet all the inclusion and exclusion criteria?
- Can they give informed consent? Patient information sheet
- Enrolled onto study

Randomisation
- Volunteers are randomised to either the experimental arm (the new drug or intervention being tested) or the control arm (the best current treatment or a placebo).
- Treatment should be blinded where possible, so that neither the volunteer or the study team know what treatment has been given.

Follow-Up
- The volunteers receive the treatment they have been randomised to.

Analysis
- The results of the study are analysed to work out which treatment worked better and whether the treatment is safe.
- The results are then published.

Experimental Arm

Control Arm

Follow Up

North West London Diabetes Local Research Network April 2013
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ProMISE (Protocolised Management In Sepsis)

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Screening/Eligibility

Eligibility needs to be confirmed as soon as possible. The following four inclusion criteria must be met, at any time, in any order, and just once and within six hours from presentation at the emergency department:

- suspected or confirmed infection;
- two or more SIRS criteria;
- evidence of refractory hypotension or hypoperfusion;
- IV antimicrobials commenced.

Randomisation

As soon as eligibility criteria are met, consent and randomisation should be completed within two hours.

Following randomisation, early, goal-directed, protocolised resuscitation commences as soon as possible or usual resuscitation continues as directed by the treating clinician(s).
Promise (Protocolised Management In Sepsis)

Timeline

0 hours
- Patient presents at ED - fulfils eligibility (within 6 hours)
- Patient randomised (within 2 hours)

Within 1 hour
- Early, goal-directed, protocolised resuscitation initiated (duration 6 hours) or usual resuscitation

6-72 hours
- Assessment – physiology/intervention

30 days
- Safety monitoring

90 days
- Survival assessment
- Quality of life/resource use and costs assessment

1 year
- Survival assessment
- Quality of life/resource use and costs assessment

Lifetime incremental cost-effectiveness

Results ???
QE Hospital: 90 day mortality: **29.5%** in treatment arm compared to **29.2%** in control arm.

Essentially NO difference!

Q. But could there really be?!

- Some of the problems experienced with recruitment.
- A&E not referring every patient that met the criteria
- Timeliness of referrals (missed recruitment)
- Bed pressures within Critical Care
What happens next?

- **The impact on practice:**
  Changes to policies, procedures and the body of knowledge/Evidence Based Practice

- **Future research:**
  Build on knowledge gained, develop/test theories, try new interventions, combine findings.
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• Future research: 
  Build on knowledge gained, develop/test theories, try new interventions, combine findings.

ProMISE is complemented by two similar trials internationally:
- ProCESS: Protocolized Care for Early Septic Shock
- ARISE: Australasian Resuscitation In Sepsis Evaluation

An individual patient data meta-analysis will be performed across the three trials.

ICNARC (2014)
The importance of research: past, present and future
- Research informs and guides future practices

Types of Research
- There are many different types of research and the research design should fit the research question

Clinical Trials
- Data from clinical trials are considered to be of high quality and often lead to direct influences on practice

Using research findings in practice
- Research influences clinical practice in a variety of ways. Ranging from using EBP to taking new approaches to care.


NIHR (2014) International Clinical Trials Day Available at: http://www.nihr.ac.uk/get-involved/international-clinical-trials-day.htm Accessed on: 01.05.2015

Additional resources:

Clinical Research Network http://www.crn.nihr.ac.uk/

ICNARC Publications https://www.icnarc.org/Our-Research/Studies/Promise/Publications