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Collaborative design of a decision aid for stroke survivors: a qualitative study engaging patients, healthcare professionals, policy-makers and researchers

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ABSTRACT

Objectives: Effective secondary stroke prevention strategies are sub-optimally used, and hence, developing interventions to enable healthcare professionals and stroke survivors to manage risk factors for stroke recurrence more effectively are required. We sought to engage various stakeholders in the design and evaluation of an intervention that adopts a Learning Health System approach to improve risk factors management and secondary stroke prevention in primary care.

Design: Qualitative, including focus groups, semi-structured interviews and usability evaluations. Data was recorded, transcribed, and coded thematically.

Participants: Stroke survivors, carers, health and social care professionals, commissioners, policy-makers and researchers.

Setting: Stroke survivors and carers were recruited from the South London Stroke Register, health and social care professionals from South London practices, researchers, commissioners and policy-makers from King's College London networks.

Results: 53 stakeholders in total participated in focus groups, interviews and usability evaluations. Thirty-seven participated in focus groups and interviews, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy-makers (N=6) and researchers (N=4). Sixteen participated in usability evaluations, including stroke survivors (N=8) and general practitioners (GPs; N=8). Eight identified themes informed the collaborative design of DOTT (Deciding on Treatments Together), a decision aid integrated with the electronic health record system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor. DOTT aims to facilitate shared decision making on personalised treatments leading to improved treatment adherence and risk control. DOTT was found acceptable and usable to stroke survivors and GPs during a series of evaluations.

Conclusions: Adopting a user-centred data-driven design approach informed an intervention that is acceptable to users and has the potential to improve patient outcomes. A future feasibility study and subsequent clinical trial will provide evidence of the effectiveness of DOTT in reducing risk of stroke recurrence.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Engaging various stakeholders in the design of an intervention ensures that the intervention is in line with the needs reported by the different stakeholders (stoke survivors, healthcare professionals and policy-makers).
- Adopting a Learning Health System approach enables the delivery of personalised recommendations in real time while simultaneously capturing additional data back into the system, in order to improve the system's predictive model and recommendations.
- Only stroke survivors who were able to attend the focus groups could participate in the study, we did not elicit the views of stroke survivors who are less mobile or housebound.

INTRODUCTION

Stroke is the second leading cause of death and a major cause of disability worldwide.[1] In 2015, there were 3.7 million people living with stroke as a chronic condition in Europe and this number is expected to reach 4.6 million in 2035.[2] Stroke survivors have a nearly 40% cumulative risk of recurrence during the first 10 years after stroke.[3] Secondary stroke prevention requires healthcare professionals to offer appropriate and effective interventions to monitor and manage risk factors, and for patients to change health related behaviours (e.g., smoking)[4] and adhere to preventative medications (e.g., to control hypertension).[5] Follow-up appointments with clinicians offer opportunities to discuss interventions for reducing the risk of future stroke among patients with multimorbidity. However, long-term stroke care is characterised by a lack of continuity[6] and modifiable risk factors are currently not well detected, managed or controlled post stroke.[7]

Interventions designed to improve risk-factor management among stroke survivors in randomised controlled trials (RCTs) have shown modest or no effect. A recent Cochrane systematic review of 42 RCTs evaluating the effectiveness of educational and behavioural or organisational interventions on modifiable risk factor control for secondary prevention of stroke,[8] found no clear benefit in any of the target outcomes (i.e., blood pressure, lipid profile, HbA1c, BMI and recurrent cardiovascular events). Possible reasons could be that these interventions have not been part of the clinical decision-making process of clinicians, did not engage various stakeholders in the design of the intervention, and were not integrated with the Electronic Health Record (EHR) (except for one[9]) - all of which are considered critical features of successful clinical decision support systems.[10,11]

Improving long-term stroke care is a complex endeavour that requires high quality up-to-date information both to plan treatments for individual patients and to guide best practice for the stroke population in general.[12] The 'Learning Health System' (LHS) approach is based on routine collection, management, and analysis of the vast amounts of clinical data produced by health providers and patients.[13] LHS outputs can then provide tailored information on optimal care decisions and be delivered at the point of clinical care.[14] Decision support systems (DSS) implement this transfer of evidence into practice, particularly when coupled with sources of 'Real World Data'[15] such as EHR systems that capture detailed data on specific conditions. Such point-of-care DSS support a range of applications, including patient risk estimation, guidance on the appropriateness of treatments, and tailor clinical information to specific patient needs - providing the right care to the right patient at the right time.[14]

Patients are expecting to be informed and involved in the process of care.[17] This shift from imposition of professional opinion towards collaboration is not only relevant when people face difficult decisions, where there are high stakes and where outcomes are uncertain, but also in situations where people need to manage long term conditions or might want to consider making changes in their lifestyles in order to reduce future risks.[18] Such shared decision making (SDM) respects patient values and preferences, and supports decision-making through the provision of high-quality, accessible information.[19] SDM has been found to be most effective if interventions are developed for use during the clinical encounter,[20] and several DSS that have been designed to facilitate SDM during the consultation (i.e., decision aids) have shown improved treatment adherence and clinical outcomes in patients with chronic conditions such as asthma and diabetes.[21,22]

In his seminal analysis, Berg criticised the 'top-down' technology centred approach to designing decision support systems.[16] He described an alternative *socio-technical* approach, where new tools needed to be designed taking into account the real-world complex networks of people involved in health care, and designed using an iterative approach which makes strong use of qualitative research with users.

We propose engaging various stakeholders in designing LHS interventions to manage risk factors more effectively, using integrated and real-time data, and based on principles of Shared Decision Making (SDM). In the present study, we engaged a range of stakeholders in the identification and design of an intervention to improve secondary prevention after stroke. The data supporting these intervention are linked datasets from the South London Stroke Register (SLSR),[23] which includes more than 6,000 records of first-ever strokes that occur in South London, and Lambeth Datanet (LDN)[24] containing primary care data of local general practices in South London. The linked data provides detailed phenotypic data on patients and their provision of care.

METHOD

Patient and public involvement

The focus group topic guide was informed by helpful feedback from stroke survivors recruited from SLSR. Stroke survivors, carers, health and social care professionals, commissioners and policy-makers were all involved throughout the study in a collaborative design process of an intervention for stroke survivors.

Data collection

We used a range of methods to engage stakeholders (N=53) in the design and evaluation of the intervention, including focus groups, interviews and usability evaluations. The process involved three main stages: (1) exploring stakeholder priorities for data and information needs to inform potential solutions for long-term stroke care; (2) collaborative design of the selected intervention with stakeholders, comprising cycles of design, prototyping and evaluation; (3) Usability and acceptability evaluation of the DSS prototype. 37 stakeholders participated in the first two stages, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy-makers (N=6) and researchers (N=4). 16 stakeholders participated in the third stage, including 8 stroke survivors and 8 GPs. Stroke survivors and carers were recruited from SLSR, health and social care professionals from South London practices, researchers, commissioners and policy-makers from King's College London networks. See Table 1 for details of all stakeholders taking part in the study. Participants could take part in the study if they were able to attend the meetings and were willing to sign a consent form.

Stage 1: Exploring stakeholder priorities for data and information needs

In total, 37 stakeholders participated in this stage. Two focus groups, the first comprising 24 participants (FG1) and the second 12 participants (FG2), as well as 9 face-to-face interviews were conducted to explore stakeholders' priorities for clinical data to inform possible interventions to improve long-term care for stroke survivors with multimorbidity (some participants took part on multiple occasions). All participants signed a consent form. Four ideas for interventions were informed: 1) Improving continuity of care; 2) Improving management of mental health consequences;

3) Better access to health and social care; and 4) Targeting multiple risk factors. A third focus group with the core stakeholder group (N=10) (FG3) then took place to seek feedback on the proposed interventions. From this process, a DSS to improve secondary stroke prevention was selected for further development. Full details of the method for this stage have been published elsewhere.[12]

Stage 2: Collaborative design and prototyping of selected intervention

The initial design of the DSS was informed by the first stage and guided by the International Patient Decision Aids Standards[18] and the SDM model for clinical practice.[25] Following feedback from the core stakeholder group at the third focus group meeting above (FG3), an updated design of the intervention was subsequently reviewed by the core stakeholder group at a fourth focus group (N=9) (FG4) and was revised following their feedback. The DSS was also presented to the King's College London's Stroke Research Patient and Family Group (SRPFG)[26], comprising 32 participants including stroke survivors and carers (22 members participated in the meeting) from the SLSR from diverse socio-economic and ethnic backgrounds, who meet once every 6 weeks to discuss and provide feedback to researchers conducting stroke research. The intervention was revised and the updated design was developed as a basic prototype and was further discussed during a subsequent focus group with the core stakeholder group (N=9) (FG5) and the SRPFG. This process allowed all stakeholders to iteratively develop and refine the DSS to a working prototype.

Stage 3: Usability and acceptability evaluation of the DSS

Sixteen participants, including eight stroke survivors and eight GPs participated in the usability and acceptability evaluation of the working prototype of the DSS. All 16 participants did not take part in the previous stages of the study.

The evaluation included simulated consultations using the DSS prototype. In the GPs session, the researcher acted as the patient, and in the stroke patient's session, the researcher acted as the GP. GPs were given a short tutorial on how to use the DSS before the simulated consultations and stroke survivors were given a short explanation about the DSS. GPs and stroke survivors were interviewed after the simulated consultation and also answered an acceptability questionnaire[27] and the System Usability Scale.[28] Ratings were provided on 5-point Likert scales from 1 (strongly disagree) to 5 (strongly agree), with higher ratings indicating higher satisfaction.

Table 1. Stakeholders taking part in the study

Type of stakeholder	FG1 (N=24)	FG2 (N=12)	FG3 (N=10)	FG4 (N=9)	FG5 (N=9)	Interviews (N=9)	Usability evaluation (N=16)	Total (N=53*)
Stroke survivor	10	2	2	2	2		8	**18**
Carer	1	1	1	1	1			**1**
Health and social care professional	**8**	**3**	**2**	**2**	**2**	**7**	**8**	**24**
GP	2	1	1	1	1	5	8	15
Physiotherapist	2	1						2
Speech and language therapist	1							1
Social care professional	1							1
Public health doctor	1							1
Consultant psychiatrist	1							1
Occupational therapist		1	1	1	1			1
Acute stroke care consultant						2		2
Policy makers and commissioners	3	2	2	2	2	2		**6**

Third sector representatives	2						**2**
Academic researchers (social scientist, researchers working with SLSR/LDN databases)		4	3	2	2		**4**

Notes:

1. *Overall 53 participants took part in the study, but a number of stakeholders took part on multiple occasions.
2. King's College London's Stroke Research Patient and Family Group (SRPFG) comprising 22 (out of 32) stroke survivors and carers also provided feedback on the design of the intervention in two of their meetings.

Data Analysis

Data from focus groups, interviews and usability evaluations were audio recorded, transcribed in full and stored in NVivo (Version 11). Qualitative data were analysed using a thematic analysis approach[29] for themes related to stakeholder perspectives informing the identification, design and evaluation of a DSS to improve secondary prevention for stroke survivors, which could be part of a LHS. This involved two authors (TP,ES) assigning codes and developing and refining themes and subthemes from the data.

RESULTS

Focus groups and interviews

Eight themes (requirements from a DSS) were identified from focus groups and interviews:

1. Involve stroke survivors in decisions concerning their treatments

Stroke survivors often articulated that in light of their multiple health conditions, and hence multiple risk factors for stroke that need to be managed, they would like to be more involved in selecting their treatments based on what is important to them and their desired outcomes. This viewpoint was further confirmed by stroke survivors attending the stroke patients and family group (SRPFG). A number of clinicians perceived that SDM did not take place on a regular basis during routine clinical consultations, and there was a need for greater involvement of stroke survivors and their carers in selecting treatments that best suit their needs and preferences. Commissioners and policy-makers agreed that SDM is a necessity and noted that policies in the UK and other countries require to involve patients in their treatment decisions. They emphasised the importance of data and evidence-based recommendations to improve decision making about treatments.

> *"When I go to my doctor I realise it's my doctor who is making the decisions…but I think that patients now know often more about their own condition than the health professionals" (stroke survivor, FG1)*
>
> *"This information (risk factors) which used to be something that I, as a doctor, only thought about, it's now something that we should think about together" (GP, FG5)*
>
> *"How do we help patients and carers and health professionals together have a discussion using data information to make decisions about treatments?" (commissioner, FG2)*

2. Present and communicate recurrent stroke risk in a meaningful way

Both stroke survivors and healthcare professionals emphasised the importance of displaying and communicating personalised risk estimation in a clear and meaningful way. Stroke survivors expressed

that current risk presentations lacked clarity, with healthcare professionals agreeing with this idea, reporting that they also find it difficult to understand and communicate risk to patients while linking it to specific actions and behaviours among patients.

> *"What is this individual's risk of a further stroke in five years… and that's really important because patients commonly ask us that 'what is the risk of me having another stroke in the next year' and we come up with a figure and we say '5% of whatever'" (hospital stroke physician, Interview)*

> *"And I think the other thing is what actually is risk, how do you convey that, I mean, is it twice as much risk if I've never had a stroke…I know exactly what you mean 50% and 5% of that are meaningless to most people" (stroke survivor, FG4)*

> *"Because the patients often think that the GPs – or the doctors/the specialists understand risk. It's really difficult to understand risk and we have to use guidelines to help us with risk. So if the guidelines say, 'This is a risk and this is the level at which you should intervene', then I'm not well enough informed to go any further than that" (GP, FG3)*

3. Compare stroke survivor's perceived stroke risk with their predicted risk

In the fourth core stakeholder meeting (FG4), a carer voiced the importance of allowing stroke survivors to articulate their own perceived risk of having a recurrent stroke, which could then be compared with the actual predicted risk. The rest of the group agreed that this would facilitate a collaborative discussion on potential risk factors and their impact on stroke risk.

> *"Patients themselves if they've been through a process will likely at some point be shown something and said either mark yourself on this, because another thing is where do you think you are on this scale at the moment with your risks, sometimes that's quite powerful" (carer, FG4)*

4. Personalise treatments to help control multiple stroke risk factors

All stakeholders emphasised the importance of controlling multiple risk factors for stroke recurrence and the need to develop effective treatments based specifically on the patient's characteristics (e.g., age, ethnicity, health conditions). Survivors from the stroke patients and family group (SRPFG) similarly voiced their preference to know their personal risk according to their personal characteristics and receive advice from professionals about what specific actions they could perform to reduce the identified risks. Commissioners were interested in care pathways for stroke patients with multimorbidity and how these care pathways could be tailored to the patient's characteristics.

> *"Patients who've had a confirmed stroke, the first thing as a family physician in terms of management is to make sure that you've controlled all their risk factors to prevent them getting another stroke" (GP, Interview)*

> *"And if the system could provide him, like, tailored for the patient taking all the information and saying OK for this patient because he had stroke, he has diabetes and high blood pressure, we recommend the following care pathway, treatments" (commissioner, FG1)*

> *"Anything that can be personalised or tailored, so you don't feel it's this off the shelf thing that you're being given, you know… you sit with your doctor and it's not just a case of giving out a*

leaflet, but actually let's have a look at your personal data" (occupational therapist, FG4)

5. Display effectiveness of recommended treatments in reducing stroke risk

Healthcare professionals, commissioners and policy-makers considered that stroke survivors with multimorbidity often have multiple risk factors to manage, and prioritising the different treatments available for secondary prevention of these risk factors is required. Stroke survivors wanted to know the relative benefit of the proposed treatments being offered by clinicians in terms of how they addressed stroke risks and to take this information into account when deciding on treatments. Commissioners specifically emphasised the importance of using evidence-based data to prioritise treatments and help patients in their decision making.

"…and you need to know, in fact, what the risk is if you do nothing compared with the risk if you do something" (stroke survivor, FG3)

"The question might be for a patient 'should I take a statin after a stroke' and we might be able to use the database to answer the question 'what would be the risk of future stroke if I do take a statin or if I don't take a statin' and you can use that information to help to come to a decision together" (commissioner, FG1)

"Well I suppose you could think about the common comorbidities, so hypertension and stroke, AF (atrial fibrillation) and stroke, diabetes and stroke and you could think about not necessarily an algorithm but a sort of stepwise prioritisation about what you should think about in terms of the patient's total management, you know, which would be the most important area of focus?" (GP, Interview)

6. Address stroke survivor concerns about treatment and barriers to adherence

Stroke survivors in some of the focus groups and the SRPFG raised concerns about the challenges of multiple treatments they were expected to adhere to in order to decrease the risks of a recurrent stroke, reporting that they do not always understand the value of these treatments. They felt that a joint discussion with a healthcare professional about these concerns would help them better understand the value of a particular treatment and reach an informed decision about it. When interviewed, several GPs agreed that it was very challenging for stroke survivors with multimorbidity to adhere to multiple medications and other treatments at any given time, and it is sometimes difficult to differentiate their medication between what is absolutely necessary and what is not.

"My experience both with the doctors at the surgery and the consulting hospital is trying to discuss the medication that they insisted I took. I had horrendous side-effects and I kept trying to say to them 'Look, I'm having these side-effects, can I change, can I reduce, can I do blah blah' and their attitude I have to say, is one of terrorising patients" (stroke survivor, FG1)

"I think that's a common problem with all patients that suffer from comorbidities. It's rationalising their medication and you know being able to take a holistic view of the person and make sensible decisions about what they absolutely need to continue on and what they don't. And you can only really do that just by having time with the patient, you know if it's important for them to be able to sort of get up and get out and about and not feel dizzy, then you may have to compromise on how much blood pressure medication they take" (GP, Interview)

7. Support continuity of care

Stroke survivors often reported that they did not have pre-set appointments with the GP or other healthcare professionals on a regular basis. Several felt that the idea of personalised care to control stroke risk factors is very important but should have a follow-up to ensure continuity of care. The selected treatments and management plan should be saved on the system for future consultations and a follow-up appointment always set in advance. Commissioners emphasised the importance of follow-up appointments and raised the concern that although follow-up appointments are an important part of stroke management and are required according to the National Institute for Health and Care Excellence (NICE) guidelines, many stroke survivors do not have follow-up appointments and do not see a GP.

> *"I'm just thinking of my practice where it's very difficult to get to see the same doctor and if I was presented with my third in line (i.e. the risk graphic display) ten times from ten different doctors I'd be starting to get a bit hacked off I think" (stroke survivor, FG4)*

> *"It's not a one time thing…there needs to be continuous interaction I think if something's going to happen (stroke survivor, FG4).*

8. Identify stroke survivors at high risk of recurrent stroke

Healthcare professionals, commissioners and policy-makers highlighted the need to proactively identify stroke survivors at a high risk of having a recurrent stroke to assess and treat them in a timely manner. They felt that many stroke survivors, especially those with more severe consequences from the stroke, do not often see a physician, and it is important to have a smart system in place that could proactively identify them and assess their risks.

> *"I think the challenge first of all who are the high-risk patients, can we identify them and, if we can, is there a way through case management or community matrons, you know, linked with the stroke teams in the community providing access to therapy and assessment when it's required in a timely fashion" (commissioner, Interview)*

Development of DOTT decision support system

The above themes and solutions were proposed, designed and refined during the above collaborative design process with stakeholders, which informed the design of DOTT (Deciding on Treatments Together). DOTT is a computerised decision aid, integrated with the EHR system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor, aiming to facilitate shared decision making on treatments to reduce recurrent stroke risk.

Specifically, DOTT will:

(1) Allow stroke survivors to indicate, in a graphic presentation (Figure 1), **their perceived risk of having a further stroke**. The graphic presentation in DOTT is based on population rank,[30,31] simulating a queue of 20 people around the same age of the stroke survivor. Stroke survivors indicate where they think they are positioned in the queue (from least to most likely). This risk would then be compared to the actual predicted risk to facilitate conversation on risk factors. Needs from theme 3 are addressed with this feature.

(2) Display the **stroke survivor's actual predicted risk of having a further stroke** in a meaningful and

understandable way for both healthcare professionals and stroke survivors. The predicted stroke risk will be calculated based on the patient's information from the EHR and on rules generated from the linked dataset (SLSR and LDN). Needs from theme 2 are addressed with this feature (see Figure 1).

(3) Provide a **list of personalised recommended treatments** for the stroke survivor based on their risk factors (e.g., hypertension, atrial fibrillation) extracted from the EHR. A list of the most effective evidence-based treatments for secondary prevention would be compiled and extracted from the recent NICE guidelines[32] and the National Clinical Guideline for Stroke.[33] This includes both clinical and lifestyle recommendations. For each recommended treatment, the evidence supporting the treatment will also be displayed. Needs from section 4 are addressed with this feature.

(4) **Prioritise the recommended treatments** based on their relative risk reduction and present the most effective treatment first. The clinician and stroke survivor can select one or more treatments and see on the graphic display, how the treatments reduce the overall stroke risk. The benefit of each treatment in terms of stroke risk will be calculated using the integrated dataset (SLSR and LDN). Needs from theme 5 are addressed with this feature.

(5) **Display stroke survivors' common concerns** on the suggested treatments (e.g., "do I have to take blood pressure drugs for life?"), which will aid in identifying and addressing barriers to treatment adherence and eliciting preferences. An initial list of concerns and their response was prepared based on qualitative studies eliciting patients' barriers to treatment adherence.[34,35] Needs from theme 6 are addressed with this feature

(6) Allow stroke survivors and their carers to discuss the different treatments with the healthcare professional and **jointly select the treatments that best suit the stroke survivor's preferences, desired outcomes and goals** (and remove the ones that do not). Lifestyle modification will be discussed during the consultation and enhanced through referral to specialists or lifestyle intervention programs. The agreed management plan and information on the different treatments will be printed and handed to the stroke survivor to take home. Needs from theme 1 are addressed with this feature.

(7) Set automatically a **follow-up appointment** in 3 months' time. The information entered, including the agreed management plan is saved and transferred back to the stroke survivor's EHR for future consultations. During the follow-up consultation, the management plan is reviewed and treatments to address risk factors for stroke recurrence can be added, modified or removed. Desired clinical and patient outcomes will also be reviewed. Needs from theme 7 are addressed with this feature.

(8) The stroke prediction model will also be used to **proactively identify individuals at high risk of a recurrent stroke** by calculating their recurrent stroke risk at defined periods of time (the practice can define the desired threshold) and alert the practice (e.g., physician, nurse, receptionist) to invite those patients for a clinical consultation. Needs from theme 8 are addressed with this feature.

(9) All information from patients and healthcare professionals (e.g., treatments selected by the patient, desired outcomes, predicted stroke risk, results in follow-up) will be **captured by the system as part of a LHS** and be used to improve the system's predictive model and treatment recommendations.

Figure 1 depicts an example screenshot from DOTT decision aid prototype.

<Insert Figure 1 here>

Usability and acceptability evaluation

Demographics

Eight stroke survivors and eight GPs participated in the usability and acceptability evaluations. GPs (4 men, 4 women) had average of 10.3 years of experience as a GP. All had experience in providing care to stroke survivors, had medium to high confidence in using new technology and low to medium experience using DSS. Stroke survivors (4 men, 4 women) had an average age of 65.5 years (SD: 11.4, range: 49-81). All had hypertension, two had heart problems, one was suffering from depression, four had mobility issues, and four had minor cognitive deficiencies (attention and memory).

Usability and acceptability

Both GPs and stroke survivors found the decision aid usable and acceptable. GPs found the decision aid easy to use (score 4.3), easy to understand (4.1) and felt very confident using it (4.2). They thought that this decision aid was better than how they usually helped patients decide about treatments for controlling their risk factors (4.4), that this strategy was compatible with the way they thought things should be done (4.3), that this type of decision aid was suitable for helping patients make informed choices (4.0) and that the decision aid complemented their usual approach (4.4). Stroke survivors would like to use the decision aid frequently (4.0), thought that it was easy to use (4.2) and felt confident using it (4.1). Initial findings of the usability evaluation can be found in Porat et al.[36]

Identified themes

Five main themes relating to the usability and acceptability of the decision aid were identified:

1. Logical and structured process that facilitates discussion

All GPs and stroke survivors (n=16) found the decision aid to be clear, and consisting of a logical flow that helped to structure the consultation. They felt that the decision aid facilitated a transparent discussion on the different proposed treatments and elicited patients' preferences.

> *"Physician pointing out what to do but the patient makes the decision since it's hard to get your head around everything. More doable if you have specific areas to work on with specific targets that suits you" (stroke survivor 2)*

2. Powerful risk display showing the benefit of each treatment

GPs and stroke survivors (n=15) found the visual display showing the risk before and after a selected intervention, easy to understand and powerful. Both stroke survivors and GPs commented that they were not aware of the effect the treatments have on reducing the stroke risk.

> *"The most powerful thing is the visual shifting of risk" (GP 5)*

> *"Wow, a small change can make a big difference, this is very encouraging" (stroke survivor 6)*

3. *The patient takes home printed information*

GPs and stroke survivors (n=10) thought that it was very important that the patient has the management plan and all the information printed so they can review it at home. Particularly stroke survivors wanted to have their current predicted risk and information on their selected treatments, including the date of the follow up appointment printed out, so it could motivate them to adhere to the treatments.

> *"The important thing is that the patient goes out with a piece of paper that summarises in bullet points the outcome of the consultation. If its black and white on paper it makes a difference" (stroke survivor 3)*

4. *Importance of a learning system*

GPs (n=3) raised the importance of a learning system providing up-to-date information. They wanted to make sure that the suggested treatments are in line with the most up-to-date evidence.

> *"The learning aspect is very important, since this system is based on evidence and evidence can change" (GP 6)*

5. *Can motivate patients to change behaviour*

All GPs and stroke survivors (n=16) believed that the decision aid could motivate patients to change behavior. Stroke survivors liked the idea of being involved in deciding on their treatments according to their preferences and abilities, receiving information on their stroke risk factors, and discussing their views and concerns with the clinician. They felt it gave them more control over their health and motivation to adhere to the treatments they selected. GPs felt it was a good way to discuss the different treatments and give patients the power to decide on treatments that suit them.

> *"I believe discussing the different options with the patients, shared decision making, is likely to improve adherence" (GP 1).*

Concerns

GPs and stroke survivors raised two main concerns from using the decision aid.

1. *Deals with one aspect of the consultation*

GPs and stroke survivors (n=6) felt that the decision aid is good but focuses on one aspect of the consultation (reducing risk of recurrent stroke) and patients may have other concerns, such as depression or social isolation.

> *"This is good, but for me the most important thing is the emotional aspect, and this tool doesn't relate to that" (stroke survivor 4)*

2. *Time*

The main concern for GPs was time (n=6), in which within the allotted 10 minutes for the consultation already provided significant limits, and most felt they will not manage to fit it in.

Suggestions for improvement

GPs and stroke survivors provided suggestions for improving the decision aid:

1. The terminology was too clinical, for example “treatments” and “management”, could be changed to “possible strategies or approaches”.
2. In addition to the management plan, information (a leaflet) on each of the selected treatments should also be printed.
3. Add clinical data, for example when clicking on “cholesterol” show the patient’s last three values, and do this also for their blood pressure.
4. Enable more than one display of risk, each one prefers a different display and understands risk differently.
5. Add emotional and mental health aspects (e.g., depression)

We have made the above changes and additions to the updated version of DOTT.

DISCUSSION

Our work focused on engaging various stakeholders in the identification, design, prototyping and evaluation of a decision aid to improve secondary prevention after stroke. Eight themes informed the design of DOTT. A number of the themes and solutions proposed by the stakeholders have been implemented previously to some extent to support other patient groups, such as diabetes and atrial fibrillation, and are recommended in SDM tools. These include, predicting a patient’s risk based on their risk factors, proposing possible treatments and displaying their benefit in decreasing the risk,[37] and incorporating patients’ concerns within the decision making process.[38]

Additional unique themes and solutions have emerged as outcomes of the collaborative design process in this study, which could be used for a range of chronic diseases requiring long-term management. Specifically:

(1) ***Present and communicate risk in a meaningful way.*** While there are many different ways to communicate multiple risks to patients, the most commonly used are absolute or relative risks presented as percentages or probabilities (e.g., “from 100 people like you 20 are expected to have a recurrent stroke”).[39] However, studies have shown that in general, healthcare professionals are as unfamiliar as their patients with risk estimates and probabilities[40] and often healthcare professionals have reported finding it difficult to combine multiple risk factors into an accurate assessment of vascular risk[41] and to communicate this risk to patients.[42] Moreover, patients may feel that statistical risk estimates do not apply to them personally.[43] To overcome this, our graphic presentation is based on population rank, simulating the patient in a queue of people around their age.[30,31] Studies have also shown that formats which present data framed as the risk of an individual were perceived as more relevant and easier to relate to than percentage risk estimates.[44]

(2) ***Prioritising treatments***. Healthcare professionals have previously expressed concerns about managing care and making decisions about treatments, including communicating risks and benefits for patients with multimorbidity and complex needs.[45] They often have to make decisions with such patients that involve a process of prioritisation or trade-offs, facilitating a discussion with the patient on what is important to the patient and what they would like to achieve in terms of their health (i.e. goal setting).[46] Aligning patient goals and desired outcomes with clinicians’ goals is likely to improve outcomes for these patients.[46]

(3) ***Identify individuals at high risk.*** Calculating periodically (in an automatic way) the stroke risk of survivors to identify individuals at high risk of recurrent stroke (based on their information in the EHR)

could be a valuable feature for improving long-term management and care for stroke survivors who are less likely or able to visit healthcare professionals on a regular basis.

These solutions, which are delivered through a DSS integrated with the EHR system and based on data from a linked population dataset, have the potential to be an instrument of change in clinical practice. This will be done by providing scientific evidence at the point of clinical care (e.g., personalised treatments and their benefit based on the individual's risk factors), while simultaneously collecting information from that care (e.g., treatments selected by the patient, desired outcomes, predicted stroke risk) to promote innovation in optimal healthcare delivery.[14]

Strengths and limitations

Although the core focus of the DSS (prevention of a future stroke) was identified by patients as a priority, having a single focus might hinder discussions of other important problems (e.g., depression, social isolation). Such issues may even have a larger perceived impact on long-term outcomes after stroke, for example, improving mental health or access to social care services, which were also brought up by stakeholders as a priority to address long-term care for stroke survivors with multimorbidity,[12] and were raised as a concern in the usability and acceptability evaluations. Depression is indeed a risk factor of stroke,[47] and was added to the updated version of the decision aid.

In a study assessing stroke survivors' self-reported needs,[48] more than 50% of long term stroke survivors reported an unmet need for stroke information (cause, prevention of recurrence). The proposed decision aid offers a meaningful starting point for addressing this common unmet need. Evidence suggests that the provision of lifestyle advice from healthcare professionals' is effective in changing health behaviours[49] and healthcare professionals' communication is positively correlated with patient adherence to treatments.[50] However, a conversation-based DSS also relies on the attitudes and communication skills of the healthcare professionals, which have been found to vary.[51] Interactive SDM skill training has improved SDM skills and promoted positive attitudes.[52] Training healthcare professionals in communication skills for SDM has also been shown to result in substantial and significant improvement in patient adherence to treatments.[50] Hence, interactive SDM skills training workshops will have to complement the use of the DSS. Patients are also likely to need support and preparation with taking part in SDM during the consultation.[52]

The design of DOTT meets the International Patient Decision Aid Standards (IPDAS) collaboration criteria for quality decision aids.[18] Specifically, DOTT was designed to incorporate principles of SDM, by presenting stroke survivors with information about their treatment options and likely outcomes, presenting the risks and benefits of each option, and engaging the healthcare professional and stroke survivor in a joint conversation about the patient's preferences.[25] Furthermore, DOTT evolves from a systematic development process, uses non-technical language and presents information in a balanced manner that allows for comparisons across alternatives.[18] In the future, data from wearable sensors (e.g., Fitbit, Apple Watch) will be integrated to the EHR, and DOTT could use this information to improve its risk prediction model and treatment recommendations.

In the usability and acceptability evaluation, stroke survivors and GPs found DOTT to be both useful and usable. GPs perceived that the decision aid helped with structuring the consultation and eliciting patients' preferences for treatments. Stroke survivors felt it provides a good way to understand the

different treatment options and select the ones that best suits their preferences. GPs' main concern was that the decision aid would increase consultation times. Indeed, time constrains were identified as the main barrier for the adoption of innovations by family physicians.[53,54] A possible solution could be to use the decision aid as part of a clinical review after stroke, which is usually longer (e.g., 3 month, 6 month and annual review) and by dedicated healthcare professionals which are less limited in time such as stroke nurses and pharmacists working in GPs' practices that are trained to consult patients with chronic and long-term health conditions.

CONCLUSION

Engaging various stakeholders throughout the design and evaluation process ensures that the intervention (features and functions) is in line with the needs reported by the different stakeholders (i.e., stroke survivors, healthcare professionals, policy-makers). DOTT has demonstrated the potential to reduce stroke recurrence by adopting a data-driven user-centred approach. DOTT urges clinicians to shift away from the advice-giving approach typically used in medical consultations to one which actively engages the patient in decision making and respects patient choice and autonomy. This will lead to stroke survivors taking ownership for the treatment decisions, improving their adherence to the agreed management plan and thus reducing their stroke risk. A forthcoming feasibility study and subsequent clinical trial will evaluate the effectiveness of DOTT in improving decision making quality, and whether it affects risk factor levels and risk of recurrence. While DOTT currently targets stroke risk factors only, the design approach could be used for a range of chronic diseases requiring long-term management, paving the way to a set of standards for delivering LHS interventions in clinical practice.

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Figure captions

Figure 1: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control blood pressure).

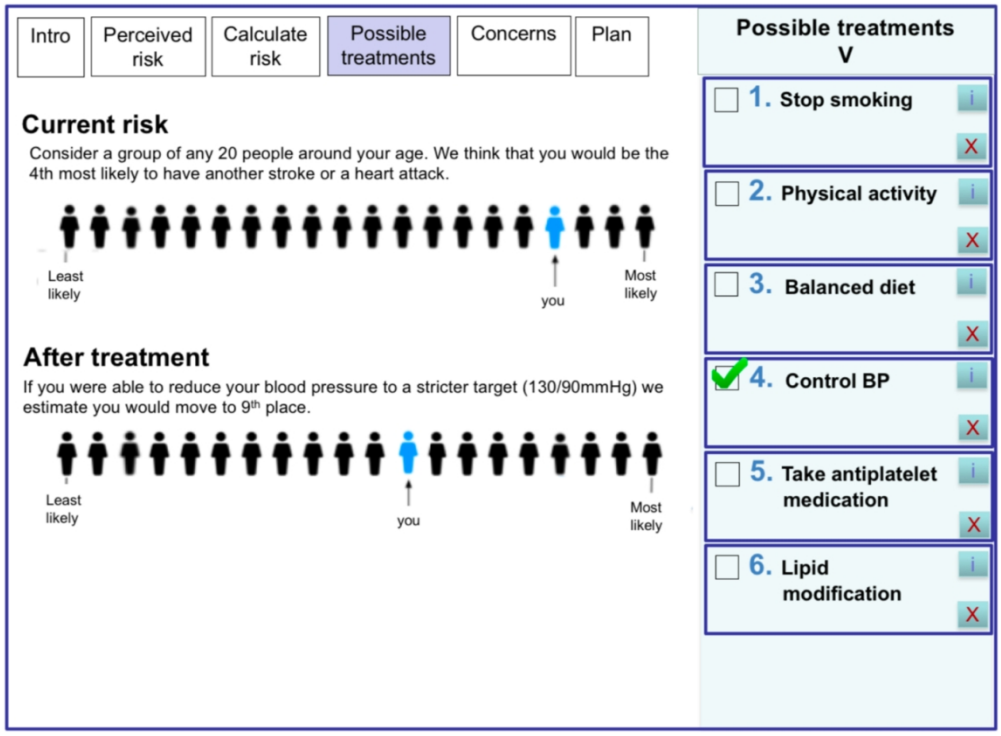

Figure 1: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control blood pressure).

Reporting checklist for qualitative study.

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		Reporting Item	Page Number
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also	4,5

		recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	NA
Context	#7	Setting / site and salient contextual factors; rationale	5
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	4
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	4, 16
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	4,5
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	5
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5,6,11
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	5

Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	6
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	6
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	6-9,11-13
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6-9,11-13
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	13-15
Limitations	#19	Trustworthiness and limitations of findings	14,15
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	16
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	16

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Collaborative design of a decision aid for stroke survivors with multimorbidity: a qualitative study engaging key stakeholders

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Collaborative design of a decision aid for stroke survivors with multimorbidity: a qualitative study engaging key stakeholders

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ABSTRACT

Objectives: Effective secondary stroke prevention strategies are sub-optimally used. Novel development of interventions to enable healthcare professionals and stroke survivors to manage risk factors for stroke recurrence are required. We sought to engage key stakeholders in the design and evaluation of an intervention informed by a Learning Health System approach, to improve risk factor management and secondary prevention for stroke survivors with multimorbidity.

Design: Qualitative, including focus groups, semi-structured interviews and usability evaluations. Data was audio-recorded, transcribed and coded thematically.

Participants: Stroke survivors, carers, health and social care professionals, commissioners, policy makers and researchers.

Setting: Stroke survivors were recruited from the South London Stroke Register; health and social care professionals through South London general practices and King's College London (KCL) networks; carers, commissioners, policy-makers and researchers through KCL networks.

Results: 53 stakeholders in total participated in focus groups, interviews and usability evaluations. Thirty-seven participated in focus groups and interviews, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy-makers (N=6) and researchers (N=4). Sixteen participated in usability evaluations, including stroke survivors (N=8) and general practitioners (GPs; N=8). Eight themes informed the collaborative design of DOTT (Deciding on Treatments Together), a decision aid integrated with the electronic health record system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor. DOTT aims to facilitate shared decision making on personalised treatments leading to improved treatment adherence and risk control. DOTT was found acceptable and usable among stroke survivors and GPs during a series of evaluations.

Conclusions: Adopting a user-centred data-driven design approach informed an intervention that is acceptable to users and has the potential to improve patient outcomes. A future feasibility study and subsequent clinical trial will provide evidence of the effectiveness of DOTT in reducing risk of stroke recurrence.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Engaging a range of stakeholders in the design and evaluation of an intervention ensures that the intervention is in line with the needs reported by the different stakeholders (e.g., stroke survivors, healthcare professionals, policy makers).
- Adopting a Learning Health System approach enables the delivery of personalised recommendations in real time whilst simultaneously capturing additional data back into the system, to improve the system's predictive model and recommendations.
- As only stroke survivors able to attend the focus groups participated in the study, we did not elicit the views of stroke survivors who are less mobile or housebound.

INTRODUCTION

Stroke is the second leading cause of death and a major cause of disability worldwide.[1] In 2015, there were 3.7 million people living with stroke as a chronic condition in Europe and this number is expected to reach 4.6 million in 2035.[2] Stroke survivors have a nearly 40% cumulative risk of recurrence during the first 10 years after stroke.[3] Secondary stroke prevention requires healthcare professionals to offer effective interventions to monitor and manage risk factors, and for patients to change health related behaviours (e.g., smoking)[4] and adhere to preventative medications (e.g., to control hypertension).[5] Follow-up appointments with clinicians offer opportunities to discuss interventions for reducing the risk of future stroke. However, long-term stroke care is characterised by a lack of continuity[6] and modifiable risk factors are currently not well detected, managed or controlled post stroke.[7]

Interventions designed to improve risk-factor management among stroke survivors in randomised controlled trials (RCTs) have shown modest or no effect. A recent Cochrane systematic review of 42 RCTs evaluating the effectiveness of educational and behavioural or organisational interventions on modifiable risk factor control for secondary prevention of stroke, found no clear benefit in any of the target outcomes (i.e., blood pressure, lipid profile, HbA1c, BMI and recurrent cardiovascular events).[8] Possible reasons could be that these interventions have not been part of the clinical decision-making process of clinicians, did not engage various stakeholders in the design of the intervention, and were not integrated with the Electronic Health Record (EHR) (with the exception of one study[9]) - all of which are considered critical features of successful clinical decision support systems.[10,11]

Stroke survivors commonly experience multimorbidity.[12] Gallacher and colleagues found that 94% of the people with stroke had one or more additional morbidities and often experienced long-term physical, psychological and social consequences.[12] This makes improving long-term stroke care a complex endeavour, requiring patient engagement, high quality up-to-date information and a holistic approach which focuses on the patient and not on the disease.[13] These aspects are important both to plan effective treatments for individual patients and guide best practice for the stroke population in general.[14]

The Learning Health System (LHS) 'focusses on approaches to capture data from clinical encounters and other health-related events, analyse the data to generate new knowledge, and then apply this knowledge to continuously inform and improve health decision making and practice.'[15(p.177)] In a recent report (2019) stating what the NHS can learn from the LHS, the authors argue that it is necessary to utilise data to transform services, not just to digitise current ways of working.[16] Thus, LHS outputs can provide tailored information on optimal care decisions and be delivered at the point of clinical care.[17]

Decision support systems (DSS) which aim to analyse a patient's characteristics to provide tailored recommendations (such as for diagnosis,[18] treatment or long-term management), implement this transfer of evidence into practice. This is done particularly when used in conjunction with sources of 'Real World Data'[19] such as EHR systems that capture detailed data on specific conditions. Such point-of-care DSS support a range of applications, including identifying patient risk estimation, providing guidance on the appropriateness of treatments, and tailoring clinical information to specific patient needs - providing the right care to the right patient at the right time.[17] A few studies have reported that engaging stakeholders to develop a LHS and integrated DSS improved patient outcomes and processes of care for individuals with long-term conditions.[20,21]

Increasingly patients are expecting to be informed and involved in their care.[22] This shift from imposition of professional opinion towards a more collaborative model of care is not only relevant when people face difficult decisions about their health, where there are high stakes and where outcomes are uncertain, but also in situations where people need to manage long term conditions or consider making changes in their lifestyles in order to reduce future risks.[23] Such shared decision making (SDM) respects patient values and preferences, and supports decision-making through the provision of high-quality, accessible information.[24] SDM has been found to be most effective if interventions are developed for use during the clinical encounter,[25] and several DSS that have been designed to facilitate SDM during the consultation (i.e., decision aids) have shown improved treatment adherence and clinical outcomes in patients with chronic conditions such as asthma and diabetes.[26,27]

In his seminal analysis, Berg criticised the 'top-down' technology centred approach to designing decision support systems.[28] He described an alternative *socio-technical* approach, where new tools needed to be designed taking into account the real-world complex networks of people involved in health care, and designed using an iterative approach which makes strong use of qualitative research with users.

Aims and objectives

The aim of this study was to engage key stakeholders to identify priorities and information needs in long term stroke care and collaboratively design and evaluate a selected intervention that could be integrated as part of the EHR system informed by a LHS approach. The data supporting the selected intervention are based on linked datasets from the South London Stroke Register (SLSR),[29] which includes more than 6,000 records of first-ever strokes that occur in South London, and Lambeth Datanet (LDN)[30] containing primary care data of local general practices in South London.

METHOD

Patient and public involvement

The design was informed by active feedback from stroke survivors and carers from King's College London's Stroke Research Patient and Family Group (SRPFG)[31], a service user research group which consists of 32 participants currently on the SLSR who are from diverse socio-economic and ethnic backgrounds. Stroke survivors, carers, health and social care professionals, commissioners, policy makers and researchers were involved throughout the study in a collaborative design and evaluation process.

Data collection

We used a range of methods to engage stakeholders (N=53) in the design and evaluation of the intervention, including focus groups, face to face interviews and usability evaluations (see topic guides and interview questions in the supplementary files). The process involved three main stages: (1) exploring stakeholder priorities for data and information needs to inform potential solutions for long-term stroke care; (2) collaborative design of the selected intervention with stakeholders, comprising cycles of design, prototyping and evaluation; (3) Usability and acceptability evaluation of the DSS prototype (See Figure 1). Thirty-seven stakeholders participated in the first two stages, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy makers (N=6) and researchers (N=4). Sixteen stakeholders participated in the third stage,

including 8 stroke survivors and 8 General practitioners (GPs). Stroke survivors were recruited from the SLSR. Health and social care professionals were recruited through general practices in South London and King's College London networks. Carers, commissioners, policy makers and researchers were also recruited through these networks. Stakeholders were purposively sampled to include stroke survivors (i.e. men and women, with a range of disabilities and long-term conditions, risk factors and length of time since their stroke) and professionals providing all types of stroke care and support. See Table 1 for details of all stakeholders taking part in the study. Participants could take part in the study if they were able to attend the meetings and were willing to sign a consent form. Transport was arranged for less mobile patients.

<Insert Figure 1 here>

Stage 1: Exploring stakeholder priorities for data and information needs

In total, 37 stakeholders participated in this stage. An initial stakeholder engagement meeting comprising 24 participants (SEM), 9 face to face interviews with key stakeholders who could not attend this meeting, and a second focus group involving 12 participants (FG2) were conducted (some participants took part on multiple occasions). The methods and findings from this stage of the study have been reported elsewhere.[14] In brief, in the initial engagement meeting (SEM), participants were introduced to the concept of a LHS and then in three separate focus groups (service user/carer; health and social care professionals; commissioners and policy makers) they were asked to identify priorities and potential solutions that may be derived from the clinical data to improve long-term stroke care for stroke survivors with multimorbidity. Then, in the larger group, through a process of priority setting and consensus led by a facilitator (ES), stakeholders identified a number of priorities and solutions to improve long-term management of stroke (i.e. improving continuity of care; improving management of mental health consequences; better access to health and social care; and targeting multiple risk factors). Targeting multiple risk factors after stroke was identified among stakeholders as a key priority, and a DSS to improve secondary prevention after stroke to target multiple risk factors was subsequently chosen within a smaller core stakeholder group (FG3) for further development. This core stakeholder group (N=12) comprised stroke survivors, healthcare professionals, carer, policy maker and commissioner, and worked collaboratively with the research team to subsequently design the intervention and to provide their active feedback.

Stage 2: Collaborative design and prototyping of selected intervention

The initial design of the DSS to improve secondary stroke prevention and target multiple risk factors after stroke was informed by the first stage and guided by the International Patient Decision Aids Standards (IPDAS),[23] which provides a framework and standards for the design of patient decision aids, and the SDM model for clinical practice.[32] The latter provides a model of how to conduct shared decision making in practice based on providing patients choice, a range of options and involving them in 'decision talk'. Following feedback from the core stakeholder group at the third focus group meeting above (N=10) (FG3), an updated design of the intervention was subsequently reviewed by the core stakeholder group at a fourth focus group (N=9) (FG4) and was revised following their feedback. The DSS was also presented to the King's College London's SRPFG. The intervention was revised and the updated design was developed as a basic prototype and was further discussed during a subsequent focus group with the core stakeholder group (N=9) (FG5) and the SRPFG. This process allowed all

stakeholders to iteratively develop and refine the DSS to a working prototype.

Stage 3: Usability and acceptability evaluation of the DSS

Sixteen participants, including eight stroke survivors and eight GPs participated in the usability and acceptability evaluation of the working prototype of the DSS. None had taken part in the previous stages of the study.

The evaluation included simulated consultations using the DSS prototype. In the GPs session, the researcher acted as the patient, and in the stroke patient's session, the researcher acted as the GP. GPs were given a short tutorial on how to use the DSS before the simulated consultations and stroke survivors were given a short explanation about the DSS. GPs and stroke survivors were interviewed after the simulated consultation, asking them to provide feedback on the DSS, including its strengths, limitations and suggestions for improvements. Stroke survivors and GPs also answered an acceptability questionnaire[33] and the System Usability Scale (SUS).[34] Acceptability relates to the comprehensibility of the components of the decision aid, including its length, pace, amount of information, balance in presentation and overall suitability.[33] Usability is 'the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use'.[35] The SUS is composed of 10 questions and has been shown to be a reliable and psychometrically validated tool.[36] Ratings were provided on 5-point Likert scales from 1 (strongly disagree) to 5 (strongly agree), with higher ratings indicating higher satisfaction.

For the usability evaluation, the DSS prototype had the following functionality and flow:

- Stroke survivors (patients) indicated their perceived risk of having a recurrent stroke.
- GPs entered the patient's characteristics (age, gender, clinical conditions).
- The system displayed a 'typical' recurrent stroke risk (age group specific average)[37] and the most effective treatments based on the patient's characteristics.
- The benefit of each treatment in terms of reducing the stroke risk was displayed. Estimated relative stroke risk reductions were calculated based on the existing literature.[38-41]
- Information and common concerns for each treatment were displayed.
- The GP and patient decided on a management plan whilst identifying desired clinical and patient outcomes.
- Patients were told that their management plan would be printed to take home.

Table 1. Stakeholders taking part in the study

Type of stakeholder	SEM (N=24)	Interviews (N=9)	FG2 (N=12)	FG3 (N=10)	FG4 (N=9)	FG5 (N=9)	Usability evaluation (N=16)	Total (N=53*)
Stroke survivor	**10**		**2**	**2**	**2**	**2**	**8**	**18**
Carer	**1**		**1**	**1**	**1**	**1**		**1**
Health and social care professional	**8**	**7**	**3**	**2**	**2**	**2**	**8**	**22**
GP	2	5	1	1	1	1	8	13
Physiotherapist	2		1					2
Speech and language therapist	1							1
Social care professional	1							1
Public health doctor	1							1
Consultant psychiatrist	1							1
Occupational therapist			1	1	1	1		1

Acute stroke care consultant		2						2
Policy makers and commissioners	**3**	**2**		**2**	**2**	**2**		**6**
Third sector representatives	**2**							**2**
Academic researchers (social scientist, researchers working with SLSR/LDN databases)				**4**	**3**	**2**	**2**	**4**

Notes:

1. *Overall 53 participants took part in the study, but a number of stakeholders took part on multiple occasions.
2. King's College London's Stroke Research Patient and Family Group (SRPFG) comprising 22 stroke survivors and carers also provided feedback on the design of the intervention in two of their meetings.

Data Analysis

Data from focus groups and interviews were audio recorded, transcribed in full and stored in NVivo (Version 11). Qualitative data were analysed using a thematic analysis approach[42] to identify themes and sub-themes related to stakeholder perspectives informing the identification, design and evaluation of a DSS to improve secondary prevention for stroke survivors, which could be part of a LHS. This involved two authors (TP, ES) assigning codes and refining themes from the data, noting similarities and differences between stakeholder perspectives. The two authors have doctoral/post-doctoral experience in conducting and analysing qualitative data in applied health research.

RESULTS

Focus groups and interviews

Eight themes related to improving secondary prevention and management of multiple risk factors after stroke were identified from focus groups and interviews:

1. Involve stroke survivors in decisions concerning their treatments

In the focus groups, stroke survivors often articulated that due to their multiple health conditions, and hence multiple risk factors for stroke recurrence, they would like to be more involved in selecting their treatments based on what is important to them and their desired outcomes. This viewpoint was further confirmed by stroke survivors participating in King's College London's SRPFG. A number of clinicians perceived that SDM did not take place on a regular basis during routine clinical consultations, and there was a need for greater involvement of stroke survivors and their carers in selecting treatments that best meet their needs and preferences. Commissioners and policy makers agreed that SDM is a necessity and noted that policies in the UK and other countries required the involvement of patients in their treatment decisions. They also emphasised the importance of data and evidence-based recommendations to improve decision making about treatments.

> *"When I go to my doctor I realise it's my doctor who is making the decisions…but I think that patients now know often more about their own condition than the health professionals" (stroke survivor, SEM)*

> *"This information (risk factors) which used to be something that I, as a doctor, only thought about, it's now something that we should think about together" (GP, FG5)*

> *"How do we help patients and carers and health professionals together have a discussion using data information to make decisions about treatments?" (commissioner, FG2)*

2. Present and communicate recurrent stroke risk in a meaningful way

Both stroke survivors and healthcare professionals (in the focus groups and interviews) emphasised the importance of displaying and communicating personalised stroke risk estimation in a clear and meaningful way. Stroke survivors expressed that current risk presentations lacked clarity, with healthcare professionals agreeing with this idea, reporting that they also find it difficult to understand and communicate risk to patients whilst linking it to specific actions and behaviours among patients.

> *"What is this individual's risk of a further stroke in five years… and that's really important because patients commonly ask us that 'what is the risk of me having another stroke in the next year' and we come up with a figure and we say '5% of whatever'" (hospital stroke physician, Interview)*

> *"And I think the other thing is what actually is risk, how do you convey that, I mean, is it twice as much risk if I've never had a stroke…I know exactly what you mean 50% and 5% of that are meaningless to most people" (stroke survivor, FG4)*

> *"Because the patients often think that the GPs – or the doctors/the specialists understand risk. It's really difficult to understand risk and we have to use guidelines to help us with risk. So if the guidelines say, 'This is a risk and this is the level at which you should intervene', then I'm not well enough informed to go any further than that" (GP, FG3)*

3. Compare stroke survivor's perceived stroke risk with their predicted risk

In one of the focus groups, a carer voiced the importance of allowing stroke survivors to articulate their own perceived risk of having a recurrent stroke, which could then be compared with the actual predicted risk. Professionals and lay stakeholders in the group agreed that this would facilitate a collaborative discussion on potential risk factors and their impact on stroke risk.

> *"Patients themselves if they've been through a process will likely at some point be shown something and said either mark yourself on this, because another thing is where do you think you are on this scale at the moment with your risks, sometimes that's quite powerful" (carer, FG4)*

4. Personalise treatments to help control multiple stroke risk factors

Different stakeholders in a number of the focus groups and interviews emphasised the importance of controlling multiple risk factors for stroke recurrence in stroke survivors with multimorbidity and the need to develop effective treatments based specifically on the patient's characteristics (e.g., age, ethnicity, health conditions). Stroke survivors from the SRPFG similarly voiced their preference to know their personal risk according to their personal characteristics and receive tailored advice from professionals about what specific actions they could perform to reduce the identified risks. Commissioners were interested in care pathways for stroke patients with multimorbidity and how these care pathways could be tailored to the patient's characteristics.

> *"Patients who've had a confirmed stroke, the first thing as a family physician in terms of management is to make sure that you've controlled all their risk factors to prevent them getting another stroke" (GP, Interview)*

"And if the system could provide him, like, tailored for the patient taking all the information and saying OK for this patient because he had stroke, he has diabetes and high blood pressure, we recommend the following care pathway, treatments" (commissioner, SEM)

"Anything that can be personalised or tailored, so you don't feel it's this off the shelf thing that you're being given, you know… you sit with your doctor and it's not just a case of giving out a leaflet, but actually let's have a look at your personal data" (occupational therapist, FG4)

5. Display effectiveness of recommended treatments in reducing stroke risk

The majority of health and social care professionals, commissioners and policy makers perceived that stroke survivors with multimorbidity often have multiple risk factors to manage, and that prioritising the different treatments available for secondary prevention of these risk factors was required. Stroke survivors wanted to know the relative benefit of the proposed treatments being offered by clinicians in terms of how they addressed stroke risks and to take this information into account when deciding on personalised treatments. Commissioners specifically emphasised the importance of using evidence-based data to prioritise treatments to help patients in their decision making.

"…and you need to know, in fact, what the risk is if you do nothing compared with the risk if you do something" (stroke survivor, FG3)

"The question might be for a patient 'should I take a statin after a stroke' and we might be able to use the database to answer the question 'what would be the risk of future stroke if I do take a statin or if I don't take a statin' and you can use that information to help to come to a decision together" (commissioner, SEM)

"Well I suppose you could think about the common comorbidities, so hypertension and stroke, AF (atrial fibrillation) and stroke, diabetes and stroke and you could think about not necessarily an algorithm but a sort of stepwise prioritisation about what you should think about in terms of the patient's total management, you know, which would be the most important area of focus?" (GP, Interview)

6. Address stroke survivor concerns about treatment and barriers to adherence

Stroke survivors in some of the focus groups and the members of the SRPFG raised concerns about the challenges of multiple treatments they were expected to adhere to in order to decrease the potential risks of a recurrent stroke, commonly reporting that they did not always understand the value of these treatments. Several felt that a joint discussion with a healthcare professional about these concerns would help them better understand the value of a particular treatment and reach an informed decision about it. When interviewed, several GPs agreed that it was very challenging for stroke survivors with multimorbidity to adhere to multiple medications and other treatments at any given time, and that it is sometimes difficult to identify among their various treatments what is absolutely necessary and what is 'good to have'.

"My experience both with the doctors at the surgery and the consulting hospital is trying to discuss the medication that they insisted I took. I had horrendous side-effects and I kept trying to say to them 'Look, I'm having these side-effects, can I change, can I reduce, can I do blah blah' and their attitude I have to say, is one of terrorising patients" (stroke survivor, SEM)

"I think that's a common problem with all patients that suffer from comorbidities. It's rationalising their medication and you know being able to take a holistic view of the person and make sensible decisions about what they absolutely need to continue on and what they don't. And you can only really do that just by having time with the patient, you know if it's important for them to be able to sort of get up and get out and about and not feel dizzy, then you may have to compromise on how much blood pressure medication they take" (GP, Interview)

7. Support continuity of care

Stroke survivors commonly reported that they do not have appointments with their GP or other healthcare professionals on a regular basis. Several felt that the idea of personalised care to control stroke risk factors is very important but should have a follow-up to ensure continuity of care, which was often lacking. Some also perceived that the selected treatments and management plan should be saved on the system for future consultations and a follow-up appointment always set in advance. Commissioners also emphasised the importance of follow-up appointments and raised the concern that although follow-up appointments are an important part of stroke management and are required according to the National Institute for Health and Care Excellence (NICE) guidelines, many stroke survivors do not have follow-up appointments and do not see a GP over the longer term.

"I'm just thinking of my practice where it's very difficult to get to see the same doctor and if I was presented with my third in line (i.e. the risk graphic display) ten times from ten different doctors I'd be starting to get a bit hacked off I think" (stroke survivor, FG4)

"It's not a one time thing…there needs to be continuous interaction I think if something's going to happen (stroke survivor, FG4).

8. Identify stroke survivors at high risk of recurrent stroke

Healthcare professionals, commissioners and policy makers highlighted the need to proactively identify stroke survivors at high risk of having a recurrent stroke to assess and treat them in a timely manner. They felt that many stroke survivors, especially those with more severe long-term consequences from the stroke, do not often see a physician, and it is important to have a smart (automatic) system in place that could proactively identify them and assess their risks.

"I think the challenge first of all who are the high-risk patients, can we identify them and, if we can, is there a way through case management or community matrons, you know, linked with the stroke teams in the community providing access to therapy and assessment when it's required in a timely fashion" (commissioner, Interview)

Development of DOTT decision aid

The above themes and solutions were proposed, designed and refined during the collaborative design process with stakeholders, which informed the design of DOTT (Deciding on Treatments Together). DOTT is a computerised decision aid (i.e., a DSS designed to facilitate SDM), integrated with the EHR system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor, aiming to facilitate SDM on treatments to reduce recurrent stroke risk.

Specifically, DOTT will:

(1) Allow stroke survivors to indicate, in a graphic presentation (Figure 2), **their perceived risk of having a further stroke**. The graphic presentation in DOTT is based on population rank[43,44] simulating a queue of 20 people around the same age of the stroke survivor. Stroke survivors indicate where they think they are positioned in the queue (from least to most likely). This risk would then be compared to the actual predicted risk to facilitate conversation on risk factors. Needs from theme 3 are addressed with this feature.

(2) Display **stroke survivor's predicted risk of having a further stroke** in a meaningful and understandable way for both healthcare professionals and stroke survivors. The predicted stroke risk will be calculated based on the patient's information from the EHR and on rules generated from the linked dataset (SLSR and LDN). Needs from theme 2 are addressed with this feature (see Figure 2).

(3) Provide a **list of personalised recommended treatments** for stroke survivors based on their risk factors (e.g., hypertension, atrial fibrillation) extracted from the EHR. A list of the most effective evidence-based treatments for secondary prevention would be compiled and extracted from the recent NICE guidelines[45] and the National Clinical Guideline for Stroke.[46] This includes both clinical and lifestyle recommendations. For each recommended treatment, the evidence supporting the treatment will also be displayed. Needs from section 4 are addressed with this feature.

(4) **Prioritise the recommended treatments** based on their relative risk reduction and present the most effective treatment first. The clinician and stroke survivor can select one or more treatments and see on the graphic display, how the treatments reduce the overall stroke risk. The benefit of each treatment in terms of stroke risk will be calculated using the linked dataset (SLSR and LDN). Needs from theme 5 are addressed with this feature.

(5) **Display stroke survivors' common concerns** on the suggested treatments (e.g., "do I have to take blood pressure drugs for life?"), which will aid in identifying and addressing barriers to treatment adherence and eliciting preferences. An initial list of concerns and their response was prepared based on qualitative studies eliciting patients' barriers to treatment adherence.[47,48] Needs from theme 6 are addressed with this feature

(6) Allow stroke survivors and their carers to discuss the different treatments with the healthcare professional and **jointly select the treatments that best suit the stroke survivor's preferences, desired outcomes and goals** (and remove the ones that do not). Lifestyle modification will be discussed during the consultation and enhanced through referral to specialists or lifestyle intervention programs. The agreed management plan and information on the different treatments will be printed and handed to the stroke survivor to take home. Needs from theme 1 are addressed with this feature.

(7) Set automatically a **follow-up appointment** in 3 months' time. The information entered, including the agreed management plan is saved and transferred back to the stroke survivor's EHR for future consultations. During the follow-up consultation, the management plan is reviewed and treatments to address risk factors for stroke recurrence can be added, modified or removed. Desired clinical and patient outcomes will also be reviewed. Current NICE guidelines[45] for 'Secondary prevention following stroke and TIA' recommend primary care follow up on discharge, six months and then annually. A three-month follow up was selected as a reasonable interval for healthcare professionals and to provide enough time for patients to adhere to the selected treatments. Needs from theme 7 are addressed with this feature.

(8) The stroke prediction model will also be used to **proactively identify individuals at high risk of a recurrent stroke** by calculating their recurrent stroke risk at defined periods of time (the practice

can define the desired threshold) and alert the practice (e.g., physician, nurse, receptionist) to invite those patients for a clinical consultation. Needs from theme 8 are addressed with this feature.

(9) All information from patients and healthcare professionals (e.g., treatments selected by the patient, desired outcomes, predicted stroke risk, results in follow-up) will be **captured by the system as part of a LHS** and be used to improve the system's predictive model and treatment recommendations.

Figure 2 depicts an example screenshot from DOTT decision aid prototype.

<Insert Figure 2 here>

Usability and acceptability evaluation

Demographics

Eight stroke survivors and eight GPs participated in the usability and acceptability evaluations. GPs (4 men, 4 women) had average of 10.3 years of experience as a GP. All had experience in providing care to stroke survivors, had medium to high confidence in using new technology and low to medium experience using DSS. Stroke survivors (4 men, 4 women) had an average age of 65.5 years (SD: 11.4, range: 49-81). All had hypertension, two had heart problems, one was suffering from depression, four had mobility issues, and four had minor cognitive deficiencies (attention and memory).

Usability and acceptability

Both GPs and stroke survivors found the decision aid usable and acceptable. GPs found the decision aid easy to use (score 4.3), easy to understand (4.1) and felt very confident using it (4.2). They thought that this decision aid was better than how they usually helped patients decide about treatments for controlling their risk factors (4.4), that this strategy was compatible with the way they thought things should be done (4.3), that this type of decision aid was suitable for helping patients make informed choices (4.0) and that the decision aid complemented their usual approach (4.4). Stroke survivors perceived that they would like to use the decision aid frequently (4.0), thought that it was easy to use (4.2) and felt confident using it (4.1). Initial findings of the usability evaluation can be found in Porat et al.[49]

Identified themes

Seven main themes relating to the usability and acceptability of the decision aid were identified. These were divided into themes relating to the importance of the decision aid, its functionality and concerns from using it.

Importance of the decision aid

Logical and structured process that facilitates discussion

All GPs and stroke survivors (N=16) found the decision aid to be clear, and consisting of a logical flow that helped to structure the consultation. They felt that the decision aid facilitated a transparent discussion on the different proposed treatments and elicited patients' preferences.

> *"Physician pointing out what to do but the patient makes the decision since it's hard to get your head around everything. More doable if you have specific areas to work on with specific*

targets that suits you" (stroke survivor 2)

Importance of a learning system

Several GPs (N=3) raised the importance of a learning system providing up-to-date information. They wanted to make sure that the suggested treatments are in line with the most up-to-date evidence.

"The learning aspect is very important, since this system is based on evidence and evidence can change" (GP 6)

Can motivate patients to change behaviour

All GPs and stroke survivors (N=16) believed that the decision aid could motivate patients to change behaviour (e.g., take their medication to reduce blood pressure, increase physical activity, eat healthy). Stroke survivors liked the idea of being involved in deciding on their treatments according to their preferences and abilities, receiving information on their stroke risk factors, and discussing their views and concerns with their GP. They felt it gave them more control over their health and motivation to adhere to the treatments they selected. GPs felt it was a good way to discuss the different treatments and give patients the power to decide on treatments that suit them. A number of GPs and stroke survivors agreed that sharing decisions and enabling patients to select the treatments that best meet their preferences and goals, may increase patients' feeling of ownership over their health and improve adherence to the selected treatments.

"I believe discussing the different options with the patients, shared decision making, is likely to improve adherence" (GP 1).

Functionality

Powerful risk display showing the benefit of each treatment

The vast majority of GPs and stroke survivors (N=15) found the visual display showing the risk before and after a selected intervention, easy to understand, with some viewing it as a 'powerful' tool. Both stroke survivors and GPs commented that they were not aware of the effect the treatments have on reducing the stroke risk.

"The most powerful thing is the visual shifting of risk" (GP 5)

"Wow, a small change can make a big difference, this is very encouraging" (stroke survivor 6)

The patient takes home printed information

GPs and stroke survivors (N=10) thought that it was very important that the patient has a copy of the management plan and all the information printed so they can review it at home. In particular, stroke survivors wanted to have their current predicted risk and information on their selected treatments, including the date of the follow up appointment printed out, so it could motivate them to adhere to their treatments.

"The important thing is that the patient goes out with a piece of paper that summarises in bullet points the outcome of the consultation. If its black and white on paper it makes a difference" (stroke survivor 3)

Concerns

GPs and stroke survivors raised two main concerns from using the decision aid.

Deals with one aspect of the consultation

GPs and stroke survivors (N=6) felt that the decision aid is good but focuses on one aspect of the consultation (reducing risk of recurrent stroke) and patients may have other concerns, such as depression or social isolation.

> *"This is good, but for me the most important thing is the emotional aspect, and this tool doesn't relate to that" (stroke survivor 4)*

Time

The main concern for GPs was time (N=6), in which within the allotted standard 10 minutes for the consultation already provided significant limits, and most felt they will not manage to fit it in.

Suggestions for improvement

GPs and stroke survivors provided suggestions for improving the decision aid:

1. The terminology was too clinical, for example "treatments" and "management", could be changed to "possible strategies or approaches".
2. In addition to the management plan, information (e.g., in the form of a leaflet) on each of the selected treatments should also be printed out and given to patients.
3. Add clinical data, for example when clicking on "cholesterol" show the patient's last three values, and do this also for their blood pressure.
4. Enable more than one display of risk, because each patient may prefer a different display and understands risk differently.
5. Add emotional and mental health aspects which are related to stroke risk.

We subsequently made the above changes and additions to the updated version of DOTT.

DISCUSSION

Our work focused on engaging various stakeholders in the identification, design, prototyping and evaluation of a decision aid to improve secondary prevention after stroke. Eight themes informed the design of DOTT. A number of the themes and solutions proposed by the stakeholders have been implemented previously to some extent to support other patient groups, such as diabetes and atrial fibrillation.[50,51] These include, predicting a patient's risk based on their risk factors, proposing possible treatments and displaying their benefit in decreasing the risk[50] and incorporating patients' concerns within the decision making process.[51] These themes were found useful and are recommended in SDM tools (e.g., in the IPDAS[23]).

Additional unique themes and solutions have emerged as outcomes of the collaborative design process in this study, which could be used for a range of chronic diseases requiring long-term management. Specifically:

(1) ***Present and communicate risk in a meaningful way.*** While there are many different ways to communicate multiple risks to patients, the most commonly used are absolute or relative risks presented as percentages or probabilities (e.g., "from 100 people like you 20 are expected to have a recurrent stroke").[52] However, studies have shown that in general, healthcare professionals are as unfamiliar as their patients with risk estimates and probabilities[53] and often healthcare professionals have reported finding it difficult to combine multiple risk factors into an accurate assessment of

vascular risk[54] and to communicate this risk to patients.[55] Moreover, patients may feel that statistical risk estimates do not apply to them personally.[56] To overcome this, our graphic presentation is based on population rank, simulating the patient in a queue of people around their age.[43,44] Studies have also shown that formats which present data framed as the risk of an individual were perceived as more relevant and easier to relate to than percentage risk estimates.[57]

(2) ***Compare patient's perceived risk with their predicted risk***. This is a novel requirement from a DSS, which to our knowledge does not exist in current systems. Perceived risk of adverse outcomes such as stroke may be an important concept in understanding patient's adherence to medication and recommended health behaviours.[58] Overall, patients tend to underestimate their own risk.[59] This tendency was also found when patients estimated their cardiovascular risk.[60] Weinstein refers to this underestimation as an "optimistic bias".[59] For example, a recent study found that people with undiagnosed diabetes or prediabetes considerably underestimated their probability to have or develop diabetes.[61] Lower perceived risk has been associated with poorer adherence to recommended health behaviours[62] and hence a more realistic perception of risk may increase patients' interest in risk reduction.[62] Research has shown that individualised risk feedback was effective in increasing perceived stroke risk among patients who had underestimated their stroke risk at baseline.[63] This may imply that eliciting patients' perceived risk and showing them the actual predicted risk can change their inaccurate risk perception and increase their interest in risk reduction.

(3) ***Prioritising treatments***. Healthcare professionals have previously expressed concerns about managing care and making decisions about treatments, including communicating risks and benefits for patients with multimorbidity and complex needs.[64] They commonly report having to make decisions with such patients which involve a process of prioritisation or trade-offs, facilitating a discussion with the patient on what is important to the patient and what they would like to achieve in terms of their health (i.e. goal setting).[64] Aligning patient goals and desired outcomes with clinicians' goals is likely to improve outcomes for these patients.[65]

(4) *Identify individuals at high risk*. Calculating periodically (in an automatic way) the stroke risk of survivors to identify individuals at high risk of recurrent stroke (based on their information in the EHR) could be a valuable feature for improving long-term management and care for stroke survivors who are less likely or able to visit healthcare professionals on a regular basis. This theme was identified and prioritised by healthcare professionals and commissioners/policy makers and not by stroke survivors or carers, emphasising the importance of treating vulnerable patients in a timely manner and provide proactive patient-centred care. This is in line with the NHS Long Term Plan set in 2019.[66] Patients/carers who participated in the focus groups were relatively mobile and maybe this was less of a priority for them.

These solutions, which are delivered through a DSS integrated with the EHR system and based on data from a linked population dataset, have the potential to be an instrument of change in clinical practice. This will be done by providing scientific evidence at the point of clinical care (e.g., personalised treatments and their benefit based on the individual's risk factors), while simultaneously collecting information from that care (e.g., treatments selected by the patient, desired outcomes, predicted stroke risk) to promote innovation in optimal healthcare delivery.[17]

Strengths and limitations

Although the core focus of the DSS (prevention of a future stroke) was identified by patients as a

priority, having a single focus might hinder discussions of other important problems (e.g., depression, social isolation). Such issues may even have a larger perceived impact on long-term outcomes after stroke, for example, improving mental health or access to social care services, which were also brought up by stakeholders as a priority to address long-term care for stroke survivors with multimorbidity,[14] and were raised as a concern in the usability and acceptability evaluations. Depression is indeed a risk factor of stroke,[67] and the treatment 'manage low mood/depression' will be displayed to all patients, enabling healthcare professionals to relate to this aspect and propose ways to manage this (e.g., medication, referral to a professional, group therapy).

In a study assessing stroke survivors' self-reported needs,[68] more than 50% of long-term stroke survivors reported an unmet need for stroke information (e.g. cause, prevention of recurrence). The proposed decision aid offers a meaningful starting point for addressing this common unmet need. Evidence suggests that the provision of lifestyle advice from healthcare professionals' is effective in changing health behaviours[69] and healthcare professionals' communication is positively correlated with patient adherence to treatments.[70] However, a conversation-based DSS also relies on the attitudes and communication skills of the healthcare professionals, which have been found to vary.[71] Interactive SDM skill training has improved SDM skills and promoted positive attitudes.[72] Training healthcare professionals in communication skills for SDM has also been shown to result in substantial and significant improvement in patient adherence to treatments.[70] Hence, interactive SDM skills training workshops will have to complement the use of the DSS. Patients are also likely to need support and preparation with taking part in SDM during the consultation.[72]

The design of DOTT meets the IPDAS collaboration criteria for quality decision aids.[23] Specifically, DOTT was designed to incorporate principles of SDM, by presenting stroke survivors with information about their treatment options and likely outcomes, presenting the risks and benefits of each option, and engaging the healthcare professional and stroke survivor in a joint conversation about the patient's preferences.[32] Furthermore, DOTT evolves from a systematic development process, uses non-technical language and presents information in a balanced manner that allows for comparisons across alternatives.[23] Wearable sensors (e.g., Fitbit, Apple Watch, blood pressure monitor) could further help patients monitor and self-manage the selected treatments (e.g., control blood pressure, increase physical activity) outside the consultation. In the future, data from wearable sensors could be integrated to the EHR, and DOTT could use this information to improve its risk prediction model and treatment recommendations.

In the usability and acceptability evaluation, stroke survivors and GPs found DOTT to be both useful and usable. GPs perceived that the decision aid helped with structuring the consultation and eliciting patients' preferences for treatments. Stroke survivors felt it provides a good way to understand the different treatment options and select the ones that best suits their preferences. GPs' main concern was that the decision aid would increase consultation times. Indeed, time constrains were identified as the main barrier for the adoption of innovations by family physicians.[73,74] A possible solution could be to use the decision aid as part of a clinical review after stroke, which is usually longer (e.g., 3 month, 6 month and annual review) and by dedicated healthcare professionals which are less limited in time such as stroke nurses and pharmacists working in GPs' practices that are trained to consult patients with chronic and long-term health conditions.

CONCLUSION

Engaging various stakeholders throughout the design and evaluation process ensures that the intervention (features and functions) is in line with the needs reported by the different stakeholders (i.e., stroke survivors, healthcare professionals, policy makers). DOTT has demonstrated the potential to reduce stroke recurrence by adopting a data-driven user-centred approach. DOTT urges clinicians to shift away from the professionally led advice-giving approach typically used in medical consultations to one which collaboratively and actively engages the patient in decision making and respects patient choice and autonomy. This may lead to stroke survivors taking ownership for the treatment decisions, improving their adherence to the agreed management plan and thus reducing their stroke risk. A future feasibility study and subsequent clinical trial will evaluate the effectiveness of DOTT in improving decision making quality, and whether it affects risk factor levels and risk of recurrence. While DOTT currently targets stroke risk factors only, the design approach could be used for a range of chronic diseases requiring long-term management, paving the way to a set of standards for delivering LHS interventions in clinical practice.

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Data sharing statement: There are no additional data available from this study.

Checklist for reporting guidelines: the authors used SRQR guidelines for reporting qualitative research.

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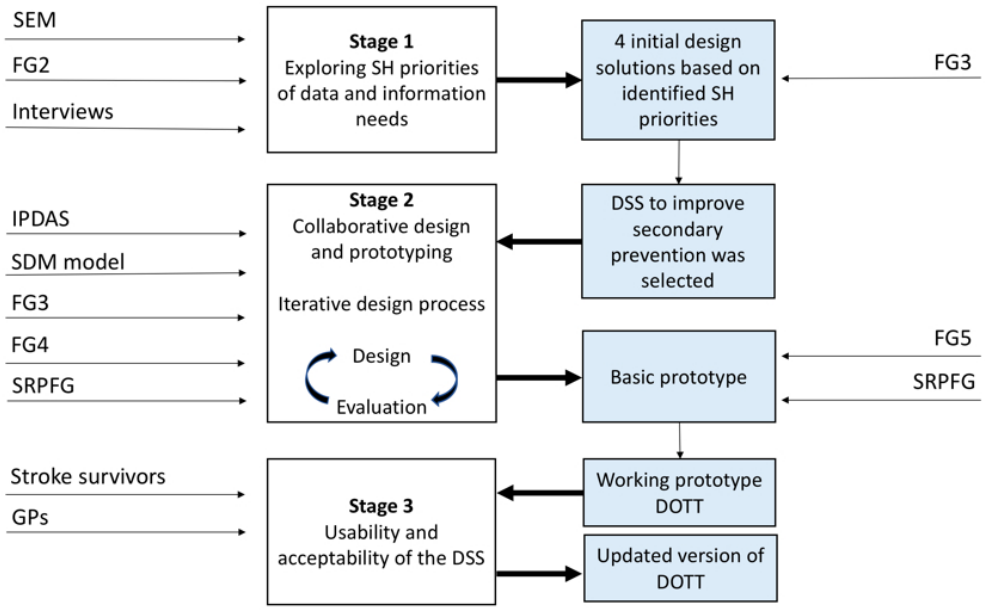
Figure captions

Figure 1: A diagrammatic summary of the development and evaluation of DOTT, including the data that fed the different stages and the outputs. SEM = Stakeholder Engagement Meeting (consisting 3 focus groups)**;** FG = Focus group; SH=Stakeholders; IPDAS = International Patient Decision Aids Standards[23]; SDM model = Shared decision making model for clinical practice[32]; SRPFG = Stroke Research Patient and Family Group[31]

Figure 2: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control of blood pressure).



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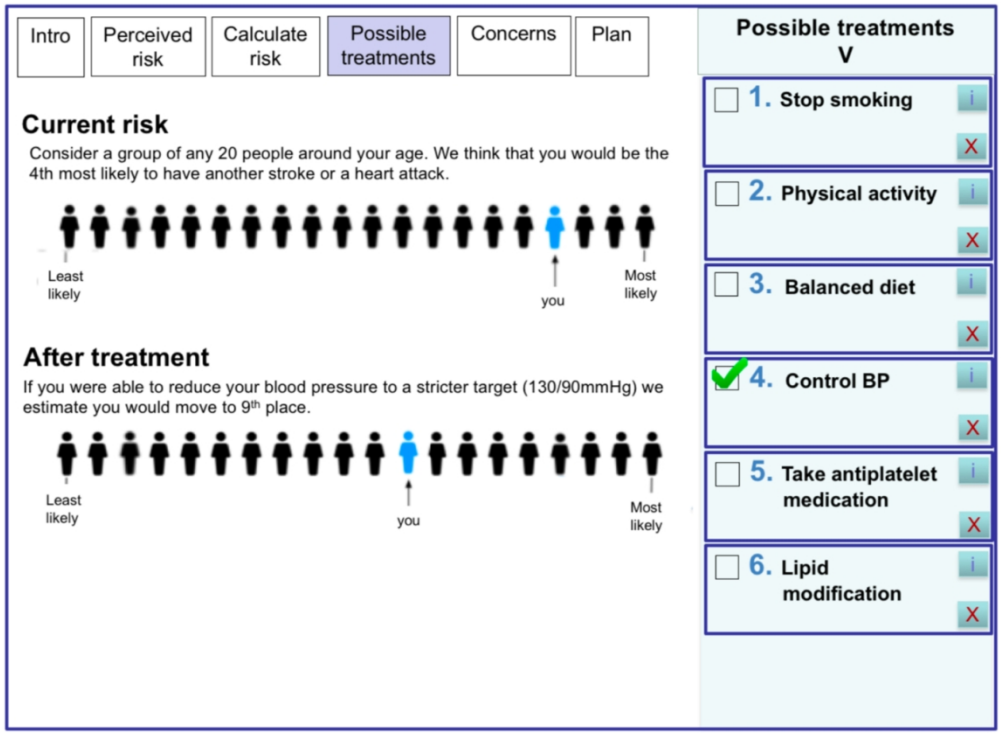

Figure 2: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control of blood pressure).

Box 1: Topic guide for the separate focus groups in the SEM

In a large group, explain:

- Study aim
- What a LHS is, and how a LHS might work in general practice
- The co-production approach we are using

In separate focus groups:

- Ask participants to provide examples of information which are/would be useful for patients/carers/clinicians/health commissioners?
- Previous experiences of information delivery: What worked well? What worked badly/not so well?

Explore stakeholders' understandings around what is data linkage, and what is a learning health system (LHS)?

- How would a LHS work in practice for stroke?
- Any ethnical concerns about this process (particularly regarding data linkage)? How can these be addressed?
- What types of information could be generated using this method?
- How broadly might they be delivered?

Discuss ideas for new information interventions

- Feedback from individual groups

Develop as a larger group a priority list for key priorities for data and information needs.

Note: Since a few healthcare professionals could not attend the focus groups, we conducted face-to-face interviews with them using the same topic guide.

Box 2: post-usability interview - patients

- Do you have any comments about today's session? Feel free to comment on anything you want.
- How did it feel having a consultation using the decision aid?
- Who do you think should be involved in making decisions about how acceptable your risks are of having a further stroke?
  - □ your doctor alone
  - □ mostly your doctor
  - □ your doctor and you equally
  - □ mostly you
  - □ you alone
- Who do you think should be involved in making decisions about ways to reduce your risk of stroke?
  - □ your doctor alone
  - □ mostly your doctor
  - □ your doctor and you equally
  - □ mostly you
  - □ you alone
- To what extent do you agree with the following statement? (from 1 strongly disagree to 5 strongly agree)
  - The decision aid will help patients with adopting healthier behaviours, such as changing Lifestyle habits and/or taking medication according to the management plan they agreed on.
  - Having seen how the decision aid works, patients will likely look for more information about stroke and its risk factors.
- (if agreed on statement above) Can you please describe how the decision aid might support patients in changing some of their health-related habits?
- What might make it difficult (barriers, hurdles) for patients to change some of their health-related habits?
- Would you find the decision aid helpful for your own health-related habits?
- What do you like about the decision aid?
- What don't you like about the decision aid?
- What suggestions do you have to improve the decision aid?

Give Acceptability and Usability questionnaires.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also	4,5

		recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	7
Context	#7	Setting / site and salient contextual factors; rationale	4,5
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5, 17
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	5,6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	4,5,6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5,6,7
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	6

Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	7
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	7-10,11-13
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6-9,12-14
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	14-15
Limitations	#19	Trustworthiness and limitations of findings	15,16
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Collaborative design of a decision aid for stroke survivors with multimorbidity: a qualitative study in the UK engaging key stakeholders

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Collaborative design of a decision aid for stroke survivors with multimorbidity: a qualitative study in the UK engaging key stakeholders

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ABSTRACT

Objectives: Effective secondary stroke prevention strategies are sub-optimally used. Novel development of interventions to enable healthcare professionals and stroke survivors to manage risk factors for stroke recurrence are required. We sought to engage key stakeholders in the design and evaluation of an intervention informed by a Learning Health System approach, to improve risk factor management and secondary prevention for stroke survivors with multimorbidity.

Design: Qualitative, including focus groups, semi-structured interviews and usability evaluations. Data was audio-recorded, transcribed and coded thematically.

Participants: Stroke survivors, carers, health and social care professionals, commissioners, policy makers and researchers.

Setting: Stroke survivors were recruited from the South London Stroke Register; health and social care professionals through South London general practices and King's College London (KCL) networks; carers, commissioners, policy-makers and researchers through KCL networks.

Results: 53 stakeholders in total participated in focus groups, interviews and usability evaluations. Thirty-seven participated in focus groups and interviews, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy-makers (N=6) and researchers (N=4). Sixteen participated in usability evaluations, including stroke survivors (N=8) and general practitioners (GPs; N=8). Eight themes informed the collaborative design of DOTT (Deciding on Treatments Together), a decision aid integrated with the electronic health record system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor. DOTT aims to facilitate shared decision making on personalised treatments leading to improved treatment adherence and risk control. DOTT was found acceptable and usable among stroke survivors and GPs during a series of evaluations.

Conclusions: Adopting a user-centred data-driven design approach informed an intervention that is acceptable to users and has the potential to improve patient outcomes. A future feasibility study and subsequent clinical trial will provide evidence of the effectiveness of DOTT in reducing risk of stroke recurrence.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Engaging a range of stakeholders in the design and evaluation of an intervention ensures that the intervention is in line with the needs reported by the different stakeholders (e.g., stroke survivors, healthcare professionals, policy makers).
- Adopting a Learning Health System approach enables the delivery of personalised recommendations in real time whilst simultaneously capturing additional data back into the system, to improve the system's predictive model and recommendations.
- As only stroke survivors able to attend the focus groups participated in the study, we did not elicit the views of stroke survivors who are less mobile or housebound.

INTRODUCTION

Stroke is the second leading cause of death and a major cause of disability worldwide.[1] In 2015, there were 3.7 million people living with stroke as a chronic condition in Europe and this number is expected to reach 4.6 million in 2035.[2] Stroke survivors have a nearly 40% cumulative risk of recurrence during the first 10 years after stroke.[3] Secondary stroke prevention requires healthcare professionals to offer effective interventions to monitor and manage risk factors, and for patients to change health related behaviours (e.g., smoking)[4] and adhere to preventative medications (e.g., to control hypertension).[5] Follow-up appointments with clinicians offer opportunities to discuss interventions for reducing the risk of future stroke. However, long-term stroke care is characterised by a lack of continuity[6] and modifiable risk factors are currently not well detected, managed or controlled post stroke.[7]

Interventions designed to improve risk-factor management among stroke survivors in randomised controlled trials (RCTs) have shown modest or no effect. A recent Cochrane systematic review of 42 RCTs evaluating the effectiveness of educational and behavioural or organisational interventions on modifiable risk factor control for secondary prevention of stroke, found no clear benefit in any of the target outcomes (i.e., blood pressure, lipid profile, HbA1c, BMI and recurrent cardiovascular events).[8] Possible reasons could be that these interventions have not been part of the clinical decision-making process of clinicians, did not engage various stakeholders in the design of the intervention, and were not integrated with the Electronic Health Record (EHR) (with the exception of one study[9]) - all of which are considered critical features of successful clinical decision support systems.[10,11]

Stroke survivors commonly experience multimorbidity.[12] Gallacher and colleagues found that 94% of the people with stroke had one or more additional morbidities and often experienced long-term physical, psychological and social consequences.[12] This makes improving long-term stroke care a complex endeavour, requiring patient engagement, high quality up-to-date information and a holistic approach which focuses on the patient and not on the disease.[13] These aspects are important both to plan effective treatments for individual patients and guide best practice for the stroke population in general.[14]

The Learning Health System (LHS) 'focusses on approaches to capture data from clinical encounters and other health-related events, analyse the data to generate new knowledge, and then apply this knowledge to continuously inform and improve health decision making and practice.'[15(p.177)] In a recent report (2019) stating what the NHS can learn from the LHS, the authors argue that it is necessary to utilise data to transform services, not just to digitise current ways of working.[16] Thus, LHS outputs can provide tailored information on optimal care decisions and be delivered at the point of clinical care.[17]

Decision support systems (DSS) which aim to analyse a patient's characteristics to provide tailored recommendations (such as for diagnosis,[18] treatment or long-term management), implement this transfer of evidence into practice. This is done particularly when used in conjunction with sources of 'Real World Data'[19] such as EHR systems that capture detailed data on specific conditions. Such point-of-care DSS support a range of applications, including identifying patient risk estimation, providing guidance on the appropriateness of treatments, and tailoring clinical information to specific patient needs - providing the right care to the right patient at the right time.[17] A few studies have reported that engaging stakeholders to develop a LHS and integrated DSS improved patient outcomes and processes of care for individuals with long-term conditions.[20,21]

Increasingly patients are expecting to be informed and involved in their care.[22] This shift from imposition of professional opinion towards a more collaborative model of care is not only relevant when people face difficult decisions about their health, where there are high stakes and where outcomes are uncertain, but also in situations where people need to manage long term conditions or consider making changes in their lifestyles in order to reduce future risks.[23] Such shared decision making (SDM) respects patient values and preferences, and supports decision-making through the provision of high-quality, accessible information.[24] SDM has been found to be most effective if interventions are developed for use during the clinical encounter,[25] and several DSS that have been designed to facilitate SDM during the consultation (i.e., decision aids) have shown improved treatment adherence and clinical outcomes in patients with chronic conditions such as asthma and diabetes.[26,27]

In his seminal analysis, Berg criticised the 'top-down' technology centred approach to designing decision support systems.[28] He described an alternative *socio-technical* approach, where new tools needed to be designed taking into account the real-world complex networks of people involved in health care, and designed using an iterative approach which makes strong use of qualitative research with users.

Aims and objectives

The aim of this study was to engage key stakeholders to identify priorities and information needs in long term stroke care and collaboratively design and evaluate a selected intervention that could be integrated as part of the EHR system informed by a LHS approach. The data supporting the selected intervention are based on linked datasets from the South London Stroke Register (SLSR),[29] which includes more than 6,000 records of first-ever strokes that occur in South London, and Lambeth Datanet (LDN)[30] containing primary care data of local general practices in South London.

METHOD

Patient and public involvement

The design was informed by active feedback from stroke survivors and carers from King's College London's Stroke Research Patient and Family Group (SRPFG)[31], a service user research group which consists of 32 participants currently on the SLSR who are from diverse socio-economic and ethnic backgrounds. Stroke survivors, carers, health and social care professionals, commissioners, policy makers and researchers were involved throughout the study in a collaborative design and evaluation process.

Data collection

We used a range of methods to engage stakeholders (N=53) in the design and evaluation of the intervention, including focus groups, face to face interviews and usability evaluations (see topic guides and interview questions in the supplementary files). The process involved three main stages: (1) exploring stakeholder priorities for data and information needs to inform potential solutions for long-term stroke care; (2) collaborative design of the selected intervention with stakeholders, comprising cycles of design, prototyping and evaluation; (3) Usability and acceptability evaluation of the DSS prototype (See Figure 1). Thirty-seven stakeholders participated in the first two stages, including stroke survivors and carers (N=11), health and social care professionals (N=16), commissioners and policy makers (N=6) and researchers (N=4). Sixteen stakeholders participated in the third stage,

including 8 stroke survivors and 8 General practitioners (GPs). Stroke survivors were recruited from the SLSR. Health and social care professionals were recruited through general practices in South London and King's College London networks. Carers, commissioners, policy makers and researchers were also recruited through these networks. Stakeholders were purposively sampled to include stroke survivors (i.e. men and women, with a range of disabilities and long-term conditions, risk factors and length of time since their stroke) and professionals providing all types of stroke care and support. See Table 1 for details of all stakeholders taking part in the study. Participants could take part in the study if they were able to attend the meetings and were willing to sign a consent form. Transport was arranged for less mobile patients.

<Insert Figure 1 here>

Stage 1: Exploring stakeholder priorities for data and information needs

In total, 37 stakeholders participated in this stage. An initial stakeholder engagement meeting comprising 24 participants (SEM), 9 face to face interviews with key stakeholders who could not attend this meeting, and a second focus group involving 12 participants (FG2) were conducted (some participants took part on multiple occasions). The methods and findings from this stage of the study have been reported elsewhere.[14] In brief, in the initial engagement meeting (SEM), participants were introduced to the concept of a LHS and then in three separate focus groups (service user/carer; health and social care professionals; commissioners and policy makers) they were asked to identify priorities and potential solutions that may be derived from the clinical data to improve long-term stroke care for stroke survivors with multimorbidity. Then, in the larger group, through a process of priority setting and consensus led by a facilitator (ES), stakeholders identified a number of priorities and solutions to improve long-term management of stroke (i.e. improving continuity of care; improving management of mental health consequences; better access to health and social care; and targeting multiple risk factors). Targeting multiple risk factors after stroke was identified among stakeholders as a key priority, and a DSS to improve secondary prevention after stroke to target multiple risk factors was subsequently chosen within a smaller core stakeholder group (FG3) for further development. This core stakeholder group (N=12) comprised stroke survivors, healthcare professionals, carer, policy maker and commissioner, and worked collaboratively with the research team to subsequently design the intervention and to provide their active feedback.

Stage 2: Collaborative design and prototyping of selected intervention

The initial design of the DSS to improve secondary stroke prevention and target multiple risk factors after stroke was informed by the first stage and guided by the International Patient Decision Aids Standards (IPDAS),[23] which provides a framework and standards for the design of patient decision aids, and the SDM model for clinical practice.[32] The latter provides a model of how to conduct shared decision making in practice based on providing patients choice, a range of options and involving them in 'decision talk'. Following feedback from the core stakeholder group at the third focus group meeting above (N=10) (FG3), an updated design of the intervention was subsequently reviewed by the core stakeholder group at a fourth focus group (N=9) (FG4) and was revised following their feedback. The DSS was also presented to the King's College London's SRPFG. The intervention was revised and the updated design was developed as a basic prototype and was further discussed during a subsequent focus group with the core stakeholder group (N=9) (FG5) and the SRPFG. This process allowed all stakeholders to iteratively develop and refine the DSS to a working prototype.

Stage 3: Usability and acceptability evaluation of the DSS

Sixteen participants, including eight stroke survivors and eight GPs participated in the usability and acceptability evaluation of the working prototype of the DSS. None had taken part in the previous stages of the study.

The evaluation included simulated consultations using the DSS prototype. In the GPs session, the researcher acted as the patient, and in the stroke patient's session, the researcher acted as the GP. GPs were given a short tutorial on how to use the DSS before the simulated consultations and stroke survivors were given a short explanation about the DSS. GPs and stroke survivors were interviewed after the simulated consultation, asking them to provide feedback on the DSS, including its strengths, limitations and suggestions for improvements. Stroke survivors and GPs also answered an acceptability questionnaire[33] and the System Usability Scale (SUS).[34] Acceptability relates to the comprehensibility of the components of the decision aid, including its length, pace, amount of information, balance in presentation and overall suitability.[33] Usability is 'the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use'.[35] The SUS is composed of 10 questions and has been shown to be a reliable and psychometrically validated tool.[36] Ratings were provided on 5-point Likert scales from 1 (strongly disagree) to 5 (strongly agree), with higher ratings indicating higher satisfaction.

For the usability evaluation, the DSS prototype had the following functionality and flow:

- Stroke survivors (patients) indicated their perceived risk of having a recurrent stroke.
- GPs entered the patient's characteristics (age, gender, clinical conditions).
- The system displayed a 'typical' recurrent stroke risk (age group specific average)[37] and the most effective treatments based on the patient's characteristics.
- The benefit of each treatment in terms of reducing the stroke risk was displayed. Estimated relative stroke risk reductions were calculated based on the existing literature.[38-41]
- Information and common concerns for each treatment were displayed.
- The GP and patient decided on a management plan whilst identifying desired clinical and patient outcomes.
- Patients were told that their management plan would be printed to take home.

Table 1. Stakeholders taking part in the study

Type of stakeholder	SEM (N=24)	Interviews (N=9)	FG2 (N=12)	FG3 (N=10)	FG4 (N=9)	FG5 (N=9)	Usability evaluation (N=16)	Total (N=53*)
Stroke survivor	**10**		**2**	**2**	**2**	**2**	**8**	**18**
Carer	**1**		**1**	**1**	**1**	**1**		**1**
Health and social care professional	**8**	**7**	**3**	**2**	**2**	**2**	**8**	**22**
GP	2	5	1	1	1	1	8	13
Physiotherapist	2		1					2
Speech and language therapist	1							1
Social care professional	1							1
Public health doctor	1							1
Consultant psychiatrist	1							1
Occupational therapist			1	1	1	1		1
Acute stroke care consultant		2						2
Policy makers and commissioners	**3**	**2**	**2**	**2**	**2**	**2**		**6**

Third sector representatives	**2**						**2**
Academic researchers (social scientist, researchers working with SLSR/LDN databases)		**4**	**3**	**2**	**2**		**4**

Notes:

1. *Overall 53 participants took part in the study, but a number of stakeholders took part on multiple occasions.
2. King's College London's Stroke Research Patient and Family Group (SRPFG) comprising 32 stroke survivors and carers also provided feedback on the design of the intervention in two of their meetings.

Data Analysis

Data from focus groups and interviews were audio recorded, transcribed in full and stored in NVivo (Version 11). Qualitative data were analysed using a thematic analysis approach[42] to identify themes and sub-themes related to stakeholder perspectives informing the identification, design and evaluation of a DSS to improve secondary prevention for stroke survivors, which could be part of a LHS. This involved two authors (TP, ES) assigning codes and refining themes from the data, noting similarities and differences between stakeholder perspectives. The two authors have doctoral/post-doctoral experience in conducting and analysing qualitative data in applied health research.

RESULTS

Focus groups and interviews

Eight themes related to improving secondary prevention and management of multiple risk factors after stroke were identified from focus groups and interviews:

1. Involve stroke survivors in decisions concerning their treatments

In the focus groups, stroke survivors often articulated that due to their multiple health conditions, and hence multiple risk factors for stroke recurrence, they would like to be more involved in selecting their treatments based on what is important to them and their desired outcomes. This viewpoint was further confirmed by stroke survivors participating in King's College London's SRPFG. A number of clinicians perceived that SDM did not take place on a regular basis during routine clinical consultations, and there was a need for greater involvement of stroke survivors and their carers in selecting treatments that best meet their needs and preferences. Commissioners and policy makers agreed that SDM is a necessity and noted that policies in the UK and other countries required the involvement of patients in their treatment decisions. They also emphasised the importance of data and evidence-based recommendations to improve decision making about treatments.

> *"When I go to my doctor I realise it's my doctor who is making the decisions…but I think that patients now know often more about their own condition than the health professionals" (stroke survivor, SEM)*

> *"This information (risk factors) which used to be something that I, as a doctor, only thought about, it's now something that we should think about together" (GP, FG5)*

> *"How do we help patients and carers and health professionals together have a discussion using data information to make decisions about treatments?" (commissioner, FG2)*

2. Present and communicate recurrent stroke risk in a meaningful way

Both stroke survivors and healthcare professionals (in the focus groups and interviews) emphasised the importance of displaying and communicating personalised stroke risk estimation in a clear and

meaningful way. Stroke survivors expressed that current risk presentations lacked clarity, with healthcare professionals agreeing with this idea, reporting that they also find it difficult to understand and communicate risk to patients whilst linking it to specific actions and behaviours among patients.

> *"What is this individual's risk of a further stroke in five years… and that's really important because patients commonly ask us that 'what is the risk of me having another stroke in the next year' and we come up with a figure and we say '5% of whatever'" (hospital stroke physician, Interview)*

> *"And I think the other thing is what actually is risk, how do you convey that, I mean, is it twice as much risk if I've never had a stroke…I know exactly what you mean 50% and 5% of that are meaningless to most people" (stroke survivor, FG4)*

> *"Because the patients often think that the GPs – or the doctors/the specialists understand risk. It's really difficult to understand risk and we have to use guidelines to help us with risk. So if the guidelines say, 'This is a risk and this is the level at which you should intervene', then I'm not well enough informed to go any further than that" (GP, FG3)*

3. Compare stroke survivor's perceived stroke risk with their predicted risk

In one of the focus groups, a carer voiced the importance of allowing stroke survivors to articulate their own perceived risk of having a recurrent stroke, which could then be compared with the actual predicted risk. Professionals and lay stakeholders in the group agreed that this would facilitate a collaborative discussion on potential risk factors and their impact on stroke risk.

> *"Patients themselves if they've been through a process will likely at some point be shown something and said either mark yourself on this, because another thing is where do you think you are on this scale at the moment with your risks, sometimes that's quite powerful" (carer, FG4)*

4. Personalise treatments to help control multiple stroke risk factors

Different stakeholders in a number of the focus groups and interviews emphasised the importance of controlling multiple risk factors for stroke recurrence in stroke survivors with multimorbidity and the need to develop effective treatments based specifically on the patient's characteristics (e.g., age, ethnicity, health conditions). Stroke survivors from the SRPFG similarly voiced their preference to know their personal risk according to their personal characteristics and receive tailored advice from professionals about what specific actions they could perform to reduce the identified risks. Commissioners were interested in care pathways for stroke patients with multimorbidity and how these care pathways could be tailored to the patient's characteristics.

> *"Patients who've had a confirmed stroke, the first thing as a family physician in terms of management is to make sure that you've controlled all their risk factors to prevent them getting another stroke" (GP, Interview)*

> *"And if the system could provide him, like, tailored for the patient taking all the information and saying OK for this patient because he had stroke, he has diabetes and high blood pressure, we recommend the following care pathway, treatments" (commissioner, SEM)*

> *"Anything that can be personalised or tailored, so you don't feel it's this off the shelf thing that*

you're being given, you know… you sit with your doctor and it's not just a case of giving out a leaflet, but actually let's have a look at your personal data" (occupational therapist, FG4)

5. Display effectiveness of recommended treatments in reducing stroke risk

The majority of health and social care professionals, commissioners and policy makers perceived that stroke survivors with multimorbidity often have multiple risk factors to manage, and that prioritising the different treatments available for secondary prevention of these risk factors was required. Stroke survivors wanted to know the relative benefit of the proposed treatments being offered by clinicians in terms of how they addressed stroke risks and to take this information into account when deciding on personalised treatments. Commissioners specifically emphasised the importance of using evidence-based data to prioritise treatments to help patients in their decision making.

"…and you need to know, in fact, what the risk is if you do nothing compared with the risk if you do something" (stroke survivor, FG3)

"The question might be for a patient 'should I take a statin after a stroke' and we might be able to use the database to answer the question 'what would be the risk of future stroke if I do take a statin or if I don't take a statin' and you can use that information to help to come to a decision together" (commissioner, SEM)

"Well I suppose you could think about the common comorbidities, so hypertension and stroke, AF (atrial fibrillation) and stroke, diabetes and stroke and you could think about not necessarily an algorithm but a sort of stepwise prioritisation about what you should think about in terms of the patient's total management, you know, which would be the most important area of focus?" (GP, Interview)

6. Address stroke survivor concerns about treatment and barriers to adherence

Stroke survivors in some of the focus groups and the members of the SRPFG raised concerns about the challenges of multiple treatments they were expected to adhere to in order to decrease the potential risks of a recurrent stroke, commonly reporting that they did not always understand the value of these treatments. Several felt that a joint discussion with a healthcare professional about these concerns would help them better understand the value of a particular treatment and reach an informed decision about it. When interviewed, several GPs agreed that it was very challenging for stroke survivors with multimorbidity to adhere to multiple medications and other treatments at any given time, and that it is sometimes difficult to identify among their various treatments what is absolutely necessary and what is 'good to have'.

"My experience both with the doctors at the surgery and the consulting hospital is trying to discuss the medication that they insisted I took. I had horrendous side-effects and I kept trying to say to them 'Look, I'm having these side-effects, can I change, can I reduce, can I do blah blah' and their attitude I have to say, is one of terrorising patients" (stroke survivor, SEM)

"I think that's a common problem with all patients that suffer from comorbidities. It's rationalising their medication and you know being able to take a holistic view of the person and make sensible decisions about what they absolutely need to continue on and what they don't. And you can only really do that just by having time with the patient, you know if it's important for them to be able to sort of get up and get out and about and not feel dizzy, then you may have to compromise on how much blood pressure medication they take" (GP,

Interview)

7. Support continuity of care

Stroke survivors commonly reported that they do not have appointments with their GP or other healthcare professionals on a regular basis. Several felt that the idea of personalised care to control stroke risk factors is very important but should have a follow-up to ensure continuity of care, which was often lacking. Some also perceived that the selected treatments and management plan should be saved on the system for future consultations and a follow-up appointment always set in advance. Commissioners also emphasised the importance of follow-up appointments and raised the concern that although follow-up appointments are an important part of stroke management and are required according to the National Institute for Health and Care Excellence (NICE) guidelines, many stroke survivors do not have follow-up appointments and do not see a GP over the longer term.

> *"I'm just thinking of my practice where it's very difficult to get to see the same doctor and if I was presented with my third in line (i.e. the risk graphic display) ten times from ten different doctors I'd be starting to get a bit hacked off I think" (stroke survivor, FG4)*

> *"It's not a one time thing…there needs to be continuous interaction I think if something's going to happen (stroke survivor, FG4).*

8. Identify stroke survivors at high risk of recurrent stroke

Healthcare professionals, commissioners and policy makers highlighted the need to proactively identify stroke survivors at high risk of having a recurrent stroke to assess and treat them in a timely manner. They felt that many stroke survivors, especially those with more severe long-term consequences from the stroke, do not often see a physician, and it is important to have a smart (automatic) system in place that could proactively identify them and assess their risks.

> *"I think the challenge first of all who are the high-risk patients, can we identify them and, if we can, is there a way through case management or community matrons, you know, linked with the stroke teams in the community providing access to therapy and assessment when it's required in a timely fashion" (commissioner, Interview)*

Development of DOTT decision aid

The above themes and solutions were proposed, designed and refined during the collaborative design process with stakeholders, which informed the design of DOTT (Deciding on Treatments Together). DOTT is a computerised decision aid (i.e., a DSS designed to facilitate SDM), integrated with the EHR system, to be used in primary care during clinical consultations between the healthcare professional and stroke survivor, aiming to facilitate SDM on treatments to reduce recurrent stroke risk.

Specifically, DOTT will:

(1) Allow stroke survivors to indicate, in a graphic presentation (Figure 2), **their perceived risk of having a further stroke**. The graphic presentation in DOTT is based on population rank[43,44] simulating a queue of 20 people around the same age of the stroke survivor. Stroke survivors indicate where they think they are positioned in the queue (from least to most likely). This risk would then be compared to the actual predicted risk to facilitate conversation on risk factors. Needs from theme 3 are addressed with this feature.

(2) Display **stroke survivor's predicted risk of having a further stroke** in a meaningful and understandable way for both healthcare professionals and stroke survivors. For the usability evaluation, the system displayed a 'typical' recurrent stroke risk based on age[37]. The final personalised stroke risk model is under development and will be calculated based on the patient's information from the EHR and on rules generated from the linked dataset (SLSR and LDN). This will include variables such as age, gender, medical history (e.g., hypertension, atrial fibrillation), type of stroke and time since stroke. Needs from theme 2 are addressed with this feature (see Figure 2).

(3) Provide a **list of personalised recommended treatments** for stroke survivors based on their risk factors (e.g., hypertension, atrial fibrillation) extracted from the EHR. A list of the most effective evidence-based treatments for secondary prevention would be compiled and extracted from the recent NICE guidelines[45] and the National Clinical Guideline for Stroke.[46] This includes both clinical and lifestyle recommendations. For each recommended treatment, the evidence supporting the treatment will also be displayed. Needs from section 4 are addressed with this feature.

(4) **Prioritise the recommended treatments** based on their relative risk reduction and present the most effective treatment first. The clinician and stroke survivor can select one or more treatments and see on the graphic display, how the treatments reduce the overall stroke risk. The benefit of each treatment in terms of stroke risk will be calculated using the linked dataset (SLSR and LDN). Needs from theme 5 are addressed with this feature.

(5) **Display stroke survivors' common concerns** on the suggested treatments (e.g., "do I have to take blood pressure drugs for life?"), which will aid in identifying and addressing barriers to treatment adherence and eliciting preferences. An initial list of concerns and their response was prepared based on qualitative studies eliciting patients' barriers to treatment adherence.[47,48] Needs from theme 6 are addressed with this feature

(6) Allow stroke survivors and their carers to discuss the different treatments with the healthcare professional and **jointly select the treatments that best suit the stroke survivor's preferences, desired outcomes and goals** (and remove the ones that do not). Lifestyle modification will be discussed during the consultation and enhanced through referral to specialists or lifestyle intervention programs. The agreed management plan and information on the different treatments will be printed and handed to the stroke survivor to take home. Needs from theme 1 are addressed with this feature.

(7) Set automatically a **follow-up appointment** in 3 months' time. The information entered, including the agreed management plan is saved and transferred back to the stroke survivor's EHR for future consultations. During the follow-up consultation, the management plan is reviewed and treatments to address risk factors for stroke recurrence can be added, modified or removed. Desired clinical and patient outcomes will also be reviewed. Current NICE guidelines[45] for 'Secondary prevention following stroke and TIA' recommend primary care follow up on discharge, six months and then annually. A three-month follow up was selected as a reasonable interval for healthcare professionals and to provide enough time for patients to adhere to the selected treatments. Needs from theme 7 are addressed with this feature.

(8) The stroke prediction model will also be used to **proactively identify individuals at high risk of a recurrent stroke** by calculating their recurrent stroke risk at defined periods of time (the practice can define the desired threshold) and alert the practice (e.g., physician, nurse, receptionist) to invite those patients for a clinical consultation. Needs from theme 8 are addressed with this feature.

(9) All information from patients and healthcare professionals (e.g., treatments selected by the patient, desired outcomes, predicted stroke risk, results in follow-up) will be **captured by the system as part of a LHS** and be used to improve the system's predictive model and treatment recommendations.

Figure 2 depicts an example screenshot from DOTT decision aid prototype.

<Insert Figure 2 here>

Usability and acceptability evaluation

Demographics

Eight stroke survivors and eight GPs participated in the usability and acceptability evaluations. GPs (4 men, 4 women) had average of 10.3 years of experience as a GP. All had experience in providing care to stroke survivors, had medium to high confidence in using new technology and low to medium experience using DSS. Stroke survivors (4 men, 4 women) had an average age of 65.5 years (SD: 11.4, range: 49-81). All had hypertension, two had heart problems, one was suffering from depression, four had mobility issues, and four had minor cognitive deficiencies (attention and memory).

Usability and acceptability

Both GPs and stroke survivors found the decision aid usable and acceptable. GPs found the decision aid easy to use (score 4.3), easy to understand (4.1) and felt very confident using it (4.2). They thought that this decision aid was better than how they usually helped patients decide about treatments for controlling their risk factors (4.4), that this strategy was compatible with the way they thought things should be done (4.3), that this type of decision aid was suitable for helping patients make informed choices (4.0) and that the decision aid complemented their usual approach (4.4). Stroke survivors perceived that they would like to use the decision aid frequently (4.0), thought that it was easy to use (4.2) and felt confident using it (4.1). Initial findings of the usability evaluation can be found in Porat et al.[49]

Identified themes

Seven main themes relating to the usability and acceptability of the decision aid were identified. These were divided into themes relating to the importance of the decision aid, its functionality and concerns from using it.

Importance of the decision aid

Logical and structured process that facilitates discussion

All GPs and stroke survivors (N=16) found the decision aid to be clear, and consisting of a logical flow that helped to structure the consultation. They felt that the decision aid facilitated a transparent discussion on the different proposed treatments and elicited patients' preferences.

> *"Physician pointing out what to do but the patient makes the decision since it's hard to get your head around everything. More doable if you have specific areas to work on with specific targets that suits you" (stroke survivor 2)*

Importance of a learning system

Several GPs (N=3) raised the importance of a learning system providing up-to-date information. They wanted to make sure that the suggested treatments are in line with the most up-to-date evidence.

> *"The learning aspect is very important, since this system is based on evidence and evidence can change" (GP 6)*

Can motivate patients to change behaviour

All GPs and stroke survivors (N=16) believed that the decision aid could motivate patients to change behaviour (e.g., take their medication to reduce blood pressure, increase physical activity, eat healthy). Stroke survivors liked the idea of being involved in deciding on their treatments according to their preferences and abilities, receiving information on their stroke risk factors, and discussing their views and concerns with their GP. They felt it gave them more control over their health and motivation to adhere to the treatments they selected. GPs felt it was a good way to discuss the different treatments and give patients the power to decide on treatments that suit them. A number of GPs and stroke survivors agreed that sharing decisions and enabling patients to select the treatments that best meet their preferences and goals, may increase patients' feeling of ownership over their health and improve adherence to the selected treatments.

> *"I believe discussing the different options with the patients, shared decision making, is likely to improve adherence" (GP 1).*

Functionality

Powerful risk display showing the benefit of each treatment

The vast majority of GPs and stroke survivors (N=15) found the visual display showing the risk before and after a selected intervention, easy to understand, with some viewing it as a 'powerful' tool. Both stroke survivors and GPs commented that they were not aware of the effect the treatments have on reducing the stroke risk.

> *"The most powerful thing is the visual shifting of risk" (GP 5)*

> *"Wow, a small change can make a big difference, this is very encouraging" (stroke survivor 6)*

The patient takes home printed information

GPs and stroke survivors (N=10) thought that it was very important that the patient has a copy of the management plan and all the information printed so they can review it at home. In particular, stroke survivors wanted to have their current predicted risk and information on their selected treatments, including the date of the follow up appointment printed out, so it could motivate them to adhere to their treatments.

> *"The important thing is that the patient goes out with a piece of paper that summarises in bullet points the outcome of the consultation. If its black and white on paper it makes a difference" (stroke survivor 3)*

Concerns

GPs and stroke survivors raised two main concerns from using the decision aid.

Deals with one aspect of the consultation

GPs and stroke survivors (N=6) felt that the decision aid is good but focuses on one aspect of the consultation (reducing risk of recurrent stroke) and patients may have other concerns, such as depression or social isolation.

> *"This is good, but for me the most important thing is the emotional aspect, and this tool doesn't relate to that" (stroke survivor 4)*

Time

The main concern for GPs was time (N=6), in which within the allotted standard 10 minutes for the consultation already provided significant limits, and most felt they will not manage to fit it in.

Suggestions for improvement

GPs and stroke survivors provided suggestions for improving the decision aid:

1. The terminology was too clinical, for example "treatments" and "management", could be changed to "possible strategies or approaches".
2. In addition to the management plan, information (e.g., in the form of a leaflet) on each of the selected treatments should also be printed out and given to patients.
3. Add clinical data, for example when clicking on "cholesterol" show the patient's last three values, and do this also for their blood pressure.
4. Enable more than one display of risk, because each patient may prefer a different display and understands risk differently.
5. Add emotional and mental health aspects which are related to stroke risk.

We subsequently made the above changes and additions to the updated version of DOTT.

DISCUSSION

Our work focused on engaging various stakeholders in the identification, design, prototyping and evaluation of a decision aid to improve secondary prevention after stroke. Eight themes informed the design of DOTT. A number of the themes and solutions proposed by the stakeholders have been implemented previously to some extent to support other patient groups, such as diabetes and atrial fibrillation.[50,51] These include, predicting a patient's risk based on their risk factors, proposing possible treatments and displaying their benefit in decreasing the risk[50] and incorporating patients' concerns within the decision making process.[51] These themes were found useful and are recommended in SDM tools (e.g., in the IPDAS[23]).

Additional unique themes and solutions have emerged as outcomes of the collaborative design process in this study, which could be used for a range of chronic diseases requiring long-term management. Specifically:

(1) ***Present and communicate risk in a meaningful way*.** While there are many different ways to communicate multiple risks to patients, the most commonly used are absolute or relative risks presented as percentages or probabilities (e.g., "from 100 people like you 20 are expected to have a recurrent stroke").[52] However, studies have shown that in general, healthcare professionals are as unfamiliar as their patients with risk estimates and probabilities[53] and often healthcare professionals have reported finding it difficult to combine multiple risk factors into an accurate assessment of vascular risk[54] and to communicate this risk to patients.[55] Moreover, patients may feel that statistical

risk estimates do not apply to them personally.[56] To overcome this, our graphic presentation is based on population rank, simulating the patient in a queue of people around their age.[43,44] Studies have also shown that formats which present data framed as the risk of an individual were perceived as more relevant and easier to relate to than percentage risk estimates.[57]

(2) ***Compare patient's perceived risk with their predicted risk***. This is a novel requirement from a DSS, which to our knowledge does not exist in current systems. Perceived risk of adverse outcomes such as stroke may be an important concept in understanding patient's adherence to medication and recommended health behaviours.[58] Overall, patients tend to underestimate their own risk.[59] This tendency was also found when patients estimated their cardiovascular risk.[60] Weinstein refers to this underestimation as an "optimistic bias".[59] For example, a recent study found that people with undiagnosed diabetes or prediabetes considerably underestimated their probability to have or develop diabetes.[61] Lower perceived risk has been associated with poorer adherence to recommended health behaviours[62] and hence a more realistic perception of risk may increase patients' interest in risk reduction.[62] Research has shown that individualised risk feedback was effective in increasing perceived stroke risk among patients who had underestimated their stroke risk at baseline.[63] This may imply that eliciting patients' perceived risk and showing them the actual predicted risk, can change their inaccurate risk perception and increase their interest in risk reduction.

(3) ***Prioritising treatments***. Healthcare professionals have previously expressed concerns about managing care and making decisions about treatments, including communicating risks and benefits for patients with multimorbidity and complex needs.[64] They commonly report having to make decisions with such patients which involve a process of prioritisation or trade-offs, facilitating a discussion with the patient on what is important to the patient and what they would like to achieve in terms of their health (i.e. goal setting).[64] Aligning patient goals and desired outcomes with clinicians' goals is likely to improve outcomes for these patients.[65]

(4) *Identify individuals at high risk*. Calculating periodically (in an automatic way) the stroke risk of survivors to identify individuals at high risk of recurrent stroke (based on their information in the EHR) could be a valuable feature for improving long-term management and care for stroke survivors who are less likely or able to visit healthcare professionals on a regular basis. This theme was identified and prioritised by healthcare professionals and commissioners/policy makers and not by stroke survivors or carers, emphasising the importance of treating vulnerable patients in a timely manner and provide proactive patient-centred care. This is in line with the NHS Long Term Plan set in 2019.[66] Patients/carers who participated in the focus groups were relatively mobile and maybe this was less of a priority for them.

These solutions, which are delivered through a DSS integrated with the EHR system and based on data from a linked population dataset, have the potential to be an instrument of change in clinical practice. This will be done by providing scientific evidence at the point of clinical care (e.g., personalised treatments and their benefit based on the individual's risk factors), while simultaneously collecting information from that care (e.g., treatments selected by the patient, desired outcomes, predicted stroke risk) to promote innovation in optimal healthcare delivery.[17]

Strengths and limitations

Although the core focus of the DSS (prevention of a future stroke) was identified by patients as a priority, having a single focus might hinder discussions of other important problems (e.g., depression,

social isolation). Such issues may even have a larger perceived impact on long-term outcomes after stroke, for example, improving mental health or access to social care services, which were also brought up by stakeholders as a priority to address long-term care for stroke survivors with multimorbidity,[14] and were raised as a concern in the usability and acceptability evaluations. Depression is indeed a risk factor of stroke,[67] and the treatment 'manage low mood/depression' will be displayed to all patients, enabling healthcare professionals to relate to this aspect and propose ways to manage this (e.g., medication, referral to a professional, group therapy).

In a study assessing stroke survivors' self-reported needs,[68] more than 50% of long-term stroke survivors reported an unmet need for stroke information (e.g. cause, prevention of recurrence). The proposed decision aid offers a meaningful starting point for addressing this common unmet need. Evidence suggests that the provision of lifestyle advice from healthcare professionals' is effective in changing health behaviours[69] and healthcare professionals' communication is positively correlated with patient adherence to treatments.[70] However, a conversation-based DSS also relies on the attitudes and communication skills of the healthcare professionals, which have been found to vary.[71] Interactive SDM skill training has improved SDM skills and promoted positive attitudes.[72] Training healthcare professionals in communication skills for SDM has also been shown to result in substantial and significant improvement in patient adherence to treatments.[70] Hence, interactive SDM skills training workshops will have to complement the use of the DSS. Patients are also likely to need support and preparation with taking part in SDM during the consultation.[72]

The design of DOTT meets the IPDAS collaboration criteria for quality decision aids.[23] Specifically, DOTT was designed to incorporate principles of SDM, by presenting stroke survivors with information about their treatment options and likely outcomes, presenting the risks and benefits of each option, and engaging the healthcare professional and stroke survivor in a joint conversation about the patient's preferences.[32] Furthermore, DOTT evolves from a systematic development process, uses non-technical language and presents information in a balanced manner that allows for comparisons across alternatives.[23] Wearable sensors (e.g., Fitbit, Apple Watch, blood pressure monitor) could further help patients monitor and self-manage the selected treatments (e.g., control blood pressure, increase physical activity) outside the consultation. In the future, data from wearable sensors could be integrated to the EHR, and DOTT could use this information to improve its risk prediction model and treatment recommendations.

In the usability and acceptability evaluation, stroke survivors and GPs found DOTT to be both useful and usable. GPs perceived that the decision aid helped with structuring the consultation and eliciting patients' preferences for treatments. Stroke survivors felt it provides a good way to understand the different treatment options and select the ones that best suits their preferences. GPs' main concern was that the decision aid would increase consultation times. Indeed, time constrains were identified as the main barrier for the adoption of innovations by family physicians.[73,74] A possible solution could be to use the decision aid as part of a clinical review after stroke, which is usually longer (e.g., 3 month, 6 month and annual review) and by dedicated healthcare professionals which are less limited in time such as stroke nurses and pharmacists working in GPs' practices that are trained to consult patients with chronic and long-term health conditions.

CONCLUSION

Engaging various stakeholders throughout the design and evaluation process ensures that the intervention (features and functions) is in line with the needs reported by the different stakeholders (i.e., stroke survivors, healthcare professionals, policy makers). DOTT has demonstrated the potential to reduce stroke recurrence by adopting a data-driven user-centred approach. DOTT urges clinicians to shift away from the professionally led advice-giving approach typically used in medical consultations to one which collaboratively and actively engages the patient in decision making and respects patient choice and autonomy. This may lead to stroke survivors taking ownership for the treatment decisions, improving their adherence to the agreed management plan and thus reducing their stroke risk. A future feasibility study and subsequent clinical trial will evaluate the effectiveness of DOTT in improving decision making quality, and whether it affects risk factor levels and risk of recurrence. While DOTT currently targets stroke risk factors only, the design approach and its features could be used for a range of chronic diseases requiring long-term management, paving the way to a set of standards for delivering LHS interventions in clinical practice.

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Figure captions

Figure 1: A diagrammatic summary of the development and evaluation of DOTT, including the data that fed the different stages and the outputs. SEM = Stakeholder Engagement Meeting (consisting 3 focus groups)**;** FG = Focus group; SH=Stakeholders; IPDAS = International Patient Decision Aids Standards[23]; SDM model = Shared decision making model for clinical practice[32]; SRPFG = Stroke Research Patient and Family Group[31]

Figure 2: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control of blood pressure).

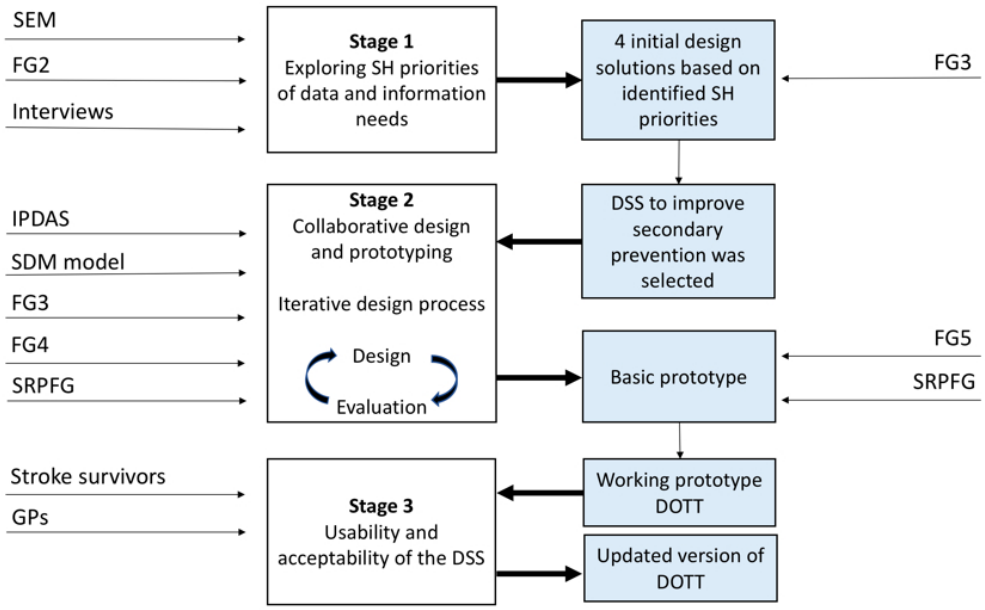

Figure 1: A diagrammatic summary of the development and evaluation of DOTT, including the data that fed the different stages and the outputs. SEM = Stakeholder Engagement Meeting (consisting 3 focus groups); FG = Focus group; SH=Stakeholders; IPDAS = International Patient Decision Aids Standards23; SDM model = Shared decision making model for clinical practice32; SRPFG = Stroke Research Patient and Family Group31

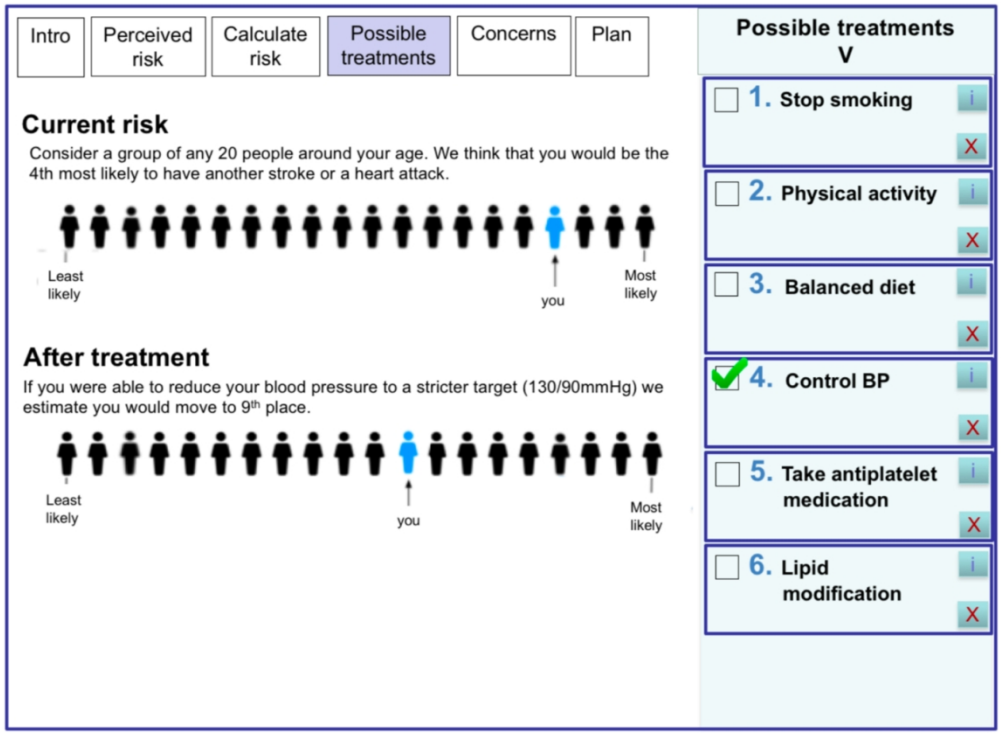

Figure 2: An example screen from DOTT prototype displaying the stroke survivor's predicted stroke risk before and after a selected treatment (e.g., control of blood pressure).

Box 1: Topic guide for the separate focus groups in the SEM

In a large group, explain:

- Study aim
- What a LHS is, and how a LHS might work in general practice
- The co-production approach we are using

In separate focus groups:

- Ask participants to provide examples of information which are/would be useful for patients/carers/clinicians/health commissioners?
- Previous experiences of information delivery: What worked well? What worked badly/not so well?

Explore stakeholders' understandings around what is data linkage, and what is a learning health system (LHS)?

- How would a LHS work in practice for stroke?
- Any ethnical concerns about this process (particularly regarding data linkage)? How can these be addressed?
- What types of information could be generated using this method?
- How broadly might they be delivered?

Discuss ideas for new information interventions

- Feedback from individual groups

Develop as a larger group a priority list for key priorities for data and information needs.

Note: Since a few healthcare professionals could not attend the focus groups, we conducted face-to-face interviews with them using the same topic guide.

Box 2: post-usability interview - patients

- Do you have any comments about today's session? Feel free to comment on anything you want.
- How did it feel having a consultation using the decision aid?
- Who do you think should be involved in making decisions about how acceptable your risks are of having a further stroke?
  - □ your doctor alone
  - □ mostly your doctor
  - □ your doctor and you equally
  - □ mostly you
  - □ you alone
- Who do you think should be involved in making decisions about ways to reduce your risk of stroke?
  - □ your doctor alone
  - □ mostly your doctor
  - □ your doctor and you equally
  - □ mostly you
  - □ you alone
- To what extent do you agree with the following statement? (from 1 strongly disagree to 5 strongly agree)
  - The decision aid will help patients with adopting healthier behaviours, such as changing Lifestyle habits and/or taking medication according to the management plan they agreed on.
  - Having seen how the decision aid works, patients will likely look for more information about stroke and its risk factors.
- (if agreed on statement above) Can you please describe how the decision aid might support patients in changing some of their health-related habits?
- What might make it difficult (barriers, hurdles) for patients to change some of their health-related habits?
- Would you find the decision aid helpful for your own health-related habits?
- What do you like about the decision aid?
- What don't you like about the decision aid?
- What suggestions do you have to improve the decision aid?

Give Acceptability and Usability questionnaires.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

		Reporting Item	Page Number
	#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
	#2	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also	4,5

		recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	7
Context	#7	Setting / site and salient contextual factors; rationale	4,5
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	5
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5, 17
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	5,6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	4,5,6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5,6,7
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	6

Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	7
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	7
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	7-10,11-13
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	6-9,12-14
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	14-15
Limitations	#19	Trustworthiness and limitations of findings	15,16
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	17
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	17