Healthcare, Quality and Improvement Directorate
Chief Nursing Officer Directorate
Chief Medical Officer Directorate
Population Health Directorate

Scottish Government
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Dear Colleague

INTERVENTIONAL PROCEDURES PROGRAMME

This letter replaces HDL (2004) 04 and reminds NHS Scotland staff of their responsibilities when undertaking interventional procedures. NHSScotland is a full partner in the programme and the guidance must be implemented.

An interventional procedure is one used for treatment or diagnosis that involves incision, puncture, entry into a body cavity, electromagnetic or acoustic energy.

An interventional procedure may be assessed by the Interventional Procedures Programme of the National Institute for Health and Care Excellence (NICE) if it is not yet generally considered established clinical practice in the NHS or UK independent sector, or if it is an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice.

Purpose of the Programme

NICE's Interventional Procedures Programme covers Scotland as well as England and Wales. It assesses the safety and efficacy of interventional procedures to determine whether they work well enough and are safe enough for use in the NHS. The programme's aims are to protect the safety of patients and to support doctors, other clinicians, Clinical Governance Committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly.

The process and methods of the Interventional Procedures Programme are designed to ensure that robust guidance is developed for the NHS in an open, transparent and timely way, with appropriate input from consultees and other stakeholders, including patients, from across the UK.

Addresses

For action

NHS Board Chief Executives
NHS Board Medical Directors
NHS Board Nurse Directors
NHS Board Directors of Pharmacy
Dental Lead Officers

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What NHS Scotland Boards should do

The ability of the Interventional Procedures Programme to achieve its aims is dependent on appropriate engagement from the NHS Scotland.

All NHS providers of healthcare should ensure they have governance structures in place to review, authorise and monitor the introduction of new interventional procedures or the use of established clinical procedure, the efficacy or safety of which has been called into question by new information or advice. These structures should ensure that any health care professional considering using a new interventional procedure which he/she has not used before, or has only used outside the NHS, seeks prior approval to do so using the appropriate governance structures of the organisation in which the procedure is to be performed. This also applies to procedures which may be used in an emergency.

If the procedure is not the subject of published NICE interventional procedures guidance as listed on NICE's website but falls within the definition and scope of the Interventional Procedures Programme, the Medical Director of the organisation (or nominated deputy) should notify the procedure to NICE, if the health care professional has not already done so.

Healthcare professionals wishing to carry out a new interventional procedure or an established clinical procedure, the efficacy or safety of which has been called into question by new information or advice must always obtain approval to do so using the appropriate governance structures within the organisation in which the procedure is to be performed.

If NICE is in the process of developing guidance on the procedure, the organisation should only approve its use if:

a. The healthcare professional has appropriate experience and training.
b. All patients offered the procedure are made aware of the special status of the procedure in the NHS. This should be done as part of the consent and shared decision-making process, and should be clearly recorded. Healthcare professionals should ensure that patients understand that the procedure's safety and efficacy are uncertain. They should inform patients about the anticipated benefits and possible adverse effects of the procedure and alternatives, including no treatment.
c. The organisation is satisfied that the proposed arrangements for clinical audit (which may include comparative or multicentre audit) are sound, and will capture data on clinical outcomes that will be used to review continued use of the procedure.

Once NICE has published its guidance on the procedure, the organisation should consider whether the proposed use of the procedure complies with the guidance before approving its continued use in their organisation, bearing in mind that NICE's final published guidance recommendations may need different arrangements to be put in place from those set out in above.

The organisation must ensure that any procedure on which there is interventional procedure guidance is coded using the coding provided by NICE in the published guidance.

When the recommendation about a procedure from NICE includes collecting data on outcomes and safety, health care organisations should ensure systems are in place to support health care professionals to supply the information requested on every patient undergoing the procedure. The data on the outcomes and safety of that procedure should be reviewed by the organisation. The individual undertaking the procedure should also be expected to discuss their outcomes as part of their annual appraisal to allow reflection, learning, and individual improvement.

When NHS Board have authorised the use of a new interventional procedure for which no NICE guidance exists.

When no request has been made for guidance, NHS Boards must have governance structures in place to review, authorise and monitor the introduction of new interventional procedures or the use of established clinical procedure, the efficacy or safety of which has been called into question by new information or advice.

The only exception to the above process is when the procedure is being used only within a protocol approved by a Research Ethics Committee (REC). Once the research is completed, the procedure should be notified to the NICE Interventional Procedures Programme in the normal way. If an adverse incident occurs in association with a new interventional procedure, this should be reported, investigated and escalated in line with local policies. Device- related incidents should be reported to the competent authority.

This process does not mandate commissioning of specific procedures. Cost- effectiveness evaluation is not within the scope of the NICE Interventional Procedures Programme.

If an adverse incident occurs when the procedure is being undertaken, it should be reported in the normal way locally to the organisation's Risk Manager. We sent a letter to Board Chief Executives, Medical Directors and Nursing Directors on 27 March 2017 which clarifies our expectations that you have assurance processes in place to demonstrate that you are following *Learning from adverse events through reporting and review*, the national framework.

An outline description of the programme is set out in the Annex to this document.

Associated Documentation

The IPP is run by NICE for England, Wales and Scotland. Healthcare Improvement Scotland will liaise with NICE in connection with the management of the programme and NHS Scotland clinicians will serve on the Interventional Procedures Advisory Committee. Enquiries about the programme should be directed to IPP at NICE. If there are any specific enquiries related to Scotland's participation in IPP please contact Dr Karen Ritchie at Healthcare Improvement Scotland (karenritchie@nhs.net or 0141 225 6891).

JASON LEITCH
National Clinical Director

CATHERINE CALDERWOOD
Chief Medical Officer

FIONA MCQUEEN
Chief Nursing Officer

ROSE MARIE PARR
Chief Pharmaceutical Officer

MARGIE TAYLOR
Chief Dental Officer

ANNEX

How the NICE Interventional Procedures Programme works

Any individual may notify a procedure to the NICE Interventional Procedures Programme by completing the *online interventional procedures notification form*.

A new notification will initiate the following process:

NICE will decide whether to develop guidance on the procedure, seeking more information from its specialist advisers and checking for a CE mark if needed.

The interventional procedures programme team will prepare a brief to initiate the assessment of the procedure. This is a short internal document covering key aspects of the procedure. The programme team seeks advice from appropriate specialist Committee members and the programme's specialist advisers when preparing the brief. Once the brief has been reviewed by the Committee, developing guidance on the procedure becomes part of the formal work of the programme.

NICE will prepare an overview of the evidence on the procedure's safety and efficacy. Specialist advice, patient commentary and evidence from device companies if available will elicited and taken into consideration as outlined in the IP programme manual.

The NICE interventional procedures advisory committee consisting of members who are independent of NICE will make draft recommendations on the efficacy and safe use of the procedure.

The NICE interventional procedures advisory committee may ask questions of Specialist Advisors and device companies before formulating its draft recommendations.

NICE publishes a consultation document consisting of the draft recommendations on the NICE website for four weeks.

At a further Committee meeting, the NICE interventional procedures advisory committee reviews the consultation document, and considers all the comments received during consultation, responds to them and makes any appropriate changes to the draft guidance.

Before guidance publication, there is a three week resolution stage. This process is a final quality assurance step where stakeholders who commented during the consultation period and who have completed a confidentiality statement are sent the final recommendations. NICE considers any requests for resolution and makes a formal response. The resolution process is not needed when no consultation comments are received or if stakeholders who provided consultation comments do not return their confidentiality statement.

Guidance is published on the NICE website once the resolution process is complete or sooner if there was no requirement for a resolution stage.

In some circumstances, NICE does not produce guidance on a procedure after receiving a notification. The most common reasons for this are that the procedure:

a. does not fit the programme's remit;
b. is not new;
c. involves a modification to an existing procedure whose safety and efficacy are sufficiently well understood;
d. relies on using a medical device but no device is available that has regulatory approval for the intended purpose.

Further information about the interventional procedures programme, including the programme manual can be found on the NICE website:

- *Process manual*
- *Interventional Procedures – further information about the programme*