Shaping the future of the pharmacy profession through pharmacy practice research

Organised by the Pharmacy Practice Research Special Interest Group (BPS)

12th October 2020
Moderator

Dr. Fernanda Stumpf Tonin

- HEOR Consultant
- Researcher, Federal University of Paraná, Brazil
- Vice-chair, FIP Pharmacy Practice Research SIG
- Member of the Editorial Board, Pharmacy Practice

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Announcements

Digital Events House Rules

1. Recording – this webinar is recorded and will be available at www.fip.org

2. Become a member of FIP at www.fip.org

3. Ask questions via Q&A box

4. Provide feedback – email to webinars@fip.org
Learning Objectives
After this webinar, participants should better understand:

• To discuss the essential processes involved in Pharmacy Practice Research
• To identify how Pharmacy Practice Research can contribute to the practice of pharmacy
• To discuss Pharmacy Practice Research priority areas
Speaker 1

Dr. Victoria Garcia-Cardenas

- Senior Lecturer, University of Technology Sydney
- Chair, FIP Pharmacy Practice Research SIG
- Associate Editor, Research in Social and Administrative Pharmacy

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Pharmacy practice research – A call to action

Introduction to pharmacy practice research

An overview

What is it?

• The scientific discipline that studies the different aspects of the practice of pharmacy, and its impact on health care systems, medicine use, and patient care \(^1\).

What is its scope?

• Clinical, behavioural, economic, and humanistic implications of the practice of pharmacy, as well as practice change and implementation of innovations in routine practice.

What is its role?

• The drive for the expanded role of pharmacists in most settings has been stimulated by health challenges, patient demand, a natural professional evolution, but also facilitated by pharmacy practice research.

Pharmacy practice research will continue to assist in shaping the future of the pharmacy profession

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Pharmacy practice key strategic areas of research

- **Developing effective services and achieving their long-term implementation and sustainability in daily practice** is crucial to **explore innovative models of care** that address population needs → **supporting the advancement and future existence of the pharmacy profession**

- The development, evaluation, implementation and sustainability of health interventions and patient-care services represents a challenging process. Previous failures in PPR:
  - **Sole emphasis on the intervention’s evaluation phase**, to the detriment of the development and implementation phases → weaker interventions, decreasing the chances of its future implementation.
  - **Aggregation of all steps** involved in health services research, rather than using a multistage approach.

- The Medical Research Council Framework, provides a structured approach to develop, evaluate, and implement complex interventions (like professional pharmacy services) in health using a wide range of qualitative, quantitative, and mixed-method research approaches.

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Pharmacy practice research – A call to action

Victoria Garcia-Cardenas 1,2, Charlotte Verner Rossing 3, Fernando Fernandez-Llimos 4, Martin Schulz 5, Ross Tsuyuki 6, Olivier Bugnon 5,8, Fernanda Stumpf Tonin 1, Shalom I. Benrimoj 7

- Explore relevant conceptual approaches for the sustainability of the pharmacist intervention or service.
- Select mechanisms to monitor and facilitate routinization.
- Identify and address sustainability determinants.

Incorporating interventions into practice

- Identify an adequate implementation framework, theory or model which is relevant to pharmacy practice research.
- Select an appropriate study design.
- Define implementation outcomes.

Identifying unmet population needs

- Identify and quantify health needs that can benefit from pharmacists’ care.
- Understand the nature of the problem and its determinants.
- Explore the context and the feasibility of a future pharmacist intervention or service that ensures a continuum of care.

Designing and modelling processes and outcomes

- Identify relevant evidence and other national and international pharmacist interventions and services.
- Explore theories, models, and frameworks applicable to the intervention or service model.
- Identify process and outcome indicators.

Assessing the intervention’s feasibility and impact

- Select study outcomes considering different stakeholders’ perspectives (ECO model).
- Select an appropriate study design.
- Consider undertaking a feasibility study before the main trial.

Adapted from the MRC framework 26
Needs assessment

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Needs assessment

*Identifying unmet population needs.*

- “The systematic method of identifying unmet health and healthcare needs of a population and making changes to meet these unmet needs”

- **Objective** → To identify and quantify unmet societal health needs that can benefit from pharmacists’ care or from wider healthcare system changes¹.

- Unless a health intervention is able to respond to current or future societal needs, its future sustainability is likely to be compromised.

# Needs assessment

## How can it be done?

- Collaborative process that is:
  - patient-focused
  - culturally sensitive
  - evidence-based
  - outcome-focused
- Paying specific attention to the local context

## Examples

<table>
<thead>
<tr>
<th>Qualitative research</th>
<th>Epidemiological approaches such as observational studies</th>
<th>Systematic reviews and meta-analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• When an in-depth understanding of a particular phenomenon is needed, with a focus on perceptions and experiences from the perspective of the patient or other stakeholders.</td>
<td>• Used to describe the health status of populations and identify possible determinants of health outcomes.</td>
<td>• Used to synthesize the results of different studies when conflicting evidence exists in a given area.</td>
</tr>
</tbody>
</table>

Help to determine priorities for the most effective use of resources, balancing clinical, ethical, humanistic and economic factors.

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"I did not know it was so important to take it the whole time" — self-reported barriers to medical treatment among individuals with asthma

Tove Hedénstam, Anika Jakobsson, Hanan B Mala and Helle Nillesen

Abstract

Background: Asthma is an expensive public health problem and inadequate disease control is not uncommon. Individuals' self-reported barriers to medical treatment for the entire treatment chain (from seeking care for symptoms to using a medication) have seldom been studied for chronic diseases such as asthma. The aim of this study was to explore self-reported barriers to medical treatment among individuals with asthma within the framework of AMO (availability, accessibility, acceptability and quality).

Methods: Individuals with asthma visiting the asthma nurse at a primary care health center, and who currently had a prescription for asthma medications, were informed about the study. The nurse asked the person for their consent to be contacted by an interviewer. The interview guide was conducted from the elements of AMO, exploring self-reported barriers to asthma treatment. Interviews were conducted in Swedish, English, Arabic, and Persian. They were transcribed verbatim and a manifest content analysis was conducted.

Results: Fourteen interviews were conducted. There was a large variation in both age and reported number of years with asthma. Self-perceived barriers to asthma treatment were experienced throughout the whole treatment chain. Barriers that emerged were health care accessibility, perceived quality of care, belief about medications, family circumstances, knowledge gap about asthma and medicines, physical obstacle to using medicines, and experiences with treatment. The self-perceived barriers covered all four elements of AMO, but there are also some barriers that go beyond these elements (i.e. circumstances and practical obstacles to using medicines).

Conclusions: Self-perceived barriers among individuals with asthma cover the whole treatment chain. We want to highlight the inadequate information/distribution of patients leading to knowledge gaps about both diseases and the effect of medicines, and also the perceived unsatisfactory treatment at the PCC, which could partly be counteracted if patients knew what to expect from health care visits.

Keywords: Barriers, Medical treatment, Asthma, Medicine, AMO, Qualitative

Examples

**Respiratory Epidemiology**

Prevalence of asthma-like symptoms with ageing

Debbie Jamieson, Roger Newton, Chirster Janson, Angelic Gerowie, Joahim Heinrich, Joseph Makris, Michael J Jaffer, Anna-Maria Kettler, Jan Paul Zudyk, Roberto Bono, Pascal Demoly, Brenda-Ishay Levyman, Chantal Ravhon, Isabel Parker, Vuko Kolar, Cécile Stokke, John van der Valk, John Wardlaw, Antonio Pereira-Vegas, Isabell Urumkin, Jose A Guillen, Bert Rombouts, Rickey Probus-Henris, Mike Parmian, Jospray Martinez-Marturrita Ravina, Gregor accordance, Roberto de Marco, Peter Barry

**Key Messages**

What is the main question?

What is the main finding?

What is the bottom line?

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Examples

• Self-reported barriers for medication adherence → What are they? Could they be targeted with a pharmacist intervention?

• Prevalence of asthma → Is it a prevalent problem? What are risk factors of poor asthma outcomes? Can pharmacists contribute to addressing these?

Intervention development and evaluation?
Prof. Dr. Martin Schulz

- Director of the Department of Medicine at ABDA
- Adjunct Professor, Institute of Pharmacy, Freie Universität Berlin.
- His research interests are efficacy and effectiveness of pharmacist-led interventions.
- He is the André Bédat Awardee 2020.

Email: m.schulz@fu-berlin.de
Intervention development and evaluation

Achieving the intervention’s sustainment
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Needs Assessment: Cardiovascular Diseases (CVDs) …

• ... are the number one cause of death globally.

• World Health Organization: 17.9 million people die each year from CVDs – that is approximately 31% of all deaths worldwide.

• Hypertension and dyslipidemia are the most common risk factors.

• Coronary heart disease and heart failure are by far the most common CVDs, associated with compromised health-related quality of life, high morbidity (hospitalizations, i.e. costs) and mortality.

Intervention Development

Designing and modelling processes and outcomes

• Identify relevant evidence ...

• Explore theories, models, and frameworks ...

• Identify process and outcome indicators.
Intervention Development

Designing and modelling processes and outcomes

- Identify relevant evidence ...
- Explore theories, models, and frameworks ...
- Identify process and outcome indicators.
Identify Relevant Evidence – Pharmacist Care: Hypertension

- **Meta-analysis** 39 RCTs
- **14,224** Patients
- **Mean difference SBD**: 
  - **-7.6 (-9.0 to -6.3) mmHg**
- **Mean difference DBP**: 
  - **-3.9 (-5.0 to -2.8) mmHg**
- **Greater effects if pharmacist-led and monthly follow-up**
Pharmacist Prescribing in Hypertension: RxACTION

• Objective: To evaluate the effect of pharmacist prescribing on systolic blood pressure (SBP) reduction in patients with poorly controlled hypertension.

• Methods:
  – RCT conducted in 23 pharmacies in Alberta.
  – 248 patients with BP >140/90 or 130/80 mmHg recruited via pharmacist case-finding.
  – Intervention: pharmacist assessment of BP, CV risk, patient education, prescribing, lab monitoring, monthly follow-up according to Canadian Hypertension Education Program.
  – Control: usual pharmacist and physician care (written educational materials and BP wallet card, follow-up at 3 and 6 months).

RxACTION: Results – 1 (Primary Outcome)

Δ 6.6 mmHg (SE 1.9), \( p = 0.0006 \)

Δ 3.2 mmHg (SE 1.3), \( p = 0.01 \)

aOR of achieving target BP 2.3 (95% CI, [1.2 to 4.2]) in favor of the intervention.

RxACTION – 2: Patients at Target Blood Pressure

Absolute Difference 20.4%, \( p = 0.002 \)

Usual Care: 38.2%
Enhanced Care: 58.6%

Intervention Evaluation

Assessing the intervention’s feasibility and impact

- Select study outcomes … (ECHO model)
- Select appropriate study design
- Consider feasibility study including
  - Fidelity to the intervention
  - Probability to achieve recruitment goals (where PHARM-CHF failed → the planned phase 3 became a phase 2 trial eventually).
PHARMacy-based interdisciplinary program for patients with Chronic Heart Failure (PHARM-CHF): rationale and design of a randomized controlled trial, and results of the pilot study

Ulrich Laufs\textsuperscript{1*†}, Nina Griese-Mammen\textsuperscript{2}, Katrin Krueger\textsuperscript{2}, Angelika Wachter\textsuperscript{3}, Stefan D. Anker\textsuperscript{4,5}, Friedrich Koehler\textsuperscript{6}, Volker Rettig-Ewen\textsuperscript{7}, Lea Botermann\textsuperscript{2}, Dorothea Strauch\textsuperscript{2}, Dietmar Trenk\textsuperscript{8}, Michael Böhm\textsuperscript{3}, and Martin Schulz\textsuperscript{2,9†}
**Study Design PHARM-CHF**

Prospective, multicenter, randomized controlled trial with a median follow-up of 2.0 years

**Physician: all patients**
Baseline visit, phone contacts at 6 and 18 months, visits at 12 and 24 months, final visit.

**Usual Care**

**Pharmacy Care**
Initial medication review in the pharmacy, followed by (bi-)weekly pharmacy visits including
- individual counselling
- measurement of blood pressure/pulse rate
- drug-related problems/change in vital signs? → physician
- medication dispensed in weekly dosing aids (pillboxes)
Endpoints

Main primary

• Medication adherence as mean Proportion of Days Covered (PDC) within 365 days for three heart failure medication classes:
  – beta-blockers
  – angiotensin-converting enzyme inhibitors or angiotensin receptor blockers
  – mineralocorticoid receptor antagonists

Main secondary

• Percentage of patients with a mean PDC ≥80%, classified as adherent
• Quality of Life (MLHFQ)
• PDC for each heart failure medication class
• Percentage of patients with a PDC ≥80% for each heart failure medication class
Pharmacy-based interdisciplinary intervention for patients with chronic heart failure: results of the PHARM-CHF randomized controlled trial

Martin Schulz¹,²,₃*, Nina Griese-Mammen¹, Stefan D. Anker⁴, Friedrich Koehler⁵, Peter Ihle⁶, Christian Ruckes⁷, Pia M. Schumacher¹, Dietmar Trenk⁸, Michael Böhm⁹, and Ulrich Laufs¹⁰, for the PHARM-CHF Investigators†
Adherence to 3 HF Medication Classes


Primary Endpoint

Proportion of Days Covered (PDC)

Baseline 365 Days 730 Days

Pharmacy Care Usual Care Pharmacy Care Usual Care Pharmacy Care Usual Care

5.7 (1.6 to 9.8), \( P=0.007 \)

3.4 (-1.2 to 8.1), \( P=0.15 \)
Proportion of Adherent Patients

OR: 2.9 (Δ18%)

% Patients with PDC ≥80%

Baseline 365 730

Mean PDC

OR: 2.7 (Δ17%)  OR: 2.2 (Δ14%)

Baseline 365 730

Beta-Blocker

OR: 2.9 (Δ12%)

Baseline 365 730

Days

ACEI/ARB

Pharmacy Care
Usual Care

**P<0.05
**P<0.01

Quality of Life (MLHFQ Global Score)

-1.9 (-7.6 to 3.8), P=0.51
-7.8 (-14.5 to -1.1), P=0.02

365 Days
Pharmacy Care
Usual Care
730 Days
Pharmacy Care
Usual Care
Speaker 3

Prof. Shalom I (Charlie) Benrimoj

• Visiting scholar at the University of Granada.

• Research interests involve the clinical, economic and implementation aspects of cognitive pharmaceutical services from community pharmacy.

• He has published over 200 papers in refereed journals, 24 major research reports

Email: Shalom.Benrimoj@gmail.com

@cbenrimoj
Intervention implementation and sustainability

Incorporating interventions into practice and achieving their sustainment

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Exploration → Installation → Initial Implementation → Full Implementation

2-4 Years

Source: Fixsen & Blase, 2008
Implementation and Sustainability

1. Implementation and Sustainability Studies:
   A. Need for different research designs and methodologies to impact studies
   B. Implementation Science provides theoretical frameworks' and models
   C. Objective is to take “Evidence to Practice”
   D. Evaluation is multifactorial and complex

Implementation research: what it is and how to do it
BMJ 2013; 347 doi: https://doi.org/10.1136/bmj.f6753
Published 20 November 2013)Cite this as: BMJ 2013;347:f6753
Implementation Theoretical Frameworks and Pharmacy specific Framework

Fig. 1. Framework for the Implementation of Services in Pharmacy (FISpH).14
Evaluation Implementation Program

Fig. 2. Model for the evaluation of implementation programs and professional pharmacy services.
Service Outcomes obtained in Impact study

Service outcome from RCT (e.g.)

**Primary Outcomes**

a. Humanistic = quality of life changes
b. Clinical = improvements in control of disease, changes number of medication etc
c. Economic = cost utility, cost effectiveness, cost benefit
d. Other business = profitability

**Secondary Outcomes**

????
Implementation Process

Define quantitatively when a pharmacy or pharmacist reaches and maintains stage.

Fig. 1. Framework for the Implementation of Services in Pharmacy (FISpH).14
Implementation Impact

Changes in implementation influences/determinants across all domains (includes changes in factors, strategies & evaluations)

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Fig. 1. Implementation factors, barriers and facilitators.

The complexity of implementation factors in professional pharmacy services


* University of Technology, Sydney, Graduate School of Health, PO Box 123 Broadway, New South Wales, 2007, Sydney, Australia
** University of Granada, Pharmaceutical Care Research Group, Faculty of Pharmacy, Campus de Cartuja sn, 18071, Granada, Spain
*** Research Institute for Medicines (IMI) (pharmacy) Department of Social Pharmacy, Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal
Implementation Outcome

Develop
1. Construct Fidelity measure and validate
2. Define Reach with target population and resources available
3. Develop Integration measures
Experience with implementation programs in practice;
1. Focus and Time of Pharmacists deliver the intervention/service not data collectors therefore need to use implementation program data as by product of service delivery.
2. To change practice requires external support since behaviour change for community pharmacy and pharmacists and other team members complex therefore need PCFs
3. PCFs need training and experience to identify and assist in resolving barriers, facilitators and strategies to facilitate change in practice
An example of Implementation programs

Table 1  Fidelity after 12 months of MRF service provision

<table>
<thead>
<tr>
<th>Service offer</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>First patient interview</td>
<td>7.95</td>
<td>1.13</td>
</tr>
<tr>
<td>Determination of patient’s current health status</td>
<td>8.62</td>
<td>0.42</td>
</tr>
<tr>
<td>Case study phase</td>
<td>8.74</td>
<td>0.19</td>
</tr>
<tr>
<td>Evaluation phase</td>
<td>8.60</td>
<td>0.17</td>
</tr>
<tr>
<td>Intervention phase</td>
<td>8.87</td>
<td>0.36</td>
</tr>
<tr>
<td>Successive interviews and evaluation of outcomes</td>
<td>8.37</td>
<td>0.42</td>
</tr>
<tr>
<td>General service aspects</td>
<td>8.19</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Figure 2  Progress of pharmacies through the different phases of the Framework for the Implementation of Services in Pharmacy model.

Table 2  Integration achieved at 12 months by the implementation programme

<table>
<thead>
<tr>
<th>Integration dimensions</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routinisation</td>
<td>3.07</td>
<td>0.99</td>
</tr>
<tr>
<td>Teamwork</td>
<td>3.07</td>
<td>0.99</td>
</tr>
<tr>
<td>Resources</td>
<td>4.39</td>
<td>0.63</td>
</tr>
<tr>
<td>Evaluation</td>
<td>2.99</td>
<td>0.11</td>
</tr>
</tbody>
</table>
Reach and Primary Outcomes

Table 6  Emergency visits: impact study (6 months) and implementation programme (6 and 12 months)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>Percentage change</th>
<th>P value</th>
<th>Between 6 and 12 months</th>
<th>Percentage change</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact study* (n=667)</td>
<td>193</td>
<td>28.9</td>
<td>90</td>
<td>14.7</td>
<td>-53.40</td>
<td>≤0.05</td>
<td>NA</td>
</tr>
<tr>
<td>Implementation programme† (n=575)</td>
<td>121</td>
<td>20.2</td>
<td>69</td>
<td>12</td>
<td>-43.00</td>
<td>≤0.05</td>
<td>NA</td>
</tr>
<tr>
<td>Implementation programme‡ (n=160)</td>
<td>44</td>
<td>25.4</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Impact study baseline is the number of emergency department visits in the 6 month period prior to the study, and from baseline to 6 months

Table 4  Number of medications: impact study (6 months) and implementation programme (6 and 12 months)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>Mean change</th>
<th>12 months</th>
<th>Mean change</th>
<th>P value</th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td></td>
<td>Mean</td>
<td></td>
<td>Mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact study (n=688)</td>
<td>7.74</td>
<td>2.5</td>
<td>7.45</td>
<td>2.4</td>
<td>-0.29</td>
<td>1.3</td>
<td>≤0.05</td>
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<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Implementation programme (n=608)</td>
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<td>3.0</td>
<td>8.99</td>
<td>3.1</td>
<td>-0.06</td>
<td>1.6</td>
<td>NS</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Implementation programme (n=176)</td>
<td>9.38</td>
<td>3.1</td>
<td>9.23</td>
<td>3.2</td>
<td>-0.15</td>
<td>1.2</td>
<td>NS</td>
<td>8.99</td>
<td>3.4</td>
<td>0.39</td>
<td>2.3</td>
</tr>
</tbody>
</table>

NA, not available; NS, not significant.

Figure 3  Reach achieved in the implementation programme.
Complexity of Factors and their Cause and effect: An example Medication Review with Follow in Spain

Under Review: Using network analysis to explore barriers and facilitators for the implementation of a medication review with follow-up service. Beatriz Pérez-Escamillas¹, Shalom I. Benrimoj¹, Fernando Martínez-Martínez¹, Miguel Ángel Gastelurrutia¹, Raquel Varas², Katarzyna Musial³, Victoria García-Cárdenas⁴.

Figure 1. Most important barriers as shown by high closeness centrality score.
Sustainability or Sustainment of Professional Pharmacy Services

- Limited Research in Implementation Science at and less in Pharmacy Practice
- Critical for Shaping our future since;
  - If future of profession dependant on services and product supply
    both product supply and services need to be professional and
    economically sustainable form the perspective of:
      - Payers
      - Population
      - Service providers (pharmacists, pharmacy owners etc)

Some evidence in countries that services where being remunerated, they are being ceased. Why?
Sustainability or Sustainment
Thank you for participating!