WARWICK EVIDENCE

Warwick Evidence annual report for period 2022/2023

1. **Summary of Contract Activity**

   As a group, we are contracted to deliver 16 TAR units each year (1 unit = 1 short report, 2.67 units = 1 long report). During this first year of the third TAR contract (2022-23), we completed 82% of our contracted activity, representing work on 10 individual appraisals, which is in line with delivery expectations. Table 1 lists the projects conducted this year and the allocated units; including those additional units which were requested.

Table 1. Projects in 2022-23

Project number and title	Type of project (e.g. STA)	Type of Additional Work (please see guidance below)	Brief description of work undertaken	Extra units approved (e.g. 0.1)
131645: Olaparib for previously treated, hormone-relapsed metastatic prostate cancer (ID1640)	STA	3rd AC and rapid review work		0.35
131841: Ixazomib citrate with lenalidomide and dexamethasone, post prior therapy for relapsed, refractory multiple myeloma (CDF review of TA505) (ID1635)	CDF review	One day additional work in 22/23		0.03
135208: Sacituzumab govitecan for treating unresectable locally advanced or metastatic triple-negative breast cancer after two or more therapies [ID3942]	STA	Critique new model (complex)	Response to company query regarding ICER and further clarifications on pre-progression utilities involving submission of additional model	0.30
135325: Artificial intelligence for analysing chest CT images (DAP60)	DA	Other	DAR was broad in terms of scope with multiple populations. An additional DA of	2.67

Project number and title	Type of project (e.g. STA)	Type of Additional Work (please see guidance below)	Brief description of work undertaken	Extra units approved (e.g. 0.1)
			units was awarded for this project	
135590: Mosunetuzumab for treating relapsed or refractory follicular lymphoma [ID3931]	STA	Analysis of new clinical data	Additional data-cuts were made available	0.76
Update of DG21 Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system) (DAP55) [ID3957]	DA / MTA	Analysis of new clinical data

Other | Presenting results using an ICER threshold.

Follow up questions from EAR.

Amendments to slides & further analysis for PMB | 2.70 |

Type of additional work' guidance, please use one of the following:
- 2nd AC attendance
- 3rd AC attendance
- 4th AC attendance
- 5th AC attendance plus
- Analysis of new clinical data
- Critique new model (simple) *e.g. same model with new parameters*
- Critique new model (complex) *e.g. attempting to re-build the model using a different approach*
- Simple PAS *e.g. straight forward discount*
- Complex PAS *e.g. one that requires monitoring of patients*
- Appeal
- Other – provide details in the 'Brief description of work undertaken' column

Please put the detail of the additional work under the 'Brief description of work undertaken' column.

2. **Additional EAG support provided to NICE outside of core TAR activity (e.g. working groups)**

Dr Dan Gallacher has participated in the NICE working group related to the new Proportional Approach to Technology appraisals. In addition, Dr Gallacher has recently been appointed to NICE TA Committee B.

3. Training and Capacity funding expenditure (£25,000/year)

We are pleased to report that the training and capacity funding (£25k per annum) has been well used for 2022-23 year. The courses and conferences attended by team members is listed in Table 2 below.

Table 2. Training in year 2022-23

Name	Title of training or capacity building activity	Type of expenditure	Cost
Iman Ghosh	Qualitative systematic review	Conference	£310
	Multiple imputation and survival analysis	Course	£1,210
Lena Al-Khudairy	Westminster Health Forum - Next Steps for NICE	Conference	£312
Anna Brown	Identifying Economic Evidence for HTA	Training	£100
	Joint information day	Meeting	£82.50
Rachel Court	Joint information day	Meeting	£53.80
Mary Jordan	Diabetes simulation	Course	£158.36
Hesam Ghiasvand	Cost-Effectiveness and Decision Modelling using R Workshop	Course	£690.25
Chris Stinton	EPPI software	Software	£120
Natalie Tyldesley-Marshall	BSA conference	Conference	£564.00
Warwick Evidence Support	Speakers and additional support	Team support	£5,907.73
Sarah Abrahamson	Warwick-Monash Alliance	Course	£2704.13
Amy Grove	Women in Medicine	Course	£80.00
	British Hip Society	Conference	£517.50
	ARC West Midlands Collaboration Meeting	Meeting	£60.35
	In which context and for whom can interventions improve leadership of surgical trainees, surgeons, and surgical teams and why	Publication	£816.00
	Investigating informed choice in screening programmes: a mixed methods analysis	Publication	£2,568
	Mixed Methods Systematic Review Course	Course	£450.00
Mubarak Patel	BMC publication "Ethnic differences between South Asians and White Caucasians in cardiovascular disease-related mortality in developed countries: a systematic literature review"	Publication	£2,328
	Analysis of Genetic Association Studies	Course	£350
Yen-Fu Chen	Society for Research Synthesis Methods (SRSM) Annual Meeting	Course	£223.36
	Diagnostics meeting	1-2-1	£110
	Publication in the Journal of Clinical Epidemiology	Publication	£650
Adel Elfeky	Evidence-Based Diagnosis and Screening	Course	£2,675
	Systematic Reviews of Diagnostic Studies	Course	£1,037.61
Team meetings	Team building and networking	Team support	£982,70
Total			**£25,061.29**

4. Financial (underspend/overspend)

The expenditure for 2022-2023 is detailed in Table 3 below. We have spent 16% of the budget by month 10, which is forecast at 20% by month 12. However, the final spend for the period Feb-Mar will not be fully finalised until all invoices for goods and services have been received and all internal recharges made.

Table 3. Actual expenditure for 2022-23

Cost Type	Budget (60 months)	Expenditure to Jan 23 (10 months)	% of total budget used
Salary Costs	£3,497,662	£587,130	17%
Travel & Subsistence	£30,000	£2,809	9%
Training Budget	£125,000	£25,061	20%
Other Costs (Equipment, recruitment, consumables, training)	£326,078	£12,025	4%
Subcontracts (McMasters and external contractors)	£372,282	£62,047	17%
Estate and indirects	£2,680,907	£446,818	17%
Total	**£7,031,929**	**£1,135,890**	**16%**

5. **Impact**

1) **Single Technology Appraisal:**

Sacituzumab govitecan for treating unresectable locally advanced or metastatic triple-negative breast cancer after two or more therapies [ID3942]

Warwick Evidence contributions resulted in the approval of this effective technology at a cost-effective value providing an important option for patients approaching the end of therapeutic options and otherwise with poor prognosis. EAG critique resulted in a revised PAS discount being offered following the conclusion of the first committee meeting.

Early Value Assessment (EVA):

qXR and other artificial intelligence (AI) software for automated detection of lung nodules from X-ray images (DAP68)

In addition to contributing to the committee's decision making, the EAG's impact in this EVA has heavily shaped the development of NICE's EVA process, which will ensure future assessments are given suitable time and attention. This supports NICE with its targets to improve efficiency and ensures appropriate attention is given to emerging diagnostic technologies. This encourages the sustainability of the technology appraisal programme healthcare provision.

2) **Paper:**

Armoiry, X., Wang-Steverding, X., Connock, M., Grove, A., Clarke, A., Arun, T., . . . Auguste, P. (2022). Is the assumption of waning of treatment effect applied consistently across NICE technology appraisals? A case-study focusing on disease-modifying therapies for treatment of multiple sclerosis. International Journal of Technology Assessment in Health Care, 38(1), E83. doi:10.1017/S0266462322003269

This paper reviewed 15 NICE technology appraisals related to multiple-sclerosis and found variation in the application of the effects of treatment waning. These did not seem correlated to the outcome, with almost all receiving a positive recommendation by NICE. The paper recommends that a standard approach is established to ensure current and future therapies are assessed fairly.

3) **Paper:**

Gallacher, D., Kimani, P. & Stallard, N. Biased Survival Predictions When Appraising Health Technologies in Heterogeneous Populations. PharmacoEconomics 40, 109–120 (2022). https://doi.org/10.1007/s40273-021-01082-x

This paper highlights the problem with extrapolating survival curves using parametric models when the data comes from a heterogeneous population where the patient survival times do not come from a single survival distribution. This paper shows how easily estimates of treatment benefit used in decision-making might be biased and recommends thorough consideration of the potential presence and effects of heterogeneity.

6. Intellectual Property

SurvInt is a tool developed by Dr Dan Gallacher that estimates the parameters of common parametric survival models which interpolate key survival time co-ordinates specified by the user, which could come from external trials, real world data or expert clinical opinion. SurvInt provides a solution to the problem when regular parametric models do not result in plausible extrapolations, or fully explore scenarios of uncertainty over future efficacy.

7. NICE
Warwick Evidence continues to work closely with NIHR ESP and NICE in an ever-changing landscape; highlights from this year are below.

New NICE methods and process

NICE have undergone a huge programme of work to update the methods and process of their technology appraisals. A new single guidance development manual was published in January 2022 aimed at streamlining and improving the way HTA is performed. This has inevitably generated some upheaval for the team as we learn another new way of working and update documentation to accommodate the new changes. We consider that the new methods and processes manual does not provide the methodological detail required for TAR teams to perform appraisals. We anticipate there will be an updated scope of work document from ESP TAR, although timing on this has yet to be clarified.

Technical engagement

In March 2023, we were notified that, in line with the new manual, NICE will be changing their approach to Technical Engagement (TE). Designed to enable fewer appraisals to

require multiple Committee meetings for a decision to be reached, TE did not yield the benefits sought. Therefore, new appraisals starting after 1 April 2023 will have an 'opt-in' approach to TE. This means that appraisals will be scheduled <u>without</u> the technical engagement stage included. Where the NICE Associate Director decides the TE step is required, it will be introduced, and subsequent timelines will be adjusted accordingly. We welcome this change, although the implications for planning are yet to be fully seen as the appraisals post April 2023 have included TE at the company's request.

Additional review processes

In addition to the new manual, NICE has also introduced two pilot processes to improve efficiency in the system and create capacity to deal with new, complicated technologies. The new PATT process (Proportional Approach to Technology appraisal) has four separate strands:

1) Streamlined approach
2) Pathway appraisals
3) Pair appraisals
4) Pre-specified assumptions

The second new process introduced by NICE this year is the development of EVAs. These assessments are to be an early phase in the Diagnostics Programme, where the intent is to provide early assessment of promising technologies that may be in use at a small number of NHS sites but before more widespread rollout, to provide a view on whether they are likely to be cost-effective and to ascertain what data collection would support later full evaluation.

Warwick Evidence have experienced our first EVA with **[DAP68] Artificial Intelligence for analysing chest x-ray images to diagnose lung cancer**. The main challenge with the EVA was the extremely short timeline given to facilitate a thorough and robust assessment of the topic, and a full DA may have been more appropriate.

Pilot processes present some unique challenges, as there is frequently no methods guidance and a dearth of supporting evidence and process documentation: templates are not yet available, which means EAGs are obliged to tailor reports designed for different purposes, with little or no guidance on what is needed. Whilst the pilot is underway, EAGs are invited to provide feedback to both NICE and ESP TAR to assist in defining methods for the finalised processes.

Diagnostic reviews

In 2021-22 NICE raised concerns with ESP TAR regarding the quality of DA reports. As a result, it was agreed that a subset of the twelve TAR teams would be allocated DARs – to match demand and to ensure quality of the reviews. However, we, as a team, have not been inundated with DA topics as anticipated by NICE. This is unfortunate as we had tailored recruitment strategies to cater for more DA appraisals (e.g., appointing a Professor of Economics and Testing Evaluation).

8. **NIHR**
   InterTASC and Annual Contract Review

2022-23 saw the end to Warwick Evidence's tenure as Chair of InterTASC (Inter Technology Appraisal Support Collaboration) (Sept 2020-Sept 2022). We have been responsible for coordinating the twice yearly all TAR meeting, liaising with NICE and ESP TAR on behalf of all TAR teams and reporting to the Department of Health and Social Care (DHSC) at the Annual Contract Review (ACR) meeting.

At the most recent ACR (March 2022) Dr Kay Pattison OBE, Head of Research Contracting at the DHSC at the NIHR informed the TAR teams that ACR will not be part of the next contract. This meeting will be replaced with smaller one-to-one meetings in June 2023 between individual teams and the ESP TAR senior team. We welcome this change, as we believe more personalised feedback will support our development and improvement as a team.