

Consensus methodology to determine minor ailments appropriate to be directed for management within community pharmacy

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Abstract

Background

National Health Service (NHS) 111, a medical helpline for urgent care used within the England and Scotland, receives significant numbers of patient calls yearly for a range of clinical conditions. Some are considered high acuity and mainly directed to urgent and emergency care. Low acuity conditions are also directed to these costly, overburdened services. Community pharmacy is a recognised setting for effective low acuity condition management and could offer an alternative.

Objective

To design and evaluate a new NHS111 pathway re-directing patients with low acuity conditions to community pharmacy.

Methods

Two consensus development stakeholder workshops were undertaken. A “low acuity” condition was defined as one that can be clinically assessed by a community pharmacist and requires a treatment and/or advice available within a community pharmacy. Retrospective NHS111 patient data (February–August 2016) from the North East of England and access to the NHS Pathways clinical decision support software were available to stakeholders. The NHS111 data demonstrated the volume of patient calls for these conditions that could have been redirected to community pharmacy.

Results

Stakeholders reached consensus that 64 low acuity conditions could be safely redirected to community pharmacy via NHS111. This represented approximately 35,000 patients (11.5% of total) being shifted away from the higher cost settings in the North East region alone during February–August 2016. The stakeholder group discussions provided rationale behind their classifications of conditions to ensure patient safety, the care experience and added value.

Conclusions

The resulting definitive list of low acuity conditions that could be directed to community pharmacy via NHS111 could result in a shift of workload from urgent and emergency care settings. Future work needs to evaluate the cost, clinical outcomes, patient satisfaction of a community pharmacy referral service that has the potential to improve integration of community pharmacy in the wider NHS.

Keywords: Minor ailments; NHS 111; Nominal group process; Consensus methodology; Framework analysis

1 Introduction

Emergency departments (ED) in England can receive up to 22.4 million attendances in one year (2014–15).¹ General practice (GP) is similarly facing unsustainable pressures with 372 million GP consultations conducted over the same period.² A recent report claimed that 5% of ED consultations and 13% of GP consultations are for low acuity conditions.³ These are defined as '*common or self-limiting or uncomplicated conditions which may be diagnosed and managed without medical (i.e. doctor) intervention*'.⁴

This issue is shared in similar economies worldwide. A recent study in Ontario, Canada reported that 12.3% ED visits between April 2008–March 2009 were for low acuity conditions made by young adults and representing the most deprived population.⁵ Another study in Norway reported that 28% of out-of-hours consultations in November and December 2008 were dedicated to conditions classified as minor ailments.⁶

The UK health department has clearly advocated for low acuity conditions to be managed in community pharmacy, thus freeing up physicians' time and costly resources in ED departments.^{3,7} In response to this political drive, community pharmacy minor ailment schemes were developed to provide patients with an alternative setting to receive timely treatment and advice.³ The Clinical Services Review identified barriers for community pharmacies in setting up such schemes, including the lack of digital interoperability that would facilitate information transfer between community pharmacy and the wider NHS.⁸

NHS 111 was officially launched in February 2014 as the telephone triage service for urgent and emergency care (UEC) in England. When a patient calls NHS 111, non-clinical staff who are supported by nurses, paramedics and GPs ask the patient a series of questions to help guide the telephonic triage process.⁹ This questioning process is guided in part by a computerised software, called NHS Pathways, which has been suggested to be risk averse and could be improved.⁹

The GP Five Year Forward View¹⁰ specifically recommended the more effective use of community pharmacy to manage patient demand and improve GP capacity. The document referred to coupling the reformed NHS 111 service with pharmacy minor ailment schemes to improve patient flows.¹⁰ However, it is currently unclear which specific patients should be redirected to community pharmacy. There has also been no extensive work undertaken within NHS 111 to establish community pharmacy as a safe and appropriate alternative pathway of care for low acuity patients away from overburdened and costly UEC.

The aim of the study was to classify low acuity conditions that could be managed within community pharmacy and design and evaluate a new NHS 111 pathway to redirect patients with these conditions to community pharmacy away from UEC.

2 Methods

This study was carried out in the North East of England, using NHS 111 data from the NHS 111 Provider using the commissioner dashboard and was financially supported by NHS England. The study received ethical approval from the Research Ethics Committee of the Durham University School of Medicine, Pharmacy and Health (ref no. ESC2/2016/PP03) to conduct two consensus development workshops.

2.1 Participants

[Fig. 1](#) provides a diagrammatic representation of key stakeholders involved in the management and operation of NHS 111 services at a regional level and their subsequent impact on any patient callers to the medical helpline.

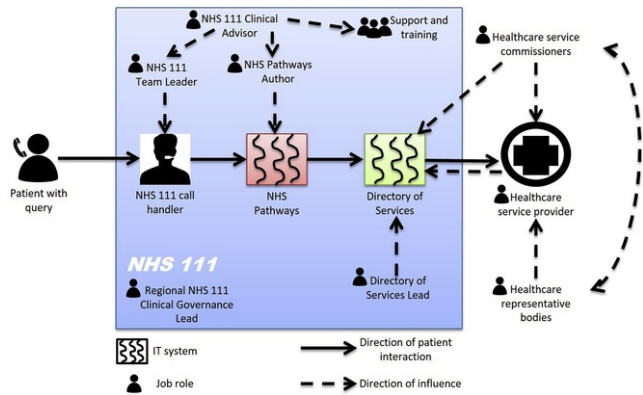


Fig. 1 The stakeholder roles and influences within the NHS 111 system that interact at every patient call.

alt-text: Fig. 1

Three members of the research team [AC, MM, and AY] work within at least one of these stakeholder groups and were therefore able to identify the individuals required to include in the consensus activities to determine a new NHS 111 Pathway. Purposive sampling was used to invite this wide range of individuals with different roles in the NHS 111 system as per Fig. 1, some of whom had clinical and/or operational expertise (S1 Appendix illustrates the knowledge and experience of the stakeholders invited). A total of 15 stakeholders were invited to attend two workshops. Ideally, a group size of between 6 and 12 participants was aimed for, as smaller numbers could possibly diminish reliability and larger numbers decrease capability to coordinate activities and consensus.^{11,12} Consensus methodologies such as an interacting group decision-making process and the nominal group process are valuable where a specific problem exists that requires a specific answer. The acknowledged debate and interactivity are reported to be more time efficient to answer specific problems than focus groups, which have the aim to reach theoretical (or data) saturation.¹¹ Individuals for the first workshop were invited by email in September 2016, with the workshop conducted in October 2016. After the first workshop, it was decided that the addition of an NHS 111 pharmacist and an NHS 111 clinical advisor to the group would be beneficial. A member of the project team [AC], who also works within the NHS 111 system, approached individuals working in these roles at NHS 111 in January 2017 and invited them to attend the second workshop, which was conducted in February 2017.

Eleven and fourteen stakeholders attended workshops 1 and 2, respectively. Each workshop included representatives from commissioners, out of hours' services (OOH), Directory of Services (DoS), and team leaders working within the NHS 111 system (Table 1).

Table 1 The attendance of key stakeholders at the two workshops.

Stakeholders	Workshop 1	Workshop 2	Comments
Community pharmacists	2 + 3*	1^ + 3*	
DoS Lead, NHS 111	1*	1* + 1	The national DoS lead was invited and attended for learning and sharing of good practice purposes
NHS 111 Team leader	1	1^ + 1	One of these participants was the NHS 111 Team manager
OOH GP Clinician	2	2^	
Regional NHS 111 Clinical lead	1	1^	
NHS 111 Pharmacist	0	1	
Regional NHS 111 Clinical Advisor	0	1	
NHS Pathways authors	0	0	
Commissioners/ OOH service providers	1	1^	
Total	11	14	

(*denotes members of the project team; ^ denotes that this is the same stakeholder as in workshop 1, and shaded boxes indicate representatives with clinical expertise)

At both workshops, participants were informed of the key objectives and format. Written consent for the audio recording of discussions was obtained prior to commencement of each workshop.

2.2 Workshop 1: identification of low acuity patient conditions

The first workshop was organised as an interacting group decision-making process. This represents the most traditional and most widely used method for group decision making in organisational committees. These follow a typical format of an interactive group meeting, where the group leader opens with a statement of the problem and an unstructured group discussion ensues that generates information and pooling of judgements among participants. The meeting then concludes with a majority voting procedure on priorities, or a consensus decision.¹² The purpose of the first workshop was to broadly discuss which patient conditions listed within NHS Pathways were “low acuity” conditions and could be potentially re-directed to the community pharmacy.

Participants were presented with six months (February–August 2016) of retrospective anonymised patient call data, which were downloaded from the commissioner dashboard; an interface for commissioning organisations to access data about service usage, demand and supply.¹³ This equated to approximately 305,646 NHS 111 calls.

These NHS 111 data contained information about:

- (1) The patient's presenting condition or “Symptom Group” (SG code) e.g., coughs;
- (2) A “Symptom Discriminator” (SD code) which indicated the level of care and skillset considered necessary to assess and manage the symptom e.g., Full primary care assessment and prescribing capability ([S2 Appendix](#) shows the 5 main SD codes and some examples of sub-types); and
- (3) A Disposition (DX code) which indicated the timeframe within which the patient was recommended to seek care (e.g., the patient is recommended to speak to a primary care professional within 24 h) and the type of attention that would be appropriate, e.g., physical attendance presentation to a healthcare professional ([S3 Appendix](#) shows the timeframe and skillset that are recommended).

To summarise, this generated a SG/SD/DX combination, as illustrated in [Fig. 2](#), which then guided the call handler to recommend a particular course of action.¹³

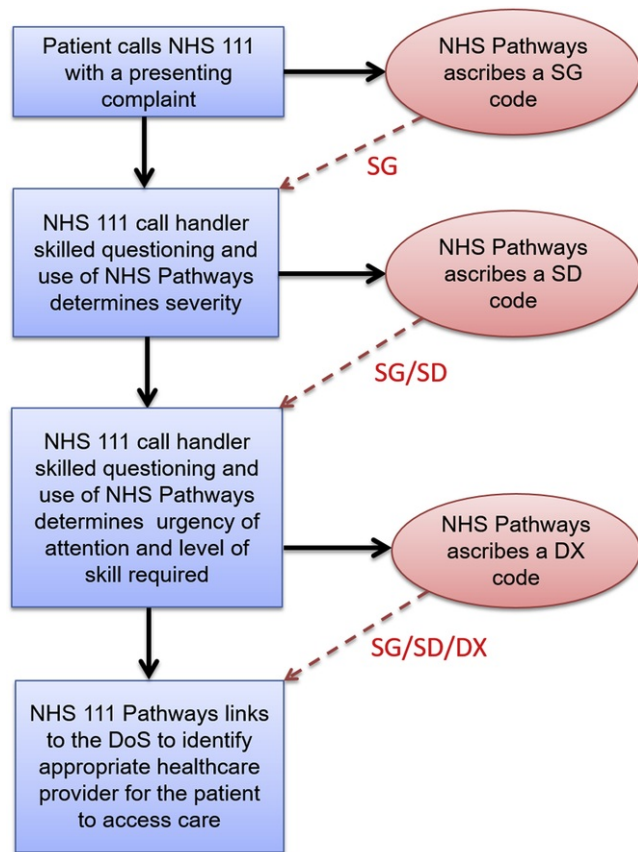


Fig. 2 A description of the different steps involved in NHS 111 Pathways system.

alt-text: Fig. 2

Participants were first presented with the 114 most highly recorded SD codes (as evidenced in the 6months NHS 111 patient caller data) out of a total 124 SD codes with a range of different acuity levels (e.g., 'primary care: minor condition' to 'emergency department: significant burn'). This was done to remove the conditions that warranted exceptionally rare and/or specific level of care that would have been inappropriate to be managed by a community pharmacist. The group was asked to assess each SD code individually (e.g., assessment and management by a community pharmacist of minor conditions) and then, if they unanimously agreed, the group went through the related list of more specific SG codes (e.g., assessment and management of 'blisters', this is the code that provides information on the presenting complaint). A unanimous opinion was required for each SG/SD combination. Agreed combinations were entered onto a live Excel spreadsheet that was projected onto one wall of the meeting room for the group to view and update accordingly.

Once all SG/SD combinations had been discussed, participants were then asked to consider the appropriate timeframe (DX code) within which patients should seek appropriate healthcare advice and/or assistance from a community pharmacy for each combination. The timeframe needed to be appropriate across all identified combinations.

At the end of the workshop, the project team collated the findings and produced a summary document of the SG/SD/DX combinations that had been selected by the panel as low acuity conditions that could potentially be re-directed to the community pharmacy.

The research team filtered the NHS 111 data (February-August 2016) to identify the volume of calls attributed to this list of consensus SG/SD/DX combinations.

After the workshop, this summary was sent to participants electronically, and they were asked to provide comment on the accuracy of the recording of the events and findings.

2.3 Workshop 2: clinical validation of the low acuity patient conditions

The second workshop was a structured process following the nominal group process (NGP). This is another formal consensus development method which provides structure to a group decision-making process, usually by adopting a rating or ranking procedure to represent extent of agreement about predefined issues or questions.¹¹ This structure was adopted where group members were required to reconsider the low acuity conditions categorised in workshop 1. The elements of evaluation and clarification afforded by the NGP provided the opportunity for more detailed clinical interpretation of the combination generated by the NHS Pathways algorithm, e.g. investigation of the call handler's specific questions, and patient answers to trigger the code, thereby clinically assessing the appropriateness of management by a community pharmacist.

The overall goal of the second workshop was to clinically validate the low acuity conditions identified in the first workshop.

Using the NGP adapted by Harvey and Holmes,¹¹ participants were provided with an individual list of the low acuity conditions described by their SG/SD/DX combinations as categorised at workshop 1 and asked to 'tick' those conditions that could be appropriately referred to community pharmacy. If participants felt that they required more information on the NHS Pathways algorithm strands to inform their decision-making, they were asked to provide a 'cross' next to it (Step 1, the 'Silent round'). In the second step, participants were invited to share their allocations by using the 'round robin' technique. This involved each participant entering their selection of low acuity conditions onto a master Excel spreadsheet, which was projected onto the wall at the front of the room. At Step 3, the group was divided into two as these groups should ideally be small to facilitate more in-depth discussions to clarify, discuss and negotiate the allocations that did not reach consensus (crosses and/or ticks) in Step 2.¹⁴ Each group was homogenous in the mix of clinical and non-clinical expertise, and discussions were guided by the following two questions:

1. Does the assessment for this condition fall within the competence of a community pharmacist?
2. Is the medicinal product or healthcare advice that is required to manage the condition available from a community pharmacy?

Where conditions achieved positive answers to these questions, the groups then considered the added value of a community pharmacist consultation, e.g. face-to-face contact with a healthcare professional, symptomatic relief with a pharmacist recommended non-prescription product, and discussed the potential of any patient safety issues that could arise.

Groups were provided with access to the NHS Pathways questioning software to work backwards from generated SG/SD/DX combinations. [S4 Appendix](#) shows the information a call handler obtained from a patient with reported rectal bleeding that resulted in NHS Pathways generating a disposition or recommendation to see a GP within 3 days in the case of no improvement. NHS 111 team members were able to explain and demonstrate within the offline NHS Pathways programme, that SG codes in NHS Pathways are initiated based upon the patient's description of the condition rather than accurate clinical terminology as perceived by a clinician. As such, participants were conscious that some clinical leniency was required in interpreting the accuracy of the presenting SG as recorded in the NHS Pathways system. It became clear that some of the terms used within the computerised system held differing connotations for the various members of the group. For example, 'painful eye', which was sometimes given an SD code of 'minor condition', was interpreted by the clinicians to be of a higher acuity than could be understood from this SD code. Clinicians deemed such a symptom could require specific medical attention for differential diagnosis in order to rule out potential conditions that a community pharmacist may not recognise and, in some cases, may not be able to manage, e.g., acute glaucoma. The discussions and demonstrations with the computerised software provided workshop members with more insight about how NHS Pathways categorises patient calls e.g. using information related to patient signs, symptoms, demographics, etc. This facilitated the ability to determine the appropriateness of managing these patients within the community pharmacy or if another healthcare professional would be more appropriate.

At the end of these parallel discussions both groups were asked to collectively allocate 'ticks' and 'crosses' against the conditions discussed in Step 3 to indicate their suitability to be managed within community pharmacy. The lists from both groups were compiled, and the low acuity conditions that achieved consensus across the two groups represented the group decision.¹³ **(This should be reference 15 not 13.)**

At the end of the workshop, the project team collated the findings and produced a summary document of the SG/SD/DX combinations that had been selected by the panel as low acuity conditions that could potentially be re-directed to the community pharmacy.

Again, the research team used the final list of low acuity conditions to identify the volume of calls attributed to the consensus SG/SD/DX combinations.

2.4 Data analysis

The nominal group discussions were audio recorded with permission and transcribed verbatim. Analysis of the qualitative data was guided by the framework analysis approach, which offers a pragmatic approach to evaluating qualitative data.¹⁶

The a priori themes of the framework were informed by the elements of failure mode and effects analysis (FMEA).¹⁷ This is a structured method, widely used in healthcare as a systematic approach of prospective risk

mitigation. In brief, a multidisciplinary team maps out a high-risk process of care to identify failures that can occur ('failure mode'). These are then characterised in terms of effects: probability of occurrence, severity of effects and detectability. A risk priority is calculated for each failure mode that then guides the prioritisation of actions and recommendations to prevent or mitigate against it.¹⁸

To develop a coding scheme to analyse the qualitative data, transcripts from 3 randomly selected interviews were each independently coded by 2 evaluators {HN and ZN}. Where other themes emerged from data they were added into the framework, and the evaluators came to consensus on the final framework. The two researchers independently coded the remaining transcripts, compared themes and came to consensus, modifying the framework as needed to ensure convergence and divergence of the thematic coding scheme.

2.5 Notes on methodology and analysis

In order to assure trustworthiness of this study as recommended by Lincoln and Guba,¹⁹ the following strategies have been employed during data collection and analysis:

1. **Credibility** of the work has been afforded by: all findings from the consensus workshops were reported back to participants to serve as 'member-checks'.¹⁹ Also the work has been a team effort with input from representatives of many of the representative stakeholder groups involved in the consensus workshops.
2. The level of detail, which can be described as 'thick description',¹⁹ provided with regards to terminology, data in NHS 111, transparency of the filtering process with extensive tables in the appendices, will facilitate **transferability**.
3. One member of the research team [ZN] was not involved in research design or collection and was able to provide an 'external audit'¹⁹ to the research process and findings. This researcher was able to critique data collected towards enhancing evidence-based discussions and conclusions and therefore enhancing **dependability** of the study findings.
4. The study design, data collection and analysis was undertaken by multiple investigators. This facilitated reflexive dialogue¹⁹ to develop complementary and divergent understandings of the study situation and allow for **confirmability** of study findings.

3 Results

3.1 Workshop findings

3.1.1 Workshop 1: the low acuity patient conditions

Fig. 3 shows how the group discussions resulted in filtering of the total 305,629 NHS 111 calls firstly by the patient presenting complaint (SD code); secondly by the level of severity awarded to this complaint (SD/SG combination), and lastly by the recommended timeframe the patient should seek care (DX code).

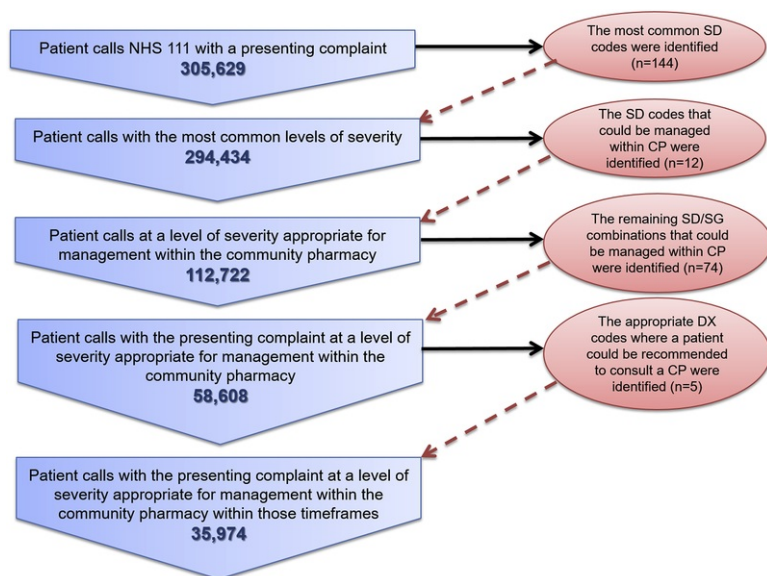


Fig. 3 The volume of NHS 111 patient calls that were represented during the process of identifying low acuity conditions within NHS Pathways.

alt-text: Fig. 3

The workgroup unanimously agreed that any patient caller whose answers to the NHS Pathways questioning generated a disposition that required them to be seen urgently, that is in less than 24 h by a healthcare professional, was not a low acuity case appropriate for referral to community pharmacy (highlighted in [S3 Appendix](#)).

The SG/SD combinations at DX PC contact 24 (Contact a primary care provider within 24 h) or less urgent were entered into the offline NHS 111 system to extrapolate the volume of NHS 111 patient calls that could have been redirected to community pharmacy during the 6 month period. [Table 2](#) shows the top ten low acuity conditions by call volume ([S5 Appendix](#) includes the full list of 74). These 74 low acuity conditions represented 35,974 patient calls that could have been referred to community pharmacy over the 6 month period in the North East (NE) of England.

Table 2 The volume of NHS 111 patient calls attributable to the top ten identified low acuity conditions. (SG: Symptom Group, SD: Symptom Descriptor, PC: primary care, NE: North East).

alt-text: Table 2

SG	SD	Approx. no. of NHS 111 patient calls (Feb–Aug 2016 in NE England) (%)
Repeat Prescription	PC repeat prescription, urgent	6812 (2.2)
Earache	PC full primary care assessment and prescribing capability	2874 (0.9)
Cough	PC full primary care assessment and prescribing capability	2582 (0.8)
Skin rash	PC full primary care assessment and prescribing capability	2554 (0.8)
Diarrhoea	PC full primary care assessment and prescribing capability	2152 (0.7)
Sore throat	PC full primary care assessment and prescribing capability	4978 (1.6)
Repeat Prescription	PC repeat prescription, routine	1876 (0.6)
Blisters	PC full primary care assessment and prescribing capability	1572 (0.5)
Headache	PC full primary care assessment and prescribing capability	1496 (0.5)
Lower back pain	PC full primary care assessment and prescribing capability	1464 (0.5)
Total		28,360 (9.3)

3.1.2 Results from workshop 2: the clinically validated low acuity conditions

Participants were presented with 74 low acuity conditions from workshop 1, of which only 11 reached consensus as appropriate to be managed within community pharmacy in the first silent round of the NGP. After the two parallel group discussions, where the NHS Pathways algorithm was reviewed and clarity gained on terminology and the extent of triage, eight SG/SD/DX combinations achieved consensus amongst the clinical participants as not being low acuity conditions appropriate for management in the community pharmacy. This was due to the inability to satisfy either of the two screening questions (i.e. the clinical assessment is outside the competency of a community pharmacist and the medicinal product and/or healthcare advice is not available at the pharmacy) ([Table 3](#)).

Table 3 The volume of NHS 111 patient calls attributable to those conditions identified as clinically inappropriate to direct to community pharmacy. (SD: Symptom Descriptor, SG: Symptom Group, PC: primary care, NE: North East).

alt-text: Table 3

SG Descriptor	SD Descriptor	Approx. no. of NHS 111 patient calls (Feb–Aug 2016 in NE England)
Abdominal pain	PC full primary care assessment and prescribing capability	286

Eye, painful	PC extended ophthalmic assessment and management capability, minor condition	0
Eye, painful	PC assessment and management capability, minor condition	0
Eye, visual loss or disturbance	PC extended ophthalmic assessment and management capability, minor condition	0
Eye, visual loss or disturbance	PC assessment and management capability, minor condition	0
Head, facial or neck injury, blunt	PC full primary care assessment and prescribing capability	414
Mental health problem	PC anxiety/panic	0
Pain and/or frequency passing urine	PC assessment and management capability, minor condition	0
Total		700

The final agreed 64 low acuity conditions (full list in [S5 Appendix](#)) were entered into the offline NHS 111 system and equated to 35,274 patient calls (approximately 11.5% of the total calls made to NHS 111 during Feb–Aug 2016) that could have been referred to community pharmacy on an annual basis in the North East alone.

During the nominal group discussions participants evaluated the categorisation of low acuity conditions but further conversations yielded three key failure mode themes that underpinned all decisions. Namely these included patient experience, patient safety and added value. Strategies to manage and mitigate for the risk of detrimental impact to the patient experience and safety and ensure added value were also discussed and could represent propositions in the design of a community pharmacy referral service. These themes are explored further during the discussion.

4 Discussion

Minor conditions have been recognised as those which often require no medical intervention.⁴ This study has identified a definitive list of low acuity conditions that do not warrant an appointment or consultation with a GP. The local community pharmacy can offer patients easy access to a healthcare professional skilled in advising on self-limited conditions and recommending products to improve health and facilitate symptomatic relief.²⁰ Porteous et al. reported important factors that have influenced patients take up of minor ailment services from community pharmacy such as the provision of information to help patients better understand and manage their symptoms; staff that are well-trained and easily accessible; the local setting and availability of parking. The authors claim that in meeting these desired elements, a shift in workload could be achieved away from high-cost UEC settings.^{21,22} The low acuity conditions determined in this study have demonstrated that a clinical debate is warranted for some of those conditions that have been posited as low acuity or minor ailments in previous research. Namely cold/flu symptoms,^{3,7,23} cough,^{3,7,20,23-25} earache,^{5,23,24} eye problems,^{3,7,20,26} have all been classified as minor ailments in published work with little clinical rationalisation.

Three low acuity conditions specifically: cold and ‘flu; cough, and earache, provoked an extended debate amongst stakeholders in this study. This was due to the skillset required for a community pharmacist to undertake a chest examination in the assessment of a cough that may also be present with cold and ‘flu symptoms, and the lack of prescribing capability of a community pharmacist to prescribe antibiotics in the case of an ear infection causing an earache. The final comments of the group were to include these combinations as low acuity conditions appropriate for referral to community pharmacy due to the anticipated low numbers of patients requiring either a chest examination (in patients suffering from cold and ‘flu, or coughs) or antibiotics (in those patients suffering from earache). The group recommended that there should be a robust mechanism for appropriate escalation where a patient may require hands on physical examination and/or prescribing of a prescription only medicine. The group emphasised that numbers should be monitored of those patients who, after being referred to community pharmacy, re-enter the system via the escalation procedure, which may highlight inefficiency, cost-ineffectiveness and a detrimental impact on patient care and experience.

Previous work to determine the burden of patients that could be managed within community pharmacy rather than GP and A&E involved retrospective review of patient cases.^{7,27} However, the limitation of those findings is that those patients would all need to present at a point of care, i.e. GP and A&E by default, to be assessed before it is determined that they meet that criteria to be managed within community pharmacy. By this point patients are already at a healthcare setting, albeit a potentially more overburdened and more expensive one, where they are able to receive care. The study presented here takes advantage of a single entry point of the medical helpline NHS 111 for patients, maps out the algorithms and classification system of the underlying Pathways decision software, in order to provide a proactive referral to the ‘right place, first time’ which may be the community pharmacy. This study estimated that 11.5% of NHS 111 calls in the North East region of England during Feb–Aug 2016 could have been redirected to community pharmacy. This corresponds well with previous studies which showed that 13.2% of GP and 5–8% of ED consultations could be directed for management within a community pharmacy.^{7,27} If this proportion of patients were to have been redirected to community pharmacy nationally, 779,314 callers could have been shifted away from UEC over this 6 month period. Recent reports record that there are approximately 11,688 community pharmacies in England,²⁸ of which approximately 900 are contracted to be open and accessible to the public 100 h a week.²⁹ If these 779,314 patients were referred to pharmacy out of normal working hours, this would represent an additional 5 patents per day per 100 h pharmacy during Feb–Aug 2016. This representation is based on assumptions of even

distribution of patient calls during the time period and of patients accessing community pharmacy services across geographical locations. The true impact of the effect on workload would need to be empirically investigated once such a service is implemented.

In the event such a community pharmacy referral service would be implemented pharmacists will be undertaking a consultation with the referred patient in order to determine the self-care and/or symptomatic relief that can be provided. A recently commissioned service that involves NHS 111 directing patient callers for repeat medicines to community pharmacy includes a consultation fee of £10 within the remuneration strategy.³⁰ Recent reports estimate GP consultations in normal hours and out of hours at £36 and £96 respectively (in the North East taking into account the block contract arrangements).³¹ However, to understand the likely reduced cost a community pharmacy referral service offers the NHS, a formal evaluation is required. Watson et al. also reported in a recent study that mean costs from an NHS perspective were significantly lower if patients were treated through community pharmacies for minor ailments when compared to general practice and A&E.³ Another recent study reviewing retrospective GP general practice and ED data for minor ailment type consultations found that approximately 18 million general practice and 650,000 ED consultations could be redirected to community pharmacy nationally, which they equated to £1.1 billion in resources.⁷ Research to date has been unable to accurately measure the shift in workload from UEC to community pharmacy and therefore determine any direct causal economic effect. However patient entry via NHS 111, as suggested through this study, offers the capability to record and monitor the patient journey as they access care and therefore potentially undertake a cost-effectiveness analysis.

The nominal group discussions accommodated the participatory redesign of the current NHS 111 system and healthcare delivery. The insider knowledge of the workings of NHS 111 and management of low acuity conditions has proved invaluable in identifying potential risks in service redesign and finding solutions to mitigate against them. All group members adopted the approach that any low acuity condition to be directed to community pharmacy would have to be one that had a high likelihood of being managed successfully and resolved within community pharmacy (high case completion). The service would then be 'adding value' since the need for escalation and potential re-entry into NHS 111 would be minimal, avoiding duplication and increasing costs of healthcare provision. This aligns to a recent systematic review assessing the success of pharmacy based minor ailment services based on reconsultation and symptom-resolution rates.³² Also the patient experience would be maintained and meeting the NHS 111 aspiration of 'right advice in the right place, first time'.⁹ In existing studies on minor ailments, the patients have, in the most part, self-presented at the community pharmacy rather than been directed.^{3,33} Watson et al. demonstrate that these patients had similar health outcomes to those in general practice and ED.³ However, with the implementation of a community pharmacy referral service NHS 111 would be responsible and accountable for patients seeking care from community pharmacy as a result of the their referral. Therefore the issue of patient safety was recognised to require careful management and governance. The group provided some strategies that could be built into the service specification to address some of the concerns. Specifically assurances around the competency of the healthcare staff, quality of the healthcare provision and processes for escalation could be guaranteed by ensuring the service was delivered by the community pharmacist themselves rather than another member of the healthcare team; utilisation of standardised condition management and differential diagnosis tools such as the Clinical Knowledge Summaries (CKS) as issued by the National Institute for Clinical Excellence (NICE).³⁴ There is recent research that also recommends that pharmacy-specific quality standards are required to promote safe and effective management of minor conditions,^{19,26} so accepted resources to aid delivery of care would be reasonable to endorse. The CKS also indicate 'red flags' that could be used to trigger the escalation process, where the community pharmacist refers back into NHS 111 for the patient to receive more appropriate care. It was clear that the group supported robust governance and monitoring process alongside any service that would be implemented with the changes to the NHS 111 system. It was not deemed acceptable for the identified risks on patient experience and safety to remain 'unknown'. The service would need project management oversight and case completion and onward escalation rates would need to be monitored over time. This information should then be fed-back into the evolving service design and development to ensure efficiency and effectiveness and mitigate against any detrimental effects to the patient journey and their safety. The three specific Symptom Groups: cold or 'flu; cough, and earache, which triggered much debate, were used as examples to demonstrate that monitoring rates of onward escalation and case completion would be instrumental to validate the continued redirection of these conditions to pharmacy. The group also determined that an 'exit strategy' be framed and built into the service proposition. This would indicate the key threshold at which the service would no longer become viable based on the measured key performance indicators. These recommendations resonate well with the Economic (e.g. cost savings from redirection of patients), Clinical (e.g. reconsultation and symptom-resolution-rates) and Humanistic (e.g. patient satisfaction) Outcomes (ECHO) model which consider the value of a pharmaceutical product or service based on the respective variables.³⁵

Future work could focus on a before and after study on the delivery of the new NHS 111 pathway to community pharmacy, evaluating for ECHOs and undertaking a process evaluation, as recommended by the Medical Research Council for evaluating complex interventions,³⁶ to further understand how the service context, implementation and delivery impact upon service success.

4.1 Limitations

This study has been undertaken in one region of England involving data and stakeholders from this area alone. However, the principle of this study to estimate NHS 111 call volume attributable to low acuity conditions is applicable elsewhere, and the basis for a community pharmacy referral service is founded on the knowledge of skills of the participants are representative of their stakeholder groups. Also the assessment of a community pharmacists' ability to manage these clinical conditions was based on the current standard of basic competencies. With the continuous clinical evolution of the pharmacist, e.g. with prescribing capabilities, this basic skillset may change with time and potentially enable a more extensive list of conditions to be safely managed within the community pharmacy. Finally the retrospective quantitative data provided by NHS 111 was based on 6 months of data that did not include the

winter months where calls to NHS 111 are significantly increased.¹ Consequently the findings here may underestimate the annual burden that could be directed to community pharmacy.

5 Conclusion

The participatory design approach towards developing an NHS 111 referral to community pharmacy for low acuity conditions has provided a framework for transparent and reproducible consensus development activities. The nominal group discussions hold a richness of expertise and insider knowledge of the system to facilitate the identification of prospective failures and strategise working solutions to mitigate their risk and impact on healthcare provision. The agreed low acuity conditions resulting from this process that could be managed by community pharmacy approximate to 35,000 patient calls per year just in the North East of England. This potentially represents the improved capacity for urgent and emergency care to manage with conditions and presentations of higher acuity. This shift in management of workload also signifies a prospective saving to the NHS. The study activities were based on the current competencies of community pharmacists in the context of that care setting. If significant changes were to occur, e.g. more widespread availability of pharmacists with independent prescribing capabilities, or review of the current mechanism of commissioning and supporting community pharmacy contractual services, then this definitive list would need to be revised and updated.

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Acknowledgements

None.

S1 Appendix. The stakeholders identified with technical and clinical expertise of care provision via NHS 111

Stakeholders	Knowledge and experience
Community pharmacists (Clinical)	Experience of frontline community pharmacy work and operation, and of managing and referring self-presenting patients with low acuity conditions. Knowledge of the types of low acuity conditions patients self-present at community pharmacy on a daily basis; awareness of the baseline competence of a community pharmacist and when patients should be referred to another healthcare professional.
NHS 111 Clinical advisor (Clinical)	Experience of clinical decision-making; managing risk through telephone triage and supporting non-clinical staff within the call centre. Knowledge of clinical assessment and clinical remit of healthcare providers within the NHS 111 urgent and emergency care system.
NHS 111 pharmacist (Clinical)	Experience of providing specialised pharmacy services currently integrated into NHS 111 for urgent and emergency care. Knowledge of the baseline competence of a community pharmacist and when patients should be referred to another healthcare professional.
Out of hours' clinicians (Clinical)	Experience of frontline urgent and emergency healthcare provision across the spectrum of acuity of patient conditions. Knowledge of the clinical assessment of patients with different levels of acuity and their subsequent healthcare needs to help identify what is possible for a pharmacist to undertake safely.
NHS 111 team leaders (Non-clinical)	Experience of managing patient calls for conditions of all levels of acuity and directing these calls to appropriate healthcare providers by using the NHS Pathways algorithms. Knowledge of the technical terminology, skilled questioning and technical operation of NHS Pathways.
Regional NHS 111 Directory of Services lead (Non-clinical)	Experience of managing the Directory of Services and analysing the data returned through NHS Pathways. Extensive experience of working within models of integrated urgent care and with technical development and adaptation of NHS Pathways. Knowledge of interpreting DoS data and the NHS Pathways algorithms, terminology and correct operation.
Regional NHS 111 clinical lead (Clinical)	Experience of managing the clinical governance structures that take into account national guidance and local commissioner requirements to support safe and appropriate services provided via NHS 111; reviewing NHS 111 call data (activity, nature, etc) and responding to serious incidents that are reported. Knowledge of the urgent care landscape including local provider organisations, all urgent care services and local practices; of the nature and consequences of incidents that have posed risk to patient safety.
NHS Pathways authors (Non-clinical)	Experience of frontline healthcare as well as extensive knowledge of urgent and emergency care. They have comprehensive experience of developing the NHS Pathways algorithms and mechanisms for generating recommendations of referrals and determining level of urgency based on the most recent clinical evidence available. Knowledge of the operation and creation of the NHS Pathways algorithms and the technical terminology used within it. They have a wider knowledge of the direction of urgent and emergency care and the consequences of the incidents that have been reported through NHS Pathways that could pose a risk to patients.

Commissioners of NHS 111 and an out of hours' service provider (Clinical)

Experience of reviewing and evaluating healthcare services for their efficiency and effectiveness of care provision; monitoring performance and managing the portfolio of services available to patients and the public.
Knowledge of the urgent care landscape including local provider organisations, all urgent care services and local practices

S2 Appendix. The NHS Pathways five main types of Symptom Discriminators (SD)

Symptom Discriminator	Sub-type	Explanation
Ambulance	Examples (non-exhaustive): Acute coronary syndrome Septicaemia Compound fracture Shock	These are diagnosis or symptom-specific and of high clinical acuity. They are used by ambulance services to help determine the skill set and resources required when attending 999 calls.
Emergency Department	Full ED assessment and management capability	This means the capability to perform a full clinical assessment of the symptom, as specified by the SG, at the skill set of an emergency department, and to provide appropriate investigation and definitive management without the need, in most cases, for onward referral. For example, an MIU or WIC without suitable imaging facilities should not accept this SD when combined with, e.g., SG 'Head, Facial or Neck Injury, Blunt'.
	ED management, significant burn	This means the capability to perform a full clinical assessment and immediate management of deep (partial or full-thickness) but not extensive (i.e. less than 20%) thermal and chemical burns, including burns to areas such as head, neck, hands/feet or joints. Onward referral to a specialist burns unit may be required following assessment and immediate management.
	Full ophthalmic ED assessment and management capability	This means the capability to perform assessment and definitive management of isolated eye problems, e.g. welding flashes, foreign body or contact lens problems, which require slit-lamp examination and ED ophthalmological skills. This may be part of a general ED, specialist eye hospital ED or a separate unit, e.g. a WIC or MIU with appropriate equipment and expertise.
Primary Care	Full primary care assessment and prescribing capability	This means a practitioner with the capability to perform a full clinical assessment of Primary Care conditions within the SG. The practitioner should be able to prescribe for and manage the conditions and arrange investigations, admission or referral for specialist opinion if required.
	Full mental health assessment and prescribing capability	This means a practitioner with the capability to perform a full clinical assessment of mental health problems within the SG. The practitioner should be able to prescribe for and manage conditions and arrange admission if required.
	Full dental assessment and prescribing capability	This means the capability to perform a full clinical assessment of dental conditions within the SG. The practitioner should be able to prescribe for and manage dental conditions relating to the SG and to arrange investigations, admission or referral for specialist opinion if required.
	Full obstetric assessment and management capability	This means a Registered Midwife or Medical Practitioner, who can provide assessment and advice for pregnancy-related problems within the Symptom Group and arrange investigation and admission if required.
	Assessment and management capability, minor condition	This means a healthcare professional, e.g. an optician or pharmacist, with the capability to clinically assess and manage specific conditions within the SG that are unlikely to require prescription medication, further investigation or onward referral.
Skill Set specific	Examples (non-exhaustive): Urinary catheter management capability Management of	These indicate the Primary Care skillset required to manage specific conditions within the SG.

	dressings Enteral feeding tube management capability Central venous line management capability	
Diagnosis/symptom-specific	Examples (non-exhaustive): Wound, complex Subungual haematoma Loose/damaged plaster Sexually transmitted infection	These enable EDs and Primary Care facilities to determine whether they are equipped to provide assessment and definitive management of specific conditions within the SG, since it is appreciated that different facilities will have different skill sets and resources.

S3 Appendix. An example NHS Pathways consultation report generated for a patient caller calling NHS 111 with rectal bleeding.

Consultation Report

Case ID c62711e1-3438-4234-85e9-906ec7dc180f

Created on 23/01/2017 15:38:48

Pathways v12.1.0

PATIENT: ██████████
TELEPHONE: ██████████
AGE GROUP: ██████████
GENDER: ██████████
PARTY: 1
POSTCODE: ██████████
NOTES:

SKILLSET: 111 Call Handler
CALL HANDLER USER ID: TEST_USER1

PATHWAY: PW846 - Rectal Bleeding
DISPOSITION: Dx16 - If symptoms don't improve, or go away and come back, get in touch with the GP practice within 3 working days.
SELECTED SERVICE: 103595, UCC: UHND Urgent Care Centre,
DOS TRANSACTIONID: dc5b59ec-a89f-1c30-82b6-1bcb7fd9faf

CONSULTATION SUMMARY:

Medical assessment of problem in last 6 months

Warm to touch

Illness - rectal bleeding

PATHWAYS ASSESSMENT:

An injury or health problem was the reason for the contact.

Heavy bleeding had not occurred in the previous 30 minutes.

An illness or health problem was the main problem. - rectal bleeding

The individual was not fighting for breath.

The main reason for the assessment was not a heart attack, chest/upper back pain, probable stroke, recent fit/seizure or suicide attempt.

The main reason for contact was not new confusion, declared diabetic hypo/hyperglycaemia, a probable allergic reaction or ICD shock.

The skin on the torso felt normal, warm or hot.

There was no abdominal pain.

The individual had not passed a black, tarry bowel motion.

The rectal bleeding was not constant.

The individual had not passed red blood in a bowel motion.

There were no splashes of blood in the toilet after defaecation.

There were no streaks of blood on the toilet paper after defaecation.

A sexual assault had not occurred.

There was no retained rectal foreign body.

There was no new spontaneous bruising or abnormal bleeding within the previous 2 weeks.

There was no new painful anal or perianal lump.

There was no anal/rectal pain on defaecation.

The problem had been assessed within the previous 6 months.

ADVICE GIVEN:

alt-text: Image 2

The individual should register as a temporary resident with a GP practice if they are not already registered.

SAFEGUARDING: From what I have heard there may be safeguarding concerns.

Before you go, I will just check whether I need to give you any further instructions or advice.

Drink 8-10 cups of fluid every day, especially water and fruit juice.

Have at least 5 portions of fruit and vegetables every day.

Getting more exercise will help to relieve constipation.

Laxatives should only be used short term and as a last resort. Try making changes to diet and fluids first.

They can be bought from pharmacies. Follow the instructions in the pack.

It's not always serious, but should be checked.

Avoid constipation.

Use moist toilet tissues or baby-wipes after opening the bowels.

If there are any new symptoms, or if the condition gets worse, changes or you have any other concerns, call us back.

Remember to take a list of any current medications if you go to the out of hours surgery.

NHS Pathways 2017

alt-text: Image 3

S4 Appendix. NHS Pathways core dispositions (DX codes) that indicate timeframe and most appropriate healthcare setting for patient callers (those highlighted in **boldblue are those receiving consensus as appropriate for referral to community pharmacy)**

Disposition term	Notes
Self-management	Would not be referred anywhere
Home management	Would not be referred anywhere

Pharmacy	
PC contact - Non-urgent for recurrent symptoms	PC: primary care
PC contact own GP non-urgent	
MUST contact own GP 3 days	
PC contact 24 h	
PC contact 12 h	
PC contact 6 h	
PC contact 2 h	
PC speak to 24 h	
PC speak to 12 h	
PC speak to 6 h	
PC speak to 2 h	
PC speak to 1 h	
ED 1 h	ED: Emergency Department
ED 4 h	
No action taken	
Speak to midwife	
Optician	
Emergency contraception 2 and 12 h	
Dental	
Repeat contact	
Ambulance required	
GUM clinic	GUM: Genitourinary clinic
Service location information	
H&SI/specific disposition	H&SI: Health and social information

S5 Appendix. The identified SG(Symptom Group)/SD(Symptom Descriptor) combinations achieving consensus in workshops 1 and 2 as appropriate for management within community pharmacy and the associated volume of patient callers filtered by the PC (primary care) contact 24 disposition threshold.

SG Descriptor	SD Descriptor	NHS 111 call volume (per annum in NE England)		Notes/comments	
		Workshop 1			Workshop 2
		All DX	DX > PC contact		

		codes	24		
Abdominal pain	PC full primary care assessment and prescribing capability	7104	286	Removed	Not appropriate for community pharmacy
Acne, spots and pimples	PC assessment and management capability, minor condition	30	24	✓	
Acne, spots and pimples	PC full primary care assessment and prescribing capability	14	14	✓	
Allergic reaction	PC assessment and management capability, minor condition	50	42	✓	
Allergic reaction	PC full primary care assessment and prescribing capability	900	144	✓	
Ankle or foot pain or swelling	PC full primary care assessment and prescribing capability	3162	912	✓	
Arm, pain or swelling	PC full primary care assessment and prescribing capability	2126	654	✓	
Athlete's foot	PC assessment and management capability, minor condition	2	2	✓	
Athlete's foot	PC full primary care assessment and prescribing capability	14	10	✓	
Bites or stings, insect or spider	PC full primary care assessment and prescribing capability	2302	16	✓	
Bites or stings, insect or spider	PC minor injury	0	0	Removed	Zero NHS 111 calls
Blisters	PC full primary care assessment and prescribing capability	4832	1572	✓	
Cold or flu	PC full primary care assessment and prescribing capability	2086	744	✓	
Constipation	PC full primary care assessment and prescribing capability	2178	486	✓	
Cough	PC full primary care assessment and prescribing capability	5384	2582	✓	
Diarrhoea	PC full primary care assessment and prescribing capability	7412	2152	✓	
Ear discharge or ear wax	PC assessment and management capability, minor condition	12	10	✓	
Earache	PC assessment and management capability, minor condition	642	12	✓	
Earache	PC full primary care assessment and prescribing capability	6522	2874	✓	
Eye, painful	PC extended ophthalmic assessment and management capability, minor condition (PEARS)	36	0	Removed	Not appropriate for community pharmacy
Eye, painful	PC assessment and management capability, minor condition	22	0	Removed	Not appropriate for community pharmacy
Eye, red or irritable	PC extended ophthalmic assessment and management capability, minor condition (PEARS)	252	210	✓	
Eye, red or irritable	PC full primary care assessment and prescribing capability	208	112	✓	
Eye, sticky or watery	PC extended ophthalmic assessment and management capability, minor condition (PEARS)	92	86	✓	
Eye, sticky or watery	PC full primary care assessment and prescribing capability	584	72	✓	
Eye, visual loss or disturbance	PC extended ophthalmic assessment and management capability, minor condition (PEARS)	30	0	Removed	Not appropriate for community pharmacy
Eye, visual loss or disturbance	PC assessment and management capability, minor condition	106	0	Removed	Not appropriate for community pharmacy

Eyelid problem	PC extended ophthalmic assessment and management capability, minor condition (PEARS)	54	50	✓	
Failed contraception	PC failed contraception	250	2	✓	
Failed contraception	PC full primary care assessment and prescribing capability	22	20	✓	
Hair loss	PC assessment and management capability, minor condition	6	6	✓	
Hair loss	PC full primary care assessment and prescribing capability	22	18	✓	
Head, facial or neck injury, blunt	PC full primary care assessment and prescribing capability	2294	414	Removed	Not appropriate for community pharmacy
Headache	PC anxiety/panic	78	72	✓	
Headache	PC depressed mood	130	122	✓	
Headache	PC full primary care assessment and prescribing capability	4896	1496	✓	
Hearing problems or blocked ear	PC assessment and management capability, minor condition	38	4	✓	
Hip, thigh or buttock pain or swelling	PC full primary care assessment and prescribing capability	1348	256	✓	
Itch	PC assessment and management capability, minor condition	104	90	✓	
Knee or lower leg pain or swelling	PC full primary care assessment and prescribing capability	4948	704	✓	
Lower back pain	PC full primary care assessment and prescribing capability	7660	1464	✓	
Lower limb pain or swelling	PC full primary care assessment and prescribing capability	310	174	✓	
Mental health problem	PC anxiety/panic	0	0	Removed	Not appropriate for community pharmacy
Mouth ulcers	PC assessment and management capability, minor condition	100	90	✓	
Mouth ulcers	PC full primary care assessment and prescribing capability	1094	46	✓	
Mouth ulcers	PC full dental assessment and prescribing capability	8	0	Removed	Zero NHS 111 calls
Nasal congestion	PC assessment and management capability, minor condition	60	50	✓	
Pain and/or frequency passing urine	PC assessment and management capability, minor condition	252	0	Removed	Not appropriate for community pharmacy
Rectal pain, swelling, lump or itch	PC assessment and management capability, minor condition	184	174	✓	
Rectal pain, swelling, lump or itch	PC full primary care assessment and prescribing capability	1036	392	✓	
Repeat Prescription	PC repeat prescription	872	850	✓	
Repeat Prescription	PC repeat prescription, routine	1956	1876	✓	
Repeat Prescription	PC repeat prescription, urgent	7118	6812	✓	
Scabies	PC assessment and management capability, minor condition	8	8	✓	
Shoulder pain	PC full primary care assessment and prescribing capability	1114	604	✓	
Skin rash	PC full primary care assessment and prescribing capability	11,672	2554	✓	

Sleep difficulties	PC anxiety/panic	14	12	✓	
Sleep difficulties	PC depressed mood	42	30	✓	
Sore throat	PC full primary care assessment and prescribing capability	8952	4978	✓	
Tiredness (fatigue)	PC anxiety/panic	2	2	✓	
Tiredness (fatigue)	PC depressed mood	12	10	✓	
Toe pain or swelling	PC assessment and management capability, minor condition	0	0	Removed	Zero NHS 111 calls
Toe pain or swelling	PC full primary care assessment and prescribing capability	1154	690	✓	
Toothache after dental injury	PC full dental assessment and prescribing capability	670	0	Removed	Zero NHS 111 calls
Toothache after dental injury	PC full primary care assessment and prescribing capability	44	8	✓	
Toothache without dental injury	PC full primary care assessment and prescribing capability	64	0	✓	
Vaginal discharge	PC assessment and management capability, minor condition	8	0	Removed	Zero NHS 111 calls
Vaginal discharge	PC full primary care assessment and prescribing capability	1702	534	✓	
Vaginal itch or soreness	PC assessment and management capability, minor condition	0	0	Removed	Zero NHS 111 calls
Vaginal itch or soreness	PC full primary care assessment and prescribing capability	700	334	✓	
Vomiting	PC full primary care assessment and prescribing capability	8950	1112	✓	
Wound problems	PC management of dressings	2178	4	✓	
Wrist, hand or finger pain or swelling	PC assessment and management capability, minor condition	0	0	Removed	Zero NHS 111 calls
Wrist, hand or finger pain or swelling	PC full primary care assessment and prescribing capability	2088	896	✓	
Total NHS 111 calls		112,722	35,974	35,274	

(N.B. The most common symptom descriptors (SD) were selected as the first filter since they describe the level of care ascribed to a presenting complaint, giving an indication of assigned severity. This was considered as an appropriate approach in deciding whether the condition could be classified as 'low acuity' irrelevant of the actual presenting symptom (SG). As a consequence a condition like vaginal discharge could have been included based on the associated symptom descriptor contributing a high volume of patient calls. However, once the filter of disposition (DX) is applied, the number of calls about vaginal discharge at that level of severity and care required may not have been assigned a disposition at the threshold of contact a primary care provider within 24 h or more. This would mean no calls would register at this SD/SG/DX combination).

Uncited reference

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Queries and Answers

Query: Please check whether the designated corresponding author is correct, and amend if necessary.

Answer: Yes this is correct.

Query: Please check the hierarchy of the section headings.

Answer: Yes these are fine

Query: Please note that we have retained bold instead of blue in S4 Appendix(Table). Kindly check and amend if necessary.

Answer: This is fine.

Query: Uncited reference: This section comprises reference that occur in the reference list but not in the body of the text. Please cite this reference in the text or, alternatively, delete it. This reference not dealt with will be retained in this section.

Answer: I have submitted an instruction to indicate where reference 15 needs to be cited

Query: Please confirm that given names and surnames have been identified correctly and are presented in the desired order and please carefully verify the spelling of all authors' names.

Answer: Yes