

Structured Assessment of FEasibility (SAFE) Version 1.1

Rating Manual

SAFE assesses the extent to which an intervention is feasible for implementation in mental health services in the National Health Service (NHS) in England. This is the SAFE Version 1.1 rating manual.

SAFE Version 1.0 was published as:

Bird V, Le Boutillier C, Leamy M, Williams J, Bradstreet S, Slade M (2014) *Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines*, British Journal of Psychiatry, 204, 316-321.

Ongoing evaluation identified the need for minor modifications (SAFE Version 1.1) and a rating manual (this document) to further improve the reliability of SAFE ratings. SAFE Version 1.1 and the SAFE Version 1.1 rating manual can be downloaded at

www.researchintorecovery.com/safe

INSTRUCTIONS

SAFE ratings are completed for a specific study (e.g. a trial report). Where the study refers to a manual or online resources, these should also be used to inform the SAFE ratings.

The SAFE measure comprises 16 items grouped into two sub-scales: Blocks (8 items) and Enablers (8 items). Exactly **one** rating is made for each item.

Blocks sub-scale

1. Do staff require training to deliver the intervention?

This item refers to the amount of time that is required for staff to be trained, before the intervention can be delivered. Training time may be needed for:

- Existing staff – rate training time additional to the standard skill-set of professions in a standard multidisciplinary team: in England this is mental health nursing, occupational therapy, psychiatry, psychology and social work.

or

- New staff – rate extra training time needed to supplement the skill-set of a non-standard professional (e.g. a music therapist). Rate the need to involve new staff under item 5.

The time must be specified by the author, not estimated by the SAFE rater. If the amount of training is not specified, rate as 'Unable to rate'. If the intervention needs another professional (e.g. a music therapist) then rate under item 5 (rate only *extra* training they would need in item 1). Booster training sessions are not rated – they are covered by item 4. If the intervention requires professional expertise not normally present in multidisciplinary teams

Rating

Yes: *The intervention requires four hours or more of training*

Partial: *The intervention requires up to four hours of training*

No: *The intervention does not require any specific training*

Unable to rate: *Not enough information provided to rate item*

2. Is the intervention complex?

A complex intervention is defined by the MRC Framework (MRC Health Services and Public Health Research Board, 2008) as interventions that contain several interacting components. This item rates the number of component parts of the intervention.

Separate each component of the intervention that staff carry out or are involved in. If an intervention includes both group sessions with service users and individual sessions with service users, these two forms of therapy sessions count as two separate components. If an intervention includes both pharmacotherapy and psychological therapy, these two forms of therapy count as two separate components. Other examples of components are team meetings or supervision sessions which are part of the intervention, or a consultation with someone who is not part of the team (e.g. a GP, an employer).

Rating

Yes: *The intervention is made up of more than three separate components*

Partial: *The intervention contains two or three separate components*

No: *The intervention only has one component*

Unable to rate: *Not enough information provided to rate item*

3. Is the intervention time consuming to provide?

The time per client should be rated. This holds for both individual and group-based interventions. For instance, if staff deliver an intervention made up of 1 hour individual therapy with 1.5 hours of group training, the total intervention should be rated as a 'Yes' because the intervention requires two hours or more per week (per client). If the report only provides information about the amount of time spent per month, then the average amount of time per week should be calculated.

Rating

Yes: *The intervention requires two hours or more per week of work (per client)*

- Partial:** *The intervention requires half an hour or more but less than two hours of work per week (per client)*
- No:** *The intervention requires less than half an hour per week (per client)*
- Unable to rate:** *Not enough information provided to rate item*

4. Does the intervention include/require ongoing support and supervision?

This item rates ongoing support and supervision for staff (not for clients). If the report mentions ongoing support and supervision, but does not specify how often sessions are required, the item should be rated as 'unable to rate'. If the report does not mention anything about supervision or support, but the likelihood is that supervision was provided, the item should be rated 'Unable to rate'.

Rating

- Yes:** *The intervention requires an extra weekly supervision or support session*
- Partial:** *The intervention requires an additional monthly supervision or support session*
- No:** *The intervention does not require any additional support sessions or supervision*
- Unable to rate:** *Not enough information provided to rate item*

5. Does the intervention require additional human resources?

An intervention requires 'additional human resources' when, in the delivery of the intervention, staff who do not usually provide care are required. This includes:

- Staff within the team who are not otherwise involved in the person's care, e.g. a whole-team intervention
- or
- New professionals (e.g. music therapists) who are not in a standard multidisciplinary team: in England this is mental health nursing, occupational therapy, psychiatry, psychology and social work.

Rating

- Yes:** *Either the whole team is required to provide the intervention or professionals not in the standard multidisciplinary team are needed.*
- Partial:** *More than one member of staff are involved in providing the intervention*
- No:** *The intervention can be provided by one member of staff*
- Unable to rate:** *Not enough information provided to rate item*

6. Does the intervention require additional material resources?

Additional material resources are described as those that are not part of the usual care of the service user or ordinarily used within the mental health team.

Rating

- Yes:** *The intervention requires sizeable resources or special equipment which staff would not usually have access to e.g. a specially equipped room, instruments, art materials*
- Partial:** *The intervention requires additional but readily available resources e.g. computers, workbooks*
- No:** *The intervention does not require any additional resources that staff would not usually have access to*
- Unable to rate:** *Not enough information provided to rate item*

7. Is the intervention costly?

This item refers to costs for both setting up and running the intervention. If the manuscript includes a statement about the costs of the intervention, then that statement should be followed in rating this item. If the manuscript does not include statements about costs then, the following guideline can be used:

- If 2 or 3 out of the ratings of items 1, 5 and 6 are 'yes', then this item should also be rated as 'yes'.
- If only 1 of the ratings of items 1, 5, and 6 are 'yes', then this item should be rated as 'partial'.
- If none of the ratings of items 1, 5, and 6 are rated 'yes', then this items should be rated 'no'.

Rating

- Yes:** *The intervention is likely to be too costly to provide without extra funding*
- Partial:** *The intervention is likely to require other costs to be de-prioritised*
- No:** *The intervention cost is low*
- Unable to rate:** *Not enough information provided to rate item*

8. Are there known *serious or* adverse events associated with the intervention?

Adverse events or serious adverse events should be mentioned in the report. Serious or adverse events are undesired harmful effects resulting from the intervention. Examples of serious adverse events are: death, hospitalisation, and harm to self or others. Examples of adverse events are: weight alteration, feeling worse rather than better after therapy, disruption of therapeutic alliance.

Rating

- Yes:** *There are known serious adverse events associated with the intervention*
- Partial:** *There are known adverse events associated with the intervention*
- No:** *There are no known serious or adverse events associated with the intervention*
- Unable to rate:** *Not enough information provided to rate item*

Enablers sub-scale

9. Is the intervention applicable to the population of interest (e.g. adults using community mental health teams)?

This item should be rated 'yes' when the intervention was originally and specifically designed for the target group. For pharmacological intervention, the medication should be included in the usual list of the medications prescribed for the target disorder. This item should be rated 'partial' when the intervention was originally designed for another group of interest, but has been adapted for delivery to the target group.

Rating

- Yes:** *The intervention has been designed for the population of interest*
- Partial:** *The intervention has been designed for a general mental health population or can be adapted to be applicable to the population of interest*
- No:** *The intervention is not applicable to the population of interest*
- Unable to rate:** *Not enough information provided to rate item*

10. Is the intervention manualised?

An intervention is fully manualised when the report refers to a manual or a protocol that is obtainable and likely to cover all the intervention's components (as defined in item 2). This item should be rated 'partial', when some of the intervention's components are manualised or when the intervention is said to be semi-structured.

Rating

- Yes:** *All components of the intervention are manualised*
- Partial:** *Some components of the intervention are manualised*
- No:** *The intervention is not manualised*
- Unable to rate:** *Not enough information provided to rate item*

11. Is the intervention flexible (i.e. can it be tailored to the context and situation)?

From the report it should be clear that the intervention can be tailored to the condition and situation of individual service users (e.g. their preferences or response to the intervention) or service needs (e.g. length or order of components). NB: The existence of a manual or a protocol does not exclude flexibility.

Rating

- Yes:** *The intervention is flexible and can be tailored to the context and situation*
- Partial:** *Elements of the intervention can be tailored to the context and situation*
- No:** *The intervention cannot be tailored to the specific context*
- Unable to rate:** *Not enough information provided to rate item*

12. Is the intervention likely to be effective (i.e. evidence based and expected to produce positive outcomes)?

The report should refer to the existence of supporting evidence for the intervention. An evidence base is established when there is evidence from one or more randomised controlled trials showing positive outcomes. There is 'Some evidence' (rated as 'Partial') when, for example, positive outcomes resulted from a pilot study, observational studies, or from trials that were carried out in a different target group.

Rating

Yes: *There is an established evidence base regarding the effectiveness of the intervention (e.g. clinical trials)*

Partial: *There is some evidence for the effectiveness of the intervention (e.g. case studies but no clinical trials)*

No: *There is no evidence base for the intervention*

Unable to rate: *Not enough information provided to rate item*

13. Is the intervention cost saving?

Yes: The interventions has been demonstrated to save costs

Partial: The intervention has been demonstrated to be cost-neutral

No: The intervention incurs more costs

Unable to rate: Not enough information provided to rate item

Rating

Yes: *The intervention has been demonstrated to save costs*

Partial: *The intervention has been demonstrated to be cost-neutral*

No: *The intervention incurs more costs*

Unable to rate: *Not enough information provided to rate item*

14. Do the intended goals of the intervention match the prioritised goals of the NHS?

When rating this item, the current priority goals of the NHS should be taken into account. At the time of development of SAFE (2013), the priority goals from 'No health without mental health' (Department of Health, 2011) were:

(i) More people will have good mental health. More people of all ages and backgrounds will have better wellbeing and good mental health. Fewer people will develop mental health problems – by starting well, developing well, working well, living well and ageing well.

(ii) More people with mental health problems will recover. More people who develop mental health problems will have a good quality of life – greater ability to manage their own lives, stronger social relationships, a greater sense of purpose, the skills they need for living and working, improved chances in education, better employment rates and a suitable and stable place to live.

- (iii) More people with mental health problems will have good physical health. Fewer people with mental health problems will die prematurely, and more people with physical ill health will have better mental health.
- (iv) More people will have a positive experience of care and support. Care and support, wherever it takes place, should offer access to timely, evidence-based interventions and approaches that give people the greatest choice and control over their own lives, in the least restrictive environment, and should ensure that people's human rights are protected.
- (v) Fewer people will suffer avoidable harm. People receiving care and support should have confidence that the services they use are of the highest quality and at least as safe as any other public service.
- (vi) Fewer people will experience stigma and discrimination Public understanding of mental health will improve and, as a result, negative attitudes and behaviours to people with mental health problems will decrease.

Rating

Yes: *The primary aims of the intervention match valued NHS outcomes e.g. improving mental health and wellbeing, supporting clinical and personal recovery, promoting good physical health, improving service satisfaction, reducing stigma and discrimination [Taken from No Health Without Mental Health, 2011, Department of Health]*

Partial: *The secondary aims of the intervention match the current valued outcomes*

No: *The primary and secondary aims of the intervention do not match the current valued outcomes of the NHS*

Unable to rate: *Not enough information provided to rate item*

15. Can the intervention be piloted?

If the intervention can be introduced incrementally by one or a small number of staff with a few service users, then rate 'Yes'. If the intervention can be provided by one or a small number of staff OR with a few service users (e.g. a whole-team intervention which can be provided to a few service users), then rate 'Partial'. If the intervention is a whole-team intervention which is provided to all service users (e.g. a service model), then rate 'No'.

Rating

Yes: *The intervention can be piloted by a few members of staff AND with only a few service users*

Partial: *The intervention can be piloted by a few members of staff OR with a few service users*

No: *The intervention cannot be piloted*

Unable to rate: *Not enough information provided to rate item*

16. Is the intervention reversible?

The intervention is irreversible when long-term or permanent harmful effects might emerge if the intervention is stopped. These harmful effects should be mentioned in the report.

Rating

- Yes:** *It is possible to stop the intervention without harmful, or unwanted, effects*
- Partial:** *It is possible to stop the intervention, but there are likely to be some harmful, or unwanted, effects*
- No:** *It is not possible to stop the intervention without serious adverse effects*
- Unable to rate:** *Not enough information provided to rate item*

SAFE scoring

It is recommended that no overall summary score is used, as barriers and facilitators differ in their importance depending on the context. See the SAFE paper (reference given on page 1) for further discussion of using SAFE ratings.