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**Title:** Decision making by the NICE Interventional Procedures Advisory Committee: An evaluation of the evidence-base

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**Abstract** (250 words):

## **Background**

This study explores the evidence-base for recommendations by the National Institute of Health and Care Excellence (NICE) Interventional Procedures Advisory Committee (IPAC); the only NICE committee not to consider cost. The four types of recommendation are: Standard Arrangements (can be done without restriction in the NHS); Special Arrangements (can be done under certain conditions); Research Only; and Do Not Do.

## **Methods**

Quantitative content analysis of data extracted from all published Interventional Procedure Guidance (IPG) for 2003-2018 (n=496). All data were extracted independently by two researchers, and disagreements clarified by consensus. Data were tabulated, descriptive statistics produced, and regression analyses performed.

## **Results**

Proportion of IPGs by recommendation: 50% Standard; 37% Special; 11% Research Only; 2% Do Not Do. There was a clear trend over time: the proportion of Standard Arrangements recommendations has decreased, while the evidence threshold has increased. Adjusted mean numbers of patients in the evidence base by recommendation type: Standard=4867; Special=709; Research Only=386. Regression analyses confirm that the year of recommendation, numbers of patients, and levels of evidence, all affect the likely recommendation.

## **Conclusion**

This study demonstrates for the first time that the likelihood of achieving the most positive recommendation (Standard Arrangements) is decreasing, and that this is most likely due to evidential requirements becoming more demanding. These findings are distinct from those reported for other NICE committees, for which the cost and statistical superiority of new therapies are among the drivers of recommendations. This is an important finding regarding changing demands in the field of health policy.

## **Introduction**

The National Institute of Health and Care Excellence (NICE) Interventional Procedures Advisory Committee (IPAC) is an independent advisory committee that has produced guidance for the National Health Service (NHS) in England and Wales since 2002. The objective of the Interventional Procedures (IP) programme is to appraise the efficacy and safety of interventional procedures, defined as those involving 'an incision, puncture, or entry into a body cavity, or the use of ionizing, electromagnetic, or acoustic energy'.<sup>1</sup> A rapid review of published evidence is conducted by NICE and detailed summaries of the most relevant evidence and data are provided to the committee, together with written commentaries elicited from clinical and surgical experts. Based on this evidence, the committee drafts recommendations for public consultation, after which they are reconsidered by the committee and revised if necessary. Interventional Procedures Guidance (IPG) is then ratified by NICE's Guidance Executive and published.

The committee can make four main types of recommendation: 1) 'Standard' (formally 'Normal') Arrangements indicate that the intervention can be performed in the NHS as routine practice. This is the most positive recommendation from the committee and requires a valid, relevant and good quality evidence-base of an appropriate size and consistency; 2) 'Special Arrangements' is more restrictive. This requires clinicians who use the procedure to inform the clinical governance lead in their trust, tell the patient about the uncertainties related to safety and efficacy of the procedure, and collect further data by means of audit or research. This recommendation is usually made if there are significant uncertainties in the evidence on efficacy or safety, or an inadequate quantity of evidence; 3) Research Only recommendations are made when there are substantial uncertainties related to the efficacy and safety of a procedure, which can only be resolved by further research; 4) Finally, the committee might recommend 'Do Not Do', if the evidence suggests that a procedure has no efficacy or poses unacceptable safety risks. It is important to note also that IPAC does not take account of cost(s) in any of its considerations.

Previous research linked to this NICE committee has focused on the role and value of input from experts and other stakeholders, so-called 'non-technical' knowledge.<sup>2-5</sup> This research had stressed the value of this input, but does not quantify its impact on recommendations. By contrast, the present study only focuses on so-called 'technical' evidence, i.e. the published data of studies included in the documents used by IPAC to make its decisions, and seeks to quantify its potential impact on recommendations.

Similar research has been conducted on other NICE committees, especially those that consider cost. In studies of factors predicting decisions for Multiple and Single Technology Appraisals (MTAs, STAs) by NICE, analyses have consistently found that cost and clinical efficacy are among the drivers

of committee recommendations.<sup>6-8</sup> This is the first study to analyse recommendations from a NICE committee that does not consider cost.

This paper therefore aims to assess on the relationship between the published evidence-base and the recommendations of IPAC. In doing so, it applies the principles of the Oxford Centre for Evidence-Based Medicine's evidence hierarchy with Level 1 (systematic review) and Level 2 (Randomised Controlled Trial [RCT]) being the highest levels<sup>9</sup>, as this is consistent with much evidence-based practice and guidelines, and is in accordance with the basic categorisations outlined for primary research by the IDEAL framework for surgical innovation.<sup>10</sup>

## **Methods**

This study used quantitative content analysis to produce a numerically-based summary of counts of key categories, and to analyse patterns of this content<sup>11,12</sup> These categories are pre-specified and independent of the source(s) being analysed, e.g. study designs.<sup>13</sup> The following data were extracted from the guidance and related evidence documents for each IPG published on the NICE website in August 2018: date; recommendation; total number of patients; number of patients in largest RCT (if there was an RCT); number of the following study designs: systematic reviews; RCTs; non-RCTs; cohort studies/case series; case reports; and registry data. A comments field facilitated data checking by recording any issues of interpretation. A single IPG was reported as multiple pieces of guidance if, for example, there were different recommendations for different populations. The majority of evidence summaries for IPGs from 2009 onwards reported the total numbers of patients, and number and type of studies, within the evidence being considered by the committee. These data were extracted, where reported. Where these summary data were not reported, numbers of studies and patients were calculated by the authors from study details tabulated for consideration by the committee. The data extraction forms were piloted by all researchers on a sample of IPGs. Independent data extraction was performed for each IPG by two researchers (CC, RD, AB and RH), and all data cross-checked for discrepancies. Disagreements were resolved with reference to the original documents. The data were collated and tabulated, and descriptive statistics were presented.

### *Statistical analysis*

Variables indicating evidence availability (i.e. systematic reviews, RCTs, registries etc.) were dichotomised into 'present' or 'not present', and total numbers of patients in the included studies were grouped into five categories to minimise the impact of outliers on the logit models: <100, 100-999, 1000-4999, 5000-9999, and >10000). Logistic regression analyses were performed to assess relationships between evidence availability variables with each level of recommendation versus all

others (Do Not Do was excluded as there were only eight such recommendations). Ordered logit models were then used to further investigate how the availability of particular evidence may predict the level of recommendation achieved. These analyses assume a hierarchy in the IPAC recommendations, i.e. Standard Arrangements, Special Arrangements and Research only, ranked from best to worst. The assumption of proportional odds across response categories was tested using a likelihood ratio test. Multiple logistic regression models were also run for individually significant predictor variables. All statistical analyses were performed in Stata 15.

## Results

The search of the NICE website identified 496 separate pieces of guidance and/or recommendations published from 2003 to 2018. Each recommendation is routinely reviewed every three years if ‘Standard’ Arrangements have not been given, thus cancelling the previous IPG and generating IPGs with designated numbers higher than 496 (e.g. IPG597). The basic results are presented in Table 1.

The following proportions of each type of recommendation were: 50% Standard Arrangements (248/496); 37% Special Arrangements (185/496); 11% Research Only (55/496); and 2% Do Not Do (8/496). If the highest level of available evidence was a systematic review, then a Standard Arrangements recommendation was most likely; if it was only cohort studies/case series, then a Research Only recommendation was more likely (see Table 1). Where the evidence-base included an RCT, these trials tended to be larger for Standard Arrangements recommendations (62% of trials had >100 participants) than for Special Arrangements (42%) or Research Only (38%).

<insert Table 1 here>

The mean number of patients included in the evidence-base considered by the committee was also much higher for procedures that received the most positive recommendation and decreased as the uncertainty around the intervention’s efficacy and safety increased, thus receiving the more restrictive recommendations: 7981 (Standard Arrangements); 3937 (Special Arrangements); 2479 (Research Only); 2012 (Do Not Do). When outliers in patient numbers that might skew the data were excluded (i.e. the three highest totals for the three recommendation-types with these clear outliers), then not only does the relative difference between the mean number of patients for each type of recommendation remain, but it also increases: Standard: 4867; Special: 709; Research Only: 386.

There were also clear trends over time. The proportion and numbers of Standard Arrangements recommendations have reduced substantially over time, while numbers of Research Only recommendations have increased (to the point where there are now more of the latter than the former) (see Figure 1).

<insert Figure 1 here>

From 2007/2008 (see Figure 2), the proportion of Standard arrangements recommendations with a supporting systematic review has increased, while the proportion with case series/cohort/case-control/case reports, and even RCTs, as the highest level of evidence has decreased. The evidential requirements for Standard Arrangements are becoming more demanding (in the sample from 2017 and 2018, n=18, none had designs other than a systematic review or RCT as the ‘best available’ evidence). This same trend was found for the recommendation Special Arrangements (data not presented). The proportion of systematic reviews included as the highest level of evidence in any IPG recommendation also increased over the period, from 23% in 2003-2010 to 33% in 2011-2018.

<insert Figure 2 here>

The descriptive findings presented in Table 1, and Figures 1 and 2 above, were confirmed by statistical analysis. The results of some of these analyses are presented in Tables 2 and 3. Logistic regression analyses found that the probability of Standard Arrangements (compared to other types of recommendation, excluding Do Not Do) is significantly higher (2.55 times higher,  $p < 0.001$ ) if there is a relevant, available systematic review (see Table 2).

<insert Table 2 here>

The most important individual predictor of Standard Arrangements was the number of patients included in the evidence-base. The odds of a Standard Arrangements recommendation increased by 10.57 times when 1000-4999 patients were included in the published evidence considered by the committee. It should be noted that the mean number of patients for Standard Arrangements, minus

outliers, falls within this range (4867). The probability of a Standard Arrangements recommendation was also found to have decreased significantly between 2003 and 2018 ( $p < 0.001$ ), while the probability of a Research Only recommendation has increased significantly: Odds Ratio (OR) 1.17, 95% Confidence Interval (CI), 1.09-1.25,  $p < 0.001$  (full data not presented).

Finally, in multiple regression analysis of the statistically significant variables presented in Table 2, the following variables were found to be significant independent predictors (at the level of  $p < 0.001$ ) of a Standard Arrangements recommendation: year of decision, non-RCT, and categorised total patients (data not presented). The highest-level of evidence, a systematic review, was no longer a statistically significant independent predictor: OR, 1.64, 95% CI, 0.95-2.81,  $p = 0.074$ .

Ordered logit models were then used to investigate further how the availability of particular evidence might predict the level of recommendation achieved. The results are presented in Table 3 and confirm the findings of the regression analyses. An interventional procedure with a systematic review was 2.45 times ( $p < 0.001$ ) more likely to receive a higher level of recommendation than one without, and categories of patients with the highest numbers were more likely to achieve a higher recommendation level than categories with lower numbers (OR 2.19, 95% CI 1.74-2.76,  $p < 0.001$ ).

<insert Table 3>

Significant predictors of a lower level of recommendation were year of guidance (with the odds of more positive recommendations decreasing by 0.11 each year) and the inclusion of case series and case reports (OR 0.43;  $p < 0.001$ ). Again, in multiple regression analyses of the statistically significant variables presented in Table 3, the same variables as in the regression were found to be statistically significant ( $p < 0.01$ ), but in this model systematic review also achieved statistical significance as an independent predictor (OR 1.89, 95% CI 1.52-3.32,  $p = 0.014$ ) (full data not presented).

To illustrate these findings further, a typical example of each recommendation and its most common evidence-base (Level 1 for Standard Arrangements, Level 2 or 3 for Special etc.) is provided in the top half of Table 4. In each case, it is clear how the level and size of the evidence-base might have contributed to the recommendation decision.

<insert Table 4>

However, the bottom half of this table also provides an atypical example of each type of recommendation. These latter examples serve to highlight the fact that factors other than the level of evidence available or numbers of patients can also play a key role.

In the case of the Standard Arrangements recommendation in IPG554 (see Table 4), the level of evidence was relatively low, as was the number of included patients (n=226), but the guidance stressed that, despite there being the ‘potential for some serious but well-recognised safety concerns’, there was some evidence of efficacy and few or no alternative interventions for those who were unsuitable for other types of surgery (i.e. there was unmet need). Tellingly, the same IPG recommended Special arrangements for patients for whom another type of surgery was an option.

IPG429 represents an example of a Research Only recommendation that appears to satisfy the ‘level of evidence’ requirements for a Standard Arrangements recommendation. However, the procedure had clear safety risks; there were uncertainties over efficacy, and the data were considered insufficiently long-term. These issues, and optimal patient selection, could only be addressed by further research. A similar set of circumstances appears to apply in the case of IPG592 (Special Arrangements), where the evidence-base included a systematic review and covered more than 1000 patients. However, as with IPG429, there were some uncertainties over efficacy (inconsistencies in findings across studies), but in this case there were no safety concerns. The recommendation was therefore Special Arrangements.

These latter cases underline how an ostensibly ‘negative’ recommendation can be made confidently because of the availability of high-level evidence and large numbers of patients, as well as explaining how the highest levels of evidence can also produce the ‘weakest’ recommendations. This is also reflected in the eight recommendations for ‘Do Not Do’ (data not presented).

## **Discussion**

The key findings of this study are that, as a proportion, fewer procedures are now achieving a Standard Arrangements recommendation, and an increasingly larger proportion of those that do have the highest level of evidence (systematic review). Therefore, the likelihood of the most positive recommendation has decreased over time, while the evidential requirements have increased, both in terms of the level and size of the evidence-base, i.e. patient numbers. The data and analyses do not demonstrate causality, but there is a clear correlation between these variables. Other NICE committees have also been less likely to give full, positive recommendations in more recent years, but previous research has not demonstrated why there might be fewer wholly positive

recommendations than previously.<sup>6</sup> In the case of IPAC, the data strongly suggests that the committee's decision-making is linked to ever-growing evidence requirements. Part of the reason for this demand might be because more and more systematic reviews are now being published and are available<sup>14</sup>, hence the increase in this level of evidence across all recommendations over this period (see Figure 2).

However, as demonstrated by the case studies, IPAC's decisions clearly involve a great deal more than simply deferring to any perceived 'evidence hierarchy'. Committee recommendations cannot be reduced to simple algorithms based on study design or patient numbers. Even procedures with large numbers of patients in the published evidence have no guarantee of the most positive recommendation, as indicated by the mean and ranges presented in Table 1. Other factors clearly also contribute to decision-making and recommendations. These might include: clinical/patient need<sup>5</sup>; clinical input<sup>2,3</sup>; the promise and plausibility of the procedure having real world impact<sup>3</sup>; and, especially, the committee's consideration of the studies and their results (particularly their homogeneity and consistency) in a patient and health system context. These factors apply to all NICE committees and act as a caution against seeking to predict all recommendations using the type and size of the evidence base alone, despite the strong evidence of this analysis.

### *Strengths and limitations*

This paper is the first analysis of the predictors of recommendations by IPAC. It involved the double-extraction and checking of data from almost 500 pieces of guidance from publicly-available documents produced by this committee from 2003-2018. However, the analyses were limited to those data where potential impact on recommendations might be evaluated. As a result, they did not take into account other potentially important variables that are more difficult to quantify. These might include the role of expert or patient input in any specific recommendation; and the consistency and relative balance of the efficacy and safety evidence for a specific population and procedure; the presence of 'unmet need'; and the degree to which the procedure being evaluated was novel or established. A relative lack of evidence – and thus the reduced likelihood of the most positive recommendations – might indicate that a procedure is new. However, it was not reasonably possible to discriminate, using the published data, between new and established procedures. Consequently, this factor has also not been analysed. The type of procedure being assessed might also be an independent predictor of the likely recommendation, but the IPGs do not specify type of procedure or surgical speciality, and categorisation using the British Medical Association's Surgical Specialities list<sup>15</sup> proved problematic. As a result, the potential for recommendations to be predicted by type of procedure is unknown. The very small number of Do Not Do recommendations (n=8) also prevented their analysis alongside the large numbers of other recommendations. Nevertheless, as demonstrated

by the case studies presented in this paper, more in-depth analysis of individual pieces of guidance might present a rather richer picture of the process.

This study has demonstrated for the first time that the level of the available evidence, and the number of patients included in that evidence-base, both strongly predict the likely IPAC recommendation. It also found that the burden of these evidential requirements has increased over time: the most positive recommendation, Standard Arrangements, now more than ever requires the highest levels of evidence and/or large numbers of patients reported to have undergone a procedure in published studies. The likelihood of achieving the most positive recommendation is therefore decreasing as evidential requirements become more demanding. This is an important finding regarding changing demands in the field of health policy. However, the case studies presented here also demonstrate that decision-making cannot be reduced to simple algorithms based on study design or patient numbers; factors other than the type and size of the evidence-base can also clearly contribute to the type of recommendation awarded.

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Figure 1

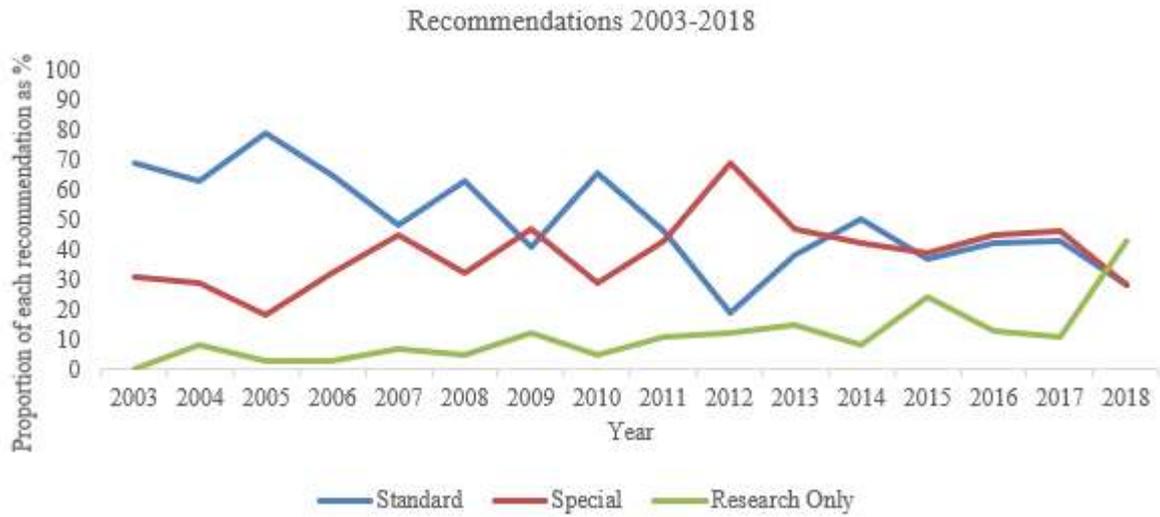
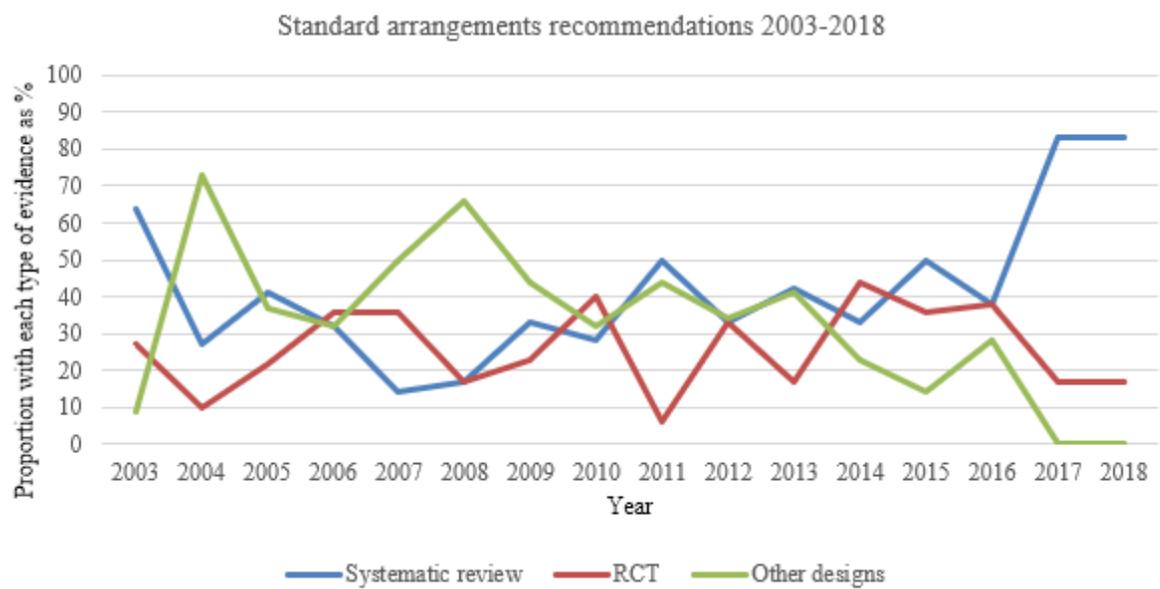


Figure 2



**Table 1:** Interventional Procedures Guidance (IPG) 2003-2018: Evidence base characteristics

Recommendation	N	Highest level of evidence					*RCTs with >100 patients	Patients	
		SR and RCT	SR only	RCT only	Non-RCT	Other designs		Mean	Range
Standard	248	42 (17%)	53 (21%)	65 (26%)	46 (19%)	42 (17%)	65/105 (62%)	7981.3	7-575,556
Special	185	20 (11%)	17 (9%)	44 (24%)	32 (17%)	72 (39%)	25/60 (42%)	3937.3	0-568,782
Research Only	55	5 (9%)	3 (6%)	16 (30%)	8 (15%)	23 (42%)	8/21 (38%)	2478.7	3-90,000
Do Not Do	8	3 (38%)	2 (25%)	1 (13%)	1 (13%)	1 (13%)	1/4 (25%)	2012.2	247-6926
Total	496	70	75	126	87	138	99		

N: Number, SR: Systematic review, RCT: Randomised controlled trial \*The denominator in this column could be different from the total number of recommendations with RCTs because numbers of patients were not reported or could not be calculated for some IPGs. IPG196 was excluded as it was a non-standard piece of guidance.

**Table 2:** Logistic regression analyses of Standard Arrangements vs other types of recommendation (excluding Do Not Do)

Variable	Odds ratio	95% CI		
Systematic review (y/n)	2.55	1.69	3.86	
Year of decision	0.90	0.87	0.94	
RCT (y/n)	1.48	1.02	2.13	
Categorised total pts (<100, 100-999, 1000-4999, 5000-9999, >10000)	2.35	1.83	3.01	
ORs by category	100-1000	4.11	2.00	8.46
	1000-4999	10.57	4.88	22.92
	5000-9999	19.13	5.24	69.80
	>10000	18.36	5.53	60.99
Non-RCT (y/n)	2.07	1.44	2.98	
Case/cohort series (y/n)	0.45*	0.20	1.02	
Registries (y/n)	0.61†	0.27	1.38	

CI: Confidence Interval, y/n: yes/no, RCT: Randomised Controlled Trial, p values all <0.0001 unless stated.

\*p=0.055 †p=0.235

**Table 3:** Ordered logit model odds of recommendations (excluding Do Not Do)

<b>Variable</b>		<b>Odds ratio</b>	<b>95% CI</b>	
Systematic review (y/n)		2.45	1.63	3.67
Year of decision		0.89	0.86	0.93
Categorised total pts		2.19	1.74	2.76
ORs by category	100-1000	2.56	1.53	4.30
	1000-4999	6.87	3.78	12.49
	5000-9999	11.97	3.61	39.75
	>10000	10.34	3.42	31.31
RCT (y/n)		1.40*	0.99	2.00
Non-RCT (y/n)		2.03	1.43	2.87
Case/cohort series (y/n)		0.43	0.20	0.97
Registries (y/n)		0.54†	0.26	1.15

CI: Confidence Interval, y/n: yes/no, RCT: Randomised Controlled Trial, p values all  $\leq 0.0001$  unless stated.

\*p=0.060, †p=0.114.

**Table 4:** Illustrative examples of recommendations and their evidence-base

<b>Recommendation</b>	<b>IPG #</b>	<b>Title</b>	<b>Highest level of evidence</b>	<b>Number of patients</b>
<b>Typical examples</b>				
Standard	489	Gastroelectrical stimulation for gastroparesis	Systematic review	1765
Special	430	Partial replacement of the meniscus of the knee using a biodegradable scaffold	RCT	600
Research Only	519	Insertion of an epiretinal prosthesis for retinitis pigmentosa	Case series	129
<b>Atypical examples</b>				
Standard	554	Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension	non-RCT	226
Special	592	High-intensity focused ultrasound for symptomatic breast fibroadenoma	Systematic review	3283
Research Only	429	Endovascular stent insertion for intracranial atherosclerotic disease	Systematic review	2241

IPG: Interventional Procedures Guidance, RCT: Randomised Controlled Trial