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Title	To HTA or not to HTA: identifying the factors influencing the rapid review outcome in Ireland
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Publication date	2019-03-06
Original Citation	Murphy, A. and Redmond, S. (2019) 'To HTA or Not to HTA: Identifying the Factors Influencing the Rapid Review Outcome in Ireland', Value in Health, 22(4), pp. 385-390. doi: 10.1016/j.jval.2018.10.011
Type of publication	Article (peer-reviewed)
Link to publisher's version	http://www.sciencedirect.com/science/article/pii/S109830151930049X - 10.1016/j.jval.2018.10.011
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Download date	2026-11-06 20:18:33
Item downloaded from	https://hdl.handle.net/10468/8306

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Murphy, A., Redmond, S. To HTA or not to HTA: identifying the factors influencing the rapid review outcome in Ireland. Value in Health. 22(4):385-390.

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FUNDING: No financial assistance was received for conducting this study.

PRÉCIS: In Ireland there are no formal decision-making criteria around the requirement of a HTA, this study examines the factors influencing this Rapid Review process.

ABSTRACT

Objectives: Reimbursement systems are evolving and endeavour to balance access and affordability. One such evolution in Ireland is the compulsory Rapid Review (RR) process, the outcome from which is a recommendation for a health technology assessment (HTA) or no HTA. For drugs that avoid a HTA, evaluation times are shorter, lengthy price negotiations are avoided and access is faster.

In the absence of formal decision-making criteria around the requirement of a HTA, this study examines the factors influencing the outcome of the RR process in Ireland.

Methods: A database was developed combining data from publicly available sources for drug evaluations conducted by the National Centre for PharmacoEconomics (NCPE) (January 2010-June 2017, (n=296)). As Irish cost data were not publicly available for all drugs, cost data from the Scottish Medicines Consortium was employed as a proxy. Employing logitistic regressions the factors influencing the RR outcome are revealed.

Results: Following a RR, a HTA was recommended for 55% of drugs. Regression results revealed therapeutic area (endocrine, musculoskeletal and neoplasm), first-in-class and orphan disease-increased the probability of a HTA. Furthermore, when proxy costs were included, results revealed that every €1,000 increase in annual drug costs per patient increased the probability of a HTA being required by 1% and that a HTA was more likely than no HTA when annual drug costs exceeded €15,000.

Conclusion: Given the current focus on access and affordability, this study identifies the factors influencing the requirement of a HTA in Ireland.

HIGHLIGHTS

1. Since 2010 Rapid Reviews are compulsory for any drug seeking reimbursement in Ireland. This unique approach is a means of achieving balance between optimising agency resources, providing patients faster access to medicines and ensuring affordability. Exploring reimbursement approaches and sharing experiences can be meaningful for HTA agencies designing and evolving their systems, particularly given the shift towards value based frameworks for reimbursement.
2. In Ireland a rapid review is submitted for all drugs seeking reimbursement; following this 55% of submissions are recommended for a full health technology assessment (HTA). This study describes the RR process employed in Ireland and indicates the factors influencing the requirement of a HTA to secure reimbursement, namely therapeutic area, first in class, orphan status and patient drug costs.
3. Establishing formal decision-making criteria around the requirement for a full HTA could contribute to better management for the introduction of new drugs particularly given current and expected future trends of high cost drugs and delays in access to medicines, suggest better management for their introduction is warranted.

1 INTRODUCTION

Reimbursement and health technology assessment (HTA) systems globally evolve in response to environmental and economic challenges. In particular, since the global financial crisis, efforts to balance access and affordability are prioritised. A somewhat unique approach was taken in Ireland with the introduction of compulsory Rapid Reviews (RR) in 2010. While employed in a variety of countries to support decision making, the definition and implementation of RRs vary in practice [1]. However, most RRs aim to synthesise evidence in a timely manner without sacrificing scientific rigour [2].

Prior to this only medicines with a significant budgetary impact were considered for a HTA in Ireland, albeit there was no explicit threshold on what constituted a significant budget impact. However as the financial crisis hit Ireland and recession ensued, budget cuts were necessary. The volume of medicines to be assessed increased at the same time and so did evaluation times. RRs were therefore introduced [3] as a means of optimising agency resources, which led to shorter evaluation times and faster patient access while ensuring affordability.

Access and affordability of medicines are longstanding issues, particularly in Ireland, where per capita pharmaceutical expenditure increased dramatically from the 20th highest of 27 OECD countries in 2000 to 3rd highest of 25 OECD countries in 2010 [4]. Following the introduction of international and internal reference pricing, pharmaceutical spend moderated in Ireland but like other countries has been rising since 2014 [5] (€1,964 million in 2016). The latest rises has been attributed to the introduction of expensive treatments; starting with the allocation of €30 a million a year for Hepatitis C treatment in the public health care system [6, 7]. Since this many high profile expensive drugs have been approved, such as eculizumab for paroxysmal nocturnal haemoglobinuria and lumacaftor/ivacaftor for cystic fibrosis [5].

Previous studies have described the reimbursement process in Ireland in detail [8-10] and examined criteria influencing reimbursement decisions in Ireland following a HTA [11]. To summarise, there are two stages to the reimbursement process, which is governed by the Supply of Medicines to Health Services Agreement between the Government and Irish Pharmaceutical Healthcare Association (IPHA), hereinafter the IPHA Agreement. In stage 1, a RR is required for all new medicines following a licensing decision. The RR is a short dossier submitted by the drug manufacturer detailing the condition and technology, price, regulatory status, placement in therapy, comparator(s), clinical evidence and budget impact [12]. The National Centre for Pharmacoeconomics (NCPE) assesses the RR within 28 days. There are two outcomes from the RR: full HTA not recommended or full HTA recommended. (In some cases a HTA is initially recommended at submitted price but is avoided following price negotiations). If a HTA is not required, a positive reimbursement recommendation is made by the national health service (Health Services Executive, HSE). Stage 2 involves a HTA and further engagement with the HSE. The HTA is assessed by the NCPE within 90 days (excluding clock stops for questions). The recommendations following a HTA are a positive decision to reimburse at applied terms; negative reimbursement decision or the decision is referred to the national agency (HSE Drugs Group) who either recommends the drug for reimbursement or not.

In an academic publication McCullagh and Barry [8] indicate that when appraising a RR and deciding if a full HTA is required, the following criteria are considered by the NCPE: robustness of clinical efficacy data indicating non-inferiority/superiority to comparator while being equal / lower in cost; small eligible population with an unmet need and low associated budget impact (less than €0.75 to €1 million per annum) or low estimated budget impact, along with existing system infrastructure capable of restricting usage. These criteria, however, are not formalised and do not appear on the NCPE website, IPHA agreement or any on any other guidance or process documentation used by manufacturers, just the academic publication [8]. Also, it is not clear how these criteria are weighted in the decision making process.

Whether a HTA is recommended or not has implications for access. As per the IPHA Agreement [13], the guidance regarding reimbursement timelines for the RR stage and HTA stage are 73 days (28 days RR evaluation plus 45 days to reimbursement) and 163 days (28 days RR evaluation, 90 days HTA evaluation and 45 days to reimbursement) respectively. While the timelines for the RR stage are generally adhered to and reimbursement almost guaranteed if no HTA is recommended [8], there are delays in the HTA stage because of clock stops during the evaluation of the HTA and delays in the further engagement phase which involve price negotiations, with the HSE [14]. Furthermore, 25% of drugs that undergo a HTA do not get reimbursed [8].

The RR is a practical tool that aims to balance timely decision making, affordability and access. Attempts at balancing access and affordability are not uniquely Irish. For example, in England NICE has recently introduced a fast track appraisal process suitable for drugs with an incremental cost effective ratio under €10,000 per QALY [15]. Elsewhere, there are specific reimbursement routes and considerations for orphan drugs in France and Germany for example [16]; for innovation status in Italy and highly specialised technologies in England.

Eight years on from the introduction of compulsory RRs and in the absence of formal decision-making criteria on the necessity of a HTA, this study examines the factors influencing the outcome of the RR process.

2 METHODS

2.1 Data

A database was developed combining data from publicly available sources for all drug evaluations conducted by the NCPE from January 2010 up to June 2017 (vaccines and devices were excluded). An overview of the variables and sources contained in the database are summarised in Table 1. Table 2 presents a comparison of drugs recommended and not recommended for HTA.

Irish data on patient drug costs were not publicly available from the NCPE website for drugs that did not require a HTA and for approximately two thirds of those that underwent a HTA. To overcome this, cost data was obtained from the Scottish Medicines Consortium (SMC) website and used as a proxy. The SMC data was used as a proxy for two reasons. First, the populations are similar in size (5.4m in Scotland [17], 4.8m in Ireland [18]). Second, the SMC appraise all new licensed medicines and make the evaluations publicly available so there was a higher likelihood that the data would be available from the SMC compared to other jurisdictions. Drug cost per patient from

the SMC was used as opposed to budget impact data because the latter was often not disclosed for confidentiality reasons and while the populations are similar, the prevalence of diseases can be different thus impacting transferability [19]. Table 3 presents a summary of SMC cost data (converted to Euros using annual average exchange rates).

2.2 Analysis

To explore the factors influencing the likelihood that a medicine requires a full HTA, descriptive statistics on the data defined above are produced after which an econometric analysis is employed. With a binary dependent variable, (HTA (1) or no HTA (0)), a logit regression is employed using STATA version 14 [25]. This predicts the dichotomous outcome of the dependent categorical variable (HTA) based on the explanatory (independent) variables using binomial probability theory. The explanatory variables included here are: year of the review (dummy variable for each year), type of reimbursement scheme (dummy variable for each), first in class; therapeutic area (dummy variable of each), submission company's experience, orphan disease, reassessment, per year. The form of logit regression equation is:

$$\text{logit}\big(p(x)\big) = log\left(\frac{p(x)}{1-p(x)}\right) = a + b_1x_1 + b_2x_2 + \cdots$$

The marginal effects are also estimated using STATA version 14. These measure the effect on the conditional mean of the dependent variable of a change in the independent variables. This provides a good approximation to the amount of change in the dependent variable produced as function of the change in the independent variables, thus are more intuitive particular for logit models.

As SMC cost data were only proxies, two econometric analyses were conducted the first without SMC cost data on the full data set (n= 296) and the second with SMC cost data on the restricted data set (n=212).

Table 1: Data Sources & Descriptive Statistics

Variable	Definition	Source	Description	Mean	Std Dev
HTA	HTA recommended (or HTA not recommended)	NCPE website [20]	Binary: HTA (1) , No HTA (0)	0.55	0.5
Therapy area	Therapeutic areas as per WHO ICD-10 classifications	WHO ICD-10 classification [21]	Binary variable per area: Yes (1) , No (0)		
			Circulatory	0.11	0.31
			Endocrine	0.13	0.34
			Musculoskeletal	0.07	0.26
			Respiratory	0.07	0.26
			Neoplasm	0.27	0.45
			Infectious disease	0.06	0.23
			Other	0.29	0.45
Reimbursement scheme	General Medical Services (GMS) High Technology Scheme (HTS) Hospital (it was assumed that all IV drugs were reimbursed by hospitals)	NCPE website and in monthly PCRS updates [20]	Binary variable per scheme (GMS, HTS, Hospital) Yes (1) , No (0)		
			GMS	0.30	0.46
			HTS	0.34	0.48
			Hospital	0.36	0.48
Year	Year of outcome of RR	NCPE website [20]	Binary variable per year (2009-2017) Yes (1) , No (0)		
			2010	0.04	0.20
			2011	0.11	0.31
			2012	0.10	0.31
			2013	0.11	0.32
			2014	0.17	0.38
			2015	0.15	0.35
			2016	0.21	0.41
			2017	0.10	0.31

Variable	Definition	Source	Description	Mean	Std Dev
First in class	Variable indicates unique mechanism of action for treatment as designated by the FDA in their annual report of novel drugs.	FDA Annual Reports [22]	Binary: Yes (1) , No (0)	0.37	0.48
Orphan status	Drug designated orphan status by the European Commission Community Register of orphan medicines.	European Commission Community Register of orphan medicines [23]	Binary: Yes (1) , No (0)	0.78	0.41
New drug	Drug designated a new drug if not previously evaluated by the NCPE.	NCPE Website [20]	Binary: Yes (1) , No (0)	0.78	0.78
Experience	Variable indicates the experience of companies navigating the reimbursement process measured by the number of RR and HTA submissions.	NCPE Website (count of submissions per company) [20]	Continuous	4.15	3.96
Cost	Cost per patient converted to Euros using annual exchange rates.	SMC Website [24]	Continuous (£ converted to € using average annual exchange rates)	See Table 3	

FDA=Food and Drug Administration, GMS = general medicines scheme, HTA= health technology assessment, NCPE=National Centre for Pharmacoeconomics, RR= rapid review, WHO= world health organisation, PCRS=Primary Care Reimbursement Service, PCRS Schemes: General Medicines Scheme (GMS): covering drugs that are prescribed and dispensed in community pharmacies. It is means tested and those eligible receive free medicines subject to a €2 prescription charge (up to a maximum €20 a month). High Technology Scheme (HTS): covering mainly oral high cost drugs that are prescribed in hospitals but dispensed in the community. Hospital scheme: covering IV drugs prescribed and dispensed in hospitals. SMC = Scottish Medicines Consortium.

Table 2 Comparison of Drugs Recommended and Not Recommended for HTA

	HTA Recommended % (n=165)	HTA Not Recommended % (n=137)
All	55%	45%
Circulatory	41%	59%
Endocrine	64%	36%
Musculoskeletal	62%	38%
Respiratory	33%	67%
Neoplasms	88%	12%
Infectious disease	35%	65%
Other Areas	33%	67%
First In Class	73%	27%
Orphan Disease	78%	22%
New Drug	52%	48%
GMS Scheme	36%	64%
HTDS Scheme	68%	32%
Hospital Scheme	58%	42%
Year 2010	50%	50%
Year 2011	34%	66%
Year 2012	58%	42%
Year 2013	36%	64%
Year 2014	47%	53%
Year 2015	58%	42%
Year 2016	68%	32%
Year 2017	77%	23%

GMS=general medicines scheme, HTS=high technology scheme

Table 3 Summary SMC Cost Data (Converted to Euro)

	Average SMC Cost €	Std Dev €	Sample Size
All	36,516	61,171	212
Circulatory	6,921	11,640	22
Endocrine	64,869	103,231	29
Musculoskeletal	56,320	147,678	13
Respiratory	17,217	21,068	13
Neoplasms	56,875	33,218	63
Infectious disease	33,269	33,271	15
Other areas	11,749	20,525	57
First in class	53,627	78,080	89
Orphan disease	82,230	92,783	50
New drug	35,430	65,094	160
GMS	11,667	73,677	55
HTS	47,977	51,204	81
Hospital scheme	42,283	56,513	76
Year 2010	36,485	45,956	7
Year 2011	22,981	62,102	19
Year 2012	24,152	48,267	22
Year 2013	17,723	24,828	28
Year 2014	23,053	26,280	38
Year 2015	32,996	39,448	35
Year 2016	60,158	95,680	47
Year 2017	72,714	68,799	16

Notes:
GMS=general medicines scheme, HTS=high technology scheme, SMC Costs converted from £ sterling to € Euros using annual exchange rates.
Time period considered: Jan 2010 to June 2017

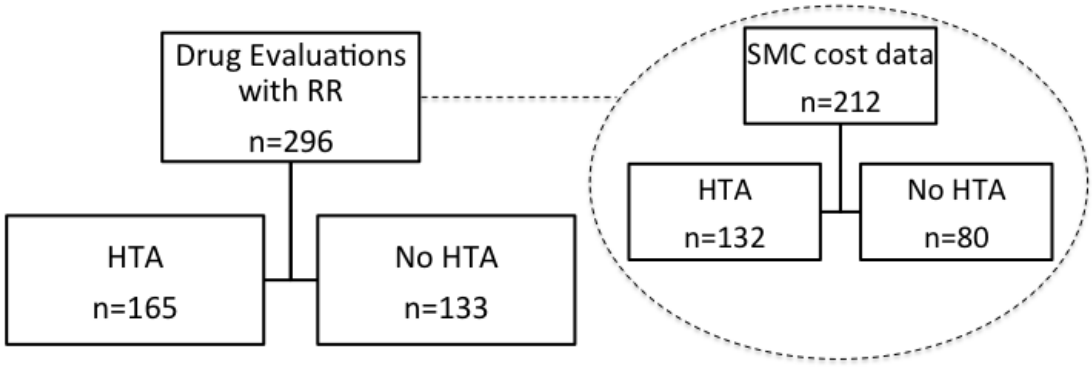
3 RESULTS

3.1 NCPE Evaluations 2010-2017

In total 296evaluations, involving a RR, were conducted by the NCPE between January 2010 and June 2017, in 55% of cases a HTA was recommended (n=163) (Figure 1 and Table 2). Table 2 shows that there was an increasing trend of HTAs being recommended and that over 70% of first-in-class and orphan drugs were recommended for HTA. With regards to therapeutic area, drugs for neoplasm, circulatory and musculoskeletal disease were more likely to be recommended for HTA compared to other therapeutic areas. Moreover, drugs seeking reimbursement for the High Technology and Hospital reimbursement schemes were more likely to attract a HTA compared to the general scheme (Table 2).

SMC cost data was available in 212 cases and a HTA was recommended in 62% of these cases (n=132). Average annual cost per patient was €36,516 (standard deviation €61,171). With regards to therapeutic area, average annual drug costs per patient were highest amongst drugs indicated for endocrine, neoplasms and the musculoskeletal systems. Average costs for drugs classified as first in class, new and orphan diseases also exceeded average in the full sample (Table 3).

Figure 1: NCPE Submissions 2010 – 2017



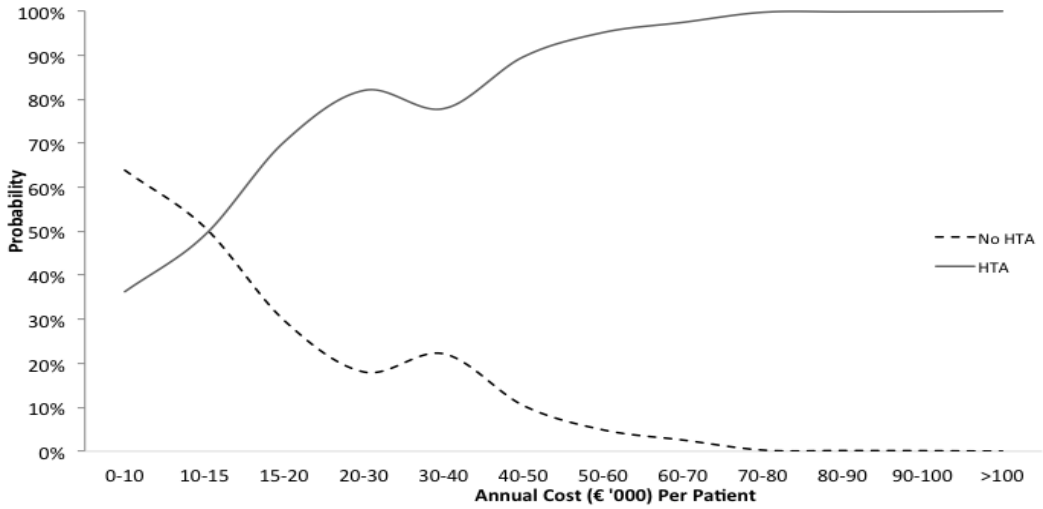
3.2 Factors Influencing Rapid Review Outcome

The logistic regression results reveal therapeutic area (specifically, endocrine, musculoskeletal and neoplasms), first in class and orphan disease status are statistically significant in influencing the RR outcome (Table 4). Specifically, a drug indicated for

the endocrine system is 21% more likely to require a HTA compared to drugs in the other therapeutic areas category, holding all else constant. In addition, drugs indicated for musculoskeletal and neoplasm systems are 21% and 41% respectively, more likely to require a HTA, than drugs in the other therapeutic area category, holding all else constant. Similarly, drugs that are first in class (19%) and those with orphan status (15%) are more likely to require a HTA.

As indicated previously, a limitation of the publicly available information used to create the data set for this regression was the absence of cost parameters. To overcome this, data on annual drug costs per patient were obtained from the SMC website and used as a proxy for Ireland. These variables were added to the original logistic regression to investigate factors influencing the RR outcome (n=212). Results reveal a positive relationship between cost per patient and RR outcome. As costs increase, the likelihood of a HTA being recommended increases. Specifically, every €1,000 increase in the annual per patient cost of a drug increases the probability of a HTA being requested by 1%. A drug indicated for the circulatory, endocrine, musculoskeletal system or a neoplasm is more likely to require a HTA, than drugs in the other therapeutic areas category, holding all else constant. Meanwhile a drug indicated for infectious diseases is less likely to need a HTA, holding all else constant. Estimating the predicted values at various cost thresholds (using regression results) indicates that when patient drug costs exceed €15,000 per annum, a HTA is more likely than no HTA (Figure 2).

Figure 2 Predicted Probability of the Requirement for a HTA



Observations from 2010-2017, n =212 and SMC costs employed as a proxy for Irish costs converted to Euros using average annual exchange rates.

Table 4 Logistic Regression Results

	Full Analysis		**Cost Analysis**	
	Marginal Effects (Std Errors)		**Marginal Effects (Std Errors)**	
Circulatory	0.08 (0.08)		0.13 (0.08)	***
Endocrine	0.21 (0.07)	*	0.12 (0.07)	***
Musculoskeletal	0.21 (0.10)	**	0.34 (0.11)	*
Respiratory	0.03 (0.10)		-0.01 (0.10)	
Neoplasms	0.41 (0.07)	*	0.22 (0.09)	**
Infectious disease	-0.04 (0.11)		-0.24 (0.12)	**
First in class	0.19 (0.05)	*	0.05 (0.06)	
Orphan drug	0.15 (0.07)	**	0.05 (0.09)	
New drug	-0.04 (0.07)		0.03 (0.07)	
GMS	-0.01 (0.07)		0.05 (0.07)	
HTS	-0.02 (0.07)		-0.11 (0.08)	
Company experience	0.00 (0.01)		0.00 (0.01)	
Year 2011	-0.16 (0.14)		0.02 (0.16)	
Year 2012	0.03 (0.14)		0.28 (0.16)	
Year 2013	-0.16 (0.14)		-0.04 (0.16)	
Year 2014	-0.13 (0.13)		-0.04 (0.16)	
Year 2015	-0.04 (0.14)		0.07 (0.16)	
Year 2016	0.03 (0.13)		0.08 (0.16)	
Year 2017	0.01 (0.15)		0.13 (0.20)	
Cost €'000 (SMC)			0.01 (0.00)	*
LR chi^2	101.86		116.99	
Prob > chi^2	0.0000		0.0000	
Pseudo R^2	0.2501		0.4039	

GMS= general medicines Scheme, HTS= high technology scheme, SMC=Scottish Medicines Consortium.
Dummy variable reference categories: Other therapeutic area; hospital scheme; and year 2010.
Statistically significant at 1% (*); 5% (**) and 10% (***)

4 DISCUSSION

Previous research elsewhere [26-29] and in Ireland [11] have explored the factors influencing reimbursement decisions following a HTA. However, in Ireland reimbursement can be secured without a HTA. In the absence of formal and transparent guidance around the requirement for a HTA, the factors influencing this decision have yet to be explored. This is a particularly important question in Ireland because 45% of drugs evaluated do not require a HTA, and for these drugs reimbursement is almost guaranteed. Consequently access is much faster for those drugs than when a HTA is required. Furthermore, this analysis contributes to the growing international evidence base on reimbursement systems.

To analyse the factors influencing whether a HTA is required or not in Ireland, ~~302~~ 296 drugs evaluated by the NCPE between 2010 and 2017 were examined and logistic regression models were employed. Results of the first logistic regression reveal that drugs that are first in-class, for orphan diseases, for cancer and for endocrine and musculoskeletal systems are more likely to require a HTA. These results are unsurprising as these medicines tend to be high cost and the scientific rigour associated with a HTA is required to investigate their cost effectiveness. Another logistic regression that included annual proxy drug costs from the SMC (n=212) indicate that costs are a factor in deciding whether a HTA is required or not. Specifically, it shows that every €1,000 increase in annual drug costs per patient, increases the likelihood of a HTA by 1%. In addition, while the endocrine, oncology and musculoskeletal remain significant in the second logistic regression, orphan drug status and first in class are no longer significant. This may suggest that it is not first-in-class and orphan status per se that is driving the need for a HTA but the costs associated with these labels. These results indicate that the RR is fit for purpose; drugs that are likely to have a high budget impact are recommended for HTA.

This study adds to the literature describing and explaining the factors influencing the requirements for a HTA. Specifically, it advances previous studies of the Irish RR system [30], by including more observations and augmenting the NCPE database with secondary data such as orphan status and proxy drug costs from the SMC. This adds to the explanatory power of the logistic regression. In addition, proxy costs allowed for exploration of a cost threshold for RR outcomes. The regression results suggest that for drugs with annual patient costs greater than €15,000 a HTA is the most likely outcome of the RR. However, costs employed are only proxies because Irish cost data are not available for drugs that did not require a HTA and for many of those that underwent a HTA. We acknowledge this is a limitation of the study.

Furthermore, we acknowledge a better indicator of the cost impact of introducing a new drug is the budget impact. Indeed, while not formalised in the reimbursement process, previous commentary on Ireland's HTA process indicate a low budget impact threshold of between €0.75 to €1 million per annum is one of the criteria that influences the outcome of the RR in Ireland [8]. Unfortunately, Irish budget impact data is not available for many of the drugs evaluated. Nor is it easily transferable between jurisdictions, so proxy budget impact data from SMC could not be used. Therefore, we could not empirically test for the existence of the €0.75-€1 million budget impact threshold.

While, McCullagh and Barry [8] outline criteria influencing the outcome of the RR (robust clinical data, low budget impact (€0.75 -€1m per year), unmet medical need, and systems in place to restrict indication), these are not formalised and lack definition. Also, it is not clear how these criteria are weighted in the decision making process. The lack of formal criteria coupled with the compulsory nature of RRs means that there is often duplication because agency staff are evaluating the same drug twice. Compulsory RRs also mean delays in initiating a HTA. For example, is it necessary for very high cost drugs such as lumacaftor/ivacaftor for cystic fibrosis to undergo both a RR and HTA? Given the new drugs pipeline is dominated by orphan, cancer and specialty medicines [31], which this study has shown are more likely to require a HTA to secure reimbursement, can the reimbursement process sustain such duplication? Moreover, how viable is the RR process in its current format; would an opt-in or opt–out approach be a better way to optimise agency resources? However, transparent and formal decision criteria would be needed if compulsory RRs were replaced with an opt-in or -out approach. This would require significant consideration, as well as capacity for frequent reviews to avoid criteria becoming "out of date", together with mechanisms to avoid moral hazard or gaming behaviour. Other jurisdictions have developed formal criteria for opt-in systems, for example, NICE's fast track appraisal process is deemed suitable for drugs with an incremental cost effective ratio under €10,000 per QALY [15].

5 CONCLUSIONS

As new, innovative medicines are diffused and demand for existing medicines grows pressure on reimbursement systems in the EU and beyond will persist. Exploring reimbursement approaches and sharing experiences can be meaningful for HTA agencies designing and evolving their systems [32], particularly given the shift towards value based frameworks for reimbursement [33].

This study describes the RR process employed in Ireland and indicates the factors influencing the requirement of a HTA to secure reimbursement, namely therapeutic area, first in class, orphan status and drug costs. These results, coupled with current and expected future trends of high cost drugs and delays in access to medicines, suggest better management for their introduction is warranted. Establishing formal decision-making criteria around the requirement for a HTA would represent significant progress.

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