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Overview of the WHSCC Clinical Impact Assessment Process 2018/19

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1. Introduction

Each year WHSSC has a duty to develop an Integrated Commissioning Plan (ICP) which outlines NHS Wales' priorities for commissioning specialised services for the next three years. Development of the plan is a complex process involving a large number of stakeholders and draws on expertise from many health sectors across the NHS.

NHS Wales and WHSSC must ensure that new investment decisions are (i) affordable and offer value for money, (ii) supported by convincing evidence of safety and effectiveness and (iii) made using a process that is consistent and transparent.

Over the last three years WHSSC has developed an annual prioritisation process of *new* interventions and technologies (identified via horizion scanning). This has enabled us to compare competing proposals for new investment so that these can be prioritised within all other competing priorities.

WHSSC has now adapted this methodology for the CIAG process. This paper describes the methodology that WHSSC will be using to rank (prioritise) all the schemes identified for inclusion in the ICP on the basis of their 'clinical impact'.

1.1 The WHSSC Integrated Commissioning Plan (ICP) 2018-21

The ICP for Specialised Services for Wales 2018-21 is a commissioner-led plan, which seeks to balance the requirements to quality assurance, risk reduction and improvement to health outcomes for the people of Wales with the challenging financial pressure that is evident in specialised services. The needs of the Welsh population for specialised services are described in the ICP.

WHSSC produces the ICP by:

- using a tested impact assessment model
- developing commissioning intentions
- setting priorities and undertaking risk assessments,
- using provider submitted information
- horizon scanning, evidence appraisal and prioritisation of new interventions
- running several Management Group workshops to agree a final list of schemes. [Management Group is made up of management representatives from each of the HBs]

During the course of the Management Group Workshops a broad selection of schemes were assessed using a three stage process, which included commissioning team peer review, review by the Executive Team at WHSSC and finally Management Group review. All of the individual schemes were 'risk-rated' and peer-reviewed through the Management

Group workshops. Whilst there was a broad level of consensus on the majority of schemes to include in the ICP there was significant variance on many others.

The results and recommendations from this process will be reviewed by the Management Group at their next workshop on the 4th January.

1.2 The CIAG

During development of the 2017-20 ICP it was noted that because of the compressed timescales th prioritisation process had received limited clinical input. This lack of independent clinical advice presented challenges in determining relative priority of schemes against whatever resource was available. Therefore a further prioritisation process was suggested to review schemes and make recommendations on relative priority from a purely 'clinical' perspective.

Therefore a Clinical Impact Assessment Group (CIAG) was proposed with membership drawn from each HB via their Associate Medical Director with responsibility for Primary Care.

Following a successful launch last year it was agreed to reconvene CIAG to assist with development of the 2018-21 ICP. The membership and terms of reference have been retained in order to ensure a consistent and independent approach. However this year we have decided to hold the CIAG meeting jointly with colleagues from Management Group. This will allow for a more broader and inclusive discussion, a better understanding of the clinical impact of the schemes and a collaborative approach to agreeing the final list of priorities.

The Group will act in an advisory capacity only and will be chaired by the WHSSC Medical Director. Invitaitons for memebship of CIAG were sent to all Health Boards in October and the list of Group members is presented in Table 1.

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Table 1. Membership of the WHSCC Clinical Impact Assessment Group (CIAG) 2018/19

WHSSC Clinical Impact Assessment Group	
Name	**Title/Representation**
Sian Lewis (Chair)	Acting Medical Director, WHSSC
Liam Taylor	Deputy Medical Director, Aneurin Bevan UHB
No nomination received	Abertawe Bro Morgannwg UHB
Fraser Campbell	Assistant Medical Director (Primary Care) Betsi Cadwaladr UHB
No nomination received	Cardiff and Vale UHB
Richard Quirke	Assistant Medical Director for Professional Standards and Regulation, Cwm Taf UHB
Mark Barnard	Associate Medical Director, Hywel Dda UHB
Stuart Bourne,	Deputy Director of Public Health, Powys Teaching HB

1.2 Schemes to be considered and scored by the CIAG

All schemes that are mandatory (for example NICE highly specialised technologies guidance and AWMSG guidance) have been excluded from this prioritisation process and will have to be funded within the ICP.

The schemes to be assessed by CIAG and Management Group are split into two lists:

- **'Pack 1'** includes all the schemes that were assessed by CIAG last year (n=17) but were not subsequently funded in the ICP
- **'Pack 2'** includes all the new schemes (n=17) that have been brought forward during the last 12 months and includes two schemes recommended by the WHSSC Prioritisation Panel. Only schemes which demonstrated a strong rationale, including good evidence of a high quality service and patient safety and appropriate consideration of risk, were included. All other schemes which didn't meet this rationale or are not fully developed will be retained on the WHSSC workplan and will be regularly monitored.

Where necessary, the schemes in Pack 1 have all been updated to include the latest supporting information and data.

The Group will be asked to score each scheme against a set of pre-determined criteria (see section 6). The resulting output of the Group will be three categories of scheme for investment - high, medium or low

clinical impact. This information will be 'layered over' existing prioritisation work and used to develop final recommendations regarding schemes for inclusion in the ICP.

1.2.1 Terms of Reference

The terms of reference were agreed last year. In the interest of time these will not be discussed at the meeting. The main elements are:

- CIAG is not a decision making body
- It has been established to undertake a process of prioritisation of specialised services to inform commissioning decisions by Joint Committee and WHSSC
- The Medical Director will Chair the Group
- Membership will be drawn from Health Board Medical Director's Offices and each Health Board has been asked to nominate the Associate Medical Director with responsibility for Primary Care
- Members have been selected for their expertise and are appointed as individuals. They are not appointed to represent the views of any stakeholder organisation to which they may be affiliated
- Members are expected to abide by the principle of collective responsibility, stand by the recommendations of the Group and support them in public.

1.2.2 Your role in this process

All CIAG members (and members from Management Group) will be asked to form recommendations on the relative prioritisation of schemes which are proposed for inclusion in the WHSSC ICP for 2018-21.

Your recommendations will be considered by the Joint Committee at WHSSC to help inform their final decision on new investments in specialised services. This process is expected to be completed by the 31 March 2017.

2. Process

The following sections briefly outline the basic process and principles that the Group will follow. The methodology has been adapted from that used by the WHSSC Prioritisation Panel when scoring new interventions for consideration in the ICP, and was sucessfully piloted by CIAG last year.

2.1 The method of prioritisation

The principle steps within a prioritisation process are (i) evidence gathering and evaluation; (ii) policy (or scheme) development including equality impact assessment; (iii) scoring to develop a ranking of interventions.

The following key principles will be applied:

1. That the process is specific for Wales and therefore reflects the needs and priorities of our population.
2. The process reflects current Welsh Government (WG) policy and in particular the principles of Prudent Health Care.
3. That in line with the principles of Prudent Health Care we do not (wherever possible) duplicate work already completed within the other UK nations around evidence evaluation and prioritisation
4. The need to ensure appropriate and timely engagement and consultation with colleagues in NHS Wales during the entire prioritisation process

The information and recommendations from the Group on clinical impact (when combined with information around demands from existing services and interventions) will underpin and feed into the development of the WHSSC Integrated Commissioning Plan (ICP).

3. List of schemes to be prioritised (2017/18)

The two lists of schemes put forward for the Group to consider (Pack 1 and Pack 2) cover the following four clinical commissioning team areas:

- Neurosciences and complex conditions
- Cardiac services
- Women, children and rare diseases
- Cancer and blood.

Pack 1

These are the unfunded schemes assessed by CIAG last year (n=17). For information we have also included their CIAG scores. The intention is to briefly revisit these schemes rather than go through them again in turn and repeat the voting.

Pack 2

These are the new schemes (n=16) that have been brought forward during the last 12 months and includes two schemes recommended by the WHSSC Prioritisation Panel. These are the schemes members of CIAG and Management Group will be asked to assess in detail and subsequently score (see section 6)

3.1 Supporting information for Group members

To help the Group with the decision-making process, each scheme will be supported by a statement prepared by lead specialist planner (these are included in Pack 1 and Pack 2). They will consist of the following package of information (where available):

- Service overview
- Patient population and growth
- Summary of the issue / risk
- Proposal
- Mitigation
- Clinical Expert Summary

Included in each proforma is a 'risk score' that was generated from a 'Patient', 'Provider' and 'Commissioner' perspective. A score of 15-20+indicates an 'extreme risk'; 8-12+ a'high risk'; 4-6 a 'moderate risk' and; 1-3 a 'low risk'.

Each scheme in Pack 2 will be presented in turn at the meeting by the lead specialist planner (2-3 minutes) followed by a brief Group discussion and scoring (5-10 minutes).

4 Preparation prior to the meeting

Before the meeting you will be expected to consider each scheme statement (included in Pack 2) against the criteria described in this paper (see section 6). You will be asked to score each scheme against these criteria to form recommendations on the relative prioritisation of all the schemes.

Although we would like you to read through each scheme in Pack 1 it is unlikely that we will be re-scoring any of these at the meeting.

The 'scores' for each of the schemes under consideration (Pack 2) will then be calculated and used to rank the topics. This part of the process will be led by Dr Sam Groves (Welsh Health Economics Support Service (WHESS)) using a group decision support system (GDSS) and will be presented in more detail at the meeting.

You are asked to use your own knowledge and experience when considering each scheme. You are not required to submit your preliminary views in advance of each meeting. Instead you should you record your preliminary views in your notes ready for discussion at the meeting. For each scheme you will have the opportunity to discuss the facts as defined in the papers so that any misunderstandings or questions are cleared.

You will be asked to score each scheme (from 1 - 10) against all of the criteria described below. A high score indicates consistency with each of the criteria.

4.1 Criteria for prioritisation

The proposed criteria that will be used in prioritisation are:

- Burden of disease
- Patient benefit (potential for positive health impact / improved safety / clinical outcomes)
- Equality and human rights (potential for improved / reducing inequalities of access)

The review of schemes will take into account how the different criteria work together, including:

- The balance of clinical benefits and clinical risks
- The balance of the timing of the application with the urgency of the clinical need, what clinical alternatives are available, and the need to strengthen the evidence for clinical impact
- The balance of clinical benefits/impact per patient and the robustness of the supporting evidence
- The balance of overall clinical impact/benefits from national commissioning perspective.

5 Expected output from the joint CIAG/Management Group meeting

Once the Group has considered the schemes and assigned each a mean score these will be tabulated and presented back to the Group at the close of the meeting. Although members will be permitted to discuss the final results, a re-vote on any intervention or a change to the order of the results will be at the discretion of the Chair.

The Group will also need to agree how best to integrate the schemes scored last year (Pack 1) with those scored and presented in Pack 2.

Members will then be asked to split the finalised list into 'high clinical', 'medium clinical impact' and 'low clinical impact' based on their overall % score. Using this approach will ensure a spread between the three groups i.e. not all will come out as 'high clinical impact'. Based upon these results and Group discussion a narrative summary of proceedings will also explain risks of non-implementation and opportunities for mitigation

The clinical impact analysis will then allow the production of a report which overlays the scores for clinical impact against the existing prioritisation outputs from WHSSC and Management Group. Finally these data when combined with information around demands from existing services and interventions will underpin and feed into the development of the WHSSC Integrated Commissioning Plan (ICP) for 2017-20.

6 Definitions for each of the assessment criteria –a guide for Panel members

This document only serves as a guide to Group Members – each Group member must consider their own conclusions and be able to discuss these with other Group members as part of the prioritisation process.

A] Burden of disease

Assessing this criteria involves a wide consideration of a number of different issues including the (serious) nature of the condition, the size of the population effected (individual, small cohort or large population) and the current availability of (effective) treatments contained within the concept of unmet need. The following serves as guidance to Group members in assessing 'burden of disease' and highlights some of the considerations each Group member will need to take.

A1] Serious condition

Regulatory bodies such as NICE and the FDA interpret the term *serious* follows:

'…. *a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one*'.

To satisfy this criterion, an intervention must be intended to have an effect on a serious condition or a serious aspect of a condition, such as a direct effect on a serious manifestation or symptom of a condition or other intended effects, including the following:

- A diagnostic product intended to improve diagnosis or detection of a serious condition in a way that would lead to improved outcomes
- A product intended to mitigate or prevent a serious treatment-related side effect (e.g., serious infections in patients receiving immunosuppressive therapy)
- A product intended to avoid or diminish a serious adverse event associated with available therapy for a serious condition (e.g., product that is less cardiotoxic than available cancer therapy)
- A product intended to prevent a serious condition or reduce the likelihood that the condition will progress to a more serious condition or a more advanced stage of disease.

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A2] Unmet clinical need

An unmet clinical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy. An unmet clinical need includes an immediate need for a defined population (i.e. to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs).

- Is there currently no available therapy to treat this condition?
- If a therapy already exists for this condition has an improved effect on an outcome(s) of the condition compared with available therapy been demonstrated?

In some disease settings, an intervention that is not shown to provide a direct efficacy or safety advantage over available therapy may nonetheless provide an advantage that would be of sufficient public health benefit to qualify as meeting an unmet clinical need.

A3] Population impact and reducing health inequalities

This is defined as the number of people who are likely to benefit from the intervention or recommendation? Things to consider include:

- What will implementation of this policy mean for the individual patient/group of patients and the wider community?
- Will this service or intervention contribute to reducing or widening health equalities within Wales?

[Members of CIAG must have regard to the need to reduce inequalities between patients in access to health services and the outcomes achieved. The Group may wish to identify potential health inequalities that may be present with the adoption of a specific policy proposition and provide WHSSC with advice on how to commission services with a view to reducing health inequalities. This may influence the Group's recommendation on the relative prioritisation of a specific scheme.]

B] Patient benefit

This is defined as the potential for the technology to have an impact on patient-related health outcomes (from no expected change in outcomes to major potential improvements in outcomes). This criterion considers the balance of harms and effects based on the evidence presented in the evaluation.

Direct patient benefit may be demonstrated in one or more of the following ways. A drug, medical device or intervention could be life-saving, life-extending, life-improving (where the improvement in symptoms or functional capacity is detectable by the patient) or it provides reduced risk of developing a condition or disease.

Will this intervention have a positive effect on mortality, longevity and health related quality of life?

The potential benefit of each proposed investment can be described using the following metrics:

- Survival
- Progression free survival
- Mobility
- Self-care
- Usual activities
- Quality of life
- Pain
- Anxiety / depression
- Replacement of more toxic treatment
- Dependency on care giver / supporting independence
- Safety

Some health metrics record clinical benefits rather than direct patient benefits, but these can be used as surrogate measures of patient benefit if it can be demonstrated that they provide an accurate, early indication of the direct patient benefit.

Where direct evidence of patient benefit is not available it may be inferred from the available clinical evidence. However, this should take into account the quality of the evidence for any clinical or patient benefit.

Members should not include in their consideration of patient benefit the following factors; societal benefit; the absolute cost of the intervention or considerations of affordability; any financial savings arising from it; the number of patients needed to be treated to give rise to the patient benefit; the prevalence of the underlying condition/illness.

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The clinical benefit offered by the intervention is described in the independent review of the clinical evidence of each policy proposition.

C] Equality and human rights

WHSSC and NHS Wales must demonstrate that it understands the potential effect of adoption of clinical commissioning policies on people with characteristics that have been given protection under the Equality Act (2010), especially in relation to their health outcomes. We must also consider both the Social Services and Well-being (Wales) Act (2014) when considering the well-being for people who need care and support (and carers who need support) and the Human Rights Act (1998).

Therefore WHSSC should have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the act
- Advance equality of opportunity between people who share a protected characteristic and for those who do not
- Foster good relations between people who share a protected characteristic and those who do not.

These are often referred to as the three aims of the general equality duty and apply to the following protected characteristics:

- Age
- Disability
- Sex (gender)
- Gender reassignment
- Pregnancy and maternity
- Race
- Belief (or non-belief)
- Sexual orientation
- Marriage and civil partnership