Guidelines for safe and effective near-patient testing (NPT)

Soft Release (Beta) Version

Approved for soft release by the National Near-Patient Testing (NPT) Consultative Group, Dublin, Ireland

April 20,2020

(This version is valid until April 20,2021)

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Chairman's foreword (soft release version)

During 2019, the National Near-Patient Testing (NPT) Consultative Group revised the Irish National Near-Patient Testing Guidelines. Due to the unique circumstances of the coronavirus pandemic, we have released this final Beta-Version on April 20, 2020 in the interests of having an updated authoritative guideline available and to provide an opportunity for early feedback. We intend to complete full formal consultation and approvals within 1 year from the date of issue. Comments on this version should be emailed to pathology@rcpi.ie, before April 30, 2020.

This soft-release version is valid until April 20, 2021.

Near-patient testing (NPT) aims to improve patient outcomes through provision of a laboratory medicine service by healthcare professionals using small analytical devices provided near to the patient rather than from a clinical laboratory.

The first Irish NPT guidelines were published in 2007 in two separate booklets covering hospital settings and primary and community care. Terminology has also moved full-cycle with the term NPT now re-introduced and replacing point of care testing (POCT) in the EU's latest IVD Regulation. This updated guideline uses the term NPT throughout, and it also covers all healthcare sectors in a single guideline. Patient self-testing is not covered by the term "NPT" and is excluded from this guideline.

The present and previous Irish guidelines stem from the work of the National NPT Consultative Group which convenes under the auspices of the Faculty of Pathology of the Royal College of Physicians of Ireland and represents national laboratory medicine organisations and regulatory bodies with an interest in NPT. Originally founded in 2006, this group now includes representatives from the Faculty of Pathology of the Royal College of Physicians of Ireland, the Association of Clinical Biochemists in Ireland, and the Academy of Clinical Science and Laboratory Medicine. The Health Products Regulatory Authority (the regulator for medical devices and IVDs in Ireland) and the pharmacy regulator (the Pharmaceutical Society of Ireland) are also represented. The National Clinical Programme in Pathology has been represented by both its former and current clinical leads.

The terms of reference of the group are to maintain guidelines for safe and effective NPT in Ireland and to disseminate the guidelines to the major stakeholders. The group also conducts surveys on NPT including compliance with the guidelines. This revision of the guidelines is timely given the recent updates to ISO 22870 in 2016, the imminent implementation of the new IVD Regulation 2017/746/EU in 2022, the introduction of NPT accreditation to ISO 15189/22870 standards by the Irish National Accreditation Board, and the expected roll-out of the national medical laboratory information system (MedLIS) in 2020.

These guidelines should be adopted by those responsible for NPT in Irish hospitals, to ensure that risks to patient health and safety are minimised. Given the active development of primary care centres with potential for on-site diagnostics capability, a framework for primary and community care organisations, community pharmacists and the IVD industry is also included.

Finally, I wish to thank the current and past members of the consultative group who gave their time generously and patiently during the original production and subsequent revision of these guidelines.

Gerard Boran
Chairman, on behalf of the NPT Consultative Group, April 20, 2020

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Version control

Soft Release (Beta) Version 5.7, released April 20, 2020. Valid until April 20, 2021

Glossary and abbreviations

CAP	College of American Pathologists
CE Mark	The CE mark that appears on an IVD or on its packaging means that the device satisfies the relevant essential requirements of the IVD Directive 98/79/EC and is fit for its intended purpose as specified by the manufacturer. Under the IVDR, the 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.
CEN	European Committee for Standardisation
CIC	Connectivity Industry Consortium, formed by the IVD industry to address connectivity solutions for NPT IVDs
CLSI	Clinical Laboratory Standards Institute (USA), formerly the National Committee for Clinical Laboratory Standards.
Competent Authority	The competent authority is the body which has the authority to act on behalf of the government of a member state to ensure that the requirements of the Medical Device Directives / Regulations are carried out in that particular member state.
EQA	External quality assurance
EU	European Union
EUDAMED	A centralised electronic system which will allow manufacturers to report serious incidents and other reportable events. This will also allow the public to be adequately informed about devices on the European market.
FDA	Food and Drugs Administration (USA)
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
GDPR	General Data Protection Regulations 2016
GP	General practitioner
HIV	Human immunodeficiency virus
HL7	Health level 7 provides a framework for the exchange, integration, sharing, and retrieval of electronic health information.

HPRA Health Products Regulatory Authority

ICT Information and communication technologies

IEEE Institute of Electrical and Electronic Engineers

IEQAS Irish external quality assessment scheme

IFCC International Federation of Clinical Chemistry

IFU Instructions for use

INAB Irish National Accreditation Board

IQC Internal quality control

ISO International Organisation for Standardisation

IVDR In-vitro Diagnostic Medical Device Regulation EU2017/746

IVD *In-vitro* diagnostic medical device. According to the IVD Directive 98/79/EC an IVD is defined as any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures

Under the IVD Regulation 2017/746/EU (IVDR) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- concerning a physiological or pathological process or state
- concerning congenital physical or mental impairments
- concerning the predisposition to a medical condition or a disease
- to determine the safety and compatibility with potential recipients
- to predict treatment response or reactions
- to define or monitoring therapeutic measures

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices.

JCCLS	Japanese Committee of Clinical Laboratory Standards
NIMIS	National medical laboratory information system
NCCLS	National Committee for Clinical Laboratory Standards
NPT	Near patient testing
POCT	Point of care testing
POCT1-A, POCT1-A2, POCT- 2P	This is the internationally accepted connectivity standard described in the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) POC Connectivity Approved Standard (NPT1-A2, the 2005 draft modification of POCT1-A). This was a co-operative effort of providers, manufacturers and representatives of CIC, NCCLS, HL7, IEEE, CAP, FDA, JCCLS, and the IFCC. POCT1-A2 is the latest iterations of the standard in 2005, and POCT-2P is a proposed guideline on implementation of NPT connectivity standards for healthcare providers.
PSI	Pharmaceutical Society of Ireland
RICO	Regional integrated care organisations
SOP	Standard operating procedure
UDI	Unique Device Identifier
US	United States
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Examples of when validation is required could include use of non-standard methods, use of laboratory designed or developed methods, significant modification to validated methods, use of standard methods outside their intended scope (such as sample types not included in manufacturer's specifications), changes involving new technology, or significant parameter changes (e.g. reagents, equipment, time, temperature).
Verification	Confirmation, through provision of objective evidence, that specified requirements have been fulfilled. However, verification is different to validation in that it is the demonstration of the performance characteristics previously found during method validation in the laboratory where it is intended to be used. Verification will demonstrate that a validated method, kit, reagent or equipment which is used without modification, can be satisfactorily performed by the user, and meet defined criteria and end user requirements. Examples of when verification is required could include: implementation of international, regional or national standard methods, use of manufacturer validated kit, reagent or equipment, used as specified and without deviation.

Chapter 1

Executive summary and recommendations for safe and effective NPT

1.1 Overall aims of this guideline

This document provides guidance for safe and effective NPT, using IVDs that are fit for purpose and operated by a competent individual on the correct patient, giving quality results which should become part of the patient record.

1. All NPT in hospital settings should be accredited to ISO 15189/22870 standards and meet the requirements as described in this guideline.

2. It is strongly recommended that community healthcare facilities including primary care centres establish a close link with their local hospital pathology service to ensure NPT is provided in a safe and effective manner and to be ultimately accredited to the required ISO 15189/22870 standards. This can only be achieved in conjunction with the local hospital pathology service.

3. Pharmacies providing NPT services should follow the Guidance on the Provision of Testing Services in Pharmacies from the Pharmaceutical Society of Ireland, and should be aiming for ISO 15189/22870 accreditation as an ultimate goal.

4. The date of application of the new IVDR is May 2022. The IVDR and role of the HPRA are described in detail in Chapter 6. The role of the Irish National Accreditation Board (INAB) in relation to accreditation is also outlined in this chapter.

1.2 Scope

The aim of this document is to provide guidance and recommendations on the implementation and management of safe and effective NPT in both hospital and community settings.

It is intended to assist those responsible for the delivery of NPT and to ensure that risks to patient health and safety are minimised. Patient self-testing is not within the scope of this document.

1.3 Key recommendations

Key Recommendations for Safe and Effective NPT

Governance	**1. Establish an NPT Steering Group and organisation-wide NPT Policy**
Commissioning	**2. Consult with local laboratory** **3. Document Case of Need involving all stakeholders**
Implementation	**4. Establish an NPT operational team** **5. Ensure all IVDs are CE marked, adequately validated and independently verified** **6. Develop standard operating procedures and protocols for all NPT** **7. Ensure that anyone performing NPT is trained and demonstrated on-going competence** **8. Implement a quality assurance programme, including performance of internal quality control and external quality assessment for all NPT** **9. Ensure patient results are reviewed and interpreted by appropriately qualified persons**
Regulation	**10. Ensure full traceability of all IVDs used, including reagents and consumables*** **11. Ensure health and safety, and waste management training for staff*** **12. Ensure all IVDs are CE marked** **13. Report adverse incidents to the designated hospital committee, the manufacturer and the HPRA** **14. Include all NPT results in patient's health record, ideally by implementing ICT connectivity**

* *Recommendations 10, 11 and 12 are required for safe implementation of NPT, and are also regulatory requirements*

1.4 Definition of NPT

A device for NPT is defined in Article 2 of the IVDR[1] as "any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional". NPT has replaced POCT as the preferred terminology in the EU's IVD Regulation[1]. NPT aims to improve patient outcomes through patient

testing using small analytical devices (such as test kits, single-use devices and analysers), provided near to the patient rather than from a central clinical laboratory.

Advances in technology have resulted in compact, easy-to-use IVDs that make it possible to carry out a range of examinations at, or close to, the patient in either a hospital or community setting. NPT may improve patient outcomes, test turn-around times and facilitate early decision making.

With the increasing use of NPT it is important that testing performed outside of a central laboratory is assured of the same quality and standards and does not represent a patient safety risk.

1.5 Accreditation of NPT

Accreditation is the process in which certification of competency, authority, or credibility is presented and enhances public confidence in medical test results. Standards for accreditation of medical testing are set by the International Organisation for Standardisation (ISO) and ISO 15189 (Medical Laboratories - Requirements for quality and competence)[2] is the standard for laboratories.

ISO 22870 (Point-of-care testing (POCT) - Requirements for quality and competence)[3] gives specific requirements applicable to NPT and is intended to be used in conjunction with ISO 15189. Increasingly regulators require laboratory tests (European Tissues & Cell Directive 2004/23/EU)[4] to be accredited to ISO 15189. With increasing use of NPT it is important that patients and health care providers have confidence that NPT results are of similar quality to laboratory tests. NPT can only be accredited to ISO 22870 in conjunction with ISO 15189.

INAB is the national body with responsibility for accreditation of laboratories and NPT and is the sole accreditation body for Ireland in line with regulation EC/765/2008[5].

Accreditation of laboratories and NPT ensures that any risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that facilitates:

- evaluation of new or alternative NPT instruments and systems,
- evaluation and approval of end-user proposals and protocols,
- purchase, installation and maintenance of equipment,
- maintenance of consumable supplies and reagents,
- training, certification and recertification of laboratory / NPT system operators,
- quality control and quality assurance,
- connectivity.

1.6 Requirements for safe and effective NPT

Both national guidelines and ISO standards require that every facility which provides NPT should have a NPT policy consistent with these guidelines.

There are still significant gaps in accreditation throughout all healthcare sectors, for both NPT and central laboratory testing. Whereas it is acknowledged that many healthcare facilities are on a journey towards full accreditation of all laboratory and NPT services, full accreditation is nevertheless the goal to minimise risk and ensure optimal patient safety.

The advent of the more stringent IVD Regulation 2017/746/EU[1] and the imperative to provide safe and effective pathology services regardless of location or technology used further emphasises this requirement.

1. All NPT in hospital settings should be accredited to ISO 15189/22870 standards and meet the requirements as described in this guideline.

2. It is strongly recommended that community healthcare facilities including primary care centres establish a close link with their local hospital pathology service to ensure NPT is provided in a safe and effective manner and to be ultimately accredited to the required ISO 15189/22870 standards. This can only be achieved in conjunction with the local hospital pathology service.

3. Pharmacies providing NPT services should follow the Guidance on the Provision of Testing Services in Pharmacies[6] from the Pharmaceutical Society of Ireland (updated October 2019), and should be aiming for ISO 15189/22870 accreditation as an ultimate goal.

4. The date of application of the new IVDR is May 2022. The IVDR and role of the HPRA are described in detail in Chapter 6. The role of the Irish National Accreditation Board (INAB) in relation to accreditation is also outlined in this chapter.

Recommendation 1: Establish an NPT steering group and organisation-wide NPT policy.

Where NPT services are provided, a system for clinical and managerial governance should be established including a person designated as responsible and accountable for the service.

- Satisfactory accountability for NPT services is achieved by the establishment of a multidisciplinary NPT steering group with responsibility to develop and oversee an organisation-wide NPT policy.

- In hospital settings, the NPT steering group is usually accountable to the executive management team via the director of pathology and chaired by a laboratory consultant.

- In all settings, regular consultation and representation from appropriate local laboratory disciplines (inclusive of all users) play a vital role in this group.

- The NPT steering group should implement a NPT policy to ensure compliance with relevant legislation, regulations, and current accreditation standards governing the use of NPT services:
  - relevant European and National legislation,
  - laboratory accreditation standards (EN ISO 15189 and EN ISO 22870),
  - HSE requirements, e.g. medical records,
  - risk management requirements,
  - infection control and prevention requirements,
  - data protection regulations.

- NPT service development requests should be evaluated by the NPT steering group to ensure that clinical need and effectiveness are defined before a NPT service is introduced and that quality objectives are defined and subsequently evaluated.

- The NPT steering group should review and monitor quality objectives as required and have the authority to withdraw and/or suspend a service in the event of a safety-related or performance issue or lack of clinical effectiveness.

Recommendation 2. Consult with local laboratory.

The clinical laboratory is a source of expertise on NPT and has an essential role in the leadership and co-ordination of NPT, in hospital settings and for local general practitioners (GP). Proposals for new NPT in the hospital setting should always involve detailed consultation with the local laboratory.

In community and primary care settings, it is advisable that providers of NPT are aware of laboratory services in their locality which can provide specialist advice and expertise if required. Communication between the hospital and primary and community care sectors is advised.

- NPT should not be considered when the local laboratory can provide a result in a timely manner appropriate to the clinical condition.

- Note that confirmatory testing in the local accredited laboratory may be required in certain conditions (such as for out-of-range or critical NPT results).

Recommendation 3. Document the case of need involving all stakeholders.

A case of need should be prepared by those proposing a new NPT service in conjunction with all relevant stakeholders including the laboratory. For example, dialogue and close cooperation may be required between local hospitals, GPs, pharmacies, patients, and representative bodies depending on the nature of the NPT under consideration to ensure the proposed NPT is fit for purpose and all patient safety risks have been considered.

Clear evidence of clinical need and effectiveness must be available before a new NPT service is introduced. A business case and cost-benefit analysis is also usually required, either as part of or separate from the case of need.

Recommendation 4. Establish an NPT operational team.

NPT operational team(s) with relevant personnel should be appointed to oversee the day-to-day operation of NPT. Each operational team must be adequately resourced to enable them to implement, monitor and audit the day-to-day NPT policy.

Recommendation 5. Ensure all IVDs are CE marked, adequately validated and independently verified.

In compliance with ISO 15189 test procedures should be subjected to independent verification before being introduced to provide objective evidence that the test procedure and/or IVD used is fit for purpose.

-Test methods are verified under conditions of normal use by use of blank samples, control samples, duplicate samples, calibration checks, IQC monitoring and EQA performance.

- Aspects of verification should include sensitivity and specificity, accuracy and precision, repeatability, reproducibility, limits of detection, limit of quantitation and comparability to existing laboratory methods if available.

- Where possible, a backup laboratory method should be available for any NPT to provide confirmatory testing, and the comparability of NPT results with central laboratory results should be established. If none available an alternative system of verification should be considered.

NPT should be subject to on-going monitoring to verify accuracy and comparability of the results to those of the central laboratory.

Recommendation 6. Develop standard operating procedures and protocols for all NPT.

Protocols should be developed and implemented for all NPT services. Standard operating procedures (SOP) should be developed and implemented for all aspects of the NPT service, including the performance of the test, record keeping, interpretation of results, patient referral criteria, expert laboratory guidance, quality assurance, patient and staff health and safety.

Recommendation 7. Ensure that anyone performing NPT is trained and on-going competence is assessed.

It is imperative that all staff performing NPT receive documented training and are competent in the use of the test. Records should be kept of staff who have been trained in carrying out and/or interpreting test results.

- Implement a mandatory staff training and competency programme.

Recommendation 8. Implement a quality assurance programme, including internal quality control and external quality assessment for all NPT.

Accreditation requires all laboratories and NPT users to have a rigorous quality management system in place, including at a minimum internal quality control (IQC) and external quality assessment (EQA). IQC must be performed on IVDs in accordance with the manufacturer's instructions, to ensure the accuracy of the test result generated. NPT providers must also participate in an appropriate EQA scheme. In the event that a suitable NPT EQA scheme is not available commercially, an equivalent arrangement must be developed with the local laboratory. Both IQC and EQA are key to assuring the accuracy and reliability of a NPT service. The two procedures are complementary.

- IQC primarily monitors day to day reproducibility (precision) and detects systematic errors in any one day's procedures. IQC samples are commercially available with known concentrations of analytes. Mean values are established for both normal and abnormal levels by repeated estimations by the laboratory or NPT operational team. Patient samples should only be run when controls are within the acceptable range.

- EQA aims to ensure that test results are reliable and comparable no matter where they are performed. Participants in an EQA scheme test samples with unknown values and the result(s) are returned to the EQA organiser. A report is then provided to participants that compares the submitted result with a target value. The participant can also see how they compare to other sites. Analytical quality is determined by assessing the difference between the result and the target value. There are national and international schemes available.

Recommendation 9. Ensure patient results are reviewed and interpreted by appropriately qualified persons.

Patient results should only be reviewed or interpreted by appropriately trained personnel whose identity should be recorded in all cases.

Appropriate referral criteria should be in place which may include referral to a local hospital or GP. Confirmatory laboratory testing is also required for some conditions such as diabetes mellitus where NPT is not considered acceptable for diagnosis[7-8].

A procedure for communication of critical NPT results should be in place. For many tests, grossly abnormal or clinically unexpected NPT values require confirmatory testing using a laboratory method. Appropriate referral criteria should be in place to ensure that confirmatory testing is performed and patients are referred for further medical attention as necessary.

All patient and quality control results should be recorded appropriately either via paper or electronic format in accordance with defined procedures and the General Data Protection Regulations (GDPR)[9]. This should also include specific test batch numbers as appropriate, the date and time of analysis and operator identification. Patient results must be recorded in the patient's health record.

Recommendation 10. Ensure full traceability of all IVDs used (including reagents and consumables).

NPT should be reviewed and monitored on an on-going basis and a test should be withdrawn or suspended in the event of a safety corrective action, for example, a recall.

Unique Device Identification (UDI) is a system used to identify and facilitate traceability and incident reporting of IVDs within the healthcare supply chain. Under the IVDR, manufacturers shall assign and maintain unique UDIs for their IVDs.

- There should be full traceability of all NPT IVDs, reagents and consumables used to facilitate incident reporting and to ensure appropriate action is taken in the event of a Field Safety Corrective Action (for example a recall or other market action for safety reasons).

- Recording of specific batch numbers is important in the event of a recall by the manufacturer or other market action for safety reasons.

- A system to review and take action on Field Safety Notices (FSNs) issued by IVD manufacturers should be in place.

- In addition, systems should be in place to review and take action where appropriate on safety notice / information notices and any other communications issued by the HPRA and any other relevant bodies.

Recommendation 11. Ensure health and safety and waste management training for staff using NPT.

Appropriate health and safety training and waste management training should be provided to staff performing NPT.

The organisation must provide appropriate facilities, premises, and NPT service delivery areas which are fit for purpose and comply with relevant health and safety legislation, building and fire regulations.

A procedure must be in place for the safe disposal of biological waste and/or sharps in accordance with the appropriate health and safety and/or infection control legislation.

Recommendation 12. All IVDs must meet national and European IVD legislative requirements.

NPT devices must be CE marked as this is an indication that the device meets the requirements of the relevant legislation.

- Only IVDs that are approved by the NPT steering group should be used for NPT. This requirement should apply to all IVDs irrespective of whether they have been purchased, loaned, gifted or leased to the organisation.

Recommendation 13. Report adverse incidents to the designated committee, the manufacturer and the HPRA.

All adverse incidents that occur with NPT devices must be reported to the designated hospital committee, and should be reported to the manufacturer, the HPRA, and the appropriate regulatory body if necessary. The HPRA website has an online tool and a downloadable form to facilitate reporting of adverse incidents.

Recommendation 14. Include all NPT results in the patient's health record, ideally by implementing ICT connectivity.

Patient results must be recorded in the patient's health record.
NPT IVDs should be password-protected and only accessible by certified users.[10] Breeches of ICT governance including password sharing precludes effective audit and is a risk to quality and patient safety.

Connectivity allows central recording of patient results and quality parameters and should be resourced to a level which avails of the latest technology including password-protection of analysers, integration of results with the patient's electronic healthcare record, operator identification, and unique patient identification.

Connectivity also facilitates remote monitoring of NPT analysers from a hub in the local laboratory or manufacturer for on-going analytical performance, fault diagnosis, preventative maintenance, and trouble-shooting in the event of problems.

1.7 Conclusion

The implementation of the recommendations in this guideline, which replaces the two previous Irish guidelines[11-12,] should facilitate a well-managed and appropriately governed system for the provision of NPT services which, if properly used, will deliver considerable benefits to the Irish health service and will minimise risks for patients.

1.8 Chapter references

1. In-Vitro Diagnostic Medical Device Regulation 2017/746/EU. HPRA website. Accessed 18/4/2020.

2. I.S. EN ISO 15189:2016 (Medical Laboratories - Requirements for quality and competence). NSAI website (purchase required). Accessed 18/4/2020.

3. I.S. EN ISO 22870:2016. Point-of-care testing (POCT) - Requirements for quality and competence. NSAI website (purchase required). Accessed 18/4/2020.

4. European Tissues & Cell Directive 2004/23/EU. Accessed 18/4/2020.

5. Regulation (EC) No 765/2008. EUR-Lex (Access to European law). Accessed 18/4/2020.

6. Guidance on the Provision of Testing Services in Pharmacies. Pharmaceutical Society of Ireland, Version 3, October 2019. PSI website. Accessed 18/4/2020.

7. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Report of a WHO Consultation. World Health Organisation, 1999. Accessed 18/4/2020.

8. Sacks DB, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care 34(6): e61-99, 2011. Accessed 18/4/2020

9. General Data Protection Regulation: Information on EU data protection rules and GDPR download, European Commission. Accessed 18/4/2020.

10. HSE Passwords Standard Policy. HSE website. Accessed 18/4/2020.

11. Guidelines for Safe and Effective Management and Use of Near Patient Testing in Primary and Community Care, 2008. HPRA website. Accessed 18/4/2020.

12. Guidelines for Safe and Effective Management and Use of Point of Care Testing. 2007. HPRA website. Accessed 18/4/2020.

Chapter 2

Definition, uses and risk/benefit analysis for NPT

This chapter defines NPT and gives an overview of the current uses for NPT as well as a risk/benefit analysis.

2.1 Definition of NPT

A device for NPT has recently been defined under the IVDR[1] (Article 2) as any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional. Accordingly, any NPT device operated by any health professional and used in either hospital or primary care/community settings is included.

Devices that are used by patients or other individuals for self-testing are not covered by the term NPT and are outside the scope of this guideline.

Pending implementation of the new IVDR in 2022, all IVDs used for NPT are currently regulated under the IVD Directive 98/79/EC[2]. The HPRA is designated as the competent authority for medical devices and IVDs in Ireland. Its role is to ensure that all IVDs placed on the Irish market comply with the essential requirements of the IVD Directive and related national legislation.

There is a statutory obligation on manufacturers to notify the HPRA of all adverse incidents involving IVDs. Direct user reporting to the HPRA, although not mandatory, is strongly encouraged. There is also a requirement to report to risk management groups in accordance with the local organisation's policy.

2.2 Existing and emerging uses for NPT

NPT remains mostly confined to the hospital setting. However, the range of NPT tests in the hospital sector has broadened and the volume of tests performed is now very large. It is now commonplace for blood gas analysers, glucose-measuring devices (glucometers), blood ketones, pregnancy testing, coagulometry, drugs of abuse and occult blood to be widespread throughout hospitals. Microbial and other maternity specific testing such as fibronectin are increasingly used.

NPT devices produce a rapid test result in the immediate vicinity of the patient often in areas such as the emergency department, intensive care unit or other designated areas of the hospital. The rapidity of obtaining a result can increase clinical effectiveness and contribute to improved outcomes for patients, but it is imperative that the result provided by the device is accurate, reliable and visible in the patient's health record.

NPT IVDs currently available on the market encompass all laboratory medicine disciplines. Table 2.1 provides examples of NPT currently in use in a hospital setting. The types of samples used for NPT include whole blood, urine, serum, stool and saliva.

TABLE 2.1

Examples of applications available on NPT devices in a hospital setting

Blood gases, co-oximetry, electrolytes, lactate, renal function, haemoglobin
Cardiac biomarkers, renal markers, bilirubin, creatinine, ionized magnesium, procalcitonin
Cholesterol, triglyceride and high-density lipoprotein cholesterol (HDL-C)
Blood glucose
Blood ketone
Haemoglobin A1c
Alcohol and toxicology (paracetamol, drugs of abuse)
Intra-operative PTH measurement
Urinalysis (with or without a reader)
Urine albumin and albumin/creatinine ratio
Placental alpha microglobulin-1 (PAMG-1)
Detection of pregnancy and ovulation
Stool occult blood
Fibronectin

Anticoagulant therapy monitoring – INR
Activated clotting time
D-dimer
Thromboelastometry
Full blood count

Infections (chlamydia, human immunodeficiency virus, hepatitis B, Hepatitis C, influenza virus)
SARS-CoV-2 diagnostics including molecular assays and serological antibody tests[2]

The improved reliability and range of NPT devices is leading to an increased use in community clinics and GP surgeries. Table 2.2 provides examples of NPT currently in use in a community setting.

TABLE 2.2

Examples of applications available on NPT devices in a community setting

Blood glucose
HBA1c
Cholesterol, triglyceride and high-density lipoprotein cholesterol (HDL-C)
Detection of pregnancy and ovulation
Urinalysis (with or without a reader)
Stool occult blood

Anticoagulant therapy monitoring

Infections (chlamydia, human immunodeficiency virus)
SARS-CoV-2 diagnostics including molecular assays and serological antibody tests[2]

2.3 Risks and benefits of NPT and the need for confirmatory testing

When a healthcare professional undertakes a pathology test adjacent to the patient rather than sending samples to a central laboratory, there is an expectation that the faster result turnaround will improve patient care. However, a faster result is only better when it is an accurate result i.e. no pre – analytical errors, equipment fit for purpose and operated by a fully trained and competent operator.

This document provides guidance for safe and effective NPT, using IVDs that are fit for purpose and delivered by a competent individual for appropriate patients, producing quality results which become part of the patient record.

The major risks to the delivery of safe and effective NPT arise from:

- poor operator training and lack of competency assessment
- lack of appropriate supervision, governance and accreditation of the NPT service
- failure to use internal quality control and/or external quality assessment schemes
- inappropriate testing by inexperienced personnel
- uncertainty on how to act on results

Advances in technology and legislative control have also resulted in more reliable instrumentation. However, users need to be aware that NPT is rarely a replacement for the conventional laboratory services, but rather a supplement to it.

In situations where critical clinical decisions are made on NPT results and where out-of-range results are obtained, confirmatory testing by the central laboratory may be required by the local NPT policy**.**

Though analytical results are provided more rapidly with NPT there are concerns about the reliability of results obtained by non-laboratory personnel.

Incorrectly performed testing or inappropriately interpreted results can put patients at risk. In some situations, it may be more appropriate to have analyses performed in a clinical laboratory. The provision of NPT should not be considered when the laboratory can provide the result in a timely manner, appropriate to the clinical condition.

2.4 Unnecessary testing and financial risks

There are financial risks associated with excessive or unnecessary NPT. The cost per test of NPT generally exceeds that of the clinical laboratory so inappropriate or excessive testing can significantly increase expenditure.

Staff costs for NPT can be substantial but are rarely identified as such in hospital budgets. Higher NPT costs may however be offset by more efficient use of resources in other areas of healthcare delivery. A comprehensive cost benefit analysis addressing these matters should be undertaken before deciding to implement a new NPT service.

2.5 Chapter references

1. In-Vitro Diagnostic Medical Device Regulation 2017/746/EU. HPRA website. Accessed 18/4/2020.

2. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Accessed 19/4/2020

3. Cheng MP, et al. Diagnostic testing for severe acute respiratory syndrome-related coronavirus-2: a narrative review. Ann Intern Med, April 13, 2020. DOI: 10.7326/M20-1301 (online). Accessed 19/4/2020

Chapter 3

Governance and management of NPT services: the role of the NPT steering group

Clinical governance is a systematic approach to maintaining and improving the quality of patient care and controlling clinical risk. It is an essential part of any NPT service and is best delivered by establishing a multidisciplinary NPT steering group. The overall approach and inter-relationship between NPT steering group and other stakeholders is summarised in Figure 1 which applies to all healthcare sectors considering NPT.

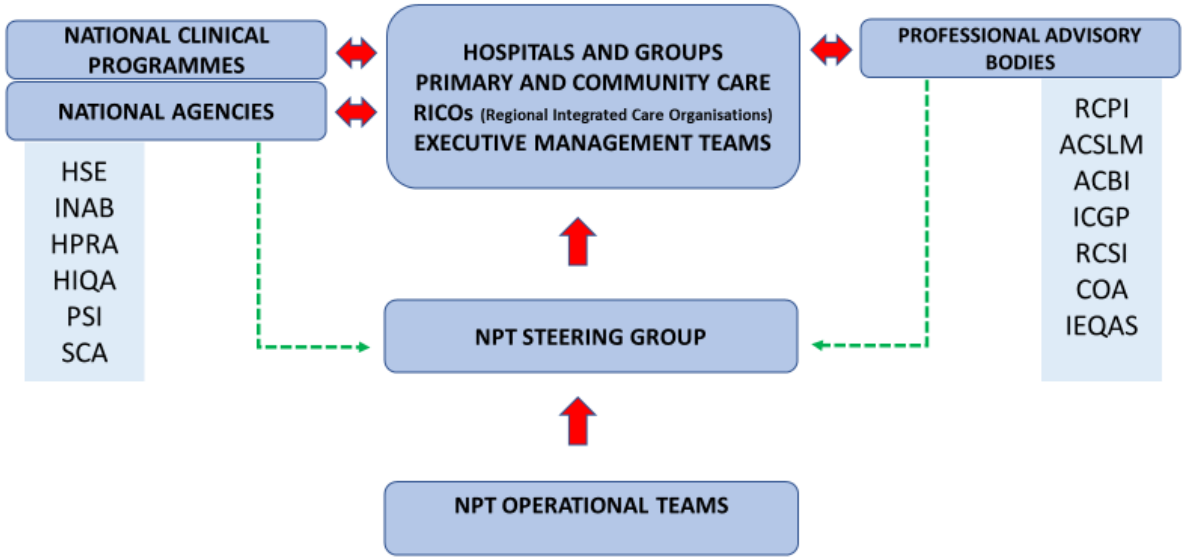

Figure 1. Clinical governance schema for NPT

3.1 Responsibility for NPT services

The primary purpose of the NPT service is to facilitate timely, evidence-based decision making in the diagnosis and treatment of patients by ensuring the delivery of safe, effective, quality-oriented tests at or near to the patient's bedside.

The NPT steering group will be accountable for the delivery of all NPT services. The chairperson of this group will usually be a laboratory consultant. Laboratory consultants from participating disciplines will provide direction for their particular NPT service. A person with overall responsibility for co-ordination must be designated for each NPT service, whether existing or proposed. This will usually be a senior laboratory scientist from the appropriate pathology discipline and will be a member of the NPT steering group.

The NPT steering group should be accountable to the organisation's executive management team, whether in the hospital sector or a primary or community care organisation. A formal link with the local pathology directorate is desirable. A template for the NPT steering group including terms of reference can be found in Appendix 1.

Note that the existence of this governance structure does not negate the responsibility of the individual analyst to work in a competent manner. The onus is on the nurse manager or head of department of each unit utilising NPT to ensure that all authorised operators have been trained and have demonstrated competence. The individual conducting the analysis is accountable for maintaining their competence and for the results they generate using NPT devices.

Recommendation 1: Establish an NPT steering group and organisation-wide NPT policy.

3.2 Terms of reference of the NPT steering group

The NPT steering group should have the objectives set out in Table 3.1.

TABLE 3.1

Objectives of the NPT Steering Group

1. Ensure safe delivery of NPT for patients.
2. Provide clinical governance for NPT services through the development and implementation of an organisation-wide NPT policy.
3. Establish NPT operational team(s) to oversee the day-to-day running of individual NPT services.
4. Advise the organisation's executive management team on all aspects of NPT, including risk, benefits, resources required, new proposals and present and future strategy.

The NPT steering group needs to document its system for clinical and managerial governance in an NPT policy, including a person designated as responsible and accountable for the service. This should also ensure the organisation is compliant with relevant legislation, regulations, and accreditation standards governing the use of NPT services, i.e.

- relevant European and National legislation,
- laboratory accreditation standards (EN ISO 15189 and EN ISO 22870),
- HSE requirements, e.g. medical records,
- risk management requirements,
- infection control and prevention requirements,
- data protection regulations.

3.3 NPT steering group membership

The minimum recommended membership is shown in Table 3.2.

TABLE 3.2
Minimum membership of the NPT Steering Group
A laboratory consultant from participating pathology disciplines. NPT manager. A senior management representative. A senior scientist from participating pathology disciplines. The manager of each or all NPT operational teams. Clinical risk manager. Senior medical representatives from participating services. Senior nursing representatives from participating services. IT representative. Risk manager. Financial advisor.

Additional members may be included or co-opted (e.g. pharmacy, supplies, clinical engineering, infection control) depending on the needs of the local service.

3.4 Responsibilities of the NPT steering group

The range of responsibilities of the NPT steering group are given in Table 3.3. Whereas the steering group must have competence and provide oversight in all of these areas, the day-to-day operational aspects may be delegated to an NPT operational team for implementation (see Chapter 5).

TABLE 3.3
Responsibilities of the NPT steering group
1. To evaluate and approve all NPT services within the organisation against the recommendations in this guideline (including new NPT proposals and existing "legacy" NPT services), regardless of whether the NPT IVDs concerned are new, gifted, loaned, or existing. 2. Both new NPT service proposals and existing NPT services should also be evaluated to ensure that clinical need and effectiveness are defined and that there are auditable quality objectives which can be monitored. 3. NPT services which are substandard or ineffective should either be rejected or, where appropriate, recommendations can be made to achieve the required standard. 4. To review and monitor quality objectives as required and have the authority to withdraw and/or suspend service in the event of a safety-related or performance issue or lack of clinical effectiveness. 5. To ensure that only approved CE marked IVDs suitable for their intended use are used for NPT.

TABLE 3.3

Responsibilities of the NPT steering group

6. To ensure that IVDs are procured and commissioned in an appropriate manner and according to the organisation's policies.

7. To establish a register of all approved NPT sites along with an asset register of all IVDs, consumables and reagents used at these sites within the organisation, which can also facilitate incident reporting and device traceability for example in the event of a Field Safety Corrective Action (FSCA)

8. To ensure that NPT devices fulfil the requirements of National and European legislation, laboratory and hospital accreditation standards (for example: JCI, ISO) and other relevant standards.

9. To comply with HSE requirements in relation to data protection, patient confidentiality, risk management and procurement.

10. To ensure that there is a procedure to document all patient results appropriately and to transfer them to the permanent healthcare record. Results should be traceable to the location where the analysis is performed, and the operator reporting the analysis.

11. To ensure an effective system for clinical review of results, including communication of critical results and confirmatory testing.

12. To monitor and review patient-safety related incidents, including adverse incident reporting and review of safety/information notices issued by manufacturers and the HPRA.

13. To ensure that the NPT IVDs are operated only by trained and competent users using password protected access.

14. To define criteria for taking action against unsatisfactory operator performance, inappropriate use and poor quality assurance practices and for withdrawal of the IVD where appropriate.

15. To review overall NPT performance and trends identified through audit and quality assurance.

16. To ensure that there is adequate support and appropriate use of resources for NPT.

17. To support the NPT manager(s) and operational team(s).

18. Traceability. To advise the organisation regarding the need to recall/withdraw an IVD in the event of a safety or performance issue until appropriate remedial action is taken, such as a field safety corrective action.

More information on the role of NPT operational groups is provided in Chapter 5.

Traceability (see also Chapter 5) is an important role for the NPT steering group who will need to be in a position to advise the organisation of any actions needed in the event of a recall or patient safety-related issue involving an NPT IVD.

3.5 Governance issues and the IVD industry

It is strongly advised that IVD industry representatives present proposals initially to the NPT steering group preferably through the chairman, or through the NPT manager, instead of approaching individual end users directly.

It will be the responsibility of the individual contacted to inform the relevant specialties concerned. No NPT device must be put in place without the prior approval of the NPT steering group.

The IVD industry has a role in supporting the operational team with commissioning, operator training, development of documentation, auditing and on-going operation of NPT services and equipment.

3.6 Primary care

GPs should be aware of the expertise in NPT available from the local hospital laboratory service and should make use of this by obtaining advice before commissioning any NPT in their practices. The local hospital laboratory should provide support and quality assurance monitoring and should be willing to do this, resources permitting. Regional integrated care organisations (RICOs) and other primary and community care organisations should also avail of the expertise of the local hospital laboratory.

3.7 Community pharmacists

Community pharmacists should avail of the expertise in NPT available from the local hospital laboratory service and should make use of this by obtaining advice before commissioning any NPT in their practices. The local hospital laboratory should provide support and quality assurance monitoring and should be willing to do this, resources permitting.

Community pharmacists should be aware of the governance issues set out in this document and their universal applicability as well as the latest version of the Guidance on the Provision of Testing Services in Pharmacies issued by the Pharmaceutical Society of Ireland.[4]

NPT should form part of a collaborative network of care with other relevant healthcare providers. The same quality standards should apply in pharmacies as elsewhere. Hence, pharmacists should give consideration to discussing their plans with the local pathology service and GPs.

Particular attention should be given to the use of clinically and analytically validated assays, recognised units of measurement, standardised methods and comparability of results with the local laboratory.

Chapter 4

Commissioning NPT services

NPT services (both new proposals and existing services) should only be introduced in consultation with the NPT steering group and have the approval of the laboratory consultant from the appropriate discipline.

Recommendation 2. Consult with local laboratory.

4.1 Case of need and business case

All new proposals must be justified by a case of need and supported by a full business case. The commissioning process up to the point of receiving approval from the NPT steering group is illustrated in Figure 5.1.

Recommendation 3. Document the case of need involving all stakeholders.

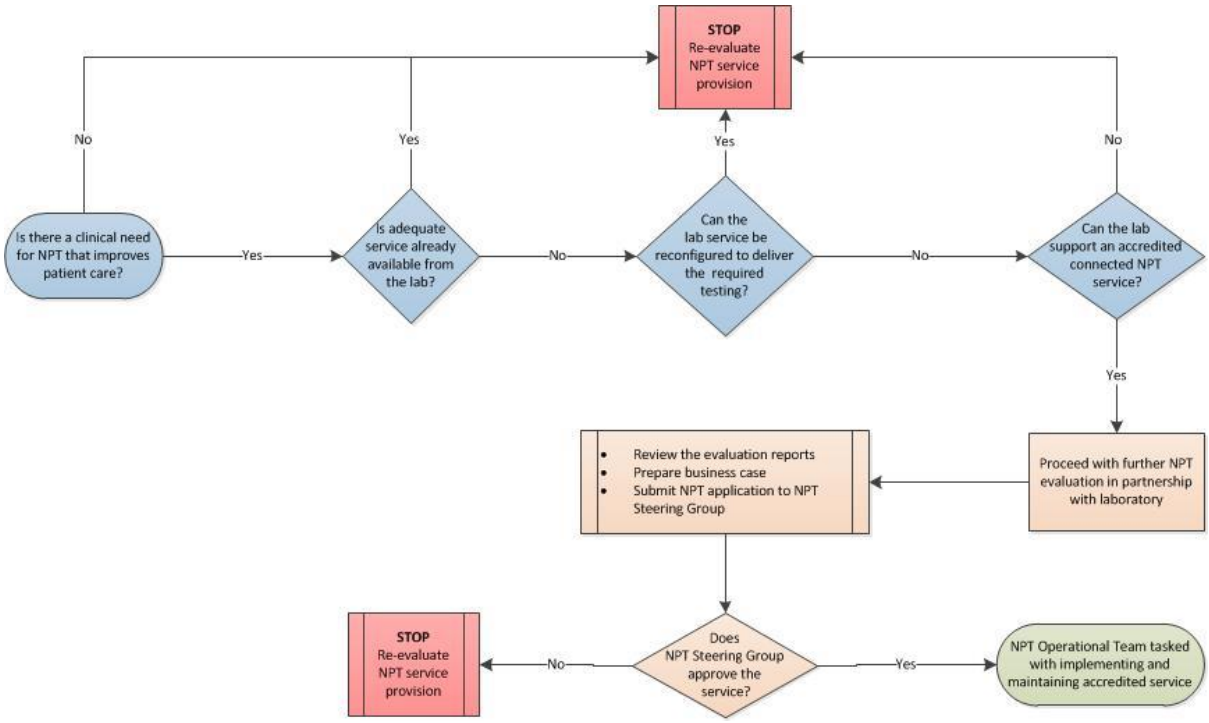

Figure 2. NPT commissioning process up to approval by NPT steering group

Appendix 2 contains an application form suitable for new NPT proposals which is intended to be completed by the end-user proposing the new NPT service, however with assistance for the more technical aspects from the laboratory. The finance department of the organisation should also assist with the business case development. Appendix 3 contains a template to help with cost-benefit analysis.

The case of need/application from should include an assessment of all options available to deliver the required pathology service, including the costs of all staff involved, training, external quality assessment schemes, equipment, reagents used, servicing and repairs. A specification of requirements (suitable for tender) and a scheduled implementation plan should be presented. It is acknowledged that increased costs associated with NPT may be offset by clinical benefits and/or cost savings achieved elsewhere in the organisation. It is also the case that improvements in turnaround time to the central laboratory frequently obviate the need for NPT.

4.2 Resources

It is important to recognise that adequate resources are required for the implementation and on-going support of NPT. A NPT manager is key to the overall operation. Link nurses are also required at ward level and a training coordinator is recommended for large organisations. Depending on the complexity and scope of NPT services, it is envisaged that the NPT management team would require dedicated staff of at least 2 whole time equivalents. These staff would often be a laboratory trained senior or specialist scientist. Ideally staff numbers should include cover for leave. The grade of chief medical scientist should be considered for very large services. A further 1 whole time equivalent designated training specialist (preferably with clinical experience i.e. nurse / pharmacist / radiographer /advanced practitioner) would also be required to coordinate the day-to day operation of NPT at ward or clinic level. Figure 3 provides an overview of the various tasks that arise once a new NPT service has been commissioned and the equipment supplied.

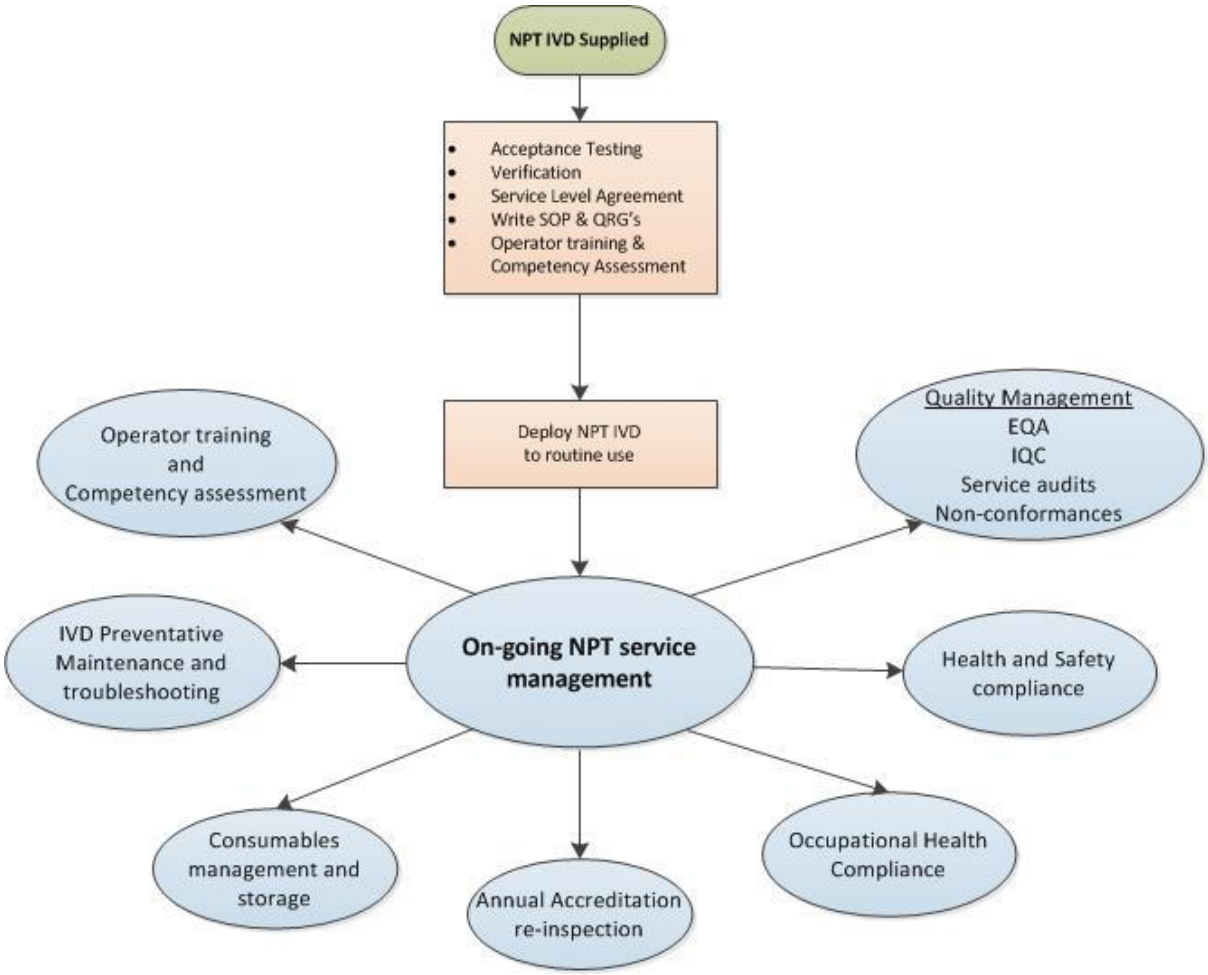

Figure 3. Various tasks involved post-approval of a new NPT service

4.3 Space

Space available must be adequate to accommodate the equipment, consumables and documentation. The location must minimise risks to the health and safety of staff and patients. It should have sufficient electrical sockets and network points or Wi-Fi coverage for the equipment. The environment should be controlled to comply with legislation and manufacturers' recommendations. A dedicated refrigerator and possibly a freezer for reagent storage should be available, if required, with temperature monitoring capability. A safe sturdy area to locate a centrifuge may also be required if serum separation is necessary. Equipment should be arranged to allow for operation in a manner that supports high quality work, internal quality control, external quality assessment, result documentation and maintenance. Provision must be made for safe disposal of sharps, clinical and non-clinical waste, and confidential information. Space requirements will vary for particular tests or groups of tests but should be defined by the laboratory discipline.

Chapter 5

Implementing NPT services

This chapter details the implementation for NPT in all settings that would be usual in order to achieve full ISO 15189/22870 accreditation (see also appendix 4 for a checklist). The NPT operational teams are responsible for implementing NPT services. All NPT services should be documented in appropriate standard operating procedures, which should be approved by the NPT steering group.

5.1 NPT operational teams

One or more NPT operational teams may be appointed by the NPT steering group to oversee the day-to-day operation of NPT services. One or more NPT managers may lead the teams.

The developmental phase of establishing operational teams may be led by a senior scientist, who may, in the established phase of NPT, hand it over to a specifically appointed laboratory scientist as NPT manager.

Recommendation 4. Establish an NPT operational team.

5.2 The role of the NPT operational team

The role of the teams is described in Table 5.1.

TABLE 5.1

Role of the NPT operational teams

1. To develop standard operating procedures for pre-analytical, analytical and post-analytical processes for each NPT device.
2. To develop a system for training, competence assessment, certification and registration of operators which includes maintaining a register of certified trained users and provision of secure operator identity codes for the NPT service access.
3. To implement and monitor quality assurance programmes, both internal and external (where available), for the IVD and review on-going performance using a quality management system.
4. To validate and compare the NPT method with the current laboratory method and provide comparative data for review by the NPT steering group.
5. To ensure that audits are conducted and appropriate corrective action is implemented where necessary.

TABLE 5.1
Role of the NPT operational teams
6. To ensure that the adverse incident reporting policy is adhered to and that non-conformance reports are completed and reviewed. 7. To establish a procedure for service and maintenance of IVDs in accordance with manufacturers' instructions. 8. To maintain a system to support Field Safety Corrective Actions (FSCA) - market actions undertaken by a manufacturer for safety reasons. For example, a recall or withdrawal of an IVD or its associated reagents and consumables. 9. To advise the NPT steering group on appropriate actions (e.g. whether to withdraw/quarantine NPT IVDs) due to a safety or performance issue, until appropriate remedial action is taken, such as a Field Safety Corrective Action (FSCA) by a manufacturer.

5.3 Validation and verification of NPT IVDs

Recommendation 5. Ensure all IVDs are CE marked, adequately validated and independently verified.

It is essential that all NPT IVDs carry a CE mark – this marking is described further in Chapter 6 (Regulatory requirements). ISO 15189 also requires that test procedures are adequately validated and undergo verification by the laboratory (independently of the manufacturer) before being introduced to provide objective evidence that the IVD is fit for purpose.

- Test methods are verified under conditions of normal use by use of blank samples, control samples, duplicate samples, calibration checks, IQC monitoring and EQA performance.

- Aspects of verification should include sensitivity and specificity, accuracy and precision, repeatability, reproducibility, limits of detection, limit of quantitation.

- Where possible, a backup laboratory method should be available for any NPT to provide confirmatory testing, and the comparability of NPT results with central laboratory results should be established.

NPT should undergo on-going verification of IVD results and on-going monitoring to ensure continued accuracy and comparability of the results to those of the central laboratory.

A QMS should ensure there is on-going verification of IVD results.

5.4 Develop standard operating procedures for NPT

Recommendation 6. Develop standard operating procedures and protocols for all NPT.

Protocols should be developed and implemented for all NPT services. Written operational procedures (including quick reference guides) must be available for all point of care analyses. These procedures must include instructions on the operation and maintenance of the equipment, internal quality control procedures, safe working practice and identified risks, the interpretation of error messages and the recording of results. Procedures should clearly identify mechanisms for communication of failures and spurious results to the NPT operational team. These operational procedures should be controlled documents and should be linked to the laboratory or other quality management systems.

5.5 Training

Recommendation 7. Ensure that anyone performing NPT is trained and demonstrates on-going competence.

All staff involved in NPT must be trained and competent in the use of the IVD (see Appendix 8 for a training record template). The training and certification of NPT users should be overseen and monitored by the NPT operational team.

Training may be provided by the NPT operational team directly, by dedicated staff members as part of a cascade trainer programme under guidance of the NPT operational team and /or the manufacturer or manufacturer's representative again under guidance of the NPT operational team. All trainers should undergo witness audits to ensure conformity of training for all devices. Many of the vendors have established training programmes. Externally provided training tools such as presentations and documentation should be reviewed, modified to suit local needs and approved by the local NPT operational team.

Advantage could be taken of e-learning programmes.

Only staff whose training and competence has been established and recorded should be permitted to perform NPT and access to the equipment must be restricted to these staff. It is the responsibility of all users of NPT devices to attend the training sessions provided and to attain and maintain competence on the relevant NPT devices at intervals as defined by the NPT operational team.

The topics described in Table 5.2 should be included in the staff-training programme for NPT.

TABLE 5.2
Components of a NPT staff training programme
Instructions on safe working practices. Principles of operation of the IVD including daily maintenance requirements

TABLE 5.2

Components of a NPT staff training programme

Action on improper and unsafe use of a NPT IVD.

Review of the manufacturer's instructions for use, basic principles of the analysis, limitations of the IVD, interferences including drugs and antibodies, unsuitability for use scenarios (e.g. patient perfusion, surgical intervention).

Review and understanding of error messages, interpretation and appropriate responses.

Calibration and internal quality control requirements, to include performance, appropriate record keeping and required actions for failed results.

Patient preparation, sample collection and handling according to health and safety regulations and the manufacturer's stated requirements and the effects of pre-analytical interferences including site preparation, pre-existing infusions, air bubbles and time from draw analysis.

Recording of patient results, interpretation of results, appropriate responses to critical results, confirmatory testing procedures, contacting the NPT operational team, and obtaining clinical advice for out-of-range and spurious results.

Facilitating the assignment of operator identification numbers to trained certified NPT users

Inclusion in the register of certified trained users and notification of the programme for retraining and monitoring.

Inventory management for NPT IVDs and their associated reagents and consumables and all operators including retraining intervals and ongoing competency assessment processes

Procedure for recording of adverse incidents with IVDs including documentation, investigation, reporting to the NPT operational team, NPT steering group, and manufacturer where required.

Procedures for receiving and actioning Safety and Information Notices from the HPRA and Field Safety Notices (FSNs) from manufacturers.

Procedures for recording of non-conformance and change control forms and recall/traceability of IVDs and their associated reagents and consumables when required.

ICT connectivity and its availability

Many of the vendors have established training programmes, which must be reviewed and modified to suit local needs. Advantage could be taken of e-learning programmes.

5.6 Competence/proficiency testing of NPT operators

The NPT operational team should assess the competence of new NPT operators and should periodically re-assess existing NPT operators. This may be done by observing an operator carrying out an actual test and assessing performance against the SOP. Deviations observed in technique from that specified in the SOP should be corrected immediately, in which case the operator can be re-certified as competent. Defects in theoretical knowledge should be addressed by appropriate educational sessions.

The advantage of this approach is that all aspects of actual NPT practice can be observed, assessed and corrected (e.g. pre- analytical considerations, specimen collection, analysis, interpretation of results and further action). The assessment should be conducted as a peer-based practice improvement measure rather than an examination.

Competence/proficiency testing is supplemental to the standard laboratory quality assurance measures. Ideally, all NPT operators should be assessed and re-certified annually, or more frequently where usage of NPT is low.

5.7 Quality assurance programme

Recommendation 8. Implement a quality assurance programme, including internal quality control and external quality assessment for all NPT.

Quality assurance is an integral component of any NPT service and includes all the measures taken to ensure the reliability and accuracy of the patient result. It is important that all NPT IVDs are included in a quality assurance programme and that this is operational prior to patient testing at each site. The quality assurance programme should be overseen and monitored by the NPT operational team and appropriate action should be taken if adherence to quality standards is not maintained. The role of the laboratory is integral to the implementation and management of the analytical quality assurance for NPT. Table 6.2 illustrates the elements which should be considered.

TABLE 5.3

Elements of quality assurance
Performance and documentation of appropriate internal quality control and / or calibration.
Correct patient identification.
Selection of the appropriate test.
Obtaining a satisfactory sample and sample integrity.
Performance of the test in accordance with the manufacturer’s instruction.
Correct interpretation of the result and appropriate action taken.
Recording of the test result in the patient record.

5.8 Internal quality control

IQC is a means of determining that the IVD is performing correctly at that specific time and that the patient result is likely to be reliable before it is released and acted on.

The SOP for each IVD should outline the material to be used, specify the frequency at which the IQC is performed and define the acceptable limits for the IQC material prior to testing a patient sample. All NPT users should be educated as to the importance of the IQC procedures, appropriate action to take in the event of failed quality control, and the implications when quality control is not performed according to the stated protocol.

It should be noted there are two main types of IQC – electronic and liquid. An effective quality management system requires correct use of both types.

5.9 External quality assessment

EQA is a means of determining how a particular IVD is performing in comparison to similar IVDs at different sites and to other manufacturers IVDs or other laboratory analysers.

The EQA material is a sample of an unknown value, which may be provided by an external quality assessment scheme such as the Irish External Quality Assessment Scheme (IEQAS), other international schemes, or alternatively prepared by the laboratory or manufacturer for provision to all NPT sites within the organisation. The laboratory should be responsible for the implementation and management of the EQA and provide feedback to the NPT operational team.

Quality assurance performance should be reviewed under the governance of a quality management system.

5.10 Recording of results and audit trail

All patient results must be recorded in the patient's permanent record. The date and time of analysis, NPT operator identity, reagent lot/batch number and the UDI should be included with the patient result to allow full traceability for NPT. A permanent record of all quality control data should be maintained.

5.11 Reviewing results

Recommendation 9. Ensure patient results are reviewed and interpreted by appropriately qualified persons.

Patient results should only be interpreted and reviewed by appropriately trained personnel and the operator identity should be recorded in all cases. A procedure for communication of critical NPT results should be in place. Grossly abnormal NPT values or values inconsistent with the patient clinical history may require confirmatory testing using a laboratory method. Confirmatory laboratory testing is also required for some conditions where NPT is not acceptable for diagnosis, such as diabetes mellitus[1-2].

Appropriate patient referral criteria should be in place, which may include referral to a local hospital or GP.

5.12 Traceability and recall

Traceability and recall of NPT IVDs including any reagents and consumables used must be possible in any NPT implementation. The NPT steering group will need to be in a position to advise the organisation of any actions needed in the event of a recall or patient safety-related issue involving an NPT IVD.

Recommendation 10. Ensure full traceability of all IVDs used (including reagents and consumables).

In turn, the NPT operational teams will need to establish and maintain a system to support traceability, for example in the event of a recall, and which will usually be linked to the organisation's asset register.

NPT should be reviewed and monitored on an on-going basis and a test should be withdrawn or suspended in the event of a safety related issue e.g. a recall.

Unique device identification (UDI) is a system used to identify and facilitate traceability of IVDs within the healthcare supply chain. The UDI is a series of numeric or alphanumeric characters created through internationally accepted device identification and coding standards and allows unambiguous identification of specific IVDs on the market. Under the IVDR, manufacturers shall assign and maintain unique UDIs for their IVDs.

The introduction of UDI under the IVDR should lead to improved incident reporting, targeted field safety corrective actions (FSCAs) and better monitoring by competent authorities.

It should also help to reduce medical errors and to fight against falsified IVDs. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

- There should be full traceability of all NPT IVDs, reagents and consumables used to ensure appropriate action can be taken in the event of a recall.
- Recording of specific batch numbers is important in the event of a recall by the manufacturer or other market action for safety reasons.
- A system to review and take action on FSNs issued by NPT IVD manufacturers should be in place.
- In addition, systems should be in place to review and take action where appropriate on safety notice / information notices and any other communications issued by the HPRA and any other relevant bodies.

5.13 Maintenance and service

A maintenance and incident logbook (paper or electronic) should be maintained for each NPT device to record details of maintenance, faults, repairs and corrective action. The NPT operational team should nominate an individual who is responsible for responding to issues logged and recording the corrective actions taken in this logbook.

The preventative maintenance and servicing of NPT devices is essential to ensure a functional and reliable NPT service within the organisation. It is important therefore that the NPT operational team identifies persons to be responsible for the day-to-day care of an IVD for each NPT site and that this is communicated to users. Responsibility for other maintenance should be clearly identified by the NPT operational team and could be the device's manufacturer/supplier, the clinical engineering staff and/or appropriate laboratory staff. All such maintenance and servicing should be conducted in accordance with the manufacturer's instructions.

A service contract with the NPT device supplier to ensure engineering support and supply of consumables is essential.

It is recommended that a register, based on the organisations asset register for all IVDS used at NPT, be used to update the maintenance and servicing records for these devices, as appropriate.

The day-to-day maintenance of a NPT device may include some of the following elements:

- ensure that the device is kept clean and in good and safe working order
- ensure good stock control of all reagents, consumables, calibrators and controls within their shelf-life
- temporarily withdraw any device from the NPT service that is not performing to the manufacturer's specification and ensure that it is not used again until the appropriate remedial action has been taken and the NPT steering group has been informed
- suspend/withdraw any NPT service in the event of a safety issue as directed by the NPT operational team

5.14 Retention of records

Records of instrument maintenance, faults and corrective action, training records, quality control records and medical records should all be retained for the length of time specified in the HSE's Code of Practice for Healthcare Records Management[3].

5.15 Health and safety

Recommendation 11. Ensure health and safety, and waste management training for staff using NPT.

A risk assessment of hazards associated with the NPT IVDs needs to be completed. Special attention must be given to avoidance of contamination of devices and the surrounding environment and disposal of waste including sharps. Protocols for decontamination of devices and their immediate environment should be available. All testing must be carried out in accordance with health and safety regulations.

- Appropriate health and safety training and waste management training should be provided to staff performing NPT.

- The organisation must provide facilities, premises, and NPT service delivery areas which are fit for purpose and comply with relevant health and safety legislation, building and fire regulations.

- A procedure must be in place for the safe disposal of biological waste and/or sharps in accordance with the appropriate health and safety and/or infection control legislation.

5.16 Chapter references

1. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Report of a WHO Consultation. World Health Organisation, 1999. Accessed 18/4/2020.

2. Sacks DB, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care 34(6): e61-99, 2011. Accessed 18/4/2020.

3. HSE standards for healthcare records management. Accessed 19/4/2020.

Chapter 6

Regulatory requirements for NPT: the role of the HPRA

6.1 The IVD Directive 98/79/EC and the IVD Regulation 2017/746/EU

The majority of analytical devices (e.g. test kits and analysers) that are used for NPT fulfil the definition of an IVD. Broadly, an IVD is a device intended by a manufacturer for the in-vitro examination of specimens derived from the human body to provide information regarding a physiological, pathological or therapeutic state.

All IVDs are currently regulated under the IVD Directive 98/79/EC and related Irish regulations. The IVD Directive became mandatory in December 2003 and was implemented in Ireland via the statutory instrument S.I. No. 304 of 2001, European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001.

All IVDs available on the European market must meet the essential requirements in Annex I of the IVD Directive and conformity to the directive is indicated by the presence of a CE mark on the device labelling.

Recommendation 12. All IVDs must meet national and European IVD legislative requirements.

NPT devices must be CE marked as this is an indication that the device meets the requirements of the relevant legislation.

- Only IVDs that are approved by the NPT steering group should be used for NPT. This requirement should apply to all IVDs irrespective of whether they have been purchased, loaned, gifted or leased to the organisation.

The essential requirements of the IVD Directive aim to ensure that IVDs do not compromise the health and safety of patients and users and are designed to achieve the performance specified by the manufacturer for its intended purpose. This legislation introduces common regulatory requirements dealing specifically with the safety, quality and performance of IVDs across Europe.

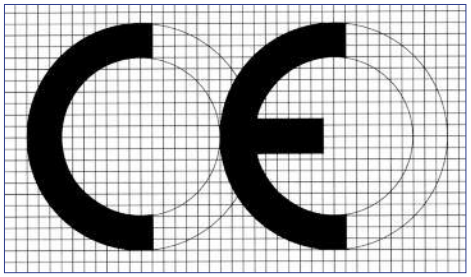

Figure 4. Representation of the CE mark that should be displayed on a medical device.

The HPRA is designated as the competent authority for medical devices in Ireland. Its primary role as competent authority is to ensure that all IVDs placed on the Irish market comply with the medical device legislation.

The regulatory system for IVDs has recently undergone substantial revision at European level. A new European regulation on IVDs was published in May 2017 (Regulation 2017/746/EU), the IVD Regulation (IVDR). This regulation will replace the existing IVD Directive and national SI and will be fully applicable five years after entry into force (May 2022). This will bring about a number of important changes to ensure safe access to new and innovative therapeutic and diagnostic devices for patients. Some key changes include the classification rules for IVDs, conformity assessment routes to be applied to demonstrate safety and performance and detailed requirements for performance studies. A 'device for near-patient testing' is defined in Article 2 of the IVDR as "any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional". Of note specific provisions are now made for near patient tests under the IVDR. It is important to note that some of the provisions of the IVDR become applicable prior to 2022 and there are important changes that manufacturers of NPTs should be aware of.

6.2 Risk assessment of IVDs used for NPT

An IVD is classified on the basis of the risk associated with the device and the relative dangers to the public and/or a patient treatment/diagnosis by an IVD failing to perform as intended. The IVD Directive requires manufacturers to perform a risk assessment for all devices. This risk assessment should consider the use of an IVD in the NPT setting and any additional safeguards that should be applied considering that the device is used outside the conventional laboratory setting and by individuals who are not professionally trained in laboratory techniques.

The essential requirements in Annex I of the IVD Directive also specify the information to be supplied by manufacturers with an IVD, to ensure it is used in a safe and proper manner. Paragraph 8.1 of this annex states that the information should consider the training and knowledge of potential users. Manufacturers should therefore ensure that this requirement is met for IVDs used as NPT, an environment distinct from the laboratory setting.

6.3 Key changes with the new IVD Regulation

One of the key changes with the introduction of the IVD Regulation will be a move away from the list based classification system currently in place under the IVD Directive. The regulation introduces a new risk-based rule-based classification system.

Seven classification rules (Annex VIII Section 2) will divide IVDs into Class A (lowest-risk) to D (highest-risk). Annex VIII Rule 4 states that devices intended for near patient testing will be classified in their own right, thus they can be classified as Class A, B, C or D devices depending on the associated risk. Application of the classification rules will be governed by the intended purpose and inherent risk of the device (or the result generated by it). For example the detection of a transmissible agent that causes a life-threatening disease (e.g. HIV) with a high or currently undefined risk of propagation will be classified as Class D, whereas devices for testing blood glucose will be classified as Class C. The level of regulatory oversight will be relative to the risk of the device.

For high risk devices, the notified body will request a reference laboratory to verify by laboratory testing the claimed performance and compliance with the regulation.

The requirements for near-patient tests regarding performance, design and manufacture have been strengthened under the IVDR to ensure they are appropriate for their intended use and in the environment in which the device is intended to be used. Annex I, Chapter II, Section 19 specifically discusses NPT and outlines how to protect patients and users from the risk posed by these devices. Devices must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills of the intended user and the potential for variation in the user's technique and environment. The information and instructions for use (IFU) provided by the manufacturer must be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device. Information regarding the level of training and qualifications required by the user should also be provided in the IFU. Furthermore where feasible, manufacturers must specify how the intended user can verify the device is performing as intended by the manufacturer and provide information regarding detection of device failure. Any information supplied must be provided in the language of the user. Finally a device must clearly state that the device is for near patient testing and instructions for use must be supplied in paper format and not only electronically.

6.4 Clinical data supporting safety and performance of IVDs

The IVDR sets high standards of quality and safety for IVDs by ensuring, among other things, that data generated in performance studies is reliable and robust and that the safety of subjects participating in performance studies is protected. The manufacturer must specify and justify the level of clinical evidence necessary to demonstrate compliance with the relevant safety and performance requirements which will be appropriate to the characteristics of the device, the classification and its intended purpose. The manufacturers will then plan, conduct and document a performance evaluation in accordance with Article 56 and with Part A of Annex XIII. The performance evaluation is a continuous process and will need to assess and analyse three types of clinical evidence; scientific validity, analytical performance and clinical performance.

6.5 HPRA safety notices, HPRA information notices and manufacturer FNS

The HPRA periodically issues safety notices in connection with issues that arise with NPT devices. Information notices and other communications may also be issued.

In addition, manufacturers of NPT devices regularly issue FSNs and other instructions or information notices.

A system to review and take action on safety notices and other communications issued by the HPRA and FSNs issued by NPT IVD manufacturers must be in place.

This includes procedures for traceability and implementation of Field Safety Corrective Actions for NPT equipment, consumables and reagents where necessary.

6.6 Adverse incident reporting

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects. In the NPT environment this may involve the health and safety of patients, users or other persons. For example, an incorrect result could lead to a delay in treatment, a life-threatening illness or injury or a serious deterioration in the state of health, or even death.

All adverse incidents, in the first instance, should be made known as soon as possible to the NPT operational team and to the designated NPT committee. The NPT IVD manufacturer will also be informed where appropriate.

The manufacturer has a legal requirement in accordance with Article 11 of the IVD Directive 98/79/EC to report all adverse incidents that occur with IVDs on the Irish market to the HPRA. Any adverse incident involving an IVD should also be reported by the organisation to the HPRA. Direct reporting of adverse incidents by users to the HPRA is not mandatory but is strongly encouraged. It is important that users are aware of the reporting requirements for adverse incidents under IVD legislation and the key role they play to ensure that all incidents that occur on the Irish market are reported to and investigated by the manufacturer.

With the introduction of the IVDR there will be a centralised electronic system called EUDAMED which will allow manufacturers to report serious incidents and other reportable events. This will also allow the public to be adequately informed about devices on the European market.

Recommendation 13. Report adverse incidents to the designated committee, the manufacturer and the HPRA.

Further information including the HPRA form for reporting safety-related issues and adverse incidents can be found on the HPRA website.

6.7 Unique Device Identification (UDI)

UDI is a system used to identify and facilitate traceability of IVDs within the healthcare supply chain.

Under the IVDR, manufacturers shall assign and maintain unique UDIs for their IVDs.

The UDI is series of numeric or alphanumeric characters created through internationally accepted device identification and coding standards and allows unambiguous identification of specific IVDs on the market. Each IVD will have a UDI composed of two parts: a device identifier (UDI-DI) specific to the model and packaging of the device, and a production identifier (UDI-PI) to identify the point of manufacture.

The introduction of UDI under the IVDR should improve incident reporting, facilitate targeted field safety corrective actions and lead to better monitoring by competent authorities.

It should also help to reduce medical errors and to fight against falsified IVDs. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

Article 24 of the IVDR states in respect of UDIs:

- as part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned,
- economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied,
- member states shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied,
- member states shall encourage, and may require, healthcare professionals to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied with.

Although it has not yet been determined nationally what will be required of health institutions and healthcare professionals in this regard, it is certainly preferable that local NPT managers would track this information as good practice. In due course, the HPRA may issue further clarification on national policy in this area. Further useful information is available at this link.

Chapter 7

ICT connectivity for NPT

Patient results must be recorded in the patient's health record either manually or preferably electronically.

Information and communication technologies (ICT) connectivity allows central recording of patient results and quality parameters and should be resourced to a level which avails of the latest technology including password-protection of equipment, operator identification, unique patient identification, and integration of results with the patient's electronic healthcare record. NPT IVDs should be password-protected and only accessible by certified users.

Connectivity also facilitates remote monitoring of NPT equipment from a hub in the local laboratory or manufacturer for quality assurance, governance, fault diagnosis, preventative maintenance, and trouble-shooting in the event of problems.

7.1 Connectivity and the national medical laboratory information system (MedLIS)

Recommendation 14. Include all NPT results in the patient's health record, ideally by implementing ICT connectivity.

Connectivity between disparate computer systems and NPT analysers is an essential component for provision of an effective NPT service within an organisation. In particular, it allows NPT IVDs to be controlled and managed centrally and facilitates exchange of information from the remote NPT site to the laboratory/hospital information system. Such connectivity is generally achieved through deployment of a device management system, commonly referred to as "NPT middleware". Key connectivity goals are given in Table 7.1.

It is anticipated that the new national medical laboratory information system (MedLIS) will go-live in 2020. MedLIS aims to deliver a complete national pathology record for all patients in Ireland including integration of NPT results. MedLIS will connect with NPT middleware systems and will not interface directly to NPT IVD's.

The national NPT consultative group recommends that a national NPT middleware system be deployed such that all NPT results might be available in the national pathology record. Indeed, without these results such a record would be incomplete. It is not financially viable, or technically practical, for each organisation to procure, deploy and maintain its own NPT middleware. Deployment of a national middleware solution would reduce duplication and mitigate redundancy in connectivity systems. It would also enable integration of a patient's NPT results from all settings so as to be visible for clinicians in the patient's pathology record.

Connectivity requirements have been described in the Clinical and Laboratory Standards Institute (CLSI) POC Connectivity Approved Standard POCT1-A2. This in turn is based on the former POCT1-A

standard in 2005. The objective of the standard is to allow seamless multi-vendor interoperability and communication between NPT devices, data concentrators and clinical information systems. The CLSI asserts that this standard provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of NPT devices to communicate bi-directionally with access points, data concentrators, and laboratory information systems from a variety of vendors.

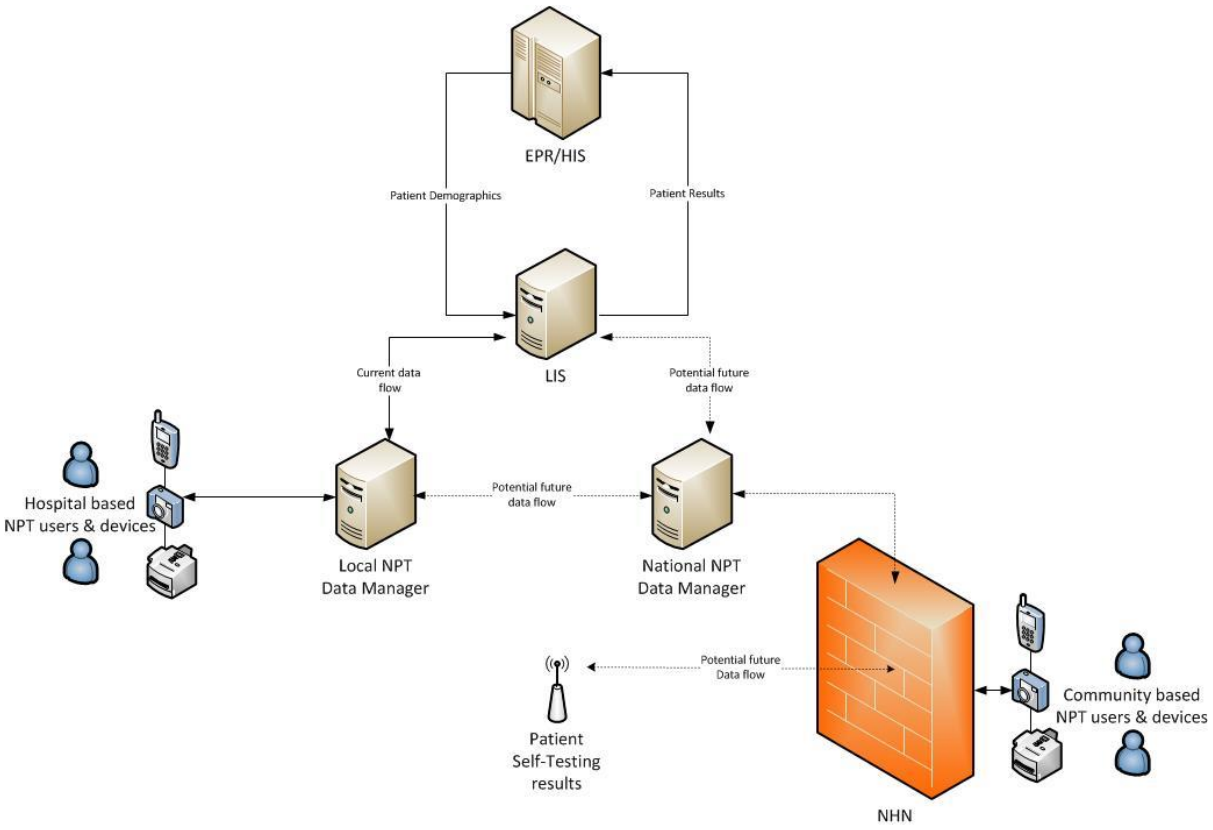

Figure 5. ICT connectivity diagram for NPT

Also available from CLSI is a proposed Guideline on "Implementation of POC Connectivity for Healthcare Providers (POCT2-P)" which discusses the requirements of a connectivity-compliant device, and describes information that users should request from the supplier. The development of POCT1-A in 2000 was a US initiative, but in 2001 a European initiative was convened to internationalise the standard.

Co-operative development has led to a modified and updated 2005 standard draft POCT1-A2, and some vendors' recent NPT IVDs are compliant with the standard, whilst others plan to implement it in their future NPT IVDs. Adopting this as an ISO, CEN and IEEE standard is an unparalleled move in the history of standardisation, and so there are still some administrative obstacles to be resolved.

TABLE 7.1

Key ICT connectivity goals

Positive identification of patient samples and patient demographics to the system.

Operator ID to allow traceability of results. Ideally the staff member's bar-coded staff ID card, registration number or similar device should be used.

Ideally identification of the UDI/equipment serial number should be captured.

Audit controls, logs, and accountability.

Password protected access to the system, login procedures and monitoring, and automatic logoff settings.

Ability to clearly distinguish NPT results from other laboratory performed results on the laboratory information system.

Integration of all results generated from NPT devices with the laboratory information system and appropriate clinical information systems.

Appropriate data storage and backup.

Remote monitoring of NPT QC and IVD performance from the clinical laboratory.

Remote ability to temporarily block certified individuals who are not conforming to the stated IQC protocol.

On-board decision support for order entry, and interpretation tailored to the analyser and particular test.

Checking for data integrity.

Ability to perform patient audit and monitoring.

The extent to which this can be achieved depends on the particular NPT device, the number of devices and the local healthcare IT services available. Use of laser technology to read bar-coded patient identification on patient armbands, user identification badges and reagent/control consumables has greatly reduced the risk of incorrect patient identification, uncertified user and incorrect reagents/controls. Incorrect transcribing of results or failure to record results is also being eliminated by the ability of devices to transmit results to the laboratory information system/ electronic patient record.

7.2 Use of ICT for generating clinical alerts

Most NPT databases can be configured to generate user-friendly reports for clinicians, including daily or periodic lists of abnormal glucometric or other NPT results which can be used to guide clinical teams.

Chapter 8

Implementing NPT services in primary care and community settings

8.1 Clinical and managerial governance of NPT outside of hospital settings

It is important that primary and community care settings have a clearly defined and well-structured approach to NPT to ensure that it is performed in a safe and effective manner and that the results generated are accurate, reliable and recorded in the patient's health record.

The best-practice goal for all NPT, regardless of where it is taking place, should be full accreditation using the ISO 15189/22870 standards as implemented by INAB in Ireland.

This goal has been stated already in Chapter 1:

1. All NPT in hospital settings should be accredited to ISO 15189/22870 standards and meet the requirements as described in this guideline.

2. It is strongly recommended that community healthcare facilities including primary care centres establish a close link with their local hospital pathology service to ensure NPT is provided in a safe and effective manner and to be ultimately accredited to the required ISO 15189/22870 standards. This can only be achieved in conjunction with the local hospital pathology service.

3. Pharmacies providing NPT services should follow the Guidance on the Provision of Testing Services in Pharmacies from the Pharmaceutical Society of Ireland, and should be aiming for ISO 15189/22870 accreditation as an ultimate goal.

4. The date of application of the new IVDR is May 2022. The IVDR and role of the HPRA are described in detail in Chapter 6. The role of the Irish National Accreditation Board (INAB) in relation to accreditation is also outlined in this chapter.

It is acknowledged however that many NPT services (perhaps the majority) are not accredited today, even in the hospital sector. Nevertheless, progress has been made in all sectors since the first edition of this guideline in 2007 and all sectors have embarked on a journey where full accreditation is the ultimate goal to optimise clinical outcomes and patient safety.

8.2 Recommendations for safe and effective NPT outside of hospital settings

The fourteen recommendations described in Chapter 1 (also shown here in Table 8.1) set out the principles that also apply in the primary and community care sector and should be considered along with the PSI guidance in the pharmacy sector.

Nevertheless, it is acknowledged that some modifications to the approach will be necessary to reflect the different settings. For example, the NPT steering group will contain personnel relevant to the sector though the presence of laboratory expertise and a laboratory consultant is strongly recommended. Full details for each recommendation are given in the earlier chapters.

Prior to the implementation of a NPT service for a specific test, careful consideration should be given to the ability of the local hospital laboratory to provide this service in a timely manner.

On consultation with the laboratory it may be agreed that the provision of a regular reliable courier service and / or electronic ordering and result reporting can provide a turnaround time for patient results by the laboratory which meets the requirements of the practice.

This in turn may negate the need for a near-patient test to be established in primary and community care settings. National and international guidance should also be considered.

8.3 Self-audit checklist

It is advisable for NPT service providers to conduct a self-audit on a regular basis to ensure that the NPT service being provided is accurate and reliable. The guidance for pharmacies issued by the PSI is also useful in this regard and it also contains a self-assessment checklist.

Additionally, the checklist for the primary and community care sector included in Appendix 5 is a useful guide to ensure the NPT service being provided is optimal.

8.4 Training and competency assessment

Training and competency assessment should be carried out as described in Recommendation 7. The local laboratory can provide suitable documentation to record training, and an example of such a document modified for the primary and community care sectors is shown in Appendix 6.

8.5 Premises

It is necessary to ensure that a designated area is available for the provision of a NPT service. This should have suitable facilities for sample collection, NPT test execution, instrument storage, safe disposal of sharps and clinical waste and storage of consumables under the appropriate conditions as defined by the manufacturer. The area shall also ensure dignity and privacy for the patient. A refrigerator may also be required for storage of certain NPT reagents which should include temperature monitoring capability. In addition, consideration should be given to the environmental conditions in which the NPT test and/or instrument is stored and operated, as incorrect temperature and/or power supply conditions may impact the performance of the NPT test and hence the test result.

TABLE 8.1

Key Recommendations for Safe and Effective NPT

Key Recommendations for Safe and Effective NPT	
Governance	**1. Establish an NPT Steering Group and organisation-wide NPT Policy**
Commissioning	**2. Consult with local laboratory** **3. Document Case of Need involving all stakeholders**
Implementation	**4. Establish an NPT operational team** **5. Ensure all IVDs are CE marked, adequately validated and independently verified** **6. Develop standard operating procedures and protocols for all NPT** **7. Ensure that anyone performing NPT is trained and demonstrated on-going competence** **8. Implement a quality assurance programme, including performance of internal quality control and external quality assessment for all NPT** **9. Ensure patient results are reviewed and interpreted by appropriately qualified persons** **10. Ensure full traceability of all IVDs used, including reagents and consumables*** **11. Ensure health and safety, and waste management training for staff*** **12. Ensure all IVDs are CE marked**
Regulation	**13. Report adverse incidents to the designated hospital committee, the manufacturer and the HPRA** **14. Include all NPT results in patient's health record, ideally by implementing ICT connectivity**

* *Recommendations 10, 11 and 12 are required for safe implementation of NPT, and are also regulatory requirements*

8.6 Recent organisational developments in the primary care sector

Recent years have seen the introduction of new primary care centres around the country. These are staffed by healthcare professionals including general practitioners, practice nurses, community nurses, and other practice staff on a much larger scale compared with the previous model which had higher volumes of small single-handed GP premises.

These new facilities offer opportunities to establish primary care diagnostic centres which could provide safe and effective NPT provided there is a close link with the local hospital laboratory. This link would be essential to secure INAB ISO 15189/22870 accreditation.

Community healthcare programmes, such as diabetes management or anticoagulant monitoring, would benefit from the availability of key laboratory investigations at these centres and patients would benefit from NPT.

There may also be potential in the largest of these facilities to provide satellite laboratory services again linked to the local hospital.

8.7 Pharmacies

Testing services in pharmacies, including laboratory testing, has been addressed in the PSI Guidance on Testing Services in Pharmacies[4].

NPT is being carried out in community pharmacies in a number of ways including:

1. Members of the public visit a pharmacy for screening tests such as for cardiovascular risk (including lipid tests) or diabetes screening (including glucose and haemoglobin A1c tests).

2. Some pharmacists are performing NPT as part of a community anticoagulant monitoring scheme under the auspices of the local anticoagulation service.

NPT services such as these should aim for full accreditation as the best-practice goal however as a minimum a quality assurance programme should be implemented.

Where NPT testing is being used primarily for screening purposes as is usually the case in a pharmacy setting, then a robust system of patient consent, follow-up and referral should be put in place.

Appendix 5 provides a template for a patient evaluation form (including consent and relevant medical and drug history), a template for a GP referral letter is given in Appendix 6, a checklist for NPT implementation in primary/community care can be found in Appendix 7, and Appendix 8 contains a training record template.

Concluding remarks

NPT has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result in a timely manner in the immediate vicinity to the patient. This may lead to increased clinical effectiveness and improved outcome for patients. However, this is only true if the result delivered is accurate and reliable.

It is important that organisations have a clearly defined and well-structured approach to NPT to ensure that it is performed in a safe and appropriate manner and conforms to acceptable analytical and clinical standards.

Because there is a paucity of published literature regarding evidence-based support for NPT in clinical management, it is incumbent on users to establish that their proposed NPT service will be effective at a local level. There is a need for well-designed studies to evaluate clinical effectiveness of NPT in relation to patient outcome.

It is recommended that these guidelines should be adopted by those responsible for NPT in Irish healthcare organisations.

The implementation of these guidelines will facilitate a well-managed and appropriately governed system for the provision of NPT services, which in turn will deliver considerable benefits to the Irish health service and to patients.

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Appendices

Appendix 1. NPT steering group template

1. Terms of reference

1.1 The steering group will advise the management team on all aspects of NPT.

1.2 The steering group will provide clinical governance for the NPT service by ensuring that the organisation's systems and processes for monitoring and improving the quality of NPT services are in accordance with best practice.

1.3 The steering group will develop and recommend policies and procedures for the proper conduct of NPT, will be responsible for the review and commissioning of NPT services and may recommend or commission focused research or development on aspects of NPT.

1.4 The existing range of NPT services will fall within the remit of the steering group, including *[list of analyses: e.g. blood gas analysis, blood glucose monitoring, pregnancy testing, and other analyses requiring instrumentation].* A survey will determine the extent and risk category (low/medium/high) of existing NPT including manual tests/dipsticks.

1.5 To review existing NPT services and receive proposals for new NPT services; and to assess the case of need and clinical effectiveness for patients compared with other options for service delivery; and to make recommendations as to their appropriateness, taking account of:

indications, contraindications and workload implications for NPT,
suitability, accuracy, limitations and scope of testing for clinical needs,
risk management and risk stratification of the various devices,
financial implications,
health and safety implications,
ability to audit quality and clinical effectiveness,
ability to trace and recall all IVDs, regents and consumables if required.

1.6 To implement a quality assurance programme for NPT including systems for internal and blind-sample external quality assessment and adverse incident reporting, and taking into account:

operator training,
machine calibration and maintenance,
correct interpretation of results,
correct recording of results, including integration with IT systems,
health and safety requirements.

1.7 To implement an education programme for clinical users of NPT and to keep a list of trained operators.

2. Membership

2.1 The **minimum** membership shall be [number locally defined], (quorum [number locally defined]) and shall serve for [duration defined locally] years.

The **minimum** steering group membership should consist of:
- a laboratory consultant from participating pathology/laboratory medicine disciplines,
- a senior management representative,
- a senior scientist from participating pathology/laboratory medicine disciplines,
- the manager of each or all NPT operational teams,
- clinical risk manager,
- senior medical representatives from participating services,
- senior nursing representatives from participating services,
- IT representative.

2.2 Other members may be co-opted as necessary.

2.3 In the event of an appointed member being unable to attend, a deputy may attend in his or her place.

2.4 Dr [name of nominee], [job title], is nominated as the first chairperson for a defined period.

3. Meetings

3.1 The steering group shall meet on a quarterly basis.

3.2 Additional meetings may be convened at the discretion of the chairperson to deal with urgent or specific matters.

4. Operational teams

4.1 The steering group may appoint operational (working) teams to deal with specific issues and with defined terms of reference. These groups will meet on an *ad hoc* basis according to the needs of the specific project.

5. Reporting and review

5.1 The steering group will report to the executive management team.

5.2 This document and the terms of reference will be reviewed every 2 years to gauge effectiveness.

Appendix 2. User application form for a new NPT service

Proposals for new NPT require detailed consultation with the local laboratory service including a laboratory medicine consultant from the appropriate pathology discipline.

The form is intended for initial completion by the end-user proposing the service, with assistance as required from the NPT Team for detailed technical aspects. Input may also be required from other services, including ICT and finance.

Please ensure the following form is completed prior to submission.

	Checklist (Applications cannot be considered without submission of all data specified)	**Tick**
1	Section 1, 2 and 3 fully completed and signed off by all parties.	✓
2	Supporting clinical documentation/validation data attached.	✓
3	Analyser verification data attached (if applicable).	✓
4	Completed ICT project mandate attached (if applicable).	✓
5	Approved business plan (to include all associated costs) attached.	✓

Section 1 – General information

- What test/test profile do you wish to perform as NPT? Please also specify sample type requirements (i.e. whole blood, urine etc.).
  Click or tap here to enter text.

- What department/area is requesting the service and who is the clinical director?
  Click or tap here to enter text.

- Is testing currently performed in your local laboratory? Please state the clinical need for a NPT service rather than a conventional laboratory service. Please attach any published data/ validation in support of your claim (see checklist item 2).
  Click or tap here to enter text.

- Name the laboratory medicine consultant with whom you have discussed your proposal and attach their written opinion as part of the evidence submitted (see checklist item 2)
  Click or tap here to enter text.

- Is testing currently performed in laboratory? Please state the clinical need for a NPT service rather than a conventional laboratory service. Please attach any published data/ validation in support of your claim (see checklist).
  Click or tap here to enter text.

- What workload is envisaged in terms of specimen numbers per year?
  Click or tap here to enter text.

- Specify who will hold clinical governance over the NPT results?
  Click or tap here to enter text.

- Who will perform the testing?
  Click or tap here to enter text.

- Will testing be performed out of hours (outside 09.00-17.00, Monday-Friday)?
  Click or tap here to enter text.

- Where exactly will this new NPT service be performed and where will the NPT equipment be located? (specify room number, ward etc.)
  Click or tap here to enter text.

- Will NPT staff and equipment service engineers have easy access to the device(s)?
  Click or tap here to enter text.

- Please identify a liaison person(s) in the area who will assist the NPT department in delivering the service.
  Click or tap here to enter text.

- Is testing currently performed in laboratory? Please state the clinical need for a NPT service rather than a conventional laboratory service. Please attach any published data/ validation in support of your claim (see checklist).
  Click or tap here to enter text.

- What benefit will accrue to staff or patients through implementation of this NPT service?
  Click or tap here to enter text.

- Identify any infection control issues. Ensure hospital policy is adhered to.
  Click or tap here to enter text.

- Identify any health & safety issues. A risk assessment will be required prior to introduction of service.
  Click or tap here to enter text.

Section 2 – Equipment and IT

- Has a suitable device/instrument been identified? If 'yes', please supply details.
  If 'no' then skip to section 3.

  Click or tap here to enter text.

- Is the device currently in use? If 'yes' please attach method verification data. Also attach correlation data with laboratory method, if applicable. Note: only electronic verification and correlation data will be accepted as several statistical calculations are required as mandated by ISO 22870 and ISO 15189.
  Click or tap here to enter text.

- Is it possible to restrict equipment access to trained operators only? Is the instrument password protected?

Click or tap here to enter text.

- Can the device be monitored remotely by the NPT department through the middleware currently in use in NPT or with new middleware software?
  Click or tap here to enter text.

- Can patient results be stored/ backed-up? If 'yes' how is this done and in what format is it stored?
  Click or tap here to enter text.

- Can the device be interfaced with the LIS (both existing and MedLIS)/HIS? Note: laboratory policy requires interfacing of NPT equipment (where possible) to ensure complete electronic patient record. ICT interfacing requires an ICT mandate form to be submitted to ICT. Include ICT contact details if they have been consulted prior to submission of this document (see checklist).
  Click or tap here to enter text.

- Does the device require network points/Wi-Fi & power sockets? Please detail requirements for the device and are they currently available in the desired location?
  Click or tap here to enter text.

Section 3 – Finance

- Attach the business plan and has it been approved by your finance officer to cover all associated costs of introducing this service? This must include the following:
  Click or tap here to enter text.

  a. What staff costs are involved (additional or existing, laboratory and/or clinical staff)?
  Click or tap here to enter text.

  b. What is the capital cost of the device/system including VAT?
  Click or tap here to enter text.

  c. If interface capability, include the cost associated with interfacing?
  Click or tap here to enter text.

  d. Include the cost of any ancillary hardware (e.g. printer, barcode reader, etc.) and software (updates).
  Click or tap here to enter text.

  e. Include the cost of annual maintenance and servicing costs.
  Click or tap here to enter text.

- Include details and costs of the external quality assessment scheme.
  Click or tap here to enter text.

- Based on the projected test numbers and IQC requirements, what are the annual costs for consumables and reagents?
  Click or tap here to enter text.
- Any additional costs that may be associated with the device.
  Click or tap here to enter text.

Signatures:

Date of application	
Signature of applicant	
Title of applicant	
Contact details	
Clinical consultant (if not the applicant)	
Laboratory consultant	
Laboratory chief medical scientist	

For NPT team use only

1. Would other departments within the hospital have similar requirements for this service?
   Click here to enter text.

2. Is the device CE marked?
   Click here to enter text.

3. Is there sufficient storage space for the device(s), consumables and reagents in the location suggested?
   Click here to enter text.

4. Will the device have an uninterrupted power supply (UPS) unit?
   Click here to enter text.

5. If equipment is already in place, has a maintenance contract been agreed with the supplier/ manufacturer?
   Click here to enter text.

6. What response time is guaranteed with the supplier regarding repairs/ replacement and is this a 24hour/ seven days a week agreement?
   Click here to enter text.

7. Who will provide operator training and competency assessment?
   Click here to enter text.

Appendix 3. NPT cost benefit analysis form

NPT Cost Benefit Analysis Form	
Is the test available through the laboratory? Yes / No	
Current test volume (number of patient samples sent to the laboratory)	……../day ……../month
Anticipated test volume of NPT	……../day ……../month
Anticipated test volume sent to lab after implementation of NPT	……../day ……../month

a. Please complete table with any capital (one-off) costs and annual revenue costs			
		Description	Cost
Capital			€0.00
Expenditure			
Non-staff costs	Consumables		€0.00
	Collection devices		€0.00
	Maintenance		€0.00
	Calibrators		€0.00
	Quality Control		€0.00
Staff time	Testing		€0.00
	Training (trainer and trainee)		€1.00
	Support / maintenance (laboratory)		€0.00
Other			€0.00
		Total Expenditure p.a. (A)	€0.00
		Total 1st year cost (capital + expenditure) (B)	€0.00

b. Please complete table with any annual savings			
Type	Description		Saving
Cash-releasing	Drugs		€0.00
	Other:		€0.00
	Other:		€0.00
		Total Cash-releasing savings p.a. (C)	€0.00
		Number	Est. Saving
Non cash-releasing	Bed days	0	€0.00
	Earlier discharge	0	€0.00
	Staff time	0	€0.00
	Other:	0	€0.00
	Other:	0	€0.00
		Total Non cash-releasing savings p.a. (D)	€0.00

NPT Cost Benefit Analysis Summary			
1st year expenditure (capital + expenditure)	B	€0.00	
Recurring annual expenditure	A	€0.00	
Recurring cash-releasing saving	C	€0.00	
Total 1st year expenditure/saving	(B – C)	€0.00	*set-up costs/savings
Total recurring annual expenditure/saving	(A – C)	€0.00	*recurring costs/savings
Total recurring non-cash releasing saving	(D)	€0.00	

Appendix 4. Implementation checklist for an approved NPT Service

This form may be used as a checklist for the NPT Operational Team to assist with implementation of a new approved NPT service. It is not intended for completion by the end-user.

1. Name and Description of NPT service to be provided

2. Is the test available in the laboratory for confirmatory purposes?

Yes	No

3. State the clinical need for NPT rather than being supplied by the central laboratory.

4. Why is the laboratory unable to meet the requirements?

5. What measurable benefits of the NPT service can be monitored?

6. What workload is envisaged in terms of specimen numbers/month?

Space

7. Where do you want to locate the NPT; is it a safe working environment?

8. What size area is available for NPT?

9. What is the distance to the nearest sink?

10. What space is available for storage of stock items?

11. Is the room air-conditioned?

Yes	No

12. Can an engineer have easy access to instruments?

Yes	No

Equipment

13. Details of IVD

14. Has the discipline/laboratory confirmed the choice?

Yes	No

15. What is the life expectancy of the device?

16. Is there data comparing the proposed NPT with the laboratory method?

Yes	No

17. Has a risk assessment been completed? If so please attach.

Yes	No

Costs/risks associated with device/equipment

18. What is the capital cost of the instrument including VAT?

19. What is the annual consumable cost?

20. What is the maintenance/servicing cost after guarantee?

21. Is the cost of interfacing the device to the laboratory computer included in the cost?

Yes
No If no, what is the cost to interface?

22. Is the cost of software and hardware to monitor and control the device from the central laboratory included?

Yes	No

23. Have you funds sanctioned to cover these costs?

Yes	No

24. Does it have to go to EU tender?

Yes	No

25. Is it CE marked?

Yes	No

26. Can the device be decontaminated?

Yes	No

27. What are the infection control issues?

28. What are the health and safety and occupational health issues?

Maintenance of the device

29. What response time is guaranteed in the maintenance contract?

30. Is this a 7 day week, 24 hour response?

Yes	No

31. What are the implications for other support departments (e.g. laboratory disciplines providing support, pharmacy, bio-engineering, etc.)?

32. Has out of hours support been agreed with the named support departments?

Yes	No

33. Is the proposed equipment compatible with similar results produced elsewhere in the hospital?

Yes	No

34. Does the device have a UPS (uninterrupted power supply unit)?

Yes	No

Responsible personnel

35. Who will be the designated person in charge of the device day to day?

36. Who will perform the test(s)?

37. Will you have designated staff to cover absences of the designated person responsible for the device and for performing the test(s)?

Yes	No

38. Is the instrument password-protected?

Yes	No

39. Who takes responsibility for issuing and maintaining passwords?

40. Who takes responsibility for internal quality control programme of users?

41. Who takes responsibility for external quality assessment?

42. Who takes responsibility for clinical action based on the NPT result?

Interfacing and patient record

43. Can the instrument be monitored through designated software in the central laboratory?

Yes	No

44. Can the device be interfaced with the laboratory computer?

Yes	No

45. How will the patient record be stored?

46. Do you need ICT connectivity and support?

Yes	No

47. Has the ICT department agreed to your requirements?

Yes	No

Clinical governance

48. Are you compliant with the hospital NPT policies for governance?

Yes	No

Traceability and Field Safety Corrective Actions

49. Describe the system for traceability of the IVD and/or associated reagents and consumables that will apply for this NPT. Attach the inventory.

50. Describe how the IVD and/or associated reagents and consumables will be identified and quarantined in the event of a patient safety-related incident.

Signatures

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NPT Manager Date

---------- ----------

Clinical Director or Division Head Date

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Laboratory Consultant Date

Appendix 5. Patient evaluation form template (for non-GP based NPT settings)

Title:				
First name:				
Surname:				
Date of birth:				
Address:				
GP name and address:				
Date of assessment:				
Are you aware of the significance of the test being performed and the consequences of an abnormal result?				
Is there any relevant medical history you would like to disclose?				
Is there any relevant medication history you would like to disclose?				
Test performed	Result	Units	Within acceptable limits (Yes/No/N/A)	Additional information (Test batch number / N/A etc.)
Referral to be made (Yes/No). *If yes include reason for referral*				
NPT service provider (print sign & date):				
NPT service provider position:				
Do you consent to a referral?				
Patient (print, sign & date):				

Appendix 6. GP Referral letter template (for non-GP based NPT settings)

Dear Dr

Please be advised that (patient's name) presented at (NPT location) on (date) and received the following test (test name).

The result of this test was as follows: XXXXX. The test was performed on xxxx manufactured by xxxx.

The following information was also provided by the patient: XXXXX.

Other comments: XXXXX

The patient was informed that this referral letter would be written and was advised to contact their own GP for follow-up.

Referee: Signed:

Referee position: Date:

Appendix 7. NPT primary/community care checklist

The following is a useful checklist for NPT providers and SOP authors.

	Points to Consider	Yes	No	N/A
1	Is the premises appropriate for the test being performed?	☐	☐	☐
2	Is the test carried out in a private dedicated area suitable for patient counselling?	☐	☐	☐
3	Is a shredder provided for disposal of waste paper containing confidential patient information?	☐	☐	☐
4	Is access to patient records and confidential information controlled?	☐	☐	☐
5	Are information leaflets available to patients?	☐	☐	☐
6	Is the necessary testing equipment available and of appropriate quality?	☐	☐	☐
7	Is the equipment maintained regularly to ensure it is operating correctly?	☐	☐	☐
8	Is there suitable storage space for consumables and reagent components requiring specialised storage e.g quality control samples?	☐	☐	☐
9	Are all materials stored in a manner which minimises risk and is legislatively compliant?	☐	☐	☐
10	Are the relevant safety data sheets available (if required)?	☐	☐	☐
11	Are suitable bins provided and is the disposal mechanism for NPT waste in compliance with environmental provisions?	☐	☐	☐
12	Is a sharps container available?	☐	☐	☐

13	Is a written procedure available and are staff trained in the management of possible contaminated spillages?	☐ ☐ ☐
14	Are suitable procedures in place for transportation of patient samples if required?	☐ ☐ ☐
15	Is there a structured quality assurance programme in place and is it reviewed regularly?	☐ ☐ ☐
16	Is a self-audit regularly carried out by the manager to review all aspects of the NPT service?	☐ ☐ ☐
17	Is personal protective equipment available (e.g. gloves)?	☐ ☐ ☐
18	Are all products checked on receipt for quality, quantity and expiry date?	☐ ☐ ☐
19	Are all IVDs CE marked and in compliance with the relevant legislation?	☐ ☐ ☐
20	Are the devices maintained, calibrated and within expiry?	☐ ☐ ☐
21	Is the NPT service provider trained and adequately competent to perform all aspects of the test?	☐ ☐ ☐
22	Are patients advised of the requirements in advance of a test?	☐ ☐ ☐
23	Has the patient completed an evaluation form?	☐ ☐ ☐
24	Is the significance of the test result explained in a clear and understandable manner?	☐ ☐ ☐
25	Are written procedures (SOPs) in place for the execution of each test?	☐ ☐ ☐
26	Is the current version of the manufacturer's instructions for use (IFU) available?	☐ ☐ ☐
27	Is the test procedure quality assured?	☐ ☐ ☐
28	Are instructions available for performing calibration and quality control, including details of the material to be used and the defined acceptable limits?	☐ ☐ ☐

29	Are guidelines available on interpretation of instrument error codes?	☐ ☐ ☐
30	Are guidelines available for interpretation of test results?	☐ ☐ ☐
31	Is there a process for documenting adverse incidents and reporting of adverse incidents to the HPRA and/or other appropriate regulatory body?	☐ ☐ ☐
32	Are results provided to the patient in a documented format?	☐ ☐ ☐
33	Is there a procedure in place to inform staff of the requirements in respect of patient referral?	☐ ☐ ☐
34	Are appropriate patient result records maintained?	☐ ☐ ☐
35	Is there a process for co-operation with Field Safety Corrective Actions such as product recalls?	☐ ☐ ☐
36	Is a documented staff training record maintained?	☐ ☐ ☐
37	Is an on-going training programme provided for all staff?	☐ ☐ ☐
38	Does on-going evaluation and monitoring of NPT service provider performance occur?	☐ ☐ ☐
39	Does the training assess current and future requirements and developments in the area?	☐ ☐ ☐
40	Do newly appointed staff members receive adequate training?	☐ ☐ ☐
41	Are all staff aware of their professional role, the associated boundaries and accountabilities?	☐ ☐ ☐

Appendix 8. Training record template

Title of Training	
Name of Device: **Model:**	
Trainer – Name: **NPT Team / Vendor:**	
Procedure (SOP) **Edition / Revision number**	
Training Date(s)	
Training Duration (hrs/mins)	
Training Method Instructor led / E – Learning /Self train	
Has the Trainee reviewed the relevant SOPs?	
Can the Trainee identify all elements of the equipment i.e. general operation, screens, scanners, stored results, connectivity?	
Is the Trainee aware of storage requirements for all reagents, IQC?	
Is the Trainee aware of pre-analytical interferences, test interferences, unsuitability of the test in certain clinical scenarios?	
Is the Trainee adequately competent to perform IQC and action failures?	
Is the Trainee aware of correct specimen collection and requirements, sample volume, sample preparation and time to analysis?	
Is the Trainee aware of the importance of Operator ID protection?	

Is the Trainee aware of the importance of correct patient demographic entry?	
Is the Trainee sufficiently competent to execute the test unsupervised?	
Is the Trainee aware of contact details of the NPT team for general advice, equipment failures, unusual / spurious results?	
Is the Trainee aware of their responsibilities in performing the test correctly and observing best practice guidance?	
Is the Trainee aware of ongoing competency assessments and retraining?	
Trainee's name (Print)	
Trainee's Signature / Date	
Instructor's Name (Print)	
Instructor's Signature / Date	
Refresher Training Due Date	