Planning for Impact: Guidance for developing a strategy to maximise the impact of your trial

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Introduction

We do clinical trials because we ultimately want to improve how patients are diagnosed and treated, or improve prevention of diseases. Clinical trials can cost millions of pounds, requiring thousands of participants and hundreds of health workers, and taking years to carry out. In order for the potential impact of a trial to be realised, the results of trials need to be communicated effectively to the people who need to know them. This document provides practical guidance for trial teams on how to develop a strategy to maximise the impact of their research.

Clinical trials have the potential to have an impact on policy, practice, and science, and in some cases, society more widely. Until the results of a trial are known, we cannot say which of these domains are most relevant for that trial. However, regardless of the results of a trial, we have an ethical duty to ensure that the efforts of trial participants and staff are not wasted. Funders (government or charitable organisations) also want to see that their substantial investments has impact, and are increasingly asking researchers to demonstrate this (eg. through ResearchFish and REF impact case studies).

Good, strategic communication throughout the course of a trial, and beyond, can increase the likelihood of a trial achieving its potential impact. The pathway from evidence to policy and practice is not always straightforward. Presenting results at conferences and publishing them in peer-reviewed journals does not guarantee that the stakeholders who need to know will, nor that they will understand or act on them. By thinking through the issues covered in this document (preferably starting at an early stage of the trial's development), research teams can identify research impact strategies that will allow them to reach the people who need to know the trial results.

When designing a research impact strategy for a trial, we need to consider the context in which the trial is operating and the audiences (or stakeholders) we need to engage with. We also need to formulate the key messages about the trial, and identify the communication channels and tools by which we will communicate those messages to our priority audiences, taking into account what we know about the context and audiences. Box 1 outlines the elements generally included in a research impact strategy.

Box 1: Suggested contents of a Research Impact Strategy

Background

Objectives

Key stakeholders

Key messages

Communication Tools and Channels

Timelines

Resources

Evaluation

This guidance document is based on the experience of the MRC Clinical Trials Unit at communicating trial results both in the UK and beyond, and on previous guidance that has been drawn up for different aspects of communicating research. It draws on real life

examples to illustrate some of the issues raised, as well as tools that have been developed elsewhere. The Further Reading section of this guidance document contains links to guidance documents and toolkits that may be helpful if you want further information on a particular topic, and the sources for particular tools are cited where they occur in the text.

This guidance document is primarily written for teams working on Phase III randomised controlled trials. It is of relevance at all stages of a trial, from the initial development of the research question through to evaluation of the impact of the trial, although different parts will be more important at different stages of the trial. Table 1 gives an indication of which parts of the guidance will be of most use depending on which stage your trial is at.

Table 1: Priority issues to consider at different stages of a trial

Topic	**Before / during a trial**	**Preparing to release results**	**After a trial**
Background (including potential barriers to uptake)	**X**	**X**	x
Objectives		**X**	
Key stakeholders	**X**	x	
Key messages	x	**X**	x
Tools and channels for communicating with key stakeholders	x	**X**	x
Timelines		**X**	
Resources	**X**	**X**	
Evaluation	x	x	**X**

While primarily aimed at trial teams, many of the principles and approaches outlined in this guidance document are also relevant to other types of study, particularly those that generate evidence that has direct implications for policy and practice, such as epidemiological studies and systematic reviews.

If you have any comments or questions on the content of this document, please email them to a.south@ucl.ac.uk

Understanding your context (background)

Why we need to understand the context in which our trials take place

Understanding the context (or background) in which your trial is taking place is important for a number of reasons.

- During the planning stage of a trial, it is important to understand what current policy and practice are in order to decide on an appropriate control, and also to understand what the alternative options are for patients and potential investigators.

Understanding the existing evidence base is also essential for selecting appropriate interventions, and developing funding applications and protocols.

- Having an understanding of potential barriers to impact when planning a study can allow you to put in place strategies to overcome those barriers.
- When preparing to release results, understanding contextual factors such as current policy, practice, evidence base and potential barriers to impact is important for developing key messages and deciding how to focus communication effort.
- Documenting current policy and practice at the beginning of the trial, and recording changes in the context as the trial progresses, provides a useful baseline when attempting to measure the impact of a trial.

Understanding current policy

The first step to understanding current policy is to understand which guidelines and policies are relevant for you trial. You may already have a good idea of this. If you do not know, it may be helpful to ask clinical members of your TMG, or contacts you have with clinicians working in the area (both geographic area and disease area) that your trial will be relevant to which guidelines and/or policies they and their colleagues use. They may also be able to give you a sense of how important these policies and guidelines are in determining clinical practice.

If you are unable to find out which guidelines are most relevant by asking clinical colleagues, you may be able to get a good idea through straightforward internet searches. The National Guidelines Clearinghouse https://www.guideline.gov/ is a good place to start, as it contains many clinical guidelines issued by different bodies (although the future maintenance of this resource is unclear at the time of writing). Professional associations (eg. BHIVA, EAU) often produce guidelines, so you may be able to find relevant guidelines through looking on their websites

When you find relevant guidelines, download them and save them along with information of the date they were published (if this is not included in the body of the file). This will be a useful record which you can use to compare future versions of guidelines to see how they have changed over time. At this stage you do not need to be comprehensive in your guideline searching; focus on those that are most important for your study (eg. national ones applying to the countries in which your study is taking place, and those from the main international organisation(s) or professional bodies working in your disease area).

As well as saving a copy of relevant guidelines, it can be helpful to put a brief summary of relevant recommendations from guidelines/policy documents in the background section of your research impact strategy.

If you do this at an early stage in the trial, you will need to revisit it when you are preparing to release results, as the context can change during the course of the trial. This may affect how you frame your messages, and the implications of your study for policy and practice.

Understanding current practice

It is important to recognise that there may be a difference between policy and practice, and that this needs to be taken into account when designing your study, and thinking about how the results of your study might influence policy and practice. Case study 1 examines the difference between policy and practice in relation to aspects of the REALITY trial, and the implications those differences have for framing messages and recommendations.

Case study 1: Differences between policy and practice in the context for the REALITY trial

The REALITY trial tested three approaches to reducing early mortality among people starting HIV treatment with low CD4 counts in sub-Saharan Africa. One of the approaches tested was around prophylaxis to prevent opportunistic infections. WHO policy at the time recommended use of cotrimoxazole prophylaxis for all adults and children initiating ART. They also recommended that people who are unlikely to have TB should be offered Isoniazid Preventive Therapy (IPT). However, in practice, IPT use was very low in many sub-Saharan African countries, with few patients being given it. Some of the reasons for this were lack of availability of drugs, and also concerns about the evidence base for who should receive it and when. Understanding this was important for designing the study, making sure supplies were available, and thinking about the messages from the trial.

Finding out about current practice is often trickier than finding out what guidelines say in relation to your topic. Sometimes there may be good quality data about what happens in current practice, easily available, while at other times you may have to gather this data yourself, or make do with more anecdotal evidence.

Clinical practice audits (eg. the National Prostate Cancer Audit https://www.npca.org.uk/ and National Lung Cancer Audit https://www.rcplondon.ac.uk/projects/national-lung-cancer-audit) can be very helpful for understanding what goes on in clinical practice, and identifying the gaps between what the guidelines say and what actually happens. Checking whether such an audit exists for your disease area, and whether the data collected relates to the topic you are researching, is a useful first step when assessing current practice. Saving (dated) copies of audit reports alongside any guideline documents you identify will help you see how practice changes over the course of your trial, and subsequently.

There may be other routine data sources that cover what you need to know. For example, for some diseases (eg. HIV and TB) international organisations such as the World Health Organisation collect and make available large amounts of data (eg. http://www.who.int/hiv/data/en/ http://www.who.int/tb/data/en/) some of which may be relevant to the question you are addressing. It is also worth doing a quick PubMed search for any published papers reporting current practice.

If you cannot find any relevant audit, routine data or published papers to help tell you what happens in practice, you may need to gather this data yourself. Before you invest lots of time and effort in gathering data about current practice, consider the level of evidence you need on this – sometimes ‘quick and dirty’ approaches may be sufficient.

The easiest approach is to ask the investigators involved in your study what happens in their sites, outside of the trial. This may be through a formal survey, or informally through emails or face-to-face. If using this approach, be aware that the information you gather may not be representative. Sites taking part in your study may be different to those that are not taking part in it; they may have more interest in the approach you are testing, and therefore more likely to use it outside of the trial, or they may be better resourced, which again might impact their practice for non-trial participants.

If you are keen to gather information about what happens in standard practice beyond your network of investigators, you could carry out a survey of clinicians working in the field more widely. It can help if you get the support of a relevant professional association to help

distribute the survey to their network, as otherwise it may be hard to get your survey to people who are not involved in your study. This may provide more representative information than just surveying investigators, but care still needs to be taken in interpreting your results, as it is still vulnerable to bias (eg. you may be more likely to get responses from people who have strong views about the topic you are focusing on, or, if they know what study you are part of, there is the possibility of social desirability bias affecting the answers given).

What is already known?

Before you start planning communication of your study, it is important to understand what is already known about that topic. A summary of this information should be available in your protocol, but if it is some time since that was written, make sure you are aware of any major advances in evidence relating to your topic.

Setting objectives

As with any strategy, it is important you are clear what you want to achieve. Before you know what the results of your study are (and therefore any implications for policy or practice), you can set some general communications objectives around communicating results effectively to key audiences. Once you know what the results of your study are, you can then set objectives, if appropriate, around changes in policy or practice you want to encourage. It is important that any objectives around changing policy or practice are discussed and agreed by the TMG, as there may be differences in opinion around the implications of the results.

Case studies 2 and 3 show the objectives from the ICON7 (an ovarian cancer trial testing adding the drug bevacizumab to chemotherapy) and PR07 (a prostate cancer trial on adding radiotherapy to hormone therapy) strategies.

Case study 2: ICON7 communication objectives

- To ensure that the results of ICON7 (including effectiveness, quality of life and cost-effectiveness) inform policy and practice on whether bevacizumab is used with chemotherapy for the treatment of ovarian cancer
- To ensure that the results of ICON7 are accessible to patients with ovarian cancer, and their meaning is clearly explained

In the short-term, until we have the final results:

- To ensure patient groups and policymakers understand the interim results, and the limitations of this information

Case study 3: PR07 communication objectives

1. To increase the use of radiotherapy in addition to hormone therapy for non-metastatic prostate cancer, through
    a. informing cancer policy-makers and practitioners in UK and globally of the results of PR07
    b. influencing guidelines on treatment of non-metastatic prostate cancer
    c. informing NGOs that provide information and advice to patients
2. To encourage enrolment of prostate cancer patients into clinical trials that further the understanding of the multi-dimensional aspects of the disease and treatment strategies designed to improve outcome

Pathways to impact

When developing your strategy, it can be helpful to think through the pathway to impact for your trial. This involves thinking through the different steps and processes that will need to

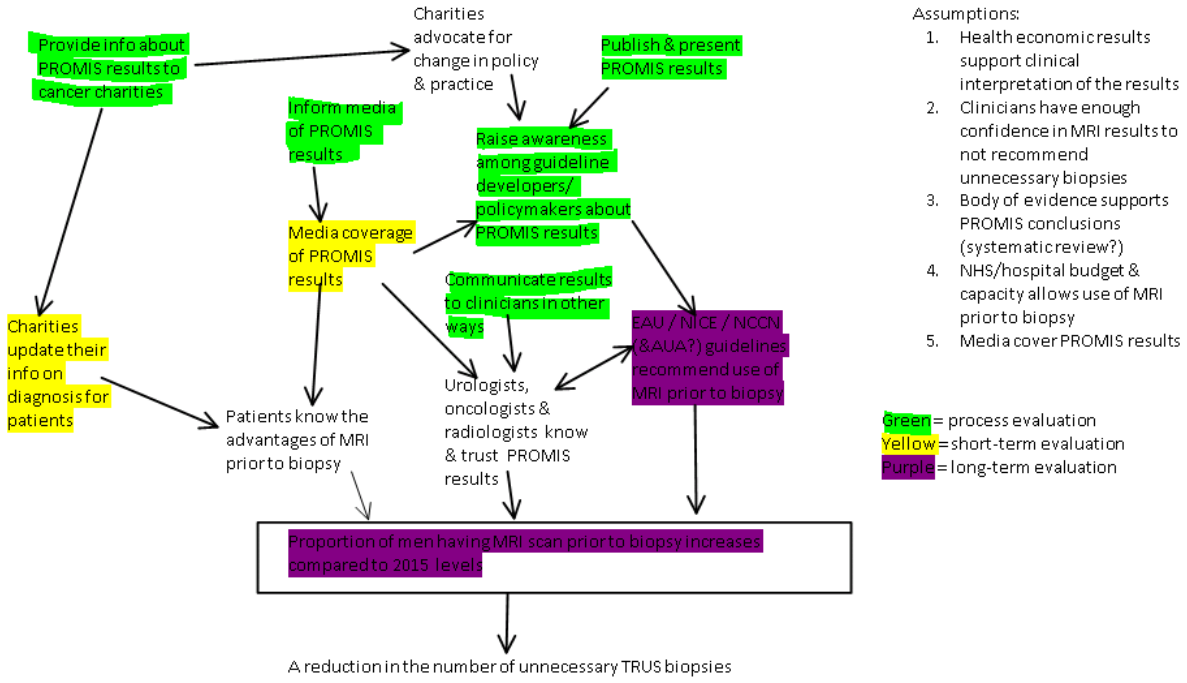
happen in order to achieve your objectives. Not all of these steps will be within the control of the trial team, and you will have to make assumptions about these, but it is helpful to think through these things and make your assumptions explicit.

One helpful approach to thinking this through is a 'Theory of Change'. At its simplest, a Theory of Change sets out in a visual way:

- **The goal** – what are you ultimately trying to achieve? For our studies, this may be improved outcomes for patients with the condition we're studying.
- **Our assumptions** – what needs to be true in order for us to achieve our goal? For example, before we know the results, we may develop a theory of change assuming that our intervention is superior to the control. Other assumptions that we may make could include factors like the drug we are testing being licensed for use, or adequate supplies being available.
- **Our activities** – what will we do to work towards the goal?

Figure 1 shows the Theory of Change developed as part of the PROMIS research uptake strategy. Items highlighted green show activities that the PROMIS team planned, and that were within the control of the team. The theory of change assumes that these activities will lead to the consequences shown by the arrows, with other stakeholders taking action as a result of what the team do, leading ultimately to the goal (in this case, a reduction in the number of unnecessary TRUS biopsies performed).

Figure 1: Theory of Change for the PROMIS study



Theories of change are designed to be living documents – as new information comes to light, or new activities are planned, you should update the document. It will help you plan what you need to do, and, later, evaluate your strategy.

Selected resources about Theories of Change

There are lots of resources available about theories of change, showing they can be developed and used in a variety of ways, some more systematic than others. Don't be put off by the complexity of some of the guidance available – do what is useful for your trial. The process of thinking through these issues is helpful, even if only done in a 'quick and dirty' way.

- https://vimeo.com/106389971
- http://www.espa.ac.uk/files/espa/ESPA-Theory-of-Change-Manual-FINAL.pdf
- http://www.researchtoaction.org/wp-content/uploads/2012/02/Key-questions-to-ask-when-putting-together-a-Theory-of-Change-for-Research-Uptake-by-Andrew-Clappison.pdf

Identifying barriers to impact

It is important to think about what barriers there may be to your study having impact at an early stage. Thinking about this during the planning of a study may allow you to put in place measures that could help overcome or reduce these barriers. Thinking about potential barriers once you know what the results of your study are can identify barriers it was not possible to anticipate when planning the study, and can help inform your strategy for communicating trial results.

Table 2 lists some of the more common barriers to impact from clinical trials, and suggests approaches that a research impact strategy might take to address these barriers.

Table 2: common barriers to impact

Barrier	Possible approach to addressing it	Example
Cost of the intervention	Plan and budget for cost-effectiveness analysis to provide evidence – expensive interventions may still be cost effective when longer-term impact is considered. If cost-effectiveness analysis finds the intervention is not cost-effective, the research impact strategy may include working with key stakeholders to encourage price reduction.	**The PROUD study** The cost of pre-exposure prophylaxis to prevent HIV with branded Truvada was seen by some as too high. Cost-effectiveness modelling found that if PrEP was targeted at those at highest risk, PrEP was likely to be cost-effective (or even cost-saving) in the UK.
Health system capacity	Engage with key stakeholders from early in the project to identify the capacity requirements for implementing the intervention, and what the current health system capacity is. Work with key stakeholders to build capacity (eg. developing training programmes, lobbying for necessary equipment)	**The PROMIS study** The PROMIS trial found that offering men with suspected prostate cancer an MRI scan prior to biopsy could reduce the number of men having unnecessary biopsies (and associated side-effects). Lack of capacity in terms of appropriate MRI scanners and staff with the necessary training could be a barrier to wider implementation. The PROMIS team worked with Prostate Cancer UK who carried out a survey of NHS hospitals to assess

Barrier	Possible approach to addressing it	Example
		availability of MRI scanner capacity, and develop an online training programme with the Royal College of Radiologists.
Availability of the drug	Engaging with key stakeholders (for example, drug manufacturers, national governments and international agencies eg. WHO, PEPFAR) at an early stage to forecast demand if the study finds the drug is effective may help to manage issues around the manufacture and supply of the drug. Providing evidence on the availability of the drug on the ground, and supply chain issues, may also help.	**ARROW trial and Lablite study** The ARROW trial found that the drug cotrimoxazole could reduce serious illness when taken by children living with HIV as prophylaxis against infections. Cotrimoxazole is a low-cost drug that is out of patent. The Lablite operational research study found that many lower level health centres in Uganda, Zimbabwe and Malawi experience frequent and long-lasting stock-outs, meaning people cannot access it. Documenting these issues helped to raise awareness around supply issues.
Acceptability of the intervention	If the intervention you are testing relies on people adhering to it, and the acceptability is unclear, it may be helpful to plan some research around acceptability. If you have missed the opportunity to carry out formal research on the acceptability, you may still be able to gather some insights by carrying out participant involvement activities.	**The REALITY trial** One of the interventions tested in the REALITY trial was ready-to-use supplementary food. The REALITY trial included a CRF with quantitative questions on the acceptability of the food, and a social science substudy that explored this issue in more detail. Had the food been found to be beneficial, this would have provided reassurance to decision-makers that the intervention was acceptable.
Timelines	Guideline developers and policymakers often have set timelines for updating their guidance/making policy decisions. This may not always fit well with the timelines for releasing trial results, meaning there can sometimes be a long gap between results being released and guidelines updated. Informing guideline developers of the study's anticipated timelines (and keeping them updated) may help to avoid unnecessary delays.	**The START trial** The START trial IDMC recommended an earlier than anticipated release of results from the study. This was planned to take place just after the release of the new WHO guidelines on HIV treatment. The START team contacted WHO as soon as they knew about this, and arranged to brief the guideline development working group, in confidence, prior to the public release of the results, to allow the results to be incorporated into the new guidelines.
Competing approaches to addressing the problem	Sometimes there is more than one way to address a particular problem. Where this is the case, it may help to present the effectiveness, safety, cost/cost-effectiveness, feasibility,	**The REALITY trial** The REALITY trial found that an enhanced package of prophylaxis, including the drug fluconazole, could reduce morbidity and mortality

Barrier	Possible approach to addressing it	Example
	availability and acceptability of both approaches. This allows the reader to draw their own conclusions, based on their own values and priorities.	among people starting HIV treatment with very weak immune systems. Part of the reduction in morbidity was due to a reduction in cryptococcal disease. Another approach to reducing cryptococcal disease is to carry out CrAG testing, and provide those who are CrAG positive with pre-emptive antifungal treatment. Both approaches have different pros and cons, with the REALITY approach being more feasible in settings without access to CrAG screening.
Lack of acceptance of the need for an intervention	It is hard for a trial to have impact if key stakeholders do not believe there is a need for the intervention. Stakeholder engagement when designing the trial can help to identify research questions that address priority questions for key stakeholders (where they do recognise there is a need for intervention). This can help facilitate impact of the study later. If your study is already underway, and key stakeholders are not convinced of the importance of the need, you will need to do work to raise awareness of the need. Evidence about the scale of the problem may be helpful, but putting a human face to the issue is also important.	**The PROUD study** Not everyone was convinced of the need for PrEP among some men who have sex with men in the UK, as other HIV prevention approaches exist (eg. condoms). When communicating the results of the PROUD study, the stories of men who had taken part in the trial were an important component. These helped put across why, for some people, PrEP is needed. This drew on social science work conducted within the PrEP study, but also involved trial participants being filmed and giving interviews to the media about their experience of PrEP.
Challenging existing beliefs or practices	1) Put your results in the context of the existing evidence base (or highlight the lack of evidence prior to your study) 2) Give people the opportunity to ask questions and explore the results in more detail, and see how your patient population compares to their own 3) If the results were surprising to you, admit it. If not, say why you expected them to be this way. 4) In this situation people often try to drill down into subgroups to find the one whose results fit with their preconceptions. Be prepared for this, and be ready to explain how to appropriately interpret subgroup results within the context of the overall results. 5) If your evidence is strong and compelling, but the response from key	**The FEAST trial** The FEAST trial found that fluid boluses were harmful for children in sub-Saharan Africa admitted to hospital with shock caused by severe infections. As this went against established practice in high-income settings, many found it hard to accept the result, despite FEAST being the first randomised controlled trial looking into this question. Face to face meetings were important to help people explore the results in detail, and ask questions. Clinicians also found it helpful to see a film that included interviews with site staff before they knew the result, where they described how they saw patients responding to treatment. It took a long time for the FEAST results to influence guidelines, as it

Barrier	Possible approach to addressing it	Example
	stakeholders is to ignore it, you may need to adopt more confrontational approaches.	went against existing beliefs.
System not designed to deal with the type of trial / intervention	Engage with key stakeholders early in the trial, to discuss the potential systemic barriers and ways around them. There may be other groups who are also keen to see these barriers addressed, so it may be helpful to join forces with them.	**The Add-Aspirin trial** Add-aspirin is a repurposing trial looking at using aspirin to prevent recurrence of cancer. Aspirin is not licensed for this indication, and as it is out of patent, no drug company is going to apply for an extension of licence. This means NICE cannot do a technology appraisal, as they are only able to look at drugs within their licensed indication. Some doctors are also reluctant to prescribe drugs outside of their license. This may reduce the impact the trial has, unless these systemic barriers are addressed. There are several organisations interested in issues around drug repurposing and how the system can deal with this.

Understanding your audiences

There are a wide range of potential audiences for clinical trial results. Some may be closely involved in the trial, while others may be much further removed. It is important to think through who the audiences for your trial are, in order to plan how to communicate with them before, during and after your trial.

The first step is to list the people and organisations who will either be interested in your trial and its results, or whom you need to communicate to in order for your trial to have impact (you may have identified some of these if you have already developed a theory of change). The following headings will help you think about different types of stakeholders, although you may also identify others that do not fit under any of these headings.

- **Lay audiences**: *including your trial participants and their families, relevant patient groups, other patients with the condition being studied, and may also include the communities in which your trial is taking place, the general public, and the media*
- **Clinical audiences:** *including the medical professionals who have been involved in your trial, other clinicians, medical schools and relevant professional associations*
- **Policymakers:** *including politicians and civil servants, healthcare commissioners, local authorities, guideline developers, regulators, national and international policymakers*
- **Scientific community:** *including scientists working on similar topics/areas, scientific bodies, research funders and research ethics committees*
- **Industry:** *innovator companies who make the drug or technology you trial was testing, generic manufacturers, and manufacturers of related technologies*

The examples given in italic are generic – you will need to think about who the specific organisations are for your study.

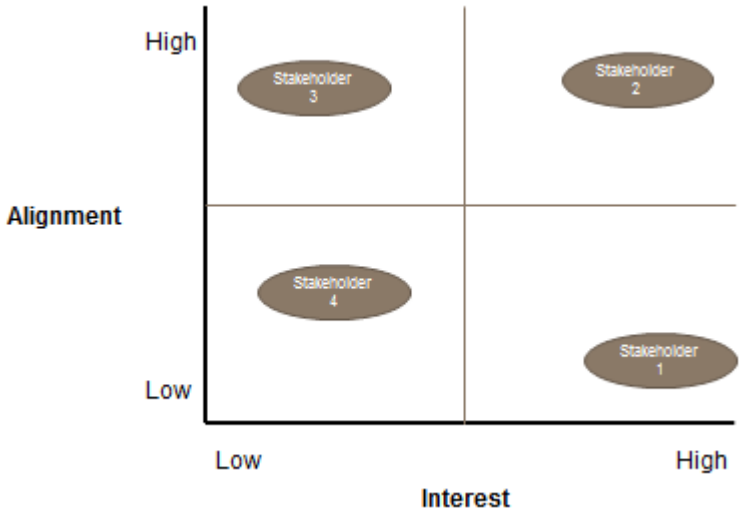
Having a list of potential audiences is just the start. We need to understand something about who they are, what their priorities are, where they stand with regard to the issue we are studying, and how they normally access information, in order to communicate effectively with

them. Stakeholder mapping is a useful next step to help us to prioritise which audiences to focus on, and help to identify which approach to take with them.

Stakeholder mapping

It can be helpful to think about how interested stakeholders are in the issue you are studying, and to what extent they agree with the approach you are testing (or your recommendations, if you have your results). Mapping this out visually in an 'Interest-Alignment Matrix' can be a useful exercise.

Figure 2: Example Interest and Alignment Matrix



For example, if you had a stakeholder who was very interested in this topic, but opposed the changes your trial may end of recommending, you'd put them somewhere around where Stakeholder 1 is in Figure 2. It may be that they don't agree with the objectives of the intervention, or they have another preferred approach to achieving those objectives, or they disagree with the way you're doing the study (eg. the population / dose / outcomes you are using)

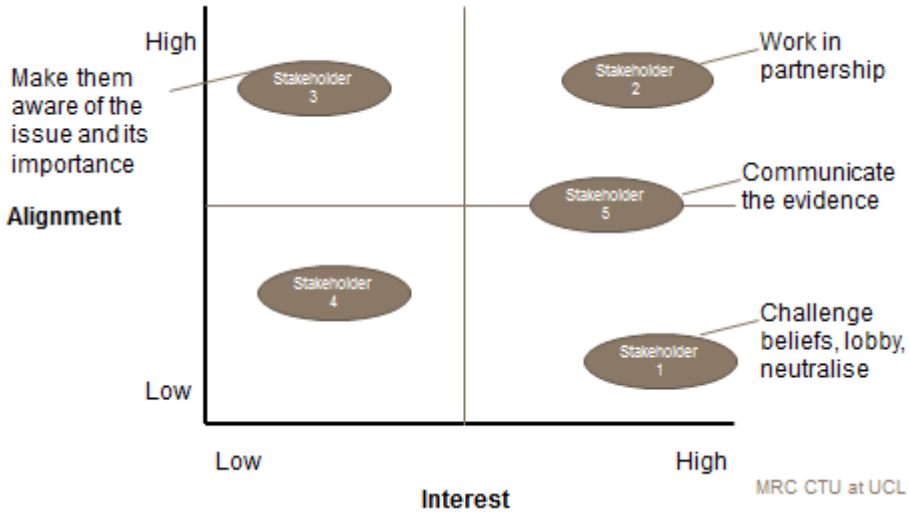
Stakeholder 2 might be an organisation or person who regularly participates in meetings on the subject, publicly (or privately) supports the objectives of the intervention, commits funds towards achieving them, etc., and/ or advocates (or is likely to advocate) for it with other stakeholders

Stakeholder 3 agrees with the intervention objectives and approach, but doesn't commit time or resources to achieving the objectives, doesn't read your papers or come to your presentations, doesn't comment on it publically…

Stakeholder 4 isn't very interested in your intervention, and doesn't support its objectives or approach.

You are likely to need different approaches to engaging with stakeholders depending on where they fit within the matrix. Figure 3 shows some examples of how you may tailor your approach depending on where they fit within the matrix.

Figure 3: using the matrix to decide on approach to take with different stakeholders



If you have lots of stakeholders, and few resources, it can help to think about which have the most influence on policy/practice. You can mark this on your matrix with a star. It may also help to think about which groups you have the best connections with, and then prioritise working with those who have the most influence and the best connections to you.
It may also be helpful to consider how some actors might be related to others. It is possible that targeting an actor that you have significant influence over (but who is not directly influential on the policy process) might have an influence over another influential, yet inaccessible, stakeholder.
When prioritising stakeholders, it is important not to forget audiences that you have a contractual or ethical duty to communicate with, in addition to those highlighted as influential on your matrix. This may include ethics committees, research funders, research participants, regulators and industry partners.

Finding out about stakeholders

Initially, you may not know where to place stakeholders on the matrix, so you may need to spend some time finding out a bit about them. You may be able to ask members of the TMG, or other contacts you have where other stakeholders stand on the issue you are researching, if they have good links to them. Another approach is to look online to see if the organisation's website, or other webpages, give you any clues. Does their webpage mention the issue? If not, that may be a sign their interest isn't particularly high. Have they spoken at conferences or meetings about it? If so, what did they say? Are they members of any groups or coalitions that have a particular position? How related is the issue to their core remit as an organisation or individual?
Once you've filled in your matrix, and prioritised your stakeholders, you will need to know more about those you've prioritised, in order to inform your communications strategy. The sorts of things that it can be helpful to know about stakeholders include:

- Where do they get their information from generally?
- What are their values and priorities?
- What are their concerns with relation to your study/issue?
- Who influences them?
- Whom do they influence?
- If they are decision-makers, what are their usual timelines? (eg. for guideline developers, when will they next be updating their guidelines on this topic?)
- Who is the best contact person at this organisation? What are their contact details?
- Do any members of the trial team already have links with this organisation/individual?

If you do not know the answers to all these questions, asking members of the TMG, other contacts and looking on line may help to answer some of them.

Role of patient and public involvement in developing and implementing research impact strategies

Benefits of patient and public involvement in developing and implementing research impact strategies

Patient and public involvement (PPI) in developing and implementing research impact strategies can bring a number of important benefits, including:

- **understanding of audiences and context**: PPI will be particularly helpful for understanding more about lay audiences, including their concerns, values and priorities, and usual sources of information. PPI can also help you to understand the context in terms of current practice from a patient perspective.
- **honing messages for patient/public audiences:** PPI can also help you to hone your messages for patient and other lay audiences, giving feedback on whether the language you are using is appropriate and understandable, and whether the content of your message is likely to be of interest to lay audiences. It is important to consider the skills of the patients and public whom you are involving: some may have particular skills in writing in plain English, in which case they may draft or edit messages for you. But being a lay person doesn't automatically make someone good at writing in plain English, so their role may be more about giving feedback and ideas than actively drafting or editing.
- **access to channels**: the patients, public and community groups you are involving in your study may have access to communications channels that may help you reach some of your target audience. For example, they may be part of a patient group that has a newsletter, website, or social media accounts that are used by other patients. Getting your message out via these channels can increase the number of people you reach.
- **as messengers:** patients and the public may be appropriate and effective messengers for some of your audiences. (See page 30 for more information on messengers). For some audiences, they may be more trusted than researchers or clinicians. For other audiences, they may be able to complement your other messengers, through giving the issue a human face and helping people see the importance of the issue and the implications of the results for real people, rather than just viewing the results as abstract numbers. See case studies 4 and 5 for examples of this.
- **as collaborators:** PPI contributors (whether as individuals or as part of patient groups or community organisations) may have expertise and capacity related to communication or research impact. In this case it makes sense to collaborate on the development and implementation of research impact strategies. This may be on a specific activity within the strategy, or across a wide range of activities. See Case Study 6 for an example of this in practice.
- **as advocates:** patients and the public can be powerful advocates for the research itself, and for changes in policy or practice based on the results of the research. Patient and community groups may be able to mobilise many people to write letters,

sign petitions or even demonstrate on issues such as access to medicines. See case studies 4 and 5 for examples of this. In addition to the potential for mobilising large numbers of advocates, patients and the public bring a different voice and perspective to that of researchers, which may complement, or be seen as more important within the policy process.

Case study 4: PPI in communicating the results of the PROUD study

The PROUD study found that pre-exposure prophylaxis (PrEP) was highly effective at preventing HIV among men who have sex with men in the UK. Patients and the public were involved in developing a strategy for communicating the results, implementing the strategy, and advocating for PrEP to be made available on the NHS. PPI activities included:

- Patient and community representatives on the trial management group, trial steering committee and IDMC gave input into discussions about the strategy and messages.
- The Community Engagement Group (made up of representatives from a number of community organisations) developed a frequently asked questions and key messages document, press statement and input into a film.
- Participant involvement meetings were held to get participants' feedback on interpreting the results and framing messages. This led to a shift in focus away from messages about high risk, because of concerns about stigma, and to focus on the effectiveness of PrEP.
- Members of the Community Engagement Group spoke to the media about the results and their implications, and were also part of the PROUD film.
- Some trial participants spoke to the media, were filmed for the PROUD film, or spoke at events about the results. This helped people understand the implications of the results for real people.
- Community organisations communicated the results to their audiences via existing communications channels, increasing the reach of accurate information about the results.
- The organisations that formed the Community Engagement Group for PROUD morphed into a lobby group called United4PrEP, to call for PrEP to be made available on the NHS. This group organised demonstrations, petitions and lobbying of MPs.

Case study 5: PPI in communicating the results of the STAMPEDE study

Patient representatives on the STAMPEDE Trial Management group:

- helped to plan a series of patient roadshows to share results of the STAMPEDE trial and other prostate cancer trials with participants and other patients
- gave talks at the roadshows
- edited participant summaries of the results
- were interviewed for films about the trials

Other prostate cancer patients were also interviewed for films and news articles about the trial results.

Patient groups communicated the results via their websites and newsletters, allowing the results to reach much wider audiences.

Case study 6: Collaboration with Prostate Cancer UK around the results of the PROMIS study

The PROMIS study found that mpMRI could be used to triage men who had been referred for prostate cancer tests, allowing a quarter of these men to avoid transrectal ultrasound-guided biopsies, which are associated with significant side-effects. Prostate Cancer UK were keen to see this become part of the standard diagnostic pathway in the UK. They did work to assess the capacity of the NHS to do this, and worked with the Royal College of Radiologists to develop training on this issue. Members of the PROMIS team advised the Prostate Cancer UK working group.

Approaches to PPI

As with PPI in any aspect of a study, there are a number of different approaches that can be used, which have different advantages and disadvantages depending on the context of your study, and what you want to achieve through PPI. These range from working with individual patient contributors, either as a one-off or over the course of a study or beyond, to working with ongoing Community Advisory Groups or ad hoc discussion groups, or partnering with established patient groups. For further discussion of models of PPI used in MRC CTU studies, see https://doi.org/10.1186/s13063-016-1488-9 and https://doi.org/10.1186/s13063-018-2471-4 [Add link to PPI SOP when available]

Developing key messages

What are key messages?

Key messages are short statements that put across the main points you want people to remember about your study or results. They should be clearly worded and seek to engage the audience they're aimed. This means you may have different key messages aimed at different audiences, depending on what is most important to communicate to different groups, and the sorts of language that are appropriate. During the course of a study, you may develop several sets of key messages. At the start of your study, your key messages may focus on the issue your study is seeking to address, and what your study is doing. When you have results, key messages are likely to focus on the main findings and implications.

It is worth investing time on developing good key messages that put across what you want to say effectively. Once your key messages have been agreed by all the relevant partners, developing communications materials (eg. slide sets, press releases, policy briefs, lay summaries etc) based on them is a relatively straightforward process.

What makes a good key message?

A good key message is:

- True – factually accurate, and not misleading
- Concise and punchy – you shouldn't include lots of detail in a key message, just the main idea
- Simple to say aloud
- Focused on one idea – if your key message covers more than one idea, you need to split it up

- Easy for people to remember and understand
- Persuasive
- Relevant to the intended audience – this means you may need to have different key messages for different audiences, depending on their interests and language they use

What to include in key messages

There aren't hard and fast rules on what key messages should cover, but a useful approach to key messages when you have results is to tell the story of your study in a few points.

1. What was the problem your study was trying to address, and why does it matter?
2. What was your study trying to find out?
3. What did your study find?
4. What does this mean?

If you are developing key messages about a planned or ongoing study, your key messages may cover points one and two, with perhaps a third point on how it is being done.

Case study 7 shows the key messages developed to communicate the results of the REALITY trial to policy audiences. This case study is given as examples to show the sorts of things that it may be useful to include. The language and content would need to be adapted for use with other audiences.

How to develop key messages

There are several stages to developing key messages.

1. **Decide what you need to communicate, and pick the most important points for your audience**
   When trying to decide on the most important points, think through why you did the study in the first place, what you learnt from it, and who will benefit. It also helps to think about what aspects of the study/results your audiences will be most interested in, have the most questions about, or be concerned about.
2. **Write down the three or four most important points you want to convey**
   If you have more than three or four key messages for an audience, they're less likely to stick, so really be ruthless about getting down to the core of what you want to say. Regardless of whether your audience is lay or professional, when writing key messages it helps to use some of the principles of writing in plain language:
   - Write in short sentences
   - Use the active rather than passive voice (eg. "we did this" rather than "this was done")
   - Use language that is appropriate to the audience – don't make your language harder than it needs to be
3. **Develop supporting messages for each key message**
   You can use supporting messages to provide facts, examples and simple explanations that reinforce your key messages. Supporting messages can vary in detail and scientific sophistication, depending on the different audiences you wish to reach.
4. **Tailor your key messages and supporting messages to different groups of stakeholders**

The central idea of your key messages may be the same for all your audiences, but they will need to be tailored to make sure the style, language and supporting arguments are appropriate for each target audience. In some cases, you may focus on different things in your key messages for different audiences, taking into account what information is likely to be most useful or compelling to different groups. For example, when addressing policymakers, you may need to focus on implications for policy, and issues around cost and feasibility, whereas for clinical audiences, the focus may be more on the intervention, efficacy and toxicity.
It can help to use analogies that will resonate with your audience to help explain your point.

5. **Refine and test your messages**
   The first step to refining your message is to read it out loud. If it is not easy to say, edit it until it is. Simplify the language, and try to reduce technical details. Key messages are broad statements, and should not include many details. Check the length of your key messages, and try to keep them short. If you can't say a message in a single breath, it's far too long.
   Testing messages on others can also be very helpful. Depending on who your audience is, try to test them out on people who are similar to your audience. This may be colleagues who aren't involved in your study, friends or relatives, or patients. You may like to get them to give you feedback using the bullet points in the section on "what makes a good key message" (page 17).

Case study 7: Key and supporting messages from the REALITY trial

1. Many people in Africa are still not starting ART until their CD4 counts are very low.
   - *Around one in every four to five people initiating ART in low and middle income countries have CD4<100 cells/mm3.*
2. People starting ART with low CD4 counts are at high risk of dying within the first few weeks of treatment.
   - *About 1 in 10 people with CD4 <50-100 at start of ART will die within 6 months of starting ART*
3. REALITY tested three strategies, in addition to standard ART, for the first 12 weeks of treatment, to reduce this early mortality:
   - *A package of enhanced prophylaxis medicines to prevent infections*
   - *Increasing the potency of ART by adding the ARV raltegravir to reduce the viral load faster*
   - *Ready-to-Use Supplementary Food to improve nutritional status*
4. Enhanced prophylaxis for the first 12 weeks of ART can prevent more than 3 deaths for every 100 people starting ART with advanced HIV
   - *Giving people with a CD4 count <100 enhanced prophylaxis for the first 12 weeks of ART reduces mortality at 24 weeks by 3.3% (absolute difference - from 12.2% to 8.9%), a 27% relative reduction in mortality compared to ART with standard cotrimoxazole prophylaxis*
5. This could save the lives of around 10,000 people each year, and protect many others from infections

Getting your message to your audience

Once you know what messages you need to communicate, you need to work out how to get that message to your audiences. For this, you need to decide on the communications channels, tools and messengers you will use. These decisions needs to take into account what you know about your audience, including where they get information from, how much time they are likely to be willing to give to finding out about your research, and which channels and messengers they are likely to trust on this issue.

Communications channels

A communications channel is the path the message takes to reach its audience. Examples of different communications channels include:

- Media (newspapers, radio, television)
- Social media
- Professional networks
- Knowledge intermediaries/brokers
- Social groups
- Publishers

Knowledge intermediaries or brokers are organisations whose role is to collate and communicate scientific knowledge to specific audiences. They may do this by building a repository of information, or repackaging information into formats that are more appropriate for the audience. They may also carry out evidence synthesis. They can be a very useful communication channel, as they have expertise at translating research for specific audiences, and already have well established ways to get information to these audiences.
An example of a knowledge intermediary whose role is communicate research evidence to healthcare professionals is the NIHR Dissemination Centre https://www.dc.nihr.ac.uk/ . They produce 'Signals', which are summaries of specific research projects; themed reviews bringing together research on a particular topic; and highlights, which explore conditions and treatments. They communicate these via their website and email lists.
An example of a knowledge intermediary that communicates research to both professionals and patients is i-BASE http://i-base.info/ , a website that summarises the latest research on HIV, and produces guides on specific issues.

Communication tools

A communication tool is the format your message is communicated in, For example, if your communication channel to reach clinicians was a relevant professional network, you could potentially use a number of different tools, including presentations at their meetings or conferences, articles in newsletters or journals, emails, or letters to members.
Table 3 summarises some of the different communication tools that the MRC CTU at UCL has experience of using, and provides links to examples where available. It is not comprehensive, and there may be other tools not listed that would be appropriate for communicating your message to your audience.

Table 3: Communications tools

Tool	Description	Considerations	Audiences	Examples	Further guidance
Animation	Can be used to summarise key aspects of the research or results, particularly where images can help explain complex science. Likely to help get people's attention.	Can be time consuming (and costly, if no in-house capacity to produce it). Needs to be short. Need channel to get it seen by the audience you want to see it.	May be useful for any audience, but has particular appeal for lay audiences, or professional audiences who are short of time.	RIVER animation (for patients) ARREST animated abstract (clinical audience)	http://www.researchtoaction.org/2017/05/power-animations-interview-betty-paton/
Articles for newsletters	If you can get space in an existing newsletter for an article, this can be a good way of reaching the audience for that newsletter.	You will normally need to provide the contents. Likely to be limited room for detail.	Suitable for a wide range of audiences, depending on the newsletter.	Article about STAMPEDE in Prostate Matters (patient newsletter) page 5	Ask the editor of the newsletter for guidance – length, use of images, tone & language.
Blog posts	Blog posts are articles that are less formal than journal articles. They offer an opportunity to reach different audiences, and to explore topics more than you can in newspaper articles. You can present a more personal perspective in blogs than some other communication tools.	Unless you plan to write frequent blog posts, it may be more effective to write guest posts for existing blogs that reach the audience you want to reach.	Can be used for a wide variety of audiences, depending on how it is written and where it is published.	http://www.insight.mrc.ac.uk/	http://www.researchtoaction.org/2014/06/tti-pec-virtual-write-shop-crafting-better-blogs-and-op-eds/
Briefing journalist	Rather than issuing a press release to all media outlets, you brief a selected journalist who is	Needs to be newsworthy. This is useful for complex or controversial issues, where you want media coverage to be well	Public Policymakers	Journalist from the Guardian was briefed about analysis paper in BMJ to put	Contact the MRC or UCL press offices for advice.

Tool	Description	Considerations	Audiences	Examples	Further guidance
	likely to be interested in the story, and handle it well. Useful for 'features'.	informed and sensitively handled. If it's a big story, other media outlets are likely to pick it up from the original coverage, and resulting coverage may be less accurate/ sympathetic. Need to be available to deal with resulting questions.		pressure on WHO to respond to FEAST results	
Briefing papers	Short documents outlining key messages and making recommendations. Covers issues such as feasibility and cost as well as efficacy and safety.	Need to think about how to get the briefing document to the target audience. Useful to complement face-to-face meetings. Include what's of interest to the audience – not the same as a summary of the peer-reviewed article. Should be about 1,500 words long.	Policymakers Clinicians	http://www.ctu.mrc.ac.uk/resources/policy/	http://www.researchtoaction.org/wp-content/uploads/2014/10/PBWeekLauraFCfinal.pdf
Conference presentation	Useful way to get results known within the scientific and clinical community.	May result in media coverage. Some conferences have press briefings on high profile presentations. Some conferences make videos and slides available freely after the presentation, others have a paywall so only members can access. Presenter needs to be able to handle questions well. Can be useful to prepare a key messages and FAQ document to help team prepare for likely questions.	Scientific & clinical audiences (depending on who attends the conference)	https://www.youtube.com/watch?v=thTXeJNP1_0&feature=youtu.be	Each conference will have specific guidance. Generic training on presentations is available from UCL
Events – eg.	Public engagement	Can be costly and time	Patients, the public	Beating Prostate	Ask Annabelle.

Tool	Description	Considerations	Audiences	Examples	Further guidance
patient roadshows	events to communicate about research to patients	consuming to organise. Need to think about how to promote events to target audience. Can be useful to work in partnership with patient group. Can be very effective at communicating with those who attend.		Cancer Roadshows https://rantfromthesuburbs.wordpress.com/2016/05/06/beating-prostate-cancer/	
Face-to-face meetings (individual/ small group)	A face-to-face meeting with an individual or a few people from a single organisation can be a useful chance to brief people about the study/results, and answer questions.	Can be done before or after results are made public. Useful for briefing people/organisations who may be asked questions about the results. Time consuming so focus effort on most important stakeholders.	Policymakers, key opinion leaders.	In our African trials partners often have face-to-face meetings with key stakeholders to brief them about the trial and its results	
Films	Can vary widely in length, complexity and cost to create, from 3 minute 'talking head' style pieces with a single person talking to camera, to documentary style.	Documentary style films can be expensive and time consuming to make. Need to consider how you will get your film seen by your target audience. Particularly useful when visual/moving images are useful to tell the story. Some capacity to make simple films in-house. Others will require external support.	Useful for a wide range of audiences (depending on contents and language).	https://vimeo.com/mrcctu	http://www.researchtoaction.org/2013/01/using-film-to-communicate-research-useful-guides-and-blogs/
Graphic novels	Graphic novels use drawings/cartoons to tell a story.	Need a story to draw out the messages you want to put across. Can be easier if there is social science component to	Lay audiences, including but not limited to children and adolescents.	http://www.ctu.mrc.ac.uk/resources/multimedia/arrow_graphic_novels/	Ask Annabelle

Tool	Description	Considerations	Audiences	Examples	Further guidance
		your research to help write stories that relate to participants' experiences. Requires budget to cover work by illustrator. Useful for getting attention of people who may not normally seek out information about research.			
Graphic recording	Key messages of a meeting or event in drawing form.	Useful for putting across key messages in an engaging, concise and eye-catching format. Can't include much detail. Popular on social media. Need to budget for someone to do this.	Useful for a wide range of audiences (although some would want more indepth information in addition to the graphic recording).	http://www.ctu.mrc.ac.uk/12602/13005/faster_results_graphic https://spark.adobe.com/page/1oXEdtZduYmAG/images/db50ad61-d99c-460d-b759-417439b9988e.png?asset_id=0b65241b-c25e-49fd-a7f3-195757a0a7a2&img_etag=745bcbb670f6b0de199a38ea4414e210&size=1024	Talk to Annabelle
Infographics	Infographics are graphic visual representations of information, intended to present information quickly and clearly.	Infographics are a good way at getting people's attention, and communicating information quickly. Work well on social media channels and as part of printed materials.	Any audience, depending on the contents of the infographic.	EURAMOS infographic STAMPEDE abiraterone infographic REALITY infographic ARREST infographic	Piktochart website helps you to design infographics simply.
Job aids / tools	These can take many formats, including	Important to consult with target audience to ensure what you	Clinical audiences	Lablite developed a job aid (wallchart and	

Tool	Description	Considerations	Audiences	Examples	Further guidance
	wallcharts, desktop quick reference guides or online tools. They aim to help healthworkers implement the intervention in practice.	develop meets their needs. Also helpful to work in partnership/get buy-in/involvement /approval of professional bodies or policymakers to help with distribution and uptake.		pocket version) to help peripheral health care facilities manage patients on ART.	
Lay summaries	Summaries of studies and/or results designed for lay audiences. May be printed or online.	Needs to be written in plain English. PPI can be very helpful in developing these.	Lay audiences, including participants and other patients	CRUK have a database of lay summaries of trials MRC CTU website study pages	Ask Annabelle for template for participant summaries of results.
Opinion pieces	Useful for raising awareness of an issue. Can be published in peer-reviewed journals or mainstream media.	Some journals accept unsolicited opinion pieces, while with others may commission them.	Depends on where the opinion piece is published.	BMJ Analysis article raising awareness of need to change WHO guidelines in the light of the FEAST results	
Podcasts / audio recordings	Like videos, podcasts can range from simple audio recordings of one person talking, to more complex audio documentaries featuring several different people.	Useful for exploring complex or controversial ideas. Quicker and cheaper to make than a film. Need to think about how to get the podcast/audio recording to target audience – working with professional networks or patient groups may help.	Depends on content and language of the piece.	ARREST podcast for professional audiences ARREST audio for lay audiences	Speak to Annabelle or Will Everett
Press release / media release	A short document summarising news from a study. Needs to get the attention of a journalist, and persuade them it's worth covering. Includes quotes from key people. Needs to be written in language that lay people	Needs to be 'newsworthy'. Can't go into very much detail.	Journalists (initially), in the hope they will cover it. If they do cover it, it will reach a much wider audience, depending on which media outlet the journalist works for.	RIVER press release	MRC and UCL press offices can help with drafting and issuing press releases.

Tool	Description	Considerations	Audiences	Examples	Further guidance
	can understand.				
Results meetings (group)	Meetings where attendees can find out about the study/ results, ask questions and discuss implications. Can be done face-to-face or via webinar.	Useful for exploring complex, controversial or unexpected results with key stakeholders. Can be done before results are publically released, to ensure key stakeholders are well briefed and able to answer questions, or after results have been made public. If done prior to results coming out, can ask attendees to sign a confidentiality statement. Face-to-face meetings may have costs for venue hire, catering and possibly travel expenses.	Particularly useful for key stakeholders with a strong interest in the results (eg. policymakers, investigators, participants).	Many trials have face-to-face meetings with investigators to share the results. FEAST invited representatives from paediatric associations from 10 African countries to attend a meeting where the results were explored. This was helpful as there were lots of misunderstandings about the results. RIVER invited participants to a results meeting prior to results being released publically.	
Social media posts	Depending on the social media channel, can be text, graphics, video or audio.	Need to think about how you can get your message in front of the relevant audience. Which social media channels do they use? How will they see your post. Can be helpful to ask related organisations to promote the info on their social media channels (reblog, retweet, share). On channels such as Twitter	Most audiences (depending on which channels you use, the content of your post and how you get it to your audience).	https://twitter.com/MRCCTU https://soundcloud.com/user-110325996-105034477 https://vimeo.com/mrcctu	Contact the MRC CTU Twitter for advice on communicating messages via Twitter. Contact the comms team to discuss other social media

Tool	Description	Considerations	Audiences	Examples	Further guidance
		and Facebook, strong visuals are important. Need to be prepared to deal with questions that arise.			channels.
Song	Songs can be used to communicate key messages in an attention-grabbing way.	Useful for reaching audiences who may not be likely to engage with more traditional forms of research communication. Can be catchy and memorable. Requires close co-operation between songwriter and scientists to ensure accuracy and musicality.	Lay audiences	START used a song to explain why the study was needed. When the results were available they produced a song summarising the results.	
Stands at conferences	Many conferences have exhibitions where organisations can have stands. Useful to share resources. Allows dialogue.	Can be costly – charges for stands are often high, and then there are costs of travel, accommodation, and materials. Need to have sufficient staffing to look after the stand whenever the exhibition is open, and allow people to take breaks and attend parts of the conference. May make sense when you have several resources to share.	Depends on the conference. Usually scientific or clinical.	ARROW and Lablite had a stand at the International AIDS Conference in 2016. This was used to distribute briefing papers, training resources, case study films and graphic novels.	Conference websites will usually have information about exhibition costs.
Submission to consultations	Many guideline developers/policymakers have formal consultations prior to deciding on guidelines. Inputting to these processes can help to make sure relevant	It may be appropriate to share unpublished results in confidence, if guideline development timelines are such that they cannot wait for publication. You may need to be registered as a stakeholder to allow you to	Guideline developers and policymakers.	The ICON7 team responded to a NICE consultation on use of Avastin for ovarian cancer.	Details of which NICE guidelines are in consultation at the moment.

Tool	Description	Considerations	Audiences	Examples	Further guidance
	scientific information is considered.	respond to consultations.			
Training materials	Contributing to the development of training materials for healthworkers may help to improve uptake of new interventions/ approaches. Materials may be written (eg. textbooks), video, online interactive, or face-to-face.	Useful to work with organisations who support training the relevant healthworkers to ensure what you produce is relevant and reaches the people you want it to. May need to get sign-off from Ministry of Health in some countries, or relevant professional association.	Health workers	A number of case studies were filmed for teaching purposes around the ARROW trial, to help support mentoring of lower level health workers in managing paediatric ART. Lablite developed a training handbook which was adopted by the Uganda Ministry of Health.	
Twitter Q&A session	A panel answers questions on Twitter about a specific topic. Questions may be sent in advance by email or tweet, or during the session, or come from the moderator.	Useful to have a panel with a variety of perspectives (eg. clinician, statistician, patient). Need to think about whether the audience you want to reach will be on Twitter. Useful to work in partnership with other organisations to promote the event – increase reach. Can reach lots of people, and does not take much time.	Can be lay, clinical or scientific, depending on how you promote the event.	PROMIS Q&A Trials Matter Q&A Small populations Q&A PrEP Q&A	Twitter team can provide guidance and support.
Websites and webpages	Could be information about a study on a broader website, or a study-specific website	Can be a useful repository of information about the study, but needs to be kept up-to-date. Also need to think about how long to keep the website going	Can be broad, but need to consider who is likely to visit the website and why.	www.ctu.mrc.ac.uk http://www.addaspirintrial.org/	Contact the web committee or DMS team for further guidance

Tool	Description	Considerations	Audiences	Examples	Further guidance
		after the study closes, and who will maintain it. Need to think about who is likely to use the website, and the sorts of content they will want.			

Who is your messenger?

Once you have your message, you need to pick a good messenger to get it across to your audience. That messenger may be a person; for example, the person presenting the results, or the spokesperson being interviewed by a journalist, or the authors of a paper. Sometimes it's not so obvious who the messenger is, for example in the case of a tweet from an organisation's twitter account. In that case the messenger is likely to be the organisation who published the information (ie. the organisation whose Twitter account it is).

When deciding on who the messenger should be, you need to consider whom your target audience will trust, and will have credibility on this issue. This may differ depending on the audience and message you are thinking about, and may not be someone who is part of the immediate trial team. The Chief Investigator is not always the best messenger for all messages for all audiences. For some audiences and messages, the best messenger may be a patient, someone from a trusted patient group, a clinicians, a scientific expert who is independent from the drug company, or someone from a relevant government body or professional association.

Whoever your messenger is, you need to ensure that they are well briefed, know the key messages well, and understand the issues. If they are likely to get asked questions about the study or its results, you need to make sure they can handle them, either knowing the answers, or being able to refer people on to where they can find out the answers if they are available elsewhere. A Key Messages and Frequently Asked Questions document, that explicitly sets out what the key messages are, and what the answers are to likely questions, can be very useful for briefing messengers, particularly those who have not been closely involved in the study or analysing the results.

Timelines for communicating about your study

Timelines for communicating about your study to different audience can be complex. During the course of a study you will have various things that you need to communicate to different audiences at different times. Alongside the operational considerations of who needs to know what when in order for you to do your study, you need to take into account regulatory requirements (which may be different in different countries, adding to the complexity of an international study), funders stipulations and embargoes imposed by journals and conferences.

When preparing to release results, you need to consider which of your audiences need to be informed prior to the results being publically released. Usually, as a minimum, that will be the investigators who contributed to the study, the funders, industry partners and the relevant press offices. You should also consider whether policymakers will want to be informed before the results are made public. This can be important for maintaining good relationships with them, ensuring they are able to answer questions they are likely to get asked about the results and how they will respond. It may also speed up the adoption of your intervention into policy, if relevant. In some cases you may want to inform participants of the results – this may be particularly important if the results are likely to be covered by the media, ensuring

accurate information gets to the people most affected, and they do not feel like they are the last to be informed. It may be tricky to balance the expectations of different stakeholders with the embargoes imposed by conferences and journals, but asking people to sign confidentiality agreements before disclosing the results to them can reduce the risk.

A Communications Grid can be a useful tool for planning the timelines for communicating about a study. This sets out what activities will be done when, for which audiences, as well as key internal and external milestones. Table 4 shows the example of a Communications Grid for the STAMPEDE Abiraterone results.

Traditionally, results are presented first at scientific conferences, and then published at a later date. There can often be a long gap between presentation and publication, although this is hard to predict, as the trial team can have little control over it. This two-stage approach presents several communication challenges.

- While the conference embargo may lift at the time of publication, many journals have policies that discourage authors from communicating their results prior to publication beyond the minimum of presenting at a conference. This can get especially tricky if the results are 'newsworthy' and likely to get picked up by the media, who often attend major scientific conferences. This can leave studies in the situation where the media is reporting their results, but the study itself is officially not meant to share its results more widely, meaning important stakeholders hear the results from the media first, which may damage relationships, and there's no guarantee the reporting will be accurate.
- Often at the time of presentation, not all the analyses have been completed, and numerical results may change between presentation and publication. This may cause confusion if people see two different sets of numbers from the same trial.
- The MRC and UCL press offices have a general policy of not issuing media releases at the time of presentation, but waiting until peer-reviewed publication. This is to encourage journalists to only report science that has been peer-reviewed, to improve the quality of science that gets reported. However, if the media have covered the results in any form based on a conference presentation, they are unlikely to cover the publication. This may mean the coverage of the story does not necessarily reflect the messages the study team would have put across in a media release.

Increasingly, major journals such as The Lancet and NEJM are publishing articles to coincide with the timing of the relevant presentation. This simplifies embargoes, and often means there is more attention on the results at a single time point. It can eliminate the challenges mentioned above. For this to work, the study team need to get the manuscript ready earlier than they traditionally would, putting more pressure on a shorter period of time. It's also likely that journals will only be willing to provide this expedited service for articles that are deemed particularly newsworthy, so it may not be an option for every study. It may be worth approaching the target journal in advance to see if this is something they would be interested in doing. This has been done successfully with the STAMPEDE Abiraterone results. In addition to overcoming some of the challenges of the two-stage release of results, it may also mean the full results are available sooner, meaning patients can benefit sooner, as many policymakers will wait until peer-reviewed publication before considering changing policy based on new results.

Table 4: Communications Grid for STAMPEDE Abiraterone results

Audience	Mar – May 2017	June 2017	July – Sept 2017	Later
External Milestones		3 or 4 June: ASCO & Publication		Licensing application from Janssen?
Internal milestones				CEA results?
Participants & their families	Consult with research nurses re. events and thank you cards Develop participant summary Develop patient film	Participant summary Infographic Patient film		
Other men with prostate cancer	Develop infographic Develop patient film	Press release PCSF AGM Series of targeted tweets Infographic Patient film	Article in Prostate Matters	Twitter Q&A
Patient groups	Brief CRUK, PCUK and Tackle Prostate	Series of targeted tweets & emails Infographic Patient film		Twitter Q&A
Healthworkers	Develop healthworker film Develop briefing paper 17 May: investigators meeting	Press release Healthworker film Briefing paper Infographic Inform NIHR Dissemination Centre		Twitter Q&A
Policymakers	Advance notice to DoH in England, Wales, Scotland & Northern Ireland Flag with Horizon Scanning Centre	Press release Healthworker film Briefing paper Infographic		Updated briefing paper with CEA results
Industry		Discussions with STAMPEDE Industry partners		

When preparing to release results, developing communications materials ahead of embargoes being lifted, it is important that everyone involved understands what the embargoes are. It may help to put the embargo information in the header of draft documents as well as including it in the text of accompanying emails.

Another important issue to clarify is whose sign-off is needed before you can release a communication about the study. This may vary depending on the communications material in question. For example, a media release will need sign-off from the press offices of the main organisations involved, as well as the key people involved in the study, whereas a briefing paper would not involve press offices. Once you know whose sign-off is needed, it may be sensible to find out if there are any dates they are unavailable (eg. on leave) during the lead-up to when you want to release the communication, to make sure your timelines take these into account. The more people who need to sign-off on something, the longer you need to allow for this process.

There may also be people you want to consult and get comments from, but do not require formal sign-off from. For example, if you needed formal sign-off from the study Chief Investigator and the project lead at MRC CTU, you may still want to run a draft past the TMG for comments prior to preparing the final version. If you want to do this, you will need to allow time for it when planning what needs to be done when.

If you are issuing a media release, this will often be done, under embargo, a few days before the results are released, to allow journalists time to prepare their stories. It is important to ensure your spokespeople are available to talk to journalists between the release of the press release and the embargo lifting, and it is worthwhile to prepare a spreadsheet of the different people who are willing and able to talk to journalists, their contact details and availability for the days between the issue of the press release up until the day after the results have been publically released.

Evaluation

Evaluating the impact of your research

Why do we evaluate the impact of our research?

There are two main reasons for evaluating the impact of our research:

1. To demonstrate the value of our research to others (for example research funders)
2. To understand the pathway to impact better, so we can learn from it and increase the impact of our future studies

Which studies should we measure the impact of?

Measuring impact takes time, so it is not something we should do for every study. If we want to measure impact to demonstrate the value of our research to others, it makes sense to select studies that we know, or think should have, had impact. This is usually studies with clear, positive results, but it may also be worth considering the impact of studies with negative findings, and even studies without clear cut results may have significant impact (see case study 8 for an example of this).

Case study 8: impact from a study without clear cut results: the QUARTZ trial

The QUARTZ trial was a non-inferiority trial that tested whether whole brain radiotherapy could be omitted for patients with brain metastases from non-small cell lung cancer. The pre-specified non-inferiority margin was set to rule out a detriment of 7 days quality adjusted life-year. In a survey prior to the results being released, clinicians were asked how they would respond to the results if the trial could not rule out a detriment to qualitative adjusted life years of more than seven days. 85% of respondents said that in that scenario the proportion of patients they treated with whole brain radiotherapy would stay the same. The final results showed little difference between optimal supportive care alone versus whole brain radiotherapy plus optimal supportive care, but the confidence interval exceeded the non-inferiority margin, meaning the trial failed to show optimal supportive care alone was non-inferior to whole brain radiotherapy plus optimal supportive care. In response to a survey of UK clinicians distributed 6-18 months after the results were released, 85% said the QUARTZ results had changed their practice, with 83% of respondents saying they gave whole brain radiotherapy to these patients less than they did two years ago.

When should we measure impact?

There is substantial variation in how long it can take for a trial to have impact, which makes it difficult to be prescriptive about when we should measure impact. For example, NHS England released a policy statement within one month of the STAMPEDE trial docetaxel results being published, whereas it took six years for the results of Study A to be incorporated into WHO guidelines. It is useful to document impacts from a study as we become aware of them. But the decision on when to spend time actively looking for impact should take into account what the timelines are that key stakeholders generally work to (for example, some guideline developers have a formal policy saying how frequently they review guidelines to see if they need updating). The decision should also take into account the purpose you are looking for impact for; if it's for internal use and interest, there may be less urgency than if you are looking to gather data for a REF case study or QQR report that has fixed deadlines.

What sorts of impact are we interested in?

It can be helpful to think about impact in terms of four domains, some of which will be more relevant for some studies than others:

1. **Impact on policy**: this includes changes to guidelines, changes to what can be commissioned in a health system, and changes in the policy discourse (how policymakers talk about an issue, and whether they talk about it at all). Changes to guidelines are often the most straightforward types of impact to identify and show evidence of.
2. **Impact on practice**: this is about what actually happens in practice, and may be different from what the guidelines say. It is possible to have impact on policy without having impact on practice, or to have impact on practice without having an impact on policy first. It can be harder to evaluate impact on practice as often good quality data on this is not available.
3. **Impact on science**: This includes assessing whether people read and or cite the research, whether it changed how people do research like this in the future, whether it changed the scientific discourse, whether it led to new avenues of research, and

whether innovative methods used in this study are taken up elsewhere. This domain of impact is particularly relevant for methodological research.

4. **Impact on society**: For the sorts of research we do, the types of impact on society we are most likely to have include saving the health system money (if the intervention is cost saving), saving lives, preventing infections, or transforming how people think about a disease or intervention.

What should we measure?

There are a wide variety of metrics that can be measured to assess the impact of a study. Different metrics will be relevant to different studies. Before you start collecting evidence around these metrics, it is helpful to think about which ones your study is likely to impact, and also which ones are possible to obtain evidence about without requiring an excessive amount of work.

Metrics for impact on policy

1. Citations in / changes to clinical practice guidelines
    a. National (eg. NICE guidelines, Ministry of Health guidelines)
    b. International (eg. WHO)
    c. Professional body guidelines (eg. BHIVA)
2. Commissioning decisions
3. Drug licensing decisions

Metrics for impact on clinical practice

4. Changes in clinical practice
    a. Local
    b. National
    c. International
5. Access to / uptake of the intervention
6. Use of results / resources from study in medical education / training

Metrics for impact on society

7. Cost-effectiveness & / or budget impact
8. Changes in the discourse (way people think) about the disease / intervention

Metrics for impact on science

9. Inclusion in meta-analysis
10. Methods developed used in subsequent studies

11. Changing the paradigm
12. Bibliometrics
13. Altmetrics
14. Generation of new hypotheses
15. Changes to control arm of subsequent trials
16. Insights into basic science/biology

Impact interviews

A useful first step when seeking to assess the impact of a study is to carry out an 'impact interview' with someone who knows the study well, and is also well connected to the domain of impact you are most interested in. This may be the Chief Investigator for the study, or a key member of the TMG or TSC. This interview can help you identify the sorts of metrics it is most worth concentrating on for this study, and point you to sources of information about the impact. You can see an example of the questions you might cover S:\All_CTU\V_Shared\Communications\Research Impact Group\Impact interviews\Topic guide

Impact interviews are a good first step, and can be done relatively quickly, but their usefulness depends on the interviewee having a good knowledge of the field. You will need to do more work to find evidence to support the impacts that are highlighted during the interview.

Guideline searching

Searching for guidelines relevant to your topic, and seeing whether and how they reflect your study findings, can provide robust evidence of impact. For some disease areas there are many guidelines available, so it can be helpful to define which guidelines you are particularly interested in before starting, rather than trying to be comprehensive. Talking to clinicians working in the field might help you identify which guidelines are the most influential. You may also choose to focus on guidelines that cover the geographic areas which are most affected by the disease.

If the guideline in produced by a professional body, it is likely to be available via their website. Other guidelines are published in peer reviewed journals, so can be found through searching databases such as PubMed. General internet searches may also help to find guidelines.

When you have found relevant guidelines, download them if you can, and save them in a folder (labelled with who published them and date of issue). You then need to assess whether your study has impacted it. A first step is to search the document for your study acronym and/or the name of first author of paper, but if that isn't there, it doesn't mean your study hasn't influenced it. Not all guidelines provide references for the basis of their decision. Conversely, some may cite your study, but the recommendations may not be in line with your results / conclusions. You need to read what the guidelines say and use your judgement. Copying the relevant recommendations into a document or excel sheet can be useful for tracking guideline changes over time, and keeping records of all guideline impacts in one place.

Some guidelines are easy to find, and well referenced making it easy to assess whether or not your study has influenced them. Others may be much harder to find and difficult to tell the extent to which they were influenced by your study. Guideline searching can be time-consuming; deciding in advance which ones to focus on, rather than seeking to be comprehensive, can be helpful.

Collecting evidence on impact on clinical practice

Depending on the topic of interest, it may be harder to find evidence of impact on clinical practice.

In some disease areas and countries there may be clinical practice audits that publish good-quality data about what happens in clinical practice. For example, in England and Wales there are national clinical practice audits on prostate cancer (https://www.npca.org.uk/) and lung cancer (https://www.rcplondon.ac.uk/projects/national-lung-cancer-audit). If these audits collect data that is relevant to the question you are interested in, looking to see the extent to which your study has been taken up into practice is straightforward (although it won't allow you to prove that any change in practice is due to your particular study).

There may be other sources of routinely collected data that are available to you, that may provide insight into what is happening in clinical practice. At the international level, organisations such as the World Health Organisation (WHO) may collect data from member countries that may be relevant. (For WHO's HIV data see http://www.who.int/hiv/data/en/ and for TB see http://www.who.int/tb/data/en/) At national level, there may be information available from disease registries such as the National Cancer Registry https://www.gov.uk/guidance/national-cancer-registration-and-analysis-service-ncras Organisations with an interest in your disease area may also have relevant data, for example Cancer Research UK have some helpful data on their website https://www.cancerresearchuk.org/health-professional/cancer-statistics-for-the-uk

Another source of information about clinical practice is the peer-reviewed literature. It is worth searching for any published papers that document relevant clinical practice, reporting analyses of audits, routine data or surveys.

If you cannot find any relevant audit, routine data or published papers to help tell you what happens in practice, you may need to gather this data yourself. Before you invest lots of time and effort in gathering data about current practice, consider the level of evidence you need on this – sometimes 'quick and dirty' approaches may be sufficient.

The easiest approach is to ask the investigators involved in your study what happens in their sites, outside of the trial. This may be through a formal survey, or informally through emails or face-to-face. If using this approach, be aware that the information you gather may not be representative. Sites taking part in your study may be different to those that are not taking part in it; they may have more interest in the approach you are testing, and therefore more likely to use it outside of the trial, or they may be better resourced, which again might impact their practice for non-trial participants.

If you are keen to gather information about what happens in standard practice beyond your network of investigators, you could carry out a survey of clinicians working in the field more widely. It can help if you get the support of a relevant professional association to help distribute the survey to their network, as otherwise it may be hard to get your survey to

people who are not involved in your study. This may provide more representative information than just surveying investigators, but care still needs to be taken in interpreting your results, as it is still vulnerable to bias (eg. you may be more likely to get responses from people who have strong views about the topic you are focusing on, or, if they know what study you are part of, there is the possibility of social desirability bias affecting the answers given). Case Study 8 explores how surveys were used to look at the impact of the QUARTZ trial on clinical practice.

Another way to gather data on clinical practice in the UK is to put in Freedom of Information requests to NHS Trusts. This approach may be time-consuming if you want to contact many different hospitals or Trusts, but can provide useful data. Details on how to make a Freedom of Information Request can be found https://www.gov.uk/make-a-freedom-of-information-request/how-to-make-an-foi-request Case Study 9 explores how Prostate Cancer UK have used Freedom of Information requests to look at use of mpMRI scans prior to biopsy in prostate cancer, following the results of the PROMIS study.

Case Study 9: Prostate Cancer UK's use of Freedom of Information Requests to gather information on the impact of the PROMIS study.

The PROMIS results showed that having a multi-parametric MRI scan prior to biopsy could improve diagnosis of prostate cancer. In 2016, Prostate Cancer UK carried out a UK-wide Freedom of Information request to assess the availability of high-quality MRI prior to biopsy within the NHS. The results of this can be seen https://public.tableau.com/profile/ali.cooper#!/vizhome/mpMRIFOIpublicdashboard-ProstateCancerUK_0/FullresultsStory

They repeated this in 2018, to see how availability has changed. This showed a 63% increase in access overall, although there are still parts of the UK without access to MRI prior to biopsy.
https://www.google.com/maps/d/u/0/viewer?mid=1a732RFPeoTWJTwF0mGhAAcb_GFz4RGCp&ll=55.5185784454211%2C-2.786392949999936&z=6

Metrics

Bibliometrics are the most commonly used approach to measuring impact on science. Common paper-level bibliometrics include citation counts for a paper (which can be found from Google Scholar, Scopus or Web of Science), and Journal Impact Factor for the journal which published the paper. Journal Impact Factors is the average number of citations per paper published in that journal in the two preceding years, and most journals give this figure on their website. There has been considerable backlash against the use of Journal Impact Factor as a surrogate for quality of individual research outputs. Bibliometrics are easy to find out, but do not tell us much: a paper could be highly cited because it has been widely criticised, or a paper could have high scientific impact even if it's not published in a journal with a high Impact Factor.

Looking at the citations a paper receives can be more informative (are they editorials? Do they support the conclusions of the research? Has the paper influenced how future researchers do things, or do they mention it in passing? Has the paper contributed to meta-analyses?) But this obviously takes more time, particularly for highly-cited papers. Brueton et al. used citation analysis to assess the impact of methodological research at the Unit https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-15-464

Alternative metrics (Altmetrics) have been developed that take into account other quantitative measures of attention for an article, including coverage by the news media, and mentions on social media. Some journals show the Altrmetric Attention Score next to articles, and you may also be able to see the 'Score in Context', which tells you how the attention this article has received compares to other articles in the field. An Altmetric Attention Score does not tell you the sentiments of these mentions, and attention may not be a good proxy for actual impact on science.

There are many other metrics that can be used. The http://www.metrics-toolkit.org provides a good overview of these, their advantages and disadvantages.

Evaluating the effectiveness of your communication

Communication activities take time to carry out, and may have additional costs (eg. printing, travel, or hiring the services of external designers/film-makers etc.), so it makes sense to put some effort into establishing whether particularly resource-intensive activities and tools are worth the effort. It is particularly useful to evaluate the effectiveness of communication activities to inform future plans (especially where future studies will require communicating with the same or similar audiences to current or past studies).

The previous section covered how we evaluate the impact of the study. It can be very difficult to attribute impact to a particular communication activity (and inevitably many factors influence clinical and policy decision-making), so it makes more sense to focus communication evaluation on things it is possible to measure: outputs, reach and quality.

Evaluating outputs

At its most basic, this is recording communication outputs from a study. This includes keeping records of papers and presentations, as well as other communications tools and activities, including interviews with the media. This information can be used to populate the Outputs section of ResearchFish.

Comparing these records to your communication and publication plans will help you see whether you achieved what you planned to in terms of outputs. If not, it can be helpful to think about why not: were your plans too ambitious? Did you have insufficient resources? Were your papers/abstracts not accepted? This can help with making sure future plans are achievable and adequately resourced.

Evaluating reach

Evaluating the reach of communications outputs is fairly straightforward for internet-based communications tools. If you control the website or social media account that distributed the information in the first place, you should be able to access analytic data that can tell you about how many people (and from where) visited or interacted with your content. It is harder to evaluate reach for non-web-based tools. If you are distributing physical copies, you can keep track of how many have been distributed, and to whom, although that does not capture whether people pass on things to others. Similarly, it is hard to know whether emails/email attachments have been forwarded to others, and reach may potentially be much wider than the initial distribution.

You could also approach evaluating reach by attempting to find out from the people you wanted to reach whether they received / accessed the information. This may be informal and ad hoc, taking advantage of meeting someone in your target audience to ask them about it,

or by doing a more systematic survey, although there are challenges in getting your survey to the right people, and getting a representative response.

Evaluating quality

Quality is more difficult to evaluate. In the case of communications outputs, perceptions of quality are likely to influenced by some or all of the following factors:

- Accuracy
- Comprehensibility for the target audience
- Clarity of design
- Relevance to the intended audience
- Usability
- Use of appropriate tone, language and imagery for the target audience
- Timeliness

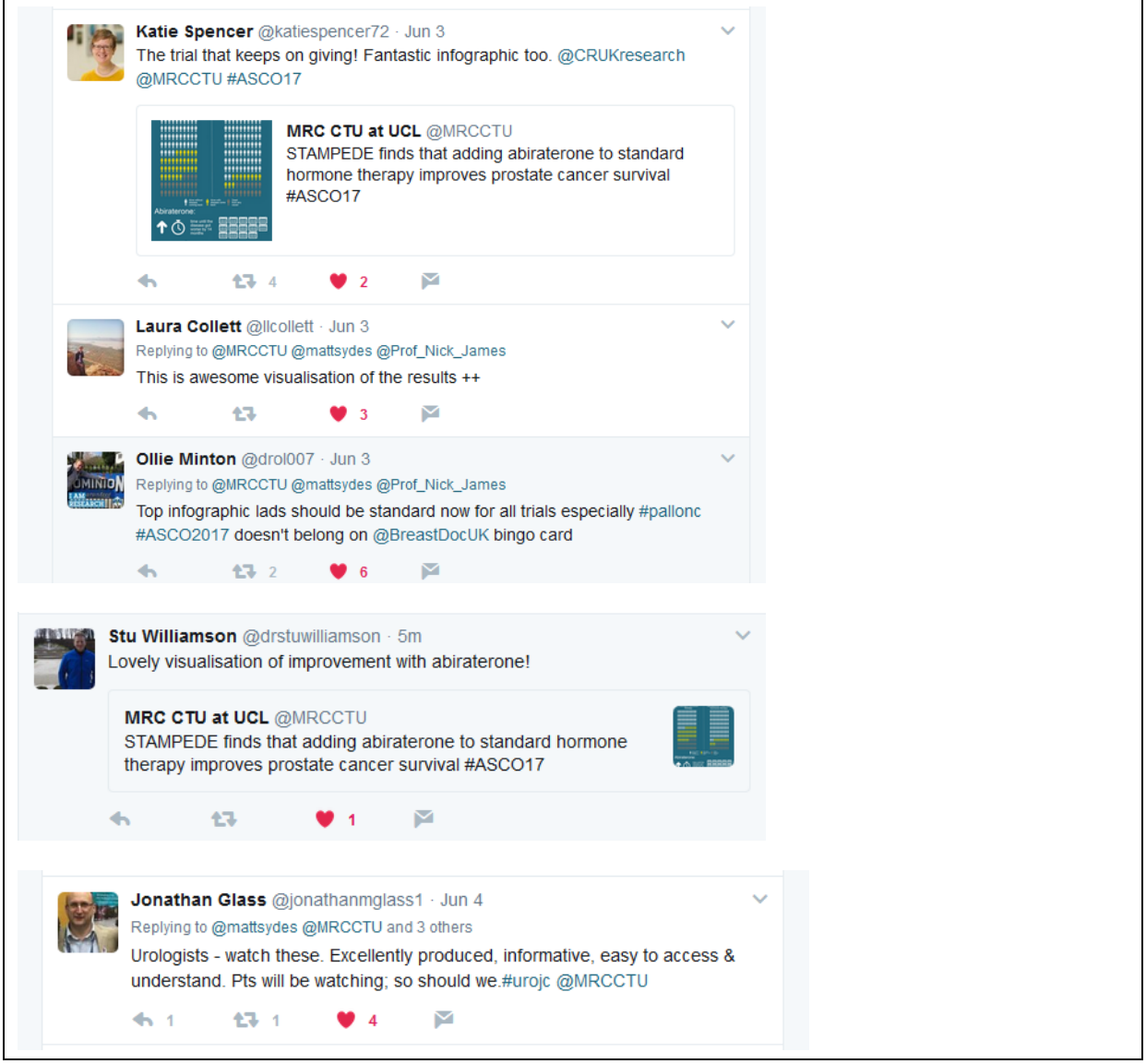
As many of these factors are specific to the intended audience, you are likely to need to involve members of that intended audience in evaluating it. This may range from informally seeking feedback from one or two members of your target audience, to carrying out a systematic evaluation (eg. carrying out a survey or interviews with members of the target audience).

It can be useful to get informal feedback during the development of a communications tool, before it is finalised and released, in order to make sure it is as useful as possible. (See the section on PPI for information about involving patients and the public in communication).

There may be proxy indicators of quality that are less time-consuming to assess than carrying out a full-scale survey or interviews with many stakeholders, depending on the communications tool you are considering. For example, for audio or videos hosted online, you may be able to access statistics that tell you about what proportion of your content users watch/listen to, which will give you an idea on whether people quickly give up, or keep going to the end. While this may tell you something about quality, if you're not sure who those people who have been engaging with your content are, it may be difficult to unpick whether the content was poor, or whether it was people you were not targeting who were giving up early.

You may also get some feedback from social media, if you are using that to share your communications tools. Case Study 10 shows some of the unsolicited feedback received via Twitter for the communication of the abiraterone results from the STAMPEDE trial. This isn't systematic, but, where you get it, it can give immediate feedback and suggestions on what you can improve.

Case Study 10: Feedback received via Twitter for communication of STAMPEDE abiraterone results



Resources for communication

The MRC CTU at UCL has some internal capacity for communications that you can access. This includes support with writing for lay or policy audiences, design, developing infographics, and some capacity for more intensive communications activities such as developing podcasts, animations and simple videos. Please consult the Communications Team as early as possible around your plans, so they can advise on exactly what they can help with, and fit it into their implementation plan for the year. We are also able to access some expert support from the MRC and UCL press offices

Other communications activities may require financial resources (eg. for convening meetings with key stakeholders, webcasting events, producing more sophisticated or lengthy films, getting support for developing comics or illustrations, paying for PPI input into communications activities, travelling to conferences or meeting). Ideally this should be

incorporated into trial budgets in grant applications, so it is important to consider what sort of communications activities you might want to do when working on grant applications. If you would like advice about this, please talk to the Policy, Communications & Research Impact Coordinator, who can also support with drafting relevant sections of the grant application (eg. Pathways to Impact, Communications Plans).

If your study has not included resources for communication within the original grant application, but does require financial support for communications activities, there are some options open to you:

- Seek additional funding for your communications, either from the original funder, or from other sources. For example, studies funded by the MRC are eligible to apply for an Alexander Fleming Dissemination Award. These awards, of up to £30,000, can be used for a variety of communication activities. However, you cannot apply for one until the results you want to communicate have been published in a peer reviewed journal, which may not fit with the timelines within which you want to carry out your activities. Another drawback is developing the grant application, and waiting for it to be reviewed and (hopefully) approved can also take a considerable time.
- Seek in-kind support from external organisations: another approach, which may be swifter (although less flexible), is looking for an organisation with similar goals and communications capacity to work in partnership with. For example, we worked in partnership with Prostate Cancer UK to produce some short films aimed at clinicians about the PROMIS results. Prostate Cancer UK provided the cameraman and editing, while MRC CTU wrote the script and organised the interviews.

Further reading

General guidance

- FHI360 Communications Handbook for Clinical Trials
- Research to Action (website with lots of guidance on research communication)

Resources about Theories of change

- https://vimeo.com/106389971
- http://www.espa.ac.uk/files/espa/ESPA-Theory-of-Change-Manual-FINAL.pdf
- http://www.researchtoaction.org/wp-content/uploads/2012/02/Key-questions-to-ask-when-putting-together-a-Theory-of-Change-for-Research-Uptake-by-Andrew-Clappison.pdf

Patient and public involvement at the MRC CTU at UCL

- https://doi.org/10.1186/s13063-016-1488-9
- https://doi.org/10.1186/s13063-018-2471-4

Evaluating impact

- http://www.metrics-toolkit.org/
- https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-15-464