National Institute for Health and Care Excellence

Technology Appraisals (TA) and Highly Specialised Technologies (HST) - Impact of charging regime

This report gives details of a review of the impact that charges to recover the costs of technology appraisals (TA) and highly specialised technologies (HST) has had on our financial position since charging began on 1 April 2019, and whether the objective to fully recover the costs of this activity has been achieved.

The Board is asked to note the findings of the report.

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Introduction

Any technology appraisal (TA) or highly specialised technologies (HST) topic with an invitation to participate (ITP) date on or after 1 April 2019 has been subject to a charge. In response to the [consultation](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/762725/government-response-to-nice-recommendations-consultation.pdf) led by DHSC, a commitment (section 6.4) was made to monitor the impact of the charges in the first year and formally review the charging regime at the end of the second year and thereafter as required. Systems are in place to monitor the impact of charges, including the quarterly accountability meetings between NICE and the DHSC, our audit and risk committee meetings and the statutory information on fees and charges we include in our annual report and accounts.

To discharge this obligation NICE, with support from DHSC, has reviewed whether charging has met the objectives to recover the costs of the programme and that the process (including offering a discount to small companies) is performing as planned. The review has been conducted internally and no input has been requested from industry.

Background

The aim of introducing charging was to transfer the cost of making a technology appraisal or highly specialised technologies recommendation to the marketing authorisation (MA) holder by:

* 1. Amending the Regulations to allow NICE to impose an upfront charge on an individual life science company calculated to recover the cost of making the recommendation for their product.
	2. Allowing NICE to impose a charge on a small company calculated on an appropriate commercial basis (i.e., at a reduced rate) and to agree that a small company may pay in instalments.

Through cost recovery, it was anticipated that charging would provide a more sustainable model that enables NICE to flex its capacity in response to the pipeline of technologies that require assessment by NICE.

Charging was implemented with the aim of reducing NICE's reliance on central Government funding (Grant-in-aid). NICE’s Government funded budget has also decreased. In 2013/14, NICE received £66.4m from Government funding; however, in 2018/19 this had reduced to £51.2m.

The aim of transferring the costs of making a recommendation to the marketing authorisation holder has partially been met, with fees charged on all evaluations that have started since April 2019. The amount of income recognised in our financial statements is helping offset reductions in our Grant-in-aid funding.

However, a key objective when fees were introduced is that we would expect to be recovering the costs in full after the second year of charging for evaluations, but in the current financial year (2021/22) this will not be achieved. We forecast that we will recognise £8.5m income this year versus £11.4m costs, a deficit of £2.9m. Full cost recovery of the programme is yet to be achieved for several reasons that are listed below and will be described in this paper:

Prices have not been uplifted since April 2019 to take into account pay and pension inflation.

COVID-19 had a significant impact on cost recovery in 2020/21 and 2021/22, with topics being paused and affecting throughput.

Vacancies (7% on average) and staff turnover in the TA/HST team have had an impact on productivity, although some of the lost income has been offset by reduced staff costs

The 75% discount for small companies is a cost pressure of approximately £0.5m per annum.

The work programme performs additional activity not charged for (for example extra committee meetings).

The charging process was subject to internal audit in April 2021, the objective of which was to provide assurance over the effectiveness of the framework of controls in place to ensure the charges are levied, received and accounted for accurately. The internal audit review gave a substantial assurance rating that the framework of governance, risk management and control is adequate and effective.

Cost recovery, funding and income recognition

There is a statutory requirement to show income and full cost of the activity in the fees and charges section of the Parliamentary Accountability and Audit report section of the annual report, including a summary of the performance. The figures for 2019/20 and 2020/21 are set out below alongside an estimate for 2021/22. Any under recovery of costs is funded using Grant-in-aid allocation.

Chart 1 - annual full cost recovery monitoring

Table 1 - charging income recognition, full costs and deficit

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Income £000** | **Full cost £000** | **Deficit/** **(surplus)** **£000** |
| 2019/20 | 3,582 | 9,458 | 5,876 |
| 2020/21 | 7,035 | 10,711 | 3,676 |
| 2021/22 (Forecast) | 8,500 | 11,437 | 2,937 |

A key objective when fees were introduced is that we would expect to be recovering the costs in full, but we are not (as shown in Table 1). This was expected in year 1 and 2 whilst older topics (those that started before 1 April 2019) were being completed. At the time of reporting, 5 evaluations which commenced pre-implementation of cost recovery, remain in the work programme and therefore income will not be recognised for these topics.

However, in the current financial year (2021/22) it was expected that we would be achieving full-cost recovery, except for the discount for small companies which is expected to be £0.5m per year. The reason for the deficit is due to several factors including increasing pay and pension costs since fees were introduced, and the disruptions the COVID-19 pandemic has caused to the work programme, alongside vacancies in the work programme. This includes:

* 1. Approximately 30 evaluations were paused due to the COVID-19 pandemic.
	2. During the review period, approximately 20 evaluations were paused due to capacity constraints because of vacancies in the work programme.

The impact of COVID-19 on productivity has reduced the income we have been able to recover, with paused topics impacting the timing of milestones being achieved. This affected the amount of income that could be recognised in 2020/21. The pausing of topics also had an impact on the volume of new topics that could be started in 2020/21, which meant that income recognition in 2021-22 (particularly in the first 6 months) was lower than expected.

Vacancies in the TA/HST team has also had an impact on the productivity and throughput of the programme, but the reduced income is also partially offset by reduced costs and wouldn't be expected to be a significant contributary factor to the deficit. The average vacancy rate in the TA/HST team has been 7% since charges were introduced.

However, there was a greater number of vacancies in 2020 when the vacancy rate was as high as 12%, causing similar disruption to the pandemic in terms of achieving milestones and starting new topics. This issue has eased since then, and in September 2021 the vacancy rate had fallen to 5% which increased the capacity of the team. Recruitment to fill vacant entry-level analyst posts is ongoing through advertising campaigns and our postgraduate opportunities.

The major consequence of pausing topics for COVID-19 and vacancies was that fewer topics started in 2020/21 than was expected, therefore reducing income. This has improved in 2021/22, with the volume of topics starting expected to be close to the planned output of 88 topics per year (compared to 78 in 2021/22 and 74 in 2020/21), but much of this income will be recognised in 2022/23.

In addition to the disruption noted above, the fees have remained the same since charging began on 1 April 2019. The fees set were based on the costs of the programme in 2018/19 and the expected volumes of activity based on the topic pipeline. However, pay inflation is a contributory factor to full-cost recovery not being achieved, including this year's 3% NHS pay award. This is in addition to increases to Agenda for Change pay bands in the 2 previous years along with increased pension costs that mean the cumulative cost increase in the 3 years to 2021/22 is 15.68% (see Table 2 below).

The fees will be updated from 1 April 2022 to include these inflationary pay cost pressures on NICE, along with the new National Insurance Health and Social Care Levy announced by the Government and an assumed 1% pay award for 2022/23. This will ensure that costs are more likely to be fully recovered in line with original aims of charging and the principles of Managing Public Money.

Pay costs account for approximately 80% of the costs of the TA and HST programme, with non-pay costs including committee meetings and overheads. These non-pay costs have reduced due to the move to virtual or hybrid committee meetings and the relocation to the new Stratford office. These reductions in non-pay costs will be recognised in our future fees and will partially offset the cumulative pay inflation costs of 18% by 2022/23 shown in Table 2, meaning the increase in fees from 1 April 2022 is likely to be approximately 13-14% per evaluation.

Table 2 - cumulative impact of pay awards and increases to Employers Pension and NI contributions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pay and Pension Changes**  | **2019-20** | **2020-21** | **2021-22** | **2022-23** |
| Annual pay increase awarded by NHS pay review body | 3.59% | 2.21% | 3% | - |
| Increase in NHS Pension Employer contributions (from 14.38% to 20.68%) | 6.30% | - | - | - |
| Increase in NI Employers costs (Health and Social Care Levy) from April 2022 | - | - | - | 1.25% |
| Estimated pay award for 2022/23 (TBC) | - | - | - | 1% |
| Compound Cumulative increase in pay costs | 9.89% | 12.31% | 15.68% | 18.29% |

\*In years 1 and 2 the increase was linked to an employee's pay band and length of service. The figures here are the average increase between the bottom and top spine points in each Agenda for Change pay band.

Evaluations subject to charging

A total of 191 evaluations have been subject to charging between 1 April 2019 and 30 September 2021 (the 'review period').

70 of those have published final guidance, 22 (33%) went straight to final draft recommendations and did not require a consultation with stakeholders.

As of 30 September 2021, 14 evaluations required a refund (see section 31 for more details) and 107 remain in progress. The number of evaluations published subject to charging, and the process followed are listed below (terminated guidance is excluded from charging and the publication numbers provided). Note that in 2019/20, no evaluations subject to charging were published as final guidance.

Table 3 - published topics by process and year

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Evaluation process (subject to charging - ITP post 1 April 2019) | 2020/21 | 2021/22 (Apr 21 to Sep 21) | Total number of publications | Topics in progress on 30 September 2021 |  |
| Single Technology Appraisal (STA) | 28 | 25 | 53 | 88 |  |
| Cancer Drug Fund (CDF) Reviews | 6 | 4 | 10 | 9 |  |
| Fast Track Appraisals (FTA) | 2 | 1 | 3 | 2 |  |
| Highly Specialised Technologies (HST) | 1 | 1 | 2 | 6 |  |
| Multiple Technology Appraisal (MTA) | 0 | 1 | 1 | 1 |  |
| Rapid Review | 1 | 0 | 1 | 1 |  |
| Total | 38 | 32 | 70 | 107 |  |

The total number of publications subject to charging and the number of publications that have not been charged for are shown below (terminated guidance is excluded from the publication numbers). Note that the 2021/22 publication information is to 30 September 2021 (6 months).

For the evaluations that remain in progress, the outstanding income to be recognised is deferred until they reach a key milestone.

Table 4 - key milestones and weightings

|  |  |  |
| --- | --- | --- |
| **Key Milestones** | **Weightings for Key Milestone (%)** | **Cumulative Weightings - Income to be Recognised (%)** |
| ITP | 5% | 5% |
| Evidence Submission | 10% | 15% |
| ERG Report Deadline | 10% | 25% |
| Technical Engagement | 35% | 60% |
| 1st Committee Meeting | 25% | 85% |
| 2nd Committee Meeting | 10% | 95% |
| Guidance Published | 5% | 100% |

During the review period, 7 published evaluations have had more than two committee meetings. At the time of reporting, there were 6 evaluations in development with more than two committee meetings. Some of the reasons why these required multiple committee meetings include:

* A lack of or insufficient data provided by companies to enable committee decision making at a single committee meeting
* Delays required for the companies to develop commercial proposals in conjunction with NHS England and improvement
* A significant amount of consultation comments received which required more time for the committee to consider in full.

Evaluations with more than two committee meetings require additional resourcing and can impact or delay other planned activity, thus reducing throughput in the programme and limiting our ability to fully recover our costs. Currently a fixed fee is charged for each TA/HST evaluation at the beginning of the process and there is no mechanism for charging for additional committee meetings that may be needed.

At the time of reporting, there are no evaluations which started with an Invitation to Participate (ITP) date after the implementation date of 1 April 2019 that have been exempt from charges.

Small company charges

Following the 2018 consultation that set out the proposal to introduce charges, the discount for small companies was increased from 25% to 75%, with the ability for small companies to pay in 3 instalments. This support was made available to minimise barriers to the participation of small companies in TA/HST evaluations. Based on historical records, it was assumed that approximately 10% of products would be manufactured or sponsored by small companies.

During the review period, a total of 18 companies have approached NICE to be considered for a small company charge. Of these applications, 5 have been declined due to failure to meet the criteria (as defined in Section 382 of the Companies Act 2006). In total, 13 applications (7% of the total evaluations since April 2019) have been classed as a small company and 9 of these utilised the phased payment option. The value of small company discount recognised in each year is shown in table 5 below.

Table 5 - Small company discount funded through GIA

|  |  |
| --- | --- |
| **Year** | **Small company discount recognised £000** |
| 2019/20 | 47 |
| 2020/21 | 534 |
| 2021/22 (Apr 21 to Sep 21) | 265 |
| **Total** | 846 |

Companies who have not paid charges

To facilitate timely payment of charges, NICE requests a Unique Reference Number (URN) from the company approximately 3 months before the evaluation is due to begin. In accordance with the current published charging procedure, NICE reserves the right to pause the evaluation if payment is not received in full by the deadline for evidence submission.

No companies have declined to pay charges for an evaluation following receipt of the charging notification or once the Unique Reference Number (URN) has been received by NICE.

Refunds

During the review period, 5 evaluations were converted from Single Technology Appraisal (STA) to Fast Track Appraisal (FTA), with NICE refunding the difference in charge as set out in the charging principles on our website.

A total of 10 partial refunds for evaluations suspended before the first committee meeting have also been processed. The current charging procedures state that when a partial refund is applicable, the amount NICE will refund will depend on the costs incurred up to that point and is linked to the milestones set out in Table 4 above. Therefore, the costs for the work done up to the point of termination are retained by NICE. Partial refunds are not applicable once an evaluation has reached the committee meeting stage.

In addition to the above, 3 companies received a partial refund when 3 STA's were converted into 1 Multiple Technology Appraisal (MTA) to recognise the cost avoided by NICE. A single refund for a company withdrawal from an MTA was also processed.

In the cases where a refund was applied because of a company action (e.g. non-submission to NICE) the appropriate administrative charge was applied. In the scenarios where a refund was required due to a decision made by NICE, no administrative charge was applied.

Other relevant programme activity not included in TA/HST fees

Within the Centre for Health Technology Evaluation (CHTE) there are a suite of wider activities that support the overall aims of the TA/HST work programme. The current fees for TA/HST do not incorporate costs for this broader work, which is considered fundamental to the development of guidance. Some of this activity is funded by other sources, such as NHS England (to support managed access agreements) and by companies engaging with our Office for Market Access (OMA).

During the review period, the Office for Market Access (OMA) have carried out paid engagement activity for 14 evaluations which have been subject to charges. Of these evaluations, 9 remain in progress and 5 have published as final guidance.

More recently, we are now supporting the Innovative Licensing and Access Pathway (ILAP), which was launched after TA/HST fees were introduced. Currently, this additional activity is supported by grant-in-aid funding on a non-recurrent basis from the DHSC, but long-term funding has yet to be secured.

Conclusion

The current fees were set based on the costs of the programme during 2018/19. Since implementation in April 2019, full cost recovery is yet to be achieved due to the several factors set out in this paper:

Prices have not been uplifted since April 2019 to take into account pay and pension inflation

COVID-19 had a significant impact on cost recovery in 2020/21 due to topics being paused, with a knock-on impact in 2021/22 due to fewer than planned evaluations starting during 2020

Vacancies and staff turnover in the TA/HST team has had an impact on productivity, but some of the lost income has been offset by reduced staff costs

The 75% discount for small companies is a cost pressure of approximately £0.5m per annum depending on the number of eligible companies.

The work programme is regularly undertaking additional activity not charged for (for example extra committee meetings that are required due to insufficient data provided by companies).

To ensure costs are fully recovered in future years, we plan to increase charges from 1 April 2022 to reflect increases in pay and pension costs.

It is further assumed that the operational impact the pandemic had on volumes and cost recovery will not be a significant issue in future years, with the number of evaluations started in the current financial year currently on track to meet the target of 88 topics per annum (with most of this income to be recognised in 2022-23).

We will also continue our push to recruit to vacancies in the TA/HST programme to avoid future disruption caused by capacity issues, and we will consider ways to recoup costs or reduce the amount of additional unplanned activity required to produce guidance.

The impact of the CHTE methods and processes changes and future ways of working is outside the scope of this review. However, these changes when implemented may impact the fees charged in the future and this will need to be considered in full at an appropriate time.

Issues for decision

The Board is asked to:

* Review the report and recognise that whilst the introduction of fees for TA/HST has resulted in a steady increase in funding to offset reductions in grant-in-aid funding, full cost recovery is yet to be achieved due to the limiting factors described in this review.
* Acknowledge the steps (such as increasing fees in line with pay inflation) that are being taken to reduce the deficit in cost recovery, along with an assumption that the impact the pandemic had on volumes and cost recovery will be less significant from 2022/23 onwards.

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