National Institute for Health and Care Excellence
Patient Organisation Submissions for Diagnostic Technologies - Submission guide

About this guide

This guide has been designed to help patient organisations to complete their submissions of evidence to NICE for diagnostic technology assessments.

The submission template is intended to cover health technologies that are used to diagnose and monitor health conditions or treatments; provide risk assessment or prognostic information; and to provide information which will influence the selection of a specific medicine (predictive tests) and/or other management decisions. From now on these will be called 'diagnostic technologies', examples are included in Table 1.

Table 1 – Types of diagnostic technology

Type of technology	Example
Medical imaging technology (including radiation technology)	Computed tomography (CT) scanners, ultrasound and x-ray equipment
Invasive diagnostic medical devices	Catheters for measuring and monitoring central venous pressure
Non-invasive diagnostic medical devices	O^2 saturation monitor, mobile health technology and telemedicine
Implantable diagnostic devices	Continuous glucose monitoring or continuous pulmonary artery wedge pressure devices
In vitro diagnostic tests (applied to patient samples such as blood or tissue)	Clinical laboratory tests (e.g. to count the number of red blood cells), and point of care or near-patient tests (e.g. to detect the presence of cancer cells on a sample tissue while performing 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.

We recognise that patients have unique knowledge about what it's like to receive information from diagnostic technologies and how this information can impact the way patients live with a specific disease or medical condition, or the lifestyle changes they might choose to make

as a result of the information they have received to prevent the onset of disease. They can describe advantages and disadvantages of all forms of health technologies including diagnostic technologies, which may not be reported in published literature. Patients 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 effects of diagnostic technologies from the perspective of the patient, their family and carers.

In all parts of the template 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. It also covers pregnant women and those who may have a genetic marker for a condition but have no symptoms. The term 'carer' refers to a person who cares for someone who is sick or disabled. This person can be paid or unpaid, and part of the family or not.

Completing the template

The guide contains prompts for each question in the template and is intended to highlight the types of issues that patients, carers and their families might find important when thinking about diagnostic technologies. It also highlights the issues for which our committees need patient evidence to address and support their decision making.

The prompts aren't an exhaustive list of all the issues that might be relevant nor do you need to address each prompt.

Please provide clear facts, information and summaries of experiences to give a concise, accurate and balanced overview of a range of patients' and carers' perspectives and 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 form from the perspective of a group of patients rather than your own individual view.

For any of the sections in the form, if there are subgroups of people with a condition, or groups that have protected characteristics under the Equality Act, please indicate the specific needs/issues of that group (e.g. children, older people, sex, gender, pregnancy/maternity, ethnic groups, religious groups, disabilities).

If a question isn't relevant to you, please mark it 'not applicable' and move on to the next one. For example, a person may not have a diagnosis or a condition or disease, or any symptoms, but might be at risk of developing a particular disease. Therefore they may not be able to comment on the disease itself but may have a view on the diagnostic technology and the information it is able to provide.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Diagnostic Technologies - Submission guide

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]().

Please read the guide fully before completing your submission

Information about your organisation
This section is for background information so that we know who is providing the responses.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Diagnostic Technologies
- Submission guide

Impact of the symptoms, condition or disease on patients

1. How do symptoms and/or the condition or disease affect people's lives or experiences?

This question is directed at populations of people who already have a health condition and have experienced a diagnostic technology to detect or monitor it, to have information on its probable course or evolution, or to help in managing or treating it. It can also be completed by people who don't have a condition or diagnosis yet but have signs/symptoms or any physical and/or psychological issue which require a diagnostic technology. Please answer the question in the most relevant way for you, or indicate if this question is 'not applicable' for your circumstance.

Issues to consider in your response:

- *Aspects of the condition that are most challenging (e.g. symptoms, loss of ability to work/go to school, psychological impact, burden on family or friends)*

- *Which symptoms or issues are the most important (e.g. pain, anxiety)*

- *Activities that people find difficult or are unable to do, due to the condition or symptoms*

- *Aspects of the condition that are the most important to control (e.g. symptoms that limit activities, uncertainty in treatment decisions)*

- *Management of the symptoms or condition (e.g. how often medicines need to be taken or how often monitoring needs to take place)*

- *Accessing treatment and support*

- *Support required for daily living*

- *People who are most or least affected by the condition (e.g. men/women, children and young people, ethnic groups)*

- *Economic burden of disease for the patient, family and carers*

- *Social challenges derived from the condition and/or the lack of information about the condition (e.g. social exclusion, impediments to healthcare insurance coverage due to non-specific diagnosis)*

- *Uncertainty about whether to undergo testing, and unease or dissatisfaction related to this uncertainty.*

National Institute for Health and Care Excellence
Patient Organisation Submissions for Diagnostic Technologies
- Submission guide

Impact of the symptoms, condition or disease on family and carers

2.   How do symptoms and/or the condition or disease affect carers/unpaid care-givers and family?

This question addresses the impact of a condition, disease or symptoms on a person's family and carers.

Issues to consider in your response:

- *Challenges faced by family and carers who support a patient to manage the condition, symptoms or access the diagnostic technology*

- *Burden on carers/care-givers, impact on their daily life (e.g. emotional/psychological effects, fatigue, stress, depression, physical challenges, financial, inability to work or go to school, need to travel or move, etc.).*

Experiences and availability of current diagnostic technologies

3.   What role do currently available diagnostic technologies play in helping people manage their symptoms and/or the condition or disease?

Issues to consider in your response:

- *List the main diagnostic technologies you are aware of, are accessible or currently used for this condition, disease, symptom, or issue*

- *The extent to which currently available diagnostic technologies provide valuable information when and where it is needed (e.g. information that helps in the choice of management strategies that control or reduce the most challenging aspects of the condition, symptom or issue; helps in making choices or plans; helps in alleviating financial burden for people and/or their family/carers; helps by having fast and accurate diagnosis, helps patients to continue with everyday activities and to have certainty of not being sick, etc.)*

- *The most important benefits of currently available diagnostic technologies*

- *The most important challenges related to currently available diagnostic technologies and any remaining unmet needs*

- *The positive and negative impact of currently available diagnostic technologies on daily life (e.g. speed of diagnosis, ease of use, effect on pain and comfort, availability of home testing, recalibration needs, availability of items such as test strips, special clinic visits, ability to get replacement technology quickly, cost borne by the patient or savings incurred, including monetary and time*

- *Side effects associated with currently available diagnostic technologies, and whether these can be tolerated.*

4.   What unmet information needs do people currently have due to the lack of an available diagnostic technology for their symptom or condition?

Your response should focus on information patients could get from a test result, rather than information about the test or testing process. Issues to consider in your response:

- *Whether a definitive diagnosis is currently possible and the route a patient may have to take to achieve that diagnosis (long journey through many healthcare providers, financial burden not supported by health insurance)*

- *the effect of a lack of diagnostic information on identifying an appropriate management strategy*

- *Treatment availability, or the need for multiple or repeated therapies.*

About the diagnostic technology being assessed

5.   What are the most important things people would like to gain from the information provided by, and/or the use of, the diagnostic technology being assessed?

Issues to consider in your response:

Information needs

- *Diagnostic accuracy*

- *Access to test results and relevant information for patients and health providers*

- *Ability to make choices on their own health status or prognosis of disease through access to diagnostic information*

- *Value of knowing about the status of the condition or its prognosis not related to treatment decisions, and/or the ruling-out of disease*

- *Future benefit from current diagnostic information*

- *Ability to plan a family, work, retirement, long-term health, financial plans with access to diagnostic information.*

- *Different treatment or management options selected through access to diagnostic information*

Experience of using the technology

- *Control of their condition or symptoms*

- *Use of diagnostic technology*

- *Direct experience of using the technology (e.g. how intrusive the technology is, any pain or discomfort experienced when the technology is used)*

- *Ease of access to diagnostic information (e.g. the impact on day-to-day activities)*

- *Experience of waiting for diagnostic test results.*

National Institute for Health and Care Excellence
Patient Organisation Submissions for Diagnostic Technologies
- Submission guide

6.   For those people <u>with</u> experience of using this diagnostic technology, what difference did the information provided by, and/or the use of, the technology make in their lives or the lives of family and carers?

Issues to consider in your response:

What was the impact of having information from the diagnostic technology?

For example:

- *Treatment, care or planning before the test which changed after the information provided by the test was considered*

- *Effect on quality of life after testing (e.g. the effect on anxiety, ruling-out of (serious) disease, etc.)*

- *Value of having diagnostic information*

- *Empowerment and ownership of their condition to make choices on their management*

- *Having a name for their symptoms and being able to seek specific support benefit from social protection systems and/or support for research on future treatment options*

- *Effect on adherence to treatments*

- *Lifestyle changes*

- *Whether there was a need for further diagnostic test/s following the first test, or,*

- *Potential avoidance of further invasive testing or procedures*

- *Consequences of receiving an incorrect test result*

- *Financial burden or relief of financial burden for patients, family and/or carers*

- *Use of healthcare services*

- *Other advantages and disadvantages of having information from the diagnostic technology being assessed compared with currently available technologies or no testing*

What was the impact of having/taking the test:

- *Increased/decreased anxiety before the test*

- *Increased/decreased anxiety after the test (e.g. waiting for test results)*

- *Pain or discomfort during the test*

- *Side effects occurred after the test from the testing process (e.g., pain, bruising, bleeding)*

- *More or less embarrassment when taking the test*

- *Time taken off work/school/other*

- *More/less concern about harm from the test (e.g. radiation dose)*

If the test is handled directly by the patient:

- *Is the new diagnostic technology easier or more difficult to use than the old one?*

- *How easy is it to understand the information provided by the test? Does this affect how people can manage their condition or symptoms?*

- *Are activities of daily living able to be performed with more or less disturbance due to the diagnostic technology?*

- *Is there more or less financial strain on the patient, their family or carers as testing and management decisions are taken at home?*

Have people actually gained what was important to them with the new test?

- *Did the new diagnostic technology meet expectations?*

7.   For those <u>without</u> experience of this diagnostic technology, but who are aware of studies or other sources of useful evidence, what are the expectations/limitations of having the information provided by the diagnostic technology and/or using the diagnostic technology?

Issues to consider in your response:

- *Perceived advantages and disadvantages of the diagnostic technology*

- *Diagnostic information people would like to have*

- *Expectations around the diagnostic accuracy of test results*

- *Impact on use of healthcare services (e.g. number of hospital visits)*

- *Financial implications to the person (e.g. travelling costs, administration costs)*

- *Groups of people who might particularly benefit or who might benefit less from knowing the results of the test being considered*

- *Aspects of people's needs or expectations that it is hoped will be addressed*

- *Influence of knowing test results on decision-making and choice of treatment, life planning, value of knowing now and in the future.*

National Institute for Health and Care Excellence
Patient Organisation Submissions for Diagnostic Technologies - Submission guide

Additional information
8.   Please include any additional information you believe would be helpful in assessing the diagnostic technology (e.g. ethical or social issues and/or socio-economic considerations).

Key messages
9.   In up to five statements please list the most important points of your submission.   *For example:*   • *The biggest challenges of living with this condition are…*   • *Current diagnostic technologies are adequate/inadequate because…*   • *This diagnostic technology being assessed will be/will not be beneficial because…*