Rare Diseases Advisory Group

Terms of reference

March 2020

NHS England and NHS Improvement

Rare Diseases Advisory Group

Terms of reference

Version number: 4

First published: April 2014

Updated: March 2020

Prepared by: Specialised Commissioning, NHS England

Classification: Official

1. Purpose

1.1 The Rare Diseases Advisory Group (RDAG) is a non-executive committee and as such has no delegated authority other than that specified in these terms of reference.

1.2 The committee is established to provide the same, consistent advice to NHS England and NHS Improvement and the devolved administrations of Scotland, Wales and Northern Ireland (the devolved administrations).

1.3 The Committee has the following delegated authority:

- The authority to obtain outside legal or other independent professional advice and to secure the attendance of non-members with relevant experience and expertise if it considers this necessary.
- The authority to exclude deliberations over services that are outside of the scope of highly specialised services.

1.3 RDAG is directly accountable to the Specialised Commissioning Health and Justice (SCHJ) Strategy Group and is operationally responsible to the SCHJ Delivery Group. It also provides advice to the Clinical Priorities Advisory Group (CPAG). A diagram is attached at Appendix B that sets out the flows of information that support the governance arrangements. The diagram sets out:

- Information that passes through RDAG to CPAG and then on to the SCHJ Strategy and Delivery Groups
- Information that passes through RDAG directly to the SCHJ Strategy and Delivery Groups
- Information that passes directly from the Highly Specialised Commissioning Team (HSCT) to the SCHJ Strategy and Delivery Groups and which may be reported to RDAG.

2. Duties

2.1 In the case of NHS England, to make recommendations to CPAG on which highly specialised services or technologies should be prioritised for investment; this includes services or technologies already commissioned and services and technologies that have not previously been commissioned. Highly specialised services are those prescribed services concerning usually no more than 500 patients and/or provided in four or fewer specialist centres in the UK. RDAG may also give advice to CPAG on technologies for patients with rare diseases where that rare disease is not managed within the highly specialised services portfolio.

2.2 To provide advice to NHS England and the devolved administrations to enable these organisations to respond to consultations issued by the National Institute for Health and Care Excellence (NICE) Highly Specialised Technology Programme. To provide advice to NHS England and the devolved administrations on the most appropriate service to deliver those highly specialised technologies that receive a positive technology appraisal determination from NICE.

2.3 To make recommendations to NHS England and the devolved administrations on developing and implementing strategy for highly specialised services.

2.4 To make recommendations to NHS England and the devolved administrations on how the UK Strategy for Rare Diseases and any successor documents should be developed and implemented.[1]

2.5 To make recommendations to NHS England and the devolved administrations on how highly specialised services should be commissioned. This includes recommending which expert centres may be nominated (or may no longer be nominated) to deliver highly specialised services.

[1] RDAG will work closely with the Rare Diseases Policy Group (RDPG) whose remit, in respect of the UK Strategy for Rare Diseases, is to monitor its implementation. In summary: the role of the RDPG is to monitor **what** is being implemented in respect of the strategy, and the role of RDAG is to make recommendations to NHS England and the devolved administrations on **how** the strategy is being implemented.

2.6 To help ensure proper provision of services commissioned, with equal access opportunities for patients across different geographies.

2.7 In the case of NHS England, to provide advice to the SCHJ Strategy and Delivery Groups and the Programmes of Care on the contract 'products' for highly specialised services.

2.8 To receive outcome information on highly specialised services and make recommendations on any action required as a consequence of any findings.

2.9 To provide advice to the Prescribed Specialised Services Advisory Group (PSSAG) on highly specialised services.

2.10 In undertaking its functions, RDAG will:

- formulate its advice by calling on sources of sound evidence from outside the NHS, such as professional bodies, and recommend the commissioning of external assessment as necessary
- improve the effectiveness and transparency of its recommendations by ensuring input from a wide range of clinical, commissioning and finance experts, as well as patients/carers and lay members; and by using a consistent decision-making process to develop recommendations
- streamline the decision-making process by combining different sources of advice and by reducing the number of endorsement tiers required before the final decision
- undertake economic evaluation of proposals for services for rare diseases as necessary.

2.11 The HSCT will provide advice to the SCHJ Strategy and Delivery Groups (some of which may be reported to RDAG) on the operationalisation of highly specialised services, including:

- information around the transfer of activity and costs where the highly specialised service being proposed is not prescribed as a specialised service and/or the activity is within other specialised services contracts
- proposed contracting arrangements
- proposed funding flows (eg where a service is based on an outreach model)

- proposed mechanisms for securing income for EU activity.

3. Membership

3.1 All members are appointed by the NHS England National Director of Specialised Commissioning.

3.2 Members are selected for their expertise even when they may be affiliated to specific stakeholder groups. As such, they are appointed as individuals to fulfil their role on the committee and it is expected that in their role as a member of RDAG they will act in the public interest.

3.3 Where applicable, members are proposed for appointment to the NHS England National Director of Specialised Commissioning by other bodies or organisations to which they are affiliated. Some members will be appointed following a public process. Details on the appointment mechanisms are outlined in the table below.

Members*	Proposed by
Chair	NHS England and NHS Improvement National Director of Specialised Commissioning
Representative from the Royal College of Paediatrics and Child Health	Royal College President
Representative from the Royal College of Pathologists	Royal College President
Representative from the Royal College of Physicians	Royal College President
Representative from the Royal College of Psychiatrists	Royal College President
Representative from the Royal College of Surgeons	Royal College President
Representative from the Royal College of General Practitioners	Royal College President

Members*	Proposed by
Representative from Public Health England	Public Health England
Geneticist	Joint Committee on Medical Genetics
Representative from the Scottish Government	Scottish Government
Representative from National Services Division, NHS Scotland	NHS Scotland
Representative from Welsh Health Specialised Services	NHS Wales
Representative from Welsh Government	Welsh Government
Representative from NHS Northern Ireland	NHS Northern Ireland
Representative from Northern Ireland Government	Northern Irish Government
Representative from Department of Health and Social Care (DHSC), England	UK Government
Clinical Programmes Director Specialised Commissioning, NHS England and NHS Improvement	Ex officio
National Medical Director Specialised Services, NHS England and NHS Improvement	Ex officio
Director of Specialised Commissioning Finance, NHS England and NHS Improvement	Ex officio
Head of Quality and Nursing, NHS England and NHS Improvement	Ex officio
Regional Medical Director, NHS England and NHS Improvement	Ex Officio
Two Regional Directors of Specialised Commissioning, NHS England and NHS	Ex officio

Members*	Proposed by
Improvement (one from London and one from another Region)	
Medical Director (Commissioning), NHS England and NHS Improvement	Ex officio
Pharmacist, NHS England and NHS Improvement	Ex officio
Patient and public voice x4	Public appointment process from all UK
Health Economist	Public appointment process
Ethicist	Institute of Medical Ethics
Representative from NICE	NICE
Non-medical Co-Chair of the DHSC Rare Disease Policy Board	Ex officio

* Members from the Royal Colleges may be the president of the Royal College or Faculty, or his/her nominee.

3.4 In addition, the following individuals are in attendance at RDAG meetings:

- Head of Highly Specialised Commissioning
- Medical Advisor, Highly Specialised Services.

3.5 Members are proposed and appointed to ensure a fair geographical representation from across the UK on the committee.

3.6 The Chair and members of the committee will be appointed for a period of up to three years, with the exception of those who sit on the advisory group by virtue of their individual institutional roles. The specific period of appointment may vary for each member to allow a gradual renewal of the membership over time.

3.7 The period of appointment may be extended by mutual agreement to a further term of up to three years and up to a maximum of six consecutive years. Appointments may be terminated at a member's request or, in the

event of unsatisfactory attendance at meetings or if their conduct is out of keeping with the committee's rules of conduct, as set out in this document or other related documents.

3.8 Patient/carer and lay members will have their expenses covered and be remunerated in line with NHS England policy. Other posts are not remunerated, although the Health Economist and Ethicist roles can claim travel allowances at the standard NHS rates.

3.9 The Chair has an active role in liaising with the relevant proposing bodies and organisations to ensure that the appropriate member candidates are proposed for appointment by the NHS England National Director of Specialised Commissioning. In particular, the Chair will provide input to ensure that a fair representation on the committee of different regions across England is achieved whenever possible.

3.10 The Chair of the committee and the NHS England National Director of Specialised Commissioning nominate a Vice Chair from among the members. They are responsible for chairing committee meetings and providing leadership if the Chair is unavoidably absent or is unable to chair the meeting due to conflict of interest for specific items on the agenda.

3.11 Members of RDAG have collective responsibility for the operation of the committee. They participate in discussions; and may move, second and vote on motions. In discharging their functions, they should engage fully in the collective consideration of issues, taking account of the full range of relevant factors, including any guidance issued by the Department of Health and Social Care, NHS England or the devolved administrations.

3.12 Members have the duty to attend the committee's meetings with appropriate frequency. If a member is unable to attend at least one full meeting in a year without a satisfactory reason, the Chair may decide to consider the position vacant, even when using deputy arrangements.

3.13 Each member has the duty to provide expert input on topics related to their discipline areas to the best of their knowledge and ability, and to make the committee aware of the full range of opinions within their discipline. Members

are also expected to contribute towards the collective determination of the committee's view on matters outside their specific area of expertise.

3.14 The Secretariat is provided by the NHS England Highly Specialised Commissioning Team. The secretariat is responsible for ensuring that the committee does not exceed its terms of reference.

3.15 Communications between the committee, CPAG, the SCHJ Strategy and Delivery Groups and NHS England will generally be through the Secretariat, except where it has been agreed that an individual member should act on the committee's behalf.

Appendix A: Additional information

Public services values for members

Members must at all times:

- observe the highest standards of impartiality, integrity and objectivity in relation to the advice they provide
- abide by the principle of collective responsibility, stand by the recommendations of the committee and not speak against them in public
- be accountable for their activities and for the standard of advice they provide to NHS England and act in accordance with NHS England policy on openness, and comply fully with the Code of Practice on Access to Government Information and any relevant legislation on disclosure of information
- follow the seven principles of public life set out by the Committee on Standards in Public Life (see Annex 1), as they apply to service on the committee
- comply with the requirements outlined in this as well as other governance documents for RDAG, and ensure that they understand their duties, rights and responsibilities, and that they are familiar with the functions and role of the committee and any relevant statements of policy
- act in accordance to the principles and values set out in the NHS Constitution for England
- not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms' businesses or other organisations
- not hold any paid or high-profile posts in a political party, and not engage in specific political activities on matters directly affecting the work of the committee. When engaging in other political activities, members should be conscious of their public role and exercise proper discretion.

Declaration of interests

This code of practice guides the Chair and the members of the committee and members of any possible subcommittees on the declaration of any relevant interest.

Where members are uncertain as to whether an interest should be declared, they should seek guidance from the Chair or the Secretariat or, where it may concern a particular product or technology which is to be considered at a meeting of the committee, from the Chair at that meeting. If members have interests not specified in this code but which they believe could be regarded as influencing their advice, they should declare them.

If a member is aware that a product or technology under consideration is or may become a competitor of a product manufactured, sold or supplied by a company in which the member has an interest, they should also declare their interest in the company marketing the rival product.

However, members are not under an obligation to search out links between one company and another – for example, where a company with which a member is connected has an interest in another company of which the member is not aware and could not reasonably be expected to be aware.

Pharmaceutical industry interests

In this code, ‘industry’ means:

- companies, partnerships or individuals who are involved with the manufacture, sale, promotion or supply of medicinal products or technologies
- trade associations representing companies involved with such products or technologies
- companies, partnerships or individuals who are directly concerned with the research, development or marketing of a medicinal product or technology which is being considered by the committee.

References to ‘the industry’ include cases involving a single company.

In this code, ‘the Department’ means the Department of Health and Social Care (DHSC), and references to ‘member(s)’ include the Chair.

Personal interests

A personal pecuniary interest is where a member has received or plans to receive a financial benefit or other benefit from the industry. This could include:

- holding a directorship, or other paid position;
- carrying out consultancy or fee paid work;
- having shareholdings or other beneficial interests;
- receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences.

Personal family interest

A personal family interest is where a member of the member's family has received or plans to receive a financial benefit or other benefit from the industry. This could include:

- holding a directorship or other paid position
- carrying out consultancy or fee paid work
- having shareholdings or other beneficial interests
- receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences.

A personal non-pecuniary interest

A personal non-pecuniary interest is where a member has expressed a clear opinion on the matter under consideration which has been:

- reached as a conclusion of a research project
- and/or expressed as a public statement.

It is also where a member is part of a professional organisation or advocacy group with a direct interest in the matter under consideration, or any other reason why people might perceive bias in the member's advice or consideration of evidence.

Non-personal interests

A non-personal interest is where a member has managerial responsibility for a department or organisation that has received (or plans to receive) a financial payment, or other benefit, from the industry. This could include:

- a grant or fellowship or other payment to sponsor a post or contribute to the running costs of the department
- commissioning of research or other work.

Members are under no obligation to seek out knowledge of work done for or on behalf of the industry within departments for which they are responsible if they would not normally expect to be informed.

Personal and non-personal interests at the time of appointment

Members of the committee must declare their relevant personal and non-personal interests at the time of their appointment. An interest is relevant if it has occurred in the last 12 months or if it is a current or planned involvement with the industry. Members are asked to inform the Secretariat before each meeting of any change in their relevant interests.

Declaration of interests at meetings

Members are required to declare relevant interests at committee meetings. They must state whether the interests are personal or non-personal and, for each agenda item, whether they are specific or non-specific to the matter or product under consideration.

The committee has power to determine its own proceedings, including whether a member with an interest shall take any part in the proceedings. The usual procedure, subject to the Chair's decision in each case, is as follows:

- any member with a personal specific interest (either a personal pecuniary interest or a personal family interest) will be required to leave the room for the discussion and decision-making on that agenda item
- any member with a personal non-specific interest (either a personal pecuniary interest or a personal family interest) will be allowed to participate in discussion but not vote on that agenda item

- any member with a non-personal specific interest will be allowed to participate in discussion but not vote on that agenda item
- any member with a non-personal non-specific interest will be allowed to participate in discussion and vote on that agenda item.

The minutes of each meeting will record declarations of interest, and whether members took part in discussion and decision-making.

The Chair or Vice Chair should not have a personal interest in any agenda item under discussion.

Individuals in attendance and observers

Officers from the DHSC and NHS England in limited number can participate in all sessions of the committee's meetings in attendance.

Finally, experts, mostly with a clinical or academic background, may be invited to meetings or sessions of meetings on an ad-hoc basis to provide opinion, information and evidence on specific matters.

Quorum arrangements

Quorum for meetings

The quorum is reached when at least two-thirds of the members are present. The quorum should be rounded up to the next whole number in the event of an odd number of members.

An appropriate spread of members' interests is also required for the quorum to be valid. For example, it is advisable that at least one region member, two royal colleges representatives, two patient and public voice members and a sufficient presence of members expert in relevant specialist areas need to be present. However, the final judgement on whether the meeting is quorate will reside with the Chair.

Who contributes towards the quorum

The following rules should apply in calculating the quorum for meetings:

- only members of the advisory group contribute towards the quorum. Officers in attendance, observers or other individuals who may be attending do not contribute towards the quorum
- deputies representing absent members contribute towards the quorum
- vacancies – but not absences – are excluded when establishing the quorum
- members excluded due to a conflict of interest from a vote or meeting, in the light of the code for the declaration of members' interests as outlined in the related 'Membership' section of this document, do not contribute towards the quorum.

Rules for changing attendance at meetings

A meeting that starts with a quorum present shall be deemed to have a continuing quorum, notwithstanding the departure of voting members, unless the quorum is challenged by a voting member. In the event of a challenge, the remaining members may choose to adjourn the meeting or to continue the meeting and ratify the decisions in the next meeting.

Deputy arrangements

When not able to attend, members may send a deputy to participate and vote on their behalf, with the exception of patient and public voice members as well as other members appointed through a public process or by personal nomination. Each member must nominate a deputy at the start of the appointment period. In case the nominated deputy is also unable to attend the meeting, the member will not be able to send any other person on their behalf. Deputies must have similar expertise and be of a similar level of seniority to the member they substitute. The table below specifies eligible deputies for all other members of the advisory group.

The Chair will endeavour to invite experts ad hoc to meetings or to a session of meetings to compensate for the absence of members who cannot send deputies on their behalf as outlined in the 'Membership' section of this document.

Members	Eligible deputy
Chair	Vice Chair
Representatives from the Royal Colleges	Royal College President nominee
Representative from Public Health England	Public Health England nominee
Geneticist	Joint Committee on Medical Genetics nominee
Representatives from the devolved administrations and DHSC	Nominees from the organisation listed in the terms of reference
Patient and public voice representatives	Not permitted
NHS England representatives	NHS England nominee
Health Economist	Not permitted
Ethicist	Institute of Medical Ethics nominee
NICE	NICE nominee
Chair of the DHSC Rare Diseases Policy Board	Vice Chair of the DHSC Rare Diseases Policy Board

Voting arrangements

Members should normally aim to arrive at decisions by a consensus. Where consensus cannot be reached, a simple majority of the present voting members (excluding the Chair) is required. Abstentions are not considered when determining the majority.

The Chair casts their vote only when the majority is not achieved by the other voting members and when their vote can be deciding.

Voting is intended to be held in secret unless otherwise stated by the Chair.

No individual member has power of veto.

Frequency of meetings

It is planned for the full committee of RDAG to meet usually between two and four times a year depending on business needs. The Chair has the right to convene extraordinary meetings when considered necessary.

RDAG will not have standing subcommittees.

The committee Secretariat will make all reasonable attempts to agree each full meeting date in advance and members will be expected to attend for the full day unless agreed otherwise in advance with the Chair.

A record will be kept of members' attendance at the meeting via the minutes. If a member is unable to attend at least one full committee meeting in a year without a satisfactory reason, the Chair may consider the position vacant. This is regardless of the use of deputy arrangements.

Publishing of agenda and minutes

The committee will make agendas available prior to meetings on the committee's website.

The minutes of the committee proceedings shall be usually drawn up and submitted to the next committee meeting for approval. Draft minutes will be ordinarily approved at the next meeting and published on the committee website subject to the redaction of any confidential or otherwise exempt material.

Publishing of statements and recommendations

The committee will provide advice in writing. Where a situation is urgent, oral advice may have to be given but will be followed by written confirmation of the advice. Advice will be in terms that can be understood by a member of the public and will explain the reasoning on which the advice is based.

Advice given will normally be made public by the committee as soon as reasonably practicable following NHS England decisions.

To help provide a full appreciation of its advice and decisions, the committee will, where appropriate, facilitate public access to documents or information that have contributed to the formulation of its advice.

The committee will publish on its website details of the applications received, so that stakeholders and interested parties have the opportunity to comment in advance of decisions being taken.

Annex 1: The seven principles of public life[2]

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for awards and benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public, and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interests clearly demands.

[2] Principles published by the Committee on Standards in Public Life.

Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

Leadership

Holders of public office should promote and support these principles by leadership and example

Appendix B: governance diagram