

Accessible Results

Work Package 3 Statistical Analysis Plan

Version 1.1

Links to protocol version 1.4 (14/04/2026)

IRAS ID: 349062

ISRCTN12339902

Sponsor's No: 2024 - 5829

Funder's number: NIHR159467

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Funder(s)	National Institute for Health Research (NIHR)- Health and Social Care Delivery Research (HSDR) Programme. NIHR159467
Committees	Project management group Study steering committee



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Aims and objectives

Primary objective:

To evaluate whether tools to enhance online test result communication improve acceptability of online test results communication.

Secondary objectives:

To determine whether tools to enhance online test result communication reduce patients' negative emotional responses to blood test results.

To assess whether tools to enhance online test result communication reduce patients' intention to contact their GP practice.

An exploratory qualitative analysis will examine participants' suggestions for improving the accessibility of laboratory test results.

Trial Design

This is a three-arm online randomised vignette study, which forms the final work package (WP3) of the Accessible Results study. Participants complete baseline demographic questions before being randomised within Qualtrics using the Evenly Present Elements randomisation algorithm. Each participant is allocated to view one of four clinical vignettes, with laboratory test results presented in one of three presentation formats, giving twelve possible vignette/presentation combinations. The purpose of the four vignettes is to improve generalisability.

The primary comparison is between the three presentation formats, pooling data across all four clinical vignettes.

Randomisation and Blinding

Randomisation is done via the Qualtrics using the Evenly Present Elements randomisation algorithm. Participants are unaware of the alternative presentation formats and are therefore blinded to intervention allocation.

Investigators are not blinded during data collection because the survey design is visible within Qualtrics. Outcome data will not be examined by randomised group prior to finalisation of this Statistical Analysis Plan. The study statistician will be aware of which presentation format is the control condition, but the two intervention presentation formats will be coded (e.g. Intervention A and Intervention B) and their identities will remain blinded until the primary analysis has been completed.

Sample size calculation

The primary outcome is acceptability of this way of showing test results to patients with a binary outcome of acceptable/unacceptable. To have a detectable difference of 50%-60%, each arm would need to have ~387 respondents with a total sample of ~1,160 for all three arms based on a significance level (alpha) of 5% and a power of 80%. For a 90% power and the same detectable difference an overall sample of ~1545 respondents would be needed.

Outcomes

Table 1 provides an overview of the study outcomes, and how these map to the study objectives.

Table 1: Overview of study outcomes for each objective

Objective	Instrument	Outcome	Responses
To evaluate whether tools to enhance online test result communication improve acceptability of online test results communication?	TFA Acceptability questionnaire (Sekhon et al) 5-point scale for each outcome	Affective attitude	How comfortable would you feel if your test results were shown like this?
		Burden	How much effort would it take to understand test results shown in this way?
		Ethicality	How fair is this way of showing test results to patients?
		Perceived effectiveness	This way of showing test results would improve my understanding of them.
		Intervention coherence	It is clear to me that seeing my results like this will help me understand my health.
		Self-efficacy	How confident would you feel about understanding your results if they were shown like this?
		Overall acceptability	How acceptable was this way of showing test results to you?
		Optional Please tell us more about your views?	Optional free text box
To assess whether tools to enhance online test result communication reduce patients' intention to contact their GP practice?	Adapted from Dolan et al and Copp et al	After reading this information, would you contact your GP practice about your test results?	Yes/no/don't know. <i>You can tell us why if you want [Optional free text]</i>
	Categories adapted from GP Patient Survey	[If answered 'yes'] How would you try to contact your GP practice?	- I would phone the practice - I would visit the practice in person



			• Online, using the practice website • Online, using the NHS App • Online, using a different website or app • Another way [please specify]
	Categories adapted from GP Patient Survey	[If answered 'yes'] How would you like your GP practice to give you more information about your test results?	• Speak to a receptionist • Telephone appointment with a health professional • Face-to-face appointment with a health professional • By text message • By online message • Over a video call • Other [free text]
To determine whether tools to enhance online test result communication reduce patients' negative emotional responses to blood test results?	Berlin Emotional Response to Risk Instrument.	How would you feel when you read this information about your blood tests? (Seven-point scale 1=not at all to 7=extremely)	1. Assured 2. Hopeful 3. Relieved 4. Anxious 5. Afraid 6. Worried
An exploratory qualitative analysis will examine participants' suggestions for improving the accessibility of laboratory test results.		*Optional* Do you have any other suggestions for how we could improve the way blood test results are shared online?	Optional free text box

Primary outcome

The primary outcome is overall acceptability measured using the single overarching acceptability item from the Theoretical Framework of Acceptability questionnaire. The overarching acceptability item will be dichotomised to address the primary policy-relevant question of whether participants considered the presentation acceptable or not.

Participants selecting Acceptable or Completely Acceptable will be classified as finding the presentation acceptable. Participants selecting Unacceptable, Completely Unacceptable or No opinion will be classified as not acceptable.

Secondary outcomes

The following construct scores from the TFA questionnaire will be analysed separately:

- affective attitude
- burden
- ethicality
- intervention coherence
- perceived effectiveness
- self-efficacy

The TFA construct scores will not be combined into an overall summary score. Consistent with the theoretical framework and the original questionnaire development, each construct will be analysed separately to explore which dimensions of acceptability differ between presentation formats. Where necessary, items will be reverse-coded before analysis so that higher scores consistently indicate a more favourable assessment of the presentation.

Anxiety

Anxiety will be measured using the Berlin Emotional Response to Risk Instrument (BERRI). Total scores will be calculated according to published scoring guidance. Consistent with the published development and validation of the instrument, the six items will be used to derive two separate subscale scores rather than a single overall BERRI score. The instrument distinguishes positive and negative emotional responses, which may occur independently.

The BERRI-negative score (BERRI-neg) will be calculated as the arithmetic mean of the available responses to the following three items:

- anxious;
- afraid;
- worried.

The BERRI-positive score (BERRI-pos) will be calculated as the arithmetic mean of the available responses to the following three items:

- assured;
- hopeful;
- relieved.

Both BERRI-pos and BERRI-neg scores' range will be from 1 to 7 and they will be treated as continuous variables.

Intention to contact the GP practice

Participants will answer the question:

"After seeing these results, would you contact your GP practice?"

Response options are:

- Yes
- Unsure
- No.

This will be treated as an ordinal outcome in order to retain all available information. To ease interpretation results will be presented for collapsed responses (a) Yes vs Unsure/No, and (b) No vs Unsure/Yes.

Baseline Characteristics

The following baseline characteristics will be summarised across the three arms:

- age
- gender
- ethnicity
- disability
- highest educational qualification
- health literacy screening response.

Continuous variables will be summarised using mean and standard deviation or median and interquartile range, depending on their distribution. Categorical variables will be summarised using frequencies and percentages. No formal statistical comparisons of baseline characteristics will be undertaken.

Analysis Population

The primary analysis population will comprise all eligible participants who:

- completed randomisation;
- viewed their allocated vignette;
- provided data for at least one outcome.

Participants will be analysed according to the presentation format to which they were randomised.

Duplicate responses or ineligible participants identified prior to analysis will be excluded, and reasons for exclusion will be shown in a CONSORT flow diagram.

Derived Variables

The following derived variables will be created prior to analysis.

Primary outcome

Binary acceptability:

- Acceptable (Acceptable or Completely Acceptable)
- Not acceptable (Unacceptable, Completely Unacceptable, No opinion).

Presentation format

Three-level categorical variable.

Clinical vignette

Four-level categorical variable.

TFA construct scores

Calculated according to published scoring guidance, including reverse scoring where required.

BERRI

BERRI-positive and BERRI-negative will be calculated according to published guidance.

Procedures for Missing Data

The amount of missing data will be summarised for all variables. Participants with missing primary outcome data will be excluded from the primary analysis. Patterns of missingness will be explored descriptively. If there is substantial missingness in the primary outcome, multiple imputation may be considered as a sensitivity analysis, incorporating relevant variables predictive of the primary outcome and/or missingness. Missing items within secondary outcome measures will be handled according to published scoring guidance where available.

Statistical Analysis

General considerations

All analyses will be conducted using the R programming language (Version R 4.6.0 or later), and the significance level will be set at 5%.

For all analyses an appropriate regression model will be selected based on the nature of the outcome. The assumptions for each model will be assessed and if required the methods will be adapted as appropriate by considering alternative distributions.

Primary Analysis

The primary estimand is the effect of presentation format on the probability that participants consider the presentation acceptable.

Binary acceptability will be analysed using a logistic regression model, that will include presentation format (three levels) and clinical vignette (four levels) as fixed effects. An overall Wald test will assess differences between presentation formats.

If statistically significant, the following prespecified pairwise comparisons between presentation formats will be undertaken:

- Control vs Intervention arm 1
- Control vs Intervention arm 2
- Intervention arm 1 vs Intervention arm 2

Results will be presented as odds ratios with corresponding 95% confidence intervals and p-values.

Secondary Analysis

The seven TFA construct scores will be dichotomised similarly to the TFA construct score of the primary analysis and analysed as separate secondary outcomes using a logistic regression model with presentation format and clinical vignette variables included as fixed effects. Results will be presented as odds ratios along with 95% confidence intervals.

The BERRI-neg and BERRI-pos scores will be analysed separately using linear regression, will include presentation format as a three-level categorical fixed effect and clinical vignette as a four-level categorical fixed effect. Adjusted mean differences with 95% confidence intervals will be reported.

Participants' intention to contact the GP practice (Yes/No/Unsure) will be analysed using a proportional odds ordinal logistic regression model. Results will be reported as odds with 95% confidence intervals and p-values.

If one response category contains very small numbers, categories may be combined following review of response frequencies and prior to comparative analyses.

Secondary analyses are considered supportive and exploratory. No formal adjustment will be made for multiple testing.

Sensitivity analysis

As a sensitivity analysis the primary outcome of overall acceptability will be treated as non-dichotomous and analysed fitting an appropriate model. A similar sensitivity analysis will be conducted for each of the other TFA construct outcomes too.

A sensitivity analysis will be also conducted to assess differences that could arise due to the clinical IT system used by each GP practice (EMIS or SystmOne), by including clinical IT system as a fixed effect in the analysis model. A further sensitivity analysis will examine potential variation between GP practices by utilising a mixed effects model.

As a further sensitivity analysis, the primary analysis will be repeated adjusting for age and gender as prespecified covariates, given their potential to be strong predictors of the outcome.

As stated above if the assumptions underlying the main analyses are not satisfied, the analyses will be repeated using alternative distributions.

Exploratory Analysis

An interaction between vignette and presentation format be assessed; if statistically significant, separate analyses will be undertaken with stratification into the four clinical vignette to explore whether the effect of presentation format differs between clinical scenarios.

Exploratory interaction analyses may investigate whether presentation format effects vary according to:

- health literacy;
- age;
- educational attainment;
- gender.

Interaction terms will be added individually to the primary regression model. These analyses are hypothesis-generating and will be interpreted cautiously.

Participants' free-text responses regarding improvements to the presentation of laboratory test results will be analysed using content analysis. Participants' suggestions for improvements will be collated into the 'table of changes' as part of the person-based approach to intervention development.

Additional analyses may be conducted based on data availability. Any results based on those will be clearly marked as post-hoc.