Recommendations for a new All-Wales Research Delivery Funding Model

1. Purpose

1.1. This paper presents the recommendations that have been formulated by a Task & Finish Group, to Welsh Government R&D Division. The recommendations are regarding the model used to distribute funding to support the set-up and delivery of research studies within health and social care settings in Wales. It is the conclusion of work undertaken and agreed by a Task & Finish Group, and incorporates feedback from wider stakeholder engagement sessions that took place on 25/27 September 2019.

1.2. Recommendations included within this paper relate to:
- The distribution of funding to support the delivery of research studies in Wales
- Implementation considerations and transitional arrangements
- Benefits, risks and mitigations

2. Scope and Exclusions

2.1. Included in scope is all delivery funding including costs associated with:
- Support & Delivery (S&D) Centre activities that support study set-up and delivery
- Centralised service support costs (direct payments to primary care, WAST, PHW)
- Specialty Leads
- Local Support & Delivery funding allocated to NHS organisations through the current Activity Based Funding (ABF) formula to support research set-up and delivery activities (“delivery spend”)

2.2. Out of scope are:
- Funding for Excess Treatment Costs
- Funding for the Support & Delivery Centre activities that do not directly support study set-up and delivery i.e. those activities that support the wider HCRW infrastructure e.g. the communications service; or are part of a UK infrastructure e.g. Approvals Service
- Funding for research grant development and wider HCRW infrastructure i.e. the research development infrastructure, programmes and grant schemes
- Local Support & Delivery funding allocated to NHS organisations through the current Activity Based Funding (ABF) formula to support the development of research grants and/or to support chief investigators (“development spend”)

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1 Although Local Support & Delivery funding is initially allocated 60% to delivery and 40% to development this distinction is not relevant for the purposes of this paper. ‘Delivery spend’ refers to the amount actually spent on delivery, rather than any suggested split. In practice, most NHS organisations use most of their Local Support & Delivery Funding on delivery.

2 Research development within the Support and Delivery eco system is a key feature of Health and Care Research Wales (HCRW) strategy and a separate parallel work stream will explore improvements in supporting researchers who wish to develop research proposals and undertake pathway to portfolio activities. HCRW will separately also work with each NHS organisation, the Support & Delivery Centre, and other funded units (e.g. Research Design and Conduct Service) to determine the appropriate strategic balance between delivery/development, recognising local needs will vary and may change over time.
3. Definitions

3.1. “Delivery”: Local and national activities that facilitate and support the local set up and delivery of Health and Care Research Wales Portfolio studies (non-commercial) in health and social care settings at the NHS organisation. This includes the study-specific activities as detailed in the research protocol, and the wider support (local and national) that facilitates or supports the study to take place. This includes workforce planning, feasibility, site selection, study set-up and approvals, screening, undertaking the study, participant follow-up and ensuring regulatory requirements are maintained throughout.

3.2. “Service support costs”: the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided.

3.3. “Development”: relating to the development of high quality research activity, including funding researchers and supporting them to submit applications to grant funders. This may include time to write the grant application or in addition, to undertake small scale pilot or feasibility studies to enable data gathering to support high quality grant applications (such studies are referred to as pathway to portfolio studies).

4. Background

4.1. Welsh Government provides Local Support & Delivery funding to Health Boards and Trusts to support research, determined through an Activity Based Funding (ABF) model introduced in 2012/13. Welsh Ambulance Services NHS Trust (WAST) and Public Health Wales (PHW) receive a fixed amount from this budget for R&D Office costs, but can then access additional funding on a study-by-study basis for service support costs associated with actual costs incurred during the research being undertaken. Funding is also provided to the Health and Care Research Wales Support and Delivery Centre, who undertake a range of NHS research support functions on a Wales-wide basis in order to maximise the use of the budget.

4.2. Whilst there is ongoing monitoring of expenditure through financial returns and key performance indicators, it is timely for R&D Division, Welsh Government to review if the funding model remains fit for purpose and aligned to future strategy. Alongside other Health and Care Research Wales activities, the review will also inform the refresh of the Health and Care Research Wales 5-year strategic plan (2020-25).

4.3. Engagement with stakeholders has confirmed a need for improvements in the way funding to support the delivery of studies is mobilised, particularly in relation to increasing collaboration between NHS organisations so that more people can access research studies, maximising the value from limited resources and overcoming the challenges from undertaking small sample size studies in areas such as paediatrics and novel therapies.

4.4. Welsh Government are keen for the review and recommendations to reflect the principles of value based healthcare. To achieve high value, delivering the best possible outcome for patients and public in the most efficient way must be the priority. The outcomes that matter to Welsh Government are that:

- Opportunities to take part in research are available to the population rather than driven through process measures or targets. This will allow more people to receive the best care or experience new services, or make a contribution to healthcare improvements, through research. This will include those participating in research by virtue of their health or social care needs, or their use of health or social care services, or as healthy members of the population.

- Investment is allocated/determined to create the maximum value out of the resource available to support high quality research (these are studies funded though externally funded peer reviewed studies and commercial contract research and are referred to as ‘portfolio studies’).
• Engagement should involve those who deliver the research and those involved in studies themselves (through study set-up or by participation in a study) to be more closely involved in value based decision making. Allowing all to participate in resource allocation or addressing a particular need will incentivise and drive value (particularly in the context of a fixed budget).

• Good quality information is used to make informed decisions and undertake cost evaluation to assess value. As part of implementation, collecting information that drives best outcomes (e.g. recruitment as planned, efficient study set up) will be key.

Current funding model

4.5. The current activity based funding (ABF) model is predicated on an assumption that NHS organisations that are more research active in previous years will be more research active in the following year. It is a static budgeting model using retrospective research activity as a proxy for future research support needs. The formula includes crude weightings to account for study complexity, and incentives for certain activities e.g. number of commercial studies, number of chief investigators in previous year.

4.6. As the total Local Support and Delivery budget is fixed, this means some NHS organisations will see increases/decreases in funding between years that may not mirror their increase/decrease in activity in the previous year, as performance within the formula is relative.

4.7. Welsh Government R&D Division have directed at least some change to the existing model will be required in order to meet the policy principles above.

A case for change

4.8. A small number of NHS organisations support continuing with the current model, particularly those that have seen increases in recent years. However, feedback from most stakeholders, particularly researchers and most NHS organisations, is of a need for change, as whilst the current model has served its original purpose in increasing transparency, it has a number of weaknesses and is no longer fit for purpose.

4.9. The following summarises the case for change, from stakeholder views gathered and analysis undertaken during 2017/8 and 2018/9:

a) Business Intelligence indicates step-change is needed in Wales
   o Research activity (pro-rata to the population) in Wales is low compared to other nations meaning people/patients in Wales are not offered the same opportunities
   o There is an imbalance between geographical areas of where studies are undertaken and areas of greatest health and social care need
   o The UK Site Identification process for commercial research offers same opportunities as other nations, but there is a relatively poor and variable uptake in Wales

b) Researcher view overall is that the current model is not fit for purpose as:
   o It is not based on in year research needs
   o It is not sufficiently responsive if needs change
   o Current study complexity bandings/weighting applied in the formula are not reflective of increasingly highly complex interventional studies i.e. these cost more than the formula provides
   o It is not fit for future trial design and clinical innovation e.g. adaptive trials, advanced therapy, shared care clinical pathways because the current model allocated funding where participant recruitment occurs, which may differ from where study tasks are completed and therefore the costs are incurred
   o Current model continues to be misinterpreted as a ‘delayed payment’ model
   o Specialty Leads roles are not joined up with ‘delivery of research’ across Wales, yet are well placed to take an all-Wales perspective

3 Types of budgeting approaches: https://www.accountingtools.com/articles/what-are-the-types-of-budgeting-models.html
c) NHS organisations’ views are that the current model is not fit for purpose as:
   - Current model incentivises undertaking only certain types of studies, not rare disease or high intensity/complex studies
   - Uncertainty in funding year-on-year creates an increase in funding of temporary posts to manage local financial risks, creating uncertainty for staff and NHS organisations

d) Current model is not aligned to Welsh Government R&D Division strategy:
   - It doesn’t incentivise collaboration between NHS organisations and networks
   - It drives competitive behaviours between NHS organisations with an unintended focus by some on ‘quick wins’ to achieve local performance metrics
   - The commercial premium does not appear to have driven the intended increase in commercial activity

4.10. Additionally in England, NIHR have indicated, for many of the same reasons above that they are changing their ABF model (on which the current ABF model in Wales is based).

5. Development of recommendations

5.1. A Task and Finish Group was established in June 2019 and has met four times (monthly) during the development of these recommendations. The context and case for change was agreed by the Task & Finish Group as described in Section 4.

5.2. The Task & Finish Group comprised representation from local NHS R&D Directors/leads, Support & Delivery Centre, NHS Finance Delivery Unit, Medical Directors, Specialty Leads, Senior Research Leaders, Welsh Government R&D Division, external advisors from the National Institute of Health Research Clinical Research Network (NIHR CRN) in England, and was chaired by the HCRW Director of Support & Delivery. Terms of Reference for the group were agreed by Welsh Government R&D Division (see Appendix 1).

5.3. A communications/engagement plan was agreed by the Task & Finish Group. Wider stakeholder contribution to the project has been provided primarily through an initial one day workshop (February 2019) and through sharing draft recommendations at briefing sessions in September 2019. Questions and comments from the briefing sessions were considered in finalising this recommendations paper (feedback is summarised in Appendix 2).

5.4. The success criteria for any model to distribute delivery funding was agreed as being to:
   - Support successful research study delivery (set-up, feasibility, recruitment to time/targets, data quality, retention of participants etc)
   - Support a Wales-wide ethos, in particular alignment to the S&D strategic framework
   - Recognition for collaborative working within and between NHS organisations
   - Agility, effectiveness and value of HCRW Support and Delivery funding
   - Support for national initiatives (Primary Care Research Delivery Network, Dental Research Network, ENRICH)
   - A facilitative, proactive, constructive, problem solving approach to ensure all available studies are delivered

5.5. The Task and Finish Group were asked to consider different models or approaches to the distribution of funding to support research delivery, weighing up their relative strengths/weaknesses. A range of approaches and financial models were considered (see Appendix 3):
   - Continuation or adaptation of the current activity based model i.e. a fully formula based model including some incentivisation elements using prior research activity as a proxy for anticipated future research resource needs

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• Activity based formula model including **fixed** and **variable** elements based on prior
  research activity as a proxy for anticipated future need. Variations of this model were
  considered:
  o Use a similar methodology to the new activity based funding model being used by
    the National Institute Health Research Clinical Research Network (NIHR CRN) in
    England (80:20 fixed/variable or a variation of the ratio to increase emphasis on
    performance)
  o Change approach to include fixed elements to increase stability or increase agility
    e.g. 3-5 year rolling average
  o Within the variable element, align to specific strategic goals in Wales, for example
    alignment to population health needs, opening specific studies or disease areas,
    level of multi-centre work (incentivising sharing activity), success in delivery
    (recruitment to time/target), increase in recruitment, increase in number of Principal
    Investigators, increase in complexity /rare disease studies, contribution to overall
    Wales target, first global patient, first Welsh patient, speed of study set-up
  o Reconsider other fixed/variable options considered and rejected in 2016\(^5\) i.e. element
    based on population size or NHS organisation financial turnover
• Activity based formula model using future predicted workload and taking into account the
  predicted complexity of research studies.
• A research needs-based approach (not formula based) providing resource for the actual
  research activity/tasks undertaken i.e. funding follows actual costs incurred, similar to
  that used in Greater Manchester Local Clinical Research Network (GMLCRN).

5.6. This paper describes the conclusion of the discussions and the agreed recommendations from
the Task & Finish Group. An impact assessment is included in Section 8.

6. Recommendation – A research needs-based approach is implemented in Wales as an overarching principle

6.1. In weighing up the strengths and weaknesses of all options the Task & Finish Group
recommend a research needs-based approach is implemented. This means funding follows
the actual costs required to deliver (or support the delivery of) research when and where
those costs are incurred and is not based on a formula

6.2. This approach is recommended as it:
• provides the greatest agility within the system to ensure that funding moves to where the
  research activities are taking place, when it is needed, and is commensurate with the
  level of costs incurred at different stages of delivery of the study
• by reducing competitiveness for funding between NHS organisations it removes the
disincentive to collaborate across NHS organisations
• has been shown to be workable elsewhere - having been developed over many years in
  a clinical research network of similar size budget, population and number of organisations
to Wales, albeit with different geography i.e. in Greater Manchester Local Clinical
  Research Network (GMLCRN)
• has been shown to be workable in Wales – it builds on the approach already in place in
  Wales for distributing actual service support costs to Welsh Ambulance Services Trust,
  Public Health Wales and general practices. In 2019/20, a research needs based
  approach has been employed in part at times of financial pressure for most NHS
  organisations (to varying degrees in HDUHB, BCUHB, PIHB, CVUHB, ABUHB, CTMUHB).
• it has been previously acknowledged as the preferred model. A similar approach was
  initially recommended when the current activity based model was introduced in 2012/13
  although could not be delivered at that time as routine data was not in place to adequately
  support implementation. Since then, the quantity and quality of routinely collected data
  has improved significantly.

\(^5\) Similar models (and options of models) with core/flexible element were considered in September
2016\(^5\) by the NHS Delivery Board (R&D Directors) and rejected, albeit wider stakeholder discussion
was not included.
6.3. All of the other options considered were formula based and all presented different strengths and weaknesses (see Appendix 3). However, the common weakness of each was a reduced level of agility and a reduced ability to provide funding to deliver the tasks required in all studies. Although the model proposed doesn’t resolve the uncertainty of funding year-on-year for NHS organisations, given the HCRW budget is set at a Welsh Government level annually, none of the funding models (including the current model) could provide absolute certainty of all funding being available in subsequent years. All of the formula based models result in relative allocations and therefore the Task & Finish Group considered they all create potential for more fluctuation than the proposed approach.

6.4. The proposed approach is in effect a zero-based budgeting approach whereby all expenditure is justified based on the research needs identified. However, in practical terms spending is already justified and agreed/committed and so much of the spending plan will continue as per the year-end position.

6.5. It is recommended this is the default process for all NHS organisations in Wales, and this replaces the current activity-based funding formula.

Implementation considerations

6.6. The Task & Finish Group recommended that the existing spending plan/national scrutiny process can be adapted to support implementation. Budget setting would be through the NHS organisation/S&DC submission of a spending plan (as is the case now) for the staff that would be required to support the activity (study-specific tasks and facilitation/support) forecasted to be undertaken in the year. The difference in approach would be that spend would then be negotiated by considering that proposed spending plan against actual forecasted activities/tasks – whether that is screening, recruitment, study visits or follow-up.

6.7. Although the detailed process will need to be developed as part of implementation, the Task & Finish Group highlight for staff delivering specific studies, one example of how this could be implemented would be to follow the approach used in GMLCRN (assessing the spending plan against activities required for studies open and in set-up, factoring in an uplift for unknown new activity) or be modelled through utilising study costing schedules (now required for all studies) which would more accurately factor in tasks relating to ongoing studies and participants. The latter would more easily enable the forecasting of study costs over time in line with study delivery tasks, enabling them to be routed to the NHS organisation where/when the costs are incurred.

6.8. For spend associated with those that facilitate/support study set-up and delivery (locally or nationally), the Task & Finish Group consider this should also be within the context of the research support needs required for the level of research activity/tasks undertaken and make a specific sub-recommendation regarding this.

6.9. Once the initial local plan has been agreed nationally, research activity would be regularly reviewed by the performance team within the Support & Delivery Centre (S&DC) on behalf of Welsh Government (as is the case now) to monitor the appropriateness of the spending plan, with revisions discussed/actioned as necessary. As is the case now, this process will be transparent to the NHS organisation and Welsh Government. It would not require all spend to be justified afresh each period if a case has already been made and accepted and activities continued as planned.

6.10. The Task & Finish Group acknowledge that increased scrutiny of spend against the context of research need may mean that not all local fixed costs (i.e. the costs of continuing to support staff on permanent contracts) are justified by the level of research activity/tasks forecasted to be undertaken in year. A local workforce plan will need to be adapted or

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6 Analysis in GMLCRN is that +20% recruitment is the calculated known unknowns at start of year and therefore a 20% uplift is applied to activity projections.
developed where not already in place to ensure there is flexibility in utilising staff in permanent contracts. Where spend is not justified by research activity, a plan will need to be agreed to either reduce spend (over time) or increase activity. Justification of spend may be different for each NHS organisation e.g. larger organisations with higher turnover of staff will be able to be more efficient, whereas organisations in more rural areas where recruitment to posts is challenging will likely carry a higher proportion of substantive posts. The Implementation group will need to take account of this. A transitional approach to implementation is recommended in Section 8.

Sub-recommendations

6.11. If the overall principle of a research needs-based approach is accepted, the Task & Finish Group make a series of sub-recommendations regarding supporting this principle (detailed in Section 7):

1. Develop a One Wales approach for the financial management of delivery funding
2. Establish a central fund and associated process for pump-priming capacity and meeting additional in-year needs
3. Align funding for clinical/social care support services to the outcomes of the all-Wales R&D service improvement projects
4. Retain a central budget for general practice service support costs
5. Retain a central budget for non-general practice primary care support costs
6. Retain a central budget for social care and other support costs
7. Undertake an all-Wales review of the costs associated with NHS study set-up and oversight
8. Review the source of funding for R&D Directors/Leads
9. Continue to support Welsh Specialty Leads in all NIHR topic areas
10. Consider investment in strategic research delivery infrastructure

7. Sub-recommendations (to support overarching principle)

Sub-recommendation 1: Develop a One Wales approach for the financial management of delivery funding

Current position

7.1. A project to standardise the costing of research across Wales (and the UK potentially) was established in 2019/20, where costing leads across Wales have already agreed common approaches and costs for research.

7.2. The Task & Finish Group recognise local financial governance process ensures financial risks associated with research income/spend are as low as possible for the NHS organisation. This results in R&D spending being subject to local controls such as vacancy review/scrutiny and local reviews of business cases for new spend. The local controls in place have generally been successful in managing R&D spend within the funding allocated annually, although there are frequent underspends reported by some NHS organisations. However, these local financial controls are applied in variable ways across Wales. In addition, although these controls support local autonomy and accountability, the Task & Finish Group note this has created inconsistency in decision making, duplication of effort across Wales (multiple organisations (or national) review of the same business case), and frequently creates delays in recruitment of staff. This results in slippage and therefore underspends. The delays to study set up as a result, within the context of a globally competitive environment, is potentially disadvantaging Welsh patients.

7.3. Over the past few years, a responsive but ad-hoc process has been in place to manage and recover in-year unspent local support & delivery budget, and using it to support a need identified elsewhere in the Support and Delivery Service. A number of NHS organisations have released underspends in the last couple of years, enabling funding to start to be managed in an agile, responsive way across Wales. Although not explicit, an all-Wales approach to financial management has therefore evolved - where financial pressures in one
organisation are relieved by utilising underspends from other NHS organisations. In addition this all-Wales approach has enabled reassurances to be provided to some NHS organisations to enable them to take increased financial risks e.g. 2019/20 in HDUHB and 2018/19 for BCUHB.

7.4. However, where underspends have arisen, it has been an implicit expectation that the NHS organisation has exhausted all efforts to make use of the funding in their local area (including moving funding between delivery and development local budget lines) and that ‘passing back’ funding (for use by another NHS organisation) is a last resort. The consequence of this approach is that funding might have been directed elsewhere to support delivery of studies as a priority if a One Wales view had been taken earlier in the local decision-making process.

Recommendation

7.5. The Task & Finish Group recommended that a One Wales financial management strategy is adopted, adapting and formalising the current ad-hoc process that has evolved over the last few years.

7.6. The Task & Finish Group recommend the existing national process needs to evolve to facilitate more quickly the release of any local underspend/slippage during the year. This will maximise the delivery funding available to support research needs as/when/where required (overarching principle and sub-recommendation 2) within the same organisation or elsewhere in Wales. Instead of being seen as a ‘last resort’, it is recommended that this is the default approach to increase flexibility across Wales and is an important mitigating action to reduce the risk of a limited budget being exhausted.

7.7. In addition, the Task & Finish Group recommend a One Wales approach to financial oversight is established by adapting the existing ad-hoc process, with the aim of more consistently reducing/removing the local efforts (and often duplication) in scrutiny of research delivery related business cases, vacancy review and local approvals of spending plans. The Task & Finish Group recognise that any future One Wales process (e.g. for vacancy review or other) must be responsive, more efficient but also maintain appropriate scrutiny in decision making.

7.8. Where active research studies or support services (clinical or management) require ongoing support then the overarching principle continues to apply – the funding follows the research need.

7.9. This recommendation would apply all NHS organisations and the Support & Delivery Centre.

Implementation

7.10. It is recommended the process by which this is administered is further evolved and developed to be both proportionate and efficient in reaching rapid decisions and find ways of reducing the burden on NHS organisations.

7.11. Although it will be for an implementation group (yet to be established) to define the detailed process, the Task & Finish Group note this has been demonstrated as practical in GMLCRN (with a budget of £18M), through a central accountant liaising with local finance leads to monitor changes to spending plans, supported by monthly finance and network-wide operational delivery meetings. The Task & Finish Group therefore propose a similar process could be established in Wales, and suggest an equivalent operational meeting could comprise senior local operational/delivery leads, as the group collectively best placed to understand the research delivery needs across Wales. Alternative approaches to implementation may be available and the Task & Finish Group will need to consider these.

7.12. In addition, the Task & Finish Group suggest the implementation group could consider including the development of a tiered process for decision making, some decisions may be possible to make immediately (locally, or nationally) against a framework or existing plan
already agreed, some may require some limited discussion and others may require a more considered review by the all-Wales operational group.

**Impact**

7.13. This approach increases agility across the national delivery budget, as where funding is released it makes more budget available for allocating to building delivery capacity - either within the same organisation or in another organisation. It also increases the scrutiny of spend on a case by case basis, increases the consistency of decision making across Wales and increases prudency on an all-Wales basis.

7.14. A national process is already in place that requires NHS organisations and the Support & Delivery Centre to submit detailed spending plans and quarterly returns to Welsh Government, and for these to be scrutinised and approved before payment is released. In order to implement the overall research-needs based approach, and create the necessary controls to manage financial planning on a One Wales basis, the current process may need to further evolve and this needs to be considered as part of implementation. The ad-hoc approach that has evolved in recent years has meant the process of national financial management and amending funding plans/allocations in year has been established and been shown to be workable, it has demonstrated positive impacts in speeding up local scrutiny and is acceptable to the NHS organisations.

7.15. The research finance leads across Wales meet at least once per year already, and therefore a network and more regular meetings could be established easily, albeit creating some additional time commitment.

**Sub-recommendation 2: Establish a central fund and associated process for pump-priming capacity and meeting additional in-year needs**

**Current position**

7.16. As described above, an ad-hoc process has evolved over the last few years to support additional needs identified in-year that cannot be met by the funding initially allocated to the NHS organisation or Support & Delivery Centre. However, this is not available until late in the financial year when underspends become apparent. From analysis of requests to set-up sites in Wales, lack of resources/capacity is currently one of the most common reasons that studies are currently being turned down in Wales.

7.17. Funding to support delivery of studies in WAST, PHW and primary care is already drawn down on an in-year research needs basis.

**Recommendation**

7.18. It is recommended a central fund would enable NHS organisations to request additional funding in order to pump-prime increased delivery capacity within teams as well as meet additional in-year delivery needs.

7.19. For pump-priming, it is recommended that each approved funding request would be time-limited and performance actively managed in order to demonstrate a case for more sustained funding as part of the routine research-needs based delivery spending plan.

7.20. This recommendation would apply to requests from all NHS organisations and the Support & Delivery Centre.

**Implementation**

7.21. The central fund will need to have an initial budget in order to be accessible from the start of the year, but it expected (based on experiences in GMLCRN) this budget will increase/be replenished through the monthly flow of potential underspends described in Sub-
Recommendation 1. Where the funding is held (and who is lead manager) will need to be determined by Welsh Government.

7.22. The Task & Finish Group recommend the process includes provision for agreeing a planned larger scale investment (likely via a small number of national calls per year), as well as being rapidly responsive to teams requiring urgent smaller amounts of additional resource.

7.23. It is recommended the process by which this is administered is developed to be both proportionate (low burden on the researcher but also ensuring appropriate financial governance) and efficient in reaching very rapid decisions. The Task & Finish Group suggest the monthly meeting of senior operational/delivery leads outlined in Sub-Recommendation 1 would be the most pragmatic mechanism to review most requests for additional in-year funding.

Impact

7.24. This approach increases agility, and increases the scrutiny of spend on a case-by-case basis; thereby increasing the consistency of decision making across Wales; increases prudency and ensures funding is directed to the areas of research delivery need on an all-Wales basis for the benefit of people/patients.

7.25. This approach would ensure NHS organisations are more frequently able to respond positively to study opportunities where a pipeline is demonstrated but activity has not yet been fully realised, enabling teams to establish the research delivery support ahead of fully being able to justify need through existing study activity.

Sub-recommendation 3: Align funding for clinical support services to the outcomes of the all-Wales R&D service improvement projects

Current position

7.26. Clinical support services includes pharmacy, radiology, pathology, and microbiology support provided to research studies. Funding for clinical support services is variable across Wales and is not currently proportionate to the volume of studies requiring support.

7.27. In addition, staff recruitment to some clinical support services is challenging and as a result capacity within the clinical service is stretched. This means that even if income follows then frequently there is no staff capacity as the NHS workforce is already stretched. This is often the case for commercial cancer trials, for example the requirement of pre-treatment and on-treatment biopsies for cancer trials is very rarely deliverable. With increasing patient stratification based on genetic profiling then increasing both pathology and radiology capacity is crucial. At least some NHS organisations solve this through outsourcing to private providers, although this is also variable across Wales.

7.28. Access to clinical support, particularly during study-set up is already a rate-limiting step in the study-set up process for some NHS organisations and will become increasingly so as improved costings and contracting processes increase efficiency.

7.29. Although some NHS organisations (e.g. BCUHB, ABUHB, CVUHB) have reassessed clinical support funding in recent years through benchmarking, this has not resolved capacity issues in many NHS organisations.

7.30. A series of projects are due to commence in 2019 to review the clinical support needs required for the research across Wales.

- A project to review pharmacy services for clinical trials has been initiated, overseen by a lead Chief Pharmacist as part of the Chief Executives Efficiency Programme, and will include analysis of timelines for pharmacy set-up, review of extent of outsourcing, benchmarking with other pharmacy departments outside Wales, and making recommendations on the local resource needs that would establish a more agile service across Wales.
• Welsh Government are also currently developing draft imaging and pathology strategy plans and clinical support for research will need to align where possible.
• In addition, the interpretation of regulatory requirements for UK research is being reviewed by the Royal Colleges which may change the resources required.

Recommendation

7.31. The Task & Finish Group recommend that funding should be aligned in response to the recommendations of the separate projects described above and that in the interim, funding should be allocated in line with the overarching principle where possible i.e. on a research needs basis including accessing additional funding in line with Sub-Recommendation 2.

Sub-recommendation 4: Retain a central budget for general practice service support costs

Current position

7.32. Currently, general practice study activities (service support costs) are resourced through two routes, either from research delivery staff employed by a health board who have a dual primary and secondary care role, or more frequently via general practices claiming direct against a primary care central budget for the costs associated with employing staff direct or other costs incurred within the practice.

7.33. Practices have also been receiving funding via a Primary Care Research Incentive Scheme (PiCRiS) and it has become apparent that many practices use this funding to support study-specific delivery activities (which they could have accessed funding for in addition to the PiCRiS funding). As part of the development of the Primary Care Research Delivery Network (PCRDN), PiCRiS funding will cease, which has triggered a Wales-wide review of the study-specific resource needs of every primary care study that will continue to be active in 2020/21. In addition, as part of testing models that increase collaboration between practices, some health boards have received additional funding in 2019/20 to pump-prime an increase in study delivery (HDUHB, CVUHB).

Recommendation

7.34. It is recommended that service support needs of general practices continue to evolve in line with the Primary Care Research Delivery Network programme. This enables a model to be agreed within each health board area – either for practices to continue to access the central budget on a per-study basis, for posts or part funding of posts to be agreed within the general practice setting or for staff to be hosted by the health board. This aligns with the overarching principle of taking a research needs based approach, but within the context of the developing PCRDN.

Sub-recommendation 5: Retain a central budget for non-general practice primary care support costs

Current position

7.35. It is recommended that service support needs of general practices continue to evolve in line with the Primary Care Research Delivery Network programme. This enables a model to be agreed within each health board area – either for practices to continue to access the central budget on a per-study basis, for posts or part funding of posts to be agreed within the general practice setting or for staff to be hosted by the health board. This aligns with the overarching principle of taking a research needs based approach, but within the context of the developing PCRDN.

Recommendation

7.36. The current approach is already a research-needs based approach.
7.37. As per sub-recommendation 4, it is recommended the central budget to support the wider primary care research delivery programme is retained and that service support costs can be claimed via the same application process as currently (already on a research needs basis).

**Sub-recommendation 6: Retain a central budget for support costs for HCRW portfolio studies in social care and other non-NHS settings (e.g. schools, prisons etc)**

**Current position**

7.38. Currently, social care and other researchers can access delivery support for HCRW Portfolio studies through two routes, either from research staff employed by a health board (generally for studies that cross the health and social care services/other settings) or by claiming direct against the central budget for the costs associated with delivery of a specific study (although in practice this has not yet been utilised).

7.39. The current approach is already a research-needs based approach.

**Recommendation**

7.40. As per sub-recommendation 4, it is recommended the central budget to support the wider primary care research delivery programme is retained and that service support costs for social care studies can be claimed via the same application process as currently (already on a research needs basis).

7.41. In addition, it is recommended that the ENRICH initiative in Wales is expanded to support a research-ready delivery network of care homes. A project to recommend the scale of such a network is underway and, based on the volume of studies available (led from Wales or from other nations), will identify the research needs-based level of coordination required to support delivery of research in care home settings in Wales.

**Sub-recommendation 7: Undertake an all-Wales review of the costs associated with NHS study set-up and oversight**

**Current position**

7.42. In 2018/19, approximately 30% (£5.8M) of the overall HCRW delivery/development spend was on management/administration to support study set-up and study oversight - equivalent to £8k per active study. This funds staff within the NHS R&D Offices (£4.3M) and staff with the Support & Delivery Centre (£1.5M) undertaking tasks related to the set-up or oversight of study delivery for all studies the NHS organisation undertakes i.e. including non-portfolio studies. A small amount (c£220k in 2018/19) of these costs are recovered from other funding sources (e.g. commercial contracts as set-up fees).

7.43. Although there has been a programme of service improvements to improve the consistency and streamlining of study set up/oversight processes in recent years, this incremental approach is based on existing structures and requires a collaborative attitude across teams and organisations, and significant programmes of change management.

7.44. NHS R&D Offices provide advice and support for all studies undertaken locally (portfolio, non-portfolio, commercial), and some also support service evaluation, innovation and improvement projects. Whilst organisations are clear that non-research support should be funded from other sources, costs to provide research support (regardless of type) is generally met from the LS&D funding, with some variable cost recovery for commercial study-setup. This is different to the arrangements in England where only portfolio research can be supported by NIHR/DHSC funding. The Task & Finish Group recognise the importance of pathway to portfolio and student research in supporting researcher development, although the balance between non-portfolio/portfolio activity is also different across Wales.

**Recommendation**
7.45. The Task & Finish Group consider the amount spent on management/administration to oversee the volume of portfolio research activity in Wales to be excessive and recommend this should be reduced over time. The Task & Finish Group highlight to be commensurate with other areas across the UK, funding allocated to support the management/oversight of research delivery is likely to be no more than 15% of the total delivery budget.

Implementation

7.46. Welsh Government will need to confirm the policy position regarding support for non-portfolio research set-up/oversight, and whether it should be funded from the delivery budget.

7.47. The Task & Finish Group recommend that a national review of the processes associated with set-up and delivery is then accelerated to consider how the needs of research/researchers in Wales can be met in a more streamlined cost-efficient way, with the expectation this would identify areas of spend that could be reduced over time.

7.48. It will be for the review to conclude how processes (and therefore how structures) may be configured in the future, however, discussion as part of this project and other service improvements underway demonstrate there is support for an all-Wales approach to many of the study set-up and oversight functions already. Although these all-Wales processes are at various stages of maturity the Task & Finish Group observed there is likely to be value in bringing together staff undertaking similar functions (e.g. an all Wales contracts and costings service; an all-Wales industry service; an all-Wales Sponsorship or study monitoring service). The Task & Finish Group acknowledge there may be a variety of options to deliver this (which will need appropriate appraisal) but observed this could be achieved by creating virtual One Wales teams – bringing together local NHS R&D and the central S&D Centre staff for relevant functions. It was considered by the Task & Finish Group that this initial step could be implemented for some functions quite quickly and, although this may not immediately realise cost savings, would provide the foundations necessary for increased cost efficiency over time. It would build on existing One-Wales arrangements where one organisation provides a service to another. Where there is staff turnover, this can then result in discussion on an all-Wales basis as to whether there is existing capacity within the system or if additional staff are required, and if so, where they are best located.

Impact

7.49. Reducing management/administration costs would increase the funding available for research study delivery, an essential mitigation for the risk of a limited delivery budget.

7.50. Although not pre-empting the outcome of the recommended review, the Task & Finish group acknowledge that, given the scale of change required, that it is likely that a current structures and processes (central and local) may need to change if the necessary refocusing of spend is to be realised.

7.51. The Task & Finish Group also acknowledge that current attribution by NHS organisations of spend against management/administration posts will need to be checked, and that any resulting reduction in spend indicated should be carefully managed through natural turnover and mutual agreement wherever possible, over a number of years so as to provide reassurance to staff already in post.

Sub-recommendation 8: Review the role and source of funding for R&D Directors/Leads

Current position

7.52. Approximately £470k of delivery funding is spent annually on salaries of local R&D Directors/Leads.
7.53. The Task & Finish Group acknowledge a significant part of the role of R&D Directors/Leads is essential in raising the profile of research at local executive level and ensuring research is embedded within the NHS organisation. Additionally, building relationships with partner universities as part of the university health board status and providing strategic leadership is considered to be an essential requirement of the role. Feedback from stakeholders indicates stronger collaboration with Welsh universities is required including support for clinical academics. The Task & Finish Group consider these activities are wider than supporting study set-up and delivery.

7.54. The other aspect of the current R&D Director/Lead role, in some organisations, is in managing the R&D Office and overseeing study set-up processes, with delegated accountability for the conduct of research in the organisation. If sub-recommendation 1-7 are accepted, the R&D Director role in delivery (supporting study set-up/study oversight) will further reduce with appropriate delegation to other senior R&D staff required.

Recommendation

7.55. The Task & Finish Group recommended that Welsh Government clarify the expectations of the role of R&D directors and other leads in NHS organisations. Once clarified, it is recommended the source of funding for R&D Director/Leads is reviewed, and costs are only met from the delivery budget where justified on a research needs basis (in line with the overarching principle).

Impact

7.56. It is outside the scope of this project to comment on whether the costs for R&D Directors/Leads are appropriate or from which budget the costs should be met.

Sub-recommendation 9: Continue to support Welsh Specialty Leads in all NIHR topic areas

Current position

7.57. The role of Speciality Leads was reviewed in 2019 and appointments made in April 2019 for 3 years. Welsh Specialty Leads are appointed in each of the 30 UK specialties, albeit with a small number of gaps where no appointment has yet been possible.

7.58. As part of the ongoing performance management of Specialty Leads, the sessional time funded for each individual is already reviewed annually.

7.59. The Specialty Leads became part of Support and Delivery Service from April 2019 and will need to be considered with the overall Support and Delivery funding envelope.

Recommendation

No change is recommended i.e. retain the roles as agreed until end March 2022.

Recommendation 10: Consider investment in strategic research delivery infrastructure

7.60. The Task & Finish Group recommended consideration be given to new initiatives relating to research delivery that may require additional investment or delivery/support to be reconfigured. E.g. Wales’s response to Life Science sector deal’s ‘Patient Recruitment Centres’ for late phase commercial studies; clinical research facilities/infrastructure to support delivery of advanced therapy/cell and gene therapy research. With these examples, further dialogue with NIHR/Office of the Life Sciences will be required and consideration and opportunities presented through the national advanced therapies programme.

8. Recommendations regarding next steps, implementation and timescales
8.1. Should recommendations be accepted in principle, the Task & Finish Group acknowledge that the immediate next step will need to be a more detailed impact assessment. This impact assessment will likely need to model the funding already committed in 2020/21 (e.g. substantive staff in post), provide an assessment of the actual costs of supporting the current research portfolio, and start to develop in more detail the most efficient and effective method for financial and decision making processes. This will enable to the risks identified in Section 9, particularly those associated with a fixed Support & Delivery budget to be described in more detail.

8.2. An implementation programme will be required should the recommendations be accepted. This will need to include transitional arrangements as well as the range of projects recommended above. Some of the projects will naturally align to (or are already underway by) existing groups e.g. PCRDN Steering Group, trials pharmacists peer group etc. For other recommendations, specific Task & Finish Groups or projects will need to be established e.g. review of study set-up management/delivery oversight processes/structures. Oversight of the implementation programme will be required.

8.3. Feedback from stakeholders regarding pace of implementation was mixed. Feedback from researchers and research leaders (specialty leads, senior research leaders) supported immediate change, moving away from the current funding model as soon as possible. Some R&D Directors raised concerns regarding loss of local autonomy/control and uncertainty over how recommendations would be implemented in practice but overall there was agreement for most of the principles.

8.4. The Task & Finish Group propose recommendations are implemented in 2020/21, albeit with some transitional arrangements so that there is some stability as processes evolve. This will allow an agile approach to be taken whereby processes can be continuously improved through the learning during implementation and to accommodate the different pace at which projects will conclude.

8.5. Subject to the impact assessment being concluded, the Task & Finish Group recommend that 2020/21 is a transitional year for some of the recommendations and the following approach be taken:
- NHS organisations and the Support & Delivery Centre are initially reserved a delivery budget for 2020/21 that matches their ongoing committed delivery spend detailed in Q4 2019/20. Organisations will need to report this spend against their research delivery needs, although this will not change the initial delivery budget reserved for them to draw down upon in 2020/21.
- The process for managing and responding to in year changes to spending plans will continue to evolve during 2020/21, building on the current practice for managing underspends and the process described above
- Spend associated with NHS study set-up and oversight (management/admin) and R&D Directors are met as in 2019/20, while a review is undertaken. This will also enable the focus of the R&D Director role to be considered and the source of funding for R&D Directors/Leads to be clarified.
- Some study set-up functions (functions to be agreed) are brought together in virtual teams

8.6. The Task & Finish Group recommend that to facilitate implementation from 1 April 2020/21 the following will be required:
- A central fund and process for pump-priming capacity and additional in year-needs is established
- A One Wales financial management process in place
- General practice, other primary care, WAST, PHW and social care support continues on a research-needs basis. Coordination support is agreed for each health board area as part of the PCRDN programme

9. Impact analysis
This section describes the potential impact of the recommendations, both the benefits that are expected to be realised and the risks and how they may be mitigated. As described above a more detailed impact analysis is recommended to assist in informing implementation.

**Benefits to be realised**

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<tr>
<th>Benefit</th>
<th>Mechanism</th>
<th>Outcome</th>
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| Increased opportunities for people in Wales to participate in research | • Study set-up across multiple sites is coordinated  
• Study set up follows clinical care pathways including across NHS organisations  
• Feasibility assessment and subsequent speed of study set up is not limited by concerns over adequate resource to support. | • Coordinated set up across multiple sites in Wales is encouraged  
• Patients have opportunities to access research in usual clinical care context  
• Funding follows research study needs throughout study lifecycle |
| A balanced portfolio of research in Wales to meet the requirements of A Healthier Wales | • Funding is distributed on a research needs based approach  
• Increased collaboration between NHS organisations to facilitate a broader portfolio of research | • Organisations are able to offer opportunities according to strengths and local priorities |
| Equitable access to specialist research opportunities | • Referral and PIC activities are recognised | • Access to research for patients is equitable in relation to services on offer in Wales, acknowledging not all patient groups or specialties will require the same level of resource to meet the same need |
| Increased agility of delivery resources across health and social care settings | • Building capacity to deliver through pump priming | • The support and delivery of research is sustained through income investment |

**Risks**

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<tr>
<th>Cause</th>
<th>Impact</th>
<th>Mitigation</th>
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| Certainty of funding year on year is not increased (over and above the limited certainty there is now) | • NHS organisations may be cautious to appoint new posts  
• Delays to study set-up caused as staff not in post to deliver | • Financial modelling of impact precedes implementation  
• Recommended national financial review ensures consistency of risk review and risk control  
• Central commitment to fund staff in post according to their current contract |
| Resource requests exceed total budget | • New studies in set-up may not be able to be supported | • Continuous improvement programme in place to increase efficiency  
• Reduction in management/administration costs release funding to support direct delivery (albeit see separate risk on speed of this being achieved) |
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| 1 |   |   | Changes to study design increase efficiency of delivery  
|   |   | Improved workforce planning increases flexibility of staff costs/deployment |
| 3 | Reduction in management/administration costs is not realised through staff turnover |  | Increasing available funding to support direct delivery is not achieved  
|   |   | Progress monitored  
|   |   | Potential to remove funding for specific posts if speed of transition needs to increase. However, this would create an additional risk to the NHS organisation which would require mitigation. |
| 4 | Removal of incentives from a financial model |  | Willingness of individuals/organisations to participate in research reduces  
|   |   | Positive behaviours driven via a revised performance management framework/key indicators |
| 5 | NHS organisation does not participate in implementation programme |  | Change towards a One Wales vision is undermined  
|   |   | Changes are reinforced within the HCRW Strategy (2020-25)  
|   |   | NHS organisation performance management framework includes alignment to All-Wales plan  
|   |   | Funding withheld |
APPENDIX 1: Task & Finish Group Terms of Reference

1. Purpose

1.1. To consider a new all-Wales research delivery funding model.

2. Context/Background

2.1. Draft Welsh Government R&D Division have established this task and finish group to advise on potential improvements and provide recommendations on a new all-Wales Research Delivery funding model to distribute Health and Care Research Wales resources to NHS organisations and the Support & Delivery Centre.

2.2. Whilst there is recognition that there have been step change improvements to the environment over the last few years (e.g. alignment of delivery staff across central and local models, streamlining approvals, increased coordination of study set up etc), stakeholder feedback has indicated that the current model for distributing funding by HCRW does not bring the added benefits to achieve HCRW’s aim to be a nation that is collaborative, maximise use of resources and achieve high value – by delivering the best possible outcomes in the most efficient way. Welsh Government R&D division have commissioned the Director of Support and Delivery (HCRW) to lead a group and a project team to develop recommendations for a new model that makes Wales meet the objectives.

3. Scope

3.1. Delivery funding includes costs associated with Support & Delivery Centre activities, centralised service support costs (direct payments to primary care, WAST, PHW), Specialty Leads, and delivery funded activities previously distributed to NHS organisations through an Activity Based Funding formula.

3.2. Funding that is made available for Excess Treatment Costs are outside the scope of the project.

3.3. The Research Development infrastructure programmes and grant schemes are outside the scope of the project. Research development within the Support and Delivery eco system is a key feature of HCRW strategy and a separate parallel work stream will explore improvements in supporting researchers who wish to develop research proposals and undertake pathway to portfolio activities.

4. Objectives

4.1. Consider different models or factors within models, weighing up their relative value in delivering:
   - Support for a Wales-wide ethos, in particular alignment to the S&D strategic framework
   - Recognition for collaborative working across NHS organisations
   - Support for cross sector initiatives (Primary Care Research Delivery Network, Dental Research Network, ENRICH)
   - Agility, effectiveness and value of HCRW Support and Delivery funding. Consider how each model will drive positive behaviours

4.2. Be informed by other UK models to ensure an approach that is fit for purpose.

4.3. Consider feedback from stakeholder groups (Specialty Leads, Senior Research Leaders, HCRW funded grant holders, centres/units, HEIs, CTUs, R&D Directors, public and other stakeholder groups considered relevant).

4.4. Describe any changes required to wider systems and process required to implement model.
4.5. Make recommendations to Welsh Government R&D Division by September 2019 (TBC) on a future funding model.

5. Membership and Chairing

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Department</th>
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<tbody>
<tr>
<td>Nicola Williams</td>
<td>HCRW (Director of Support &amp; Delivery)/ Project Lead (Chair)</td>
</tr>
<tr>
<td>Chris Fegan</td>
<td>NHS R&amp;D Director (Cardiff &amp; Vale University Health Board)</td>
</tr>
<tr>
<td>Keir Lewis</td>
<td>NHS R&amp;D Director (Hywel Dda University Health Board)</td>
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<td></td>
<td>Specialty Lead (Respiratory)</td>
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<tr>
<td>Rob Jones</td>
<td>Specialty Lead (Cancer)</td>
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<tr>
<td>Andrew Carson-Stevens</td>
<td>Specialty Lead (Primary Care)</td>
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<tr>
<td>Kerry Hood</td>
<td>Senior Research Leader</td>
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<tr>
<td>Anne-Marie Cunningham</td>
<td>Medical Director Representative (AMD Primary Care, NWIS)</td>
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<tr>
<td>Helen Grindell</td>
<td>Support &amp; Delivery Centre (Head)</td>
</tr>
<tr>
<td>Hywel Jones</td>
<td>NHS Finance Delivery Unit</td>
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<tr>
<td>Ceri Phillips</td>
<td>Value Based Healthcare Institute, Swansea University</td>
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<tr>
<td>Debbie Vinsun</td>
<td>UK External Representative (COO, Greater Manchester CRN)</td>
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<tr>
<td>Sarah Thorp</td>
<td>UK External Representative (Head of Finance, NIHR)</td>
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<tr>
<td>Carys Thomas</td>
<td>Welsh Government (Interim Head of R&amp;D Division/Co-Director HCRW)</td>
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<tr>
<td>Bev Luchmun</td>
<td>Welsh Government (Head of NHS R&amp;D Performance and Delivery)</td>
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6. Project team

6.1. A project team led by Reshma Raycoba, Cluster Lead (funding and performance) and Jayne Jones, Head of Research Delivery will support modelling, operationalise thinking and produce analysis to support discussion at the meetings. Staff from the project team will attend meetings as required.
APPENDIX 2: Stakeholder Feedback

1. Purpose

1.1. This appendix provides a summary of the stakeholder feedback received during the development of recommendations relating to a new all-Wales delivery funding model.

2. Approach to engagement and communication

2.1. Key stakeholders (NHS R&D/senior delivery staff, Wales Speciality Leads, Clinical Trials Units, Support & Delivery Centre) were invited to provide feedback at two stages in the development of recommendations.

2.2. A ‘Value Based’ stakeholder event was held in February 2019 (at the start of project) and was facilitated by the Professor of Health Economics, Swansea University. This informed the scope of the project and the case for change.

2.3. Further sessions with a focus on briefing stakeholders on the draft recommendations that had been developed including a question & answer session were held prior to submission of recommendations to Welsh Government. These sessions were held on:
- 25th September 2019 - two sessions in Cardiff: one open meeting and one with R&D Directors/Support & Delivery Centre only
- 27th September - open session in Swansea

2.4. In addition, although not specifically requested, a small number of comments (mainly from those not able to attend) were received by email. In addition, BCUHB R&D Office sent detailed comments (although also attended both Cardiff sessions). Attendance lists from the sessions can be found in the Appendix.

3. Initial feedback informing the case for change

3.1. Feedback from the initial workshop held in February 2019 was that most stakeholders, particularly researchers and most NHS organisations, view there is of a need for change, as whilst the current model has served its original purpose in increasing transparency, it has a number of weaknesses and is no longer fit for purpose. This is consistent with the wider analysis of business intelligence.

3.2. Researcher views overall were that the current model is not fit for purpose as:
- It is not based on in year research needs
- It is not sufficiently responsive
- Current study complexity bandings/weighting applied in the formula are not reflective of increasingly highly complex interventional studies i.e. these cost more than the formula provides
- It is not fit for future trial design and clinical innovation e.g. adaptive trials, advanced therapy, shared care clinical pathways
- It continues to be misinterpreted as a ‘delayed payment’ model
- Specialty Leads roles are not joined up with ‘delivery of research’ across Wales

3.3. R&D Directors views were more diverse but most agreed that the current model is not fit for purpose as:
- Current model incentivises undertaking certain types of studies, which does not include rare disease or high intensity/complex studies
- Uncertainty in funding year-on-year creates an increase in funding of temporary posts to manage local financial risks, creating uncertainty for staff and NHS organisations
3.4. A detailed summary of themes from this workshop was produced.

4. Feedback on the draft recommendations proposed

4.1. In total approximately 70 individuals attended the briefing sessions in September 2019, and 75+ comments/questions on the draft paper were collected.

4.2. Comments and questions related to the following themes:
- Overall support for the principles, particularly from researcher community. This reflects feedback at the initial workshop.
- Most questions raised were points of clarification – these were either clarified in the session or resulted in minor amendments to the draft paper.
- Many questions related to implementation, ‘how it will work in practice’ - particularly relating to speed and process for responding to ‘in-year’ additional funding/pump-priming support. Most commented on the need to ensure the process did not create delays.
- NHS R&D Directors commented on importance of local knowledge in decision making. This supports the recommendation regarding local involvement to the all-Wales review of requests.
- NHS R&D Directors were concerned about ‘centralisation’, loss of local control/autonomy to make decisions.
- Some commented that the recommendations do not improve certainty of funding for staff. This related to two issues a) ensuring communication regarding recommendations are carefully managed so as not to create unnecessary anxiety for staff in post during transition/implementation; b) that recommendations don’t fully address uncertainty of funding for NHS organisations.
- Some comments relating to wider HCRW strategy e.g. increasing collaboration with Welsh HEIs.
- Some comments on the opportunities the recommendations provide to increase input of Speciality Leads in decision making.
- R&D Directors requested further detail on the other options that had been considered and how these had been appraised.

4.3. The final paper submitted to Welsh Government was revised in light of the feedback received, where relevant.
### Briefing Session attendance

**25 September 2019 Cardiff**

<table>
<thead>
<tr>
<th>Name</th>
<th>Organisation</th>
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<tbody>
<tr>
<td>Sue Bale</td>
<td>ABUHB</td>
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<tr>
<td>Jeanette Wells</td>
<td>ABUHB</td>
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<td>Sue Palmer</td>
<td>ABUHB</td>
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<tr>
<td>Sara Shankland</td>
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<tr>
<td>Jemma Hughes</td>
<td>Swansea Bay</td>
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<td>Mark Simpson</td>
<td>Swansea Bay - Finance</td>
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<td>Yvette Ellis</td>
<td>Swansea Bay</td>
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<td>Jayne Caparros</td>
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<tr>
<td>Lynne Grundy</td>
<td>BCUHB</td>
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<td>Lona Tudor Jones</td>
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<td>Richie Morton</td>
<td>BCUHB - Finance</td>
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<td>Senior Nurse</td>
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<td>Team Lead</td>
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<td>Melanie Maxwell</td>
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<td>Chris Fegan</td>
<td>C&amp;VUHB</td>
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<td>Jane Jones</td>
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<td>Sue Figuerido</td>
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<td>Matthew Wise</td>
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<td>Rob Mahoney</td>
<td>C&amp;VUHB - Finance</td>
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<td>Howard Cooper</td>
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<td>Gemma Beynon</td>
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<td>Alisha Davies</td>
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<td>Mark Griffiths</td>
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<td>Rhiannon Leyshon</td>
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<td>Sarah Townsend</td>
<td>VUNHST</td>
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<td>Jonathan Patmore</td>
<td>VUNHST  - Finance</td>
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<td>Jane Darmanin</td>
<td>VUNHST</td>
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<td>Nigel Rees</td>
<td>WAST</td>
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<tr>
<td>Lisa Roche</td>
<td>CTMUHB</td>
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<td>John Geen</td>
<td>CTMUHB</td>
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<tr>
<td>Emma Thomas Jones</td>
<td>CCTR</td>
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<tr>
<td>Kerry Hood</td>
<td>CCTR/T&amp;F Member</td>
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<tr>
<td>Alison Hanbury</td>
<td>Cardiff University</td>
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<td>Helen Falconer (obo Chris Shaw)</td>
<td>Cardiff University</td>
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<tr>
<td>Raza Alikhan</td>
<td>Specialty Lead</td>
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<td>Tamas Szakamy</td>
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<td>Aled Rees</td>
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<td>Jonathan Hewitt</td>
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<td>Kate Button</td>
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<tr>
<td>Sian Griffin</td>
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<tr>
<td>Rhian Thomas Turner (obo Phil Conner)</td>
<td>Specialty Lead</td>
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<tr>
<td>Helen Grindell</td>
<td>S&amp;DC</td>
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**27th September 2019 Swansea**

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<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Steve Bain</td>
<td>Swansea Bay</td>
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<tr>
<td>Jeff Stephens</td>
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<tr>
<td>Chris Bimson</td>
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<td>Leighton Phillips</td>
<td>HDUHB</td>
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<tr>
<td>Lauren Theater</td>
<td>HDUHB</td>
</tr>
<tr>
<td>Kayleigh Nelson</td>
<td>STU</td>
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<tr>
<td>Timothy Driscoll</td>
<td>STU</td>
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<tr>
<td>Scott Davies</td>
<td>JCRF/SBU</td>
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<tr>
<td>Chin L'ye</td>
<td>Specialty Lead</td>
</tr>
<tr>
<td>Ceri Battle</td>
<td>Specialty Lead</td>
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<tr>
<td>Angahrad Davies</td>
<td>Specialty Lead</td>
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<tr>
<td>David Hill - Dialling in</td>
<td>Specialty Lead</td>
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<tr>
<td>Ernest Azzopardi</td>
<td>SBUHB</td>
</tr>
</tbody>
</table>

### Support & Delivery Collaboration Group

**Meeting 25 September 2019:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sue Bale</td>
<td>ABUHB</td>
</tr>
<tr>
<td>Jemma Hughes (obo S Bain)</td>
<td>SBUHB</td>
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<tr>
<td>Howard Cooper</td>
<td>PIHB</td>
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<tr>
<td>John Geen</td>
<td>CTMUHB</td>
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<tr>
<td>Chris Fegan</td>
<td>C&amp;VUHB</td>
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<tr>
<td>Lynne Grundy</td>
<td>BCUHB</td>
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<tr>
<td>Melanie Maxwell</td>
<td>BCUHB</td>
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<tr>
<td>Helen Grindell</td>
<td>S&amp;DC</td>
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<tr>
<td>Jacinta Abraham</td>
<td>VUNHST</td>
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<tr>
<td>Nigel Rees</td>
<td>WAST</td>
</tr>
<tr>
<td>Alisha Davies</td>
<td>PHW</td>
</tr>
</tbody>
</table>

**All sessions attended by:**

- Bev Luchmun: WG
- Carys Thomas: WG
- Claire Bond: WG
- Reshma Raycoba: S&DC
- Nicky Williams: S&D
APPENDIX 3: Consideration of Options

1. Purpose

1.1. This appendix describes in more detail the funding model options that were considered by the Task & Finish Group and how they were evaluated during the development of recommendations.

2. Preliminary Options appraisal

2.1. At their first meeting in June 2019, the Task & Finish Group discussed a paper outlining four main types of formula-based options that could have been developed further for consideration and wider stakeholder engagement.

<table>
<thead>
<tr>
<th></th>
<th>Simplified version of current Activity Based Funding model (formula based)</th>
<th>No change to outcome but simplification of formula - factor analysis to simplify elements included, recognising some elements may offset or be closely correlated with others.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Redesigned Activity Based Funding model</td>
<td>Reworked formula/other elements included.</td>
</tr>
<tr>
<td>1b</td>
<td>Mirror NIHR CRN model – core funding and incentivisation element based on prior activity</td>
<td>Similar models (and options of models) with core/flexible element were considered in September 2016 by the NHS Delivery Board (R&amp;D Directors) and rejected, albeit wider stakeholder discussion was not included.</td>
</tr>
<tr>
<td>2</td>
<td>Activity Based formula-driven model based on future predicted workload/complexity</td>
<td>Similar to any of above but using future predicted activity</td>
</tr>
</tbody>
</table>

2.2. The T&F group were invited to identify other options through the discussion at the meeting, including variations of the four described as well as discuss those presented. The following provides a summary of the main points made during the discussion:

- The current ABF model could have been more granular and complex but financial modelling at the time (2012/13) had confirmed similar outcomes in terms of amounts of funding distributed.
- The current ABF model with ‘fixed allowances’ for studies isn’t working for researchers or organisations. In part this is due to limitations associated with recognising ‘activity’ as being only at time of recruitment; it does not meet the resource needs for complex studies that require multiple follow-up visits over multiple years or in different organisations; yet simple low-cost studies gain significant financial rewards.
- Recognition that including incentives within any model can produce negative behaviours as well as positive ones. Incentivisation (if included in any model) was agreed would usefully include undertaking of complex research studies and the sharing of studies.
- The preferred solution when the current ABF formula was developed in 2012/13 had been to create a model that was responsiveness funding actual costs incurred, however, at that time there was a lack of data to assist in operationalising the model. It had been agreed at the time that it was only practical in primary care (resulting in establishing the responsive central service support costs budget for primary care).
- If an ‘actual costs’ approach was considered again it would be important to consider the bureaucracy required for administering any model in evaluating the relative strengths/weaknesses.

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7 See NHS Delivery Board paper: ABF Review - Core Funding Options Paper (NHS DB2), 28 September 2016
A number of data platforms introduced since the last ABF model had been developed which meant an ‘actual costs’ model option should be reconsidered e.g. the Business Intelligence, Local Portfolio Management System, schedules of events/activities/costing schedules for all studies all now available.

It was agreed it would be fairer to consider the true cost of doing a study and therefore taking into account the complexity of the tasks to be undertaken.

Recognition that there was consensus support at the initial stakeholder engagement workshop (February 2019) for a one Wales approach.

2.3 An NIHR review of the approach that different LCRNs take to distribute funding to NHS organisations within their network demonstrated there are many models in place, and there is no clear correlation between the model used and the success in delivering the NIHR CRN High Level Objectives. Therefore weighing up pros/cons of various options is challenging as this suggests there is no ‘right’ answer – as such the Task & Finish Group agreed they should endeavour to recommend what is best for Wales overall.

2.4 In conclusion at the June 2019 meeting, the group agreed it was necessary to move away from an ABF model that used retrospective data and the case to do so was so strong that no further consideration of Options 1a/1b as viable options should be undertaken. It was agreed to explore in more detail the other two options plus a non-formula ‘actual costs’ approach:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Mirror NIHR CRN model – core funding and incentivisation element based on prior activity</td>
</tr>
<tr>
<td>3</td>
<td>Activity Based formula-driven model based on future predicted workload/complexity</td>
</tr>
<tr>
<td>4</td>
<td>A non-formula driven approach based on research study activity needs</td>
</tr>
</tbody>
</table>

Similar models (and options of models) with core/flexible element were considered in September 2016 by the NHS Delivery Board (R&D Directors) and rejected, albeit wider stakeholder discussion was not included.

2.5 At the July 2019 meeting the Task & Finish Group then considered in detail

- The strengths and weakness of each model above (options 2-4)
- The breadth of options that would continue to be developed/scoped in more detail i.e. should all three options continue to be developed and be more widely consulted on, or do the relative strengths/weaknesses suggest removing any options from further consideration
- The stakeholder and engagement plan – at what stage in the development of these options does discussion extend to wider stakeholder groups? What is the purpose of that discussion?

3. Discussion of the relative pros/cons of each model

3.1 At the July 2019 meeting of the Task & Finish Group discussed a paper outlining more detail of each approach, with strengths/weaknesses drafted. These are provided below amended following discussion:

**Option: Fixed and variable elements based on prior activity (mirror or variation of new NIHR CRN model)**

Overview of NIHR CRN model

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8 See NHS Delivery Board paper: ABF Review - Core Funding Options Paper (NHS DB2), 28 September 2016
Key features:
1. Model used to distribute NIHR CRN budget to LCRNs
2. Based on activity undertaken in previous year
3. Total budget is top-sliced for specific centralised NHS Support activities, Specialty Leads etc (see separate paper)
4. Remaining delivery funding is allocated to LCRNs as follows:

<table>
<thead>
<tr>
<th>Fixed element</th>
<th>80% of the total core allocation awarded to LCRNs in proportion to the 2018/19 LCRN allocations…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable element</td>
<td>20% of the total core allocation awarded to LCRNs based on performance metrics (to be agreed each year) that aim to direct CRN funding to meet DHSC national priorities (see below)</td>
</tr>
</tbody>
</table>

5. The variable element is calculated using balanced scorecard used to determine variable element allocation:

<table>
<thead>
<tr>
<th>Variable element</th>
<th>Basis - 2017/18 published data used throughout</th>
<th>%</th>
<th>% of Target Achieved (success rate)</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLO 1</td>
<td>Recruitment total x success rate of the LCRN total target</td>
<td>5%</td>
<td>&lt;84.99%</td>
<td>0.9</td>
</tr>
<tr>
<td>HLO 2a</td>
<td>Number of studies x success rate</td>
<td>5%</td>
<td>85% to 94.99%</td>
<td>0.95</td>
</tr>
<tr>
<td>HLO 2b</td>
<td>Number of studies x success rate</td>
<td>5%</td>
<td>95% to 101%</td>
<td>1</td>
</tr>
<tr>
<td>Specialty objectives</td>
<td>Success rate.</td>
<td>5%</td>
<td>&gt;101%</td>
<td>1.05</td>
</tr>
</tbody>
</table>

6. 5% cap & collar applied
7. 2% ring-fenced funding to be spent on initiatives to increase participation in selected disease areas

Variations to NIHR CRN model were also discussed:
- Change fixed-variable ratio from 80:20 e.g. to 70:30 or 60:40 etc. to increase emphasis on performance
- Change approach to fixed element to increase stability or increase agility – e.g. 3-5 year rolling average
- Within the variable element, align to specific strategic goals in Wales, for example:
  - Alignment to population health needs
  - Opening specific studies or disease areas e.g. rare diseases, alignment with disease delivery plans
  - Level of multi-centre work (incentivising sharing activity)
  - Success in delivery (recruitment to time/target)
  - Increase in recruitment
  - Increase in number of Principal Investigators
• Increase in complexity / rare disease studies
• Contribution to overall target (e.g. if an organisation has overachieved to help another that is struggling)
• First global patient / first Welsh patient
• Speed of study set-up / valid application to first participant

3.2. The Task & Finish Group agreed the strengths/weaknesses of such a model were:

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
</table>
| - Emphasis on performance  
- Creates stability in funding for NHS organisations if cap/collar included  
- No change to notification timescale - organisations notified of allocations as soon as total HCRW budget is confirmed | - Performance measures/points may not generate sufficient financial incentive to drive performance (NIHR Finance indicate no evidence any incentives correlated with increase in activity)  
- No increased agility in system  
- Designed for NIHR CRN distribution of resources (equivalent to all-Wales) not LCRN distribution to NHS organisations (although some may choose to use pass through model)  
- Does not address many of the disadvantages of current model (previous activity not necessarily predictor of future activity, funding is not following activity in current year, not accounting for complexity/workload)  
- Activity in individual NHS organisations fluctuates year on year due to scale of activity so no improved stability |

Option: Activity Based formula-driven model based on future predicted workload/complexity

3.3. As above, albeit using future predicted activity (not retrospective). The strengths and weaknesses are similar to Option above, with the exception being this option addresses the weakness in Option above that previous activity not necessarily predictor of future activity, and that funding is not following activity within year. The Task & Finish Group agreed strengths/weaknesses of this model were:

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
</table>

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9 Similar models (and options of models) with core/flexible element were considered in September 2016 by the NHS Delivery Board (R&D Directors) and rejected, albeit wider stakeholder discussion was not included.
- Emphasis on performance
- Creates stability in funding for NHS organisations if cap/collar included
- No change to notification timescale - organisations notified of allocations as soon as total HCRW budget is confirmed

<table>
<thead>
<tr>
<th>Option 3: Research needs based model based on future predicted workload/complexity (funding follows actual costs) – not formula based</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview of GM LCRN model</td>
</tr>
<tr>
<td>GM LCRN model.pptx</td>
</tr>
<tr>
<td>Key features:</td>
</tr>
<tr>
<td>1. Model used to distribute LCRN budget to NHS organisations (similar size budget/population coverage to Wales)</td>
</tr>
<tr>
<td>2. Funding follows activity in year according to known needs/actual costs incurred for all NHS organisations. Doesn’t use intensity tool in GMCLRN, but uses experience to determine what’s appropriate level of resource for study specific activities required</td>
</tr>
<tr>
<td>3. Process is prospective based on NHS organisation/LCRN agreed predication recruitment forecasted to undertaken in current year by each NHS organisation</td>
</tr>
<tr>
<td>4. Model is based on moving existing resources around.</td>
</tr>
<tr>
<td>5. Value for money is assessed every quarter (resource committed vs. what’s been delivered, taking out outlier studies) and move funding around if required</td>
</tr>
<tr>
<td>6. Total LCRN budget is top-sliced for specific network-wide LCRN support activities, Specialty Leads, generic workforce (provides maximum of 3 months additional support) etc (see separate paper) and for contingency (unknown complex studies in year)</td>
</tr>
<tr>
<td>7. A method where all expenses must be justified for each new period - every anticipated spend is analysed for its needs and costs</td>
</tr>
<tr>
<td>8. Remaining delivery funding is allocated to NHS organisations as follows:</td>
</tr>
</tbody>
</table>
Variations to this model were also discussed:

a) Implement for some NHS organisations (with lower or more variable activity) but not all (other NHS organisations with more stable activity allocated funding via another model above)

b) Reconsider arrangements for WAST, PHW

c) Reconsider primary care support costs – currently a mixed model where some activity is support by HBs and some via central service support costs pot

d) Consider arrangements for tertiary centres/ specialist centres

e) Consider arrangements for supporting social care studies

3.4. The Task & Finish Group agreed the strengths/weaknesses of such a model were:
4. Conclusions regarding options

4.1. At the July 2019 meeting, the Task & Finish Group discussed options in detail and concluded the balance of strengths/weaknesses significantly favoured a model that recognised the resource needs in individual studies and that this would enable a more agile model than any formula-based approach could deliver. If this approach could be operationalised, which the group agreed following discussion that it could, then the Task & Finish group concluded this was preferable and should be the focus of the future discussions and the final recommendation paper.

4.2. As a result, it was agreed by the Task & Finish Group that discussion with wider stakeholders regarding multiple options was not required and that engagement should focus on testing the response to the preferred approach (once further developed).

4.3. It was agreed that should discussions about the development of that as the recommended approach reveal that there were insurmountable practical issues with its implementation, then discussion regarding other options (now discounted) would be reopened.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most agile approach as funding follows actual costs wherever/whenever incurred</td>
<td>Total fund may run out mid-year.</td>
</tr>
<tr>
<td>Consistency of approach across NHS organisations</td>
<td>Risk of becoming resource intensive to administer. Administration costs may increase if not possible to make use of data efficiently</td>
</tr>
<tr>
<td>Aligned to in-year needs</td>
<td>Increases risk of not being able to justify committed spend e.g. permanent staff in post.</td>
</tr>
<tr>
<td>Model developed over years for similar population/number of NHS organisations</td>
<td></td>
</tr>
<tr>
<td>Agility further created by contingency fund/ generic workforce pool</td>
<td></td>
</tr>
<tr>
<td>Already in place for primary care (in part), WAST, PHW service support costs (central service support costs budget held by S&amp;D Centre and accessed via application).</td>
<td></td>
</tr>
<tr>
<td>Initially the preferred model in 2012/3 but data was not in place to facilitate (but now is) –</td>
<td></td>
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<tr>
<td>Opportunity to automate via LMPS</td>
<td></td>
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<tr>
<td>Could include element of fixed/core costs e.g. for R&amp;D office staff, clinical support etc at an agreed amount</td>
<td></td>
</tr>
<tr>
<td>Opportunity to trigger payments when/where costs are incurred more accurately (e.g. follow-up extending across years, or study activities in different locations)</td>
<td></td>
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</tbody>
</table>