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Title: PROPOSALS TO INTRODUCE EXEMPTIONS FROM HUMAN MEDICINES REGULATIONS FOR ORTHOPTISTS ACROSS THE UNITED KINGDOM IA No: 5195 Lead department or agency: National Health Service England Other departments or agencies: Department of Health, Medicines and Healthcare Products Regulatory Agency, British and Irish Orthoptic Society (UK wide), Devolved administrations	Impact Assessment (IA)		
	Date: 01/12/2015		
	Stage: Consultation		
	Source of intervention: Domestic		
	Type of measure: Other		
Contact for enquiries: enquiries@ahp.nhs.net			
Summary: Intervention and Options		RPC Opinion: RPC Opinion Status	

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies as Two-Out?
£44.5m	£m	£0m	Yes NA

What is the problem under consideration? Why is government intervention necessary?

Due to an ageing population and development of treatments, demand for ophthalmic services has increased UK wide. Supply and administration of medicines is controlled by government regulation and efficiency is restricted by the current mechanisms; patient-group directions (PGDs) require development and renewal in every hospital; and patient-specific directions (PSDs) require professional time to review and sign off. This can delay treatment, require additional appointments and increase cost. It can also exacerbate inequalities across areas and social groups. There are potential efficiencies, equity gains and improvements in patient experience from improving supply and administration of medicines.

What are the policy objectives and the intended effects?

The objectives are: a) to reduce inefficiencies associated with current supply and administration mechanisms, b) to reduce inequalities in access to medicines for orthoptic patients, c) to facilitate service re-design through the better use of orthoptist skills within the multidisciplinary team. Intended effects are: reducing cost of treatment while maintaining patient safety, reducing delays to diagnosis and treatment, greater choice of treatment options, improved equity of access to eye care, earlier access to ophthalmologists for patients who need their skills, enhanced experience of care, and better value in the use of resources for eye health.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 - No change
 Option 2 - Introduction of a specified list of exemptions under human medicines regulations for orthoptists

Will the policy be reviewed? It will not be reviewed. If applicable, set review date: Month/Year					
Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro No	< 20 No	Small Yes/No	Medium Yes/No	Large Yes/No
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

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Signed by the responsible Minister: George Freeman Date: 22nd February 2016

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £2.5m	High: £75.3m	Best Estimate: £44.5m

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	£3.8m
High	Optional	Optional	£4m
Best Estimate			£3.8m

Description and scale of key monetised costs by 'main affected groups'

Costs of educational programme to train orthoptists to use exemptions. Training will be undertaken by orthoptists working both within the NHS and also in non-NHS settings where a service need/role has been identified and entry criteria met. The financial cost would be met in general by employer or education commissioners although they may be met by individuals or non-NHS organisations if working within the independent sector.

Other key non-monetised costs by 'main affected groups'

Enhanced clinical supervision, marginal increase only.
Time taken off work to re-attend eye clinic to access prescribed medicines.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low		Optional	£6.5m
High	Optional	Optional	£79.1m
Best Estimate			£48.3m

Description and scale of key monetised benefits by 'main affected groups'

Reduction in clinicians' time to establish and renew patient group directions (PGDs). Reduction in orthoptist and ophthalmologist time requirements to obtain/sign patient-specific directions (PSDs). Reduction in multiple attendances with creation of 'one stop shops'. Reduced time away from work and school for parents/carers and children to re-attend clinic to collect a medicine where medicines are not accessible at the time of orthoptist appointment.

Other key non-monetised benefits by 'main affected groups'

Reduction in time requirement of NHS Trusts' Medicines Management Committees time to review PGDs when there is a change in the orthoptist team.
More appropriate choice of treatment options in line with patient needs
Improved patient experience
Reduction in number of appointments required to access medicines.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%
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Risks: Errors in the supply/ administration of medicines; overuse of antibiotics; insufficient communication about supply/ administration of medicines to health care professionals by orthoptists; orthoptists do not acquire sufficient information to make informed decisions around supply/administration of medicines.
Assumptions: entry criteria are met for training in the use of exemptions; appropriate local governance arrangements are in place to support the safe use of medicines.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	Benefits:	Net:	No	NA

Evidence Base (for summary sheets)

Policy Background

The *Review of Prescribing, Supply and Administration of Medicines*¹ in 1999, chaired by Dr June Crown, proposed that changes to prescribing and supply and administration of medicines be extended to a range of health professionals in order to improve services to patients, make better use of the skills of professional staff and thus make a significant contribution to the modernisation of the health service. Following the review, revised regulations have enabled an expansion of non-medical prescribing so that experienced nurses, optometrists, pharmacists, physiotherapists and podiatrists can train to independently prescribe medicines within their clinical competence. This has been championed through such publications as *High Quality Care for all*², *Modernising allied health professions careers: a competency based career framework*³, and more recently the *Allied health professions (AHP) prescribing and medicines supply mechanisms scoping project report*⁴ and *Operational guidance to the NHS: extending the patient choice of provider*⁵.

Within the Government's response to the consultation on refreshing the mandate to NHS England, there were numerous suggestions on how to make better use of resources, one of which is the more effective use of medicines⁴. Changes to medicines legislation, in line with these recommendations to allow eligible orthoptists to train to sell, supply and administer medicines under exemptions within Human Medicines Regulations, will support changes to models of care to allow patients to access the right medicines at the right time, in the right place without any unnecessary delay.

In the publication *Five Year Forward View*⁶ NHS England sets out how the health service needs to change, arguing for a more engaged relationship with patients, carers and citizens so that we can promote wellbeing and prevent ill-health. One that no longer sees expertise constrained by traditional boundaries, fragmented services, or patients having to visit multiple professionals for multiple appointments. One organised to support people with multiple health conditions, not just single diseases. A future that sees far more care delivered locally but with some services in specialist centres where that clearly produces better results. One that recognises that we cannot deliver the necessary change without investing in our current and future workforce.

The use of exemptions by orthoptists also supports the achievement of a number of ambitions across the devolved nations such as, *Transforming Your Care: A Review of Health and Social care in Northern Ireland*⁷, *Transforming Your Care: Strategic Implementation Plan*⁸, *Improving Outcomes by Shifting the Balance of Care: Improvement Framework*⁹, *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*¹⁰, *Together for Health: A Five Year Vision for the NHS in Wales*¹¹ and *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales*¹². These documents set out the vision for the future of the NHS which no longer sees expertise constrained by traditional boundaries, fragmented services or patients having to visit multiple professionals for multiple appointments.

¹ Department of Health (1999) *Review of Prescribing, Supply & Administration of Medicines*, London.

² Department of Health (2008) *High Quality Care for All: NHS Next Stage Review Final Report*. London.

³ Department of Health and Skills for Health (2008) *Modernising Allied Health Professional Careers: a competency based career framework*. London.

⁴ Department of Health (2009) *Allied health professions (AHP) prescribing and medicines supply mechanisms scoping project report*. London

⁵ Department of Health (2011) *Operational guidance to the NHS: extending the patient choice of provider*. London

⁶ NHS England (2014) *Five Year Forward View*, London

⁷ Northern Ireland Department of Health, Social Services and Public Safety (2011) *Transforming Your Care: A Review of Health and Social Care in Northern Ireland*, Belfast

⁸ Northern Ireland Department of Health, Social Services and Public Safety (2013) *Transforming Your Care: Strategic Implementation Plan*, Belfast

⁹ NHS Scotland (2009) *Improving Outcomes by Shifting the Balance of Care: Improvement Framework*, Edinburgh

¹⁰ NHS Scotland (2011) *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*, Edinburgh

¹¹ NHS Wales (2011) *Together for Health: A Five Year Vision for the NHS in Wales*, Cardiff

¹² NHS Wales (2012) *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales*, Cardiff

Problems with the current mechanisms for supplying and administering medicines by orthoptists

Supply and administration of medicines used by orthoptists in the diagnosis and treatment of eye conditions is restricted by government legislation. Current supply and administration mechanisms allow orthoptists to supply and administer identified medicines to patients under patient group directions (PGDs) and patient-specific directions (PSDs). PGDs are written instructions for the supply and/or administration of a licensed medicine (or medicines) in an identified clinical situation where the patient may not be individually identified before presenting for treatment. Each PGD must be signed by both a doctor and pharmacist; and approved by the organisation in which it is to be used. A PSD is a prescriber's (usually written) instruction that enables an orthoptist to supply or administer a medicine to a named patient. PGDs have to be updated regularly (at least every two years or when there is a change of staff in a department). PSDs require review and signature in the patients' notes by a prescriber, taking time away from direct patient care. If a prescriber is not present, the patient or carer has to return to the clinic to access medicines which can delay diagnosis and timely treatment.

Equity of access is constrained by PGDs and PSDs. An orthoptist employed across different hospitals may be named on a PGD in one hospital and not on another. These systems of access to medicines can create health inequalities across geographical areas.

It is common that a patient will need more than one medicine and if a combination of medicines is required, a number of PGDs will also be required to cover each possible combination. An example of this is in patients with dark irises (coloured part of the eye) whose eyes do not always respond well to a single medicine to dilate pupils. Consequently patients with dark irises may wait longer for a diagnosis if the required combination of medicines is not available under a PGD.

Orthoptists are trained to manage children with amblyopia (lazy eye) but current legislation limits the delivery of cost-effective eye care for children by orthoptists. Evidence published demonstrates that atropine occlusion is as effective as an eye patch to treat a child with amblyopia¹³ and has a higher rate of compliance¹⁴. Currently, atropine occlusion cannot always be supplied by orthoptists under a PGD and therefore needs to be prescribed for example by an ophthalmologist. This leads to suboptimal care for children who could benefit from timely access to atropine. Appointments could be released for patients with more complex presentations if atropine could be included in the list of medicines exemptions for orthoptists. There are 5.5 million children aged 7 years and under. It is estimated that on average 5% of children under seven years in the UK (276,500 children) experience eye problems and 50% of children with eye problems (138,250 children) require treatment for amblyopia.^{15 16 17 18}

Rationale for intervention

An Allied Health Professions (AHPs) Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken in 2009¹⁹ to establish whether there was evidence of service and patient need to support extending prescribing and medicines supply mechanisms available to AHPs. The project found there was a strong case in support of exemptions for orthoptists for a specific list of medications including antibiotics used in the diagnosis and treatment of disorders of binocular vision.

¹³ Repka MX, Wallace DK, Beck RW, Kraker RT, Birch EE, Cotter SA, Donahue S, Everett DF, Hertle RW, Holmes JM, Quinn GE, Scheiman MM, Weakley DR; Pediatric Eye Disease Investigator Group. *Two-year follow-up of a 6-month randomized trial of atropine vs patching for treatment of moderate amblyopia in children.* Arch Ophthalmol. 2005 Feb;123(2):149-57.

¹⁴ Holmes JM, Beck RW, Kraker RT, et al., Pediatric Eye Disease Investigator Group. *Impact of patching and atropine treatment on the child and family in the amblyopia treatment study.* Arch Ophthalmol. 2003;121(11):1625-1632

¹⁵ Eibschitz-Tsimhoni M, Friedman T, Naor J, Eibschitz N, Friedman Z. *Early screening for amblyogenic risk factors lowers the prevalence and severity of amblyopia.* J AAPOS 2000;4:194-9

¹⁶ Barrett BT, Bradley A, Candy TR. *The relationship between anisometropia and amblyopia.* Prog Retin Eye Res 2013; 36: 120-158

¹⁷ C. Williams, R.A. Harrad, I. Harvey, et al. *Screening for amblyopia in preschool children: results of a population-based, randomised controlled trial.* ALSPAC Study Team. Avon Longitudinal Study of Pregnancy and Childhood Ophthalmic Epidemiol, 8 (2001), pp. 279-295

¹⁸ Holmes JM, Clarke MP. *Amblyopia.* Lancet. 2006 Apr 22;367(9519):1343-51

¹⁹ Department of Health (2009) *Allied Health Professionals (AHP) Prescribing and Medicines Supply Mechanisms Scoping Project Report.* London

http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_103948

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The recommendations in the scoping report were prioritized and phase 1 of the AHP Medicines Project was focused on attaining independent prescribing responsibilities for Physiotherapists and Podiatrists. Following the successful completion of this work in the summer of 2013 phase 2 of the project commenced and included the proposal for the use of exemptions by orthoptists. The drivers in the system are now even stronger and strengthen the case in support of exemptions for orthoptists. For example, an increase in orthoptic led services and satellite clinics mean that increasingly orthoptists need to be able to have access to the medicines patients require for diagnosis and/or treatment. Introducing exemptions within Human Medicines Regulations for orthoptists could lead to improvements in patient quality including outcomes, experience and safety.

Economic case

The use of exemptions by orthoptists has the potential to improve the supply and administration of medicines and increase the range of services that can be provided by orthoptic practitioners to meet increasing demand for eye care. Health gains and cost reductions could be achieved by diagnosing and treating eye morbidity earlier, improving patients' experience of care, reducing the need for additional clinic appointments and reducing inequalities in access to eye care. This could lead to overall efficiency in the health system if these gains outweigh the additional risks of relaxing regulations on medicine supply in eye health.

Policy objectives

The intended effects of introducing exemptions within Human Medicines Regulations 2012 for orthoptists are:

- greater equality in access to medicines for patients with eye problems;
- improved patient experience;
- improved choice and convenience for patients and carers;
- improved use of orthoptists' skills;
- reduced administrative burden on health care professionals associated with the development and approval of PGDs;
- releasing orthoptist and ophthalmologist time by reducing the need for PSDs;
- improved access to evidence-based treatment for children with amblyopia;
- reduced need for an additional clinic visit for patients, just to obtain the medicines they require;
- improved health and wellbeing for all patients with eye problems;
- facilitating service re-design to better meet patient needs;

Description of options considered (including do nothing);

Option 1: 'No change'

It is required to include a 'No change' option in an impact assessment. This option is to maintain the status quo and has costs and benefits of zero. All costs and benefits of other options are calculated relative to this. This option involves no initiation of specific measures in terms of supply and administration for orthoptic patients, and therefore continuation of current supply and administration of medicines via PGD's and PSD's. This would result in the continuation of the limitations of clinical practice described earlier.

Option 2: Introduce exemptions within human medicines regulation for orthoptists.

Appropriately trained orthoptists would be able to supply and administer the medicines on an approved exemptions list within their scope of practice and competence without the need for a PGD or a PSD. The proposed list of medicines is below.

It was proposed by NHS England that in the course of their professional practice, orthoptists annotated on the HCPC register to use exemptions would be able to sell (when they are providing care in the

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private sector), supply or administer any eye drops or ointments containing any of the following substances for any condition within their scope of practice and competence. All of the substances listed below are for topical administration only

List of medicines (including antibiotics) to be included for orthoptist supply under exemptions to human medicines regulation

- Atropine
- Cyclopentolate
- Tropicamide
- Lidocaine with fluorescein
- Oxybuprocaine
- Proxymetacaine
- Tetracaine
- Chloramphenicol
- Fusidic acid

In addition, the list includes non-prescription medicines (medicines which are available over the counter from a shop or pharmacy) for supply and administration in the course of professional practice (e.g. phenylephrine 2.5%, fluorescein and ocular lubricants).

All qualified orthoptists who are registered with the Health and Care Professions Council (HCPC), and meet other entry requirements would be eligible to undertake training to supply these medicines on a voluntary basis which, if satisfactorily completed would enable them to be annotated on the HCPC register as being qualified in the use of exemptions.

Private sector impact

The British and Irish Orthoptic Society (BIOS) estimates that there are 6 orthoptists (0.4% of the workforce) working full-time in the private sector with up to 40% of orthoptists doing some private practice alongside their NHS work. However it is not anticipated that the proposed change in regulations will have any impact on the private sector for the following reasons:

There are important contrasts between NHS and private eye clinics that mean that the proposal affects each sector differently. Between 5 and 7 patients would usually be booked into a private clinic on any given day whereas in NHS clinics there can be up to 40 patients per clinic. Private patients are seen in ophthalmologist-led clinics where the consultant has a sub-specialty in a relevant area of eye medicine for the patients booked into that clinic. In the time available, the consultant is able to triage all patients before the start and can decide then whether a PSD is required. In the NHS context by contrast, the prescribing clinician may not have the time before the clinic to triage all patients or may not have the required sub-specialty knowledge to sign a PSD for all patients who need one during their consultation. Patients may sometimes be triaged by a non-prescribing health care professional (for example, an orthoptist or staff nurse). The change in medicines regulations has been proposed to address the dual problem in the NHS of the lack of time to triage patients and issue PSDs before the start of a clinic and the lack of access to clinicians with the appropriate knowledge during clinics to issue PSDs; this problem does not arise in the private sector due to the lower throughput per clinic, additional time for triage and access to prescribing clinicians with the required sub-specialisation to issue PSDs where required.

Therefore the change in regulation addresses an NHS problem and is expected to have no impact or very negligible impact on the private sector.

Public consultation

NHS England led a 8 week public consultation between 26 February and 24 April 2015 on the proposal to allow Orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012). The UK-wide consultation was developed in collaboration with: the

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devolved administrations; the Medicines and Healthcare Products Regulatory Agency (MHRA); the Department of Health (DH); and the British and Irish Orthoptic Society who are the professional body representing orthoptists.

There were 204 responses in total to the consultation. 198 responses were received via the online portal, and 6 were received in hard copy. In total, 57 responses were received from organisations and 143 from individuals. Four responses did not state whether they were responding as an individual or on behalf of an organisation. There were 32 responses from Scotland, 4 responses from Wales, 17 responses from Northern Ireland and 139 responses from England. Twelve respondents did not state where they were responding from.

Monetised and non-monetised costs and benefits of each option (including administrative burden);

Overview of costs and benefits associated with Option 2: Introduce exemptions within medicines legislation for orthoptists.

Costs:

Option 2 will require orthoptists to be trained in the use of exemptions and require them to be away from work for up to two days.

Benefits

Option 2 will result in cost savings in the following areas:

- Reduction in development, approval and renewal costs of PGDs because orthoptists will be able to supply and administer some medicines without the need for a PGD once orthoptists are annotated on the HCPC register to use exemptions
- Reduction in time needed to seek clinical review and signature in the patients' notes from a prescribing clinician for some medicines that are currently supplied or administered to individual patients under PSDs.
- Reduction in patients' (and carers') time to return to clinic to access medicines that require a PSD when a prescribing clinician is not present in clinic to provide one at the time.
- Health gains from a reduction in delay in access to medicines although this gain is only marginal and not quantifiable, and therefore is not monetised.

Monetised costs

Cost of training

Costs of educational programmes for supplying and administering medicines under exemptions within the Human Medicines Regulations 2012.

Figures for November 2014 showed that there are 1362 orthoptists registered with the HCPC in the UK and it is projected by BIOS that approximately 60 newly qualified practitioners (4.4% of the current workforce) joined the register in 2015. Taking into account orthoptists leaving the profession every year, BIOS estimated that the workforce would expand by 20 in year 1 and increase by the same rate in subsequent years (1.47%).

Where there is an identified service need, all orthoptists who meet the entry criteria would be eligible to undertake training to use exemptions. It is estimated by BIOS that 20% of qualified orthoptists would undertake training in the first year with 15% in the second and third year. Going forward to steady state, taking into account that a proportion of orthoptists trained in using exemptions will leave the profession every year and untrained orthoptists will join the profession, it was estimated by BIOS that approximately

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5% of orthoptists in the workforce at the end of the previous year would need to take up training each year in order to maintain a 60% rate of orthoptists trained in exemptions in the workforce²⁰.

Estimates suggest a training course (excluding backfill) for orthoptists to use exemptions would cost between £495 and £545. This is based on a telephone survey of providers by BIOS, November 2014. The cost varied by region. Based on the uptake estimates reported above, it was assumed that 20% of orthoptists would enter the training programme in the first year, 15% in years 2 and 3 and 5% every year from year 4 onwards (Appendix, table 1).

Assuming the lower cost estimate per person for a training course (£495) the ten-year discounted training costs would be between £541,000 and £595,000 depending on the cost of the course (Appendix, table 2, lines 1 and 2).

In the longer term (after 5 years) it is planned that this education programme would be subsumed into undergraduate training courses in-line with other professions such as optometrists and podiatrists. At this point, all orthoptists successfully completing undergraduate orthoptic degree courses would qualify with the exemptions annotation on the HCPC register. It is assumed that 5% of the workforce would require this training to maintain 60% orthoptists trained to supply medicines under exemptions.

Cost of staff replacement (backfill) while on training

Although staff may not be replaced while on training, there is an economic value of their lost time as it will be reflected in diminished service provision or otherwise; this cost is proxied by assuming full back-cover. The training programme is estimated to take practitioners out of service for two days. It is assumed that this time could be backfilled by Agenda for Change Band 6 orthoptists (same band as orthoptists on training) who would be required to cover a 7.5 hour shift. The marginal cost per hour of staff covering colleague's absence is assumed to be lower than average hourly cost as overheads do not have to be included as there are no (or marginal) capital or management costs.

The total discounted 10-year financial cost of staff backfill while training was estimated to be £354,000 (Appendix, table 2, line 3).

Total financial and opportunity cost of training and staff backfill

The total 10-year discounted financial cost was estimated to be £895,000 and £950,000 (Appendix, table 2, lines 4 and 5).

Given the NHS budget constraint, both the cost of the training and the cost of staff backfill will inevitably displace health services that would have been provided to patients; this is the opportunity cost of the proposal²¹. The discounted opportunity cost of staff training was estimated to be £3.8 million over ten years (Appendix, table 3, line 2).

²⁰ This assumes the following: in steady state with N staff and net growth in the workforce of 1.47% at the end of the following year there will be $(1+1.47\%)N$ staff. If 60% of the workforce trained in exemptions is kept as a constant, and if alpha is the percentage of trained orthoptists who leave the workforce each year then we had to train an extra $.6(1+g)N - .6*(1- \alpha)N$ to maintain 60% trained staff. Since BIOS has estimates that 5% of the staff in post would need to be trained each year in exemptions, then $5\% * (1+1.47\%)N = .6(1+1.47\%)N - .6(1- \alpha)N$. Rearranging this we get $(11 \times 1.47\%) + 12. \alpha = 1$. Therefore the proportion of trained orthoptists leaving every year in order for 5% to be the proportion of the workforce the following year that needs to be trained in exemptions to maintain a 60% trained workforce is 7% [$\alpha = (1-16.17\%)/12$]

²¹ Following current DH guidance, the opportunity cost is calculated at one Quality Adjusted Life Year (QALY) per £15,000. The stream of QALYs foregone is then discounted at the rate of 1.5% per year. The social value of the displaced QALYs is re-monetised at a value of £60,000 per QALY, representing the social value of a QALY (what people are on average willing to spend to improve their healthy life expectancy by one QALY). DH guidance advises that each QALY could also generate on average £14,000 of wider societal benefit (for example by reducing dependency). In this consultation document the wider societal benefit has not been calculated.

Non-monetised costs

Option 2: Introduce exemptions to medicines legislation for orthoptists.

There are no identifiable additional health risks associated with orthoptist supply and administration of medicines under exemptions than the current supply and administration of medicines via PGDs and PSDs.

The quality-adjusted life year (QALY) loss associated with side-effects is likely to be negligible as most medicines used by orthoptists are diagnostic and short-acting and therefore have transient and limited side-effects such as temporary blurring of vision and stinging of the eyes.

However orthoptists should have the knowledge to be aware when it is inappropriate to use antibiotics as it would be taught in the professional educational programme. Therefore the use of antibiotics by orthoptists would be infrequent and unlikely to pose a hazard in terms of antibiotic resistance

It is not expected that an automatic increase in salary will result from the completion of training. Some orthoptists who have completed training may move into new roles or take on new responsibilities depending on service needs. On its own, training in the use of exemptions by orthoptists would not be sufficient grounds for a salary upgrade.

There are minimal risks of additional adverse events associated with the use of exemptions by orthoptists; they already supply the vast majority of these medicines under PGDs and PSDs on a daily basis in their current practice [see Risks section below].

Monetised benefits

Option 2: Introduce exemptions within medicines legislation for orthoptists.

Reduction in the use of patient group directions for the supply and administration of medicines by orthoptists

No published evidence was identified to estimate cost saving. All estimates are based on the expert opinion of the membership of BIOS.

Per PGD, the hours of administrative time required to develop, approve, renew and update PGDs in every hospital that employs orthoptists is estimated as follows: orthoptist - four hours; consultant time - half an hour; hospital pharmacist 10 minutes. However, as a response to the public consultation, the UK Ophthalmic Pharmacy Group suggested that the time spent by pharmacists on PGDs has been underestimated and that the time cost savings would be higher than predicted. Given the lack of robust data in this area, we have used the most conservative estimate in the calculations. Higher time values would lead to even greater savings associated with the proposed change in medicines regulations.

The total cost of updating a PGD was calculated by multiplying administrative time by staff costs. The total estimate per PGC update was £339 (Appendix, table 4). The cost impact across hospitals depends on the number of PGDs to be renewed and/or updated per year. A high estimate of 3 PGDs per hospital (low estimate 1, best estimate 2) was used. It was assumed that 174 hospitals employ orthoptists.

The cost savings depended on the numbers of orthoptist workforce trained in supply and administration of medicines under exemptions as a proportion of the total workforce. The annual cost savings was calculated by multiplying the maximum cost savings by the proportion of orthoptist workforce able to supply and administer medicines under exemptions in that year.

If all orthoptists could supply and administer medicines under exemptions, then the financial impact would be between £59,000 and £177,000 per year, and the best estimate would be £118,000. (Appendix, table 5).

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Reduction in patient-specific directions for medicines (prescriber present)

Estimates from BIOS suggest that it takes approximately 5 minutes of a prescribing clinician and orthoptist time to obtain a PSD if the prescriber is present while the patient is in clinic. Also it estimated that up to five PSDs per orthoptist are required per week for medicines that fall outside a PGD. The cost saving depends on the number of orthoptists with exemptions to supply and administer medicines (up to 50% projected after 5 years), the number of PSDs per week required, the proportion of PSDs that would be avoidable and the number currently required.

The highest estimate of the total cost saving per year for the NHS (if all orthoptists could supply and administer medicines under exemptions) was £3.5 million per year assuming 95% of 5 PSDs per orthoptist per week could be avoided. The lowest estimate was £74,000 assuming 10% of one PSD per orthoptist per week could be avoided under option 2. The most favourable estimate was £1.9 million per year assuming 5 PSDs of which 50% could be avoided. (Appendix, table 6)

Reduction in the use of patient-specific directions for the supply and administration of medicines by orthoptists (prescriber not present)

If a prescriber is not present when a PSD is required, the patient has to return to the clinic to collect medicines. It is estimated by BIOS that one patient per week per hospital needs to return to the clinic for this reason. The estimate assumes 174 NHS hospitals have clinics employing orthoptists. The cost saving if all hospitals benefited from this change in regulation is estimated to be between £95,000 and £189,000 depending on how many return visits could be avoided (Appendix, table 7). The best guess is the most conservative (lower) estimate reported here.

Reduction in the use of PSDs to supply atropine to treat amblyopia in children:

A PSD may be required for an orthoptist to supply atropine. If a prescriber is present in clinic to obtain a PSD where one is required, there is a cost of the ophthalmologist and orthoptist time to acquire a PSD. The cost-saving if all orthoptists could supply atropine under exemptions was £157,000 (assuming 10% of children were eligible for treatment with atropine) to £783,000 (assuming 50% of children were eligible for treatment with atropine). The best guess was the higher estimate reported here (Appendix table 8).

Not all hospitals require a PSD for atropine so this cost saving is likely to be an over-estimate.

Total financial savings and opportunity cost of savings in health service utilisation

The annual financial savings from avoiding PGDs and PSDs was estimated to be between £385,000 and £4.7 million with a best estimate of £2.9 million (table 9). Total discounted ten-year financial savings were estimated to be between £1.5 million and £17.8 million with a best guess estimate of £10.9 million; the total discounted opportunity cost was estimated to be between £6.5 million and £79.1 million, reflecting the wide uncertainty in the assumptions. The best guess estimate was £48.3 million (Appendix, table 10).

Non-monetised benefits

Option 2: Introduce exemptions within medicines legislation for orthoptists.

- Improvements in health as a result of earlier access to treatment. This is thought to be marginal as the delay in treatment to access a prescribing clinician would not cause a long-term detriment to health-related quality of life.
- Improvements in patient experience.
- Improved accountability and responsibility for medicines supplied/administered as no prescriber would be asked to prescribe for a patient not directly under their care.
- Reduced time away from work and school to attend clinic appointments as the additional health gain would only make the intervention more cost-effective.

Net present value

Estimates assumed for the highest, lowest and best guess estimates of net present value are presented with the table in the appendix.

The net present value of option 2 not taking into account any change to service configuration is between £2.5 million and £75.4 million, reflecting the wide uncertainty in the estimates. The best guess estimate of net present value was £44.5 million (Appendix, table 11).

Longer term changes in local service configuration

Supply and administration of medicines under exemptions by orthoptists could lead to the development of orthoptist-led clinics for the management of eye conditions requiring regular review. This could reduce costs of service delivery and increase choice, access and patient experience.

Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

The estimate of monetised benefits shown above indicate that under conservative assumptions, this change in regulations is likely to be cost saving over ten years. Additional savings would further increase the cost-effectiveness of this proposal. It is therefore justified to describe but not quantify the value of these benefits, especially since the scale and value of these benefits will be difficult to quantify given that there is no robust evidence on which to base any estimates of effectiveness.

Risks and assumptions;

Supply and Administration – To alleviate the risk of unsafe or inappropriate supply and administration and antibiotic overuse an orthoptist using exemptions should know what medication the patient is currently taking including over-the-counter and herbal preparations before supplying and administering new medicines. Supply of medicines is not an activity that occurs in isolation. Information must be shared with other health professionals who need to know the information for the benefit of the patient and this will include the patient's GP. Where possible, the orthoptist using exemptions to supply and/or administer medicines should have access to other professionals' prescribing decisions where they impact upon their own decisions. This will include communication across NHS-private practice boundaries where it is necessary to ensure that clinicians have appropriate information to inform their practice.

An orthoptist using exemptions must make it clear to the patient that medicines supply and/or administration cannot be undertaken in isolation. The orthoptist should inform anyone else who may be in a position to prescribe for that patient of their actions to avoid medicines errors. This is most likely to be the patient's general medical practitioner, but may also include other health and social care professionals. If the patient refuses to consent to sharing such information the orthoptist should offer an explanation of the risks of not doing so. If the patient continues to refuse to give consent, the orthoptist should consider which course of action, including to not supply medicine, would be in the best interests of the patient. This must be documented in their records.

Level of training and education

There are strict eligibility criteria for orthoptists to undertake training for exemptions. The candidate must:

- Be registered with the HCPC as an orthoptist
- Be professionally practising in an environment where there is an identified need for the individual to regularly use exemptions
- Be able to demonstrate support from their employer
- Be able to demonstrate medicines and clinical governance arrangements are in place to support safe and effective use of exemptions

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- Be able to demonstrate how they reflect on their own performance and take responsibility for their own Continuing Professional Development (CPD) including development of networks for support, reflection and learning.
- In England and Wales, provide evidence of a Disclosure and Barring Service (DBS) or in Northern Ireland an Access NI check within the last three years or, in Scotland, be a current member of the Protection of Vulnerable Groups (PVG) scheme.

Any orthoptist using exemptions will only be able to supply and administer medicines from the list of exemptions within their scope of practice and competence. There is always a risk associated with supplying and administering medicines. Orthoptists already have a history of supplying and administering the medicines on the exemptions list safely and effectively through the use of PGDs and PSDs and therefore orthoptists are familiar with these medicines and will have the necessary training to safely supply and administer these medicines within the course of their professional practice.

The Health and Care Professions Council (HCPC) have the authority to approve education programmes for the provision of exemptions training for orthoptists. An outline curriculum framework for education programmes to prepare orthoptists to use exemptions has been developed BIOS and can be accessed on BIOS website at hcpc-uk.org/aboutus/consultations. The HCPC has also developed draft Standards for the Use of Exemptions by Orthoptists. This will ensure consistency of standards to enable education providers to interpret and apply the requirements. These standards will be put to public consultation in 2016.

Monitoring and evaluation

As part of phase 1 of the AHP Medicines Project, which took forward independent prescribing by physiotherapists and podiatrists, the project team worked with the Research and Development Directorate at the Department of Health (DH) to agree funding and a specification for an evaluation. DH initiated an open tender process and the University of Surrey was awarded the contract to undertake an evaluation of independent prescribing by physiotherapists and podiatrists. The study has commenced and is expected to be completed in 2016. We intend to follow a similar approach to evaluation in respect of exemptions within Human Medicines Regulations for orthoptists.

Summary and preferred option with description of implementation plan

While the existing supply and administration arrangements have helped to improve the effectiveness of care for some patients, there is potential for orthoptists to contribute much more. Service efficiency and innovation are currently hampered by incongruence between the existing mechanisms and patient need.

The introduction of exemptions within human medicines regulation for orthoptists (option 2) would quickly improve existing care pathways and lead to more effective, efficient and safe patient care. It would also future-proof health care organisations with a flexible frontline workforce able to support rising demand for ophthalmic services.

Appendix – Orthoptists

**Option 2 - Exemptions within human medicines regulation for specified medicines
Projected demand, training costs and opportunity cost of training**

Table 1. Projected demand for training and numbers entering training by orthoptists, years 1-10

Estimates of values and assumptions:

Net growth of the workforce is 1.47%

7% trained orthoptist leave the profession every year (see footnote 20 of the Impact Assessment document for further explanation)

In steady state from year 5 onwards, 5% of the current orthoptist workforce will require training every year to maintain 60% of the orthoptic workforce with training in medicines exemptions

Uptake of training was based on estimates from BIOS members and education providers. Orthoptists currently practicing was taken from HCPC list of registered practitioners in 2014 (hcpc –uk.org.uk, accessed November 2014).

Assumes that from year 4 onwards, there is a 5% turnover of staff (leaving the profession or retiring and coming into the profession who require training)

N = 1362	Workforce	% in training	Cumulative % trained	Number in training (rounded)
Year 1	1,362	20%	20%	272
Year 2	1,382	15%	35%	207
Year 3	1,402	15%	50%	210
Year 4	1,423	5%	55%	71
Year 5	1,444	5%	60%	72
Year 6	1,465	5%		73
Year 7	1,486	5%		74
Year 8	1,508	5%		75
Year 9	1,530	5%		77
Year 10	1,553	5%		78
Total				1,211

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Table 2: Projected financial cost of training and staff backfill, years 1-10

Estimates of values and assumptions:

Cost of training valued as £495 per participant (lowest estimate) and £545 (highest estimate) based on estimated provided by Higher Education Institutes to BIOS (November 2014)

Cost of backfilled staff is estimated at £22 per hour, based on PSSRU (2014) Unit costs for Band 6 staff, excluding qualifications and overheads.

Staff training assumed to be 2 days of a 7.5 hour shift. Cost of staff backfill is therefore £22 x 7.5 hours x 2 days = £324. Discount rate: 3.5%

	Training cost (low estimate) – line 1	Training cost (high estimate) – line 2	Cost of staff backfill - Line 3	Total (low estimate) - line 4	Total (high estimate) -line 5
Year 1	£134,838	£148,458	£88,169	£223,007	£236,627
Year 2	£99,143	£109,158	£64,829	£163,972	£173,987
Year 3	£97,197	£107,015	£63,556	£160,753	£170,571
Year 4	£31,763	£34,972	£20,770	£52,533	£55,741
Year 5	£31,140	£34,285	£20,362	£51,502	£54,647
Year 6	£30,528	£33,612	£19,962	£50,491	£53,574
Year 7	£29,929	£32,952	£19,570	£49,500	£52,523
Year 8	£29,342	£32,306	£19,186	£48,528	£51,492
Year 9	£28,766	£31,671	£18,810	£47,575	£50,481
Year 10	£28,201	£31,050	£18,440	£46,642	£49,490
Total	£540,848	£595,479	£353,653	£894,502	£949,133

Table 3. Total discounted ten-year financial and opportunity cost of training, cost of training courses and staff backfill

Estimates of values and assumptions:

Total time for backfill is based on an 7.5-hour shift and 2 training days per orthoptist.

'Low' or 'high' refers to the cost of training (see table 2 above). Discount rate for financial costs: 3.5%

To estimate the opportunity cost of health care displaced by training and staff replacement, the financial cost (actual spend) was translated into quality adjusted life years (QALYs) at a rate of £15,000 per QALY. The social value of the health benefit displaced by orthoptist training (course fees and backfilled time) was calculated by re-monetising the QALYs displaced at a rate of £60,000 per QALY. Discount rate for opportunity costs: 1.5%.

	Financial cost (low)	Financial cost (high)	Opportunity cost (low)	Opportunity cost (high)
Year 1	£223,007	£236,627	£892,027	£946,507
Year 2	£163,972	£173,987	£668,812	£709,659
Year 3	£160,753	£170,571	£668,604	£709,439
Year 4	£52,533	£55,741	£222,799	£236,406
Year 5	£51,502	£54,647	£222,729	£236,332
Year 6	£50,491	£53,574	£222,660	£236,259
Year 7	£49,500	£52,523	£222,591	£236,185
Year 8	£48,528	£51,492	£222,522	£236,112
Year 9	£47,575	£50,481	£222,452	£236,039
Year 10	£46,642	£49,490	£222,383	£235,965

Valuation of benefits

Option 2 - Exemptions within human medicines regulation for specified medicines

Table 4. Annual Financial cost of renewing and updating patient group directions (PGD)

Estimates of values and assumptions:

Estimates the total cost if all orthoptists could supply under exemptions within human medicines regulations

The cost of the Medicines Management Committee is not included as the estimated time and cost to review a PGD is not possible to identify the professionals involved or quantify their time commitment
The cost of an orthoptists at grade Agenda for Change 8a is not reported in the PSSRU data so the estimated cost was taken from a clinical psychologist on the same salary band.

Professional group	Hours	Unit cost per hour	Total cost per PGD	Source PSSRU 2013/14
Orthoptist manager (Agenda for Change Band 8)	4	59	£236	Based on a Band 8 clinical psychologist estimates in PSSRU Unit Costs of Health and Social Care 2012/13
Consultant ophthalmologist	0.5	99	£50	Ibid, per contracted hour
Hospital pharmacist	0.17	41	£7	Ibid.
Total			£339	Rounded to nearest £

Table 5. Annual financial cost per hospital and for the NHS of the renewing PGDs

Estimates the total cost if all orthoptists could supply under exemptions within human medicines regulations

Total cost saving calculated by multiplying the cost saving per clinic by the number of hospitals employing orthoptists in the NHS

	Total no. PGDs per year	Cost saving per clinic*	Number NHS hospital trusts employing orthoptists	Total cost saving NHS per year
Low estimate	1	£339	174	£59,044
High estimate	3	£1,018		£177,132
Best estimate	2	£679		£118,088

*values rounded to nearest £

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Financial cost saving from a reduction in patient-specific directions (PSDs)

a) Annual financial costs associated with PSDs (when a prescribing clinician is present)

Table 6. Annual financial cost of PSDs (prescribing clinician in clinic).

Estimates of values and assumptions:

Estimates the total cost if all orthoptists could supply under exemptions within human medicines regulations (necessary to calculate the cost for a proportion of the workforce trained in medicines exemptions). Assumes salary costs are for a Band 6 orthoptist and a specialist registrar (PSSRU 2013/14).

Cost per orthoptist per week is calculated by multiplying the cost of a PSD (£11.33) by the number of PSDs per week, by the % avoidable

Annual cost per orthoptist is calculated by multiplying the cost per orthoptist per week by 48 weeks. The total annual cost saving to the NHS is calculated by multiplying the cost per orthoptist per year by the number of orthoptists practising in the NHS (approximately 1362).

Estimated no. hospitals employing orthoptists in eye clinics			174
Estimates	Most favourable	Least favourable	Best estimate
PSDs per week	5	1	5
time required	5	5	5
Cost of a PSD per week	£11.33	£11.33	£11.33
% avoidable	95%	10%	50%
Cost saving per orthoptist/week (n-1362)	£53.83	£1.13	£28.33
Cost saving per orthoptist / year (48 working weeks)	£2,584	£54	£1,360
Total cost impact per year if <u>all</u> orthoptists were trained to supply medicines under option 2.	£3,519,408	£74,093	£1,852,320

b) Annual financial costs associated with PSDs (when a prescribing clinician is not present)

Table 7: Estimated cost of return visits to access medicines.

Estimates of values and assumptions:

Table 7 reports the estimated total cost if all orthoptists could supply under exemptions within human medicines regulations

Assumes no seasonal variation in demand for PSDs

Total savings per week calculated by multiplying the cost of a PSD (£11.33) by the demand per week for a PSD (1 to 2), by the number of

NHS hospitals with clinics employing orthoptists (n = approximately 174)

Estimates	Most favourable	Least favourable	Best estimate
Additional visits by patients / carers per hospital per week if prescribing clinician not present:	2	1	1
Total saving per week	£3,944	£1,972	£1,972
Total saving per year	£189,312	£94,656	£94,656

ERROR! UNKNOWN DOCUMENT PROPERTY NAME.**Financial savings from a reduction in PSDs to supply atropine for amblyopia**

Table 8. Annual financial savings from avoiding unnecessary PSDs for atropine under different assumptions about the demand for atropine in children with amblyopia

Estimates of values and assumptions:

Estimates the total cost if all orthoptists could supply under exemptions within human medicines regulations. Number of children in the UK is based on ONS estimates for live birth cohorts in 2013. 5% of children have eye problems, 50% children with eye problems have amblyopia. Assumes eligibility of 10% (least favourable to option 2) to 50% (most favourable to option 2) for the treatment of amblyopia with atropine. Total cost per year is calculated by multiplying the number of children with amblyopia (approximately. 138,250) by the proportion eligible for treatment (10% to 50%), and cost of a PSD (£11.33).

Number of children under 7 years in the UK			5,530,000
No. children under 7 years with eye problems in the UK (5%)			276,500
No. children with amblyopia (50%)			138,250
	Most favourable	Least Favourable	Best estimate
% children eligible for atropine	50%	10%	50%
Total cost PSDs per year	£783,417	£156,683	£783,417

Table 9. Total annual financial savings from a reduction in PGS and PSDs (sum of tables 5 to 8 above)

	Least favourable	Most favourable	Best estimate
Reduction PGDs	£59,044	£177,132	£118,088
Reduction PSDs	£74,093	£3,519,408	£1,852,320
PSDs - return appointments	£94,656	£189,312	£94,656
Reduction PSDs (atropine)	£156,683	£783,417	£783,417
Total	£384,476	£4,669,269	£2,848,481

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Table 10. Total ten-year discounted financial savings and opportunity cost of reduced demand for PGDs and PSDs, by proportion of the orthoptist workforce trained to supply medicines under exemptions within human medicines regulations.

Estimates of values and assumptions:

Assumes no benefits of training accrue in year 1 and benefits accrue as a proportion of the total number of orthoptists who have been trained (all previous years)

Most favourable estimate assumes low cost of training (least favourable, high cost, best guess, low cost), three PGD renewals per hospital per year avoided (least favourable, 1, best guess 2), 5 PSDs avoided per hospital per week (least favourable 1, best guess 5), 2 re-booked appointments saved per week (least favourable 1, best guess 1), and 50% children with amblyopia would be eligible for atropine (least favourable 10%, best guess 50%). Annual savings calculated by multiplying the cumulative proportion of orthoptists trained in using exemptions by the total cost saving reported in table 9. Discount rate: 3.5%

Following DH guidelines, the opportunity cost of savings in health care utilisation was estimated by converting the financial cost (actual spend) into health benefits as quality adjusted life years (QALYs) at a rate of £15,000 per QALY. The social value of freeing up health services to treat other people was calculated by re-monetising the QALYs displaced at a rate of £60,000 per QALY. Re-monetised QALYs were discounted at a rate of 1.5% per year.

Year	Cml % trained in the workforce	Financial savings – lowest estimate	Financial savings – highest estimate	Financial savings - best estimate	Opportunity cost – lowest estimate	Opportunity cost – highest estimate	Opportunity cost - best estimate
1 – no savings							
2	20%	£74,295	£902,274	£550,431	£303,035	£3,680,212	£2,245,108
3	35%	£125,619	£1,525,584	£930,681	£522,475	£6,345,193	£3,870,876
4	50%	£173,388	£2,105,706	£1,284,583	£735,362	£8,930,602	£5,448,101
5	55%	£184,277	£2,237,949	£1,365,257	£796,944	£9,678,485	£5,904,346
6	60%	£194,231	£2,358,839	£1,439,007	£856,545	£10,402,312	£6,345,916
7	60%	£187,663	£2,279,072	£1,390,345	£843,887	£10,248,584	£6,252,134
8	60%	£181,317	£2,202,002	£1,343,328	£831,416	£10,097,127	£6,159,738
9	60%	£175,185	£2,127,538	£1,297,901	£819,129	£9,947,908	£6,068,707
10	60%	£169,261	£2,055,592	£1,254,011	£807,024	£9,800,895	£5,979,022
Total discounted		£1,465,236	£17,794,557	£10,855,544	£6,515,818	£79,131,317	£48,273,947

Cost-benefit analysis

Option 2 - Exemptions within human medicines regulation for specified medicines

Table 11. Ten-year discounted net present value

Estimates of values and assumptions:

Most favourable estimate assumes the cost of training varies is £545 (£495 least favourable, best estimate £495)

3 PGDs avoided per hospital (least favourable 1 PGD, best guess 1 PGD)

5 PSDs a week at 5 minutes, 95% of which are avoidable (least favourable assumes 1 a week, 5 minutes, 10% avoidable, best estimate is 5 a week, 5 minutes, 50% avoidable)

2 return visits avoided per week (least favourable, one appointment, best guess, one appointment)

Assumes no benefits are incurred in year that a student is in training.

The net benefit is the difference in social value of training and backfill costs in table 3 and cost savings reported in table 10 measured as opportunity cost.

Discount rate 1.5%

Year	Least favourable	Most favourable	Best estimate
1	-£946,507	-£892,027	-£892,027
2	-£406,624	£3,011,400	£1,576,296
3	-£186,964	£5,676,589	£3,202,272
4	£498,956	£8,707,803	£5,225,302
5	£560,612	£9,455,755	£5,681,616
6	£620,287	£10,179,652	£6,123,256
7	£607,702	£10,025,993	£6,029,543
8	£595,304	£9,874,605	£5,937,216
9	£583,090	£9,725,456	£5,846,255
10	£571,059	£9,578,512	£5,756,639
Total	£2,496,914	£75,343,738	£44,486,368