Evaluability assessment of the Distress Brief Intervention programme in Scotland

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☎ **0131 314 5300**

✉ **nhs.healthscotland-alternativeformats@nhs.net**

Executive summary

- The aim of the Distress Brief Intervention (DBI) programme is to provide a framework for improved inter-agency working and collaboration to support the delivery of an effective response to people in distress.

- A DBI is a time-limited and supportive problem-solving contact with an individual in distress. It is a two-level approach. DBI level 1 is delivered by front-line staff and involves a compassionate response, signposting and offer of referral to a DBI level 2 service. DBI level 2 is provided by specially trained staff who would see the person within 24 hours of referral and provide community problem-solving, support and signposting for a period of up to 14 days.

- The approach is being initially piloted over four years in four sites across Scotland. In addition to being a 'partner' site one of these four sites is also the 'host' site, responsible for recruiting and accommodating the DBI Central Team.

- For the purposes of the pilot, the DBI approach will be tested primarily in relation to people presenting in distress to A&E, police and ambulance services, primary care and social services.

- To evaluate the effectiveness of the approach the Scottish Government will be commissioning an independent evaluation. The purpose of the evaluability assessment was to identify the desired outcomes, evaluation questions, potential data sources and evaluation options to inform the design of the evaluation brief. The evaluability assessment took place over the period April–November 2016. The intervention and the local partnerships responsible for implementation were, and continue to be, in development. Some of the detail contained in the evaluability assessment may therefore be subject to change or modification.

- Over the period of the evaluability assessment, the definition of 'distress' for the purpose of the DBI programme was revised and is currently (as of November 2016) taken to mean 'An emotional pain for which the person sought, or was referred for, help and which does not require (further) emergency service response'.

- As part of the evaluability assessment a theory of change was developed for the DBI programme (**Figure 1**). This identified 13 desired outcomes (**Box 1**). Outcomes 1–7 relate to the development and implementation process. Outcomes 8–10 focus on the individual and service outcomes. Outcomes 11–13 address the potentially wider service system and societal outcomes. For the purposes of identifying evaluation options the focus has been on outcomes 1–10.

- In relation specifically to client outcomes the primary evaluation question which emerged through the evaluability assessment process was 'Are Distress Brief Interventions effective in helping people to manage their current episode of distress and manage future episodes?'.

- On the basis of the evaluability assessment five evaluation options were proposed:
    - Option 1: process evaluation
    - Option 2: routine monitoring of numbers/characteristics of clients identified as eligible, offered referral, referred to and take up the offer of a DBI level 2
    - Option 3: qualitative analysis of staff and clients' experiences and self-perceived impacts
    - Option 4: control trial to assess effectiveness
    - Option 5: economic evaluation.

- Options 4 and 5 would require a measurable and robust indicator of 'effectiveness'. Early consideration would also need to be given to a control group/setting.

- The Scottish Government is commissioning an evaluation. Consideration should, however, be given to the mechanisms for maintaining the links between the evaluation team and the pilot sites.

Chapter 1: Introduction

The Distress Brief Intervention programme

Distress Brief Interventions (DBIs) are an innovative way for supporting people in distress. The DBI approach emerged from the Scottish Government's work on the Suicide Prevention and Mental Health strategies.[1,2] The need to improve the response to people presenting in distress has been strongly advocated by service users and front-line service providers.

The overarching aim of the DBI programme is to provide a framework for improved inter-agency coordination, collaboration and cooperation across a wide range of care, settings, interventions and community supports. This will work towards the shared goal of providing a compassionate and effective response to people in distress, making it more likely that they will engage with and stay connected to services or support that may benefit them over time.

A DBI is a time-limited, supportive and problem-solving contact with an individual in distress. It is a two-level approach delivered to all presentations of distress (including self-harm) that have an emotional component and that do not require (further) emergency service involvement. The first level (DBI level 1) is provided by front-line staff who have undertaken online DBI level 1 training. This level comprises a compassionate response, signposting and offer of referral to a DBI level 2 service. The DBI level 2 service is delivered by a worker who has undergone DBI level 2 training. The worker would see the person within 24 hours of referral. The role of the worker would be to explore with the individual, for a period of up to 14 days, the problems that are leading to their distress, and provide community problem-solving and support. This may include signposting and supporting the person to specialist services and documenting this in a shared distress management plan. By intervening early, the DBI seeks to better engage and equip people in managing their own health and to offer a systematic and structured approach for staff to use that promotes a medium- to long-term reduction in distress in service users.

It is planned to pilot this intervention across four sites over the four-year period 2017–2020/21. Coordination will be managed by a host site responsible for recruiting and accommodating a DBI Central Team. Scottish Government funding of £4.2 million is available to cover the costs of the DBI Central Team and the salaries of four site leads, the creation and delivery of training, and for monitoring and commissioning an independent evaluation. It is anticipated that funding for the pilot sites will be through the re-allocation/use of local distress funding from the Mental Health Innovation Fund.

The host and partner sites were selected following a competitive tendering process. The selected sites, announced by the Minister for Mental Health[3,4] on 19 July 2016,[*] are:

- Health and Social Care North Lanarkshire and South Lanarkshire Social Care Partnership (host and partner site)
- Penumbra, Aberdeen
- Support in Mind, Inverness
- NHS Borders Joint Mental Health Service.

For the purposes of the pilot, the DBI approach will be tested primarily in relation to people presenting in distress to A&E, police and ambulance services, primary care and social work services. Delivery of DBI level 1 will be by front-line staff. In each of the pilot sites DBI level 2 will be delivered by third sector agencies.

The intervention and associated training modules for staff delivering DBI level 1 and DBI level 2 are being developed by a team from the Suicidal Behaviour Research Laboratory, Institute of Health and Wellbeing, University of Glasgow. Following an initial period of development, controlled implementation in one pilot site will commence from June 2017, with full implementation across the four pilot sites by April 2018.

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[*] A fifth site, NHS Greater Glasgow & Clyde and associated Health and Social Care Partnerships, subsequently chose not to proceed with the DBI test programme in order to maximise and focus capacity on their significant mental health change agenda.

An evaluation of the DBI programme is included among the Scottish Government's proposals for its new 10-year Mental Health Strategy.[4,†] The outcome of the evaluation will inform recommendations for the future. The evaluation will be undertaken by an independent evaluation team commissioned by Scottish Government through a competitive tendering process. The novel nature of the DBI approach, the range of different delivery settings and types of provider underline the importance of undertaking an evaluation. By the same token they point to the value of a preliminary evaluability assessment to help shape an effective evaluation design. The following describes the evaluability assessment undertaken over the period April–November 2016. From this process a number of provisional evaluation options are proposed (Chapter 4). These options may be subject to review as the intervention itself is further developed and the pilot sites progress toward implementation.

The evaluability assessment process

An evaluability assessment is a systematic way of thinking through if and how to evaluate new policies, programmes or interventions like DBIs. It provides an opportunity to weigh up the value of an evaluation in terms of informing future decisions against the costs and feasibility of collecting the evidence. A number of evaluability assessments have been published that provide further examples of the process.[5,6,7]

Evaluability assessments comprise a number of stages:

1   Developing an initial 'theory of change'. This maps out the links, or logic between the desired outcomes (short, intermediate and long term) and the mechanisms through which these outcomes will be achieved. It also provides an opportunity to identify potential external factors that might impact positively or negatively on implementation and outcomes, and also the potential unintended consequences (again, positive and negative).

2   Identifying data and evidence sources to assess whether or not and for whom (and why) these outcomes are achieved. This can include routinely collected

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† The consultation on this strategy closed in September 2016.

data as well as the data or evidence that would need to be specifically collected.

3   On the basis of (1) and (2), to identify a number of evaluation options and agree a possible way forward.

The evaluability assessment of the DBI programme

Before developing an evaluation brief, the Scottish Government, with the support of NHS Health Scotland, and with input from the team developing the intervention, undertook the preliminary stages of an evaluability assessment. This involved developing an initial theory of change, including identifying the outcomes of interest, and proposing some evaluation questions. This was done before the four pilot sites were confirmed.

Once confirmed the pilot sites were invited to inform the further development of the theory of change, the outcomes and evaluation questions, so that they reflected the proposals for delivering DBIs within and across the sites (see **Appendix 1** for the list of contributors to the evaluability assessment). A revised theory of change was subsequently developed.

As part of the intervention development process a revised definition of distress was proposed:

> *'An emotional pain for which the person sought, or was referred for, help and which does not require (further) emergency service response.'*

As **Appendix 2** illustrates, this definition can include people who self-harm who do not require (further) emergency service input, as well as a much broader target population, including people with medically unexplained symptoms. At the time of the evaluability assessment it had not been possible to assess the likely level of demand, based on this broad (and, in many respects heterogeneous) population.

The referral process from DBI level 1 to DBI level 2 was also refined: it was proposed that all people who received a DBI level 1 intervention would be offered the option of being referred for a DBI level 2.

For the purposes of the evaluability assessment the following working definitions of DBI level 1 and DBI level 2 are used. These are likely to be further refined as the intervention develops:

- A DBI level 1 intervention comprises a compassionate first-line response and signposting, including an offer to make a referral for a DBI level 2.
- A DBI level 2 intervention includes initial contact by the DBI level 2 worker with the person referred within 24-hours of referral; further community-based support for up to 14 days; and, as appropriate, development of a distress management plan and connection to other ongoing community supports.

Chapter 2 sets out the revised theory of change. On the basis of the theory of change, Chapter 3 describes the desired outcomes, evaluation questions and potential data sources. Provisional evaluation options and next steps are set out in Chapter 4.

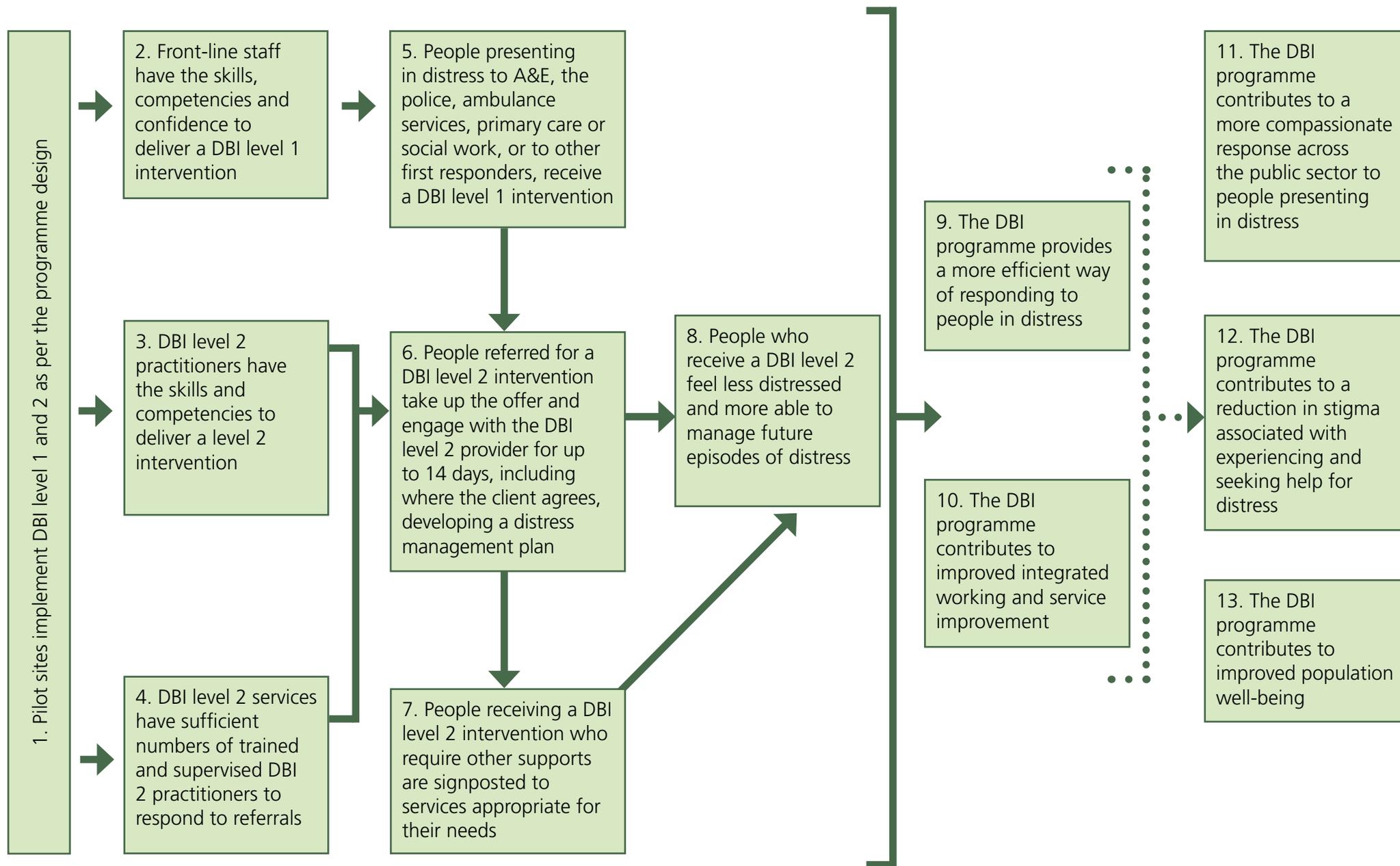# Chapter 2: A theory of change for the DBI programme

Identifying outcomes

In order to assess the evaluability of the DBI we need to address a critical question: *What difference is the intervention likely to make, for whom, and what are the key variations we might expect to observe?*

One of the challenges, however, in this context is the limited existing evidence drawing from comparable models of delivery. A review of the international research literature undertaken by the Scottish Government Analytical Services Division,[8] identified a number of studies of Distress Brief Interventions and Brief Intervention and Contact, but these varied significantly from DBIs in terms of intervention design (e.g. often using non-direct methods of contact such as postcards), 'target population' (people who self-harmed or had attempted suicide) and assessed outcomes (reductions in self-harm or suicide attempts). The evaluation of the DBI pilot may therefore be more about developing the evidence base, rather than building on a pre-existing one.

An initial theory of change was developed by Scottish Government with support from Health Scotland, an external adviser and the team from the University of Glasgow developing the intervention. This drew on the issues raised by the review of the international literature, a rapid trawl for further evidence, and knowledge acquired in the course of discussions with service users and first responders as part of the DBI development process. The initial theory of change was subsequently revised following input from the pilot sites and in discussion with the University of Glasgow team. The revised theory of change (**Figure 1**) identified 13 desired outcomes. The outcomes relate to the sites/settings implementing the DBI programme, e.g. facilitating staff in front-line services to undertake DBI level 1 online training.

Figure 1: Distress Brief Intervention Programme: Theory of Change*

1. Pilot sites implement DBI level 1 and 2 as per the programme design

2. Front-line staff have the skills, competencies and confidence to deliver a DBI level 1 intervention

3. DBI level 2 practitioners have the skills and competencies to deliver a level 2 intervention

4. DBI level 2 services have sufficient numbers of trained and supervised DBI 2 practitioners to respond to referrals

5. People presenting in distress to A&E, the police, ambulance services, primary care or social work, or to other first responders, receive a DBI level 1 intervention

6. People referred for a DBI level 2 intervention take up the offer and engage with the DBI level 2 provider for up to 14 days, including where the client agrees, developing a distress management plan

7. People receiving a DBI level 2 intervention who require other supports are signposted to services appropriate for their needs

8. People who receive a DBI level 2 feel less distressed and more able to manage future episodes of distress

9. The DBI programme provides a more efficient way of responding to people in distress

10. The DBI programme contributes to improved integrated working and service improvement

11. The DBI programme contributes to a more compassionate response across the public sector to people presenting in distress

12. The DBI programme contributes to a reduction in stigma associated with experiencing and seeking help for distress

13. The DBI programme contributes to improved population well-being

* Distress is defined as 'an emotional pain for which the person sought, or was referred for, help and which does not require (further) emergency service response.'

Key: The solid arrows indicate the short-term and intermediate outcomes which can be directly related to the implementation of the DBI programme. The dotted arrow indicates the wider or longer-term outcomes to which it may contribute, but which cannot be directly attributed to the programme.

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Outcomes 1–7 relate primarily to the development and implementation process. Outcomes 8–10 focus on the individual and service outcomes. Outcomes 11–13 address potentially wider service system and societal outcomes. For the purposes of the evaluability assessment the emphasis is on the key evaluation questions for the pilot programme (outcomes 1–10). The findings from the pilot may, however, begin to indicate the plausibility of some of the wider and longer-term outcomes (11–13). **Box 1** summarises the 13 outcomes.

Box 1: Summary of desired outcomes

Outcome 1: Pilot sites implement DBI level 1 and 2 as per the programme design.

Outcome 2: Front-line staff in A&E, police and ambulance services, primary care and social work and other first responders who have undergone DBI level 1 online training have the skills, competencies and confidence to deliver a DBI 1 level intervention.

Outcome 3: DBI level 2 practitioners have the skills and competencies to deliver a level 2 intervention.

Outcome 4: DBI level 2 services have sufficient numbers of trained and supervised DBI level 2 practitioners to respond to referrals within the timeframe set out in the programme design.

Outcome 5: People presenting in distress (as per the programme definition) to A&E, police and ambulance services, primary care and social work or other first responders receive a DBI level 1 response.

Outcome 6: People referred for a DBI level 2 intervention take up the offer and engage with the DBI level 2 provider for up to 14 days including, where the client agrees, developing a distress management plan.

Box 1: Summary of desired outcomes

Outcome 7: People receiving a DBI level 2 intervention who require other support are signposted to services appropriate for their needs.

Outcome 8: People who receive a DBI level 2 intervention feel less distressed and more able to manage future episodes of distress.

Outcome 9: The DBI programme provides a more efficient way of responding to people in distress who present to A&E, police and ambulance services, primary care and social work and other first response services.

Outcome 10: The DBI programme contributes to improved integrated working and local service improvement.

Outcome 11: The DBI programme contributes to a (/an even) more compassionate response across the public sector to people presenting in distress.

Outcome 12: The DBI programme contributes to a reduction in the stigma associated with experiencing and seeking help with distress.

Outcome 13: The DBI programme contributes to improved population wellbeing, including to appropriately manage distress.

Potential unintended consequences and external influences

In addition to the desired outcomes the programme may also generate unintended and unanticipated outcomes. External factors, outwith the direct control of the programme, may also impact on what the programme can achieve.

Potential *negative* unintended consequences of the programme might include:

- increased demand on mainstream services, e.g. through additional time to provide a compassionate response, or increased numbers of people in distress seeking help in response to the better quality of service
- DBI level 2 providers unable to meet demand
- inappropriate referrals to DBI level 2 (serious mental or physical health problems missed)
- unrealistic expectations of what DBIs can deliver
- DBI level 2 has unintended negative consequences, e.g. increases risk of self-harm
- differential patterns of referral and uptake of DBI level 2 risks contributing to increases in inequalities between population groups
- DBIs create a substitution effect with individuals ceasing to present in one context but presenting in another less able to provide an appropriate response.

Potential *positive* unintended consequences might include:
- a reduction in alcohol or substance misuse among people who receive a DBI level 2
- improved social connectedness among people who receive a DBI level 2, including, as appropriate, with and between the person presenting in distress and their family/social networks.

There are also potential external factors (outwith direct control of DBI programme) that may affect implementation and outcomes.

Potential *negative* external factors:
- providers of DBI level 2 interventions are unable to sustain delivery
- uptake of DBI level 2 is affected by various factors, e.g. travel costs, people unable to take time off work/cover for caring responsibilities, etc.
- confidentiality/information governance issues between providers
- clients' own confidentiality concerns
- front-line service providers unable to provide time for staff to undertake online training (for DBI level 1)

- limited public sector/community resources to address wider social factors impacting on the causes of distress, e.g. housing, employability, welfare benefits, limiting the potential impacts of the DBI programme
- third sector unable to respond to potential increases in demand for support services.

Potential *positive* external factors:
- wider social policy focus on improving mental health and well-being
- emphasis on providing person-centred care across the public sector
- primary care transformation
- extension of 'link worker' model for supporting people holistically in primary care.[9]

Chapter 3: Evaluation questions and possible data sources

Based on the revised theory of change, **Table 1** presents the outcomes of interest, potential evaluation questions and examples of data sources. The outcomes are distinguished between those relating to the implementation process and those concerned to capture the impacts on clients and services.

In relation to client outcomes the primary evaluation question is: *Are Distress Brief Interventions effective in helping people to manage their current episode of distress and manage future episodes?*

As discussed in Chapter 4 below, questions remain about the most appropriate approach to robustly assess effectiveness. This includes identifying the most appropriate comparator groups. Examples of potential comparator groups are indicated, where relevant, in square brackets in the table.

In relation to data sources, preliminary discussions between NHS Lanarkshire, as the DBI host site, and NHS National Services Scotland (NSS) Information Services Division (ISD) suggest there may be scope for some routine data collection at national level. **Appendix 3** presents a summary of available routine data collected by ISD. Additional data may also be available from NHS 24.

Table 1: Outcomes of interest, potential evaluation questions and examples of data sources.

Outcomes	Supplementary evaluation questions	Suggested data sources
Process 'outcomes'		
1. Pilot sites implement DBI level 1 and 2 as per the programme design	Do pilot sites implement DBI level 1 and level 2 (including processes for identifying, supporting and referring people on) as set out in the programme design? What are the key variations in the models of implementation and delivery of DBI levels 1 and 2 across and within settings and sites? What contextual factors influence these variations, including patterns of inter- and within-agency working, collaboration and coordination, supporting infrastructure? What are the implications of these variations for client outcomes?	Qualitative data collection
2. Front-line staff in A&E, police and ambulance services, primary care and social work and other first response services who have received DBI level 1 training have the skills, competencies and confidence to deliver a DBI level 1 intervention	To what extent do front-line staff have the skills, competencies and confidence to deliver a DBI level 1 intervention? What impact does the DBI level 1 training have on the extent to which front-line staff have the skills, competencies and confidence to deliver a DBI level 1 intervention? What are the key variations in the uptake of DBI level 1 training among front-line staff within and across sites/settings? What are the implications of these differences for client outcomes?	Qualitative data collection/survey Post-training assessment as part of online DBI level 1 training module
3. DBI level 2 practitioners have the skills and competencies to deliver a DBI level 2 intervention	To what extent do DBI level 2 practitioners have the skills and competencies to deliver a DBI level 2 intervention?	Qualitative data collection, e.g. staff surveys and brief multiple choice assessments after training

Outcomes	Supplementary evaluation questions	Suggested data sources
	What impact does the DBI level 2 training have on the extent to which DBI level 2 staff have the skills, competencies and confidence to deliver a DBI level 2 intervention?	
4. DBI level 2 services have sufficient numbers of trained and supervised DBI level 2 practitioners to respond to referrals for a DBI level 2 intervention within the timeframes set out in the programme design	Are DBI level 2 providers able to respond to referrals within the 24-hour timeframe? What are the key variations in response times between DBI level 2 service providers? What contextual factors influence these variations? What are the implications of these variations for client outcomes?	Quantitative data to capture response times, etc. Qualitative data collection to identify contextual and practice issues
5. People presenting in distress (as per the programme definition) in A&E, primary care, police, social work or to other first responders receive a DBI level 1 intervention (compassionate response and offer of referral to DBI level 2)	What proportion of people presenting in distress receive a DBI level 1 intervention? What are the key variations within and across different sites/settings and by characteristics of people presenting in distress (including by socio-economic group) in the patterns of delivery of DBI level 1 interventions, including patterns of referral/offers of referral to DBI level 2? What contextual factors influence these variations, e.g. opportunity/time available to first responders to deliver a DBI level 1 intervention? What are the implications of these variations for client outcomes? Do people who receive a DBI level 1 experience a compassionate response from frontline staff? What impact does delivery of a DBI level 1 have on clients' own perceived ability to manage their current episode of distress?	Routine data sources (e.g. A&E, police, ambulance service statistics) Quantitative monitoring data Qualitative data collection to identify contextual and practice issues Qualitative/self-report data to capture clients' experience of a DBI level 1, e.g. Consultation and Relational Care Empathy (CARE) measure Indicators of 'compassionate response' based on DBI level 1 training

Outcomes	Supplementary evaluation questions	Suggested data sources
6. People referred for a DBI level 2 intervention take up the offer and engage with the DBI level 2 provider for up to 14 days, including where the client agrees, developing a distress management plan	What are the key variations in levels of uptake following referral to DBI level 2: between and within sites and types of referral settings; by DBI level 2 provider; and by characteristics of people presenting in distress (including by socio-economic group)? What are the key variations in patterns of engagement (by length/intensity of support) by: DBI level 2 provider; and by characteristics of people presenting in distress (including by socio-economic group)? What are the implications of these variations for client outcomes?	Quantitative monitoring data Qualitative data collection to identify barriers and facilitators to uptake of/engagement with DBI level 2
7. People receiving a DBI level 2 intervention who require other support are signposted to services appropriate for their needs	What arrangements/processes are in place for signposting or referring people who receive a DBI level 2 to services/support to help them manage their distress? What is the pattern of referral (types of services to which people are referred/numbers of referrals to different services)? What is the pattern of uptake of these services among people referred? What arrangements are in place for identifying and addressing gaps in services for people who receive a DBI level 2 intervention? What are the key variations in the arrangements for referral to and uptake of services and support across sites/settings? What are the implications of these variations for client outcomes?	Quantitative monitoring data Qualitative data collection to identify barriers and facilitators to uptake of support services Case study analysis

Outcomes	Supplementary evaluation questions	Suggested data sources
Client and service outcomes		
8. People who receive a DBI level 2 feel less distressed and more able to manage future episodes of distress	To what extent does delivery of a DBI level 2 meet clients' own goals or objectives? What impact does the delivery of a DBI level 2 have on clients' feelings of distress at the end of their period of contact with the DBI level 2 service and over time (e.g. over 3–6 months)? What impact does the delivery of a DBI level 2 have on the ability of clients to manage their distress at the end of their period of contact with the DBI level 2 service? What impact does the experience of a DBI level 2 have on the ability of clients to anticipate, prevent or manage future episodes of distress (e.g. over 3–6 months)? [Compared with: (1) the same individuals' experience of presenting with distress prior to DBI programme, where appropriate; (2) the experience of a comparable group of people receiving 'usual care'; and/or (3) in the same areas/settings prior to implementation'] To what extent does delivery of DBI level 2 prevent subsequent episodes of distress (e.g. a similar experience to that which brought them into contact with the DBI programme) (e.g. over 3–6 months)? [Compared with: (1) the same individuals' experience of presenting with distress prior to DBI programme, where appropriate; (2) the experience of a comparable group of people receiving 'usual care'; and/or (3) in the same areas/settings prior to implementation.]	Routine data collection (e.g. A&E, police, ambulance service statistics) Qualitative data collection to obtain clients' views/perceptions of the process Qualitative data from routine follow up contacts by DBI level 2 provider Indicators/measures of distress Indicators/measures of self-efficacy/capacity to manage 'distress' Case study analysis

Outcomes	Supplementary evaluation questions	Suggested data sources
	What impact does delivery of a DBI level 2 have on patterns of repeat presentations to A&E, primary care, police and other first responders for distress (e.g. over a 3–6 month period)? [Compared with: (1) the prior experience of the same individuals, as appropriate; (2) and/or for the population of people receiving a DBI level 2 compared with the previous population-wide rates of repeat attendances for 'distress'; and/or (3) with the rates of repeat attendances for distress in comparable areas not implementing DBI (usual treatment).] Does the rate of repeat attendances post DBI level 2 change for some groups more than others?	
9. The DBI programme provides a more efficient way of responding to people in distress who present to A&E, police and ambulance services, primary care, social work or other first response services	What are the direct and indirect economic costs and benefits of the DBI programme (including for the statutory and third sectors, clients and wider society)?	Economic evaluation

Outcomes	Supplementary evaluation questions	Suggested data sources
10. The DBI programme contributes to improved integrated working and local service improvement	What impact does delivery of the programme locally have on joint/integrated working, e.g. between health, social care, third sector, other public sector (police, fire and rescue, etc.) at: • a strategic/planning level • an operational/service delivery level between front-line staff/services. What impact does the delivery of the DBI programme have locally on service improvement or development?	Qualitative data collection to obtain strategic and operational level staff views on impact of DBI programme on joint working and service development
Potential contribution to wider and longer-term outcomes‡		
11. The DBI programme contributes to a (/an even) more compassionate response across the public sector to people presenting in distress.		
12. The DBI programme contributes to a reduction in the stigma associated with experiencing and seeking help with distress		Social Attitudes Survey

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‡ Evaluation questions have not been developed for the wider and longer-term outcomes to which the DBI programme may contribute but which cannot be specifically attributed to the programme.

Outcomes	Supplementary evaluation questions	Suggested data sources
13. The DBI programme contributes to improved population well-being, including the ability to appropriately manage distress		Warwick–Edinburgh Mental Well-being Scale (WEMWBS)

Chapter 4: Evaluation options and suggested next steps

Evaluation options

On the basis of the evaluability assessment to date the following evaluation options are proposed to address the outcomes identified. Although described as 'options' they are not intended to be mutually exclusive.

- **Option 1:** Undertake a process evaluation, including tracking the early development of the programme, design and implementation, and variations in implementation (programme 'fidelity'). This would address outcomes 1–7 and 10.
- **Option 2:** Routine monitoring of numbers/characteristics of clients identified as meeting the criteria of 'distress', offered referral to, referred to and take up the offer of a DBI level 2. This would contribute to assessing outcomes 4–8 and provide the data for an economic evaluation (outcome 9).
- **Option 3:** Qualitative analysis of staff and clients' experiences and self-perceived impacts. This would contribute to an assessment of outcomes 1–8 and 10.
- **Option 4:** Control trial to evaluate effectiveness. This would be aimed at addressing outcome 8 and contribute to outcome 9.
- **Option 5:** Economic evaluation. This would address outcome 9.

To robustly assess the 'effectiveness' (including economic effectiveness) of the intervention there is a need for a measurable and agreed indicator of what 'effective' would look like, and to have a control group in order to identify the specific impact of the intervention over 'usual care'.

In terms of comparator groups, if these are to be recruited from settings outwith the pilot sites, any decision would need to be made fairly soon so that first

responders in the control sites can be identified, recruited and undertake DBI level 1 training (to identify potentially eligible clients). Data collection systems would also need to be set up in control sites.

An alternative approach might be a 'mini randomised controlled trial (RCT)' – people in pilot sites who would be eligible for a DBI level 2 would be randomly allocated to a control and intervention group. Consideration would need to be given to the processes for allocating people to groups, particularly as the offer of a referral is made by the DBI level 1 staff (first responders).

Some of the issues associated with identifying a control group are set out in **Appendix 4**. As part of the commissioning process, potential evaluation teams could also be invited to consider how they would assess effectiveness, including the relevant comparator group(s).

To undertake an economic evaluation (option 5) to assess outcome 9 would be dependent on identifying a measurable, robust indicator of effectiveness.

Next steps

The Scottish Government will commission the evaluation. As part of the commissioning and on-going oversight of the evaluation, consideration should be given to the mechanisms for maintaining the links between the commissioned evaluation and the four pilot sites. Issues for consideration are:

- supporting partners to put in place relevant data collection systems for monitoring and evaluation purposes
- monitoring the progress of the evaluation and acting as a channel for communication between the commissioned evaluation team and the four pilot sites.

Appendix 1: List of contributors to the DBI evaluability assessment

Neil Anand, NHS Health Scotland.

Bruce Armstrong, Support in Mind.

Joan Blackwood, NHS Greater Glasgow & Clyde.

Jane Cumming, Penumbra.

Beth Hamilton, Scottish Government.

Niall Kearney, Scottish Government.

Fiona Mackenzie, ISD.

Martin McCoy, ISD.

Ambrose (Jack) Melsom, University of Glasgow.

John Mitchell, Scottish Government.

Anita Morrison, Scottish Government.

Fiona Myers, NHS Health Scotland.

Rory O'Connor, University of Glasgow.

Kevin O'Neil, NHS Lanarkshire.

Steve Platt, University of Edinburgh.

Frances Simpson, Support in Mind.

Rachel Smith, NHS Borders.

Diane Stockton, NHS Health Scotland.

Peter Whitehouse, Scottish Government.

Shirley Windsor, NHS Health Scotland.

Appendix 2: Potentially eligible population

Diagram illustrating the potential eligible population for whom a DBI may be appropriate (level 1/level 2). **(Not to scale.)**

People in distress

People who self-harm

People at potential risk of suicide
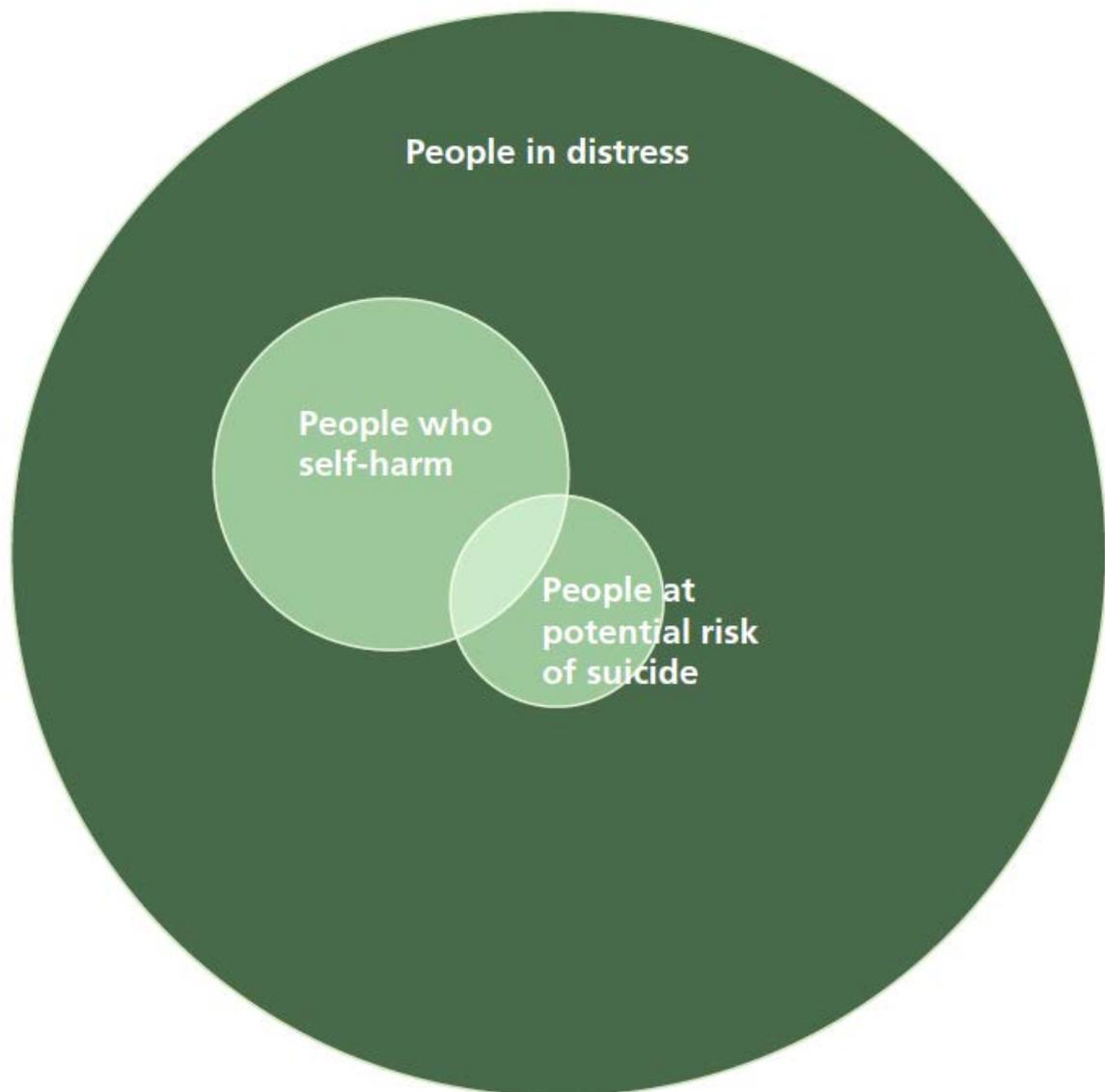
Appendix 3: Information Services Division service access data sources: relevant mental health information

Data source	Data item (field)	Details	Limitations
A&E datamart	Disease Code§	ICD10 (International Statistical Classification of Diseases and Related Health Problems – revision 10)	Field not complete so will be undercounted
A&E datamart	Diagnosis text§	NHS Board drop down	Field not complete so will be undercounted Based on NHS drop down lists Drop-down lists vary by NHS Board
A&E datamart	Presenting complaint§	Details of what patient provides on arrival about their illness	Field not complete so will be undercounted
A&E datamart	Diagnosis§		Field not complete so will be undercounted Very broad field

§ The A&E datamart fields are inconsistently collected and therefore not comparable between NHS Boards. Please consult the following link for completeness information:
www.isdscotland.org/Health-Topics/Emergency-Care/Emergency-Department-Activity/Data-Collection/The%20Recording%20Completeness%20of%20Optional%20Data%20Items%20in%20the%20AandE%20Datamart.xlsx

Data source	Data item (field)	Details	Limitations
A&E datamart	Intent of injury[§]	Includes details such as 'self-harm'	Field not complete so will be undercounted Data completed by only some of the DBI Partnership NHS Boards (e.g NHS Grampian, Highland and Lanarkshire do not submit this data)
Unscheduled care datamart (UCD): Scottish Ambulance Service (SAS)	Advanced Medical Priority Dispatch System (AMPDS) code	The diagnosis code recorded by the paramedic after treating the patient (including details such as 'suicidal behaviour', 'overdose', etc.).	Only one code per patient, so secondary conditions/injuries/details will not be included
Unscheduled care datamart (UCD): Scottish Ambulance Service (SAS)	Presenting complaint code	The initial diagnosis code recorded by SAS.	Only one code by patient, so secondary conditions/injuries/details will not be included
Unscheduled care datamart (UCD): Scottish Ambulance Service (SAS)		If the SAS patient is admitted as an inpatient the SAS incident code can potentially be linked to ICD10 codes in SMR01, which has up to six diagnosis codes per	Data linkage issues

Data source	Data item (field)	Details	Limitations
		patient, so does include secondary diagnosis codes	
Unscheduled care datamart (UCD): NHS24	Number of free text fields	Free-text fields using search term 'anxiety'.	Free-text field so will vary depending on the choice of wording used at entry
Unscheduled care datamart (UCD)		Potential to track patients through Unscheduled Care Datamart based on SMR04 (mental health) information and linking to other parts of UCD.	Data linkage issues
GP Out of Hours (OOH)	Read Codes	Read Codes are the recommended national standard coding system in Scottish general practices for recording clinical information (signs, symptoms, diagnoses or activities). The clinician may, however, not record the underlying	There may be inconsistency in the codes used between NHS Boards. Codes for some conditions, e.g. anxiety, may not be available

Data source	Data item (field)	Details	Limitations
		condition, e.g. chronic obstructive pulmonary disease (COPD) or asthma, but only the acute presentation.	
SMR01	ICD10 (main and other condition fields)	Emergency ICD10 codes	
Drugs and Alcohol (SMR25)		Co-occurring health issues, including mental health, may be available	
Police healthcare		Data may become available over time.	National data set not available until late 2017 (possibly later) May be potential to look at Lanarkshire police data

Appendix 4: DBI evaluation development issues

To robustly assess the effectiveness of the intervention there would be a value in being able to compare the outcomes for people who receive the intervention with those who would be eligible, and share similar characteristics, but do not receive the intervention over the pilot period. This would help to build confidence that any changes in someone's ability to manage their distress (outcome 8) was due to the intervention. To do this there are a number of issues for consideration if the aim was to build in a control group. The team commissioned to undertake the independent evaluation could be invited to propose options for addressing this component of the study.

Identifying relevant setting-specific control groups

'Settings' here refers to the different routes through which people may be identified as in distress and offered a referral for a DBI level 2. At present (at least) five potential sources have been identified:

1 A&E departments
2 police service
3 ambulance service
4 primary care
5 social work.

To ensure a robust control group, a number of core issues must be addressed:

- Ensuring that staff in the control settings are able to systematically identify people who meet the criteria of being in distress (as defined in the programme design): this has implications for staff training in control settings.
- Avoiding/controlling for the 'Hawthorn effect': even if no service is available, the risk is that the training itself increases awareness and with it increases the numbers identified as 'eligible' (i.e. meet the criteria of 'distress') than

would be the case without the training. In effect the training contaminates the data.

- Having a flagging system in place to ensure systematic and accurate recording of people in control settings who are identified as meeting the criteria of being in distress.

- Identifying comparable 'settings' so that referral patterns reflect the 'normal' usage of the different settings, e.g. A&E departments serving rural/remote populations as well as those serving urban populations; police divisions (or sub-divisions) serving similar populations; ambulance teams (or sub-teams) serving similar populations; and primary care practices of similar sizes serving similar populations. Criteria for determining similarity would need to be agreed.

- The numbers 'eligible' for a DBI in both control and intervention settings have sufficient 'power' in order to draw conclusions about the effectiveness of the intervention. The successful evaluation team would need to undertake the power calculations, but it would be useful to have some 'ballpark' indicators of likely demand.

Matching populations

In addition to matching types of setting, the populations receiving the intervention and those in the control group would need to be matched, with regard, for example, to socio-demographic/socio-economic characteristics, previous history of presenting in 'distress', history of self-harm/suicidal behaviour, mental health problems or substance misuse problems.

The intervention group also needs to be clearly defined, particularly as there are a number of potential sub-groups, for example:

- people who meet the programme definition of being in 'distress' who receive a DBI level 1 (compassionate response, signposting as per 'usual care' and offer of referral to DBI level 2)

- people who initially take up the offer of a referral, but subsequently decline when approached by DBI level 2 provider and/or are uncontactable

- people who take up the offer of a referral and receive a DBI level 2 ('dosage' – to be defined).

Given these issues, options to consider might be:

- Set up control and intervention groups in one type of setting likely to generate sufficient numbers, e.g. A&E, with comparisons between A&E departments serving similar populations (see above). This could be extended to the police and ambulance services, perhaps after first six months when there is a sense of the numbers coming through.
- Consider a 'mini-RCT' – people in the pilot sites eligible for a DBI level 2 being randomly allocated to a control and intervention group. Consideration would need to be given to the processes for allocating people to groups, particularly as the offer of a referral is made by the DBI level 1 staff (first responders).

Given the likely small numbers generated via primary care it is suggested that this setting is excluded for the purposes of any controlled study component.

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