1 Introduction

Non-medicine technologies encompass a wide range of healthcare interventions, ranging from devices and diagnostic tests to changes in treatment pathways in health and social care. There are over 500,000 medical devices on the market with an annual UK market of £11 billion for medical devices alone and 1 in 25 people have an implanted medical device. This group of interventions may prove to be transformative in the delivery of care, however the assessment and regulatory structures, processes and profile of non-medicine technologies are significantly less visible than for medicines. Medicines have historically received greater focus within the research community, with closer integration to the structures that deliver health care and greater prominence in the wider media. There is some evidence that this focus may have produced a mismatch between the priorities of patients and clinicians for research and the research that is actually done (Crowe et al.). Certainly, the non-medicine technologies arena has received less attention despite an innovative environment, a greater number of interventions with potential safety and risk implications and a significant capital spend. If we are to gain significant opportunity from non-medicine technologies to improve health outcomes and experience, a significantly greater focus and resource is required to support the key issues and challenges described in this plan.

This document outlines our plan to improve the use of non-medicine technologies and our key actions for 2016–2018.

2 About Healthcare Improvement Scotland

Healthcare Improvement Scotland's role is to drive improvement in the quality of health and social care for all people in Scotland. The organisation's work supports the vision for Scotland of people able to live longer healthier lives at home, or in a homely setting.

To deliver its work, Healthcare Improvement Scotland works with health and social care providers and aims to drive improvement in the care people receive by:

- empowering people to have an informed voice in managing their own care and shaping how services are designed and delivered
- using the best available evidence to provide national clinical standards, guidance and advice for all health and social care providers to use, including assessment and improvement for both medicine and non-medicine healthcare interventions
- providing programmes of world-class improvement support to help services improve, and
- delivering quality assurance activity which is fair but challenging and leads to improvements in the care that people receive.

We work in partnership with those delivering care, including Health and Social Care Partnerships, third sector organisations, the independent care sector, housing organisations and NHS boards to make improvements in health and care services which are cost effective and sustainable.

3  **Methodology**

This plan has been developed by a working group; membership described in Appendix 1. Further information was gathered from a questionnaire distributed to NHS boards on national guidance and local health technology assessment (HTA) processes (see Appendix 2).

Draft versions of the document were submitted through Healthcare Improvement Scotland’s consultation process to members of the healthcare community, patients and the public.

4  **Definition**

Non-medicine technologies are a diverse range of healthcare interventions extending from devices and diagnostic tests to pathway interventions. In considering non-medicine technologies, this document aims to reflect the life cycle of non-medicine technologies from innovation to obsolescence.

The proposed definition for non-medicine technologies, already in use by the Scottish Health Technologies Group (SHTG), is modified from the International Network of Agencies for Health Technology Assessment (INATHA).

The definition includes:

“All intervention, except pharmaceuticals, which may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes devices, diagnostic tests, ehealth, procedures and organisational systems used in health care.”

The wide range of possible interventions means that a focus on specific areas is required to achieve effective improvement actions. The initial areas of focus will include work on devices and diagnostics and their related pathways. The landscape for non-medicine technologies is best developed for devices which is reflected in this paper. However, we acknowledge that the issues faced by devices, including lack of evidence, are more marked for other non-medicine technologies.

5  **NHS board survey of existing assessment and governance structures for non-medicine technologies**

A questionnaire survey was distributed in April–May 2015 to NHS boards and other stakeholders assessing three key areas:

- national guidance (UK and Scotland): awareness, perceived status, pathway for consideration and assessment of level of support for local decision-making from national guidance
- local assessment: processes if no national guidance for devices and diagnostics, and separate service pathways, local resource and skills available and implementation of advice, and
- improving non-medicine technologies decision-making processes.

The questionnaire was distributed using Healthcare Improvement Scotland’s communication and engagement processes, with recipients encouraged to forward to colleagues. One hundred and thirty-two responses were received. Although there is some variation in response rates, all 14 NHS board areas responded. A structured analysis of the responses is presented within Appendix 2.
There was good recognition of Healthcare Improvement Scotland products by study respondents (66–84%) but the status of advice was poorly understood for all products. The respondents indicated that a wide variety of groups were used to consider advice for non-medicine technologies, a significant proportion of which were ad hoc. One third of respondents thought the level of support from national guidance bodies was satisfactory or highly satisfactory.

Just over 50% of respondents indicated that if no guidance was available they would undertake a local assessment. The majority of assessments used ad hoc clinical groups which did not have access to specific expertise in evidence assessment or health economics. There was variability in the implementation structures used for non-medicine technologies but the significant majority used relevant clinical groups.

Participants were asked to rank strategies to improve decision-making within NHS boards. The development of a larger programme of national guidance and improved use and dissemination of guidance were the highest ranked responses. Local improvements included a greater educational and training role for national bodies to improve local decision-making.

6 Key issues in the non-medicine technologies landscape

6.1 Innovation

The non-medicine technologies arena is highly innovative. In 2012, non-medicine technologies registered over 10,000 EU patents; twice as many as medicines. The trend over the last decade has seen a progressive increase in patents for non-medicine technologies per year while other health intervention areas have remained relatively static. The potential positive impact of innovation is recognised by the Scottish Government which has defined a clear strategy and direction to improve the adoption of innovation in Health and Wealth: A Statement of Intent for Innovation in Health.

Innovation is a multi-stakeholder landscape and considerable work has already been undertaken to develop a landscape that fosters innovation and helps break down barriers between the innovators and the NHS. Early evidence, which is always limited for non-medicine technologies, will often not satisfy conventional HTA methods. A key challenge is the development of a system of early assessment which is rapid, accessible and works in an integrated fashion within the non-medicine technologies landscape allowing a ‘Once for Scotland’ approach. Healthcare Improvement Scotland has a key role in supporting the assessment of innovation and SHTG has piloted a new evidence product and pathways to aid assessment of CE marked innovative technologies. Effective and safe implementation of key new technologies would be greatly supported by the development of methods of national data collection on critical outcomes for ongoing surveillance and assessment.

6.2 Stakeholders

The breadth of the non-medicines technologies landscape encompasses a large number of diverse stakeholders. In the innovation landscape, this is particularly notable and organisations from industry, academia, NHS service, digital health and procurement all need to integrate effectively to ensure an effective outcome. This integration is complex and there can be a lack of clarity about relative roles and responsibilities which are sometimes incompletely described. In addition, this is further complicated by an absence of a shared taxonomy for the activities of the respective bodies; organisations may use similar terms to describe different roles and actions (for example assessment). Effective communication between stakeholders is challenging and sharing of information would be enhanced by a clearer
understanding of roles. An initial taxonomy outlining key non-medicine technologies stakeholders is presented in Appendix 3.

The patient and public voice is particularly important for non-medicines technologies as overall there is typically less established engagement through the non-medicine technologies life cycle. The evidence base for non-medicine technologies is often limited and the methodology for patient engagement with assessment bodies is less established and currently not routine. In addition, there is less transparency of access to non-medicine technologies which results in less patient engagement. Increasingly, particularly as the patient may be the direct user of medical technology, patient evidence may be more important given the lack of clinical evidence.

6.3 HTA and guidance
The assessment of medicines in Scotland is undertaken by a single body: the Scottish Medicines Consortium (SMC) which is constituted from representatives from local Area Drugs and Therapeutics Committees (ADTCs) in each NHS board. All new medicines and new indications for existing medicines (approximately 80 products per year) are assessed by SMC, apart from medicines being considered as part of National Institute for Health and Care Excellence (NICE) Multiple Technology Assessments (MTAs).

SHTG is the national body responsible for providing evidence-based advice on non-medicine technologies and undertakes approximately 25 assessments per year. At local level, the assessment of non-medicine technologies is much more distributed throughout a variety of predominately local NHS board groups. An accurate number of non-medicine technologies considered per year is not available however this is likely to reach thousands of products. The large number makes assessment by a single body impractical. A number of other bodies, including procurement bodies, local ADTCs, clinical governance groups and other ad hoc clinical bodies will undertake assessment according to local needs.

The diversity of assessment groups makes it difficult to ensure similar standards of assessment informed by robust consideration of clinical effectiveness and cost effectiveness. There is also a gap in knowledge about the effectiveness of distribution of structured non-medicine technologies assessment as there is no single natural landing zone for advice within NHS boards. The combination of variation in local assessment methods and variation in structures make it difficult to communicate effectively between different bodies to ensure we are getting best value and equity of access to non-medicine technologies.

The diversity of non-medicine technologies across health and social care means that assessment decisions by a single body is unfeasible. In a few specific areas, partnerships have developed between SHTG and external groups to facilitate assessment, for example diagnostic tests and the molecular pathology evaluation panel.

6.4 Regulation
The competent authority for the regulation of devices and medicines within the UK is the Medicines and Healthcare products Regulatory Agency (MHRA) working to EU legislation. For medicines, achieving marketing authorisation usually requires good quality, high-volume evidence and data from 100–1000s of patients which then guides assessment and implementation. In non-medicine technologies, the range of products makes a single evidence threshold inappropriate: Class I devices, for example simple walking aids, need proportionately less regulation than Class III
devices, for example pacemakers. However, even for the most complex devices (Class III), while demonstration of safety and product performance is required, robust evidence of clinical effectiveness is less often available.

The requirement to generate evidence is traditionally less for non-medicine technologies. Technology developers may lack expertise in evidence generation and this leads to uncertainty in the utility of the evidence base to inform national, regional or local adoption. The limited amount of data available challenges conventional HTA methods, as there is often a lack of clear evidence of clinical and cost effectiveness and sometimes limited evidence relating to safety. There is a need to ensure that, in specific situations, data can continue to be collected for both clinical effectiveness and safety reasons as devices are used in practice. At present, there are limited models available for data collection on outcomes post-CE marking for non-medicine technologies.

Adverse incident reports are the traditional method of collecting data on safety of devices. The diversity of stakeholders, lower visibility of non-medicine technologies and a more complex reporting structure all contribute to the complexity of receiving and distributing information relating to non-medicine technologies. Pharmacists play a vital role in adverse incident reporting and safety and improvement in medicines management. There is considerably less resource within the non-medicine technologies system for safety and improvement and there may be opportunities to consider the local leadership roles that may be played by NHS board equipment coordinators and other groups such as the innovation champions.

The EU device regulations are currently being amended and will change significantly in the next few years, and the Scottish Government is developing a Medical Device Strategy to be released in 2016–2017; this represents an opportunity to consider the structures and processes for devices.

6.5 Finance
The diversity of non-medicine technologies makes exact calculation of spend related to this group of interventions difficult. Expenditure on medicines is much more readily identified within current national statistics. This permits a greater focus on ensuring best value and an improved ability to forecast future cost pressure. A number of areas within non-medicine technology have seen, and are likely to continue to see, significant increases in volume of interventions and associated spend; particularly medical devices and diagnostic tests. The medical device market alone in the UK was estimated to equal an £11 billion annual spend in 2014. It may be helpful to explore more structured national reporting for key areas of non-medicine technology.

6.6 The changing landscape: hybrid devices and information technology
The traditional boundary between medicines and non-medicines will be progressively eroded in the next 5–10 years. Devices already incorporate drug elements either to improve physical interactions or to permit controlled delivery of an active drug. Emerging diagnostic technologies, such as genomics, will be transformative in delivering stratified medicines to permit better understanding of diagnosis, prognosis and response to proposed treatment at individual patient level. Information technology and detector advances will permit the capture, analysis and presentation of physiological information directly to the public on smartphones and other devices. This evolution will challenge the current demarcation between medicines and non-medicines, and future assessment and regulatory structures will need to be sufficiently flexible to permit appropriate assessment.
7 Key challenges

- Non-medicine technologies need to be recognised as a priority at least equivalent to medicines if we are to gain the significant opportunity for improvement to health outcomes and experience.
- Multiple stakeholders and decision-making structures present a challenging landscape for effective communication and distribution of information relating to HTA and safety.
- Currently, the majority of decisions in the assessment and implementation of non-medicine technologies are taken in groups using different assessment methodologies and often without access to specific expertise in evidence assessment or health economics.
- Non-medicine technology is a highly innovative area with a relatively low evidence threshold. Alternative assessment and adoption processes are required in such low evidence environments and the development of systematic methods of ongoing data collection to support evaluation of safety and critical outcomes are needed.

8 Our plan for improvement

Our framework for improvement will ensure that Healthcare Improvement Scotland plays a lead role in NHSScotland and beyond in relation to the evidence, improvement and quality assurance of non-medicine technologies.

Addressing the challenges and opportunities identified will require both partnership and ownership by a range of key stakeholders across NHSScotland.

Our plan is based around thematic areas which reflect the landscape and key challenges. There is a need to:

- raise and improve awareness of the importance of safe, clinical and cost effective use of non-medicine technologies.
- work collaboratively to understand roles and responsibilities with a wide range of non-medicine technologies stakeholders, including evidence assessment and regulatory organisations, manufacturers and patient and public bodies.
- improve communication networks and structures to ensure that evidence assessment and improvement information are received and considered by the most appropriate local groups. There is a need for clearer focus and co-ordination for non-medicine technologies and a clearer landing zone for advice and improvement information.
- contribute to the development of a shared framework for the assessment of non-medicine technologies at a local level. There is an opportunity to share local assessment and reduce duplication and improve equity of access.
- support the pathway for assessment of CE marked innovative technologies, ensuring structures are sufficiently flexible to permit assessment and ongoing surveillance.

The work plan to support this work is described in Table 1.
<table>
<thead>
<tr>
<th>Theme</th>
<th>Action</th>
<th>Stakeholders</th>
<th>Timescale</th>
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<tbody>
<tr>
<td>Improving awareness</td>
<td>Profile the role and challenges of non-medicine technologies with key stakeholders</td>
<td>Healthcare Improvement Scotland/NHS boards/innovation partners</td>
<td>2016-2018</td>
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<td>Improving awareness</td>
<td>Develop patient and public information about the role of non-medicine technologies</td>
<td>Healthcare Improvement Scotland</td>
<td>2016-2018</td>
</tr>
<tr>
<td>Working collaboratively with stakeholders</td>
<td>Develop structured public engagement processes</td>
<td>Healthcare Improvement Scotland</td>
<td>2016-2018</td>
</tr>
<tr>
<td>Working collaboratively with stakeholders</td>
<td>Create a map and role descriptors of stakeholders for evidence, improvement and quality assurance for non-medicine technologies</td>
<td>Healthcare Improvement Scotland/Scottish Government/innovation partners</td>
<td>2016-2018</td>
</tr>
<tr>
<td>Working collaboratively with stakeholders</td>
<td>Work to support the Medical Device Strategy</td>
<td>Healthcare Improvement Scotland/Scottish Government</td>
<td>2016-2018</td>
</tr>
<tr>
<td>Working collaboratively with stakeholders</td>
<td>Develop closer links with regulatory structures (MHRA) and HTA structures (NICE)</td>
<td>Healthcare Improvement Scotland/MHRA/NICE</td>
<td>2016-2018</td>
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<tr>
<td>Improving communication networks and structures</td>
<td>Engage with NHS boards to develop a clearer landing zone for HTA information and advice</td>
<td>Healthcare Improvement Scotland/NHS boards/Scottish Government</td>
<td>Healthcare Improvement Scotland priority area for 2016</td>
</tr>
<tr>
<td>Improving communication networks and structures</td>
<td>Work to ensure the clarity of the status of evidence products</td>
<td>Healthcare Improvement Scotland</td>
<td>2016-2018</td>
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<tr>
<td>Developing a distributed model of assessment</td>
<td>Assess available models of local HTA processes and develop a suitable adaption for NHSScotland</td>
<td>Healthcare Improvement Scotland/NHS boards</td>
<td>Healthcare Improvement Scotland priority area for 2016</td>
</tr>
<tr>
<td>Developing a distributed model of assessment</td>
<td>Develop educational material to support local HTA processes</td>
<td>Healthcare Improvement Scotland/NHS Education for Scotland</td>
<td>Healthcare Improvement Scotland priority area for 2016</td>
</tr>
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<td>Theme</td>
<td>Action</td>
<td>Stakeholders</td>
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<tr>
<td>Developing a distributed model of assessment</td>
<td>Develop a pilot project to develop complete life cycle guidance and assessment to inform utilisation</td>
<td>Healthcare Improvement Scotland / NHS boards</td>
<td>2016-2018</td>
</tr>
<tr>
<td>Supporting the innovation landscape</td>
<td>Provide strategic support to the Health Innovation Partnership and other innovation structures</td>
<td>Healthcare Improvement Scotland / Scottish Government / NHS National Procurement</td>
<td>2016-2018</td>
</tr>
<tr>
<td>Supporting the innovation landscape</td>
<td>Support the development of processes for ongoing data collection in evolving technologies</td>
<td>Healthcare Improvement Scotland / Scottish Government / ISD / Innovation Partnership Board</td>
<td>2016-2018</td>
</tr>
</tbody>
</table>
References


Appendix 1: Membership of the Non-medicine Technologies Strategic Plan Working Group

Sara Twaddle (Chair)  Director of Evidence
Healthcare Improvement Scotland

Richard Brewster  Programme Manager, Medicines Technology Strategy
Healthcare Improvement Scotland

Edward Clifton  Senior Health Economist
Healthcare Improvement Scotland

Sara Davies  Public Health Consultant, Patients and Quality Division
Scottish Government Health and Social Care Directorates

Deirdre Evans  Divisional Director
NHS National Services Scotland

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Jenny Long  Senior Programme Manager
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Scottish Government Health Directorates – Capital and Facilities

Karen Macpherson  Lead Health Services Researcher
Healthcare Improvement Scotland

Laura McIver  Chief Pharmacist
Healthcare Improvement Scotland

Andrew Marsden  Vice Chair
Scottish Health Technologies Group

Susan Myles  Unit Head for Scottish Health Technologies Group /Lead Health Economist
Healthcare Improvement Scotland

Iain Robertson  Chair
Scottish Health Technologies Group

Suzanne Wilson  Senior Health Information Scientist
Healthcare Improvement Scotland
Appendix 2: Results of the non-medicine technologies survey

This questionnaire sought to understand existing assessment and governance structures for non-medicine technologies within NHS boards.

Methodology
A web-based electronic survey was developed to capture the views of staff regarding decisions about the use of in NHS boards. The survey focused on understanding national guidance status and pathways, local assessment methods and resource, and opportunities to improve non medicine technologies decision-making processes.

Healthcare Improvement Scotland’s clinical communication pathway was used to distribute an email with a link to the electronic survey. Recipients of the email were asked to cascade the communication to staff involved with non-medicine technologies in NHS boards or other organisations. Recipients were also asked to distribute the survey to any public representatives who had been involved in non-medicine technologies processes within NHSScotland. There was a 6-week survey consultation period, with the survey closing on 5 June 2015. The survey data was collated and analysed by a health services researcher.

Results
One hundred and thirty-two responses were received: 123 from the 14 NHS boards and nine from organisations or individuals which comprised an ‘other’ category. A self-employed complementary therapist and the following organisations were represented in the ‘other’ category: Healthcare Improvement Scotland, Scottish Government, City of Edinburgh Council, NHS National Services Scotland and Scottish Lifesciences Association. Figure 1 shows the distribution of responses.

Figure 1 Distribution of responses to survey (n=132)
The greatest proportion of responses were received from NHS Lothian (27.2%) followed by NHS Borders (11.2%). The responses received for the remaining NHS boards and ‘other’ category ranged from 1.6% to 8%.

Of the 132 people who responded to the survey, 114 specified their job title. These were allocated to job categories, informed by staff group lists used in NHS Workforce statistics (https://isdscotland.scot.nhs.uk/Health-Topics/Workforce/docs/Workforce_Staff_Groups.pdf?15:54:42) and WHO classification of health professionals (http://www.who.int/hrh/statistics/Health_workers_classification.pdf), and are presented in Figure 2.

**Figure 2**  **Response by job category (n=114)**

The greatest proportion of responses came from medical professionals (26 responses, 22.8%) and managers (with healthcare and non-healthcare managers equally represented and totalling 44.7%). This was followed by staff roles in nursing and midwifery and allied health (9.6% and 8.8% respectively). The occupations classed as ‘other’ included professionals in academia and volunteers and accounted for 7% of the responses.

Figure 3 shows the awareness of respondents of UK authorities that provide guidance on non-medicine technologies. Overall, the vast majority of respondents were familiar with the Scottish Intercollegiate Guidelines Network (SIGN) and SMC at 94% (110/117 respondents) and 83.9% (94/112 respondents) respectively. Respondents were less aware of SHTG at 65.8% (75/114 respondents). In terms of the guidance that NICE produces, most of the respondents (74.6%) were familiar with the interventional procedure guidance (IPG), while just over half (51.3%, 57/111 respondents) were aware of NICE MTAs.
The respondents’ understanding of the status of the advice given by each of the guidance bodies was mixed as seen in Figure 4. In all, 62.1% of respondents understood the status of SMC advice to be mandatory, while 26.2% correctly thought it was required to be considered by NHS boards; 11.6% thought it was for information only. The advice provided by SHTG was thought to be for consideration only by 56.9% and for information by 34.3%. The majority of respondents (73.7%) thought that SIGN guidance needed to be considered while only 55.3% and 47.8% thought the NICE IPG and MTA guidance needed consideration. Just over 30% thought both advice types were for information.
Ninety-six respondents provided information on which groups consider published advice within their NHS boards and could tick multiple groups where it applied. Therefore, for each guidance body, there could be a greater number of responses compared with the number of respondents. The results are presented in Figure 5.

Published SHTG, SIGN and both types of NICE advice were most commonly considered by clinical governance groups – 39.7%, 67.8%, 42.6% (IPG) and 42.4% (MTA) respectively – and by ‘other groups’ such as planning, managed clinical networks, clinical advisory groups, or department groups – 47.1%, 32.2%, 38.2% (IPG) and 42.4% (MTA) respectively. SMC advice was largely considered by ADTCs (57.5%) as well as clinical governance and ‘other groups’ (32.5% and 27.5% respectively).

Respondents reported that advice from SHTG and NICE (IPG and MTA) was most likely to not be considered within NHS boards compared with SIGN and SMC guidance (about 17% compared with 6%). For all types of advice, Healthcare Improvement Scotland liaison co-ordinators play a minor role in its consideration, with their involvement ranging from 8.8% (SMC) to 17.6% (SHTG).

Figure 5  Groups responsible for considering published advice within NHS boards

When asked how supportive national bodies were in helping NHS boards to consider the evidence about non-medicine technologies, 90 people responded (Figure 6), and just over 30% reported support to be satisfactory while about a quarter of respondents considered it to be unsatisfactory. Only 2.2% felt that national support was highly satisfactory. Over 40% (38/90 respondents, 42.2%) were not aware that support was available.
Figure 6  
Satisfaction with support provided by national guidance bodies in considering non-medicine technologies guidance (n=90)

Figure 7 shows how the effectiveness of a health technology is assessed in NHS boards if no national guidance is available as reported by 89 respondents. About half reported that they undertook a local clinical assessment based on available clinical knowledge and expertise, 21.3% undertook a local structured systematic HTA that included health economic and clinical input and 19.1% submitted a request for national guidance to an appropriate national body. About 10% reported other approaches which included a review of the evidence, such as a systematic review or rapid review, or consulting clinical experts. Nearly 30% did not know how health technologies were assessed in their NHS boards when no national guidance is available.
Eighty-seven respondents provided information on how different service models are assessed if no national guidance is available and the results are presented in Figure 8. Local clinical assessment based on available clinical knowledge and expertise was the most common method of assessment, as reported by 58.6% (51/87 respondents); 27.6% (24/87 respondents) undertook a local structured systematic HTA that included health economic and clinical input and 12.6% (11/89 respondents) submitted a request for national guidance to an appropriate national body. Just over 11% reported other approaches which included an evidence synthesis/rapid review, process mapping or development of a pathway in collaboration with clinicians. Nearly a quarter of respondents did not know how service models were assessed in their NHS boards when no national guidance is available.
Seventy-four respondents provided information about local expertise available to assess non-medicine technologies and the results are presented in Figure 9. In all, 41.9% had local expertise available to undertake a structured systematic process (for example HTA), with 18.9% reporting that it included both cost/health economic and clinical analysis. However, 58.1% did not have specific expertise to evaluate health technologies available and used ad hoc clinical groups depending upon the topic.

Seventy-five respondents provided information about how advice on non-medicine technologies was implemented in their NHS board (Figure 10). Advice is most commonly considered by an appropriate clinical group (69.3%) followed by a local planning group (36%), a board executive group (26.7%) or other groups (24%) such as a governance group.
clinical management group, and by procurement. Several respondents noted that it could be any of the three options but depended on the technology or its potential impact.

Figure 10  Groups that consider implementation of non-medicine technologies advice (n=75)

When asked about how decision-making on non-medicine technologies could best be improved in their board areas, 74 people responded and rated five improvement options on a 5-point scale according to their importance, with 5 denoting the most important and 1 denoting the least important. Using the average rating of this scale, respondents ranked the improvement options in the following order, with 1 being most important and 5 being least important:

1. Development of a larger programme of national guidance.
2. Improved use and dissemination of national guidance.
3. Provision of training and support by national bodies to territorial boards to enable them to undertake structured local assessments.
4. National bodies providing a clearing house function to share locally produced guidance among NHS boards.
5. Better local decision-making with structure dependent upon particular technology and other factors.

Improvement options ranked 3 and 4 were closely rated by respondents. Respondents were divided as to the importance of the option ranked fifth, with a breakdown of the data showing that it was the second most important improvement option (16/74 respondents, 21.6%) as well as the least important improvement option (28/74 responses, 37.8%).
Appendix 3: Taxonomy of key non-medicine technologies stakeholders

Initial concept/introduction to healthcare market
Stakeholders that provide stimulation for ideas and provide support and advice for the life science sector surrounding the creation of new products and technologies that have the potential to improve patient care. Such support may involve the facilitation of access to NHS clinical expertise and advice about NHS requirements for the life sciences sector’s ideas and potential new technologies.

- Innovation Champions
- NHS Innovation Centre (Golden Jubilee National Hospital)
- Scottish Centre for Telehealth and Telecare
- Digital Health Institute
- Health Sciences Scotland
- Scottish Health Innovations Limited
- Medical Devices Unit (NHS Greater Glasgow and Clyde)
- Strathclyde MedTech Centre
- Other innovation centres (for example CENSIS)
- Health Innovation Partnership Scottish Lifesciences Association
- Scottish Enterprise
- NHS National Procurement (via Health Innovation Assessment Portal)
- NHS board research and development departments
- University research and development departments

Research and development/funding
Stakeholders that assist in bringing industry ideas closer to market, for example through access to NHS research expertise and test environments. R&D support may include the initiation, support, funding or conducting of research.

- NHS Innovation Centre (Golden Jubilee National Hospital)
- Digital Health Institute
- Health Sciences Scotland
- Scottish Health Innovations Limited
- Medical Devices Unit (NHS Greater Glasgow and Clyde)
- Strathclyde MedTech Centre
- University Research Centres
- NHS National Research Scotland /Chief Scientist Office
- Health Innovation Partnership /Scottish Lifesciences Association
- Scottish Enterprise
- NHS board research and development departments

Regulation
Stakeholders who are responsible for ensuring that medical devices meet applicable standards of safety, quality and effectiveness.

- Medical and Healthcare Products Regulatory Agency
Enablers/collaborators
Stakeholders who work across boundaries with industry, academia, local authorities, NHS boards and voluntary and independent sectors to develop awareness and recognition surrounding life science non-medicine technologies. Stakeholders who encourage the development of processes which serve to strengthen the link between, for example, the life sciences sector and NHSScotland.

- Innovation Champions
- NHS Innovation Centre (Golden Jubilee National Hospital)
- Scottish Centre for Telehealth and Telecare
- Digital Health Institute
- Health Sciences Scotland
- Scottish Health Innovations Limited
- Medical Devices Unit (NHS Greater Glasgow and Clyde)
- Health Innovation Partnership Scottish Lifesciences Association
- Scottish Enterprise
- Innovation Partnership Board
- Scottish Lifesciences Advisory Board
- NHS board test beds/key opinion leaders

Evidence assessment
Stakeholders that provide advice and/or guidance relating to the evidence surrounding the clinical and cost effectiveness of existing or new non-medicine technologies, where a key purpose of such advice/guidance is to support planning and decision-making processes in NHS boards. Also, stakeholders that carry out empirical and methodological research surrounding the use of a technology - to make a difference to both the effectiveness and delivery of health services and to the health of populations in Scotland.

Owing to the varied nature of evidence assessment, this category has been split into two subcategories:

a) Formal evidence assessment. Here, assessment is carried out by bodies with structured assessment criteria.

- Scottish Health Technologies Group
- Scottish Intercollegiate Guidelines Network
- Scottish Medicines Consortium
- Molecular Pathology Evaluation Panel
- National Institute of Health and Care Excellence
- University research centres

b) Informal evidence assessment. This encompasses ad hoc assessment of the available evidence, which may be unpublished and gathered in a less structured format. For example, manufacturer or hospital data.

- Scottish Centre for Telehealth and Telecare
- NHS National Procurement
- SHTG Innovative Medical Technology Overviews
- NHS test beds
Support for adoption within NHSScotland

Stakeholders that have a role within the decision-making surrounding the adoption of non-medicine technologies within NHSScotland. Stakeholders may focus on the adoption of individual technologies, or provide frameworks through which adoption decision-making processes can be developed.

- NHS National Procurement
- Regional procurement hubs
- NHS board committees
- Innovation Partnership Board

Ongoing surveillance

Stakeholders that undertake a role in the ongoing assessment of technologies in situ. This may refer to the relative effectiveness of the technology, or the investigation and reporting of adverse incidents.

- Incident Reporting and Investigation Centre
- NHS National Procurement audits

Who are these stakeholders?

Academic research units

- The Health Economics Research Unit (HERU, University of Aberdeen) aims to develop and encourage the application of appropriate economic methods to improve health and health care in Scotland, specifically through four theme areas: research of economic approaches to health and health care at standards of international excellence, develop and apply economic techniques to improve health care and population health in Scotland, make available to the health service a body of expertise in health economics, and build and sustain capacity in the economics of health.

- The Health Services Research Unit (HSRU, University of Aberdeen) has a national remit to research the best ways to provide health care. Specifically, its remit is to: study or evaluate clinical activities with a view to improving effectiveness and efficiency in health care; work for the implementation of proven changes in clinical activities; encourage and support similar work throughout Scotland; build capacity in health services research through training and other development activities.

- Health Economics and Health Technology Assessment (HEHTA, University of Glasgow) covers a broad set of activities relating to the appraisal of health service interventions, including policies, procedures, devices, drugs and diagnostics. Its research is divided into seven programmatic themes: decision analytic modelling and simulation for evaluation in health; economic evaluations alongside clinical trials; economics of population health; evidence synthesis, incorporating perspectives and experiences; statistical analysis of linked health data; and global HTA.

Digital Health & Care Institute (DHI)

- DHI incorporates a network of partners that spans health and social care providers, third and private sectors, higher education and business development agencies. This partnership offers a strong supply of diverse innovation opportunities that can: identify and articulate demand for solutions and innovative approaches, offer realistic and compelling experience of the integration of technologies in the target environment, and help build the right mechanism to take an idea much closer to market and deployment - including embedding and scaling up of innovations. Source: https://dhi-scotland.com/who-we-are?locale=en
Health Innovation Partnership (HIP)

- HIP focuses on helping companies to bring forward products and ideas that are well developed and to establish if these can deliver real benefits for patients and families through testing in an NHS setting. This direct engagement helps companies to get early answers and makes sure that NHSScotland is not losing out on access to innovative solutions, especially those on its own doorstep. Source: [http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health](http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health)

Health Science Scotland (HSS)

- HSS was formed as a partnership of medical universities and their associated NHS boards in Scotland to promote excellence in the field of clinical and translational medicine. The HSS vision is to ‘promote and enhance Scotland as a world-leading hub of innovative health research and development’, and has the following objectives to: increase the level and quality of health research and development in Scotland, improve and facilitate collaborative and innovative early phase clinical trials between academic and industry partners, and increase the number of Scottish patients participating in and benefiting from clinical research.

Incident Reporting and Investigation Centre (IRIC)

- As part of NHS NSS, IRIC co-ordinates the investigation of adverse incidents and, where necessary, issues an Estates and Facilities Alert or proposes that the MHRA issues a Medical Device Alert.

Innovation Champions

- Since 2013, each NHS board has had an Innovation Champion. Innovation Champions serve as internal and external contact points on innovation and as drivers around the Scottish Government’s innovation agenda. Source: [http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health](http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health)

Innovation Partnership Board (IPB)

- The Innovation Partnership Board, formed in December 2012, represents a unique attempt to make progress on health and innovation on a joint basis, with board members from across the NHS, life sciences industries, Scottish Enterprise, the research community and the Scottish Government. Source: [http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health](http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health)

Medical and Healthcare Products Regulatory Agency (MHRA)

- MHRA is the UK’s regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness.

Medical Devices Unit at NHS Greater Glasgow and Clyde

- The Medical Devices Unit is part of the Department of Clinical Physics and Bioengineering within NHS Greater Glasgow and Clyde. The Unit seeks to: evaluate by researching emerging technologies, supporting clinical trials, and providing regulatory advice; innovate by designing, developing, and validating the next generation of medical devices; and exchange by managing the knowledge exchange between the NHS, industry, and academia. Source: [http://www.medicaldevicesunit.org/](http://www.medicaldevicesunit.org/)

National Institute for Health and Care Excellence (NICE)

- NICE provides national guidance and advice to improve health and social care by: producing evidence-based guidance and advice for health, public health and social care practitioners; developing quality standards and performance metrics for those providing and commissioning health, public health and social care services; and providing a range of informational services for commissioners, practitioners and managers across the spectrum of health and social care. Source: [https://www.nice.org.uk/about/what-we-do](https://www.nice.org.uk/about/what-we-do)
**NHS National Procurement**
- NHS National Procurement seeks to deliver the best value supply chain services that support Scotland's health, with a mission to increase savings and maximise health impact. Source: [http://www.nhsscotlandprocurement.scot.nhs.uk/about-us.aspx](http://www.nhsscotlandprocurement.scot.nhs.uk/about-us.aspx)

**Health Innovation Assessment Portal (HIAP)**
- HIAP, managed by NHS National Procurement, is the first step in a national process that is being developed to provide health innovators with feedback, signposting and onward direction from NHSScotland - including SHTG and Scottish Government. Innovations submitted via the portal are assessed by a panel of relevant experts, including NHS clinicians where appropriate. Source: [http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health](http://www.gov.scot/Topics/Health/Quality-Improvement-Performance/Innovation-Health)

**NHS Innovation Centre (Golden Jubilee National Hospital)**
- The NHS Innovation Centre is a venue that provides a focal point for training and research activity for healthcare professionals across Scotland. Individuals and organisations are able to submit healthcare devices for review by experts, who will test their potential for use within the NHS. The facility brings together health professionals and clinical experts, who are responsible for turning new ideas into better treatment for patients.

**NHS National Research Scotland (NRS)/Chief Scientist Office (CSO)**
- The aim of NRS is to ensure that NHSScotland provides the best possible environment to support clinical research and that it can attract both commercial and non-commercial funders to invest in research. This is achieved through the application of best practice and processes that can support delivery at the highest level, as well as providing the solid infrastructure that is needed to support all research undertaken in the NHS for patient benefit.

- Alongside NRS, CSO supports and promotes high quality research aimed at improving the quality and cost effectiveness of services offered by NHSScotland and securing lasting improvements to the health of the people of Scotland. Source: [http://www.cso.scot.nhs.uk/](http://www.cso.scot.nhs.uk/)

**NHS test beds/key opinion leaders**
- Within NHS boards, product testing/evaluation may be undertaken surrounding particular devices and devices may be championed by expert opinion leaders. Although the methods used may differ from NHS board to NHS board, enablers within NHS boards can help bring a product to market and such tests and evaluations may provide valuable evidence relating to the performance, safety, and cost effectiveness of the technology.

**Scottish Centre for Telehealth and Telecare (SCTT)**
- The SCTT supports the development of technology enabled health and care services across Scotland by providing support and advice to all key stakeholders and to help evaluate the potential benefits of new technologies. The SCTT is tasked with: providing consultancy and facilitation services for partner organisations; sourcing funding and leading the development of new services; providing practical support, both clinical and technical; evaluating the impact of telehealth and telecare on service redesign; and supporting knowledge transfer and learning within Scotland and internationally. Source: [http://sctt.org.uk/](http://sctt.org.uk/)

**Scottish Enterprise (SE)**
- Within health care, SE seeks to encourage Scottish businesses towards an innovative approach to products and services – to drive global growth and boost competitiveness. More specifically, SE will: encourage collaboration between academia and business,
help companies use R&D to generate revenue, improve support for entrepreneurial companies, and capitalise on Scottish and global supply chain opportunities.

**Scottish Health Innovations Limited (SHIL)**
- SHIL works in partnership with NHSScotland to protect and develop new innovations that come from healthcare professionals. By developing these ideas, SHIL creates new products and technologies that will improve patient care and generate income for NHSScotland. SHIL services include: project management, market research, sourcing of funding, intellectual property protection, sourcing of development partners, spinout set up and regulatory consultancy. Source: [http://www.shil.co.uk/About-Us/about-shil.html](http://www.shil.co.uk/About-Us/about-shil.html)

**Scottish Health Technologies Group (SHTG)**
- SHTG is an advisory group set up to provide assistance to NHS boards when considering selected health technologies, excluding medicines which will be reviewed by the Scottish Medicines Consortium (SMC). The remit of the SHTG is to provide advice on the evidence about the clinical and cost effectiveness of existing and new technologies likely to have significant implications for patient care in Scotland.

**Scottish Lifesciences Association (SLA)**
- The SLA, comprising 125 member companies and organisations, is the voice of Scotland’s life sciences industries to investors, NHSScotland, the Scottish and UK Governments, and the wider community. Driven by, and networking with, their members through 11 Special Interest Groups, the SLA helps them grow their businesses, while engaging with the NHS and Government to grow the life sciences sector in Scotland. In addition, the SLA delivers the Health Innovation Partnership (see above) on behalf of the Scottish Government. Source: [http://www.gov.scotTopics/Health/Quality-Improvement-Performance/Innovation](http://www.gov.scotTopics/Health/Quality-Improvement-Performance/Innovation)

**Scottish Life Sciences Advisory Board (LiSAB)**
- LiSAB was formed in 2009 to help drive, develop and deliver Scotland’s life sciences strategy. LiSAB includes members from industry, universities, research institutions, NHSScotland, financial institutions, the Scottish Government and the Scottish Enterprise network. Source: [http://www.gov.scotTopics/Health/Quality-Improvement-Performance/Innovation](http://www.gov.scotTopics/Health/Quality-Improvement-Performance/Innovation)

**Strathclyde MedTech Centre**
- Strathclyde MedTech is a new Scottish Government and European Regional Development Fund (ERDF) funded project designed to assist Scottish Small and Medium Enterprises in developing new products and services. Companies can be those looking to expand their portfolio or those looking to enter the market for the first time.
## Non-medicine technologies stakeholders

*Note: columns labelled to reflect the stages within a broad product development cycle*

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<th>Evidence assessment</th>
<th>Support for adoption</th>
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