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Synopsis

Responding to people in danger: a community pharmacy response service for domestic abuse and suicidal ideation, a development and feasibility study

Josie Solomon-Taylor,[1,2*] Rebecca Barnes,[1,3] Ana Maria Barcelos,[1] Tracey Latham-Green,[1] Peter Knapp,[4] Graham Law,[5] Claire Henderson,[6] Hayley Gorton,[7,8] Mahomed Khatri,[9] Darrin Baines[10] and Mark Gussy[11]

[1]School of Pharmacy, University of Lincoln, Lincoln, UK
[2]School of Allied Health Professions, Nursing and Midwifery, University of Sheffield, Sheffield, UK
[3]Department of Population Health Sciences, University of Leicester, Leicester, UK
[4]Department of Health Sciences, Hull York Medical School, University of York, York, UK
[5]Lincoln Clinical Trials Unit, University of Lincoln, Lincoln, UK
[6]Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[7]Department of Pharmacy, University of Huddersfield, Huddersfield, UK
[8]Pharmacy School, Aston University, Birmingham, UK
[9]Public Contributor, Leicester, UK
[10]Independent Consultant, Leominster, UK
[11]Lincoln International Institute for Rural Health, University of Lincoln, Lincoln, UK

[*]**Corresponding author** j.e.solomon@sheffield.ac.uk

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Abstract

Background: Domestic abuse and suicidal ideation are highly prevalent and often co-occur. These issues are distressing and put people in danger from themselves or others. Numerous practical and psycho-social barriers inhibit help-seeking. Community pharmacies are accessible healthcare environments that deliver various public health functions. However, no studies have yet developed and tested a robust intervention for responding to domestic abuse and suicidal ideation in community pharmacy.

Objectives: To co-develop a domestic abuse and suicidal ideation response service in community pharmacy; and to test whether the co-developed intervention and a future trial to evaluate it would be feasible and acceptable in community pharmacies.

Design and methods: Service scope and resources were co-developed with 36 people (lay and professional) who participated in focus groups, interviews and/or workshops. A randomised feasibility trial tested the deliverability and feasibility of consenting clients and collecting study data, including data for a future economic evaluation. A nested process evaluation, comprising staff focus groups, customer interviews and a wider public survey, assessed the fidelity, acceptability and accessibility. A final feasibility workshop reviewed all feasibility objectives.

Setting, participants and interventions: The service was tested for 6 months in eight intervention pharmacies in Lincolnshire. Four more pharmacies acted as controls, providing usual care. In intervention pharmacies, trained staff provided triage assessment and structured signposting to those identified at risk of domestic abuse and/or suicidal ideation.

Main outcome measures: Data were collected on the number and type of relevant patient contacts from intervention and control pharmacies. Staff training was evaluated using the Continuing Professional Development-Reaction

questionnaire, with before-and-after data analysed via paired *t*-tests. Feasibility objectives were assessed in a multistakeholder workshop. Qualitative process evaluation data were thematically analysed.
Results: Co-development participants considered community pharmacies to be an ideal service setting. Their recommendations for safety, equity, empowerment and discretion were incorporated into service design. Following training, staff showed statistically significant improvements in their perceived ability and confidence in responding to people in need of help for suicidal ideation and/or domestic abuse. The public and pharmacy customers showed positive support and acceptability. During the intervention period, 24 patients needing support were identified in the intervention pharmacies compared to two in the control pharmacies. Stakeholder workshop findings confirmed community pharmacy as an appropriate setting for a staff-initiated intervention and the dual focus on domestic abuse and suicidal ideation. The findings do not support a client-initiated service at this stage due to challenges related to marketing and ensuring sufficient staffing capacity to deliver a safe, high-quality service.
Limitations: Limited participant diversity and significant gaps in data collection from clients due to complexities of gaining consent in a pharmacy setting for this type of intervention.
Conclusions: A co-developed, staff-initiated response service for suicidal ideation and/or domestic abuse in community pharmacy was found to be feasible to deliver and acceptable to patients and staff.
Future work: An implementation study to scale-up service roll-out, evaluate it in diverse settings and streamline operational processes across more organisations is required. Further work is needed to determine how to collect outcome and cost-effectiveness data from people receiving a rapid intervention and/or in distress.
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Introduction

This synopsis outlines the co-production and feasibility testing of a new pharmacy response service for people in danger from suicidal ideation (SI) and/or domestic abuse (DA). The motivation to develop such a service arose from the bleak times during the COVID-19 pandemic when there were fears that the numbers for people experiencing SI and/or DA would increase during lockdown.[1,2] The number of deaths from suicide and DA were already a concern pre-pandemic and remained significant. In year ending March 2022, an estimated 1.7 million women and 699,000 men experienced DA in England and Wales, equating to 1 in 20 adults. In nearly two-thirds of cases of cases, the perpetrator was a current or former partner.[3] The estimated cost of DA to the economy is £66 M a year.[4] There were 6069 suicides registered in England and Wales in 2023, the highest number since 1999. Three-quarters of registered suicides are of males, and suicide was highest among people aged 50–54 years.[5] It is estimated that every life lost through suicide costs the economy £1.67 M.[6] The effects of the pandemic worsened an already-critical situation in terms of mental health crises and DA, which was compounded by worsening mental health associated with increased alcohol consumption.[7] It is recognised that much of this harm is preventable if people at risk can access appropriate and timely support.[5,8]

Accessing appropriate support can be challenging for four main reasons. First, healthcare services in the UK were already under strain before the pandemic, which was exacerbated during COVID-19, and they have remained overstretched since.[9,10] Second, as distressing and stigmatising issues, both SI and being a victim of DA carry a psychological burden and are difficult to talk about and reach out for help.[11,12] Third, the fluctuating nature of these issues, often including periods of significant worsening of the problem, means that the timing and availability of healthcare support are an important consideration.[13–15] It is important that assistance is available and accessible at moments of need; care needs to be available opportunistically. Fourth, the intensity of these issues varies, and people need to be referred to the most appropriate service according to the level of severity of the danger in which people find themselves.[16,17]

This research proposed that a response service in a community pharmacy setting could address these access issues of capacity, psychological burden, timing and severity. Community pharmacists and their teams are ideally placed as an accessible service. They are widely distributed in a variety of settings and provide NHS services to around 1.6 million people a day.[18] Throughout England, more than 89% of the population have access to a community pharmacy within a 20-minute walk from home.[18] Within areas of highest deprivation, this increases to almost 100%.[18] Furthermore, by nature of being a walk-in, no-appointment service with long opening hours, they enable care to be patient-led at a time of their choosing.[19] Therefore, this significant existing healthcare provision has the potential to increase the capacity of overall healthcare services and enable flexible timing as an access consideration.

The services that pharmacies offer have expanded over time to include public health and clinical services in addition to the supply and sale of medicines. Their contractual framework includes the Pharmacy Quality Scheme that requires pharmacy staff to be trained in safeguarding and suicide prevention. There has been an increasing interest in the role of pharmacies in supporting people suffering from DA. During the first national COVID-19 lockdown in March–May 2020, many pharmacies followed other European countries by offering their consultation rooms as safe spaces for victims of DA as part of the 'Safe Spaces' scheme.[20,21] This offer was then extended with the launch of the 'Ask for ANI' initiative. Using the code word 'ANI', people suffering from DA could access support from pharmacies to call either the Police or the National Domestic Abuse Helpline.[22] However, the service remains relatively basic and under-researched.

As yet, there is currently no UK provision of formal suicide prevention services through pharmacies.[18] There is evidence that the pharmacy environment and strength of relationships between pharmacists and their customers lend themselves to pharmacists being ideally placed to engage in suicide prevention but that staff feel inadequately prepared and would benefit from a more formalised facilitated training and referral pathway.[23] An advanced psychiatric medication service has been developed in Australian pharmacies, which includes Mental Health First Aid training in both intervention and control groups.[24] Similar work was conducted in Canada through the 'Bloom Program', a service for mental health and addiction in pharmacies involving advanced medication support and listening.[25]

These developments evidence the potential for pharmacies in this new role and adds further impetus to developing a formalised service, training package and referral system for people in danger from either DA or SI. These foundations underpinned the proposal to co-develop and test the feasibility of an easily accessible community pharmacy response service for people in danger, as a complex healthcare intervention. This would allow more people in need to access appropriate and timely care, thus reducing preventable deaths and suffering, with consequent improvements in health and longer-term prognosis.

Aim

The aim is to co-develop and evaluate the feasibility of a community pharmacy response intervention for people in danger from DA or SI.

Objectives

1. To develop a point of contact and triage referral resource in partnership with relevant experts and local referral organisations, for both DA and SI.
2. To co-develop with patients/public and professionals the scope and features of a discreet response intervention in community pharmacy, to include the name, logo, promotional strategy and protocol for delivery in a pharmacy.
3. To co-develop with patients/public and professionals a training package and mentoring support service for pharmacy staff delivering the intervention.
4. To deliver the intervention in a purposive sample of community pharmacies and collect feasibility data on intervention usage and consequent referrals.
5. To ascertain and evaluate client, public and professional views on accessibility, acceptability, implementation, feasibility and intervention fidelity in practice.
6. To evaluate the potential for the intervention to be scaled up for a future trial, including economic and statistical considerations.
7. To engage with the public and professionals to disseminate findings and reporting of the intervention as an output.

Methods

This was a two-phase co-development and feasibility study, as outlined in *Figure 1*. The intervention scope and components were co-developed with people with lived experience and relevant professionals, followed by a 6-month implementation of the intervention in 12 pharmacies, 8 of which were randomised to deliver the intervention, plus 4 controls that delivered their usual service (see *Appendix 1* for details of the intervention components).

Summary of results

Co-development phase (A1, A2 and A3)

Overall, 36 individuals (lay and professional) contributed at least once to a series of focus groups, interviews and/or workshops to co-develop the service components. A rich qualitative data set was collected and analysed, which is more fully reported on in our co-development paper (see also *Appendix 2*).

All participants were supportive of community pharmacy as a setting, including both issues (DA and SI) together, that the service should be both client- and staff-initiated and use the name 'Lifeguard Pharmacy' as a non-medicalised

ENGAGEMENT AND INVOLVEMENT (objective 7)	A: CO-DEVELOPMENT PHASE (objectives 1–3)
Regular steering group meetings Regular public and patient involvement meetings (every 2 months) Active engagement with over 22 relevant organisations	**A1: LIVED EXPERIENCE FOCUS GROUPS/INTERVIEW** 2 × focus groups with people with lived experience of SI, ***n* = 8**, 1 × focus group with people with lived experience of DA, ***n* = 11**, 1 × interview with person with lived experience of both DA and SI, ***n* = 1**. Total of 20 participants *Explored their experiences and barriers to accessing care, co-developed the Name, Logo and marketing material, Client Flow Chart and design of the service from a client perspective* **A2: REFERRAL ORGANISATION INTERVIEWS** 5 × interviews with representatives from relevant organisations, plus 5 × research meetings with representatives from relevant organisations (preferred not to participate in a formal interview) *Explored the role of relevant DA and SI organisations to identify relevant risk assessment criteria, referral criteria and pathways, to inform the Consultation Guide and Referral Tool* **A3: CO-DEVELOPMENT WORKSHOPS** Workshop 1: 7 × people with lived experience, 6 × pharmacy staff and 1 × representative from mental health organisation Workshop 2: 5 × people with lived experience, 5 × pharmacy staff, × representative from mental health organisation Workshop 3: 6 × people with lived experience, 10 pharmacy staff and 2 × representatives from relevant organisations *Explored scope and content of staff training package and staff support package. Finalised content of all intervention components.*
	B: FEASIBILITY STUDY PHASE (objectives 4–6) **B1: PHARMACY RECRUITMENT AND TRAINING** Recruited 8 × pharmacies for intervention and 4 × pharmacies as controls, using purposive sampling to cover rural/urban, small/large pharmacy and differing socio economic areas. Recruited and trained 37 patient-facing staff from the intervention pharmacies (6-hour facilitator-led training, 2-hour mock consultations in their pharmacy, 4-hour online learning and own reading). Recruited 4 staff in control pharmacies Staff completed CPD-Reaction Questionnaires × 2 (1 for SI and 1 for DA) before and after training **B2: IMPLEMENTATION OF INTERVENTION** 6-month feasibility testing of the intervention in the pharmacies. Induction visits to both intervention and control pharmacies, followed by 5 × monthly visits to intervention pharmacies to collect data and monitor fidelity. Promotion of the service to the public via website, social media and distribution of posters to local community venues. Data collection over 6 months **B3: PHARMACY STAFF FOCUS GROUPS** 3 × focus groups with the trained pharmacy staff from the intervention pharmacies. Focus group 1 = 14 participants, focus group 2 = 13 participants, focus group 3 = 10 participants. In total, 27 out of the 37 intervention participants self-selected to participate *Explored how staff had used their learning from the training, their use of the intervention resources and their perceptions on the feasibility of both the service and the intervention as a research study* **B4: CUSTOMER INTERVIEWS** Interviews with 13 regular customers from 7 of the 8 intervention pharmacies *Explored their awareness of the service, their views on acceptability of the service and their views on how the service impacts or not on normal pharmacy activities and their experience as a customer* **B5: PUBLIC SURVEY** Promotion of an online questionnaire about the public's awareness and attitudes towards the acceptability of the service. 501 respondents from Lincolnshire residents
	B6: MULTI STAKEHOLDER FEASIBILITY WORKSHOP Summary workshop in person with 14 staff participants from 6 of the 8 intervention pharmacies, 11 members of the research team, 7 co investigators, 6 members of the public and patient involvement panel, 2 senior members of staff from the pharmacy organisation and 3 representatives from local mental health organisations (NHS and charity). A repeat workshop was held online with 2 staff participants. Total 44 participants *Explored 4 main areas that had been challenging: Scope, Setting, Client Access and Record Keeping, and evaluated the feasibility of the intervention plus recommendations for future practice and research*

FIGURE 1 Feasibility study phases. CPD, continuing professional development.

metaphor for the service. Participants with lived experience emphasised the need to create hope in otherwise hopeless situations and developed the logo of the life-ring integrated with a green pharmacy cross, a marketing poster and the strapline 'Bringing Hope to Life' (see *Appendix 1* for images of intervention materials). Under the overarching concept of creating hope through connection, five main themes emerged: Safety, Empathy, Empowerment, Equity and Discretion.

Although participants were predominantly positive about the service, concerns were raised about how discretion would be maintained, whether pharmacies would have sufficient capacity and how staff would be adequately trained and supported. The importance of equity was emphasised, including how to make the service inclusive to people who particularly face barriers to help-seeking, including speakers of languages other than English and men, and offering a choice of a male or female 'Lifeguard', where possible. Safety issues were also discussed, particularly among a focus group of female DA survivors who emphasised how closely their movements were controlled and how explicit advertising of the service could have alerted their abusers to the service and/or inhibited them from using the pharmacy.

These findings informed the development of the Pharmacy Operating Manual which contained full details and resources for the intervention (see *Appendix 1*). *Figure 2* presents the population, intervention, control/comparison, outcome (PICO) framework for the Lifeguard Pharmacy intervention.

Feasibility study phase (B1–B6)

Pharmacy recruitment and training (B1) Twelve pharmacies from one pharmacy chain were recruited; 8 to deliver the intervention and 4 to act as controls, providing their usual service (*Table 1*). Pharmacies were purposively selected to include a mix of size, location and socioeconomic deprivation in the local population and were then randomised.

In the 8 intervention pharmacies, 37 patient-facing staff were trained, including pharmacists, technicians, dispensers and counter assistants. Seven out of the eight pharmacies remained in the intervention for the entire 6 months. One was removed due to a fall in levels of trained staff below the specified minimum.

Following training, intervention pharmacy staff showed statistically significant improvements in their perceived

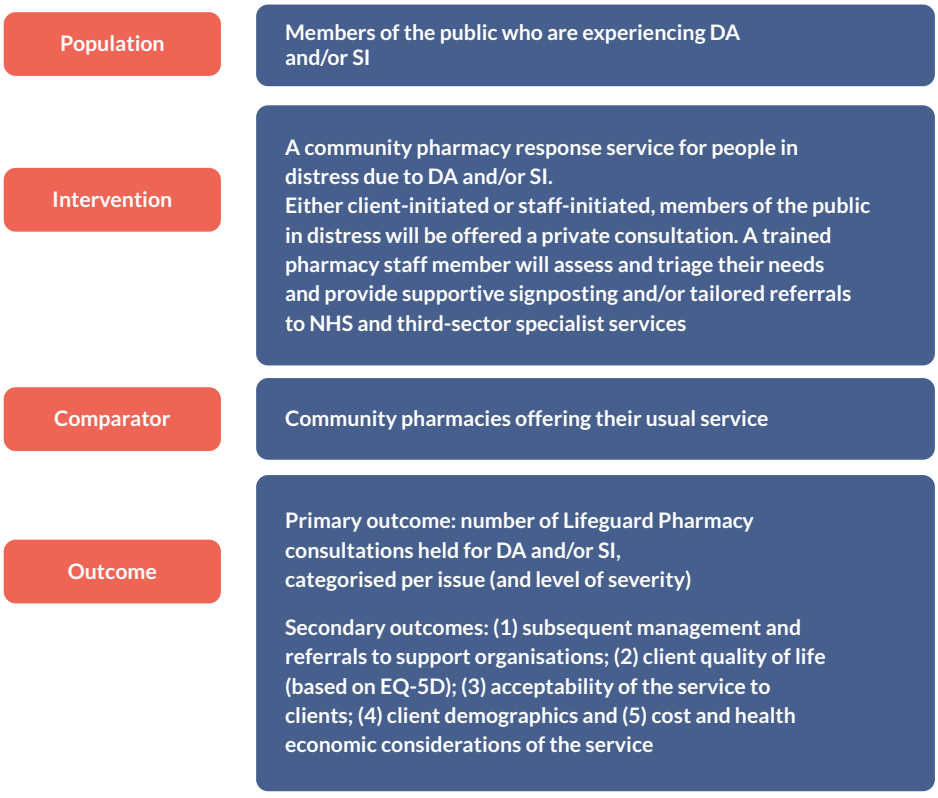

FIGURE 2 The PICO framework. EQ-5D, EuroQol-5 Dimensions.

TABLE 1 Characteristics of recruited pharmacies

Pharmacy ID code	Sampling category	Intervention or control	Index of Multiple Deprivation in decile[a]
A	Large rural	Intervention	6
C	Large urban	Intervention	4
D	Large urban	Intervention	2
E	Small rural	Intervention	3
F	Small rural	Intervention	10
H	Small urban	Intervention	10
I	Small urban	Intervention	3
J	Large rural	Intervention	3
B	Large rural	Control	8
G	Small urban	Control	1
W	Large rural	Control	10
X	Large urban	Control	6

ID, identification.
a Whereby the lowest number indicates the most deprived area.

levels of ease, ability and confidence for responding and referring people experiencing DA and/or SI, measured before and after the training using the CPD-Reaction questionnaire.[26] These findings are presented in *Appendix 4*, *Table 7*.

More detailed results from BI, B2, B3 and B6 can be found in our paper reporting on the feasibility study, still in pre-print at the time of writing.

Implementation of intervention (B2)

The intervention was implemented at the eight intervention pharmacies between January and July 2023. During this time, staff applied their Lifeguard training and used the intervention resources to provide support to 24 cases of SI and/or DA. A key finding of this study was that patient-facing staff of different role types successfully engaged in the training and conducted consultations, as shown in *Table 2*.

Cases were not evenly distributed across the eight intervention pharmacies. Three pharmacies had no cases, and one pharmacy had 11 out of the 24 cases. It is notable that such a large proportion of cases were concentrated in one pharmacy. This was a large pharmacy in a more deprived area, where staff were highly motivated to support their community through this intervention. The pharmacies which had no cases tended to be in more rural or close-knit areas, where staff in focus groups suggested that concerns about confidentiality might be a barrier to using the service. By contrast, two cases were identified in one of the control pharmacies, and none was identified in the other three controls.

Intervention staff encountered barriers in recruiting the 24 clients to the study because most conversations were staff-initiated in an opportunistic manner rather than being client-initiated, and therefore it seemed disruptive to discuss the study with clients. Clients were reluctant to formalise the conversation, and both staff and clients found the paperwork to be overwhelming. Consequently, written consent was only achieved for 4 of the 24 cases, and the full data set was collected for these clients. The accounts of the remaining 20 cases are based on the staff's experiences of applying their learning, as discussed at the staff focus groups. Data were only collected on implementation; no robust data on effectiveness were collected.

Out of the 24 cases, 8 were for SI, 9 for DA and 7 for both. The majority (83%) of cases in which it was possible to determine gender were women. One-quarter (25%) of all cases were known to involve drugs and alcohol misuse (see *Appendix 4*, *Table 8*). Clients were signposted or supported to access NHS and third-sector services, tailored to their needs.

Twenty-two out of the 24 cases were staff-initiated and 2 were client-initiated. Both client-initiated cases presented towards the end of the intervention period, which may

TABLE 2 Number of Lifeguard consultations conducted by trained staff, by job role

Job role	Frequency
Pharmacist/trainee pharmacist	7
Dispensers	6
Counter assistants	5
Pharmacy technicians	4
Not known	2
Total	24

be a reflection of the time it takes for people to become aware of, and/or confident to access, a new service. It was possible to determine that eight clients (24%) returned to the pharmacy to speak to staff on at least one occasion after their initial consultation. This outcome was reassuring in terms of safety-netting, with the potential for returning clients to be re-triaged for changes in their needs and level of severity and be signposted or supported to access other services if initial suggestions were unavailable or not suited to their needs. The high levels of staff-initiated consultations, together with the high numbers of returning clients, suggest that pharmacy staff had good relationships with their customers and developed trust and rapport.

In addition to the SI/DA cases, staff reported using their learning and support resources in 33 additional interactions with customers about lower-level issues, including bereavement, loneliness and other mental health needs.

Pharmacy staff focus groups (B3)

The findings from the staff focus groups (n = 27) found that staff perceived the intervention to be of overall benefit. They reported that they had good relationships with their regular customers and that 'Lifeguard' consultations strengthened the bond between them and the clients even further.

Community pharmacy was considered an ideal setting for an SI/DA response service because it is a neutral environment and customers often have good relationships with staff because of their connection to medicines and other healthcare services. The motivation to engage in the intervention was greater in pharmacies where a local need was perceived. However, staff in pharmacies located in more close-knit or rural areas which had no or few cases reflected that concerns about confidentiality may have inhibited help-seeking, as the following example points to:

> *I just wondered if they would rather take the information, and go and find it themselves, rather than speak to us. So, it's just a bit of, pride, really. They don't want us to, you know, because we're like a village setting. Everybody knows everybody, but cue cards are really good because I have seen some go into pockets and things.*

Staff considered 30 minutes to be the ideal amount of time for a Lifeguard consultation but noted that a crisis would require longer. Staff reported that the training and the provision of the support and referral resources had increased their confidence, ability and motivation to identify and refer people who may be experiencing SI and/or DA. Seeing what was 'hidden in plain sight' was a recurring theme, as the following quotation from a trained staff member illustrates:

> *We notice people a lot more. We have a bit more patience, I think [. . .] like this lady that came in last week, I think, before the training, we would probably not have noticed that she needed some help, but with the training, I think, we realised that she wasn't doing so well. As it turns out, we've managed to get her referred. Several staff described embracing the role of being a Lifeguard with a sense of duty, satisfaction, and pride. However, some difficulties were noted in relation to blurring of the Lifeguard role with counselling when clients just wanted to talk, and looking after their own mental wellbeing whilst supporting others.*

Customer interviews (B4)

Although for safety and ethical reasons, we did not interview Lifeguard Pharmacy clients, interviews with regular pharmacy customers who were purposively selected (n = 13) provided some valuable data on awareness of the intervention and acceptability.

Customer interviews identified mixed awareness about the service, which indicated that the marketing had not been sufficiently effective. Participants thought there was a definite need for the service as it could be difficult to access other services, that pharmacies are already seen as safe spaces and that this service would formalise what is happening already. Concerns were raised about capacity during the winter vaccination period.

Participants understood and resonated with the Lifeguard Pharmacy name and logo. However, they thought that the poster (which had been developed in the co-development phase; see *Appendix 1*, *Figure 4*) was not sufficiently self-explanatory. It was recognised that there is an inherent

dilemma posed by advertising a service that needs to be discreet. Four out of the 13 participants spoke about their own experiences of either feeling suicidal themselves and/or having been bereaved by suicide. Participants considered it appropriate to include both SI and DA in the same service and recognised the role that drug misuse can play in contributing to people to feel suicidal.

A community pharmacy setting was considered to be suitable for this service due to it offering caring healthcare-trained staff, a convenient walk-in location and a safe neutral place that was perceived as being more accessible and less judgemental than other services. The strong relationships that develop between pharmacy staff and customers were seen as an asset for the setting of a DA/SI response service.

Participants did not feel that the service had any negative impact on their usual customer experience rather the contrary; knowing that the staff had taken on this additional role would make them more likely to use the pharmacy. Participants said that they would recommend the service to others and considered the service to be needed and the right thing to do but only if staff were sufficiently trained and supported.

These findings, along with the public survey findings (B5), are reported further in our paper about the acceptability of the intervention.

Public survey (B5)

The results from the wider public survey to measure awareness and acceptability (n = 501) triangulated the findings from the customer interviews, in that people were mostly unaware of the service but were very supportive. Two-thirds (67%) of respondents indicated that they had not heard of Lifeguard Pharmacy, but the majority of respondents (75%) were supportive of the concept of the service. Only 9% of respondents were not in favour and the remainder were neutral.

Perceived benefits included that it is for the greater good, that it offers increased access to services and choice, reduces stigma and that pharmacies are seen as trustworthy. Pharmacies were considered to be accessible in terms of being within walking distance and being able to drop-in.

The majority of respondents thought both SI and DA should be included in the service. Some suggested increasing the scope to other mental health issues, sexual violence and drugs and alcohol misuse. There was also a suggestion to include under-18-year-olds.

Table 3 summarises respondents' views about some of the key components of the intervention, showing strong support for the name, logo and use of a flash card that customers could show to staff for client-initiated help.

Respondents generally had confidence in pharmacy staff to effectively deliver the service (65%), with 25% neutral and just 1% indicating a lack of confidence. Concerns were raised about staff being over-worked, that this could be a cost-cutting means of providing psychological support and that it could be unprofessional. However, despite some reservations, 80% of respondents were willing to either use the service themselves or recommend it to a friend or family member. However, some respondents anticipated feeling shame or embarrassment, with some suggesting that they might be reluctant to return to a pharmacy to collect prescriptions after using the service. A resounding 99% of participants indicated that it would not impact their likelihood of using the pharmacy for regular pharmacy services, or that they would be more likely to do so.

Overall, this survey demonstrated strong public support for the concept of the Lifeguard Pharmacy service. However, it is also evident that the current marketing and promotional strategy had not been sufficiently successful in reaching local residents.

Multi-stakeholder feasibility workshop (B6)

The majority of the 44 participants at the multistakeholder workshop thought that a future service should include SI, DA and other mental health conditions. They considered community pharmacy to be a suitable setting and thought that Lifeguard Pharmacy could be rolled out nationally to pharmacies that have been accredited

TABLE 3 Survey respondents' views on key features of the Lifeguard Pharmacy service

Component	Like (%)	Neutral (%)	Dislike (%)	*n*
Lifeguard Pharmacy name	243 (60)	140 (34)	24 (6)	407
Symbol/image/logo	247 (61)	123 (31)	32 (8)	402
Use of a flash card to alert pharmacy staff to a customer's need	273 (67)	104 (26)	29 (7)	406

as having suitable quality criteria, numbers of trained staff, specified minimum staffing levels and a supportive organisational culture.

In-person facilitator-led training was considered to be the most suitable, but it was acknowledged that online training would increase uptake but that it should be live and facilitator-led. Participants thought that staff from all patient-facing roles should be included.

The majority of participants thought that a future service could accommodate both client-initiated and staff-initiated consultations if the conditions (quality criteria and staffing levels) were right. They thought there should be more marketing that was more explicit about what the services were for. Lastly, they thought the administration should be lighter-touch and digital.

Views about the feasibility of collecting the data needed for a definitive evaluation were more mixed. The majority of participants responded 'Maybe' to questions about whether following clients up would be advisable or possible and whether additional data could be collected from clients about their views and preferences. However, participants were more confident about the prospect of collecting additional demographic data from clients (38.5% 'yes', and 33.3% 'maybe').

Summary

The study successfully co-developed and feasibility-tested the Lifeguard Pharmacy response service, drawing on the perspectives of people with relevant lived and professional experience and collecting data on pharmacy staff experiences of implementing the intervention and public views on acceptability.

The findings from all the research components strongly support:

- community pharmacy as being a suitable setting for a response service
- the inclusion of both SI and DA in the response service, with recognition of co-occurrence (as was found in 29% of the 24 cases)
- the Lifeguard Pharmacy name and logo.

Cautions to this support are that not all pharmacies were considered suitable to deliver this kind of service. From the co-development phase and the feasibility study, several quality criteria were identified for the suitability of pharmacies, along with specifications about minimum staffing levels, minimum numbers of 'Lifeguard' trained staff and availability of a consultation room.

The findings also support possibly extending the service to other mental health issues, sexual violence, drugs and alcohol misuse and under-18-year-olds, depending on capacity. However, the training and consultation guide would need amending and extending to include these issues.

It was also clear that the original poster, designed by people with lived experience in the co-development phase, was too discreet and the members of the public did not understand it. This presents a conundrum; the marketing needs to be sufficiently discreet and non-triggering and also sufficiently self-explanatory. The need to be discreet supports the use of a code name and metaphor, but that name needs to become known. During co-development, it was envisaged that the response service would primarily be client-initiated, but the findings do not support the feasibility of a client-initiated service at this stage. This is due to challenges with marketing and ensuring adequate staffing levels in pharmacies. Despite these issues, the findings provide evidence that it is feasible for pharmacy staff across a variety of job roles to identify, intervene and signpost, or refer clients experiencing a range of levels of SI and/or DA to appropriate support organisations in a timely manner. This is contingent on staff being provided with appropriate training, staff support, a consultation guide, referral systems, client support resources and having sufficient workload capacity and access to a consultation room. Importantly, prior to implementation, the research team contacted the key referral agencies for DA and SI to check their capacity and make them aware that service users/patients may be referred or signposted from the eight intervention pharmacies. This step in the process was vital to ensure a joined-up approach and avoid clients being turned away by services after finding the courage to seek help.

The feasibility of a future trial and economic evaluation is currently less certain. Consent and full data sets were only collected from four clients, out of the 24 cases, and pharmacy staff talked about their difficulty and discomfort with collecting informed consent and study data from people in distress. These issues are considered further in the *Discussion/interpretation* section.

The research papers listed in *Table 4* are synthesised in this synopsis.

Discussion/interpretation

Principal findings per project outcome

The primary outcome measure for this study was the number of community pharmacy consultations for people enquiring about or seeking support for domestic violence or SI, categorised by the issue and level of severity. The secondary outcome

TABLE 4 Research papers arising from this project

Journal	Paper title
International Journal of Pharmacy Practice	Lifeguard Pharmacy: the co-development of a new community pharmacy response service for people in danger from domestic abuse or suicidal ideation *The submission included a COREQ reporting checklist* Published: https://doi.org/10.1093/ijpp/riae043
BMC Public Health	Responding to people in danger. A feasibility trial of a novel pharmacy-initiated intervention for people experiencing domestic abuse and/or suicidal ideation *The submission included a CONSORT Extension reporting checklist* Resubmission under review. Pre-print of first submission available at https://doi.org/10.21203/rs.3.rs-4077284/v1
Research in Social and Administrative Pharmacy	Public acceptability of a novel response service in community pharmacy for people in danger from domestic abuse and/or suicidal ideation *The submission included a COREQ and a STROBE reporting checklist* Published: https://doi.org/10.1016/j.sapharm.2024.07.002

measures collected were the subsequent management of clients and referrals to support organisations, client demographic and public acceptability of the service. As a feasibility study, the feasibility of the intervention itself and of conducting a future randomised controlled trial were evaluated. Cost and economic considerations were also assessed, in preparation for a future health economic evaluation.

Lifeguard Pharmacy usage data

Number of consultations, categorised by issue and level of severity Full data were only collected from the four clients who were willing to provide informed consent. Of these four cases, two were for DA (one at action level and one at assistance level) and two were for a combination of both SI and DA (one at action and one at assistance level).

A further 20 consultations took place in the intervention pharmacies with clients who had SI or DA concerns, but staff were unable to complete the full explanation of the study and invitation to consent for data collection. Data about these cases were compiled from staff reports of their experiences of applying their learning, from the staff focus groups and monthly research team visits.

As reported in Solomon *et al.* (2024, PREPRINT), out of the total of 24 cases:

- 8 cases were for SI (33.3%).
- 9 cases were for DA (31.5%).
- 7 cases were for both DA and SI (29.2%).

This fairly even split affirms the appropriateness of the Lifeguard Pharmacy service addressing both DA and SI.

In the four control pharmacies there were two cases; one for SI and one for DA. However, these cases are likely to have been caused by contamination because the member of staff who identified these clients had previously worked in an intervention pharmacy and had been Lifeguard-trained.

During triage, intervention pharmacy staff used the information gathered from clients to determine the level of severity, ranging from 'assistance' (the lowest), to 'action' and finally to 'alert' (the highest). Out of the total cases, six were at the assistance level, nine at the action level and one at the alert level. In seven cases, it was not possible to determine the level of severity or urgency from the data (see *Appendix 4*, *Table 8*).

Management of clients and referral to support organisations For the four cases for which informed consent was received, one consultation was client-initiated and the other three were staff-initiated. One consultation was conducted by a pharmacist, one by a pharmacy technician and two by dispensers. Two of the consultations took between 15 and 30 minutes, one between 30 and 60 minutes and a time period was not recorded for the other consultation.

In terms of consultation outcomes, pharmacy staff referred these four cases to variety of services from the referral directory; namely, DA services (n = 2), general practitioner (GP) (n = 2), drugs and alcohol service (n = 1), the crisis team (n = 1) and other charity support services (n = 2). One of the clients was referred to four relevant services. This shows that staff used the resources provided to tailor referrals and signposting to clients' individual needs.

Client demographics Self-reported demographic data are only available for the four cases in which consent, and the full data set was obtained. All four of these participants were women and White British. One participant was between 25 and 34 years old, two were 55–64 years old and one was over 65 years old.

For all 24 cases, including the 20 further cases in which no formal study data were collected, in 83.3% of all cases where gender could be determined, the clients were women. All the DA cases and all cases involving both SI and DA were known to be women. While it is arguably unsurprising that primarily women sought help for DA – given both the higher prevalence of DA among women and the greater stigma associated with disclosure of DA for men – it is more surprising that fewer men accessed the service for SI. Given that an overwhelming proportion of suicides are of men,[5] more engagement with men is needed to understand how to align the service to their needs and preferences.

Reasons for using the Lifeguard Pharmacy service, other service usage and willingness to be followed up All four consenting participants agreed to give their personal details. All participants reported that their visit was opportunistic rather than being planned. Reasons for using a pharmacy service included familiarity with staff (two participants), rapport with staff, it being a walk-in service (two participants), it being a familiar environment and it being in-person.

The DA was involved in all four cases, but none of these clients had previously accessed any DA services in the last 3 months. One had accessed mental health services and one had accessed the drugs and alcohol service.

The four consenting participants were asked whether they would be hypothetically willing to be followed up: one was unwilling and three were unsure.

Evaluation of feasibility

Feasibility of the intervention As discussed in the summary of results, the study found that it was feasible to deliver the intervention as a staff-initiated response for people experiencing SI and/or DA. The intervention was successful at equipping pharmacy staff with the knowledge, skills, motivation, confidence and resources to identify signs of DA/SI and to proactively explore in an empathic and discreet manner with the client and then refer or signpost appropriately. However, at this stage, the findings do not support the feasibility of a client-initiated response service. Further development work is required to determine an appropriate tone for the marketing material and appropriate levels of staffing to support such a service.

Although acceptability data could not be collected from clients, the intervention was shown to have high acceptability with the public, and the majority of public participants would recommend the service. However, there were concerns about whether the staff would be sufficiently trained and supported as well as staff capacity at busy times.

Feasibility of a future randomised controlled trial Challenges were identified with the fidelity of the intervention, and it was found that it would not be feasible to conduct a future randomised controlled trial in its current format, for the following reasons:

- *Not feasible to randomise pharmacies*: After initial randomisation, it became necessary to switch two of the intervention pharmacies to controls and vice versa. This was because staff pharmacy failed to complete all the training, and in the other pharmacy, the local GP practice was not supportive. Meanwhile, two of the control pharmacies were disappointed not to be intervention pharmacies, therefore, the decision was made to switch them.
- *Not feasible to recruit pharmacy staff participants prior to randomisation*: Staff wanted to know which arm they would be in before consenting and therefore it was not possible to recruit staff participants prior to randomisation.
- *Limited feasibility to consent client participants and collect baseline and follow-up data*: The pharmacy staff participants struggled to recruit client participants because the consenting process did not work well in a pharmacy context. Most cases of DA and/or SI were identified by proactive staff-initiated interventions that occurred opportunistically during routine pharmacy activities rather than being client-initiated. These situations did not lend themselves to the flow of explaining about the study, consenting, conducting a consultation and collecting data. Additionally, it seemed inappropriate to go through the consent process if a client was distressed or in a hurry. Pharmacy staff found the consenting paperwork cumbersome and were not used to a culture of obtaining written consent from patients as verbal consent is adequate for other pharmacy services. Some patients stated that they wished to have a consultation, but they did not wish to provide their personal details for the purpose of the study. Potential to follow up clients is also uncertain and alternatives to individual follow-up may be needed.

- *Intervention fidelity*: One intervention pharmacy involvement was paused due to the staffing levels falling below the minimum acceptable levels. This raises concerns about the safety of an intervention that is advertised to the public, because it would be necessary to guarantee that a trained staff member would always be available to respond to any clients who presented.
- *Defining trial inclusion criteria*: Despite the above limitations, the recruitment of staff participants was successful. Staff embraced the learning and resources and used their learning widely with a variety of patients and for a variety of related conditions in addition to DA and SI. This means that it is difficult to contain the inclusion criteria to specific conditions. This was evidenced by staff reporting using their Lifeguard Pharmacy training and resources to assist 33 other pharmacy customers with lower-level issues.

Cost and economic considerations

The study protocol included work to identify the feasibility of a future economic evaluation, and, in particular, identifying whether the costs required to deliver the intervention could be identified and what type of economic evaluation would be most appropriate for a definitive study.

The cost of the Lifeguard Pharmacy service

The study has been able to start to develop a costing model for the Lifeguard Pharmacy service, and *Table 5* outlines the cost categories. The costing of a response service would include the costs incurred by the pharmacy and the costs of training and accreditation. In the interests of the safety and well-being of both staff and clients, it is recommended that an external organisation should provide the training and accredit the pharmacies, with regular reviews to ensure adherence to the Pharmacy Operating Manual. Cost categories are listed for the option of providing a staff-response service only (option 1) and for both a client-initiated and staff response service (option 2).

The rationale and explanation of each of these categories are provided in *Appendix 5*.

Plans for a future economic evaluation

The intention for this study had been to conduct a cost–utility analysis, using EQ-5D as the primary outcome measure. However, pharmacy managers and staff were not willing to collect EQ-5D data because they thought this would be cumbersome and too time-consuming, and ethically they were concerned about administering this instrument with people in distress. Consequently, an ethics amendment was submitted to remove this aspect of data collection. This, combined with the very limited amount of quantitative data collected from the four consented clients, means that plans for a future economic evaluation are at an earlier stage of development than anticipated.

The potential value of a pharmacy response service for DA and/or SI is based on the following hypothetical principles, which are that people experiencing DA and/or SI may find pharmacies to be more accessible than other services and therefore a pharmacy service may reach people:

- who would not have presented at other services, therefore treating people who otherwise would not have received support and addressing unmet need
- at lower levels of severity, thereby preventing escalation
- more quickly in times of crisis than other services, therefore preventing harm.

We had planned to approach the economic evaluation from an NHS and personal social services perspective. This would have included use of pharmacy services, medications, primary care consultations, including GP and practice nurse appointments, hospital in-patient stays, outpatient visits, accident and emergency (A&E) attendances and formal and informal social care services. However, over the course of this study, it has become apparent that this would need to be extended to encompass a social impact assessment (SIA), using Social Return on Investment (SROI) to calculate cost savings related to the physical and emotional harms of abuse and the impact of a wide range of agencies, including criminal justice agencies and employers.[4]

Both SI and DA have wider reverberations on families, friends, coworkers and communities, as well as the costs for other public agencies. For example, survivors of abuse may need secure housing, income-related benefits or time off work and their children or other family members may need therapeutic support. There may also be costs for the involvement of criminal justice agencies. Both DA and SI are also issues where it can take a long time to see a positive return on initial investment. Initial costs may be higher when help-seeking occurs. In the case of DA, the process of leaving an abusive relationship can be protracted and dangerous, and recovery is gradual.

As is the case with the questions surrounding the feasibility of a future randomised controlled trial, further work and consultation with key stakeholders are required to consider options for improving rates of consenting and data collection, and to consider options for follow-up, which could

TABLE 5 Lifeguard Pharmacy service cost considerations

Cost categories for the pharmacy organisation	**General staffing levels, trained staffing levels and consultation room availability and indemnity insurance** ***Option 1: staff-initiated response only*** – sufficient to provide the flexibility and capacity for staff to identify and respond to suspected cases and conduct a 30-minute consultation with those cases, based on anticipated level of need in that area, with sufficient consultation room availability ***Option 2: client-initiated and staff-initiated response*** – sufficient to ensure that all customers are served promptly and that anybody presenting for Lifeguard has a consultation arranged within 10 minutes. Capacity to conduct a 30-minute consultation with those cases based on anticipated level of need in that area. Coverage for all the opening hours of the pharmacy, with sufficient consultation room availability ***Both options*** – appropriate indemnity insurance. Support from trained area manager, relief pharmacist and superintendent pharmacist
	Staff training costs – to attend 8 hours of contact time training plus 4 hours self-study
	Consultation room requirements – accessible, private, sound-proof, safe, internet, phone, computer, security alert, chaperone policy poster
	Quality criteria – chaperone policy, supervised consumption alone, option for written in prescription hand-out
	Potential for loss and gains in other pharmacy activities – reduced capacity due to delivering other services due to staff workload and consultation room availability, but enhanced reputation. Better capacity to handle patients in crisis
Cost categories for the accrediting organisation	**Training** – provision of 6 hours of live training, 2 hours of mock consultations per staff member, verification of self-study requirements
	Accreditation of premises – based on numbers of general and trained staff, consultation room criteria and availability and quality criteria
	Service resources – website, referral directory, support cards, consultation guide – provision and regular review
	Marketing costs (*option 2 only*) – extensive marketing would be required for a client-initiated service, including posters and flyers, advertising in local media, promoted social media posts and radio advertisements
	Staff support – provision of appropriately trained counsellor or mental health professional for emotional debrief as required and advice on client cases

ID, identification.

include the use of routinely collected data. We also need to understand whether the barriers to collecting EQ-5D are real or perceived due to pharmacy staff's unfamiliarity with using such outcome measures. If the latter was the case, further training could help to overcome this issue.

This study has also developed the principles of a Markov model that could potentially be used for future health economic modelling for this intervention, drawing on similar Markov models for other SI and DA interventions (see *Appendix 6*).

Contribution to existing knowledge

This study adds to the increasing evidence base for the role of community pharmacies in suicide prevention, with key studies having been conducted in the UK, Ireland, Canada, the USA and Australia.[23,28–31] This includes exploration of the role of pharmacy staff as gatekeepers, who engage people through conversation and then signpost or refer on to appropriate services, and their role in restricting access to the means of suicide, particularly medicines.

Research into the role of pharmacy staff in supporting people experiencing DA is less widespread, although there is evidence from the UK[32] and USA[33] to support this emerging role. Despite the limited evidence base, the expectation that DA support will be offered by pharmacies has been increasingly adopted into routine practice. This was fuelled during the pandemic when there were fears around increasing rates of DA, and many pharmacy organisations across Europe responded by adopting code word initiatives for people to signal that they needed support and a safe space.[34] In England, this was known as the 'Ask for ANI' initiative.[22]

Despite these advances, it has been identified that clearer staff training and referral pathways are needed to support staff in both these roles of suicide prevention and supporting people experiencing DA.[23,29,30,32]

Standardised training is beginning to emerge for suicide prevention. Since 2021, 72,000 pharmacy staff members in England have completed the Zero Suicide Alliance training, as incentivised through their pharmacy contract,[35] while

Washington state in the USA has taken suicide prevention training a step further by making it compulsory for all pharmacists.[36] However, despite the increasing evidence base for pharmacy staff in this role and the increased training on offer, there remain no commissioned services for suicide prevention in pharmacy in the UK.

In summary, the role of pharmacies in DA has become increasingly seen as a routine expectation, but there is a limited evidence base and a lack of standardised training or support. The evidence base for the role of pharmacies in suicide prevention is more extensive and there is more training available, but there are no commissioned services. Furthermore, both issues have been researched in isolation, with no research available on the role of pharmacies for a service for both DA and SI combined.

In addition, the focus on research in this area so far has predominantly been from the perspectives of pharmacy staff themselves or from a policy- or commissioner-based perspective. There has been limited exploration of the views of the public on whether they would use such a service and how it should be designed to accommodate their needs and priorities. To date, there is one study about potential service users' attitudes towards pharmacies offering DA[37] and none relating to suicide prevention services. This study has contributed to addressing this gap, showing strong public support for the delivery of a response service for DA and SI within community pharmacy.

This study was novel in several regards:

- the combination of both SI and DA in the same intervention in community pharmacy
- exploration of the perspectives of the public and people with lived experience for a pharmacy-based service for SI and DA
- the use of a non-medicalised name and logo for an SI intervention in community pharmacy
- there are similarities with the Ask for ANI initiative for DA support,[22] but this intervention differed in:
  - being for both DA and suicide prevention
  - being co-developed
  - being embedded into local referral pathways
  - providing live facilitator-led training
  - having a detailed consultation guide and support cards for clients
  - providing the facility for staff to debrief with a psychotherapist
  - having specification for pharmacy quality criteria
  - having accredited trained staff with a clear role and identity.

The study findings show support for all the above novel features. Most strikingly, the details of the cases, with around one-third of the 24 cases being for DA, one-third for SI and one-third for both DA and SI gives support for this dual focus of the intervention.

Strengths and weakness of the study/in relation to other studies

This study was developed from substantial patient and public involvement work consisting of 13 focus groups with members of the public or relevant professionals from 2015 to 2019, followed by individual consultation meetings with 11 members of the public and representatives from over 15 relevant organisations between 2020 and 2021. This created a firm foundation for the co-development phase of this study, which involved a further 36 participants with either lived or professional experience. Lay engagement continued with regular meetings of the patient and public involvement (PPI) panel during the 24 months of the study and continued engagement with 7 relevant local organisations. This study was developed in a grass-roots manner, by and for people with lived experience, and was embedded locally into community, healthcare and social care networks.

The emphasis on public perspectives continued with the evaluation of public acceptability of the intervention through qualitative customer interviews and the public survey. The use of a mixed-methods approach of both qualitative interviews and a quantitative survey with free-text qualitative comments provided robust triangulation.

Similarly, the evaluation of the intervention's feasibility used a mixed-methods approach of quantitative data from the cases, alongside the qualitative staff focus groups and a mix of qualitative and quantitative evaluation in the multi-stakeholder feasibility workshop.

Limitations

The major limitation of the study was that only 4 of the 24 people who were identified as experiencing DA and/or SI were recruited to the study as participants, and therefore, the full data set was only collected for these 4 clients. The information about the other 20 cases and of the 33 interactions with customers about lower-level issues are based on the reflections of staff about their own experiences of applying their learning, as was captured in the qualitative elements of the study. However, this difficulty with recruiting and consenting participants and collecting data, despite clients being willing to be assisted, reveals important findings about the unfiltered, unscheduled, in the moment, opportunistic and less formal healthcare interactions that occur in community pharmacy.

Related to this, another key limitation is that data are only available about the implementation of the intervention and feasibility of a future trial rather than there being any data to support the effectiveness of the intervention. Further, the data on service usage are based on a relatively small number of cases (n = 24) over a 6-month period. Along with it not being feasible for pharmacy staff in this study to collect EQ-5D data that would have assessed the quality of life (QoL), this has made it extremely difficult to make clear plans for a future economic evaluation. This will need to be revisited once approaches to collecting data of sufficient quantity and relevance have been identified.

A further limitation was the lack of ethnic diversity among participants. However, the ethnicity of participants did reflect the ethnic make-up of Lincolnshire, which is predominantly White British and White Eastern European. Further development work would be needed to explore the needs of different ethnic communities and geographical areas in relation to a response service. Similarly, because all pharmacies were recruited from the same pharmacy organisation, further work would need to be done on the feasibility of a service in different pharmacy organisations.

Take-home messages

- There is support from the public, people with lived experience, pharmacy staff and relevant community, healthcare and social care organisations, for a community pharmacy response service for people experiencing SI and/or DA. It is relevant to include both issues because these often co-occur and because of the similarity of barriers to accessing care. Such a service needs to be underpinned by the principles of safety, empathy, empowerment, equity and discretion.
- Community pharmacies are widely perceived to be accessible due to their nearby location, neutral environment, drop-in and drop-out (i.e. leave) as required service and staff being trained healthcare professionals with a friendly and approachable nature.
- It is feasible to train pharmacy staff to effectively identify and assist people experiencing SI and/or DA. The pharmacy staff can be from all patient-facing roles, for example, counter assistants, dispensers, technicians and pharmacists. The response service is feasible as a staff-initiated response service in a community pharmacy, providing that there is fidelity to the pharmacy specification checklist (see *Appendix 1*) to ensure a safe and high-quality service.
- There is a strong appetite from the public, people with lived experience, pharmacy staff and relevant community, healthcare and social care organisations for a community pharmacy response service for people experiencing DA and/or SI that is directly advertised to the public as a client-initiated service. The intervention is not yet ready to be delivered in this way because further work is required to develop more explicit yet still discreet promotional materials, implement a more extensive marketing strategy and ensure that staffing capacity and consultation room availability can meet demand for the service. Ongoing monitoring of the capacity of services to which clients would be referred or signposted is also essential to avoid clients being refused support.

Reflections on the project, key challenges and what could have been done differently

Many aspects of the study were very successful. There was a groundswell of support from the pharmacy community, local referral organisations, the wider healthcare community and people with lived experience. There was a genuine sense of goodwill and commitment to work together to reach out to people who are in danger. The dedication and enthusiasm demonstrated by the 'Lifeguards' pharmacy staff was inspirational. The PPI panel named themselves 'The Insight Panel' and were invaluable in grounding the research team in public priorities and concerns.

This has been an initiative that has touched hearts and minds. Although the study has ended, the training has left a legacy with the pharmacy staff. When asked what will change when the project ends, one staff member stated his intention to carry on using the skills he learnt.

> *You wouldn't lose anything because you'd still continue because you'd have those valuable skills to help people in the future, whether unofficially or officially, wouldn't you, really. You wouldn't not help anybody so I think it would carry on.*

There was a wealth of informal positive feedback. The staff received thank you e-mails and comments from clients who had been supported. However, capturing this positive reaction as research data was challenging. The two main challenges were that pharmacy staff found the client recruitment process cumbersome and at odds with the flow of pharmacy activities and that the marketing was not sufficiently effective.

A longer intervention period of 12 months, rather than 6 months, would have allowed changes to be made to the protocol, with ethics and research governance approval of amendments, to simplify the data collection and client recruitment process. A facility for clients to give verbal consent or much simpler digital consent would have been preferable. A longer intervention period would also have enabled changes to be made to the promotional materials

and for a more sustained marketing campaign. Some of the challenges around marketing were the difficulties in balancing the emphasis on discretion that was communicated by co-development participants – particularly women who had survived DA – and the subsequent issue of members of the public not understanding what the Lifeguard Pharmacy service was for, because the materials were too opaque. It is important to reflect on the disconnect between the priorities and preferences of the co-development participants – despite involving a diverse and sizeable sample (n = 36) with varied experience – and what resonates, or not, with the wider population. This was not because co-development participants were unrepresentative of the wider population. However, because they self-selected due to their interest in these issues, often took part in multiple data collection events and became very invested in the journey of co-developing Lifeguard Pharmacy, they potentially were less able to view the intervention components and materials from an outsider's perspective.

During the course of the customer interviews, the research team developed a clearer poster that was considered to be suitable and easier to understand by the customers that were interviewed (see *Appendix 3*, *Figure 6*). Arrangements were made for a version of this new poster to be printed as an advert in a free magazine that is distributed to all households in Lincolnshire. However, the organisation which produced this considered the new poster to be triggering, and therefore it was not used. This presents a marketing conundrum; how can you let people know about the service without causing any distress? DA and SI are incredibly difficult issues to talk about, and the purpose of the intervention was to facilitate an accessible way to receive help. As our PPI members attested, people experiencing these issues become trapped and suffer in silence because it is too difficult and upsetting to others to talk about. At a project management level, there was an initial setback with difficulties in recruiting a suitable postdoctoral research associate. The successful candidate finally joined the research team in May 2022, 8 months after the start of the study. The time frames of the study were also put under pressure by needing to submit an amendment to research ethics after the co-development phase

Changes to data collection

An amendment to ethics was submitted after the co-development phase in November 2022. This detailed the changes that had been made to simplify the data collection requirements and from client participants to comply with the company's safeguarding requirements, to reduce the data from the pharmacy business, to add enhanced requirements for pharmacy staff training and to add demographic data collection to the customer interviews.

The changes were:

- removal of EQ-5D measures for client participants
- amendment to the nature of business data collected (removed business income, staff satisfaction survey and number of days of staff sickness)
- removed question about whether consultation was for them or somebody else
- changes to the question about which services the client had considered accessing to which ones they have accessed
- added collection of client's personal details and GP contact details to comply with the company's safeguarding polices; amendment to data storage arrangements accordingly, with personal identifiable data being kept in a separate locked cabinet to non-identifiable data
- training changes – added mock consultations and given option of online training instead of face to face (3 × 2 hours online or 6 × in-person – plus mock for a SI and a DA consultation for all in situ in their pharmacy)
- the addition of the Pharmacy Operating Manual with revised triage tool
- addition of collecting demographics in customer interviews (gender, age and ethnicity)
- amendments to the protocol, data collection sheets, participant information sheets and participant consent forms to reflect all the above.

No other changes were made. A training update was sent to staff participants after 1 month of the intervention to clarify that SI includes both passive and active suicidality and that DA includes abuse by any household member, not just partners.

Individual training and capacity-strengthening activities

JS-T was leading a National Institute for Health and Care Research (NIHR) grant for the first time and received mentorship from other co-applicants, in particular, MG.

The study also built capacity in PPI, developing RB's skills and experience in leading PPI and MK's experience as a public co-applicant. Most of the Lifeguard Insight Panel (LIP) members were new to PPI, and capacity-building activities included training on what PPI members can offer and on feasibility studies. The majority of the LIP members expressed an interest to contribute to further studies.

Institutional capacity strengthening

This was the first practice-based research grant that the School of Pharmacy at the University of Lincoln had hosted and the first NIHR grant for the College of Science. Several students worked on the project as student interns,

which gave them valuable real-world research experience and an insight into pharmacy services.

Patient and public involvement

Aim

The aim of this project's PPI was to ensure voices of people with relevant lived experience would steer the project, ensuring public relevance and accessibility.

Methods

As part of extensive pre-award PPI and public engagement work carried out, a lay co-applicant, MK, joined the team to input between stages 1 and 2. MK brought a breadth of relevant lived experience to the project. He was an integral part of the team, attending team and steering group meetings, being a conduit between these mechanisms and the LIP.

The LIP was the project's wider PPI group, with seven members (plus MK). Members had diverse protected characteristics and were recruited because of their relevant experience, including that in mental ill health, SI and/or DA either personally or in their personal networks. Project PPI lead and joint lead investigator, RB, co-ordinated Insight Panel meetings. An independent lay member of the study steering committee was recruited. All PPI members were paid at NIHR rates. They received induction into the PPI members' role and more specific training, for example, on what a feasibility study is.

The LIP met bi-monthly on 10 occasions, including in-person attendance at the feasibility workshop. Meetings included project updates with opportunities to ask questions and give feedback and more focused input into aspects, including the intervention name and logo, Lifeguard intervention protocol and training and dissemination strategies. Follow-up tasks elicited more detailed feedback from members after time for reflection. Additionally, one PPI member attended the Lifeguard training and fed back to the panel.

Results of patient and public involvement input

The LIP inputted into the intervention components' development, including a Lifeguard Person Specification, emphasising the importance of empathy, listening skills and being motivated to help others. They advocated for counter and dispensing staff to be eligible to become Lifeguards, which was implemented, and has subsequently been praised as an intervention strength. They had recommended that prescription delivery drivers should be trained as Lifeguards, but because of safety issues associated with interacting with people in their homes, this was not pursued. However, it remains a future consideration for people unable to attend the pharmacy in person.

The research team initially intended that Lifeguard Pharmacy would be a purely client-initiated service, but the Insight Panel cautioned against this, drawing on lived experience of supporting people in distress who would lack the confidence to ask for help. They advised that Lifeguards should be trained to recognise signs of distress and initiate conversations. This was subsequently reflected in the intervention protocol and training, and was a critical decision, as almost all Lifeguard consultations were staff-initiated. They also suggested including a buddy system for peer support in the Lifeguards' support package, which was implemented.

Lifeguard Insight Panel members also inputted into the dissemination strategy, suggesting a range of different communication channels and advising on how to produce 'bitesize' and accessible outputs for different audiences.

Discussion and conclusions

Patient and public involvement input has been central throughout this study, informing the decisions made at each step: research design, intervention development and implementation and dissemination. The co-development phase enabled public voices to shape intervention development as research participants. PPI has been holistic, tracking the project from pre awardto completion.

Patient and public involvement has been a motivational and encouraging presence for the research team, with PPI members being strongly invested and sharing passion for the project. The breadth of lived experience in the LIP has been a strength, enabling members to offer input from a variety of experiential, geographical and demographic perspectives.

Reflections and critical perspectives

Patient and public involvement delivered many meaningful and tangible impacts in this study; however, sometimes PPI members made sensible and public-centred suggestions and comments, but these could not be taken up, either due to resources, the complex networks of stakeholders or governance frameworks. For example, when Lifeguards were finding it difficult to gain client's informed consent, the PPI suggested collecting consent retrospectively, asking clients to visit a consent website after leaving the pharmacy or simplifying to use verbal consent. However, these suggestions would have required a Health Research Authority ethics amendment, which was not feasible in the time available. This highlights the importance of managing PPI members' expectations about the extent to which

their suggestions can consistently be taken on board to avoid them feeling undervalued.

Equality, diversity and inclusion

Demographic trends in domestic abuse victimisation and suicidal ideation

Inclusion has been a central concern for this research project, the long-term ambition of which is to increase the accessibility of support for people who are experiencing DA and/or SI.

Neither DA nor suicide is evenly distributed in the population. Women are more frequently victims/survivors of DA, and one-third of female homicide victims are killed by a current or former partner compared to 4% of male homicide victims.[38] Yet, 1 in 10 men have experienced partner abuse since the age of 16 years,[39] and rates of DA are markedly higher among lesbian, gay and bisexual people.[40] There are also particular barriers to help-seeking for other underserved groups such as disabled people, migrants and people of faith. Suicide is disproportionately responsible for the premature deaths of men, particularly 45- to 64-year-olds.[41] Other groups report disproportionately higher rates of SI such as lesbian, gay, bisexual and transgender (LGBT+)[42] and autistic[43] people. Socioeconomic deprivation also increases the risk of both DA and SI.[44]

Some of these sociodemographic risk factors for DA and suicide were presented in the training for Lifeguards, with consideration of intersectionality, but we also emphasised that anyone could experience either of these issues. Inclusive language was critical, and the training cautioned against making assumptions (e.g. not to assume the use of male pronouns when talking to a woman about her abuser).

Approach to research inclusion

The 12 community pharmacies that took part in the feasibility trial were purposively selected to include a mixture of geography (e.g. urban, suburban and rural) and levels of socioeconomic deprivation. Ethnic diversity is limited in Lincolnshire as white people are over-represented compared to the average England and Wales population. However, there is a large White Eastern European population.

Accessibility needs such as dyslexia informed the design of promotional materials, and participant information sheets and consent forms were translated into the most spoken languages in Lincolnshire. Where possible, there has been a choice of online and face-to-face formats for data collection activities and training for the Lifeguards to maximise accessibility. While the community survey was online, student interns also delivered this in the vicinity of intervention pharmacies as an interviewer-administered survey, using iPads, to minimise the impacts of digital exclusion.

Equality, diversity and inclusion data collection and the participation of underserved groups

There were challenges to collecting protected characteristic data for participants. Firstly, ethical approval did not allow us to collect protected characteristic data of the Lifeguard staff delivering the intervention. However, based on observation, the majority were women and White British, which reflects the demographics of community pharmacy staff and Lincolnshire, which is much less ethnically diverse than the average England and Wales population (For example: Census 2021 – Boston is 94.7% white compared to 81.7% in England and Wales population Ethnic group – Census Maps, ONS). Secondly, written consent and full data sets were obtained for only 4 out of the 24 clients who used the Lifeguard Pharmacy service. These four were all women. The details of the remaining 20 client cases were based on the reflections of pharmacy staff from the qualitative elements. Based on these accounts, most clients assisted were White British women, and 25% of clients assisted were known to be receiving opioid substitution treatment, which is an important underserved population.

Equality, diversity and inclusion data were collected during the process evaluation for customer interviews and the community survey (n = 501). Gender balance was achieved, but people from minoritised ethnic groups, including White Eastern European people, are under-represented.

The biases towards women clients and towards the White British population in all the research components have impacted on the generalisability of the findings. Further research is needed to assess whether different forms of service delivery would be required to meet the needs of different ethnic groups as well as men and younger people.

Reflections on research team and wider involvement

The research team included investigators and research staff with a range of protected characteristics with regard to sex, race and ethnicity, disability and sexual orientation.

The LIP spanned a broad age range (from early 20s to 70s), was gender-balanced, included some ethnic and religious diversity members and disabled and LGBT+ members.

The study steering group was predominantly comprised of women and included a range of academics and public representatives. The majority of members belonged

to minoritised ethnic groups, including a Polish public member based in Lincolnshire.

Impact and learning

Overall impact

Following training, staff reported feeling more confident, able and motivated to identify and assist people who are experiencing DA and/or SI. A strength of the study is that it includes a wide range of job roles within community pharmacy, contributing to building the capacity of non-pharmacists to both delivering public health interventions and taking part in research.

Involvement in feasibility-testing the Lifeguard Pharmacy service has also helped intervention pharmacies to become connected to a broader range of local services. Previously, staff referred patients to the GP, the mental health crisis team or to social care, but they were not aware of the local services, for example, mental health crisis cafes or DA organisations.

This intervention identified the importance of certain quality and safety criteria being in place and the provision of specified minimum staffing levels. This indicates that, if implemented more widely, Lifeguard Pharmacy should not be rolled out universally but should be delivered only by pharmacies that meet the given criteria.

The rationale for the study was to provide a more accessible route for people in danger to access help and support. The findings showed that pharmacies are perceived to be more accessible from both a practical and psychological perspective. This lays a foundation for the development of a formalised response service that has the potential to enable people to access help, who would not otherwise access it, and for people to access help sooner, thus minimising harm and potentially reducing fatalities.

Accessibility

This study provided evidence that people consider pharmacies to be more accessible than other services because they are drop-in, open long hours, provide a neutral, more discreet environment, there is less taboo, staff are friendly and they have trained healthcare professionals. There was overwhelming support from all stages of the study for a response service in a community pharmacy setting for both DA and SI. In addition, 24 cases of SI and/or DA were proactively identified by the pharmacy staff. This supports the hypothesis that community pharmacy is perceived to have advantages in terms of both practical and psychological accessibility.

It is noteworthy that, in four cases, the clients were in a hurry, or needed to leave because their partner was waiting. This indicates that pharmacy is an accessible setting because of the drop-out nature as well as drop-in. There are very few services that you can just walk out of. Three of these were for DA, and it was known that the person waiting was the abusive partner.

Despite this perception of improved accessibility, pharmacy staff noted that there could be reluctance from people at three stages of encounter: the initial making contact, the move into a more formalised consultation in the consultation room and then agreeing to onward referral. Together with the findings that staff found it either difficult or inappropriate to consent clients, and that it is known that four clients explicitly stated that they did not wish to provide any personal details, there is further work to be done to build trust and encourage uptake of onward support.

From the four cases that were fully consented and for whom full data were obtained, all agreed to give their personal details. In terms of a future study and whether they would be hypothetically willing to be followed up, one participant said she would definitely be unwilling and three were unsure. This supports the view that following up clients would not currently be feasible.

All participants reported that their visit was opportunistic rather than planned. Reasons for using a pharmacy service included familiarity with staff (two participants); rapport with staff; it being a walk-in, no appointment-needed service (two participants); it being a familiar environment and in-person service. These findings support the accessibility of community pharmacy.

Addressing unmet need

As to whether the improved accessibility was able to reach people who would be unlikely to access other services, it could be argued that the 20 cases in which the full consent process was not able to be operationalised, would not make their need known to other services given their reluctance in this setting. For the four cases with the full data set, DA was involved in all four cases, but none of these clients had previously accessed any DA services in the last 3 months. One had accessed mental health services and one had accessed the drugs and alcohol service. This suggests that a pharmacy-based service may have potential in identifying clients

experiencing DA, who would not otherwise access support for DA. In addition, pharmacy staff used their training and the referral directory to support 33 other pharmacy customers with lower-level issues (e.g. loneliness and bereavement), again indicating the opportunity, through the Lifeguard Pharmacy service, to meet needs which could otherwise go unmet.

Preventing escalation

The consultation guide used three levels of severity and urgency: assistance, action and alert. From the four cases, one was categorised as being at 'action' level for DA, one at 'action' for DA and SI, one at 'assistance' for DA and one at 'assistance' for DA and SI. Therefore, all four of these were not at a crisis level of needing to call emergency services.

Pharmacy staff referred the four cases to a variety of services from the referral directory; namely, DA services (n = 2), GP (n = 2), drugs and alcohol service (n = 1), the crisis team (n = 1) and other charity support services (n = 2). One of the clients was referred to four relevant services. This shows that staff used the resources provided to tailor referrals and signposting to clients' individual needs. Providing support at lower levels of severity has the potential to prevent escalation. However, it was beyond the scope of this study to follow up clients to see whether they were subsequently supported by these services and to track changes in their outcomes.

Preventing harm

Out of the total 24 cases, 1 DA case was at alert level, and there were 9 overall cases at action level, 6 at assistance level and the level was not recorded for 7 of the cases. The one case at alert level demonstrates that it is feasible for this service to identify and intervene with people who are at immediate risk of harm.

Additional benefits

This study has strengthened collaborations and partnerships between the University, the pharmacy organisation and the referral organisations. This has improved pathways for supporting students with medicine-related issues who present at Student Well-being and enhanced teaching of pharmacy students by guest lectures from pharmacy staff.

A key part of the study was the creation of a website that provided the public with details of the service, how to access it and listed support organisations for SI and DA, including translations in Polish and Lithuanian. In total, 1607 users visited the website, with a total of 3121 views during the intervention period. It is therefore clear that the website was used extensively.

The future: real-world impact and future work

Meetings have been held with local commissioning organisations about next steps. Funding has been obtained for two of the original pharmacies and a third new pharmacy to provide a staff-initiated response service across geographical areas that are known to have high suicide rates, for 6 months. This will be hosted by the Local Pharmaceutical Committee who will host the website and manage the referral directory. The staff training, accreditation of sites, support visits and provision of a facility for emotional support will be provided by the University.

This 6-month service evaluation will provide further information on the uptake and costings and will provide a foundation for a longer-term model and plans for scalability and service expansion to different pharmacy organisations and a wider, more diverse population. This study has laid the groundwork for developing a commissioned service to support populations in line with the vision for community pharmacy.[45] We suggest that a suitable not-for-profit organisation would be required to host the training delivery and monitoring of Lifeguard accreditation.

Networks have been established with researchers, in the UK and internationally, who are working on suicide prevention or DA services in pharmacies. The research team presented at two conferences[46,47] and an article aimed at the pharmacy profession was published.[48] A summary of this study will be disseminated through these networks and a round-table meeting is planned for key policy stakeholders in this area in the UK.

Implications for decision-makers

Community pharmacy is currently facing significant challenges and also new opportunities. The NHS Long-term Plan envisages a future where patients receive more options, better support and properly joined-up care at the right time in the optimal care setting.[49] To achieve this vision, Integrated Care Systems (ICSs) have been developed. ICSs were formalised following the passage of the 2022 Health and Care Act, growing out of informal partnerships developed since 2016 between Clinical Commissioning Groups, providers across healthcare and social care and voluntary sector organisations. There are 42 ICSs across the UK which aim to provide more joined-up care across health systems, tackling health inequalities, improving patient outcomes and enhancing productivity and value for money within the healthcare system, supporting broader social and economic development within the NHS.[50]

Since 1 April 2023, ICSs have taken on delegated responsibility for commissioning pharmacy, general ophthalmic and dental services from NHS England,[51] meaning all four pillars of primary care – general practice, pharmacy, optometry and dentistry – can now be supported at a local/regional level.

Services such as Lifeguard Pharmacy could help to facilitate the integration of community pharmacy into healthcare and social care networks as an integral part of primary care. This aligns with the three essential offers outlined in the Fuller Stocktake report: streamlining access to care and advice for people, ensuring care is always available in their community when they need it; providing more proactive, personalised care with support from a multi-disciplinary team of professionals; helping people to stay well for longer.[52] This intervention provides a unique opportunity to maximise the services available within pharmacies while contributing towards the sustainability of the sector.

The community pharmacy government budget for England has remained static since 2017–8 with no increase to cover the inflationary pressures they face, resulting in many recent high-profile closures/sales of community pharmacies.[53–55] Between 2015–6 and 2017–8, the budget reduced from £2.8 B to £2.592 B.[56,57] Since 2017, pharmacies have taken on delivery of many new services, while the global sum has remained static in value, representing a 35% decrease in real terms in the budget, when the National Living Wage alone has risen over 60% from £6.50 per hour in 2015 to £10.42 per hour.[58] The government's announcement of £645 million over 2 years for community pharmacy in England is positive, with these monies contributing towards IT improvements, expansion of hypertension case finding and contraceptive services in community pharmacies as well as the new Pharmacy First service.[59]

The latest estimates in the pharmacy sector from the Community Chemists' Association suggests that annual funding falls £750 M short of meeting current needs. The Association argues that this money represents less than half of the necessary funding to ensure stability in the sector.[60] A regular payment for availability of trained support such as the Lifeguard Pharmacy intervention could help maintain a sustainable community pharmacy network.

Through interventions such as Lifeguard Pharmacy, community pharmacy has the potential to build links with other NHS and third-sector services as part of a multiagency response to DA and SI. The data collected from pharmacy staff of all levels in the focus groups highlighted their strong commitment and enthusiasm towards being a Lifeguard. Investing in the community pharmacy workforce by training counter staff, dispensers, technicians and pharmacists to develop appropriate skills and confidence in responding to people in danger and distress increased staff capability and appeared to increase staff morale at a time when morale and staff well-being in the community pharmacy sector are worryingly low.[61]

In the longer term, the opportunity for staff to develop these more specialist skills and roles could contribute to staff job satisfaction and retention. However, there is also a human cost to delivering interventions which deal with very sensitive issues. Any future commissioning of Lifeguard Pharmacy or similar services should include measures to protect staff well-being, including access to a counsellor to debrief.

With these points in mind, we offer the following recommendations:

1. *Recognise the potential of community pharmacy to contribute to multiagency responses to DA and SI.*

Policy-makers in health care, social care and crime and justice are yet to fully capitalise on the contribution that community pharmacy can make as part of a wider multi-agency response to DA and SI. This research found that pharmacy staff who participated in the study and received the intervention training were eager to take on 'Lifeguard' roles and quickly came to see this as a critical part of their role. In the 6-month intervention period, 24 customers experiencing DA and/or SI were identified by trained pharmacy staff, substantially more than in control pharmacies. Pharmacy staff highlighted the personal and professional benefits of taking on this new role and receiving training that increased their confidence to ask pertinent questions to customers in distress. Although the effectiveness of the intervention is yet to be evaluated, pharmacy customers and the wider public were supportive of this intervention being delivered in community pharmacy, highlighting the accessibility and discreet nature of this setting.

2. *When commissioning and monitoring services that respond to the complex issues of DA and/or SI ensure that these services are adequately resourced and maintain high quality and safety standards.*

The co-development phase emphasised the importance of carefully assessing pharmacies to ensure that they have the motivation, capacity and facilities to deliver a safe and high-quality response service for DA and/or SI (see *Pharmacy specification checklist*, *Appendix 1*). We

therefore envisage that Lifeguard Pharmacy – if found to be effective – would not be a service that all pharmacies would deliver, and there would be risks to quality, safety and fidelity if it was introduced as a compulsory part of the pharmacy contract.

Commissioning, monitoring and management of a response service such as Lifeguard Pharmacy would need to ensure that the service is adequately and flexibly resourced, including at times when competing priorities such as flu vaccinations will stretch capacity and place demands on consultation room space. This is particularly pertinent, given the strain that community pharmacy is currently experiencing. However, given this context of financial pressures, a service such as Lifeguard Pharmacy, if appropriately resourced, could promote the financial sustainability of community pharmacy while also having the potential to deliver value for money.

3. *Ensure that mechanisms are in place to ensure the emotional debriefing and well-being of community pharmacy staff who support customers with distressing issues*.

One of the 'best practice' features of the Lifeguard Pharmacy intervention was the opportunity for pharmacy staff delivering the intervention to debrief with a counsellor; this was incorporated into the project budget and staff were regularly reminded of this opportunity. Pharmacy staff who participated in focus groups commended this aspect of the support for staff even though few actually took up this opportunity. Similarly, staff were very positive about the availability of a buddying scheme which linked them to trained Lifeguards in other intervention pharmacies. Staff also reflected on their own strategies for self-care, such as taking a 5-minute break between holding a Lifeguard consultation and returning to their other duties. To maintain a healthy and productive workforce and deliver a safe and high-quality DA and SI response service, these support provisions should be included in the service specification for Lifeguard Pharmacy or similar services tackling sensitive or distressing issues.

Research recommendations

It was originally envisaged that this co-development and feasibility study would lay a foundation for a future randomised controlled trial. However, this study found that it was not possible to randomise pharmacies and there were significant limitations in terms of consenting client participants and collecting data from them. This limits the potential for a future randomised controlled trial. An alternative option could be a stepped-wedge trial, in which all pharmacies start out as control pharmacies and later switch to the intervention group.

It was challenging to consent clients accessing the service due to the consent process and paperwork being cumbersome and not keeping in with the pace and nature of interactions in community pharmacy. A future trial would need to identify alternatives such as verbal or digital consent.

Additionally, the outcome measures would need to be reconsidered to be data that staff can measure, for example, the number of referrals to the respective referral organisations rather than details about the actual clients. Data collection from referral organisations (e.g. by including pharmacies as a referral source for new clients/service users) could also be explored. Plans for a health economic evaluation using a SROI approach also need to be solidified.

There is a need for further methodological research to develop a good practice guidance for obtaining research consent and collecting data during rapid or drop-in interventions that are time-pressured and/or from people in distress. With an intervention focusing on DA and/or SI, safety considerations and sensitivity to clients' emotional needs were major imperatives. However, to understand and potentially increase the benefits which Lifeguard Pharmacy may offer, data of a sufficiently high quantity and quality are required. There may be relevant lessons from research in similarly sensitive and high-pressured environments, such as emergency medicine and ambulance care interventions, mental health crisis services (including anonymous telephone, text and online services).

From a wider perspective, this study has raised important questions that would benefit from further research.

Research into the support needs of women coping with addiction

It is notable that the majority of clients assisted by this service were women and that a quarter of the 24 clients assisted were known to be under the care of the drugs and alcohol service. While this may indicate that the study was limited by not accommodating a wider diversity of demographics, it does highlight that there is a population of vulnerable women who are experiencing DA and/or SI and coping with addiction. For them, pharmacies are an important place of contact and safety. A female participant with lived experience in the co-development phase gave a harrowing account of the extent of coercive control,

addiction and exploitation that she had experienced. She said that the pharmacy was the only place she could legitimately go alone and that had anybody in the pharmacy asked her about either DA or SI she would have asked for help.

The original motivation to undertake this research came from JS-T's public engagement research on DA and child safeguarding.[62,63] Focus group participants with lived experience all said that it was too difficult to approach the major services, and they advised that there should be the facility of a drop-in service in an everyday trusted place. The subsequent public and patient engagement for this study confirmed pharmacies as being such a place, and for women, pharmacies were considered to be a place they could legitimately go to alone to obtain sanitary products or contraception without the scrutiny of a male partner. Further research is required into how women coping with addiction access support and what role the community pharmacy can play. This is relevant, given the very frequent contact which some substance users have with pharmacies, particularly when receiving methadone substitution therapy.

The potential extended scope of Lifeguard Pharmacy and the role of community pharmacy in responding to other support needs

The focus of this study was to co-develop and test the feasibility of pharmacy-based response service for DA and/or SI. However, a major theme that emerged from the feasibility testing was that the need identified was not limited to DA and/or SI. Notably, pharmacy staff spontaneously used their learning and resources from the training to intervene and assist in at least 33 other interactions with customers on other related issues, outside of the 24 cases that could be categorised as DA and/or SI. These other interactions included other mental health issues, being bereaved by suicide, bereavement in general and social issues. This broader scope was also supported by feasibility workshop participants. There is scope for community pharmacies to provide wider well-being support and signposting, capitalising on their knowledge of their local community and the relationships that they have with customers, and to become a well-being hub that can signpost to charity and voluntary community services as well as traditional health and social care services for a wide variety of issues. Further research is needed to understand how community pharmacy might respond to other needs, what sort of partnership-working would be required and what implications the expansion of Lifeguard Pharmacy would have on client demand and, relatedly, staff capacity.

Conclusions

This study co-developed and tested the feasibility of a community pharmacy-based response service for people in danger from DA and/or SI.

The findings confirmed community pharmacy as a suitable setting for a response service that addressed both DA and SI. Community pharmacy offers a highly geographically accessible service, with no need for an appointment which allows access to care to be client-led, at the time and place of their choosing. Accessibility is further enhanced by the nature of pharmacies as an everyday, neutral environment. There was also widespread support for the Lifeguard Pharmacy name and logo. Most cases were identified opportunistically in the normal course of other pharmacy services, and 30 minutes was considered to be the average time needed for a consultation. The 24 clients assisted were at different levels of severity and urgency, thereby offering early intervention, potential to prevent escalation as well as crisis intervention. It is noted that around one-quarter of the 24 cases were in people known to be under the care of drugs and alcohol service, which suggests that pharmacies are particularly effective at reaching this population.

It was found that patient-facing pharmacy staff of all types can proactively identify, intervene and assist people experiencing DA and/or SI if: they have been trained for this role; have a consultation guide with a referral tool that is embedded into local referral pathways; have client support resources and have access to staff support and emotional debrief. However, offering a response service requires sufficient pharmacy capacity, both in terms of the availability of appropriately trained staff and consultation room availability. This underlines the need for specific quality criteria and a potential future accreditation process.

It was also found that staff spontaneously used their learning and client support resources for over 33 other interactions for related issues, such as other mental health or social issues. This offers an important source of safety-netting and support for people who may have risk factors for DA/SI and suggests there may be merit in exploring a remit for community pharmacy to address a wider range of mental health and social well-being needs.

There was strong public acceptability and support for a response service that was advertised directly to the public for DA and/or SI. However, the marketing material developed by people with lived experience was considered to be too discreet and not sufficiently self-explanatory to the public. Despite extensive marketing in the vicinity of

each pharmacy, there was a lack of awareness in local communities about the service.

For this reason, a direct to the public, client-initiated service is not recommended at this time until a satisfactory tone of marketing material is achieved (i.e. discreet enough not to alert abusers or be too triggering or alarming but is sufficiently self-explanatory for people to know what the service is for). In addition, a client-initiated service requires a commitment to maintain sufficient staffing levels of trained staff over all the pharmacy's opening hours.

In terms of the feasibility of conducting a future randomised controlled trial, several issues would need to be addressed. In this study, it was not possible to randomise pharmacies; staff either really wanted to participate or not based on the motivation of the staff team and the perception of local need. Furthermore, it was challenging, but not impossible, to gain written client consent to be in the study and to collect demographic data. Further implementation research is required in geographical areas with greater ethnic diversity and in different pharmacy organisations.

Additional information

CRediT contribution statement

Josie Solomon-Taylor (https://orcid.org/0000-0003-1022-5759): Conceptualisation (lead), Formal analysis (supporting), Funding acquisition (lead), Investigation (equal), Methodology (lead), Project administration (lead), Resources (lead), Supervision (lead), Visualisation (equal), Writing – original draft (lead), Writing – reviewing and editing (lead).

Rebecca Barnes (https://orcid.org/0000-0002-8085-9936): Formal analysis (supporting), Investigation (equal), Methodology (supporting), Project administration (supporting), Resources (supporting), Supervision (supporting), Visualisation (equal), Writing – original draft (supporting), Writing – reviewing and editing (supporting).

Ana Maria Barcelos (https://orcid.org/0000-0003-2727-5058): Data curation, Formal analysis (lead), Investigation (equal), Methodology (supporting), Project administration (supporting), Resources (supporting), Visualisation (equal), Writing – original draft (supporting), Writing – original draft (supporting), Writing – reviewing and editing (supporting).

Tracey Latham-Green (https://orcid.org/0000-0001-7104-0884): Project administration (supporting), Resources (supporting), Writing – original draft (supporting), Writing – reviewing and editing (supporting).

Peter Knapp (https://orcid.org/0000-0001-5904-8699): Funding acquisition (supporting), Methodology (supporting), Writing – reviewing and editing (supporting).

Graham Law (https://orcid.org/0000-0001-7904-0264): Formal analysis (supporting), Funding acquisition (supporting), Methodology (supporting), Writing – reviewing and editing (supporting).

Claire Henderson (https://orcid.org/0000-0002-6998-5659): Funding acquisition (supporting), Writing – reviewing and editing (supporting).

Hayley Gorton (https://orcid.org/0000-0001-5017-9174): Methodology (supporting), Writing – review & editing (supporting).

Mahomed Khatri (https://orcid.org/0000-0003-3444-8770): Methodology (supporting), Writing – reviewing and editing (supporting).

Darrin Baines (https://orcid.org/0000-0001-9502-4678): Funding acquisition (supporting), Methodology (supporting), Writing – reviewing and editing (supporting).

Mark Gussy (https://orcid.org/0000-0002-5010-6407): Funding acquisition (supporting), Methodology (supporting), Writing – reviewing and editing (supporting).

Other contributions

Josie Solomon-Taylor (https://orcid.org/0000-0003-1022-5759): PPI contributions (supporting).

Rebecca Barnes (https://orcid.org/0000-0002-8085-9936): PPI contributions (lead).

Mahomed Khatri (https://orcid.org/0000-0003-3444-8770): PPI contributions (supporting).

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Data-sharing statement

Due to the sensitive and confidential nature of the qualitative data and business and feasibility data used in this study, it cannot be shared. Any queries or requests for access to anonymised questionnaire data from the customer survey can be made via e-mail to Professor Josie Solomon, j.e.solomon@sheffield.ac.uk.

Ethics statement

Research ethics approval was received on 4 May 2022 from the Health Research Authority: NW, Preston Committee (22/NW/0016/AM01).

Information governance statement

The University of Lincoln is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Lincoln is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: https://secretariat.blogs.lincoln.ac.uk/data-protection-information-compliance/.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/SSWW9994.

Primary conflicts of interest: Hayley Gorton: Co-Chair of the International Association for Suicide Prevention special interest group for Suicide Prevention in Primary Care. The authors declare that there are no other conflicts of interest.

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This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by the interviewees in this publication are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health and Social Care Delivery Research programme or the Department of Health and Social Care.

This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

Research paper submissions

Barcelos AB, Latham-Green T, Barnes R, Gorton H, Gussy M, Henderson C, *et al.* Lifeguard Pharmacy: the co-development of a new community pharmacy response service for people in danger from domestic abuse or suicidal ideation. *Int J Pharm Pract* 2024;**32**:452–60. https://doi.org/10.1093/ijpp/riae043

Solomon J, Barcelos A, Barnes R, Gorton H, Latham-Green T, Knapp P, *et al.* Lifeguard Pharmacy – a feasibility trial of a novel pharmacy-based intervention for people experiencing domestic abuse and/or suicidal ideation. 2024 Mar 27, PREPRINT (Version 1) available at Research Square. https://doi.org/10.21203/rs.3.rs-4077284/v1 (Resubmission under review.)

Solomon J, Gorton H, Barcelos A, Latham-Green T, Williams S, Rowan E, *et al.* A mixed-methods cross-sectional study to evaluate the public acceptability of a novel pharmacy-based response service for domestic abuse and/or suicidal ideation. *Res Soc Admin Pharm* 2024;**20**:969–77. https://doi.org/10.1016/j.sapharm.2024.07.002

Conferences

Society for Social Medicine and Population Health (SSM). 67th Annual Scientific Meeting, Newcastle, September 2023. Abstract ranked in the top 10 for the conference.

Barnes R. *Co-developing, and Testing the Feasibility of, a First-response Service in Community Pharmacy for People Experiencing Suicidal Thoughts or Domestic Abuse: The Lifeguard Pharmacy Intervention*. In Society for Social Medicine and Population Health (SSM) 67th Annual Scientific Meeting, Newcastle, 2023;**8**:e750. https://doi.org/10.1016/S2468-2667(23)00223-2

International Association for Suicide Prevention, Piran, Slovenia, September 2023.

Solomon J, Barcelos A. *Lifeguard Pharmacy – The Co-development of a New Suicide Prevention Response Service in UK Community Pharmacies*. In International Association for Suicide Prevention Abstract Book, Piran, Slovenia, 19–23 September 2023. p. 127. URL: www.iasp.info/wp-content/uploads/IASP-32nd-World-Congress-Abstract-Book-2023.pdf (accessed 21 January 2025).

Other seminars

Presentation to the Suicide Awareness Steering Group of Lincolnshire County Council, December 2023.

Presentation to Lincolnshire Coop staff event, November 2023.

Presentation to Lincolnshire Mental Health and Well-being Partnerships Group, January 2024.

Study registration

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This synopsis provided an overview of the research award *Responding to people in danger. A development and feasibility study to co-develop a community pharmacy response service for domestic abuse and suicidal ideation*. For other articles from this thread and for more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR133132).

About this synopsis

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Copyright

Glossary

Cases The instances of clients experiencing domestic abuse and/or suicidal ideation, which were assisted.

Client Refers to somebody accessing the service.

Customer Refers to a person using the pharmacy.

EuroQol-5 Dimensions A questionnaire that is commonly used to measure people's quality of life.

List of abbreviations

A&E	accident and emergency
CPD	continuing professional development
DA	domestic abuse
ED	emergency department
EQ-5D	EuroQol-5 Dimensions
GP	general practitioner
HSS	health and social service
ICS	Integrated Care System
LIP	Lifeguard Insight Panel
NIHR	National Institute for Health and Care Research
PI	principal investigator
PICO	population, intervention, control/comparison, outcome
PPI	patient and public involvement
QoL	quality of life
SI	suicidal ideation
SIA	social impact assessment
SROI	Social Return on Investment

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Appendix 1 Outline of the intervention

The scope and resources for the intervention were designed in the co-development phase. This included the name and logo (*Appendix 1*, *Figure 3*), marketing strategy, training package, staff support package, consultation guide, referral resources, client flow chart and a pharmacy specification checklist.

Staff participants engaged in 6 hours of facilitator-led training, were required to complete 4 hours of self-directed study (which included the pharmacy organisation's normal safeguarding, DA and suicide prevention training) and then undertake two mock consultations in their pharmacy (one for DA and one for SI). Upon successful completion of all the training components, they received a certificate and Lifeguard badge.

Each intervention pharmacy was required to display a Lifeguard poster (*Appendix 1*, *Figure 4*) in the store window and on the door and not to display any Lifeguard posters inside the store.

Lifeguard cue cards, which were business size cards with the logo and website details on, were placed immediately by the door and at till points. For the client-initiated service, customers could request a consultation by showing a cue card at the counter, by showing the logo on their phone from the website or by asking for assistance. For the staff-initiated service, staff would use their training to identify signs of distress and offer a private conversation in the consultation room. Staff would then follow the 'client flow chart' to make arrangements for the consultation and take care of the client while waiting.

A trained member of staff 'a Lifeguard' would then conduct the consultation in the consultation room using the consultation guide. Referral pathways had been set up with the main relevant referral organisations locally. Colour-coded A5 support cards were supplied with details of the relevant signposting and referral organisations: one for DA services (green card), one for SI services (purple) and one for safeguarding services (yellow card). Staff used these with clients to identify the relevant organisations and signpost and refer. All clients were offered a relevant DA and/or SI support card to take away with them, or a business card-sized discreet QR code version (with no mention of DA, SI or Lifeguard on it) that linked to the support cards on the project website (*Appendix 1*, *Figure 5*). Staff also had an extensive directory of local and national service and access to a 24/7 helpline for professionals.

Staff had a monthly site visit from one of the researchers for support and to check adherence to the pharmacy specification checklist.

Pharmacy specification checklist

Each pharmacy operating the Lifeguard service must have the following in place:

- Appropriate indemnity insurance that covers the scope of the service.
- Consultation room that complies with the Equality Act 2010 as being accessible and sound-proof.
- The consultation room should be private. It should not be possible to see inside the room from the shop floor. The room must be kept clear of potentially dangerous objects at all times. Any confidential data in there must be securely locked away (e.g. a locked filing cabinet or on a password-protected computer). There must also be access to a phone and internet in the consultation room.

FIGURE 3 Lifeguard Pharmacy logo.

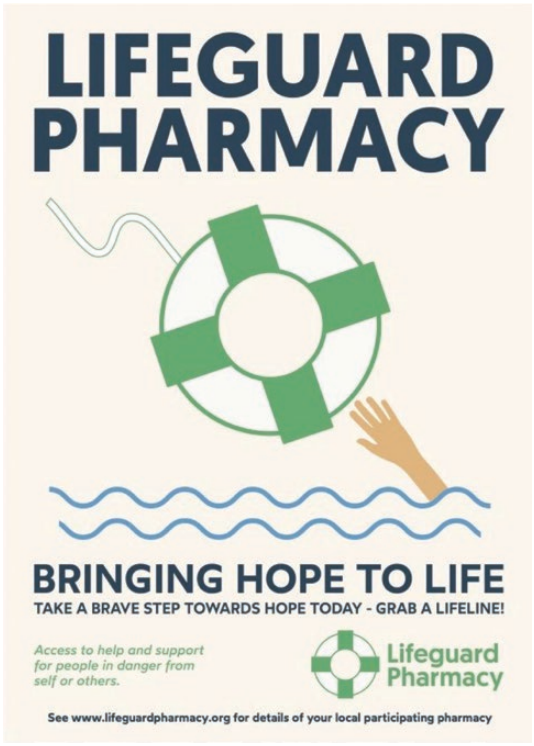

FIGURE 4 Poster to promote the Lifeguard Pharmacy intervention.

FIGURE 5 Image of discreet QR code cards to access specialist support.

- Security system fitted with a panic alarm that can be triggered from the consultation room if required and a protocol for responding to security alerts.
- Chaperone policy and a poster in the consultation room about this policy.
- Two lockable cabinets or drawer to store the client data (one for patient-identifiable data and one for non-patient-identifiable data).
- A signed agreement between the pharmacy organisation and the University of Lincoln.
- A regular pharmacist (not run solely on short-term locums).
- A minimum of three members of staff that are Lifeguard-trained (more in larger stores). One of these members of staff should be a pharmacist and the others can include technicians, dispensers or counter assistance. The rest of the staff should also be supportive. In addition, it is beneficial to have a balance of genders in the selection of the trained staff and the ability to speak any additional languages that are relevant to the local community would be an advantage. In the selection of staff to be trained as Pharmacy Lifeguards, we are looking for a natural ability to relate to others in an empathetic, sensitive and non-judgmental manner in addition to demonstrating an enthusiasm for delivering the service.
- Confirmation from your superintendent pharmacist that your pharmacy has sufficient capacity and consultation room availability to be able to run the service.
- A policy that all customers who attend for supervised consumption of methadone or other substance misuse medicines must be provided with this separately, not as couples. Supervising clients alone provides them with an opportunity to speak up safely if there are problems. Any sort of substance misuse (drugs or alcohol) heightens the danger from both DA and suicidal feelings.
- A prescription hand-out policy that allows customers to follow their prescription without needing to say their name and address out loud. They can show ID with their address on it instead to verify their identity. You can ask for their date of birth but not for their address outloud. This is because, anybody in safe housing is potentially put at risk if their address is shared within earshot of others.

In terms of support, staff were offered a confidential 30-minute debrief session with a psychotherapist once a month if required. They were also paired with a 'Lifeguard buddy' from another store for peer support.

All the above were detailed in the comprehensive 'Pharmacy Operating Manual' along with details of the study requirements of how to recruit and consent clients, record and store data, plus copies of participant information sheets, consent forms (with translations) and data collection sheets. *Table 6* outlines the key components of the Lifeguard Pharmacy intervention, as decided through the co-development phase, and maps how these were operationalised in the Pharmacy Operating Manual.

TABLE 6 Pharmacy Operating Manual components

Key components of the Lifeguard Pharmacy intervention	Corresponding items in the Pharmacy Operating Manual
Community pharmacy setting	Pharmacy specification checklist
The triage and referral package	Consultation guide, support cards for clients, QR code discreet versions of the client support cards, support materials on website, referral directory for staff
Trained staff members ('Lifeguards')	Selection criteria to become a 'Lifeguard' and meeting minimum thresholds for staffing capacity to deliver the intervention (detailed in *Pharmacy specification checklist*)
Consultation room as a safe space	Criteria for both the layout and availability of the consultation room (included in *Pharmacy specification checklist*)
The education and training package for staff	Specification of prerequisite training, plus 6 hours of facilitator training and successful completion of 2 × mock consultations (1 for SI and 1 for DA) in own pharmacy. Upon successful completion, staff are awarded a certificate and a Lifeguard badge. Training materials were developed and provided in manual
The mentoring support for staff	Specification of provision of bookable optional emotional support sessions with a psychotherapist, emergency phone number to contact research team, staff paired up as 'support buddies' and staff provided with details of support organisations
The name of the service as a symbol or code for discreet access	Name of 'Lifeguard Pharmacy' with green and white life-ring logo, with strapline 'Bringing Hope to Life' Cue card – business card-sized card with life-ring logo and website address Detailed client flow chart showing how clients should be greeted, consultation arrangements made and then how to guide clients as they leave the pharmacy
The promotional strategy	Full version and brief version of Lifeguard Pharmacy posters, specification about where posters should be displayed and where not to display

Appendix 2 Abstract of co-development phase

Aim

To co-develop a community pharmacy response service for people experiencing DA and/or SI.

Material and methods

Overall, 36 individuals contributed to focus groups, interviews and/or a series of workshops to co-develop the service components. Participants had lived experience of DA/SI or were professionals from DA/SI support services or pharmacies. Audio recordings and field notes from events were thematically analysed using Framework Analysis. Specific themes were generated for each of the service components (e.g. marketing and staff training).

Key findings

Participants supported the development of this new service and considered community pharmacies to be an ideal setting. They perceived the service as an opportunity for people experiencing DA and/or SI to find hope to by making a connection with pharmacy staff. Under the main concept of hope, five main overarching themes were identified: Safety, Empathy, Empowerment, Equity and Discretion, which were used to underpin the service components. Participants' practical considerations were also incorporated within the service design, including the name choice of 'Lifeguard Pharmacy'.

Overall, the findings supported the development and introduction of this pharmacy-based intervention, which may help overcome barriers to help-seeking for DA or SI due to its human-centred approach, sense of hope, accessibility and discretion.

Limitations

Extensive consultation and co-development were conducted, but the majority of participants were White British. This lack of diversity is partly due to the lack of diversity within the region. Further research is required on the views of people with lived experience from a greater diversity of ethnicities.

Inter-relationship with other parts of the award

The components of the service were developed during this co-development phase. A Pharmacy Operating Manual was created, which contained all the specifications and resources for the service intervention (detailed in *Appendix 1*). The intervention was then implemented into eight intervention pharmacies and tested for feasibility in the second phase of the study.

Appendix 3 Abstract of public acceptability interviews and survey

Aim

To assess public acceptability of a novel response service in community pharmacy for people in danger from DA and/or SI.

Material and methods

Data collection consisted of an open public survey running for 6 weeks gaining 501 responses and 12 qualitative interviews with pharmacy customers. Descriptive statistics were used to present the survey results and interviews were analysed using the Framework Analysis method and NVivo 11 (QSR International, Warrington, UK).

Key findings

Although the survey showed service awareness was low, the majority of respondents supported the service within community pharmacies, believing it to be ethically appropriate, noting they would recommend such a service to friends or relatives and use it themselves if needed.

Findings from the pharmacy customer interviews indicated that the original poster designed in the co-development phase (see *Appendix 1*, *Figure 4*) was ambiguous and too discreet. This led to the research team swiftly designing a more explicit poster (see *Appendix 3*, *Figure 6*).

There is strong public support for a defined, responsive service in community pharmacies covering both SI and DA.

The findings support the development of a tiered approach in which only pharmacies meeting specified criteria are accredited to offer a response service, where appropriate training and support are provided to pharmacy staff.

Limitations

The questionnaire used for the survey had been developed specifically for this study. Because this was not a validated tool, it was not possible to produce a power calculation, which limits the interpretation of the statistical findings for this survey. The customers who were interviewed were all regular customers of the intervention pharmacies and, as such, they provide valuable insight into those pharmacies. However, there was a bias towards recruiting customers who had a positive relationship with staff. Although both the survey and interviews have limitations, the use of both provides triangulation and increases the robustness of this evaluation of public acceptability.

Inter-relationship with other parts of the award

The evaluation of public acceptability was a stand-alone component that was conducted parallel to the feasibility testing of the intervention. It informed the feasibility findings by identifying that the marketing of the service had not been adequate and therefore there was limited awareness of the service. However, it also identified the strong positive service for a response service for DA and/or SI in community pharmacies, which provides impetus to invest in further development of the service and finding solutions to the marketing difficulties that were identified.

FIGURE 6 Revised poster, developed in response to customer interview findings.

Appendix 4 Abstract of feasibility phase

Aim

To evaluate the feasibility of a community pharmacy-based response service for people experiencing DA and/or SI.

Material and methods

Twelve pharmacies were recruited from a single pharmacy organisation, randomised into 8 intervention pharmacies and 4 controls. Thirty-seven pharmacy staff were recruited as participants and were trained to deliver the intervention, which involved providing a consultation and structured referral or signposting to those identified as experiencing DA and/or SI. Participants' learning from the training was evaluated using the validated CPD-Reaction questionnaire, with data analysed via an independent paired *t*-test using SPSS (Statistical Product and Service Solutions, SPSS Inc., Chicago, IL, USA) version 28.0

The intervention ran from January to July 2023 and was accompanied by a nested process evaluation consisting of staff focus groups (n = 27) and two multi-stakeholder final evaluation workshops with a mix of lay, pharmacy staff and representatives from referral organisations (n = 44). Data were collected on the number and category of client contacts from intervention and control pharmacies. The focus groups were conducted using a topic guide, were audio-recorded, transcribed verbatim and analysed thematically. Data from the workshop were collected on individual participant data collection sheets and were analysed using a mix of thematic analysis and descriptive statistics.

Key findings

Compared to before the training, afterwards, staff showed statistically significant improvements in their levels of perceived ability, ease and confidence in responding to and referring people in need of help for SI and DA, with increased confidence in the ability of other pharmacy staff to support DA and SI (*Appendix 4*, *Table 7*).

Twenty-four cases of support were identified in intervention pharmacies. Out of the total cases, eight were for SI, nine for DA and seven were for both DA and SI. Twenty-two were staff-initiated and two were client-initiated. Two cases (1 × SI and 1 × DA) were encountered in control pharmacies. *Appendix 4*, *Table 8* provides further detail about the cases, including the triage assessment for each category, the sex of clients and whether there were co-occurring drug or alcohol issues.

Staff participants had a positive perception of the service and its impact on them and their clients, with staff feeling empowered through their experience as a Lifeguard. The multistakeholder workshop findings confirmed the feasibility of a staff-initiated response service for both DA and SI in a community pharmacy setting.

It is feasible to implement a staff-initiated response service for DA and/or SI in pharmacies. The combination of staff training, consultation guide, referral tool and client support resources empowered staff to proactively identify people experiencing DA and/or SI.

Limitations

Although staff participant recruitment and the implementation of the intervention went well, challenges were experienced in gaining written consent from clients who were assisted. This was because, most cases of DA and/or SI were identified opportunistically by staff rather than clients specifically asking for help with these issues. This meant that explaining about the study and asking for consent seemed counter to the flow of the interaction. Consequently, the data collected about clients were very limited.

No data about client outcomes were collected, and further work is needed to determine how to collect the outcomes data and follow up clients up in a way that is safe and acceptable. However, the staff focus groups yielded rich data about the staff's experience of using their learning from the training.

All the participating pharmacies were from the same pharmacy organisation that simplified the approval process and implementation of the intervention. However, this limits the generalisability of the findings to other pharmacy organisations with different systems and organisational cultures.

Inter-relationship with other parts of the award

This feasibility phase was the main substance of the project, with the co-development phase laying the foundation for this phase and the public acceptability phase running parallel to the feasibility phase and informing it.

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TABLE 7 Pharmacy staff responses to CPD-Reaction questionnaire

CPD-Reaction questionnaire questions for DA/SI			Mean score before	Mean score after	*t*-test score	SD	Paired *t*-test, two-sided *p*-value
Q1	I intend to effectively respond and refer (where appropriate) people in danger of DA)/SI: *1 = strongly disagree, 7 = strongly agree*	DA	6.6	6.5	0.357	1.221	0.724
		SI	6.2	6.2	0.09	2.306	0.929
Q2	To the best of my knowledge, the percentage of my colleagues who effectively respond and refer (where appropriate) people in danger of DA/SI is: *0–20, 21–40, 41–60, 61–80, 81–100*	DA	3.2	4	−2.795	1.327	**0.011**
		SI	3.1	3.7	−2.03	1.438	0.055
Q3	I am confident that I could effectively respond and refer (where appropriate) people in danger of DA/SI if I wanted to: *1 = strongly disagree, 7 = strongly agree*	DA	4.9	6	−2.643	2.064	**0.016**
		SI	4.9	6.1	−2.921	1.999	**0.008**
Q4	Effectively responding and referring (where appropriate) people in danger of DA/SI is the ethical thing to do: *1 = strongly disagree, 7 = strongly agree*	DA	6.3	6.5	−0.429	1.526	0.673
		SI	6.4	6.4	0	1.931	1.00
Q5	For me, effectively responding and referring (where appropriate) people in danger of DA/SI would be: *1 = extremely difficult, 7 = extremely easy*	DA	3.9	5	−4.6	1.091	**0.001**
		SI	3.9	5	−3.861	1.296	**0.001**
Q6	Now think about a coworker whom you respect as a professional. In your opinion, does he/she effectively respond and refer (where appropriate) people in danger of DA/SI? *1 = never, 7 = always*	DA	5.1	6	−2.795	1.327	**0.011**
		SI	5	5.5	−1.358	1.996	0.188
Q7	I plan to effectively respond and refer (where appropriate) people in danger of DA : *1 = strongly disagree, 7 = strongly agree*	DA	6.6	6.4	0.548	1.195	0.59
		SI	6.3	6.4	−0.245	1.703	0.809
Q8	Overall, I think that for me, effectively respond and refer (where appropriate) people in danger of DA/SI would be: *1 = useless, 7 = useful*	DA	6.6	6.6	−0.326	0.669	0.748
		SI	6.6	6.7	−0.196	1.065	0.847
Q9	Most people who are important to me in my profession effectively respond and refer (where appropriate) people in danger of DA/SI: *1 = strongly disagree, 7 = strongly agree*	DA	5.5	6.1	−3.081	0.921	**0.006**
		SI	5.7	6.2	−2.206	0.945	**0.038**
Q10	It is acceptable to effectively respond and refer (where appropriate) people in danger of DA/SI: *1 = strongly disagree, 7 = strongly agree*	DA	6.4	6.5	−0.288	1.513	0.776
		SI	6.5	6.5	0	1.243	1.00
Q11	I have the ability to effectively respond and refer (where appropriate) people in danger of DA/SI: *1 = strongly disagree, 7 = strongly agree*	DA	4.7	5.9	−2.891	1.887	**0.009**
		SI	5.1	6	−2.201	1.800	**0.039**
Q12	Overall, I think that for me effectively referring/responding to (where appropriate) people in danger of DA/SI would be: *1 = harmful, 7 = beneficial*	DA	6.4	6.7	−2.092	0.730	**0.049**
		SI	6.5	6.7	−1.283	0.650	0.213

SD, standard deviation.
Note: Figures in bold are statistically significant at the level of $p < 0.05$.

TABLE 8 Breakdown of cases

	Number of cases collated from staff reports	Number of cases with complete data set	Total number of cases
SI – assistance	3	0	3
SI – action	4	0	4
SI – alert	0	0	0
SI – category not known	1	0	1
Total SI	**8** Male × 3, female × 4, not known × 1 1 case known to involve drugs or alcohol	0 N/A	**8** Male × 3, female × 4, not known × 1 1 case known to involve drugs or alcohol
DA – assistance	1	1	2
DA – action	2	1	3
DA – alert	1	0	1
DA – category not known	3	0	3
Total DA	**7** All female 4 cases known to involve drugs or alcohol	**2** All female No cases known to involve drugs or alcohol	**9** All female 4 cases known to involve drugs or alcohol
Both SI and DA – assistance	1	1	2
Both SI and DA – action	1	1	2
Both SI and DA – alert	0	0	0
Both SI and DA – category not known	3	0	3
Total for both SI and DA	**5** All female No cases known to involve drugs or alcohol	**2** All female 1 case known to involve drugs or alcohol	**7** All female 1 case known to involve drugs or alcohol
TOTAL	**20** Male × 3, female × 16, not known × 1 5 cases known to involve drugs or alcohol	**4** All female and White British 1 case known to involve drugs or alcohol Ages: 25–34 years old × 1, 55–64 years old × 2, over 65 × 1.	**24** Male × 3, female × 20, not known × 1 6 cases known to involve drugs or alcohol

This synopsis should be referenced as follows: Solomon-Taylor J, Barnes R, Barcelos AM, Latham-Green T, Knapp P, Law G, *et al.* Responding to people in danger: a community pharmacy response service for domestic abuse and suicidal ideation, a development and feasibility study. *Health Soc Care Deliv Res* 2026;**14**(13):1–46. https://doi.org/10.3310/SSWW9994

Appendix 5 Rationale and explanation of cost categories

Cost categories for the pharmacy organisation

Staffing

In this feasibility study, there were 24 cases in 6 months across 8 intervention pharmacies, which would suggest a relatively low number of cases per pharmacy per month. However, the cases were not spread evenly across pharmacies. Three pharmacies did not have any cases, one pharmacy had one case, two had 4 cases and one pharmacy had 11 cases. The level of local demand should be considered in the planning of staff capacity for the anticipated demand. In terms of time per consultation, the consensus from the staff focus groups was that 30 minutes would be ideal. The actual time taken was recorded for three of the consented cases. Two of the consultations took between 15 and 30 minutes and one took between 30 and 60 minutes. This supports the view that an average of 30 minutes would be required per consultation.

A key finding of this study was that patient-facing staff of different role types successfully engaged in the training and conducted consultations (see *Table 2*). This means that in contrast to many other pharmacy services, this role does not need to be done by a pharmacist. This has benefits for the cost of staffing and may also provide greater stability, as non-pharmacists may be more likely to work in the same pharmacy for a longer period, that is, less transient than pharmacists.

It was found that the implementation of the Lifeguard Pharmacy intervention worked best in pharmacies which had a strong staff team led by a Lifeguard-trained pharmacist who was permanently based at that pharmacy, where the non-Lifeguard staff were supportive. In this study, relief pharmacists were trained to provide cover for the regular pharmacist, the area managers received an induction and the superintendent pharmacist was trained and fully supportive.

The levels of staffing required would depend on whether the service was provided as an advertisement to the public, client-initiated service or as an opportunistic staff-initiated response service only. The staffing requirements for a client-initiated service are more onerous, as you would need to guarantee that if a client presented themselves at any time during the pharmacy's opening hours, there would be sufficient staff for the person to be initially served at the counter without waiting more than a few minutes. The findings from the people with lived experience showed that it is a huge psychological step to take to reach out for help. Therefore, it could be damaging if a person summoned up the courage to access the service and then was left waiting or turned away. The Pharmacy Operating Manual for this study advised staff member at the counter to keep a watch on any clients who had been asked to wait for up to 10 minutes while arrangements were made for their consultation.

If the service was provided as an opportunistic staff response service, there would be a requirement to have sufficient levels of trained Lifeguard staff to be able to respond to clients, who they suspect to be experiencing SI and/or DA, and enough general staff capacity for them to be able to cover for Lifeguard staff while they were conducting consultations.

There is a start-up cost of paying for staff time to complete the training. Given that the training required 8 hours of contact time, and 4 hours of self-study (of which 2 hours were the usual company SI, DA and Safeguarding training), this is a considerable investment for a pharmacy company.

Consultation room availability and criteria

A safe and accessible consultation room, with sufficient availability is essential. Since, this is a talking service rather than a clinical examination service, a private interview room may be acceptable. The room should be private and sound-proof. It should not be possible to see inside the room from the shop floor. The room should be kept clear of any potentially dangerous objects at all times. Any confidential data in there should be securely locked away (e.g. a locked filing cabinet or on a password-protected computer). There must also be access to a phone and internet in the room. There should be an emergency panic button that alerts staff members outside the room and a protocol for responding to security alerts. Additional costs include indemnity insurance for the service and the provision of suitable IT equipment in the consultation room to record client data. The loss of earning due to keeping sufficient consultation room availability is an important consideration.

Opportunity costs or gains

Public trust

Part of the feasibility involved consideration of the impact of the intervention on normal pharmacy activities. The interviews with regular customers indicated that the intervention did not have any effect on their normal customer experience, other than enhancing the already positive perception they had of the pharmacy staff.

The general sentiment was that knowing that staff had taken on this worthwhile role made the staff seem more professional. Therefore, customers were more likely to be loyal to that pharmacy. The public survey found that 75% of respondents were in favour of the service, with only 9% not in favour. The others were neutral.

It was also noted in the co-development phase that four of the main five referral organisations responded favourably to being supplied with the details of the Lifeguard pharmacies (the fifth type of organisation was the GP practices that already had good connections). They valued having trustworthy pharmacies that were known to be caring and competent in mental health and safeguarding. Those organisations said that they would be likely to make connections with those pharmacies about patient issues (e.g. discharge medications). The intervention pharmacies also valued having a list of key local services and named contacts, so it became a two-way connection.

Loss of earnings

A safe and accessible consultation room with sufficient availability is essential. There must be access to a phone and internet in the room and there should be an emergency panic button that alerts staff members outside the room. Additional costs include indemnity insurance for the service and the provision of suitable IT equipment in the consultation room to record client data. The loss of earning due to keeping sufficient consultation room availability is an important consideration.

The numbers of prescription items dispensed and service items conducted per month for each of the pharmacies during the 6-month intervention period were collected and compared with the equivalent data from the year before. These data are publicly available at Dispensing contractors' data on the NHS Business Services Authority's webpage.[64] The number of prescription items in intervention pharmacies increased by a mean of 4.85% from the year before, and there was an equivalent 7.78% increase in control pharmacies' prescription items numbers. Intervention pharmacies showed a mean 36.39% decrease in service items compared to a 40.55% decrease in control pharmacies. It is not possible to make any causal inferences from these data, but it can be noted that it is feasible to collect prescription item and service item data as an indication of general pharmacy activities that could potentially be affected by the intervention.

Costs incurred by pharmacy

This study provided 8 hours of training per staff member, which included the completion of two mock consultations and checking that they have met the requirements for the self-directed study. The training in this study was live, facilitator-led training and the mock consultations were done in situ in the staff member's pharmacy with a member of the research team. The training was shown to be highly effective and motivating. There are questions as to whether this model of training is scalable, but there would be concerns that the effectiveness of the training may be compromised if it became non-facilitator-led or reduced in content and time. It could be detrimental to both client and staff safety to compromise on the quality of the training.

In terms of accreditation costs, the pharmacy's premises would need to be accredited based on affirmation that the pharmacy meets the criteria for staffing and quality criteria.

The provision and regular review of service resources would include the website, keeping the referral directory up-to-date, the support cards and the consultation guide. If the service was available as a client-initiated service that was advertised directly to the public, there would be additional costs of marketing and provision of the cue cards. The marketing used in this feasibility study was not sufficiently effective. Further development work is required.

The feasibility study found that emotional debrief with an appropriately trained professional (e.g. a psychotherapist) was required on five occasions and support from the research lead was required on three occasions.

Many pharmacy services are paid on a fee on a per item basis, but the vision for this service, inherent in the choice of metaphor 'Lifeguard', is the principle of being paid for being on duty and for having a pharmacy that meets specified quality criteria in place rather than being paid per 'save'.

Human capital gains: saving the lives

Assessing the relative costs and opportunities of taking on this additional Lifeguard role is complex. However, it was noted by the pharmacy staff in the staff focus groups that they encounter clients in crisis anyhow, and it is less stressful and quicker after being trained and having a consultation guide and referral resources to hand. This situation was witnessed by the principal investigator (PI) who was on a site visit to a pharmacy when a patient phoned the pharmacy and expressed her intentions to take her life immediately with a clear plan. The PI observed the staff using the consultation guide and their skills from the training to reassure the patient, calm the situation and successfully refer her to the Crisis Mental Health

service with her consent. The patient then e-mailed the staff later to express her thanks to them for saving her life. This case had the potential to disrupt the entire activity of the pharmacy, but the staff responded calmly and in a problem-solving manner. They commented that they would not have been able to do this without the training.

Appendix 6 Future economic evaluation considerations

Objective

Within the overall project aim of co-developing and evaluating the feasibility of a community pharmacy response intervention for people in danger from DA or SI, the objective of the economic component was to evaluate the potential for the intervention to be scaled up for a future trial, including economic and statistical considerations. In particular, the feasibility study was designed to determine whether a cost-effectiveness, cost–consequences or cost–benefit study would be most appropriate in this context.[65] The following questions guided this work: (1) Can cost and outcome data be successfully collected? (2) Can a viable model be built that produces robust data for an economic study? (3) Can an appropriate form of evaluation study be performed using robust methods? (4) Does the economic modelling align with the objectives of the clinical study? (5) Can results be presented in a way useful to NHS decision-makers and can accompanying uncertainty analysis be performed?

Background

The economic analysis of the DA and SI community pharmacy intervention requires an evaluation of both the costs and benefits of providing support to clients. The avoidance of significant events (such as injury and death) reduces health and social service (HSS) costs and also increases the client's QoL while minimising harm and deaths. The structure of the intervention means that there are training costs, followed by resources used at each site to provide services. The cost of the intervention itself is predictable because it is based upon a planned amount of resources expended on staff and materials. For instance, one pharmacy may employ one staff member to provide services.

In addition to intervention costs, there are HSSs costs.[66] For instance, a victim of domestic violence may use hospital services after an episode of abuse, while a successful intervention may reduce harm and service costs. Clients at greater risk of harm will probably have the greatest potential to generate improvements in well-being and reductions in potential resource use. The economic analysis is based upon the assumption that cost savings may be made by the intervention compared with normal Standard of Care.[67]

Outcome measurement

Because the trial was a feasibility study, the appropriateness of using QoL measures (such as the EQ-5D) was evaluated.[68] However, this was not able to be used as intended because pharmacy managers and staff felt that it would be inappropriate and unfeasible to administer this type of instrument for practical (time) and ethical (dealing with clients in distress) reasons. Further work is needed to ascertain and better understand the barriers to collecting EQ-5D data and to see if these can be overcome. For example, it is possible that lack of familiarity with administering such outcome measures made it feel overly burdensome, but this could potentially be overcome with training.

Costs and perspectives

Economic analysis not only considers the direct costs of an intervention but also considers other resources used by clients while they are receiving care.[69] For instance, a client may make an A&E visit while receiving services from the project. Therefore, a decision must be made on which costs and benefits to include in an economic analysis. Formally, this is specified in terms of choosing an economic perspective. For instance, HSS and societal perspectives could be appropriate for future modelling studies. If future studies wish to measure the direct cost to HSSs only, then a HSS perspective should be adopted. However, as we discuss below, this approach may be too narrow for complex and enduring issues such as SI and DA.

Heterogeneity

If patients are divided into subgroups on this basis, then the benefits they derive from the intervention, potential benefits (and cost savings) are likely to be greater for higher risk patients.[70] Clients were triaged according to risk and need from Assistance (lowest), to Action, to Alert (highest). In terms of funding implications, this implies that the service should be focused on more severe clients in the Alert group because they offer the greatest gains in

welfare improvements and cost reductions. Because when predicting how many people will escalate from Assistance to Action to Alert, there is merit in offering a service for clients at lower levels of risk. This is because the benefits that accrue over time are likely to outweigh the initial intervention cost.

Because SI and DA are not one-off events, clients in these groups often experience an escalation of event occurrence and severity over time. Therefore, early intervention can be successful in reducing a long series of damaging events that are costly to service providers. From an economic point of view, there is clearly a case for early intervention with less severe people because this will prevent escalations and reduce clinical risk. Given the difficulties in predicting pathways of harm and the positive benefits that may accrue, evidence suggests that funding patients in all groups makes economic sense.

Earlier Markov models: suicide studies

Our feasibility work included the development of the principles that could underpin a Markov model for future economic modelling. A literature search was performed to identify published suicide studies that use Markov model structures in their analysis. The key studies found during the pragmatic search are summarised below:

1. Comans *et al.* performed a cost-effectiveness study of a community-based crisis intervention programme for people bereaved by suicide, which aimed to ameliorate distress and reduce future incidences of suicide.[71] The authors constructed a Markov model based on a theory of grieving. The five states of the model are: (1) acute grief, (2) normal bereavement, (3) complicated grief, (4) recovered state and (5) death.
2. Pil *et al.* evaluated the cost-effectiveness of a suicide helpline in Belgium using a Markov model with a 10-year time horizon.[72] The model includes six states: (1) the initial state (at risk), (2) first attempt, (3) reattempt, (4) follow-up, (5) suicide and (6) death from other causes.
3. Alam *et al.* introduced a cloud-based mental state monitoring system for suicide risk reconnaissance using wearable bio-sensors, which depends upon the successful prediction of mental states. The authors model the mental status of patients using a discrete set of states of hidden Markov model. The states are: (1) normal, (2) atypical and (3) suicidal.[73]
4. Yip *et al.* built a Markov chain model for studying suicide dynamics to illustrate the Rose theorem. Assuming a population with replacement, the suicide risk of the population was estimated by determining the final state of the Markov model. The model consists of four states: (1) healthy population, (2) population with mental illness considered to be at high risk, (3) death due to suicide and (4) death due to other causes (not suicide).[74]
5. Denchev *et al.* evaluated the cost-effectiveness of interventions to reduce suicide risk among hospital emergency department (ED) patients using a Markov state-transition model.[75] The model begins with initial ED presentation, followed by these states: (1) non-fatal suicide event (i.e. an attempt or a reattempt), (2) death by suicide, (3) death by other manner or (4) none of these.
6. Woodaman created a dynamic model of military suicide using a Markov model that partitions the population into states related to mental health and suicide risk and draws on two psychological theories: (1) the Combat and Operational Stress Continuum and (2) Thomas Joiner's Interpersonal Psychological Theory of Suicide.[76] The base model contains six states: (1) ready, (2) reacting, (3) ill, (4) ideating, (5) attempting and (6) suicide.
7. Lebenbaum *et al.* evaluated the cost-effectiveness of a suicide prevention campaign implemented in Ontario, Canada.[77] They used a Markov model with four states: (1) alive and no recent suicide attempt, (2) suicide attempt, (3) death by suicide and (4) death other than suicide.

Earlier Markov models: domestic violence studies

Our Google Scholar (Google Inc., Mountain View, CA, USA) search found that only three studies that used a Markov model to study domestic violence or abuse:

1. Juillard *et al.* studied a hospital-based violence intervention, which included victims of domestic violence.[78] They developed a Markov model with an initial state of violent injury, followed by three injury states of: (1) no more injury, (2) reinjury and (3) no-initial reinjury, as well as the absorbing states of (4) death and (5) healthy survival.
2. Norman *et al.* developed a Markov model to estimate the cost-effectiveness of education and support for primary care clinicians to increase their identification of survivors of intimate partner violence and to refer them to a specialist advocacy agency or a psychologist with specialist skills.[79] Their model includes states for: (1) no abuse, (2) abuse unidentified, (3)

psychologist/advocate, (4) disclosed not seeking intervention, (5) medium-term improvement and the absorbing state of (6) death.

3. Devine *et al.* modified the Markov model developed by Norman *et al.* The reduced model contains states for: (1) no abuse, (2) abuse unidentified, (3) advocacy, (4) identified existing victim and the absorbing state of (5) death.[80]

Recommended Markov structure

A Markov structure is recommended for future cost–utility modelling.[81] The common use of Markov models in economic, service delivery and risk studies of suicide prevention suggests that the framework is suitable for future use. The initial findings of the pragmatic literature review are:

1. A Markov structure is suitable for modelling interventions for suicide prevention.
2. A diversity of states is employed by different authors in their various models.
3. A Markov model with suicide-related states can be used for a cost-effectiveness study.

These findings suggest that appropriate health states must be found for future models. A proposed structure for a future model is outlined in *Appendix 6*, *Figure 7*. The initial cohort consists of patients identified in community pharmacy as in danger from SI or DA. Thereafter, individuals transition into three groups based upon their danger states: (1) active concern of DA, (2) active concern of SI and (3) immediate danger of suicide or harm. The transitions between states are represented by the solid arrows, and within-state transitions are represented by the dashed arrows. The model has three absorbing states of: (1) serious harm, (2) escape from DA or an immediate intervention and (3) suicide.

Pharmacy cost/profit model

When analysing the feasibility of an economic study, our main concern was whether any future economic analysis would be robust enough to provide NHS decision-makers with the information they need to assist commissioning. We also examined whether a cost/profit model for pharmacy providers could be constructed, which could be used to demonstrate the net benefits of providing the DA and SI services in a community pharmacy setting. The cost/profit model would be designed to take a pharmacy perspective and would consider the costs of hiring additional staff and running the service, including a sensitivity analysis for estimating the profitability for a range of cost and NHS fee scenarios. From our analysis of available data, we conclude that a cost/profit model could be built alongside the main economic model. The data on patient activity, costs of the service and costs to the pharmacy provider would all be readily available if a full trial was undertaken.

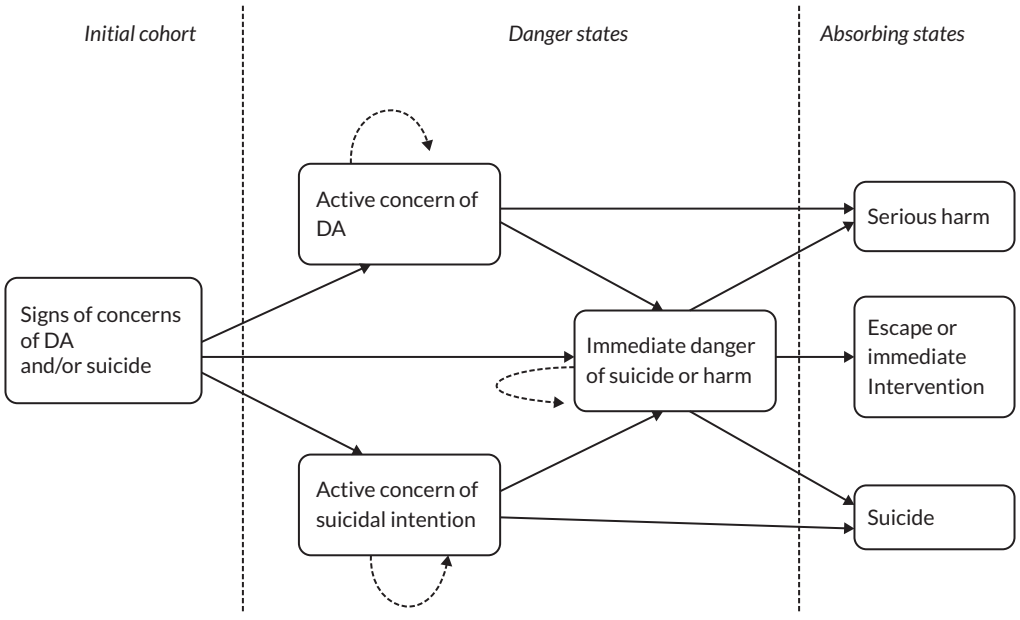

FIGURE 7 Proposed structure for future Markov model.

Social impact assessment frameworks

In contrast to very clinically focused approaches, SIA measures a change either over time because of an intervention or compares engagement with non-engagement.[82,83] The issue with 'proving prevention' is complex, as, in effect, you are attaching proxy values to the savings made because something was avoided, like a return to criminality, for example, in the case of the criminal justice system or the avoidance of attendance at A&E departments in the case of those with suicide ideation and/or victims of DA. In this study, the assistance given by the Lifeguards was wider than just for SI and DA, with the training enabling Lifeguards to spot signs of crisis for a diverse range of reasons, including bereavement, loneliness and social isolation, signposting individuals to relevant support groups and organisations, for which an assessment of savings to society in terms of their well-being can be estimated using SIA.

The use of frameworks to measure social impact is recommended[84] to enable comparability, with frameworks being used in diverse areas such as rural broadband[85] leisure centre impact,[86] the youth criminal justice sector[87] and canals and waterways impact.[88] It should be noted that organisations such as Refuge have used proxy values to calculate SROI for their organisation[89] and proxy values are available from sources such as the Social Value Portal[90] and the Unit Costs for Health and Social Care Report 2022.[91]

Approaches such as SROI are particularly suitable for issues such as SI and DA, which:

- tend to have a long trajectory between initial investment and economic benefit
- have wider reverberations on children, other family members, friends, neighbours, coworkers and wider communities
- involve many different NHS and non-NHS agencies, often over a long period of time (e.g. criminal justice agencies, charities, social services and employers).

For this reason, although it was not one of the approaches that we initially set out to explore, given the challenge of collecting QoL data and the recognition of the prolonged trajectory to economic benefit, we are favouring a SIA using Social Return in Investment for future work.

Conclusions

The conclusions of our work are:

- A SIA using SROI would be most appropriate to capture the NHS and non-NHS costs and cost savings, recognising the long-term trajectory to economic benefit for both DA and SI, and their wider familial and societal ripples. Because of the nature of the intervention, collecting costs and QoL data in a pharmacy setting with patients at risk from DA or SI may be challenging because of the burden and time required to collect such information. This possibility should not, however, be dismissed until further work is conducted to understand the barrier and assess whether and how they could be overcome.
- Following a review of previous pathway and economic studies, we propose that a Markov structure would be sufficient for future economic modelling (although other modelling types should be considered during the model conceptualisation phase). Unlike previous studies, we suggest that a 'hybrid' model should be constructed that incorporates both DA and SI disease states because this will give better face validity to any model built, incorporating an appropriate SIA framework proxy figures where appropriate.
- Given the structure of the intervention tested during the feasibility study, our experience suggests that any future economic modelling could readily align with the objectives of the clinical study. Moreover, the combination of clinical and economic results could be useful, if presented in the correct manner, to NHS decision-makers.

Overall, we conclude that a future economic analysis should adopt SROI but that further work is needed to determine which costs should be included and how to collect these data. Although this deviates from the preference of the National Institute for Health and Care Excellence [from 2013 – formerly from 2005 National Institute for Health and Clinical Excellence formerly the National Institute for Clinical Excellence] Reference case for cost–utility analysis, but this approach has been deemed unsuitable, given both the nature of both DA and SI and the challenges in collecting EQ-5D data during client consultations. The result of this analysis, if presented correctly, would be useful to NHS and public health decision-makers. Moreover, we did not identify any issues with the statistical analysis of the economic data beyond those normally experienced in economic evaluation studies. Therefore, we make no recommendations about statistical analysis except to follow standard analytical procedures.