

National Institute for Health and Care Excellence

Patient Organisation Submissions for Diagnostic Technologies

- Information for patient organisations

1. Overview of the submission form

We recognise that patients have unique knowledge about what it's like to experience a diagnostic test and receive information from diagnostic tests. They can also describe the impact of that information on the way they live with a specific disease or medical condition and the way early diagnosis might help people to change their lifestyles to prevent disease onset or progression. Patients can describe advantages and disadvantages of all forms of health technologies including diagnostic tests, which may not be reported in published literature. They can tell us what they value most from a diagnostic technology and how difficult trade-offs can be made, becoming key sources of high quality information for the assessment of the direct and indirect effects of diagnostic technologies from the perspective of the patient, their family and carers.

Scope

This submission template has been created to help patient and carer organisations provide information for the assessment of a particular **diagnostic technology or technologies** that are able to:

- Determine which disease or health condition explains a person's symptoms and signs (diagnosis/detection)
- Predict the course of a disease (prognosis/risk assessment)
- Provide continuous detailed information on the progress of the health condition and/or treatment (monitoring)
- Predict the response or the likelihood of an adverse event to a treatment (prediction)

This template is intended to cover specifically health technologies that are used to diagnose and monitor health conditions; provide risk assessment or prognostic information; and to provide information which will influence treatment decisions. NICE calls these '**diagnostic technologies**' and examples include:

- Medical imaging technology (including radiation technology) such as computed tomography (CT) scanners, ultrasound and x-ray equipment
- Invasive diagnostic medical devices such as catheters for measuring and monitoring central venous pressure
- Non-invasive diagnostic medical devices such as an O² saturation monitor, mobile health technology and telemedicine
- Implantable diagnostic devices such as continuous glucose monitoring or continuous pulmonary artery wedge pressure devices.
- In vitro diagnostic tests (applied to patient samples like blood or tissue), including clinical laboratory tests (e.g. to count the number of red blood cells), near-patient tests (e.g. to detect the presence of cancer cells on a sample tissue while performing a surgery, rapid diagnostic tests to detect an infectious disease in the doctor's office and tests which are used by patients themselves (e.g. blood glucose monitoring for home use).

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2. How to complete the submission template

A submission guide is provided with the template to help you complete your submission and provide prompts as to the sorts of issues you might want to comment on when thinking about diagnostic technologies and their impact on patients and carers.

In all parts of the form the term “**patient**” refers to anyone living with, or who has lived with, the condition for which the diagnostic technology is indicated, or who has experience with the diagnostic technology even if they didn’t test positive for the condition including healthy individuals.

Care-givers (carers) refers to a person who cares for someone who is sick or disabled. This person can be part of the family or not.

Please provide clear facts, information and summaries of experiences to give a concise, accurate and balanced overview of a range of patients’ and care-givers’ (carers’) perspectives/views. State the source of your information (e.g. web survey, helpline analysis, social networking, focus group, patients’ records, one-to-one conversations with those in clinical studies, patient stories, research studies). You should complete the template from the perspective of a group of patients rather than your own individual view.

There is no need to send us published scientific papers, as we already have access to those. However, if you have any references or views about the interpretation of a paper about a particular study, or consider a paper or study particularly relevant, we would be happy to hear them.

For any of the sections in the template, if there are groups that should have special consideration, please indicate the specific needs/issues of that group (e.g. children, women/men, ethnic groups, those living in a particular location, those with other disabilities, disease sub-types).

If you require help in understanding any of the terms used, please refer to the [NICE glossary](#). There are also training resources relating to health technology assessment on the [HTAi website](#).