



Identifying the important outcomes to measure for pharmacy-led, clinical services within primary care: A nominal group technique approach

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ABSTRACT

Background: The introduction of clinical pharmacy services is part of a multi-disciplinary approach to reduce pressure on primary care. Ascertaining the impact of clinical pharmacists in general practice is vital to ensure intended benefits are achieved. However, this is complicated by poor quality evidence, multiple interventions, and a lack of agreement regarding outcome measures.

Objectives: To develop an outcomes framework for clinical pharmacy services delivered in Scottish general practice using a consensus methodology.

Methods: A modified nominal group technique (NGT) was conducted using Microsoft Teams and Qualtrics. This involved a pre-NGT questionnaire, silent generation of ideas, round robin, discussions, ranking, and a final consensus exercise. A selective sampling strategy recruited experienced pharmacists from Scottish health regions. NGT ranking results were used to signify relative importance of the outcome areas. NGT discussions underwent inductive thematic analysis to explore key areas considered.

Result: Overall, 13 (median: 24 years of experience) pharmacists participated, representing 11 of 14 Scottish regions. In total, 21 outcome areas, derived from the literature and a pre-NGT questionnaire, were considered during the NGT ranking exercise. Consensus identified five important outcome areas: Patient Experience, Medication Related Adverse Events, Cost-Effectiveness, Medication Optimisation, and Health Related Quality of Life. Thematic analysis highlighted the importance of the outcome framework's target audience, factors influencing the interpretation of outcomes, and the feasibility of the associated outcome measures.

Conclusions: The five key outcome areas will facilitate evidence-based decisions regarding service delivery. Future work should develop a measurement plan, involving routinely collected sources of outcomes data. The feasibility of collecting outcomes in the real-world context should be considered, identifying measures which are easy to collect within existing data infrastructures. This paper describes a replicable method to gain consensus for a national approach to data collection from a strong theoretical basis using an online methodology.

1. Introduction

The global population is ageing, with those over 60 years old now more numerous than those under 5 years of age; however, this does not automatically translate into a healthier ageing population.¹ Within developed countries, use of healthcare services by adults increases with age.² This demand – coupled with high patient expectations and the movement of service provision from secondary to primary care³ – has translated into a primary care crisis. Primary care settings (e.g. medical

centres, community-based clinics, and general practices) report increased demand for their services – for example, within England, between 2010/11 and 2014/15, General Practitioner (GP) consultations increased by over 15%.³ Meanwhile, the GP and nurse workforce increased by only 4.75% and 2.85% respectively, suggesting an overall increase in workload.³ This is supported through reports of moderate to high burnout levels for GPs.⁴ To reduce the pressure on primary care physicians, a multi-disciplinary approach is being increasingly used in primary care involving the input of nurses⁵, healthcare assistants,⁶

Abbreviations: ECHO model, Economic, Clinical, Humanistic Outcomes model; GPs, General Practitioner; GPCPs, General Practice Clinical Pharmacists; NGT, nominal group technique; SEIPS, Safety Engineering Initiative for Patient Safety; SP₃AA, Scottish Practice Pharmacist and Prescribing Advisers Association.

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paramedics,⁷ and pharmacists.⁸

Internationally, the role of pharmacists has expanded into clinical services within primary care to increase capacity within general practice^{9,10} – which has involved pharmacists reviewing medication and prescribing.¹¹ This delivery model is becoming enshrined within national health service funding models.^{12–14} For example, within England, a five year contractual framework introduced in 2019 outlines additional funding to employ clinical pharmacists in a bid to better support patients with complex needs,¹² and the Australian Department of Health has established clinical roles of pharmacist within general practice including medication reviews and responding to queries.¹⁴ When integrating pharmacists within primary care, pharmacists are perceived by GPs as offering valuable clinical input and are considered vital members of the primary care team.⁸

The effectiveness of pharmacists in clinical roles within a general practice setting is mixed. Positive results of their activities have been seen in areas such as cardiovascular disease^{15,16} and cost-effectiveness¹⁷; however, other work has reported mixed effects of pharmacists within general practice.¹⁸ It is suggested that conclusions regarding the effectiveness of non-hospital pharmacy services are affected by lack of agreement regarding populations, intervention and outcome measures¹¹; and also the poor quality of the evidence.¹⁹

Assessing the impact of clinical pharmacy services is complex. As pharmacy-led services become more clinically focused, while offering increasingly complex interventions designed to improve patient’s overall quality of life, it becomes imperative to develop and collect data on outcome measures to ensure intended outcomes are achieved.¹⁰ It is important to identify patient groups which benefit most from the clinical input of a pharmacist, enabling efficient service delivery by targeting areas where pharmacists have most impact²⁰; additionally, such data will also ensure patients’ safety – i.e., that new clinical pharmacy services are doing no harm.^{21,22} The standardisation of outcome measures

facilitate evidence based-practice, as this will allow for cross-comparison of findings between services and settings to develop an evidence-base.²³ It is also important to develop outcome measures specifically for pharmacy services in general practice to ensure they adequately reflect the input of pharmacists and the specific outcomes which they can contribute to,²⁴ rather than measures for specific clinical conditions. Finally, inappropriate outcomes evaluation may have unintended consequences on the workforce; for example, within NHS England, unsuitable outcome measures meant that the input of primary care pharmacists was hidden, resulting in pharmacists perceiving they were undervalued and treated unfairly.²⁴

A recent umbrella literature review by Weir and colleagues²³ examined the outcomes associated with primary care, pharmacy-led clinical services. This focused on pharmacotherapy services which were considered as medication therapy and/or disease management. This work expanded upon the pre-existing ECHO model^{25,26} - which considers the economic, clinical, and humanistic outcomes – to include ‘service’ outcomes. Seventeen outcomes across the four areas were identified, with clinical and service outcomes being the most commonly applied outcomes (Fig. 1). An initial outcomes framework was developed to guide future primary-care pharmacy research (see Fig. 1). However, the 17 outcomes are derived from studies of randomised controlled trials and need to be operationalised for routine clinical practice.

In Scotland, a pharmacy service has supported general practice since 2018.²⁷ This is an evolving, three-tiered “pharmacotherapy” service within which general practice clinical pharmacists (GPCPs) deliver advanced and specialist services (see Table 1 for services), while other services (such as prescription management services) are primarily delivered by pharmacy technicians and support workers.²⁸

It is expected that all GP sites have access to this service to support medication management.²⁷ Having clarity over important outcome

OUTCOMES FOR PRIMARY CARE PHARMACY-LED SERVICES

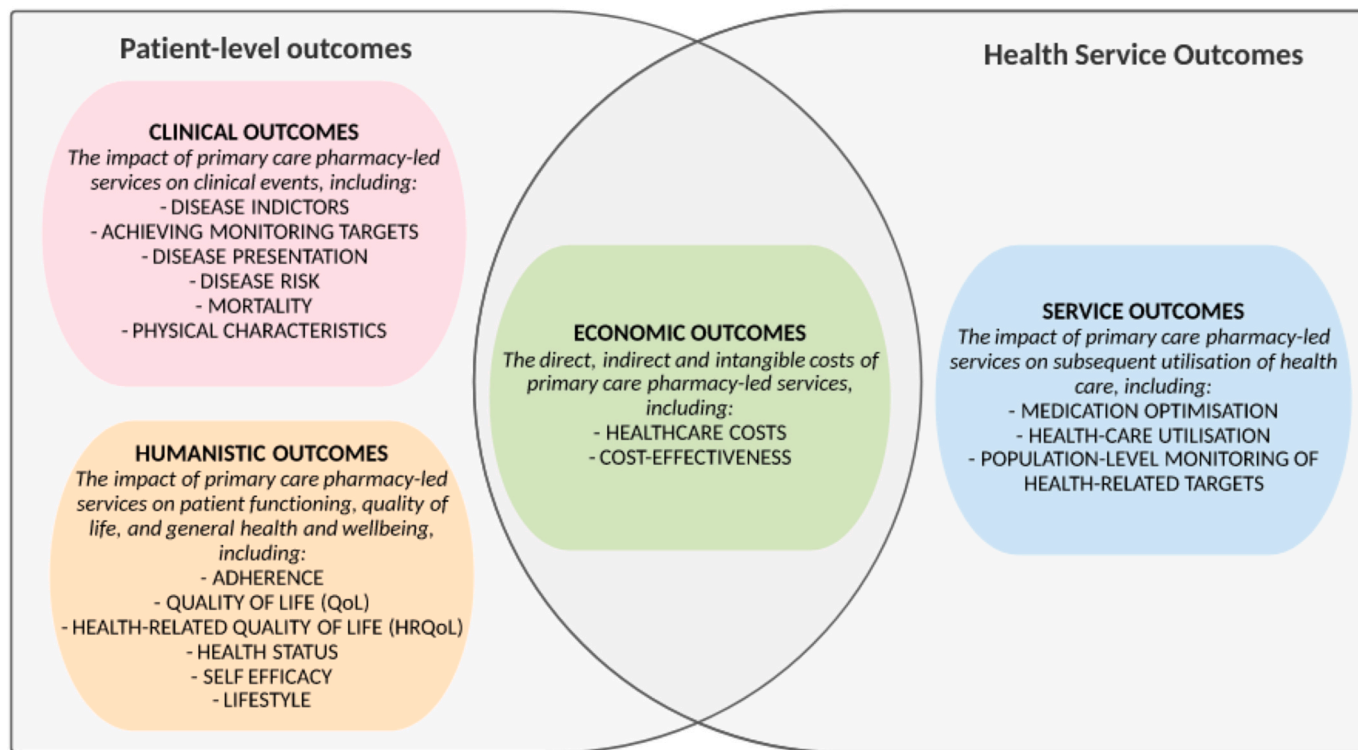


Fig. 1. Proposed outcomes framework for primary care pharmacy-led services showing the clinical, humanistic, economic and service outcomes. Within this model, clinical and humanistic outcomes are patient-level outcomes, and service outcomes is a health service level outcome. Economic outcomes could be at either a patient or health service level depending on local healthcare funding models [reproduced from Weir et al., 2021²³].

Table 1
Advanced and specialist pharmacotherapy services.¹

Pharmacotherapy level	Services
Advanced (Level 2 tasks)	Medication review (more than 5 medicines) Resolving high risk medicine problems
Specialist (Level 3 tasks)	Polypharmacy reviews Specialist clinics (e.g. chronic pain, heart failure)

areas will support conclusions regarding effectiveness¹¹ and will help towards the overall aim of ensuring evidence-based service delivery within Scotland's primary care. The aim of this work is to build upon Weir et al.'s review to develop an outcomes framework specifically for the Scottish pharmacotherapy advanced and specialist services. This will focus on establishing consensus regarding the important outcomes for the advanced and specialist pharmacotherapy services and exploring the key areas associated with the important outcomes. Ultimately, this will help to ensure intended outcomes are achieved¹⁰ to enable evidence-based decision making on funding and service development to target areas where pharmacists may have most impact.²⁰ The methods adopted in this study may also act as a blueprint for other regions internationally to develop an outcomes framework for their evolving primary care pharmacy workforce.

2. Methods

The study was conducted between April and June 2021. This study's methods, and associated materials, underwent review by representatives of the Scottish Practice Pharmacist and Prescribing Advisers Association (SP₃AA) group (a strategic group which supports the design of the pharmacotherapy service and influences stakeholders on the GP pharmacy teams' behalf), some of whom participated in the research activities. Ethical approval was granted by the Ethics Committee.

2.1. Study design

To gain consensus regarding the outcomes of importance for the pharmacotherapy service, a modified, mixed-method nominal group technique (NGT)²⁹ was used. A traditional NGT comprises 5 steps: silent generation of ideas, round robin, serial discussion, ranking and re-ranking; however, the method is often modified.²⁹ For this study, the initial silent generation of ideas was conducted through a pre-NGT questionnaire and the subsequent NGT was conducted online.

2.2. Setting and participants

A panel of experienced pharmacists was identified via representatives of the SP₃AA group. SP₃AA group members were invited to participate themselves or suggest eligible participants. The SP₃AA group comprises representatives from the different health regions within Scotland and NHS Education for Scotland (a healthcare organisation responsible for the education and training of the pharmacists working within General Practice). A selective sampling strategy was used to recruit representatives from all Scottish health regions. In this way, a pool of 16 potential participants was formed with representatives from the 14 Scottish health regions and NHS Education for Scotland.

3. Materials and procedure

The questionnaires were hosted on Qualtrics © [version 2021].

3.1. Pre-NGT questionnaire

Potential participants were contacted in April 2021. They were asked to read a participant information sheet, complete a consent form and the pre-NGT questionnaire. They were sent up to two reminders by email; all

participants were sent a reminder after 6 days, with a final reminder sent to non-responders after a further 2 days. The pre-NGT questionnaire collated demographic information and focused on idea generation by asking participants to reflect upon the 17 outcomes from the umbrella review²³ and offer any additional outcomes (with associated definitions and examples) which they felt were also relevant to the advanced and specialist tasks. They were explicitly asked to consider outcomes which would be pertinent across all tasks rather than for specific tasks. This questionnaire was piloted by five GPCPs with minor amendments. The questionnaire is included in Supplementary Information 1.

3.2. NGT meeting

Participants were invited to participate in an NGT on April 20th, 2021 (Fig. 2 presents an overview of stages). Participants who did not complete the pre-NGT questionnaire but took part in the NGT group completed the demographics and consent form. The NGT was conducted online, using Microsoft Teams. The script for the NGT was devised in accordance with the structure suggested by Delbecq et al.³⁰ and Dunham.³¹ A PowerPoint presentation facilitated the group through the NGT and two questionnaires enabled the ranking exercises. The first questionnaire enabled all outcomes to be ranked from most to least important, and the second questionnaire facilitated the selection of the seven most important outcomes and for these seven to be ranked in terms of importance. The optimal number of outcomes to be identified was unknown, but seven was considered a manageable number of key outcomes for the participants and would reflect a third of the eventual outcome set. All questionnaires were piloted by three GPCPs. Minor amendments for clarity were made to the NGT script. Additionally, the interface of the ranking questionnaires was amended to facilitate usability on different IT systems.

During the NGT, the group leader (RN) facilitated participants through the stages. After introductions and orientation, participants reflected upon the outcomes for 10 min considering the question "What are the key outcomes for [advanced and specialist tasks] of the pharmacotherapy service?" They were encouraged to make notes before verbalising their thoughts for 2 min each during the round robin. This was followed by a 10-min group discussion to consider their overall thoughts in relation to those voiced by the rest of the group. Participants then ranked all outcomes for importance, with one being the most important and 21 the least important (due to the addition of four outcomes following the pre-NGT questionnaire). The research team collated the results for presentation back to the group. Participants were given the opportunity to reflect on the rankings and discuss inconsistencies, surprises or differences. Participants were then invited to select their top seven outcomes and again rank for importance. Following the NGT, the research team collated the results. A consensus exercise was then undertaken whereby the outcomes ranked most important were disseminated by email, and participants were asked to indicate whether they agreed that they were the most important outcomes.

4. Analysis

4.1. Pre-NGT questionnaire

The data were extracted into a Microsoft Excel© file. Independently, members of the researcher team (RN, AF, KP and NW) considered each suggested outcome to identify new outcomes - considering relevance and uniqueness (i.e., not already covered within the framework). Any outcomes deemed a process measure, which indicate the extent by which a task is carried out, were not included. Through discussion, members of the research team (RN, ED, AF, KP and NW) reached consensus regarding which new outcomes to include.

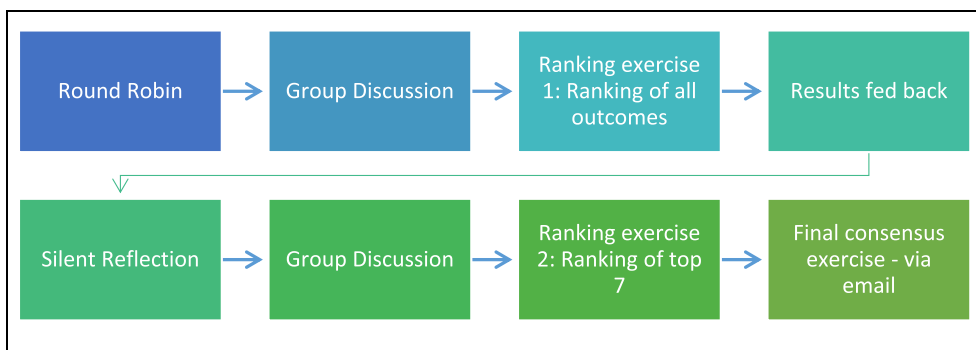


Fig. 2. Stages for NGT meeting.

4.2. Ranking outcomes in NGT

For ranking exercise 1, all outcomes identified from the umbrella review and suggested by participants were ranked, with one being the most important and 21 the least important. The rankings allocated to each outcome were summated to give a total ranking score. The total ranking score was based on the number of participants taking part, with lower scores indicating greater importance. The outcomes were then ranked according to score.

For ranking exercise 2, participants identified and ranked their seven most important outcomes, from one to seven, with one being the most important. The scores were reverse coded and summated. A higher score was indicative of greater importance with the outcomes ordered according to rank. The data were then visually inspected to identify any natural cut-off point as it was acknowledged that seven areas was a pragmatic rather than theory-driven decision. .

4.3. Final consensus exercise

There is no agreed upon level of acceptable consensus for NGTs²⁹ – Keeney et al.³² found no agreement regarding consensus level using Delphi methods and suggested that authors should decide this prior to data collection. Pragmatically, a consensus level of two-thirds (66%) was considered to be an acceptable level of consensus for the most important outcomes.

4.4. NGT qualitative data

The discussions occurring during the NGT were transcribed using the intelligent verbatim approach and analysed by RN using inductive thematic analysis (e.g., Kiger and Varpio³³) to explore the research question "What key areas were considered when discussing the important outcomes?". Following familiarisation with the data, initial descriptive codes were generated through an initial review of the transcript using Microsoft Word. These codes were imported into NVIVO© where the subsequent stages of analysis were conducted. Initially the transcript was coded descriptively within NVIVO©, these descriptive codes were then thematically linked and high-level themes identified. The analysis underwent face-validation by NW who familiarised herself with the thematic analysis, and through discussion with RN agreed on the final analytical coding.

5. Results

5.1. Participants

Overall, 13 (81.3%) participants from the prospective sample of 16 participated in the project. Seven completed the pre-NGT questionnaire and 12 attended the NGT. All were experienced pharmacists, with a median of 24 years of experience and 11 (84.6%) held qualifications

which allowed them to prescribe medication. All but one participant had experience working within general practice (n = 12; 92.3%), for a median of 11 years; six (46.2%) currently delivered the pharmacotherapy service (see Table 2 for complete demographics).

5.2. Pre-NGT questionnaire

Twelve additional outcomes were suggested for inclusion. Four were identified as unique: Societal Costs, Medication Related Adverse Events, Utilisation of Holistic Care/Wellbeing Services, and Patient Experience (see Fig. 3). The complete list of all 21 outcomes considered during the NGT is presented in Supplementary Information 2.

5.3. NGT – ranking exercises

For each ranking exercise, 11 of the 12 participants returned completed questionnaires (with the missing data due to IT issues). For ranking exercise 1, the lowest possible score was 11 and the highest 231, with lower scores indicating greater importance. For ranking exercise 2, the highest possible score was 77 and the lowest being 0 if no participant selected an outcome within their top seven – these scores were then reverse coded so that a higher score was indicative of greater importance. The complete results from both ranking exercises are presented in Supplementary Information 3 and 4.

Inspection of ranking exercise 2 revealed that five outcomes were ranked by more than 60% of respondents as being within their top seven, and the decision was therefore made to focus on the top 5 most important outcomes. These outcomes were: patient experience, medication-related adverse events, cost-effectiveness, medication optimisation and health related quality of life, which reflected service, clinical, economic, and humanistic outcomes. These five outcomes were

Table 2 Demographics of participants.

Demographic variables	pre-NGT questionnaire (n = 7)	NGT (n = 12)
Gender – Female (n, %)	6 (85.7%)	9 (75.0%)
Number of Health Regions	7/14	10/14
Member of SP ³ AA (n, %)	7 (100%)	11 (91.7%)
NES representative (n, %)	0 (0.0%)	1 (8.3%)
Years qualified as pharmacist (median, IQR)	25 years (16–28)	24 years (19–26)
Qualified prescriber	7 (100%)	10 (83.3%)
Worked within General Practice (GP) pharmacy (n, %)	6 (85.7%)	11 (91.7%)
Years' experience working within GP pharmacy (median, IQR)	15 years (6.25–20)	10 years (4.5–19)
Currently work in GP pharmacy (n, %)	3 (42.9%)	5 (41.7%)
Currently deliver pharmacotherapy service (n, %)	3 (42.9%)	5 (41.7%)

SP³AA = Scottish Practice Pharmacy and Prescribing Advisors Association; NES = NHS Education for Scotland; NGT = Nominal Group Technique.

ECONOMIC OUTCOMES <i>The direct, indirect and intangible costs of health care.*</i>		
Outcome	Definition	Examples
Societal Costs	Impact of medicines usage on individual in relation to societal function	Employability Addiction Crime
CLINICAL OUTCOMES <i>Clinical events that occur as a result of health care provision.</i>		
Medication Related Adverse Events	An undesirable experience associated with the use of a medicine**	Falls Related to Medication Acute Kidney Injury
SERVICE OUTCOMES <i>The impact of healthcare on subsequent utilisation of health care services, including medication.</i>		
Utilisation of Holistic Care/ Wellbeing Services	Onward referral to services which may be outwith traditional health care setting	Referral to Gym Referral to Mental Health Services
Patient Experience	Patients' experience of the service	Satisfaction Levels Patient Empowerment Patient Involvement in Decision Making

* Outcome categories' definitions adapted from Gunter²⁶, San-Juan-Rodriguez, Newman, Hernandez, Swart, Klein-Fedyshin, Shrank, Parekh³⁴

** U.S. Food and Drink Administration³⁵

Fig. 3. Additional outcomes identified and added to the outcomes framework (see Supplementary Information 2).^{26,34,35}

also amongst the highest scoring within the first ranking exercise (see Table 3 and Supplementary Information 3). Four outcomes were scored zero – that is, no participant selected them to be included in their top seven outcomes: physical characteristics, self-efficacy, lifestyle, and utilisation of holistic care/wellbeing services.

5.4. Consensus

The final consensus exercise was completed by 11 of the 12 NGT participants. Ten respondents (83.3%) agreed these were the top five most important outcomes, which was greater than our *a priori* established consensus level of 66%.

5.5. NGT – qualitative analysis of discussions

The analysis of the NGT discussions is presented here. Due to technology issues, one participant did not participate in the round robin.

The research question “What key areas were considered when discussing the important outcomes?” was considered. There were three main themes which emerged: audience of the outcomes framework, interpretation of outcomes, and practicalities of the outcomes framework.

Table 3

Five most important outcomes, ordered according to total ranked score of ranking exercise 1.

Rank	Outcomes	Score ^b	Participants who ranked in top 7 n (%)
1	Patient Experience	49	10 (90.9%)
2	Medication Related Adverse Events	45	8 (72.7%)
3	Cost-Effectiveness	41	11 (100.0%)
4 ^a	Medication Optimisation	39	10 (90.9%)
4 ^a	Health-Related Quality of Life	39	7 (63.6%)

^a = tied ranking.

^b Higher scores indicate greater importance.

5.6. Audience of the outcome framework

The concept of “who the framework was for” was considering when discussing the different type of outcomes – economic, humanistic, service and clinical. There were four potential audiences identified: patients, pharmacists, policy-makers, and service providers. For patients, the importance of quality of life was acknowledged and treating patients as experts in their own health journey. The importance of patient experience and ascertaining what matters to the patient was highlighted.

“The stuff that I rated way down the list were actually the clinical outcomes because that’s, if we’re talking to the patient first then the clinical outcomes become defined by the patient rather than looking at SIGN¹ – P11, male, qualified for 24 years.

The participants reflected that there were “traditional” outcomes associated with pharmacy and pharmacists – for example medicines optimisation, medication adherence, and adverse drug-related events.

“And then, I suppose, our [main focus as pharmacists] – the next thing I was looking at was more around the medication optimisation” – P12, female, qualified for 8 years.

However, as pharmacists move into more clinical roles how they view their role – and the key outcomes – may evolve. One participant highlighted that clinical and humanistic outcomes were important to pharmacists delivering the service.

“The clinical and the humanistic bits as a, as a you know practitioner and a clinician are the things that are really important to you delivering the service and you know care to patients.” – P14, female, qualified for 22 years.

The importance of considering the national and international landscape – for example, the World Health Organisation (WHO)’s focus on medicine harm reduction and public health measures – were considered. Additionally, the function of the pharmacotherapy service to support general practice was raised, as well as demonstrating that the pharmacotherapy service is cost-effective within primary care was deemed

¹ Scottish Intercollegiate Guideline Network, the organisation responsible for clinical guideline development.

important. There was a perceived need for the service to be accountable as its publicly funded, and the importance of knowing the overall cost to the NHS rather than solely, for example, the “cost-per-tablet”.

“I do feel quite strongly about the value for money because we do cost more, we take longer to do things than GPs so there is that argument around having a cost effectiveness” – P6, female, qualified for 25 years.

5.7. Interpretation of outcome data

This theme explored whether the outcomes could be interpreted meaningfully, which mainly concerned barriers to interpretation due to: lack of detail regarding delivered service, inter-relatedness of outcomes and task delivery, and difficulty knowing if the pharmacotherapy service was responsible for specific outcomes. It was reported that features of how the pharmacotherapy service were delivered would affect interpretation of outcomes. In part, this was due to a lack of an overall “vision” for the service.

“We kind of need to go on a bit of a journey in terms of defining what we’re actually doing that helps us to achieve these outcomes.” – P1, male, qualified for 24 years.

The inter-relatedness of outcomes also emerged, alongside the importance of selecting the correct outcome measure within the patient pathway. This indicates the possibility that some outcomes may be best collected at different times and that early outcomes in a patient’s journey may affect later outcomes. It was considered that some outcomes areas may influence later outcomes – for example improving measures related to adherence would affect patient related outcomes.

“So for me I suppose things like adherence is an intervention and improving adherence improves outcome, in terms of disease indicators and that improves outcome in terms of you would hope quality of life and humanistic outcomes” – P3, female, qualified for 22 years.

Attributing outcomes specifically to the pharmacotherapy service or to a pharmacist’s input was considered problematic due to the wider health-care context within Scotland, inter-relatedness of the pharmacotherapy tasks and a multi-disciplinary team working approach. It was proposed that initially simple tasks could escalate into more complicated tasks, which had implications regarding interpreting which delivered task affected the outcome.

“even when it’s just level 1 things it does kind of overlap into level 2 and level 3 tasks, so if you’re just doing a simple acute [prescription] request you then may actually be looking at kind of recommendations, medication discrepancies, medication use, medication related problems and then go off on tangents ...” – P15, male, qualified for 10 years.

5.8. Practicalities of the outcome framework

This theme considered two practicalities of the framework: the framework design and the feasibility of measuring outcomes. Discussions around outcome framework design included the reflection by one participant that the framework’s name needed to reflect that it is newly conceptualised and, therefore, should not be reminiscent of a previous outcomes framework within primary care. Consideration was taken regarding whether the outcomes framework was specific to the pharmacotherapy service only or could be broader, with one participant suggesting that there may be both generic outcomes and task-specific outcomes. The framework’s design needed to reflect the breadth of the framework and consider the importance of balancing the framework in order to be meaningful to a broad audience.

“I’m kind of conscious as well that any outcomes framework needs to kind of speak to lots of different parties here if we’re trying to kind of build our own evidence base I guess around the impact we can have so, so it need to kind of have the breadth and that balance around outcomes.” – P3, female, qualified for 22 years.

Feasibility of measuring the outcomes emerged through the analysis. The practicalities of collecting data related to the outcomes were considered by some participants, including the need for a standardised

approach. The issue of which measurements to use was raised for some of the outcomes with participants being concerned that some of the outcomes were not relevant to, or demonstrable by, the pharmacotherapy service activities. This could be due to a perceived disassociation between the outcomes and the tasks, or not enough GPCPs delivering a service to obtain meaningful data.

“I am kind of struggling about what we’re trying to demonstrate here if we’re, you know if we’re looking at how we demonstrate outcomes I don’t think we’ll ever be able to demonstrate an outcome on mortality and is it what we are going to be able to demonstrate through pharmacotherapy” – P6, female, qualified for 25 years.

6. Discussion

This project sought to develop an outcomes framework for the Scottish pharmacotherapy service, encompassing outcomes considered the most important. Consensus was obtained regarding the five key outcomes of importance: Patient Experience (Humanistic); Medication Related Adverse Events (Clinical); Cost-Effectiveness (Economic); Medication Optimisation (Service); and, Health-Related Quality of Life (Humanistic). These represented the four outcome areas of clinical, economic, humanistic and service. Thematic analysis of the panel’s discussions highlighted important areas of consideration. These included the framework’s focus – for example the potential audience, and their priorities. Outcomes should also be interpretable, with demonstrable relationships between tasks and measured outcomes. Finally, the panel raised the importance of designing a useable framework, with feasible measures.

The five most important outcomes identified encompassed all four outcome categories, suggesting the importance of a broad set of outcomes when evaluating complex clinical pharmacy services in primary care. The importance placed on both positive outcomes (Medication Optimisation) and negative outcomes (Medication Related Adverse Events) associated with medicines is unsurprising given the panel comprised pharmacists who may consider such medicine-related outcomes to be ‘core’ and traditional to pharmacy practice. The focus on patient-related outcomes (Patient Experience and Health Related Quality of Life), as opposed to clinical disease indicators (e.g., reduced blood pressure) was surprising as, within the umbrella review by Weir et al., disease indicators were cited notably more than patient-related humanistic outcomes.²³ This may represent a local Scottish interest in having patients define their health, as opposed to clinical biomarkers, exemplified by ongoing Scottish campaigns such as “What matters to you” which aims to engage patients with healthcare decision.³⁶ Equally, however, it may reflect a bias inherent within Weir et al.’s paper. The majority of reviews cited focused on randomised controlled trials which may – by design – give greater importance to clinical outcomes.¹⁰ The importance of cost-effectiveness may represent the panel’s acknowledgement that the pharmacotherapy service should offer benefits greater than just improved care, particularly as the role of pharmacists has evolved in primary care to support the ‘primary care crisis’,³ and that the service should be financially viable considering the investment.¹⁷

Key challenges identified from the qualitative results related to the interpretability and feasibility of the outcomes. The interpretation of outcomes is challenged by the inter-relationship between outcomes and task delivery, as well as working as part of a multi-disciplinary team. This is similar to what was identified within England’s primary care evaluations, where there were challenges attributing outcomes to the input of pharmacists specifically, rather than the whole multi-disciplinary team in primary care.²⁴ The challenge of feasibly collecting outcome measurements was also highlighted by participants in this study. This highlights a key limitation with the umbrella review: the studies identified were all conducted in a trial setting.²³ It is, therefore, unknown if existing infrastructures in real-world, non-experimental settings can collect the relevant outcomes. For this to be a success, data

acquisition needs to be user-friendly, alongside continuous data cleansing so the data is readily useable to offer real-time analysis.²⁰ Ambitions laid out within the Royal Pharmaceutical Society's 2030 Vision for GP Pharmacy includes automatic data collection within systems to overcome time constraints associated with manual data input and collection.³⁷ Future work should therefore focus on the feasibility of collecting outcome in the real-world contexts, considering measures which are easy to collect and interpret within existing infrastructures.

6.1. Implications of research

This study presents a robust consensus approach towards developing an outcomes measurement plan, which will be of value to multiple stakeholders including patients and policy makers, particularly considering the rise of the inclusion of pharmacy-led services in primary care funding models and the necessity to exemplify their value.³⁸ It is widely acknowledged that new services, regardless of how plausible and intuitive they appear in design, require systematic evaluations to ensure intended outcomes are achieved.³⁹ This is particularly pertinent when the services are novel and represent significant investments, as is the case with the Scottish pharmacotherapy service.⁴⁰ Within Scotland, the identification of the most important outcomes and their subsequent evaluation will enable targeted evidence-based service delivery, which will facilitate cross comparison and identification of the most cost-effective services. This will ultimately inform future decision making and will support future service enhancements and improvements.^{41,42}

The framework presents the clinical, humanistic, economic, and service outcomes which can be used to evaluate pharmacists' tasks associated with the pharmacotherapy service (Fig. 4). This builds upon Fig. 1 presented in the introduction. As reflected in the paper by Groenewegen and colleagues,⁴³ context is important when considering outcomes. For a Scottish healthcare context – patient-level outcomes would be clinical and humanistic outcomes, whereas health service-level outcomes are service and economic outcomes. The measurement of the key outcomes areas which have been agreed upon through this work will be dependent on (i) the tasks carried out and (ii) whether the outcomes are proximal (happen immediately) or distal (happen further down the line/emerge over time). This is based on the Safety Engineering Initiative for Patient Safety (SEIPS) model, a Human Factors model, which provides a framework/guide for examining all elements of a work system (including tasks) contributing to specific outcomes.⁴⁴

The next step involves identifying feasible measures for the key

outcomes. It is currently unknown, for example, which questionnaire(s) would best capture Patient Experience or which specific costs should be calculated for a cost-effectiveness evaluation. Future research should therefore focus on developing an actionable measurement plan, which should identify routinely collected sources of outcomes data, and a plan for capture of these at a national and local level. Wider stakeholder engagement would also be valuable to understand perspectives of patients, GPs and policy makers who may offer valuable, complementary insights into the development of an outcomes framework for the pharmacotherapy service. Additionally, as emphasised by the SEIPS 2.0 model,⁴⁴ to understand outcome data, it is also important to collect process and work system data (e.g., who received the pharmacotherapy services). This will drive evidence-based planning to ensure appropriate cohorts are targeted for specialist clinical pharmacy services, particularly as future pharmacotherapy service delivery is anticipated to have a focus on high risk patients and high-risk medicines.²⁸

6.2. Strengths and limitations

The study was undertaken during the COVID pandemic, necessitating a flexible approach to the study's design. Fortunately, the NGT approach lends itself to flexibility⁴⁵ and was able to be adjusted to reflect the online methodology. Additionally, the initial idea generation stage was conducted prior to the NGT meeting itself, which allowed for more time to discuss during the meeting. Conducting the study entirely online had both strengths and limitations. The move to remote working resulted in communication via video-conferencing being embedded within the service when the study deployed. This meant that delivering the NGT via video conferencing is likely to be more natural than pre-pandemic. The accessibility of video-conferencing enabled representation from a diverse array of people from health regions which may not have been possible in a traditional face-to-face format. Additionally, the consensus results indicated a natural cut-off for agreement regarding the most important outcomes areas, which offered reassurance regarding the validity of the number of outcome areas. However, the online methodology was problematic with IT challenges affecting participation. Additionally, although alterations were made to the design of the NGT ranking tasks during the pilot phase, these tasks displayed differently depending on the computer system used which affected the ease of their completion. It is anticipated that an online methodology will be useful post-COVID crisis to support wider accessibility, but needs to be balanced with risks of non-participation associated with IT issues.

In general, a limitation was that not all participants returned the pre-NGT questionnaire and therefore were not able to influence the outcomes to be ranked. However, the inclusion of the new outcomes – and the retention of two of these in the final five outcomes – supported the methodology used to operationalise these within a Scottish context. Additionally, the high level of agreement in the consensus exercise indicated that the majority of participants supported the five most important outcomes identified supporting that the conclusions are valid.

7. Conclusion

The five key outcomes for the Scotland's primary care pharmacy services were: Patient Experience (Humanistic); Medication Related Adverse Events (Clinical); Cost-Effectiveness (Economic); Medication Optimisation (Service); and, Health-Related Quality of Life (Humanistic). Operationalisation of the outcomes will lead to development of a measurement plan which will facilitate evidence-based decisions regarding future service delivery, particularly when considering which high-risk patients and clinical scenarios should be targeted. To achieve this, future work should focus on routinely collected sources of outcomes data.

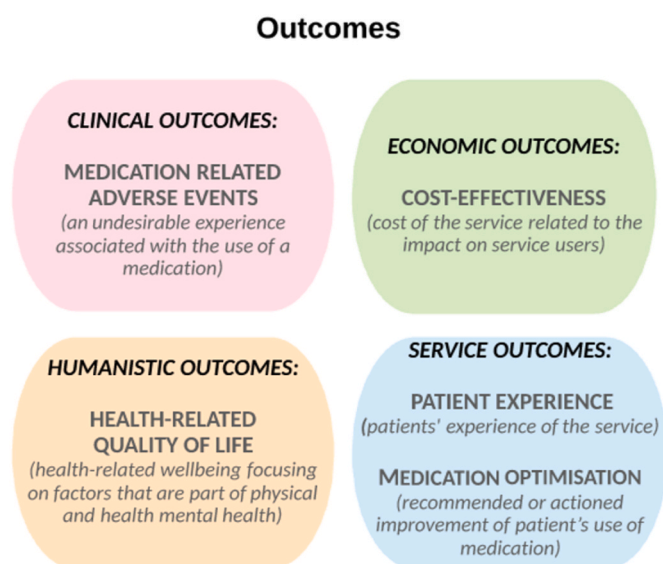


Fig. 4. Scotland-specific, framework for primary care pharmacy services.

Author statement outlining your contribution

Rosemary Newham: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Supervision; Visualization; Roles/Writing - original draft; Writing - review & editing.

Natalie Weir: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Validation; Writing - review & editing.

Aimee Ferguson: Investigation; Data curation; Validation; Writing - review & editing.

Marion Bennie: Conceptualization, Funding acquisition, Project administration, Methodology; Supervision; Writing - review & editing.

Declaration of competing interest

None.

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Aspects of SQUIRE 2.0 (standards for QUALity improvement reporting excellence): [SQUIRE-2.0-checklist.pdf (equator-network.org)] informed an early report of this research project for the sponsors.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sapharm.2022.11.003>.

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