Community pharmacy minor ailment services in England: Pharmacy stakeholder perspectives on the factors affecting sustainability

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Abstract

Background: Self-care advice and management of minor ailments have long been provided in community pharmacies across England. However, formal pharmacy minor ailment service provision is geographically variable and has yet to gain recognition and political support as a valued sustainable service for nationwide adoption and commissioning.

Objective: To investigate the sustainability potential of pharmacy minor ailment services from the perspective of community pharmacy stakeholders within the North East of England.

Methods: A mixed methods approach was adopted to survey and interview stakeholders from the North East of England who commission; provide; and/or represent groups influencing the design, delivery and investment in community pharmacy clinical and public health services. The 40-item Programme Sustainability Assessment Tool, a validated instrument to assess a public health programme's capacity for sustainability across eight domains, was administered to fifty-three stakeholders, identified from a pharmacy minor ailments showcase event. The same stakeholders were invited for a semi-structured interview to explore issues further. Interviews were audio-recorded, transcribed verbatim, and underwent framework analysis.

Results: Forty-two (79.2% response rate) stakeholders representing commissioning, provider and influencing (e.g. Local Professional Network) organisations completed the assessment tool. Pharmacy minor ailment services were rated as unsustainable across the majority of the domains. Elements within the domain 'Partnerships' demonstrated potential for sustainability. Stakeholder interviews provided detailed explanation for the low scoring sustainability domains, highlighting the multifaceted challenges threatening these services.

Conclusion: The Programme Sustainability Assessment Tool allowed stakeholders to evaluate the potential sustainability of pharmacy minor ailment services in England. Follow-up interviews highlighted that initial design and implementation of services was poorly conceived and lacked evidence, thereby impeding the services' sustainability. There are many challenges facing a

widespread provision of pharmacy ailment services, but it is clear the profession needs to be clear on the service objectives to secure future interest and investment.

Keywords: health service research; pharmacy practice; programme sustainability; minor ailments; self-care.

Introduction

A recent review of international pharmacy-based minor ailment services report that such services exist in Scotland, parts of Wales, parts of England and parts of Canada. They are also on the current political agenda in Australia, New Zealand and increasing parts of Canada. The review concludes that these services differ in their structural characteristics which need to be considered when assessing for success and sustainability.[1]

The United Kingdom (UK) Nuffield report 1986 was one of the first documents that encouraged the diversification of the community pharmacists' role away from routine prescription dispensing towards more public health roles such as providing self-care advice for minor ailments.[2] To date, free pharmacy minor ailment services (PMAS) have been widely adopted by local authorities and commissioning groups be it in an uncoordinated and unstandardized manner.

A review of PMAS in the UK carried out in 2011, found that more than half of the primary care organisations in England had reported commissioning and implementing one form of a PMAS.[2] A subsequent systematic review included one randomised control trial amongst the large number of reviewed studies testing the effectiveness of minor ailments services. Clinical and humanistic outcomes were lacking and the focus was on symptom resolution, referral and reconsultation rates.[3] PMAS demonstrated similar performance in these measures to general practice (GP) and/or accident and emergency (A&E). However, due to the design of that research and lack of a non-randomised control, the findings are potentially less representative and widely applicable.[4] Further research has suggested that the mean costs, from the perspective of the UK National Health Service (NHS), were

significantly lower if patients were treated within the community pharmacy, but this is based on the assumption that the outcomes from medical practice and community pharmacy would be the same.[4] The lack of rigorous, outcomes-based research on PMAS, could be one factor that currently hinders national investment and equitable provision across the country.

In 2016, an independent review of community pharmacy clinical services, commissioned by NHS England was carried out to help inform the future provision of clinical pharmacy services.[5] This review suggests four thematic barriers to successful clinical service provision through community pharmacy. These included the recognised poor integration of community pharmacy within the wider NHS provision with the lack of digital interoperability as a key contributing factor. Prevailing behavioural (health-seeking behaviours) and cultural issues, pertaining to the perception of the roles and competencies of community pharmacists, within both the public population and healthcare professional communities, mean that community pharmacy often fails to be considered as a healthcare option. The overly complex and disjointed commissioning and regulatory systems were also reported to hinder the credibility of community pharmacy as an investable resource. Lastly, the varied funding routes, with the focus on a range of post-registration solutions to equip the workforce to be flexible to patient need, means the skill mix is diverse and utilisation of this workforce is ineffective.[5]

These issues have not been specifically related to PMAS, and therefore their empirical applicability in explaining the lack of widespread adoption, and routinisation, of PMAS needs to be investigated.

There is a developing interest to raise the awareness and appreciation of how implementation science will enhance understanding and inform the future advancement and spread of pharmacy practice innovation.[6] Crespo-Gonzalez *et al.* promotes that, as services have been implemented and routinised into daily pharmacy healthcare provision, the next focus is to understand the sustainability of innovations to maintain and improve patient care over time.[7] Sustainability has been described as the process of maintaining an innovation through continued innovation use integrated as routine practice; with ongoing capacity, a supportive environment and persistence of benefits.[8] A recent review of

78 studies investigating public health interventions, with input from an expert panel, developed a
79 conceptual framework for programme (intervention) sustainability in public health.[9] The study defined
80 an intervention's capacity for sustainability as
81 *'the existence of structures and processes that allow a programme to leverage resources to effectively*
82 *implement and maintain evidence-based policies and activities'*[9]
83 Following the development of this conceptual framework, the Centre for Public Health Systems
84 Science (CPHSS) at Washington University in St Louis developed the Sustainability Framework and the
85 Programme Sustainability Assessment Tool (PSAT) to address the lack of reliable sustainability
86 measurement tools. Based on consistency and reliability testing in a sample of 592 respondents
87 representing 252 public health programmes, it was proposed that the PSAT has the capability to
88 capture the distinct elements of programme sustainability.[10]
89 This study aims to investigate the perceptions of commissioners, providers and representatives of
90 groups who influence public health services, on the factors impacting the routinisation of PMAS and
91 those contributing to the sustainability of PMAS. This will serve as a descriptive analysis to understand
92 the barriers and facilitators to wide-spread adoption of PMAS and whether the process factors have
93 limited the capacity to derive outcome-based evidence thus far. The cross-sectional perspective will
94 also identify the crucial factors influencing the sustainability of PMAS going forward.
95
96 **Methods**
97 ***Design***
98 A sequential mixed methods approach was employed for this study to elicit the perspectives of
99 stakeholders working in the commissioning, influencing and delivery of PMAS. The quantitative data
100 was collected first and obtained by means of the self-completed PSAT questionnaire adapted for use
101 within this study. Qualitative data collection was obtained following analysis of questionnaire data in
102 the form of semi-structured interviews with participants. The aim was to investigate further the
103 perceived: barriers and facilitators to coherent adoption and rountinsation of PMAS, and; issues

impacting the sustainability of PMAS quantitatively captured by the PSAT tool. Calhoun *et al.* commend the PSAT for its simplicity and accessibility to assess sustainability across a range of parameters. However, there is an acknowledgement that the tool is limited in providing a deep understanding of sustainability capacity. The authors recommend complementary discussions with stakeholders to explore nuances of setting and situation that the PSAT does not capture[11], which provided the rationale for the sequential mixed methods approach.

The study received ethical approval from the Research Ethics Committee of the Durham University School of Medicine, Pharmacy and Health (ESC2/2016/03). Participants were asked to provide written consent to participate in the semi-structured telephonic interviews.

Setting

The North East of England provides a region to investigate in detail the commissioning and delivery of PMAS. There are between 250-300 community pharmacies spread across this region, which includes some of the most deprived areas in England. This localised investigation aims to develop an in-depth understanding about the observed episodic and wavering support that has been afforded by PMAS across England as perceived by pharmacy stakeholders.

Participants

Participants involved in the design, commissioning, operation and delivery of PMAS within the North East England were identified from a North East Minor Ailment Service Showcase event (March 2016) where these stakeholders were in attendance. Four areas within the North East presented their respective Minor Ailments service in terms of delivery and reflections on achievements at this event. The organisers of this event were able to provide an attendance list with job roles and contact details. Fifty-three attendees were identified from this attendance list and represented various organisations (commissioners, providers and influencers of services, e.g., representatives of the Local Pharmaceutical Committee (who have a role to influence the commissioning and provision of public

health services regionally), Clinical Commissioning Group (commissioner within a region), and/or community pharmacy healthcare team (service provider)) from within the commissioning landscape for public health services as illustrated in Figure 1.

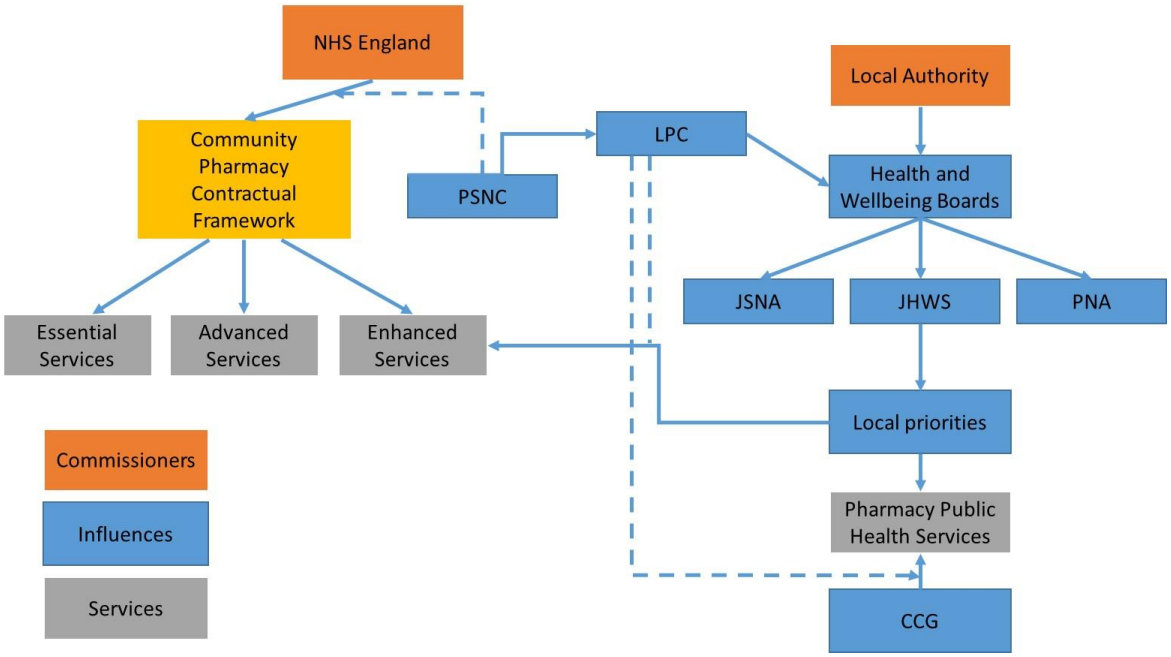


Figure 1. The commissioning landscape in the England (Adapted from Royal Society of Public Health).[12]

(**PSNC**: Pharmaceutical Negotiating Services Committee: promotes and supports the interests of all NHS community pharmacies in England and is the body that represents NHS pharmacy contractors; **LPC**: Local Pharmaceutical Committee: represent all NHS pharmacy contractors in a defined locality. LPCs are recognised by local NHS Primary Care Organisations and are consulted on local matters affecting pharmacy contractors; **Health and Wellbeing boards**: forum where key leaders from the health and care system would work together to improve the health and wellbeing of their local population and reduce health inequalities; **JSNA**: Joint Strategic Needs Assessments: involves collecting and analysing data on the health state of a population and assessing the results to understand which aspects of health (and social care) need attention; **JHWS**: Joint Health and Wellbeing Strategies: these, with JSNAs, will form the basis of clinical commissioning groups, the NHS Commissioning Board and local authority commissioning plans, across all local health, social care, public health and children's services; **PNA**: Pharmaceutical Needs Assessment: each health and wellbeing board must assess needs for pharmaceutical services in its area, and publish a statement of its first assessment and of any revised version; **CCG**: Clinical Commissioning Groups: consist of GP's, other health professionals and lay members and are responsible for commissioning services for their local community from any service provider which meets NHS standards and costs. They are expected to work with local organisations and partners to design services which meet the needs of the local population).

These represented the population to administer the PSAT questionnaire and then sample for follow-up interviews. The fifty-three identified stakeholders were contacted via email and provided with an electronic participant information sheet, the electronic PSAT and a consent form for the subsequent semi-structured interviews.

157 ***Data collection***

158 **PSAT**

159 The 40-item PSAT questionnaire was electronically downloaded from the Centre for Public Health
160 Systems Science website[13] and assessed by the research team for face validity. Minor adaptations to
161 the tool were required to tailor wording to the context and landscape of programme commissioning,
162 and delivery within England. The face and content validity of the adapted tool was assessed by
163 practicing pharmacists (n=10) at a regional professional meeting (May 2016). No further comments or
164 suggestions were made to adapt the tool further. The tool contains recognises and defines eight
165 domains of sustainability capacity as outlined in Table 1.

166 **Table 1.** The eight domains of the PSAT to assess the sustainability of public health
167 programmes/interventions.[9]

Sustainability domains	
Funding sustainability	Making long-term plans based on a stable funding environment.
Political support	Internal and external political environment which influences programme funding initiatives and acceptance.
Partnerships	The connection between programme and community.
Organisational capacity	The resources need to effectively manage the programme and its activities.
Programme adaptation	The ability to adapt and improve in order to ensure effectiveness.
Programme evaluation	Monitoring and evaluation of process and outcome data associated with programme activities.
Communications	The strategic dissemination of programme outcomes and activities with stakeholders, decision-makers, and the public.
Strategic planning	The process that defines programme direction, goals, and strategies.

168

169 Each of the items spread across these domains assesses an element of sustainability. Respondents
170 are required to rate the extent to which they perceive each element was present in the PMAS by using
171 a Likert scale with anchors of 1 ("Little or no extent") to 7 ("A very great extent"). The psychometric
172 study of PSAT across its domains, items and with this scale has evidenced that this tool is reliable
173 and ready to use for assessing capacity for sustainability.[10]

174 The fifty-three stakeholders were emailed and invited to complete the PSAT (June 2016). An additional
175 section was added to the questionnaire which asked for the respondents' job role, membership to any
176 professional and/or pharmaceutical organisations and committees, and whether they were a qualified

pharmacist. The questionnaires were sent out using the Bristol Online Survey (www.survey.bris.ac.uk), and were requested to be completed and emailed back within 14 days. Non-respondents were sent a reminder once this deadline had been reached and given a further 7 days to submit their completed questionnaires.

Semi-structured interviews

An invite and consent form to participate in a telephonic interview was also sent out with the PSAT questionnaire to the fifty-three stakeholders. A semi-structured interview guide was used by the researcher to guide the conversation. The eight sustainability domains of the PSAT formed the main topics areas; the specific items of the tool were used to explore further the granularity of these factors. The four key barriers identified by the independent Clinical Services Review[5] and the contributing issues (Appendix 1) were also included within the discussion to obtain rich and contextualised information about the stakeholders' perspectives on the state of PMAS. Appendix 1 shows how the four barriers map across to the sustainability domains and demonstrate relevance for discussion.

These elements informed the interview guide to probe further the factors affecting routinisation and sustainability of PMAS. Interviews were conducted by phone by one researcher {HN} trained and skilled in qualitative research design. The interviewer, also a qualified pharmacist, ensured only the neutral cues and prompts that had been noted on the interview guide were used during the interview to limit the possibility of offering subjective opinion or critique. Interviews were audio-recorded then transcribed verbatim.

Data analysis

The answers from the completed PSAT questionnaires were entered into Microsoft Excel. Respondents were classified as per their job role into 'commissioner', 'representative of an influencing group' and/or 'service provider'. Respondents also qualified as pharmacists were also identified.

The mean of each of the PSAT 40 items were calculated from all respondents, as has been carried out in a study using the PSAT to evaluate the sustainability of a paediatric asthma care coordination

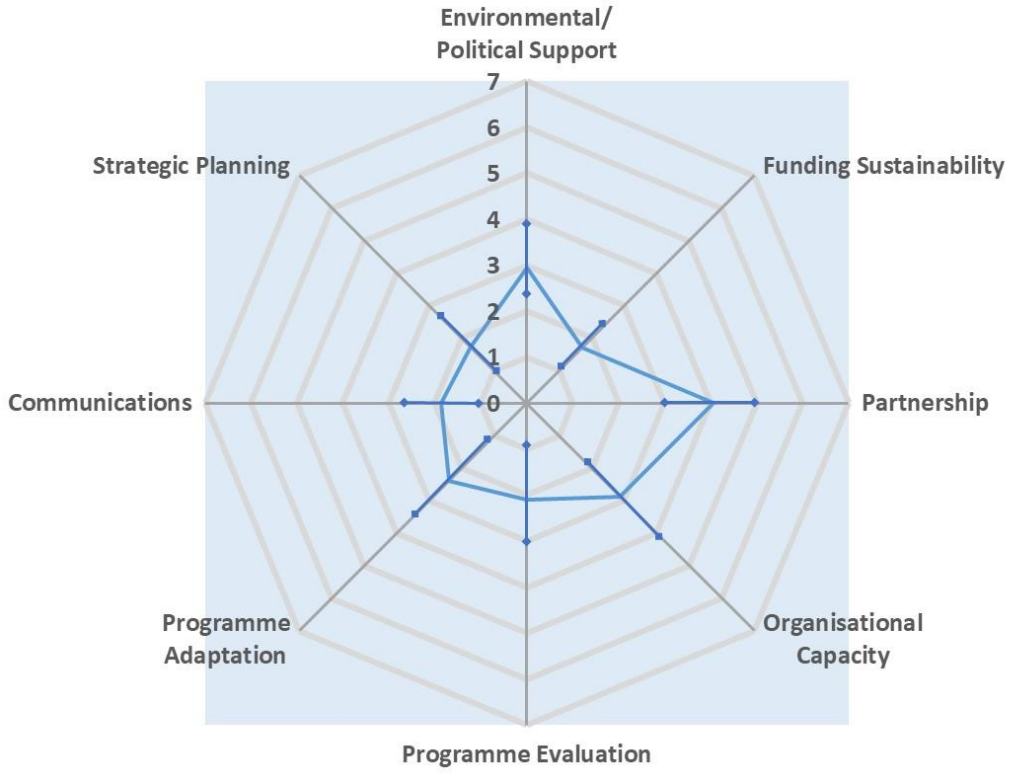
programme.[14] Overall domain scores were obtained by calculating the mean scores for each domain, and standard deviations were calculated to show variability across the items.

The framework analysis approach as developed by Ritchie and Spence,[15] was adopted for qualitative data analysis. The *a priori* themes were derived from the eight PSAT domains, with subthemes including the forty PSAT items and the issues identified in the clinical services review. To develop a coding scheme within this framework, transcripts from three randomly selected interviews were each independently coded by two evaluators to understand the data from different perspectives. Where difference was found, a third external party to the research team, was involved in discussions to adjudicate. Through constant comparison analysis of these initial transcripts,[16] the *a priori* themes were adapted, and emerging themes were then added into the framework. The evaluators came to consensus on the final framework, which was the original framework plus an additional theme of 'strategies to overcome the barriers'. This version of the framework was tested by the two researchers, to analyse independently two more randomly selected interviews. On finding that no further themes were identified with this framework, the two researchers independently coded the remaining transcripts, comparing the generation of themes and development of the findings.

In order to assure trustworthiness of this study as recommended by Lincoln and Guba:[17] the methods and analyst triangulation enhances the credibility of the work; the 'thick description,[17] yielded from the interviews about the context of PMAS design, delivery and commissioning within England will facilitate transferability of findings; the dependability of the study was augmented by the involvement of a third party, external to the research team not involved in research design or collection, to provide an 'external audit'[17] to the research process and findings, and the combined effects of the triangulation and external audit enhances the confirmability of the study findings.

Results

228 Forty-two completed questionnaires were received from the stakeholders (79.2% response rate). All
229 but one of the respondents (a service commissioner) were pharmacists, and most of the respondents
230 (n=24, 57%) represented more than one job role as categorised from the self-reported
231 professional/pharmaceutical memberships (service provider, commissioner, representative of an
232 influencing group).
233 The mean and standard deviations of the 40 PSAT items are shown in Figure 2. The respondents rated
234 the majority of domains on the lower end of the Likert scale (<3) which indicates that PMAS currently
235 exhibits 'little or no extent' to the listed elements recognised to support a sustainable programme.
236 The 'Partnership' domain was rated slightly higher (4.1 ± 1.0), indicating there are some existing
237 partnerships that improve the sustainability of PMAS (full data on mean scores and standard
238 deviations per item are presented in Appendix 2). 'Funding sustainability' (1.7 ± 0.7) and 'Strategic
239 planning' (1.7 ± 0.8) were particular domains that scored low across all respondents as demonstrated
240 by a relatively narrow spread of scores. There was recognition that PMAS lacked stable and sustainable
241 funding streams in an unsupportive economic climate, which contributed to the low score for 'Funding
242 sustainability'. The low score for 'Strategic planning' is attributed to low ratings on the items relating
243 to perceived lack of sustainability and long-term financial plans, and that the programme goals and
244 stakeholder roles and responsibilities are poorly understood. The two domains with the widest spread
245 of scores across the component items were 'Organisational capacity' and 'Programme adaptation'.
246 Sub-group analysis was unable to demonstrate a significant difference in responses based on the
247 reported role of the respondent.



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249 **Figure 2.** The mean scores (± SD) for the domains of the PSAT awarded by the responding stakeholders
250 (n=42).

251

252 Twenty of the stakeholders provided consent for an interview. Most held more than one of the job
253 roles, i.e. service provider, representative of an influencing group, commissioner. These twenty
254 interviews were carried out between Sept-Nov 2016 and lasted on average 48 mins ± 12 mins. The
255 qualitative data can be categorised by the eight domains of the PSAT. Interviewees provided in-depth
256 critique of the domains, and the issues impacting routinisation of PMAS and threats to its
257 sustainability. A further theme emerged which focussed on key facilitators towards achieving
258 improved sustainability capacity. These relate to underpinning concepts of successful implementation
259 of an innovative service or programme. Fundamentally, the findings suggest that the current challenge
260 to widespread adoption and future sustainability of PMAS can be ascribed to the perceived ill-
261 informed and lack of evidence-base behind the initial service design and implementation. Each of the
262 themes are described below. Verbatim quotes and codes to denote the type of respondent (S: Service

provider; I: representative of an influencing group; C: commissioner; P: Pharmacist) with specific PSAT items and their ratings have been provided in Appendix 3.

Funding sustainability

The majority of respondents emphasised the inadequate alignment and complexity of NHS funding. This is further confounded by the incentivisation towards driving quantity of prescription-related and clinical service activities not the quality of delivery and having little focus on patient outcomes.

Some of the interviewees reflected that the current national structure, where community pharmacies provide NHS services under a Contractual Framework, combined with local clinical commissioning groups deciding additional service provision (namely 'advanced and enhanced'), means that overall accountability and management of funding is complex.

This has propagated the belief among the interviewees, that budgets to support the delivery of clinical services, such as PMAS, are held in siloes by professions. This has contributed to issues around poor integration of pharmacy in the wider NHS and lack of joined up healthcare provision. As such, interviewees related that funding and incentivisation at the local level is highly dependent on the specific drivers, skills and understanding of local commissioners and effectiveness of the relationship with local pharmacy influencers. There was also a view that pharmacy is not always represented at health policy and commissioning arenas and, in some cases where they are, the role of the community pharmacist may not be positively promoted. This may be due to professional isolation, where pharmacists working in commissioning or influencing organisations do not have clear understanding of pharmacy practice specifically within the area of community pharmacy, or due to poor relationships based on personal and/or professional perceptions.

Environmental/Political support

Competing payment structures between general practice and community pharmacy, exacerbated by the lack of awareness of the potential role of community pharmacy, was identified as a key barrier to the integration of community pharmacy in the wider NHS.

Further comments emphasised the lack of strong and visible pharmacy representation at local and national level to champion PMAS and gain support at the influencing and commissioning stages.

Interviewees also acknowledged that there is currently a lack of coherency on what PMAS should be achieving, as there have been no clear performance indicators stipulated or description of what success looks like. This has resulted in a deficiency in evidence of effectiveness and outcomes, unable to support valid and credible business cases, and consequently achieving little or no buy-in from commissioners.

Partnerships

Respondents to the PSAT reported passionate commitment from within the pharmacy profession to the PMAS programme (mean rating 5.0 ± 0.7) and are engaged with the development of the programme (mean rating 4.3 ± 0.7). These high scores contributed to the overall high score for this domain.

However, the semi-structured interviews revealed that this theme could provide an explanation for issues relating to the incongruity within pharmacy. The overwhelming feeling of the interviewees was that community pharmacy is often seen as professionally isolated, with very poor integration into local clinical teams but also within the various sectors of their own profession. Silo working was a predominant observation, where pharmacists working in different fields and/or roles (e.g. hospital *vs.* community, service provider *vs.* commissioner roles) lacked an understanding and appreciation of one another. This has been both a consequence of, and perpetuated by, the lack of strong relationships within the profession and with other healthcare professionals.

As a consequence, awareness amongst other professionals of community pharmacy's potential contribution is not harnessed towards better utilisation and integration in the wider NHS system.

All interviewees referred to the poor understanding held by healthcare professionals of community pharmacy, related back to the silo working and detachedness from the NHS. Consequently, there is no coherent message externally projected by the NHS and healthcare providers within it, to promote the role of community pharmacy to the patients and public.

Organisational capacity

There was a unanimous perception amongst the interviewees that community pharmacy was the best location for patients and public with minor ailments to access care, with easy accessibility to an appropriate level of knowledge, skills and expertise.

However, despite the overall perceived support for PMAS delivery from community pharmacies, interviewees suggested that there was a lack of coherency amongst the pharmacy workforce:

- Community pharmacists do not share information and learning of best practice with each other;
- Community pharmacists do not have a consistent vision of their role in patient care and the wider NHS;
- Community pharmacy lacks an effective scaffold to support and manage the establishment and maintenance of a collective vision of pharmaceutical care and strategy towards achieving it;
- Community pharmacy lacks an effective communication strategy to ensure 'on-the-ground' service providers have an appreciation of the main objectives behind PMAS and how it aligns with the national political agenda around self-care.

Some of the interviewees acknowledged that because of the lack of clear objectives around self-care, support staff have been observed to divert patients and public away from self-care and provide treatments free under the PMAS. This has had a detrimental impact on the perceptions of commissioners who observe this as an increased cost to be reimbursed by the NHS. This highlights the need for coherent collective awareness of the key purpose and political agenda of self-care underpinning PMAS.

Programme adaptation

Interviewees recounted that episodic review of individual, local PMAS resulted in very little critical appraisal and only minor tinkering of superficial service details. There was an appreciation that PMAS needed a holistic critical overhaul to be fit for purpose.

Programme evaluation

There is a lack of coherency of what PMAS should be achieving as there have been no clear performance indicators stipulated or description of what success looks like.

A few interviewees did mention how digital integration through using PharmOutcomes, a web-based platform supporting clinical service delivery, has enabled better oversight of the service activity.

However, the potential for sharing of information between healthcare professionals and within the profession was regarded as most appropriate to ensure joined up patient care.

Communications

Unsurprisingly the distorted vision and funding within the political and professional arenas is reflected in the reported variation of services and even the specifics of individual services that are provided from each pharmacy and each locality. As such the patients and public are confronted with a confusing picture of the role of community pharmacy as a profession and specific offerings within their geographical area.

Some of the interviewees observed that there is very little engagement with the patients and public in the design of these services. Therefore, there is little understanding of patient behaviours and preferences, which would aid service design, implementation and delivery.

Some interviewees channelled that the lack of buy-in and understanding amongst staff within community pharmacy of the NHS self-care agenda, could be the contributing factor to inappropriate marketing of PMAS and diversion of previously self-caring populations to the ever-growing burden of the NHS.

Strategic planning

Respondents observed that no one body, or collective, has claimed accountability and taken the so-called 'risk' to: develop a PMAS; operationalise; govern; quality assure and evaluate towards optimising care, defining success, and providing evidence to improve future service design and commissioning.

There was reference to the Pharmaceutical Negotiating Services Committee, as an organisation that has been advocating for a national PMAS that was rejected just recently. There are also documentation and support provided online for contractors and pharmaceutical stakeholders towards developing business cases for PMAS.

However, engagement with commissioning, influencing groups, providers and patient stakeholders was again recommended as key to service redesign at a national level. In this way, a shared vision aligned with the national healthcare agenda, and definition of 'success' could be established.

The standardised PMAS should then be developed and a management and governance structure positioned to performance manage, quality assure and gather evidence of outcomes and impact.

Until this is achieved, most respondents, despite being in favour of the further pursuance of PMAS for the patients and public, demonstrated low expectations of any significant developments in the near future for a more coherent system to support an effective PMAS.

Strategies to improve sustainability capacity

Many interviewees suggested that bringing together pharmacists and GPs at the service design and development stage would facilitate understanding and engagement towards delivering services that are focussed on the best patient care. Interviewees recommended that engagement with commissioning, influencing, providers and patient stakeholders is required in service redesign at a national level.

Respondents proposed that there should be clear referral pathways to community pharmacy from GP practices, out of hour's services and NHS 111 (the telemedical helpline) for appropriate patients to receive management for their complaints.

One interviewee emphasised the importance for a service project manager that would monitor progress and outcomes and feed this back into service optimisation and delivery. Similar reflections were reported in other interviews; lack of accountability and responsibility of the management and performance monitoring of the service, and conversely how the survival of some of the individual services were due to the proactive initiatives of individuals to make it successful locally.

Every respondent highlighted the need to raise patient and public awareness of community pharmacy as an access point for healthcare advice and services. Suggestions were made for well-planned campaigns and media coverage to divert patients away from the overburdened healthcare providers, e.g. A&E, GP surgeries.

Positive press stories about community pharmacy were also recommended to offset the trend of only bad stories makes good news. However, there was no consensus amongst the interviewees on the *who* should do this and *how* to do it most appropriately to avoid misuse.

Discussion

This study offers an opportunity to reflect on the current delivery of a relatively long-running service and consider the potential contributing factors that have hindered wider adoption and threaten future prospects of the PMAS. It is also one of the first investigations that responds to a recent call to pharmacy practice research to focus on the sustainability stage of an intervention.[5] The PSAT offers a useful assessment framework that maps across the characteristics for the sustainability phase as identified through a review of current literature undertaken by Crespo-Gonzalez *et al.*[7] In this study, the tool was particularly pertinent as a guide for qualitative data collection, as it incorporated aspects that have been recently identified as barriers to the implementation and adoption of clinical services within community pharmacy.[5] Therefore, streamlining the investigation of service routinisation and sustainability.

The current success and survival of PMAS was attributed to the fact that there are diverse professional pharmacy organisations invested in the success of this service, e.g. LPC, Local Professional Networks; there is passion amongst the providers of this service (community pharmacy teams) and engagement to develop the ultimate goals (high scoring items in the 'Partnerships' domain). PMAS was also scored relatively highly on the perception that there are adequate numbers and skilled staff to operate PMAS within community pharmacy (an individual items within the 'Organisational capacity' domain). However, the general perspectives of the stakeholders involved in this study is that PMAS currently has low capacity for sustainability. Some of the key issues are integral to the pharmacy profession, as

there is a recognised lack of clarity on the purpose of PMAS as it relates to wider healthcare, and a need for a cohesive, credible representation in negotiating the role and potential contribution for community pharmacy. Externally there are also many issues pertaining to: the combination of centralised and devolved funding of community pharmacy services, which have been historically driving community pharmacy as a supply service; the deficient awareness of community pharmacy competency by other healthcare professionals and the public, meaning that community pharmacy is often not considered an integral part of the wider NHS. Lastly, operationally PMAS suffers from historical poor service design, development and implementation, and lacks the capability to evaluate and generate self-supporting evidence.

This latter issue could be ameliorated by following the recommended steps of design, impact assessment and implementation phases of innovative service creation and delivery articulated in a recent review.[7] Crespo-Gonzalez *et al.* describes that innovative services should be collaboratively designed and evidence informed. The service should be well defined in relation to the target population; context; objectives; methodology; outcomes and expected benefits. An impact assessment for key outcomes, patient and economic, via a pilot study would also test for feasibility, and a process evaluation would determine factors impacting service success.[7] The design and implementation of PMAS has failed to follow this prescriptive series of activities, which has meant the implementation has been ill-informed, poorly-evidenced and lacking in empirical verification. Scheirer *et al.* suggest that investigation for sustainability be considered as an interlinked dynamic with adoption and implementation, rather than a stand-alone phase in the life-span of a service.[18] Consequently, it is the maturity of adoption and implementation that best determines the optimum time to assess for sustainability. From this study, it is clear that PMAS have yet to demonstrate sufficient adoption and implementation to appropriately determine sustainability.

A recent comprehensive report by Watson *et al*. document a series of methodologies undertaken to determine the nature and extent of evidence to support PMAS. Authors also recognise incoherency amongst community pharmacy teams on the aim of the service. Clear and consistent communications

443 from the pharmacy profession are recommended to other healthcare professionals and the public on
444 the potential of community pharmacy to provide care for minor ailments.[19] A recent scoping review
445 highlighted the importance of marketing activities to bridge the divide between community
446 pharmacies and potential market, augmenting the success of a service.[20]
447 The findings of this study suggest that the pharmacy organisation structural issues should be a priority
448 towards progressing any investment in clinical service provision from community pharmacy. As such
449 an established vision and voice will be achieved that will facilitate more coherent and transparent
450 interprofessional relationships; provide a cohesive, holistic voice for the representation and
451 negotiation of the pharmacy profession that policy-makers and commissioners will find hard to avoid.
452 A key limitation to this study, aside from its derivation of findings from stakeholders based in one
453 locality of England, is the absence of the patient perspective. It is crucial to consider service design
454 and delivery in the context of patient acceptability and preferred health-seeking behaviour. There are
455 studies that report that patients and the public have been satisfied with pharmacy minor ailment
456 treatment[21,22] and would be in favour for more pharmaceutical care of this nature in community
457 pharmacy.[23] Furthermore Hibbert *et al.* present an interesting perspective that the public are
458 increasingly approaching self-care and minor ailment treatment from a consumerist perspective. Their
459 study shows that the more prevalent 'challenging consumers' felt confident in their knowledge to self-
460 treat their minor ailments and had a focus to buying a medicinal product. These tendencies were
461 coupled with a reluctance to be questioned by a pharmacist and indifference towards pharmaceutical
462 self-care advice.[24] This dichotomous representation of the public presents its own challenges to the
463 success of future PMAS, therefore signifying the importance of patient and public involvement in
464 service redesign and delivery.
465

466 **Conclusions**

467 Pharmacy Minor Ailment Services have been provided by community pharmacies across England for
468 the past two decades. The service is unstandardised across the country and has failed to generate

sufficient evidence to support a model of care delivery for national commissioning and adoption. Commissioners, community pharmacists and representatives of pharmaceutical organisations acknowledge that the challenges of implementation and future provision of the service are diverse and complex. Underlying and fundamental problems appear to be: the poorly executed design and implementation of PMAS at conception, and the lack of integrity of the pharmacy professional learning community. The former issue highlights the significance the service design and implementation process plays on service success, and assessment of sustainability is only of value once evidence-based implementation has led to routinized practice. The latter problem pertains to the organic nature of the profession, in which the negative effects have long since been recognised and reported on, however real progress has yet to be made in furthering efforts to create local and national learning communities within the profession. The Royal Pharmaceutical Society, the representative pharmaceutical professional body in the UK, provide a platform both online and through local practice forums for networking opportunities which may in the future facilitate such professional learning communities to develop but evidence of this is yet to be reported.

This study can be used to inform commissioners, service designers and providers on future service design, implementation and evaluation, by raising awareness of the supportive elements required to improve an intervention's capacity for sustainability.

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557 **Appendix 1.**The mapping of the thematic barriers to community pharmacy clinical services to the PAST eight domains of sustainability.

Barriers to community pharmacy providing clinical services	Programme Sustainability Assessment Tool: Domains of Sustainability							
	Funding sustainability	Environmental/Political support	Partnerships	Organisational capacity	Programme adaptation	Programme evaluation	Communications	Strategic planning
Integration - **Part of the NHS Family** - **A member of the out-of-hospital clinical team** - **Digital**	X	X	X	X	X		X	X
Behavioural - **Public awareness and expectation** - **Pharmacy workforce** - **Perceptions of other health professionals**		X	X	X	X	X	X	X
System - **Contractual issues** - **Contractor constraints**	X	X	X	X	X	X	X	X

- **Commissioning constraints**								
Skill mix and workforce issues		X	X	X	X	X	X	X

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559 **Appendix 2.** The mean scores from the respondents (n=42) for the 40-items spread across the eight
560 sustainability domains .

PSAT (8 domains and 40 items)	Mean score (±SD)
Environmental/Political Support	
1. Champions exist who strongly support the programme.	3.0 (0.8)
2. The programme has strong champions with the ability to garner resources.	3.0 (0.7)
3. The programme has leadership support from within the larger organisation.	3.0 (0.8)
4. The programme has leadership support from outside of the organisation.	2.8 (0.6)
5. The programme has strong public support.	3.0 (1.2)
Funding Sustainability	
1. The programme exists in a supportive state economic climate.	2.1 (0.7)
2. The programme implements policies to help ensure sustained funding.	1.7 (0.7)
3. The programme is funded through a variety of sources.	1.6 (0.5)
4. The programme has a combination of stable and flexible funding.	1.0 (0.0)
5. The programme has sustained funding.	2.1 (0.9)
Partnership	
1. Diverse community organisations are invested in the success of the programme.	3.8 (0.7)
2. The programme communicates with community leaders.	3.4 (1.0)
3. Community leaders are involved with the programme.	3.8 (0.8)
4. Community members are passionately committed to the programme.	5.0 (0.7)
5. The community is engaged in the development of programme goals.	4.3 (0.7)
Organisational Capacity	
1. The programme is well integrated into the operations of the organisation.	2.9 (0.8)
2. Organisational systems are in place to support the various programme needs.	2.0 (0.8)
3. Leadership effectively articulates the vision of the programme to external partners.	2.3 (1.2)
4. Leadership efficiently manages staff and other resources.	2.3 (0.7)
5. The programme has adequate staff to complete the programme's goals.	4.8 (0.8)
Programme Evaluation	
1. The programme has the capacity for quality programme evaluation.	2.0 (0.7)
2. The programme reports short term and intermediate outcomes.	1.6 (0.7)
3. Evaluation results inform programme planning and implementation.	1.9 (1.1)
4. Programme evaluation results are used to demonstrate successes to funders and other key stakeholders.	2.3 (1.0)
5. The programme provides strong evidence to the public that the programme works.	2.7 (1.2)
Programme Adaptation	
1. The programme periodically reviews the evidence base.	2.0 (1.4)
2. The programme adapts strategies as needed.	2.5 (1.0)
3. The programme adapts to new science.	2.4 (1.0)
4. The programme proactively adapts to changes in the environment.	2.5 (0.9)
5. The programme makes decisions about which components are ineffective and should not continue.	2.4 (0.9)
Communications	
1. The programme has communication strategies to secure and maintain public support.	1.8 (0.7)
2. Programme staff communicate the need for the programme to the public.	1.5 (0.5)
3. The programme is marketed in a way that generates interest.	1.5 (0.5)
4. The programme increases community awareness of the issue.	2.2 (0.7)

5. The programme demonstrates its value to the public.	2.4 (0.5)
Strategic Planning	
1. The programme plans for future resource needs.	2.0 (1.0)
2. The programme has a long-term financial plan.	1.8 (0.8)
3. The programme has a sustainability plan.	1.2 (0.4)
4. The programme's goals are understood by all stakeholders.	1.5 (0.5)
5. The programme clearly outlines roles and responsibilities for all stakeholders.	2.1 (0.7)

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563 **Appendix 3.** The main themes generated from the qualitative analysis of interviews and illustrative verbatim quotes. (C: commissioner, S: service provider, P:
564 pharmacist, I: representative of an influencer group; # denotes participant identifier code)
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Main themes and supporting PSAT item and rating	**Illustrative quotes**
Funding sustainability	
The programme exists in a supportive state climate, average rating 2.1 ± 0.7	*'In the CCG, we don't hold the core contract for community pharmacy, so people just kind of brush it off as actually this isn't my job because we don't hold the contract.'* (C, #4) '*I'm a pharmacist working in a CCG, and I'm not even going to claim to be an expert in commissioning and community pharmacy and service delivery, and I know quite a lot, because it's an absolute minefield.'* (C, P, #2)
The programme has sustained funding, average rating 2.1 ± 0.9	*'The reality is, if budgets weren't so siloed, it would make so much more sense to be pushing people through [PMAS], and keeping them out of A&E, walk-in centres, GP practices; it's the most cost-effective means of treating a minor ailment, but we just can't maximise its benefits because of budget lines.'* (I, S, P, #1) *'I don't think they* [commissioners] *appreciate what community pharmacy could do, so I don't think they have an understanding of the skill set that is already there and could be developed further. I think the financial constraints are what are overriding the CCGs , so it's the bottom line that tends to put the block on everything, and sadly, I think some of our pharmacy colleagues, within medicines optimisation tend to be a block on community pharmacies being developed further.'* (I, S, P, #9) *'We've now got the on-the-ground GPs sitting on executives. Which means that if the GP has a poor relationship with community pharmacy, or has a perception that community pharmacy isn't very good or very high quality or they have had a bad experience, those experiences are now escalated all the way through to those decision-making bodies.'* (I, S, P, #11)
Environmental/Political support	

Champions exist who strongly support the programme, average rating 3.0 ± 0.8; The programme has strong champions with the ability to garner resources, average rating 3.0 ± 0.7	*'I think conversations…have caused people to question the way they've been commissioned and it caused people to question their objectives with minor ailments and efficacy in terms of achieving those objectives.'* (C, P, #2) *'But how many patients are you redirecting* [through PMAS}*? How many GP appointments are you actually saving? When people go to pharmacy, are they getting the same standard of care? All these questions cannot be answered. So it's very difficult to make a case.'* (C #4)
Partnerships	
	'I am expecting them [CCG pharmacists], *just because they have the word pharmacist and letters next to their name, they've got a degree in pharmacy, we expect them to be able to understand community pharmacy and how patients operate.'* (I, S, P, #7) *'I think that kind of baseline knowledge of experience of community pharmacy* [speaking of pharmacists working within commissioning groups] *does not give a good grounding for making decisions about community pharmacy, because you've never been a dispensary, they don't know what the pressure is like in a community pharmacy. they don't know what the skill mix is; they probably don't even know how long a pharmacist trains for….When it comes to pharmacy, why would they need to know, because they've never had to know before, so why would they suddenly know now.'* (S, P, #20) *'I had a meeting with one* [GP colleague] *last night, and he was saying that we don't know, we as in general practice, don't know enough about community pharmacy, like their potential roles, and community pharmacy don't know enough about general practice.'* (I, S, P, #19)
Organisational capacity	

The programme has adequate staff to complete the programme's goals, average rating 4.8 ± 0.8	'*it's a no-brainer…business as usual.*.' (I, S, P, #13) '*Accessibility and seven-day NHS and cost-effectiveness, no need for an appointment, all the barriers that are currently in place* [referring to GPs]*…are not there for community pharmacies to deliver that to the patient*' (S, P, #12) '*There isn't even any peer reviews. So most often you're a pharmacist on your own, so you will never be observed by another pharmacist to benchmark yourself….The infrastructure just isn't in place to driver quality improvement.'* (I, S, P, #11) *'What we do lack is a coming together of pharmacists to chat stuff through'* (I, S, P, #5) *'I think there's something about identity there, like what are all supposed to be achieving together…and it's also about cultural change of the pharmacy staff.'* (I, P, #17)
Organisational systems are in place to support the various programme needs, average rating 2.0 ± 0.8	*'I think it's about clinical leadership of the pharmacist at the pharmacy level. I don't think we really equip community pharmacists in the best way that we could to fulfil roles of leading their staff, as seeing pharmacies as an NHS provider, who has obligations and something to offer the NHS.'* (I, P, #17)
Leadership efficiently manages staff and other resources, average rating 2.3 ± 0.7	*'They are a diverse population* [community pharmacy staff]*. And trying to catch them all and trying to think about how to alter the way they kind of approach things like self-care and minor ailments will be challenging. I mean, education training is maybe the first step, but actually if we're being realistic. That's the tip of the iceberg.'* (I, S, C, P, #10)
Programme adaptation	
The programme periodically reviews the evidence base, average rating 2.0 ± 1.4; The programme adapts to new science, average rating 2.4 ± 1.0	*'You have to go through a process with the commissioner; you have to do the engagement; you have to be looking at the evidence. You have to get buy in, in order to move anything forward. So you almost can't tweak it at the edges, you kind of have to totally review and recommission or do nothing at all.'* (C, P, #2) *'But if you don't engage your providers with service design to get the right design for your patients and your citizens and the providers, then actually your service is never going to work in the first place.'* (I, S, C, P, #10)
Programme evaluation	
	'I think conversations…have caused people to question the way they've been commissioned and it caused people to question their objectives with minor ailments and efficacy in terms of achieving those objectives.' (I, S, P, #19) *'We've moved it over to PharmOutcomes now…it certainly gives us more access to data. And then I guess more access to evidence of use of the service.'* (C #4)
Communications	

The programme has communication strategies to secure and maintain public support, average rating 1.8 ± 0.7	*'I'm pretty sure that XXXXX* [locality] *formulary is much more comprehensive than ours, the conditions that are on there, is bigger, and sort of longer than ours. So that suggests that they may be moving a little further ahead than we are.'* (S, P, #15) *'Now if the intention is to really push this service and take the pressure off the practices, we need to be seeing marketing and media on a regular basis. It doesn't need to be constant in terms of media, but we need to see regular reminders to patients.'* (I, S, P, #11) *'It's good news stories; it's showing it's working…that should hopefully be picked up nationally, and people will start to see a change.'* (I, S, P, #18) *'We were pushing for some sort of marketing and promotion of the scheme. The PCTs at the time weren't at all keen on that, I guess on the basis that the more marketing you do, the more people will use it and the more pressure will be put on the budget. So it's not something we've been able to promote consistently amongst community pharmacies. I mean, individual pharmacies will have their own bits and pieces …like stickers in windows, etc, but we probably won't do that.'* (C, P, #2)
Programme staff communicate the need for the programme to the public, average rating 1.5 ± 0.5	*There's been a lot…we talk to healthcare professionals who interact with us. They've said what they want, but we're not necessarily very good at asking patients and the public what they want. And I think that probably is a big piece of work that really needs to be done before you do anything I think.'* (C, P, #2) *'Anecdotally there are reports that patients going to pharmacy, quite happy to buy it, and being directed then onto the scheme and then they're querying 'well, if we are moving into a self-care agenda nationally, how does it fit?''* (C, P, #2)
Strategic planning	
The programme has a sustainability plan, average rating 1.2 ± 0.4	*'But the risk* [to national rollout], *the problem is no-one is brave enough to take that risk from a leadership perspective because they're worried that if it's not project managed appropriately then it could be a bottomless pit of money that could get out of hand.'* (I, S, P, #11) *'so there are ways of managing it and then you need someone to project manage a whole service, whether that's done regionally or nationally, and the cost of having project managers compared to the cost if it all went pear-shaped is just a no-brainer.'* (I, S, C, P, #10)
The programme 'goals' are understood by all stakeholders, average rating 1.5 ± 0.5	*'To move it forwards, it needs that clear mandate and it needs a clear one person to say have we got all the right stakeholders in the room, rather than one person trying to drive it off in different directions'* (I, S, P, #19)

Strategies to improve sustainability capacity	*'We've got an enlightened CCG, obviously carefully informed by major pharmacy representatives locally. But they're engaged and they understand and they went with a broad formulary* [for the local MAS] *which was excellent. Over in XXXX* [locality], *they have a very narrow formulary, which is informed by a very medicalised model of care. It's very GP dominated in the CCG.'* (I, S, P, #16) *'I think the GPs, if their patients rocked up and wanted paracetamol or ibuprofen, they should not really give a prescription and give them a minor ailments leaflet. That might be a way of, sort of, training the patients not to go to their GP first, to go to the pharmacy.'* (S, P, #15) *'the reason a regional one is important because it will cover an NHS 111 catchment area and it will provide that standardised approach for patients to easily understand what they can get from community pharmacies and the healthcare practitioners so they can refer patients into it.'* (S, P, #20)

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