

Introduction of the framework for developing, feasibility-testing, evaluating and implementing pharmacist's intervention

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為何?

是何?

如何?



### Areas to be covered 内容大綱

This talk aimed to give an overview of the methodological framework to develop and evaluate the complex healthcare interventions that involved pharmacists.



- Why do we evaluate the complex pharmacy services?
- Why do we need a framework to evaluate the pharmacist-related services?
- What is the UK Medical Research Council (MRC) complex intervention framework?
- How does the UK MRC framework apply to develop and evaluate pharmacy services?

## Why evaluate pharmacy services? 為何要評估藥事服務

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- Pharmacy services are complex healthcare interventions.
- Poor design and development of the interventions will lead to research waste, ineffective / inefficient services, and potentially lead to harms.
- Pharmacy service is an expensive service for a health service to provide.
- If pharmacy cannot prove to be effective and cost effective, then it is less likely that scare funds will be directed towards it.

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# Why do we need a framework? 為何需要評估架構

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 Convergent data from mixed methods
 需用不同的研究方法

- Patient and Public Involvement (PPI)
- Participatory research and coproduction

需有病患及公眾參與 研究評估的各個階段

# The UK Medical Research Council's Complex Intervention Framework

英國醫學研究委員會所提出的複雜性介入處置之評估架構 (方法)







### **Development of complex interventions**







- 2 Clarify which causal factors have greatest scope for change
  - Identify how to bring about change: what is the change mechanism?
- Identify how to deliver change mechanism
- Test and refine the intervention on a small scale
- 6 Co

Collect sufficient evidence of effectiveness to justify rigorous evaluation/ implementation

Wight D et al. Six steps in quality intervention development (6SQuID). *Journal of Epidemiology and Community Health* 2015;0:1-6

## **Developing an intervention systematically** 在設計(建立)介入處置的階段,該做些甚麼?

Use best available evidence, ideally from systematic review(s) 系統性回顧

• Develop theoretical understanding of process of change 改變的理論基礎

• Modelling process and outcomes 模擬流程及成果

Developing an intervention

- Implementation considerations should guide all phases

   "Would it be possible to use this?" 是否可能用?
- An iterative not a linear process
- Maybe useful to follow a formal framework
  - 6SQuID breaks the intervention development process into 6 steps



# **Example of service development -**Pharmacists' roles in post-cancer survivorship

#### 【案例一】藥師對於癌後存活患者照護的角色為何?

Mapping the trajectory of patients with cancer to find out pharmacists' roles. 癌症病患的治療歷程及藥師的角色 ٠



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- Qualitative Quantitative Result
- Qualitative study:



- Face to face presentation followed by discussion/workshop
- Telephone interviews as an alternative



Delivering cancer information and support to everyone who has a cancer diagnosis, their carers and loved ones

#### Specially trained to support you

If you or a loved one has cancer, having someone to turn to when you need help can make a real difference.

That's why many of our pharmacies now have Boots Macmillan Information Pharmacists, who are specially trained to support you if you're affected by cancer.

#### Side effects of treatment

If you're worried about how treatment may affect you, they can help you understand and deal with your symptoms.

Emotional support

If all you want is someone to talk to, our trained pharmacists are happy to listen.

#### Living with cancer

They can give you practical tips to help take control of your life again, such as taking gentle exercise to increase your energy.

#### Finding further support

If you have worries about money or caring for your family, they can help you find support groups in your area.

Mixed methods: exploratory sequential design



# Explore the medication-related problems in breast cancer survivors 乳癌後存活的患者可能有的長期用藥相關問題

 Quantitative study: Mapped out treatment pathways of breast cancer survivors in primary care in England





Lydia Tutt, <u>Li-Chia Chen</u>, Claire Anderson, Tracey Thornley. Exploring the treatment pathways of breast cancer survivors in primary care in England. Pharmacoepidemiology and Drug Safety 2016;25(S3): 83



## **Development of complex interventions**





研究設計及流程

隨機分配,收案方法及 收案率,執行困難,測 量方法,追蹤時間



# Feasibility and pilot studies

在可行性測試及預試驗的階段,該做些甚麼?



**Pilot study** 

可行性測試

Pre-study research to gather pieces of information needed to formulate the plan for the main study.

Questions around discrete aspects of the study processes or design.

#### • Main study 主研究是否可行?

- Research done before a main study
- To answer the question "Can this study be done?"
- Inform the development and conduct of a planned research project.

A small-scale study or small smaller replica of a study to test study design or methodology.

Use same protocol and assess same primary outcome similar to main trial.

預試驗

Test how well the main study will work together when the trial protocol is launched.



# Example of feasibility study-Who is the best person to promote health literacy?

#### 【案例二】社區藥師應用數位工具教育病患癌症自覺症狀的可行性?

### **Risk Assessment Tool (RAT)**

- Series of population based case control studies
- Clinical Practice Research Datalink (CPRD)
- No other risk factors
- Positive predictive values (PPVs) for symptoms of cancer
- No validation, use in clinical practice have been



### **Q-cancer**

- Series of cohort studies
- Q-Research database (754 practice in the UK)
- A range of other risk factors

\*\*\*\*

- Absolute risk of cancer for a patient with potential symptoms
- Sub-cohort validation for some cancer, external validity REFLECT Reflect On Your Life Choices



Welcome to Reflect, here we can estimate your future chance of developing cancer and offer advice for lowering this risk.

Reflect is most accurate for people aged over 40 who have never had an type of cancer before, because the best way to fight cancer is to stop it before it starts!

I acknowledge that I have read the disclaimer.



# Risk Estimation for Additional Cancer Testing (REACT) 可行性測試

#### 由誰來推廣(執行)最佳?



LLOYDSPHARMACY PILOTS CANCER RISK ASSESSMENT SERVICE IN TWO MANCHESTER BRANCHES

By Neil Trainis - January 8, 2018



LloydsPharmacy is taking part in an initiative which is designed to encourage people to go to a community pharmacy to assess their risk of cancer.

- Trial on recruiting from community pharmacists, NHS Health Check staff, health workers
- · Collect user experiences collected by online survey after trying the tool

RAECT tool www.react-manchester.com Evaluation for users <u>https://apps.mhs.manchester.ac.uk/surveys//TakeSurvey.aspx?SurveyID=983I4641</u> Evaluation for providers (Pharmacists and Cancer Champions) <u>https://apps.mhs.manchester.ac.uk/surveys//TakeSurvey.aspx?SurveyID=963I3p23</u> The pharmacy chain has partnered with the University of Manchester and Greater Manchester Cancer Vanguard Innovation to set up a service that can spot signs of the disease at an early stage using an online symptom-checker tool. Two branches of LloydsPharmacy in Manchester are piloting the service.

Pharmacists from LloydsPharmacy will help patients complete a questionnaire, known as REACT (Risk Estimation for Additional Cancer Testing), during a private face-to-face consultation in the pharmacy.





### **Development of complex interventions**





臨床果效 病患及照護者的經驗 過程

資源使用



### **Evaluation** 在評估的階段,該做些甚麼?

- Evaluation is a process aims to determine value or worth.
- It must be designed to address any questions that stakeholders may want answered.
  - Assessing effectiveness
  - Understanding change process
  - Assessing cost effectiveness

#### 該測量什麼?



The Health Foundation. Measuring patient experience. London 2013

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# Assessing effectiveness and process 評估效益及過程的方法

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- Stepped wedge designs
- Non-standard and preference (complete cohort) designs
- Randomised consent

•

• Single-subjects designs

- Interrupted time series analysis design
- Comparison with external/national benchmarks
- Control group comparison

#### MANCHESTER **Assessing patient experiences**

#### 評估患者經驗的方法

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- More recently there has been an increased focus on patient stories as a strategy for improvement and other methods of eliciting patient experience.
- The depth and extent to which these are representative of the population varies depending on the method.
- Those methods that provide more in-depth information can often be more time consuming and may not be as generalisable.





# Example of evaluation - Impacts of dedicated ward based pharmacy team in hospital

#### 【案例三】病房專責藥師的成效?

 A service evaluation at the East Lancashire Hospital Trust



- Length of stay:
- Readmissions:
- Time of discharge:
- E-discharge letter completion rates
- Pharmacy interventions

#### Dedicated ward pharmacists make an impact

Related articles

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#### 1 March, 2017 11:35 AM

The dedicated ward pharmacy initiative at Royal Blackburn Hospital in the UK has resulted in falls in readmission rates, savings on medicines, more efficient discharges and improved the patient experience

Alistair Gray BSc (Hons) MRPharmS Dip Clin Pharm Clinical Services Lead Pharmacist Joanna Wallett MPharm (Hons) MRPharms Dip Clin Pharm IP

Senior Clinical Pharmacist (Cardiology) Neil Fletcher BSc (Hons) MBA MRPharm S Clinical Director of Pharmacy East Lancashire Hospitals NHS Trust, UK Email: alistair.gray@elht.nhs.uk

Putting a pharmacist on a consultant-led ward round is nothing new;<sup>14</sup> - in fact, many of your reading this article will think, 'Well, we do that'. And there will be many centres where this happens – often at large teaching hospitals and tertiary centres.

The reality for many hospitals is that resources are limited and a pharmacist may be responsible for 'covering' two, three, four or more wards, with or without the support of a pharmacy technician. This is what pharmacy services were like in 2013 in East Lancashire Hospitals NHS Trust (ELHT) before a series of pilots led to the development and roll out of the Dedicated Ward Pharmacy project (DWP). This is the story of how we got there, what we did, what we found out – and of persistence and serendipity.



Ward pharmacist Sabeela Yasin with other members of the ward team (image courtesy of East Lancashire Hospitals NHS Trust Communications Department)

http://www.hospitalpharmacyeurope.com/featured-articles/dedicated-ward-pharmacists-make-impact

https://www.pharmaceutical-journal.com/opinion/comment/tearing-down-walls-to-deliver-adedicated-ward-pharmacy-service/20203927.article

# Tearing down walls to deliver a dedicated ward pharmacy service

The Pharmaceutical Journal | 13 DEC 2017 | By Alistair Gray, Clare Mackie, Susan Holgate, Jill Francis, John Eatough

How East Lancashire Hospitals NHS Trust introduced a pharmacy service that comprises one pharmacist delivering pharmaceutical care to one ward to help implement a range of innovations in the field.



Courtesy of Alistair Gary

Farhat Yasmin, specialist pharmacist, speaks with a patient on the respiratory ward at Royal Blackburn Teaching Hospital.

You may often hear at conferences, what would a hospital pharmacy service look like if all the many innovations developed in recent years were implemented at one site?<sup>[1]</sup> Implementation may not be feasible for many local reasons, but, at East Lancashire Hospitals NHS Trust (ELHT), the pharmacy team has been given the opportunity to explore several possibilities with the introduction of the dedicated ward pharmacy (DWP) service.

# Hello- it's the pharmacist calling

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#### 【案例四】評估藥師新藥服務成效

#### Intervention

 Pharmacist telephoned 2 weeks after new Rx for chronic illness to discuss medication

#### Patients

- Already on >3 medications: >74 or stroke, cardiovascular disease, asthma, diabetes, RAs
- Results: at 1 month follow-up
  - Self-reported non-adherence: 8% versus 16% (p=0.030)
  - Medication related problems: 23% versus 34% (p=0.019)
  - Mean total patient costs (NHS): £77.8 versus
     £113.9 (p<0.05)</li>



• The New Medicine Service (NMS) started in October 2011 and will run until March 2013 with funding of up to £55 million in 2011/12 and 2012/13.

Clifford S, Barber N, Elliott RA, Hartley E, Horne, R. P.W.S. 2006; 28: 165-170 Elliott RA, Clifford S, Barber N, Hartley E, Horne R. P.W.S. 2008; 30: 17-23



#### **New Medicine Service (MNS)** 社區藥局藥師所提供的新藥服務

- NMS provides support by community pharmacists for people with long-term conditions who are newly prescribed a medicine.
- Apply professional discretion where a formulation change occurs.
- Follows the prescribing of a new medicine for: Asthma or COPD, Diabetes (Type 2), Antiplatelet / Anticoagulant therapy. Hypertension https://www.cppe.ac.uk/e-learning/newmedicineservice/story\_html5.html

Patient engagement (day 0)	Informed consent	Intervention (day 7-14)	Follow up (14-21 days after)
Outline service specification - New Medicine Service (NMS)	Pharmacy Name Address 1 Address 2 Address 3 Pharmacy Pharmacy Poitcode	New Medicine Service - record keeping requirements	NHS New Medicine Service WHS Feedback Form 22 Sectember 2011
<text><text><section-header><text><text><text><text><text><text><text><text><text><text></text></text></text></text></text></text></text></text></text></text></section-header></text></text>	Consent to participate in the NHS New Medicine Service         Patient name         Addressi         I agree that the information obtained during the service can be shared with:         • my doctor (IGP) to help them provide care to me         • the Primary Care Trust (PCT) or successor organisation to allow then to make sure the service is being provided organisation, the NHS Burness Services Autority (IMSBA) and the Serversor of State for Headth to make sure the pharmacy is being correctly paid by the NHS for the service they give me.         Signature       Date         The NHS asks us to collect information on the ethnicity of people using this service.         What is your ethnic group? Please choose one section from Ato 6, thag tick the appropriate box to indicate our ethnic group? Please choose one section from Ato 6, thag tick the spropriate box to collect information on the ethnicity of the and Black. Caribbean (Mixed - White and Black. Caribbean (Mixed - Mixed a Adain (Mixed	Pharmacy renords for the service will be maintained to support the delivery of the service and addt: Pharmacy contractors will need to maintain records of the following for each patient who receives the HMS:	<form></form>
medicines. Pharm World Sci (2004) 22:145-170. Page 1 of 5	to contact you: Home / Work / Mobile (delete as applicable)	Point in the state of the	CONFIDENTIAL

# New Medicine Services study 社區藥局藥師新藥服務之評估研究

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- Evaluate the impact of the NMS on patien medicines-taking behaviour, outcomes, and cost-effectiveness from an NHS perspective.
- Explore the operation of the NMS, the complexity and nature of resulting consultations in terms of patient engagement, advice-giving and support.
- Determine acceptability to stakeholders, reasons for success or lack of success, feasibility within the service delivery environment and generalisability and replicability across diseases and settings.







# **NMS trial framework and economic model**

#### 社區藥局藥師新藥服務之評估架構及經濟學模組

- Pragmatic patient-level parallel randomised controlled trial, in 46 community pharmacies in England.
- Patients 1:1 block randomisation stratified by drug/disease group within each pharmacy.



- Six Markov models were developed in TreeAge Pro (TreeAge Software Inc, One Bank Street, Williamstown, MA, 01267, USA).
- The most commonly prescribed medicine within the four NMS areas was used to inform a model representative of that disease group.

#### Elliott, et al. PharmacoEconomics (2017) 35:1237–1255



### Cost-effectiveness of NMS 社區藥局藥師新藥服務之成本效用

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# **Implications of New Medicine Service study**

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#### 評估社區藥局藥師新藥服務之 研究結果及其影響

#### NMS evaluation proves value

#### NMS proves effective

The New Medicine Service can significantly increase patients' adherence to their new medicines and will save the NHS money through better patient outcomes at overall reduced costs, an evaluation of the service has concluded. Research showed that NMS consultations increased adherence by around 10 per cent and increased the number of medicine problems identified compared to standard practice.

The evaluation, commissioned by the Department of Health and carried out by researchers from the University of Nottingham and University College London, recommended that the service could be improved by expanding the range of conditions covered, improving training and engagement with GPs, and giving pharmacies access to GP records. It also suggested some other changes, such as making the service more patient-focused and better integrating it into care pathways. The evaluation concluded that the service should be commissioned in the future.

Lead researcher Professor Rachel Elliott, from the University of Nottingham, said: "Evaluating real life health services is challenging, and it is difficult to fully predict the long-term outcomes of the NMS, but our research suggests that patients will ultimately be better off as a result of the NMS and patients who receive the service will cost the NHS less money in the long term." Report finds new medicine service improves treatment adherence and saves NHS money

The Pharmaceutical Journal | 14 AUG 2014 | By Janna Lawrence 🚺

The new medicine service is cost effective and increases the number of patients who are adherent to their medicines by around 10%.



Source: Photofusion / Rex Features

A consultation service provided by community pharmacists offering advice on new medicines has led to an increase in patient adherence

A service delivered by community pharmacists that helps patients take new medicines effectively has been found to increase the number of patients who are adherent to their treatment by about 10%.

# Pharmacy service will save NHS £517.6m, finds study



A scheme launched by the Department of Health in 2011 to help patients stick to their drug regimens has been so successful, that in its first five years, it will save NHS England £517.6m in the long-term, a team of health economists has found.

Lead researcher <u>Professor Rachel Elliott</u> from The University of Manchester says <u>the New Medicine</u> <u>Service</u> – a free scheme where community pharmacists help patients take new medicines - has improved medicines adherence by 10%.

The study was conducted by experts at The Universities of Manchester, Nottingham, UCL and a Patient and Public Representative.

Even in the short term, say the team, the scheme –where pharmacists are paid  $\pm 24.60$  each time they look after a patient as part of NMS has saved the NHS  $\pm 75.4$ m.

The team used self-reported adherence at 10 weeks, considered the minimum time required to demonstrate behavioural change in a sample of 503 patients

# **Community pharmacy injection treatment services**

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#### 【案例五】評估病患對於社區注射治療的經驗及看法



• Focus groups of hospital and community service users

- A new model of care has been developed by North Lincolnshire and Goole in partnership with McKesson UK.
- The Lloyd's Infusion and Injection Clinic was first established in November 2018.
- The model has been designed in line with recent NHS initiatives including the Five Year Forward View and Long-Term Plan both with the ambition to reduce the number of visits patients make to the hospital setting.







### **Development of complex interventions**





發表結果 執行服務 追蹤及調查 長期評估



### Implementation

在執行的階段,該做些甚麼?

Dissemination

- Surveillance and monitoring
- Long term follow-up
  - -What should we be doing?
  - -Are we doing it?
  - -How can we improve?



- Full reporting is essential
- Important to include a detailed description of the intervention and the context
- Wide-ranging set of guidelines now available

### **Reporting strategies** 成果報告



Your one-stop-shop for writing and publishing high-impact health research find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines

#### Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



Visit the library for more resources

# Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions	Other
Observational studies	STROBE	Extensions	Other
Systematic reviews	PRISMA	Extensions	Other
Case reports	CARE	Extensions	Other
Qualitative research	SRQR	COREQ	Other
<u>Diagnostic / prognostic</u> studies	<u>STARD</u>	TRIPOD	<u>Other</u>
Quality improvement studies	<u>SQUIRE</u>		<u>Other</u>
Economic evaluations	CHEERS		Other
Animal pre-clinical studies	ARRIVE		Other
Study protocols	<u>SPIRIT</u>	PRISMA-P	Other
Clinical practice guidelines	AGREE	<u>RIGHT</u>	Other

See all 398 reporting guidelines

Possible strategies		
Open data Open/ydang-reals and the underlying data with other scientists	•	
Pre-registration NARO; registering the justical before a study to contracted	••••	
Collaboration Intelling with other research groups, both Tomaty and internally	<b>0</b> 0	
Automation Teday Intercepti key of conducting partice, thereby educes the apportunity for future error.	00	
Open methods halds patterny the detailed a study pattern.	<u> </u>	
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Reporting guidelines Gasteres and checking halfwig reservices ment prices when guideling chains	000	
Funders: reporting guidelines key for research reproducibility and reliability		



# Implementation is a behavior change problem!

• Considering the COM-B wheel:



Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42. Published 2011 Apr 23. doi:10.1186/1748-5908-6-42

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### **Continuous service improvement cycle**

Kubler Ross Change Curve

• Clinical audit for service quality



Lewis, Angela. Finding a model for managing change [online]. <u>Training & Development</u>, Vol. 39, No. 5, Oct 2012: 6-7. Availability:<<u>https://search.informit.com.au/documentSummary;dn=835342976215713;res=IELBUS></u>ISSN: 1839-8561. [cited 19 Jul 2019].



## **Influencing decision makers** 影響決策

- Ask research questions that matter to patients, practitioners and policy-makers
- Involve stakeholders in planning and conducting the research
- Provide evidence in an integrated and graded way
- Identify the elements relevant to decisionmaking
- Make recommendations as specific as possible
- Take a multifaceted approach
- Exploit opportunities for long-term follow-up





- Why do we evaluate the complex pharmacy services?
- Why do we need a framework to evaluate the pharmacist-related services?
- What is the UK Medical Research Council (MRC) complex intervention framework?
- How does the UK MRC framework apply to develop and evaluate pharmacy services?

# Re-cap: The development of complex interventions





# Thank you for your listening!

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