UK Health Security Agency

Standard evaluation framework for interventions designed to reduce inequalities in immunisation uptake

Explanatory notes

Produced to accompany the immunisation evaluation framework tool (Excel workbook)

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Introduction

Why the immunisation intervention design and evaluation framework tool were produced

A health equity audit of the national immunisation programme in 2019, led to the production of a strategy to address inequalities in immunisation and ensure equity in the delivery of infant, childhood and adult vaccination programmes.

During the strategy consultation process the need for a standard evaluation framework was identified; for use by local service providers and commissioners. There is currently no standard evaluation framework and consequently if local interventions are evaluated (often they are not), it is not easy to compare interventions.

Presently there is a section on ‘Vaccine update’ (the regular update email to which interested persons can subscribe) which details ‘How we did it’ for successful local interventions. The standard evaluation framework tool has been designed so that once completed by the user, the evaluation details can be placed in a centralised, searchable database. This will enable interested parties to easily access relevant information and contact details of colleagues who may be able to share best practice.

Ideally, information on interventions that were not associated with the desired change in behaviour would also be useful to collate in a centralised repository, to ensure that other local providers can learn from colleagues and interventions that have previously been unsuccessful. However it is important to consider that what works or does not work is often very context specific, so inclusion of detailed description of cohorts and settings is salient.

Publication in a peer reviewed journal is the gold standard for dissemination of research and service evaluations, especially since this level of evidence is considered and/or prioritised when guidelines and white papers are produced. Consequently the immunisation standard evaluation framework tool aims to provide users with collated information that will assist manuscript and/or conference abstract preparation.

The Evaluation Checklist (found on the ‘4. Evaluating’ tab) contains a list of ‘essential’ and ‘optimal’ criteria required for a comprehensive and robust evaluation. Essential criteria are the minimum data and information recommended to perform a basic evaluation of an immunisation intervention. Optimal criteria are additional data that would improve the quality of an evaluation; enhance understanding about what has been achieved and the processes that have taken place during the intervention. Users also have the option to select the type of evaluation – ‘Process’ or ‘Impact’ (or both) and the relevant criteria are displayed in the checklist for completion.

Aim of the immunisation intervention design and evaluation framework tool

The tool and accompanying explanatory notes aim to ensure:

1. Interventions are designed based on a clear understanding of the issue that the intervention seeks to address

This includes consideration of the capability, opportunity and motivation of target groups the intervention seeks to influence, in the local context, and how these factors act as drivers or barriers to influence the behaviour that the intervention seeks to change (COM-B model).

2. Interventions are comprehensively described

A step by step guide to produce a Logic Frame Model is included which aids the detailed description of the planned intervention, facilitating a shared understanding amongst those involved at each stage of the intervention, and helping to focus the evaluation.

3. Data measurement and capture is planned in advance

The measurement plan enables users to consider how, when and by whom data will be captured and what evaluation question the resulting information will address.

4. That the evaluation is considered and incorporated into the design and implementation of the intervention, and ideally performed prospectively

A standard template, and supporting guidance, to collect all of the essential (and optimal) information required for a comprehensive evaluation will facilitate the dissemination of results to other interested parties within the immunisation and vaccination field, improving the ease of comparison between a number of interventions through the use of a standard format.

5. A summary, including the most key information is automatically produced to facilitate sharing between stakeholders

The resulting summary, pre-populated with details entered by the user in the preceding sections of the tool curates the salient information to facilitate production of an abstract.

Who can use the immunisation intervention design and evaluation framework tool

The evaluation framework tool was produced for use by local providers, commissioners and screening and immunisations teams when designing and implementing immunisation and vaccinations interventions. It aims to be accessible to those who have not evaluated interventions before, as well as those who are more experienced.

How to use the immunisation intervention design and evaluation framework tool

The tool has been designed to be used prospectively. The user is advised to work their way through each of the steps (1 to 5) sequentially in the accompanying Excel workbook. Certain information may change with time, so the process may be an iterative one with users returning to amend the information gathered at earlier stages as necessary.

Using the Immunisation Evaluation framework tool at the initiation stages of the intervention will help with the assimilation of information regarding the issue that the intervention aims to address, which may feed into the design of the intervention itself, and will ensure that the steps necessary for a comprehensive evaluation, including identification of what questions the evaluation will seek to answer, are considered from the start.

Some users will seek to use the tool retrospectively – once an intervention has already been designed and/or implemented. Whilst not ideal, the framework tool still provides a useful structure for detailing the design of the intervention, describing what has already been done and how data was measured or collected. When approaching the evaluation retrospectively it is more likely that there will be some areas of the evaluation checklist that can not be completed, as the data capture was not planned in advance of the intervention start. It is for this reason that we recommend the tool be considered and completed from the beginning of the intervention process.

1. Designing the intervention

Capability, opportunity, motivation and behaviour (COM-B) model

The capability, opportunity, motivation, behaviour (COM-B) model was developed from the behaviour change wheel and was relevant to any behaviour in any setting. The WHO adapted the COM-B model to increase its relevance for vaccination behaviour as part of the Tailoring Immunisation Programs (TIP) work. Evidence has shown that each of the COM domains are important determinants of vaccination behaviors. However testing performed by the WHO determined that there was little benefit in differentiating between the subcategories for motivation (automatic and reflective) and the subcategories for capability (psychological and physical) when designing and/or analysing interventions. As such these subcatogories are grouped in the modified COM-B model used by the immunisation evaluation framework tool.

It is important to consider that each of components of the 3 COM domains could act as drivers towards vaccination or barriers against it. For more detailed information regarding the modified COM-B model and its relevance to vaccination, please see the WHO Europe TIP Tailoring Immunization Programmes (2019).

2. Describing the intervention

Logic frame model

Logic frame models help to identify primary and secondary outcome indicators,describe the relationship between each element of an intervention and the anticipated direction of change. They can be useful in describing and explaining what is expected to happen, provide a mechanism to check that selected indicators are appropriate and that the objectives are likely to be achieved.

Inputs

Inputs can include costs (venue, staff, training and equipment), staff time, materials and the evaluation plan.

Activities

Activities can be considered in 2 sections, planning and delivery. Planning activities include assessment of need, development of intervention based on evidence and identified need, identification of a suitable venue, staff recruitment and/or training. Examples of delivery activities include running of specific vaccination sessions and information sharing activities.

Pathways

Pathways are the links between inputs, activities and outputs. It is important to consider that the transition between each of the components in the logic frame may not be linear or unidirectional.

Outputs

This should detail the tangible products or services that the intervention aims to produce. For example, ‘adolescents attend immunisation session’ or ‘immunisation teams receive e-consent forms and prepare for sessions’.

Short-term outcomes

A measure of a change induced over a more immediate timescale; these include the key outcomes which need to be carefully measured, against which the intervention will be evaluated. There will likely be larger number of these short-term outcomes than the medium-term outcomes and impacts. An example is the change in proportion of returned vaccination consent forms.

Medium-term outcomes

These are the results of the intervention relevant to a longer time frame than short-term outcomes. Medium-term outcomes are often linked to the short-term outcomes, either resulting from a combination of more than one short-term outcome or have a direct link between 2 outcomes, but with a different timescale.

Impacts

Changes expected from the intervention on a longer timescale. These impacts can be much broader than short- and medium-term outcomes, for example, ‘increased uptake of vaccination amongst the target population’. These broader impacts may be more difficult to measure or to observe a noticeable change over the available timeframe. For smaller interventions it may therefore be more relevant to precisely document short- and medium-term outcomes than look for a broader impact that may not yet be acheived. A plan to recapture certain data at a later date in order to assess impact may be pragmatic in certain situations.

3. Measuring: data capture

Evaluation question

The evaluation question to which the rest of the information in this row of the table refers. There is likely to be a number of questions sought to be addressed by an evaluation. It is helpful to explicitly state each question when planning what data will be required to address the question, and how it will be measured, collected, stored and managed and so on.

Output or outcome

A drop-down menu listing the outputs and outcomes previously specified by the user when completing the '2. Describing' section of the evaluation framework tool.

Measure

What information will be measured or collected including units.

Timepoints to be measured

Specific information regarding when measurement should take place. This is usually counted in the time elapsed since the intervention started. If data is collected before the start of the intervention these timepoints are conventionally described using a minus (-) sign. For example, if data is collected 2 weeks prior to the initiation of the intervention, this timepoint would be denoted as, '-2 weeks'.

Data source

Identifying the source of the data will then allow necessary steps to be taken to access, store and manage data in an appropriate format for the evaluation. Data sharing agreements may be necessary, and/or design of data collection tools and storage databases, identification of individuals to capture, input and manage data.

Routinely collected or study specific

Knowing whether or not the data can be accessed from a routinely-collected source will identify what needs to be done (and the associated resources) in order to collect and/or access the data.

Ethical considerations

Ethics of data collection, storage and management should be considered, from both the point of view of the study participant and the professionals collecting data. Personal data should be limited to that which is necessary for the intervention or evaluation to take place. The Data Protection Act 2018 must be adhered to when collecting personal information. Refer to section

‘Ethical considerations, data privacy or sharing and participant confidentiality’ for more information.

Actions

This section should detail the actions necessary in order for the appropriate information to be collected and used to answer the evaluation question.

Who is responsible

A named person, persons and/or team to whom responsibility for this task is delegated. Seeking agreement at an early stage of the evaluation will help to avoid misunderstanding in where responsibility and accountability lies for each of the measurement tasks.

4. Evaluating: standard framework criteria

The accompanying excel workbook presents a list of the core elements of the standard evaluation framework, linking to the COM-B and logic frame models where relevant and self-populating fields that relate directly to inputs from these models. The level of evaluation ('Essential' or 'Optimal') can be selected by the user, and the resulting criteria for completion are then displayed by the tool.

The criteria allocated as 'Essential' represent the minimum data and information recommended to perform a straightforward evaluation of an intervention aimed at reducing inequalities in immunisation uptake. In order to improve the breadth and quality of the evaluation and include further relevant information users of the framework tool have the option to populate 'Optimal' criteria. These criteria will enable a more complete picture to be shared with colleagues working in immunisations, improve the quality of evaluation, and aid the publication process of findings in journals or through presentation at conferences.

The desired type of evaluation ('process' and/or 'impact') can be selected in section 1d. As a result of the selection only relevant criteria are displayed by the tool for completion.

Explanatory notes

Part 1. Overview of intervention details

Title or name of intervention: essential

A record of the name or title of the intervention, for example, ‘Use of electronic consent forms in school-aged immunisation programmes’. This field is self populated using the text entered into the ‘COM-B model input’ sheet.

Contact details for project lead: essential

Name, job title and contact details of the project lead.

Contact details for key people involved with planning, delivery and evaluation of the intervention: essential

List the key people involved in the intervention planning, delivery and evaluation, and include contact details. As staff may change jobs during the course of the intervention, details of staff positions should be included.

Commissioners of the intervention and sources of funding: essential

Include details of the commissioners and the route through which funding was allocated to the intervention.

Declaration of interests: optimal

This covers any potential conflicts of interest in carrying out the intervention and/or evaluation. This is particularly important if the evaluation is funded by an agency that could be perceived as wanting to influence the results for commercial reasons. The National Institute for Clinical Excellence (NICE) has produced a clear statement covering different categories of potential conflicts of interest that should be declared, including pecuniary interests (where a financial payment or other benefit has been received) and a non-pecuniary interest (where someone may have publicly expressed a clear opinion on the intervention in question, and this may influence their impartiality). In general, it is best to declare any potential conflicts even if they do not appear to be important. Perceived conflicts of interest do not necessarily mean the intervention or evaluation should not go ahead as planned; it may be acceptable to state how potential conflicts are going to be avoided.

Aim: essential

A broad statement of intent setting out the purpose of the project. For example, ‘the project aims to reduce inequalities in second dose of measles vaccine uptake amongst children under 5 in Tower Hamlets.’

Objectives: essential

What are the necessary steps that need to be taken in order for the intervention to meet its aim? Aims and objectives need to be as clear as possible and, ideally, SMART, that is: Specific, Measureable, Achievable, Realistic and Time-bound. See the PHE introductory guide to

evaluation for more detail. Is there a primary immunisation outcome target such as increasing proportion of a specified population who have received a complete course of a specific vaccine? Does it have a secondary outcome target such as increasing knowledge of disease or vaccine? It may be helpful to refer to the Logic Frame figure when defining the objectives of the intervention.

Short-term outcomes: essential

Results of the intervention relevant to a short time frame (see page 7).

Medium-term outcomes: essential

Results of the intervention relevant to a longer time frame (see page 8).

Impacts or long-term results brought about by the intervention: essential

Long-term health outcomes targeted by the intervention. Whilst it may not be possible to measure them during the timeframe of the intervention and/or evaluation, it is important to explicitly state which impacts or long-term health outcomes are being targeted, to facilitate collection and interrogation of appropriate baseline data (also see page 8).

1a. Intervention description and wider context

Rationale for intervention: essential

It is essential to state the reasoning behind the design of the intervention. It may be helpful to refer to the COM-B model at this point. A description of the methods that will be used and the theories or scientific evidence on which the intervention is based is also essential. Evidence could be peer reviewed research studies, NICE guidance on immunisation interventions, theories about health promotion and behaviour change, or immunisation commissioning guidance.

Innovative components of interventions need to be explicitly stated as such, along with the rationale for including it in the intervention. For example ‘insight work with the local target community informed adaptations of a previously used intervention, to make it more culturally appropriate’.

You may also wish to refer to any equality impact assessments that have been performed locally, or other routes that have identified the intervention’s target population as experiencing inequality with current service provision and/or having an unmet need.

Relevant policy and performance context: optimal

It may be useful to show how an intervention fits into any strategic policies, or whether it is a priority intervention as outlined in, for example, a joint strategic needs assessment.

For example, 25 national indicators directly relating to immunisations and vaccination are included in the Pubic Heath Outcomes Framework:

- D03a - Population vaccination coverage - BCG - areas offering universal BCG only
- D03b - Population vaccination coverage - Hepatitis B (1 year old)
- D03c - Population vaccination coverage - Dtap / IPV / Hib (1 year old)
- D03d - Population vaccination coverage - MenB (1 year)
- D03e - Population vaccination coverage - Rotavirus (Rota) (1 year)
- D03f - Population vaccination coverage – PCV
- D03g - Population vaccination coverage - Hepatitis B (2 years old)
- D03h - Population vaccination coverage - Dtap / IPV / Hib (2 years old)
- D03i - Population vaccination coverage - MenB booster (2 years)
- D03j - Population vaccination coverage - MMR for one dose (2 years old)
- D03k - Population vaccination coverage - PCV booster
- D03l - Population vaccination coverage - Flu (2 to 3 years old)
- D03m - Population vaccination coverage - Hib / MenC booster (2 years old)
- D04a - Population vaccination coverage - DTaP/IPV booster (5 years)
- D04b - Population vaccination coverage - MMR for one dose (5 years old)
- D04c - Population vaccination coverage - MMR for 2 doses (5 years old)
- D04d - Population vaccination coverage - Flu (primary school aged children)
- D04e - Population vaccination coverage - HPV vaccination coverage for one dose (12 to 13 years old) (Female)
- D04e - Population vaccination coverage - HPV vaccination coverage for one dose (12 to 13 years old) (Male)
- D04f - Population vaccination coverage - HPV vaccination coverage for 2 doses (13 to 14 years old) (Female)
- D04g - Population vaccination coverage - Meningococcal ACWY conjugate vaccine (MenACWY) (14 to 15 years)
- D05 - Population vaccination coverage - Flu (at risk individuals)
- D06a - Population vaccination coverage - Flu (aged 65 and over)
- D06b - Population vaccination coverage – PPV
- D06c - Population vaccination coverage – Shingles vaccination coverage (71 years)

Details of health needs assessments that have been conducted: optimal

Both commissioners and providers should consider undertaking Equality Impact Assessments to ensure that the needs of protected characteristics are considered. In addition, local areas should consider undertaking health equity audits of intervention provision to identify areas in which interventions may not be equitable.

Has a health needs assessment been conducted that identifies a gap in this intervention being provided for the target population? Information may come from a specific needs assessment conducted for the intervention, or it may be available from other sources. For example, data relating to health inequalities and gaps in intervention provision may already be available from policy documents such as the Joint Strategic Needs Assessments (JSNAs) or Children and Young People's Plans.

If information is not readily available from these documents, other existing data sets may be helpful:

- Public Health Outcomes Framework
- Health Profiles
- Census
- SHAPE atlas

When using data to identify gaps in intervention provision and to justify resource allocation, it is important to assess the quality of the data being used. For example, how robust is the data at the geographical level at which you wish to use it? How old is the data? How well validated is the tool used to collect the data? If it is estimated data, how has it been modelled and how accurate an estimate is it likely to be?

A more robust approach could be to use findings from a number of different data sources and support these by carrying out local research. This could include the use of local health and wellbeing questionnaires, focus groups or face-to-face interviews with the target population or community.

Short summary description of intervention: essential

It may be useful to refer to the Logic Frame figure when summarising the intervention and/or include the Logic Frame figure at this point of your evaluation. The headings below are only intended as a guide. It may be that these points are described differently for a particular intervention.

Active intervention content

It is important to provide a clear description of the intervention content, so it is obvious what the results of your evaluation are attributable to, and helpful to others who may wish to adopt the approach used. Clearly state what the active intervention is going to do, and how it is going to do it. List all of its major techniques and theoretical components and activities (for example, weekly vaccination clinics at hostel or shelter).

It is important here to state if the intervention is tailored to participants needs (for example, written advice provided in easy read format or languages other than English). It is also important to note if modifications to the original intervention had to be made, what these were, why and when they were made. Where possible, provide links to, or append, intervention handbooks, protocols, participant information or delivery materials.

Delivery method

How will the intervention be delivered? For example, in existing clinical facilities, mobile units, school, or a combination of these. Who is the intervention aimed at? For example, individuals, families or parents or carers, or particular groups.

Details of quality assurance mechanisms
What mechanisms are in place to ensure the intervention is being delivered in the way in which it was planned?

Examples of quality assurance mechanisms are spot-checks carried out by an external assessor, or self-assessment check-lists that can be used by those delivering the intervention. Include details of any relevant health and safety checks, risk assessments and Disclosure and Barring Service checks if the intervention involves children or vulnerable adults.

Locations and settings: essential
Where is the intervention taking place? For example, the location could be a GP surgery, school or community centre. It may be that it takes place in several settings and they should all be included here. It may be useful to mention if any transport is being provided as part of the intervention.

Intervention timescale: essential
Intervention duration, frequency and number of sessions provided. How long will the intervention run for each group of participants? How many sessions, episodes or events will be delivered? How long is the active intervention intended to last? For example, ‘the intervention was delivered in 24 2-hour sessions, twice a week for 12 weeks’. Please note, the duration of the active intervention may differ from the duration of the service.

Intervention delivery dates: essential
This includes dates for the initial invitation or recruitment, first point of contact and any subsequent contacts and/or follow-ups.

Duration of funding of specific intervention (including dates): optimal
What are the start and finish dates for the service? The active intervention may be run a number of times throughout the duration of a commissioned service.

1b. Resources required

Intervention staff and core competencies required: essential
It may be helpful to refer to Logic Frame 'inputs' you have already described. Who is designing and delivering the intervention? For example, school nurse, health trainer, health professional or teacher. What is their background, expertise and specific training and qualifications. What is their role in the intervention?

What are the core skills needed by everyone involved in delivering the intervention? For example, facilitation skills, administrative skills, experience of working with children, young people, or individuals with disabilities, communication skills, and basic knowledge of infectious disease and vaccination.

What are the basic training requirements for the delivery of the intervention? Do they have to have a qualification in nursing and/or delivering immunisations? Do they have to be trained to a

specific level, or be a member of a certain professional body? What intervention specific training is provided, and how is it delivered? Further information about requirements for those administering vaccines can be found in the Green Book chapter 5.

This information is important in helping others who may want to replicate the approach taken by this intervention.

Equipment and resources required: essential

It may be helpful to refer to Logic Frame 'inputs' you have already described. Is a particular type of venue required? For example, one with cold chain storage or handwashing facilities. Are specific resources needed such as information leaflets, sharps disposal, electronic equipment to record or access patient information.

Details of type and extent of any clinical involvement: optimal

Will clinicians be involved at any stage of the intervention? This includes during development, delivery and carrying out quality assurance of the delivery. Information may need to be relayed to primary care or centralised immunisation records for those who participate.

Details of resources required for any incentivation of participants or staff: optimal

Participant incentives: Have any participant incentives been provided to encourage individuals to take part in the intervention and, if so, what are they? If incentives have been used it is important to record their use and uptake as this may have an impact on the success of the intervention and the feasibility of wider roll out.

Provider incentives: Some intervention commissioners may provide incentives to intervention providers such as payment based on attendance rates or results. It is also important to record these incentives which may provide insight into the completeness of findings and considerations regarding future sustainability.

Details of any costs to participant: optimal

This could include financial, time and/or emotional costs, and could be actual or potential. It should be noted if participants are charged for any part of the intervention. There may also be additional participant costs such as travel or child care which is important information to capture, as this could provide further insight into differences in attendance. Conducting interviews with participants may be helpful in exploring the impact of these broader participant costs.

Detailed breakdown of intervention cost: optimal

A detailed breakdown of all intervention costs is important for a full economic analysis, in order to judge whether or not it is good value for money. Take into account costs incurred in planning and development stages as well as during the delivery stages. Some examples of input costs are staff time, transport, venue hire, equipment, publicity and incentives.

It is especially important to factor in ‘invisible’ or ‘in kind’ costs. For example, a room in a local authority leisure centre may be hired free of charge as part of a partnership agreement with the

local authority or clinical commissioning group. However, these cost needs to be taken into account so that if the intervention is repeated, financial resources can be planned accurately.

Average estimated cost of intervention per participant: essential

It is often important to local commissioning, delivery and assurance arrangements to demonstrate the economic value of an immunisation intervention. It is therefore advised that as a minimum, the cost per participant is provided as part of the evaluation. However, some evaluations may require more detailed cost benefit analysis, which is beyond the scope of this guidance. For evaluators wishing to undertake more advanced economic assessments it would be advisable to seek advice from a health economist.

1c. Participant recruitment, confidentiality and ethical considerations

Method of participant recruitment and/or referral: essential

How have participants been recruited to the intervention? What percentage of those that are eligible have been recruited? Has there been a referral process or was it self-referral? For example, have participants been referred by a GP or have leaflets and posters been used to advertise in GPs, social media or community centres so participants can sign up themselves?

Please give brief details here of any sampling process that was undertaken, if applicable (such as if the intervention is delivered as part of a formal trial or pilot). Was there any targeting of particular groups by, for example, advertising the intervention in certain communities or at specific locations?

The method by which people have been recruited should be taken into account when carrying out the evaluation. For example, a self-referred group of participants may be more motivated than participants referred by a professional, and thus may be more likely to participate in the intervention and/or choose to take up the offer of vaccination. A description of any incentives used should also be included.

Participant consent mechanism: essential

The appropriate mechanism for gaining participant consent must be considered. The nature of consent will vary for different groups of people. For example:

- those able to consent for themselves
- those with parental responsibility and consenting on behalf of a child or young person under the age of 16 years
- those who lack the capacity to consent

Policy guidance on seeking consent from different groups and a wide range of consent forms are available from the Health Research Authority website.

Participant inclusion or exclusion criteria: essential

Criteria should include details of demographics of target groups.

Participants should meet pre-defined criteria. For example, the target population may be:

- adults aged 70 to 79 who are unvaccinated for shingles, from x local authority, self-identifying as belonging to a minoritized ethnic group
- individuals who have had a serious allergic reaction (including an anaphylactic reaction) in the past to a previous dose of the shingles vaccine, or to any of the ingredients in the vaccine, or to a previous dose of varicella (chickenpox) vaccine should be excluded
- individuals with weakened immune systems should be assessed by a GP or practice nurse to determine which vaccine is suitable. If only Zostavax is offered as part of the intervention, those with weakened immune systems due to a condition, treatment or medicine should be excluded from the intervention

Ethical considerations, data privacy or sharing and participant confidentiality: essential

Depending on the type of intervention you may be required to obtain formal ethical approval from an independent research ethics committee. With service evaluations this may not be required, however study protocols may be required to have an internal review by your organisation's Research Ethics and Governance Group to ensure the intervention complies with regulatory requirements. More information can be found on the NHS Health Research Authority's website.

The Data Protection Act must be adhered to when collecting personal data from individuals. A data protection statement should be given to participants before any personally identifiable data is collected. It should explain exactly which personal data is being held, why, where it will be held, and who will have access to the data and for how long. This is particularly important when collecting sensitive data such as home postcode, ethnicity and socioeconomic status. More information about the requirements of the Data Protection Act can be found on the UK government website.

1d. Details of evaluation

Type of evaluation (drop-down list): essential

Your selection here determines which fields are included below. Either process, impact or both process and impact can be selected.

Process evaluation details the implementation of activities planned as part of the intervention; whether implementation occurred as intended, and if not what the reason was for this. Process evaluation may be performed multiple times during the lifetime of the intervention.

Impact evaluation assesses the effect of the intervention on defined outcomes. The effects of the intervention could be as intended (for example, an improvement in vaccine uptake) or could be found to counteract the overall aim. Both direct and indirect impacts of the intervention should be considered.

Evaluation design: essential

The way in which an evaluation is designed to collect data, and the method by which data may be analysed to measure impact, should be recorded here. For example, does the evaluation involve a pre- and post- design? Is there a control group or control population? Was formative research conducted to inform the development of the intervention? Does the evaluation use qualitative and/or quantitative data? This information is important as it will determine what inferences can be made about the evaluation findings. See 'Introduction to evaluation in health and wellbeing' for a more detailed explanation of evaluation designs.

Part 2. Demographics: summary statistics of those reached by intervention. For each criterion, include a measure of average and distribution of data.

Under the Public Sector Equality duty set out in the Equalities Act 2010, public bodies are required to analyse the effect of their organisation's functions on all population groups with protected characteristics. It requires equality considerations to be reflected into the design of policies and the delivery of services, including internal policies, and for these issues to be kept under review. Public authorities will therefore not be able to meet the duty unless they have enough usable information.

It is therefore recommended that the following essential data should be collected on an individual level throughout the intervention. It will be useful to use a data capture tool (either pre-existing or adapted from existing data capture tools such as the PHE data capture tool).

Age: essential

It is essential to record the age of all participants in the intervention. The choice of summary age categories depends upon the vaccine program to which your intervention is related. For example, If the intervention seeks to increase uptake of 'flu vaccine in those aged 65 and over, appropriate age bands for use in summary statistics may be 65 to 74, 75 to 84, 85+ years.

If the intervention seeks to increase uptake of primary immunisation in children, appropriate age bands for use in summary statistics may be less than 6 months, 6 to 12 months, 12 to 24 months and 24 months and over.

Sex: essential

Record the sex of all participants. This is useful for identifying whether or not the intervention tends to be more effective for males or females, and in assessing whether the intervention is appealing and accessible to both sexes. It may also be appropriate to collect data on self-identified gender, offering participants the option to not disclose their sex or gender or describe themselves as non-binary or gender fluid.

Ethnicity: essential

It is standard practice in healthcare interventions to record the ethnic origin of participants. If the intervention is targeted at members of a specific ethnic group, then a record of ethnic origin is essential for screening participants for eligibility. If the intervention is not targeted in this way, it is still important information for raising understanding about the extent to which uptake and response to the intervention may vary between people from different ethnic groups. For example, ethnicity of those reached by a specific intervention can be compared to the ethnicity of the overall population of the area to determine whether the intervention has reached a group that is representative of the local population, and if not, it would be important to discover why this is.

It is salient that interventions do not exacerbate health inequalities, but instead work towards reducing them. Analysis of ethnicity becomes even more vital when there are specific ethnic groups with a lower vaccine uptake than others.

Such monitoring demonstrates that policies for equality are working in practice. It is a way of identifying potential discrimination and whether policies promoting equality of opportunity and good relations between different ethic groups are being implemented.

It is recommended that public authorities and their partners use the following Census 2011 categories for monitoring ethnicity in England and Wales:

White

- English, Welsh, Scottish, Northern Irish or British
- Irish
- Gypsy or Irish Traveller
- any other White background, please describe

Mixed or multiple ethnic groups

- White and Black Caribbean
- White and Black African
- White and Asian
- any other mixed or multiple ethnic background, please describe

Asian or Asian British:

- Indian
- Pakistani
- Bangladeshi
- Chinese
- any other Asian background, please describe

Black, African, Caribbean or Black British:

- African
- Caribbean

- any other Black, African or Caribbean background, please describe

Other ethnic group:

- Arab
- any other ethnic group, please describe

Disability: essential

The Equality Act 2010 defines disability as a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on your ability to do normal daily activities'. The Public Sector Equality Duty (PSED) was introduced in April 2011 as part of the Equality Act 2010. At the heart of the PSED is the requirement that public bodies must have due regard to the need to:

- eliminate unlawful discrimination
- advance equality of opportunity
- foster good relations

Children and adults with learning or physical difficulties or disabilities may be at a higher risk of infection and/or severe outcomes of infection with some vaccine preventable diseases, and as such vaccination of certain population groups may be recommended. For example:

- seasonal influenza vaccination for individuals with chronic neurological disease
- pneumococcal vaccination for individuals with chronic neurological disease
- hepatitis B vaccination for individuals with severe learning disability and those with learning difficulties in residential accommodation

It is important to address health inequalities by tailoring interventions and information for particular groups. This may be relevant for individuals with disabilities, whose needs are different from that of standard practice. This could include access requirements, location or method of service delivery, patient information and informed consent.

Socioeconomic status (for example, IMD acquired from home postcode): essential

An indicator of socioeconomic status (SES) should be recorded. There is evidence associating SES with differences in uptake of immunisation. Barriers to access childhood immunisations have been described for those with lower SES, and MMR uptake in the UK and Germany has been shown to be lowest among those with higher SES.

It is important to build evidence of effectiveness of an intervention among different socioeconomic groups and to monitor uptake of an intervention by different socioeconomic groups, to ensure the intervention is not systematically excluding any groups through their design, delivery, recruitment or referral methods.

Another indicator of socio-economic status that is often used in public health is the Index of Multiple Deprivation (IMD), which can be assigned from a home postcode.

IMD combines a number of indicators covering a range of economic, social and housing issues and creates a single deprivation score for each small area in England. This allows areas to be ranked according to their level of deprivation and can be derived from postcodes. These rankings have been produced at Lower Layer Super Output Area level (LSOA), of which there are 34,753 in England.

LSOAs can be mapped against postcode which allows an individual's address to be given a general IMD ranking. Any ranking given is 'modelled' against a number of criteria and relates to an overall ranking for an area which may not necessarily be indicative of the characteristics of an individual household. Further information about IMD is available on the Communities and Local Government website.

Interventions for children should, where possible, collect this information about their parents or carers. Analysis of socio-economic data can be complex so it may be necessary to seek specialist help. Local public health analysts or researchers may be able to assist with this type of analysis.

Religion: essential

Religion can be recorded using the following census criteria:

- Christian
- Buddhist
- Hindu
- Jewish
- Muslim
- Sikh
- other religion
- no religion
- person prefers not to say

Collecting data on religion may help in terms of improving understanding about the extent to which uptake of interventions may vary between different religious groups, and whether adaptations to components of the intervention are required to accommodate different religious practices. For example:

- providing additional information on vaccine components
- statements from religious leaders as part of participant information
- timing, date or location of vaccination sites

Employment status: essential

Participant employment status (or parental or carer employment status in child interventions) is an important consideration as it will help plan intervention timetables to ensure they fit within participants working patterns and do not present an additional barrier to attendance.

Employment status is also an important standard indicator of socioeconomic status used in the Census 2011. The National Statistics Socio-economic Classification (NS-SEC) is a structured occupationally-based classification that also includes categories for the non-employed. The NS-SEC categories are:

1. Higher managerial, administrative and professional occupations
    1.1. Large employers and higher managerial and administrative occupations
    1.2. Higher professional occupations
2. Lower managerial, administrative and professional occupations
3. Intermediate occupations
4. Small employers and own account workers
5. Lower supervisory and technical occupations
6. Semi-routine occupations
7. Routine occupations
8. Never worked and long-term unemployed
9. Not classified (this includes Students; Occupations not classified or inadequately described; and Not classifiable for other reasons)

Further information on these categories and how they have been derived is available on the Office for National Statistics (ONS) website, and an online tool is available to assist with correct coding.

Sexual orientation: essential

Some interventions may be targeted at certain population groups based on their sexual orientation. For example HPV vaccination in men who have sex with men. In this example it would therefore be important to record this information as part of the inclusion criteria. Additionally, as a protected characteristic it is important to record sexual orientation, using the following categories:

- heterosexual or straight
- gay or lesbian
- bisexual
- other not listed
- person does not know or is not sure
- person prefers not to say

Known co-morbidities: essential

As well as assessing whether the intervention is reaching the target audience proportionately, certain co-morbidities determine recommendations for specific immunisations, and therefore it may be important to record comorbidities as part of the inclusion criteria of an intervention (Table 1).

Table 1. Specific indications for immunisation of vulnerable groups (1)

Recommended vaccine	Hepatitis A	Hepatitis B	Influenza	Meningococcal	Pneumococcal
Asplenia or dysfunction of the spleen (including sickle cell)			✓	✓	✓
Cerebrospinal fluid leaks					✓
Chronic heart disease			✓		✓
Chronic kidney disease (including haemodialysis patients)		✓	✓		✓
Chronic liver disease	✓	✓	✓		✓
Chronic neurological disease			✓		✓
Chronic respiratory disease			✓		✓
Cochlear implants					✓
Complement disorders			✓	✓	✓
Diabetes			✓		✓
Haemophilia	✓	✓			
Immunosuppression (due to disease or treatment)			✓		✓
Morbid obesity			✓		

Additional information: optimal

For example, medical history, marital status, housing tenure, pregnancy, social support needs and so on.

The suggested information below may be helpful in determining why an intervention may be more or less successful in some individuals than others. Any relevant supplementary fields can also be added.

Medical history
This can indicate confounders such as participants with an existing clinical disorder that may make it more difficult to attend, or could influence a person's willingness to engage, or perceived importance (salience) of the disease being vaccinated against. For interventions aimed at children it may also be relevant to collect the medical history of the parent.

Marital status
Marital status is a 'protected characteristic' so it is illegal to discriminate against anybody on the basis of their marital status, which can be recorded using the following census criteria:

- single
- married or civil partner
- divorced or person whose civil partnership has been dissolved
- widowed or surviving civil partner
- separated

This may be a useful indicator for certain interventions, for example where both partners are eligible to take part, or to determine whether or not marital status influences uptake of the intervention in any way.

Pregnancy, breastfeeding and number of children
For some interventions pregnancy may be part of the inclusion criteria (for example, pertussis immunisation during pregnancy), or counterindicated. Number of children may be an important consideration for interventions aimed at adults and children as this may represent a barrier to attendance, and/or previous experience of childhood immunisation programs.

Housing tenure
Housing tenure can provide an alternative indicator of socio-economic status and can be collected using the Census categories as follows:

- owner occupied: owned outright
- owner occupied: owned with mortgage or loan
- owner occupied: shared ownership
- social rented: rented from council
- social rented: other social rented
- private rented: private landlord or letting agency
- private rented: employer or a household member
- private rented: relative or friend of a household member
- private rented: other
- living rent-free

Part 3. Baseline data: summary of population group targetted by intervention

Given the timescale of an intervention and associated evaluation it may be impractical to track very long-term health outcomes (such as prevention of disease in individuals or outbreaks). Therefore it may be necessary to use intermediate or shorter-term health outcomes or markers, such as completion of consent forms, attendance at vaccination clinics and so on.

It is extremely important to collect baseline data before an intervention begins, and data should be collected on an individual level throughout the intervention.

Pre-intervention immunisation status (for example, proportion of population immunised; partial or full): essential

Information on current (or recent) immunisation coverage for section 7a immunisation programmes is available through Immform, COVER and PHE fingertips.

Pre-intervention coverage, %: essential

The proportion of the eligible population who have been vaccinated.

Pre-intervention uptake, %: essential

The proportion of eligible people who received a vaccination during a specific time period.

Pre-intervention participant knowledge (for example, of disease, of vaccine): optimal

This may be estimated or inferred from scientific literature or previous research, or can be assessed by collecting data through questionnaires, focus groups, structured and/or semi-structured interviews. For more information on these techniques see the Better Evaluation website. There are a number of published tools for measuring vaccine confidence and hesitancy (2, 3).

Pre-intervention participant intention to vaccinate: optimal

See ‘Pre-intervention participant knowledge’ section above.

Pre-intervention acceptability or vaccine confidence in target group: optimal

See ‘Pre-intervention participant knowledge’ section above.

Part 4. Follow-up data

Process evaluation

Number of interventions staged (for example, training sessions or outreach clinics held): essential

This descriptive analysis of the intervention is a crucial part of the evaluation. The number and type of session should be described with details of time and date where relevant.

Number of people reached by intervention (for example, attendees at training session or clinic): essential

It is important to record the number of unique individuals who interacted with the intervention and at which point, as well as those who may interact more than once. The flow of participants through the pathway (and subsequent loss of some) is equally as important as the number experiencing the ultimate aim of the intervention (for example, receiving a vaccination). This information may enable the evaluator to identify gaps or drop-off points in pathways of the intervention.

This is particularly important as these points may represent times when inequalities could be exascerbated. For example, recording the number of people invited to an intervention, those who respond positively to the invitation by scheduling an appointment, those who attend a clinic and those who go on to receive the vaccination, rather than just a count of those vaccinated, could provide insight into the stages of the process that would benefit from improvement.

Details of any unexpected outcomes and/or adverse events: essential

It is important to ensure that an intervention does no harm, and is is essential to systematically record and report any unexpected outcomes or adverse events in the evaluation of an intervention. Were there any unexpected side effects or outcomes from the intervention? For example, did participants vaccine confidence reduce?

An example of an unexpected outcome was that when an e-consent form was provided directly to parents, instead of a paper form sent home with students, adolescents were bypassed and therefore were not provided with as much information about HPV vaccination as when paper consent forms were used. Importantly unexpected outcomes do not necessarily have to be negative, and there can be unexpected positive health outcomes which should be considered and documented as part of the evaluation.

Participant's feedback on experience: essential

All participants should be provided with the opportunity to feedback their satisfaction with the intervention. Satisfaction questionnaires are frequently used as part of evaluations, they can be a bespoke locally defined questionnaire, or standard questionnaires such as the NHS friends and family test.

If participants are dissatisfied with the way in which an intervention is being delivered, or unhappy with an element of the overall design of the intervention, it is unlikely they will attend again (for example in the instance that more than one vaccine dose is required, or use the service for a subsequent child within the same family). Participant dissatisfaction may also result in others within the target population deciding not to participate. Consequently, the intervention is less likely to achieve its defined outcomes.

When undertaking research into participants' satisfaction, it should be noted that it is often very difficult to glean unbiased opinions from participants if there have been problems and difficulties. Therefore, any research of this nature should be carefully and sensitively conducted.

To identify strengths and weaknesses of the intervention, it can be more useful to use qualitative methods of research such as focus groups or semi-structured interviews.

It may also be advisable for the deliverer of the intervention not to carry out the research. Participants may feel more able to be honest with another person whom they have not previously encountered as part of the delivery team. These issues also apply to people who have 'dropped out' of the intervention pathway at some stage (see 'Reasons for non-attendance at intervention' below).

In many cases, interviews with such people are more likely to provide useful information about intervention improvement than talking to people who have participated successfully.

Reasons for non-attendance at intervention: optimal

While this information is not always the easiest to gather, it is vitally important to understand why participants might chose not to participate or drop out along the pathway of a intervention.

This is particularly useful if the active intervention is going to be run more than once as part of a rolling intervention, but is also useful to share insight with others working in the same area. This sort of information can be collected in a number of ways and is similar to gathering information on participants' overall satisfaction with the intervention (see 'Participant's feedback on experience' above). The difference here is that participants may have to be contacted directly.

This needs to be handled sensitively so they do not feel like they are being chased. It is advisable to let participants know when they first participate with the intervention that, if they choose not to participate further, they will be contacted for feedback which will be used to improve how the intervention is delivered in the future. It is especially helpful to collect information about the demographics of people who have chosen not to participate futher in the intervention, to investigate whether it is contributing to health inequalities.

Acceptability or feasibility of process amongst professional stakeholders: essential

All professional stakeholders should be given the opportunity to feedback their views on the intervention. In order for the intervention to be sustainable long-term, those involved at all stages and levels should have the ability to offer insight into areas for improvement and/or suitability of intervention design and implementation. Without buy-in from professional stakeholders even the most successful intervention is likely to not reach its optimum capacity for delivering improvements to vaccination for target populations.

Plans for sustainability: essential

Consider whether plans have been made to ensure the continuation of the intervention in some way. This may be individual participants given the opportunity to continue with the intervention in some way, for example if the first dose of a 2-dose schedule is delivered in a mobile clinic, will the second dose also be offered in this way? If the intervention is to deliver a vaccine that is offered annually, will it be offered to the same people in the same way next year?

Continuation of the intervention may also mean offering the intervention to different people for a prolonged period of time; for example a vaccination clinic is offered in a religious setting every Friday evening for a month. Information regarding this service is shared amongst the target community, and more people would like to participate. How sustainable is the offer of the clinic and for how many weeks will it run? Will it return next year?

This will help the intervention's effect to be sustained over time. There may be resource or logistical implications for this type of long-term planning, and these should be included in the evaluation.

Impact evaluation

A like-for-like comparison to pre-intervention or baseline levels (see Part 3: Baseline data; summary of population group targetted by intervention) should be made for each of the following criteria:

- Post-intervention immunisation status: essential
- Post-intervention coverage, %: essential
- Post-intervention uptake, %: essential
- Post-intervention participant knowledge (for example, of disease, of vaccine): optimal
- Post-intervention participant intention to vaccinate: optimal
- Post-intervention acceptability or vaccine confidence in target group: optimal

Part 5. Analysis and interpretation

Findings from process evaluation - summary of results: essential

All relevant information from the Process Evaluation section should be presented as clearly as possible. This has 2 main functions: to help improve the intervention in the future and to help replicate the intervention in another area or setting.

Findings from impact evaluation - summary of results compared to baseline regarding short-term outcomes: essential

The bare minimum is to show whether primary and secondary outcomes have changed over the course of the intervention. The method for analysing and presenting results from the evaluation will depend on the study design. This in turn will determine the degree of confidence in the results .

Evaluation of weight management, physical activity and dietary interventions: an introductory guide describes the main study designs used for evaluations, all of which have appropriate analysis methods. In experimental designs, such as randomised controlled trials (RCT), results are presented as a change in the intervention group compared to change in the control group. If the difference between the intervention and control group is statistically significant (usually expressed as a p value of <0.05), there can be confidence this was caused by the intervention itself, and not by some external factor.

The stepped wedge cluster randomised trial is a relatively new pragmatic study design, that is increasingly being used for intervention evaluations with political or logistical constraints. The design uses random and sequential crossovers of clusters from control to intervention until all clusters are exposed. As a result more clusters are exposed to the intervention towards the end of the study than in its early stages, thus sample size calculations and analysis must make allowance for both the clustered nature of the design and the confounding effect of time. This approach has been described in detail by Hemming and others.

Quasi-experimental designs usually include a control group. Unlike the RCT, they do not randomly allocate individuals to intervention or control. Like the RCT, results are stated in terms of differences between intervention and control. The main limitation is the lack of certainty that the difference between intervention and control group was due to the intervention.

As stated in the introductory guide to evaluation of weight management, physical activity and dietary interventions, pre-experimental designs provide the weakest evidence and should only be used when other possibilities have been explored (4). Like experimental designs, data from pre and post studies is usually presented as difference between data before and after the intervention. The limitation here is that we cannot be sure that any change would not have happened anyway, as there was no control group.

Findings from impact evaluation – summary of results compared to baseline regarding medium-term outcomes: essential

As described above for short-term outcomes, but regarding medium-term outcomes.

Findings from impact evaluation: detail of any further analyses or statistical methods used: optimal

It is beyond the remit of this document to detail the statistical methods that could be used in the analysis of collected data and the nature of the statistical methods used will vary depending on the research and evaluation study design. Below are some key points about data analysis which may assist the evaluation.

Statistical significance

This describes the extent to which we can be certain that a result did not occur by chance. Statistical significance is usually expressed as a p value, often shown to be $p<0.05$. This means that there is a 5% possibility that the result occurred due to chance, and was not as a result of the intervention. Statistical significance is related to the power of a study, which can be determined through sample size calculations. These should be conducted before the study begins to calculate how many observations or individual samples (for example people) are needed in the study to enable measurements that will be statistically significant. It is important to seek the advice of a statistician before a study commences to ensure that it is large enough and that the sample is constructed correctly.

Confidence intervals

These describe the range of possible values around an observed outcome. For example, there may be a mean change in vaccine clinic attendance in a target group of 10% following an

intervention, with 95% confidence intervals stated as 7.5 to 11.3%. This means there is a 95% likelihood that the true improvement in attendance lies between 7.5 and 11.3%.

Findings regarding resource input versus beneficial output: essential

Whilst this criteria may include results of a full economic evaluation, return on investment analysis, incremental cost effectiveness ratio and so on, these are not always feasible evaluations to perform. It is still valuable to include descriptive information regarding whether the cost per successful intervention or participant was comparable to other interventions. One way of considering this is, was the financial input justifiable for the outcome reached?

Limitations and generalisability: optimal

Limitations and generalisability are also a key component of manuscripts submitted for peer-reviewed publication.

Limitations should discuss any potential weaknesses in study design and implementation that may contribute towards the findings of the evaluation. It is not possible to implement a ‘perfect’ evaluation in a real-world setting, and as such rather than ignore limitations a complete and honest presentation of them adds value to the evaluation, especially for people seeking to replicate a similar intervention in future. Examples of limitations include, limited access to data, lack of previously published research on the topic or lack of directly applicable research and/or time constraints. Limitations should be identified, the potential impact on the evaluation discussed, and improvements proposed that would address or mitigate the limitations in future work.

The generalisability of the evaluation results should detail the extent to which the findings can be applied to other settings or similar interventions. This will be a key criteria of interest for other members of the professional community as it will provide insight to them regarding implementing similar interventions in their setting or population.

Conclusions: effectiveness of the intervention at influencing the target behaviour: essential

Conclusions serve to summarise the salient points of the evaluation. It may help to structure the conclusions as follows:

- convey the problem statement explored
- summarise the findings
- list the key take-home messages

Recommendations: essential

This section should be used to apply the findings of the evaluation to the area of work going forward. It may be helpful to consider:

- how do the findings from the evaluation of the intervention impact business as usual?
- what parts of the intervention should be continued and how?
- what are the opportunities for scale up?
- how could the intervention be improved going forward?

Summary

The table is autopopulated based on entries into earlier sheets in the workbook. This table, when combined with 'Fig. 1 COM-B model' and 'Fig 2. Logic Frame' will provide a concise yet comprehensive overview of the intervention design, description and evaluation.

Resources for the evaluation of immunisation interventions

- WHO Europe TIP Tailoring Immunization Programmes (2019)
- LSHTM Centre for Evaluation
- Better Evaluation
- Evaluation Works
- Introduction to Evaluation in Health and Wellbeing
- UK Research and Innovation
- A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

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