The
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The Use of Psychological Tests in Healthcare Research

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Introduction

This guidance adapts and extends the original *Principles for the use of Published Psychological Tests in Research* issued by the British Psychological Society (the Society or BPS) in 2005. It is intended to apply to research using tests in healthcare, forensic and related settings (hereafter, healthcare settings). As most research of this type in the UK occurs in or through the National Health Services (NHS) in the four nations, the primary focus is on research in these settings. However, the principles and implementation proposals are relevant to healthcare research in other contexts.

The Society's *Principles* (BPS, 2005) relating to testing in research assume that typically, this is not used to inform decisions affecting participants. Instead, it envisages research testing as providing data about the tests themselves, or being undertaken for the development of new tests and models, and for theoretical work. Research testing in healthcare encompasses such uses but introduces further considerations: the testing process itself can have a strong impact on individual testees and test results can influence conclusions about the nature of their clinical condition and hence decisions about their care. Further, research test data can also influence service provision more generally, impacting directly on the services for other service users. Hence, while the original *principles* remain fundamental and relevant in all research, their *implementation in healthcare* introduces new and particular challenges for the researcher. Consequently, this extension introduces changes and widens the scope of the original principles document, with the aim of fostering good practice in testing in healthcare research. It is intended, where relevant, to complement but not override other healthcare research ethics requirements.

The NHS context: ethics and research governance in healthcare

Research involving people commonly requires ethical clearance through appropriately constituted ethical committees. The Department of Health (DoH) *Research Governance Framework for Health and Social Care* (DoH, 2005a; b) requires that any research in the NHS involving humans, their tissue and/or data, must be ethically reviewed. Specific research proposals are evaluated by local Research Ethics Committees (RECs). Using Standard Operating Procedures issued by the NHS National Patient Safety Agency, National Research Ethics Service (NHS NRES, 2010) for the evaluation process, these committees aim to protect the rights, safety, dignity and well-being of participants (including past NHS patients and carers of patients), in research undertaken in or through the NHS. New proposals intended to expedite the governance process have been put forward by the Academy of Medical Sciences (AMS, 2011). A *Code of Human Research Ethics* (BPS, 2010), currently in draft form, which specifically addresses research in the NHS, has recently been published. The Society and its Divisions have also issued a number of other guidance documents relevant to research in healthcare settings. Those not specifically referred to in the text are detailed in the Appendix.

This 'ethical' orientation reflects the overarching position that research involving NHS service users is dealing with a group who, while having their basic rights, may also be vulnerable because of their health status and the power imbalances implicit and explicit in healthcare relationships. These inequalities can arise from the physical and psychological dependence of patients and carers on the specialist knowledge, skills and access to resources controlled by healthcare professionals. For these and other reasons, governance committees include expert and lay representative judgements in decisions as to whether or not project proposals can proceed or need modification.

Inevitably, ethical oversight encompasses issues of methodological adequacy: poorly conceived or implemented research (through producing ambiguous or untrustworthy outcomes), inappropriately exploits the goodwill and circumstances of patients and wastes

resources. In these senses, poor research can be unethical. In a similar vein, improper or incompetent management and use of psychological tests and test data in healthcare research can constitute unethical practice. As will be emphasised later, responsible test use goes beyond the selection of instruments with appropriate psychometric properties. Among other things, it encompasses robust informed consent procedures, standardised administration and scoring, competent interpretation and feedback, secure data storage, proper management of confidentiality, and procedures for managing associated risks. While such considerations may apply in other research contexts, all have a particular and significant salience in healthcare research. As noted above, this derives at least partly from the special status of testees, their situation, and the ways in which test data can be used in healthcare.

In order to understand the scope of this document, it is necessary to clarify what is encompassed by the term 'test'.

Definition of 'psychological test'

The term 'psychological test' tends to be most closely associated with questions and tasks specified in a booklet that are administered, scored and interpreted in a standardised manner using numerical scoring systems. However, many procedures may be considered as constituting a psychological test. These can range from normative questionnaires (including paper and pencil tests, online versions or standalone computer administration) and performance tasks (which may also be computerised), to observational methods, clinical and other interviews, and psychophysiological monitoring devices. The definition used here follows Cronbach's (1990) characterisation of psychological tests as comprising:

> 'standardised or reproducible tasks (e.g. questions, stimuli or indeed tasks), standardised or reproducible methods of observation, and standardised or reproducible methods of scoring these tasks and/or observations, which are deemed psychological in providing measures or examinations of a person's abilities, skills, interests, preferences, disposition, attitudes, emotions or well-being'.

Or, in abbreviated form: psychological tests are rule-governed or systematic procedures contrived to enable the quantification of behaviours, expressed through some form of numerical scale or category system (adapted from Cronbach, 1970). Most commonly, the psychological mechanisms and processes of interest are higher-level constructs assumed to be provoked into operation, sampled and then quantified through the use of the test.

Test use in healthcare

The following instances illustrate different uses of tests in healthcare research and support the need for special arrangements for healthcare testing:

- Test data contribute to diagnosis and other forms of participant characterisation and selection, for instance in epidemiological and intervention studies.
- Test data are used to allocate or exclude individuals from experimental or other treatments that may have a beneficial effect.
- Test data form the basis of decisions about the benefits or otherwise of existing and innovative health interventions. The quality of testing can therefore have a profound impact on treatment options both for the research participant and for others requiring health services concurrently and in the future.

Process issues

In undertaking research in healthcare settings, a number of special features also need to be taken into account. These include:

- The healthcare context requires particular attention to informed consent, the nature of which is covered by special guidance arising from the Mental Capacity Act (2005)[1], Society guidance (see later), other legislation, and legal precedents.

[1] http://www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1

- Particular groups may require additional, special consideration. These groups include children[2] and young people, some older people, those whose lack of capacity may be transient, and people with learning difficulties.
- Research data may need to be included in the clinical record and may therefore be shared with others, including team members and other NHS services as well as non-NHS agencies through data sharing protocols. It should be pointed out to participants that such data may also be used anonymously in future research, audit and service evaluation.
- Such data may be covered by formal guidance on confidentiality, security, record retention and other NHS requirements.
- Psychological research can involve dealing with individuals who are in atypical or distressing mental states; or testing may provoke these, necessitating careful management of testing and the associated risks.
- The process of testing or test findings may indicate the need for further, sometimes urgent, clinical action.
- It is common to use assistants who may or may not be qualified psychologists to administer and score tests, and possibly provide feedback. This requires the introduction of careful training, regular monitoring, and possible retraining arrangements, in order to minimise risk to the test taker and ensure data of sufficient quality for use in the research.
- With regard to ethical approval, a distinction is drawn between audit, service evaluation, and research activities in healthcare settings. Whereas the latter requires formal ethical approval, audit and service evaluation do not. Nevertheless, the position adopted here is that all applications of testing should strive ensure best practice, irrespective of the type of application.

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[2] See for example the Royal College of Paediatrics and Child Health Guidelines on research with children link http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_088301

Purpose

Given the above considerations, the principles and procedures set out here seek to encourage best practice by identifying key factors that should be taken into account when using tests in healthcare research. It must be noted however that this document is not all-encompassing nor is it intended to be prescriptive. Each project will have its own characteristics to which some of the principles and practices listed here may not apply. Or, if they do apply, may still not be practicable for any of a variety of seemingly good reasons. In the latter case, and before making a final decision, researchers are encouraged to further reflect on: the implications of the principles and procedures for the design and implementation of their projects; on the impact their research may have on participants and others; on the healthcare testees may or may not receive as a consequence; on other risks that may be entailed; on the perception of the research enterprise; on perceptions of the researchers and their profession; and on psychological testing more generally.

Principles and practices

The following are offered as broad principles and, where appropriate, more specific considerations relating to the use of psychological tests in healthcare research:

1. Members of the Society are required at all times to act in conformance with the various BPS codes of ethics (BPS, 2009; 2010), the prevailing ethical standards of the NHS Research Ethics framework, and those of the sponsoring organisation (e.g. university, professional or charitable association, research laboratory).

2. At the same time it should be recognised that NHS RECs may not have input from individuals with the expertise to evaluate the psychological tests proposed for the project and the use and management of test data as covered in point 6 below. Hence, clear statements should be provided in the research proposal as to why the particular tests chosen are appropriate for the research aims. Evidence relating to the psychometric properties of the chosen tests should be documented and their 'fitness for purpose' justified.

3. The administration requirements for the testing, including test apparatus and material and their secure housing, as well as rooms required to carry out the procedures, should be specified.
4. Tests and performance records (paper or electronic form) should only be used in the format provided (e.g. test publishers may provide a research copy of the test or refer the researcher to an online version), or in the form of adaptations approved by the test publisher and/or copyright owner. Such adaptations should not violate evidence for test reliability and validity, for instance through changes to administration or test content.
5. Confidentiality, copyright and security of test materials need to be considered at all times (e.g. test materials should not be photocopied or downloaded from a website without authorisation).
    a. Copies should only be made available to individuals qualified in test use or to unqualified individuals under the supervision of a competent practitioner.
    b. Details should be provided regarding the arrangements for the secure storage of test records and data. This should cover the content of both paper and electronic research records, and their processing. For instance, the data may be anonymised – participant identity not discoverable from record form or electronic store; or pseudonymised – participant identity recoverable from the record itself but only with secure, confidential separately stored knowledge.
    c. Encryption of electronic versions should be considered, with arrangements for access to the encryption key specified. This key should be available to at least two responsible individuals.
    d. Back-up copies of test data should be made and stored securely, preferably in a different location to the original data set.
    e. Details should be provided about the management of test records and data when the project is completed, including duration of retention and security arrangements. For instance, the proposals for the disposal of completed test record sheets need to be documented.

6. The research proposal should detail the competence requirements for use of the research tests. These should take into account the competence levels expected of test users, details of which are available from the Society's Psychological Testing Centre. In particular, details should be provided in advance of testing to cover the following:

    a. Knowledge and skills required to administer the tests (i.e. who is competent to administer the tests).

    b. Knowledge and skills required for scoring and interpretation of the tests (i.e. who is competent to score and who to interpret the tests).

    c. Supervision and monitoring of test administration, scoring, interpretation (i.e. who has supervisory responsibility for the use of the tests).

7. Individual test scores and records may also part of the clinical record and are therefore subject to regulations regarding the storage and retention of NHS records (DoH, 2006), relevant provisions of the Data Protection Act (1998), and provisions under Freedom of Information legislation .

    a. Consideration will need to be given as to how test-related information is included in the participant's clinical paper record or, increasingly, electronic record, and to whom and how it is to be communicated (see 12 below).

    b. Record access and disclosure protocols of the NHS body responsible for the participant may also apply. Apart from confidentiality provisions and requirements of the Data Protection Act, these considerations may not necessarily apply to participants recruited outside of the NHS (e.g. control groups).

8. The administration of tests for the purposes of research should abide by the principles of informed consent. Participants in research should be told in advance:
    a. What will be required of them.
    b. What will happen to the information collected through the tests.
    c. Who will have access to this information.
    d. What if any impact it may have on their care or access to services.
    e. Their rights of refusal to participate and the implications of such refusal.
    f. The procedures in place in the event they wish to lodge a complaint specifically about the testing interaction and outcome, or if subsequently, they require further information or to wish to withdraw consent to testing already given.
    g. The consent agreement should clearly describe the uses to which the scores will be put.
9. In special cases (for instance, minors, or of those who demonstrably lack capacity permanently or transiently), specific guidance regarding consent is detailed in various sources, including national variations and provisions arising from the Mental Capacity Act and other relevant Acts. The Society has prepared detailed guidance for researchers in relation to meeting the requirements of the Mental Capacity Act (BPS, 2008). If applicable, the research proposal should detail how consent for testing will meet this Society guidance.
10. Where possible, written consent to participate and be tested should be obtained from the individual or someone with recognised authority. The agreement should note the key points in 8 above.

11. In healthcare research, it is important that consideration should be given as to how the clinicians responsible for the research participant are to be involved in the research process. Good practice in this regard will facilitate collaboration in further projects by the team/clinicians. Particular attention should be paid to the following:

    a. Ensuring that individuals and/or teams responsible for the clinical care of the participant are informed in advance of the desire to recruit and test one of their clients.

    b. Providing information about the project, its aims, and the nature of the test to all service staff immediately involved – commonly those with a need and a right to know.

    c. Obtaining agreement in advance from clinicians, carers and/or participants to approach specific participants who are under active care or, if relevant, who were previously involved with the service.

    d. If appropriate, seek views regarding the suitability of potential participants for the specific project.

12. Feedback also requires particular attention:

    a. Even if the test data do not lead to a decision, the informed consent process should identify the form of feedback required and to whom it can be given.

    b. It is the recommended that, in the case of *in vivo* assessment leading to a decision regarding a test taker, written or oral feedback is provided as part of normal practice.

    c. However, it may be the case that owing to the numbers of participants involved, the developmental nature of the tests being used, or for confidentiality issues inherent in the research design, the provision of feedback may create practical difficulties (e.g. staffing and costs) or conflict with research objectives (e.g. criterion contamination). In such cases, participants taking tests should be told in advance that feedback will not be provided and why, with the option for the participant to pull-out from the study clearly stated or re-stated at that point.

d. When feedback is to be provided, this should be in accordance with the standards for competence in test use (See footnote 4).

e. It is especially important that a note that the participant has been tested is recorded in the clinical notes, together with a suitable interpretation from a competent practitioner (as per 6 above).

f. Consideration should also be given to feedback about the outcome and implications of the project, such as providing a copy of the report or a paper arising from the study, both to the participant and the clinicians or team who supported recruitment.

13. The research protocol should make clear what is to happen in the event of a crisis or distress during testing or, in the event of test results that give rise to concern. This is particularly important if the tests are being administered by an assistant. Such protocols should include emergency contact information for the responsible researcher.

a. A requirement that testing is only undertaken when other colleagues are on site – out of hours and off-site testing should be avoided if possible.

b. Clear guidance about the limits of pressure to exert for continuation of testing; how to abandon testing if the circumstances point to such a decision; and where and how to record this, in addition to making a note in the test log (see 14).

c. Protocols, established in advance, to cover certain contingencies. These should include a section on dealing, if necessary immediately, with test results that may have implications for the welfare and clinical management of participants; the people to be informed, such as the responsible clinician/team; and if relevant, the participant's GP. A record should be made in the research log if one is being kept (see 14 below) about the event and action taken, signed, with date and time of entry.

d. If the Principal Investigator is not carrying out the testing, clear arrangements need to be put in place to inform assistants of these protocols and to ensure they have been understood and are implementable.

14. Good practice should include a written, signed, timed and dated log of all testing. The place of testing should also be noted. The main purpose of the log is to record incidents that may impact on the quality of the test data and to provide a detailed description of events should any untoward incidents arise in the course of testing or subsequently.

    a. This should be done if possible in a bound notebook or, if electronically, in a system that allows tracking of modifications to the record.

    b. Any alterations to the log should be signed and dated.

    c. Information in such a log can also be useful if there are concerns later about unusual test data.

Further information

Please see the Society website (www.bps.org.uk) or the Psychological Testing Centre website (www.psychtesting.org.uk).

Further information can also be obtained from the Society's Leicester address:

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St Andrews House, 48 Princess Road East
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The following publications are available from the Psychological Testing Centre's website:

- *The Code of Good Practice for Psychological Testing*
- *Test User's Handbook*
- *Psychological Testing: A User's Guide*
- *Psychological Testing: A Test Taker's Guide*

References

(References marked with * are available via the Society website. Department of Health documents are available through the DoH (England) website.)

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DoH (2006). *Records management: NHS code of practice, Parts 1 & 2.* London: DoH.

NHS NRES (2010). *Standard operating procedures for research ethics committees, version 4.1.*

Appendix – additional Society resources

British Psychological Society (2005).* *Good practice guidelines for the conduct of psychological research within the NHS.*

British Psychological Society (2007).* *Conducting research on the internet: Guidelines for ethical practice in psychological research.*

Dobson, C. (2008).* *Conducting research with people not having the capacity to consent to their participation. A practical guide for members.*

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