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## **The Impact of Commissioning for Rhinosinusitis in England**

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### **Competing interests**

CH was the Chair of the Commissioning Guidance for Chronic Rhinosinusitis Development group<sup>1</sup> and CP was a member of the group. All authors declare no competing interests. No external or internal funding was received for this work.

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## Author declarations

ASJ collected and analysed the data, performed the literature search and wrote the paper. CH was responsible for the design and conception of the study, had full access to the data, contributed to the final paper and is guarantor. CP reviewed and edited the paper.

## Ethical approval

Not required

## Abstract

**Objectives:** To assess the compliance of clinical commissioning groups (CCG) in England with the ENT-UK Rhinosinusitis commissioning guide produced in collaboration with the Royal College of Surgeons England and the National Institute of Clinical Excellence. We also aimed to assess the ease of accessibility of data from CCG's.

**Design:** Audit of compliance of English CCG's with the ENT-UK rhinosinusitis commissioning guide.

**Setting:** CCG's in England

**Participants:** 58 of the 221 CCG's in England were included, chosen because they were the first CCG's authorised by NHS England or alternately, the CCG's forecast to have a deficit in their first year of operation. Their websites were reviewed; when information was not easily accessible, a freedom of information request was submitted to the relevant CCG.

**Main outcome measures:** Compliance with commissioning guidelines for rhinosinusitis.

**Results:** 13% of CCG's had restrictive referral criteria in place, largely unrelated to published evidence-based guidance. The routine use of multiple courses of oral steroids, prescription of antibiotics, CT scanning within primary care, and delaying referral for a year, prior to referral to a specialist were recommended against published advice.

**Conclusions:** Restricting access to surgery may contribute to poorer outcomes and a decrease in the patient's quality of life. This is against the NHS constitution and open to legal challenge. We encourage all ENT surgeons to review policies of their local CCG and engage with commissioners to ensure that their patients have evidence-based care.

## Introduction

In 2009 a report commissioned by the Department of Health (DH) recommended that a £20 billion reduction in National Health Service (NHS) spending be made by 2014. It was suggested that one of the ways in which this would be achieved would be through a reduction in spending on non-essential procedures and operations. In April 2011 a report published by the NHS audit commission summarised that reducing Primary Care Trusts (PCT) spending on 'low clinical value' treatments, would save the NHS about £500 million annually. It suggested that individual PCT's identify 'low clinical value' treatments within their area and reduce spending on these<sup>2,3</sup> Common Otorhinolaryngology procedures such as tonsillectomy and insertion of ventilation tubes soon appeared on these lists, as there was a paucity of evidence at the time to support their long-term effectiveness. Unfortunately, lack of evidence to support effectiveness has widely been assumed to be equivalent to evidence of ineffectiveness.

Commissioners within this old system have subsequently been criticised. They have been condemned for ignoring both clinical evidence and published guidance, restricting access to necessary surgical procedures as a cost-cutting exercise, aimed at making short-term savings within the NHS<sup>4</sup>. There has also been variation in commissioning between PCT's around the country, leading to a postcode lottery for access to surgical treatment locally. This goes against the NHS constitution, which states that all patients should have equal access to treatment and the need for treatment must be based on individual clinical merit following discussion between a patient and their clinician<sup>5</sup>.

2013 saw clinical commissioning groups (CCG's) replace both Strategic health authorities and PCT's, where clinicians, namely general practitioners, became responsible for commissioning local services for their patients. The aim of commissioning, as set out by the Department of Health's quality, innovation, productivity and prevention 'Right Care' program; is to provide the highest quality of care, within a safe and effective NHS, whilst delivering the best *value* for the whole population from this investment in healthcare<sup>6</sup>. Under Right Care, the Royal College of Surgeons (RCS) and surgical specialty associations have worked to establish evidence based, value-based, commissioning guidelines, with participation from all stakeholders, for elective surgical procedures<sup>7</sup>.

As part of this project, ENT-UK, representing ENT services in the United Kingdom, and the Royal College of Surgeons, have produced three high quality, evidence based, clinical

commissioning guidelines for Tonsillectomy, Otitis Media with Effusion (OME) and Rhinosinusitis. These guidelines are accredited by the National Institute for Clinical excellence (NICE) and designed to not only provide CCG's with evidence based commissioning advice, but aim to reduce the postcode lottery across the country and standardise the rates of surgical procedures carried out between different healthcare trusts. The Rhinosinusitis guidelines are based upon the most recent iteration of the European guidelines (EPOS) published in 2012<sup>8</sup>.

In July 2014, the RCS England, audited compliance amongst English CCG's, for four common operations, hip replacement, tonsillectomy, inguinal hernia and OME, with their published commissioning guidance. They found that despite clear and consistent guidelines, many local commissioners were still imposing arbitrary referral criteria for the surgical procedures listed and national variation in commissioning of surgical services persisted<sup>4</sup>.

The aforementioned Rhinosinusitis Commissioning guide was also published by ENT-UK in 2013 as part of the 'Right Care' commissioning program, funded by NHS England. Within this commissioning document, separate, high value care pathways are provided for use by primary care and secondary care physicians, managing patients suffering with rhinosinusitis<sup>1</sup>.

Through this study, we aimed to assess compliance of CCG's across England, with the primary care pathway within the ENT-UK Rhinosinusitis Commissioning guide, using the same criteria as those employed by the RCS England report discussed above<sup>4</sup>.

## **Methodology**

Ethical Considerations; Not applicable

In their report; 'is access to surgery a postcode lottery'; the Royal College of Surgeons of England, analysed commissioning policies for four commonly performed surgical procedures. They looked at 58 of the 211 CCG's in England. The CCG's chosen by them fell into two groups, named 'wave 1' and 'deficit'. Wave 1 consisted of the first 35 CCG's authorized by NHS England and were chosen as they felt these would have the most developed commissioning plans in place. The deficit group was made up of 24 CCG's, forecast to have a deficit in their first year of operation. They felt that these CCG's were more likely to have restrictive referral criteria in place<sup>4</sup>.

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For this study, we employed the same 58 CCG's as the report published by the RCS. The website for each individual CCG was browsed to identify any available published commissioning guidance for patients with Rhinosinusitis who may require Endoscopic Sinus Surgery. If this information was not available on-line, a Freedom Of Information (FOI) request was submitted to the individual CCG. The FOI requests were submitted in November 2014. For those CCG's that did not respond to the FOI, a further request was submitted six weeks later in December 2014. A comprehensive list of these CCG's may be found in appendix 1.

The commissioning policies were collated and then audited against the 'primary care guidance' contained within the joint RCS & ENT-UK commissioning guide on Rhinosinusitis<sup>4</sup>. The primary diagnostic and treatment criteria that should be performed in primary care, prior to referral to secondary care, contained within this document may be seen in Figure 1.

For CCG's with Rhinosinusitis commissioning policies in place, the 'Right Care Quality Dashboard' (<http://www.rightcare.nhs.uk/index.php/resourcecentre/procedures-explorer-tool/>, accessed 17/1/15) was searched to find the age and sex adjusted activity rates for surgery performed for Rhinosinusitis within their catchment. The methodology of the Dashboard is beyond the scope of this paper, but draws on Hospital Episode Statistics data and is validated by professional coding auditors to provide data on secondary care activity sorted into relevant conditions to support Value Based Commissioning. The mean adjusted rate of surgery for chronic Rhinosinusitis is 26.01/100,000 population.

## **Figure 1**

### **Result**

Thirty-five of our selected fifty-eight CCG's had detailed descriptions of their commissioning policies available to the public, on their website. FOI requests were sent to the remaining twenty-three CCG's (40%), where these policies were not freely available. Six of these twenty-three failed to respond to two formal FOI requests and hence fifty-two CCG's were included in the data analysis.

Seven out of the fifty-two CCG's (13%) have restricted referral criteria in place for chronic rhinosinusitis, and have 'procedure of limited clinical effectiveness' (PoLCE) policies in

place for the management of patients with rhinosinusitis. These CCG's are Kernow, Wokingham, North Hampshire, Barnet, Bury, Haringey and Islington.

The '2013 Rhinosinusitis commissioning guide' has not been acknowledged or used verbatim by any of the seven published PoLCE policies reviewed by us on CRS.

Two CCG's, Barnet and Haringey, adopt the 'CRS in adults management scheme for primary care and non-ENT specialist' pathway published within the 'European Position paper on Rhinosinusitis and Nasal polyps, 2012' (EPOS) with one modification<sup>8</sup>. The time frame for referral to an ENT specialist in the EPOS document, following initiation of therapy is 4 weeks, whilst both of these CCG's have modified this to three months, adopted by them from them the 'NICE clinical knowledge summary (CKS) for chronic sinusitis' management pathway, available on NICE's website<sup>9</sup>. Islington CCG has also adopted the NICE CKS criteria.

Four CCG's do not provide advice on the diagnostic criteria essential on history and examination for the diagnosis of chronic rhinosinusitis, whilst a fifth one lists examination criteria that are not in-line with those listed within the RCS guidance. The use of a Visual Analogue scale (VAS) to assess severity of disease is not advised by any CCG although Wokingham does suggest using the SNOT-22 patient reported outcome measure. It does not provide a reference range for severity assessment when using this tool. No CCG's provide advice for the further investigation of allergic rhinitis and asthma.

Six out of seven CCG's suggest the use of intranasal saline irrigation and all seven of them suggest intranasal steroids, prescribed by the General Practitioner (GP), prior to referral to a specialist, which is in line with the RCS guidance. Four CCG's recommend that the GP prescribe the patients a course of antibiotics, with one insisting on 3 months of macrolide antibiotics being given to all patients with symptoms of sinusitis prior to specialist referral. This is not in line with guidance provided by the RCS, which clearly states that they do not recommend the use of antibiotics in primary care due to limited evidence of efficacy in unselected groups.

The RCS recommends a trial of oral prednisolone for 5-10 days followed by topical fluticasone drops if large nasal polyps are clearly visible. It recommends that the patient be reviewed and referred if there is no improvement in symptoms or polyp size, after four weeks. Three CCG's discuss this in their guidelines but contrary to advice, two of them suggest that the oral steroids be administered repeatedly, up to a total of three times, three months apart.

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One of these two CCG's goes on to state that patients may only be referred on to a specialist after a trial of treatment, including three courses of oral steroids, after a period of 12 months. 2 CCG's do not include a time frame for referral to a specialist and a further four state that referral may be made if little improvement is seen by the patient after three months of topical treatment, however they do not discuss symptom severity that may be necessary prior to referral.

The national mean adjusted rate of surgical activity for chronic rhinosinusitis (CRS) is 26.01. Five out of seven CCGs with PoLCE policies in place have activity rates for the first Quarter, 2014 – 2015, below the national mean, and 2 (those CCG's with the most restrictive policies) have rates greater than 2 standard deviations below the national mean. These are true outliers, and the variation is significant.

## Table 1

### Discussion

#### *Synopsis of key findings*

A positive finding of this study was that eighty-seven percent of the fifty-eight CCG's audited do not have restrictive referral criteria in place for patients within their local population suffering with rhinosinusitis.

Thirteen percent of CCG's did have POLCE policies in place for rhinosinusitis but disappointingly none had followed the rhinosinusitis commissioning guideline published in partnership between ENT-UK, the RCS England and NICE. However, three out of these seven CCG's had followed alternate high quality published evidence, servicing their local population with appropriate commissioning guidelines.

The use of antibiotics within primary care or the prescription of more than one course of oral steroids, are not supported by the published guidance. Despite this, multiple CCG's have included this practice within their commissioning guidelines, perhaps as a means to delay onward referral to a specialist. Macrolides are recommended for selected patients with CRS without polyps by the EPOS guidelines<sup>8</sup>. A low grade of recommendation is made, reflecting the conflicting results of 2 randomised controlled trials (RCT) examining the effectiveness of long-term antibiotics, highlighting the further need for RCT's<sup>10,11</sup>. Macrolide antibiotics have an anti-neutrophilic, anti-inflammatory response, and may not be beneficial in patients with

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predominantly eosinophilic disease, which includes most patients with CRS and polyps. Without endoscopic examination, it is difficult to differentiate between phenotypes, or indeed confirm the diagnosis to be correct. We must keep in mind, that one in two patients meeting a symptomatic definition of sinusitis will have both normal endoscopic and radiological findings. Thus, treating all patients presenting to primary care with symptoms suggestive of CRS cannot be supported by current evidence. Antibiotic resistance has been quoted as the 'biggest threat to European Health'<sup>12</sup>. In addition there are small but significant cardiovascular risks associated with long term macrolide antibiotics<sup>13</sup>.

There is limited evidence and no specific guidelines to define the optimum dose and duration of systemic steroid treatment in patients with nasal polyps. However, studies have shown that once an initial trial of maximum medical treatment (MMT), including 7 days of oral prednisolone, have failed, disease specific symptom scores decline<sup>14</sup>. Insisting on three to four repeated courses of prednisolone over 12 months before making a definitive diagnosis is not supported by the literature, and risks deterioration in the patient's quality of life while waiting for specialist referral, not to mention the potential for side-effects from the potent systemic corticosteroids.

Policies aimed to restrict access were further seen by the imposition of forced waiting times of a year prior to referral for more specialist treatment. 'Right Care' has stated that a minimum duration of symptoms, or a specific threshold of severity should not be used to restrict access to care, and this minimum waiting period of a year clearly contravenes this<sup>6</sup>. Denying a patient early access to surgery, by imposing long waiting times prior to referral, may inversely impact on the outcome of the surgery; increase the risk of complications and negatively impact the patient's quality of life. Recent work has shown that surgery within the first 12 months of persistent symptoms, for those who have failed MMT, achieves greater reductions in disease specific symptoms, measured using the SNOT-22 and post-operative healthcare utilization, both in terms of doctor visits and prescription medication usage, when compared with patients who have surgery at a later stage in their CRS disease<sup>15,16</sup>.

Finally, while we are encouraged that CCGs are no longer recommending plain X-ray imaging of the sinuses, we were disappointed to find that one CCG requires a CT scan prior to referral. The role of the CT scan is primarily to assist surgical dissection as in many cases the diagnosis is confirmed on endoscopic examination, and is normally only requested after MMT has failed or in complex cases (e.g. local complications, systemic disease). Use in

primary care will expose many patients to unnecessary radiation, waste resources, and if not readily available to ENT surgeons, may not even benefit those who require surgery.

We may debate if the commissioning guidelines for rhinosinusitis should be adopted by every CCG within England. This would homogenise practice, eliminating variation in referral rates and hence eradicate the post-code lottery effect. It would provide G.P's with high quality, evidence based management guidelines, allowing for appropriate referral, which may be at an earlier stage in their disease for some patients, but achieve a more cost-effective outcome. We have seen an unexplained decrease in the rates of sinus surgery in England and Wales between 2008 and 2012, based on hospital episode statistics (HES) data (Figure 2). We do not know whether this is due to improved medical management of patients with CRS, but it is likely that restrictions in referral have contributed.

## **Figure 2**

### *Strengths of the study*

This is the first study to assess and discuss the implications of restrictive funding criteria amongst English CCG's for patients with rhinosinusitis. Seeing a specialist for an accurate diagnosis and early treatment is in a patient's best interest and denying them this treatment, perhaps as a money saving exercise, is against the NHS constitution.

### *Limitations of the study*

Only 58 CCG's out of a total of 221 were analysed, hence providing a snapshot of practice around the country.

### *Comparison with other studies*

There are no other published studies looking at this particular question.

### *Clinical applicability of the study*

CCG's are required by law to publish their local commissioning policies. Despite this, forty percent of the CCG's did not have this data freely available on-line, of which twenty five percent ignored two Freedom of Information requests when asked to supply this data. A proportion of the reviewed policies are not evidenced based and open to legal challenge by patients. This study should encourage all ENT surgeons to review the policies of their local

CCG and engage with commissioners to ensure that their patients have evidence-based access to care.

#### *Conflict of interest*

CH was the Chair of the Commissioning Guidance for Chronic Rhinosinusitis Development group<sup>1</sup> and CP was a member of the group. All authors declare no competing interests. No external or internal funding was received for this work.

#### **References**

1. Royal College of Surgeons (2013). Rhinosinusitis; Commissioning Guide; available at: <http://www.rcseng.ac.uk/healthcare-bodies/nscc/commissioning-guides/guide-topics>
2. Audit Commission (2011). Reducing spending on low clinical value treatments; Health Briefing; available at: <http://www.archive.audit-commission.gov.uk>
3. Soni-Jaiswal A, Anderco I, Kumar BNK (2013). Paediatric tonsillectomy; Impact assessment using a validated patient reported outcome measure. *Clinical Governance: An International Journal*. **18**(2),132-8.
4. Royal College of Surgeons England (2014). Is access to surgery a postcode lottery; available at: <http://www.rcseng.ac.uk/news/docs>
5. Department of Health (2013). The NHS Outcome Framework 2014/15; available at: <http://www.gov.uk>
6. NHS England (2013). Commissioning for value; Right Care; available at: <http://www.rightcare.nhs.uk>.
7. Beasley N, Cripps J, Swift S (2013). A Surgical approach to value-based commissioning. *Health Service Journal*.

8. Fokkens WJ, Lund V, Mullol J, Bachert C, Alobid I, Barody F et al (2012). European Position paper on Rhinosinusitis and Nasal Polyps. *International Journal of Rhinology*.**50**(s 23), 1-298.
9. National Institute of Clinical Excellence (2013). clinical knowledge summaries- sinusitis; available at: <http://www.cks.nice.org.uk/sinusitis>
10. Videler WJ, Badia L, Harvey RJ, Gane S, Georgalas C, van der Meulen FW, et al (2011). Lack of efficacy of long-term, low-dose azithromycin in chronic rhinosinusitis: a randomized controlled trial. *Allergy*. **66**(11),1457-68.
11. Wallwork B, Coman W, Mackay-Sim A, Greiff L, Cervin A (2006). A double-blind, randomized, placebo-controlled trial of macrolide in the treatment of chronic rhinosinusitis. *Laryngoscope*. **116**(2),189-93.
12. Watson R (2007). Antibiotic resistant microbes biggest threat to European health. *British Medical Journal*.**334**(7605),1187.
13. Gibbins NE, Theokli C, Hopkins C (2013). Time to reconsider guidelines on clarithromycin in chronic rhinosinusitis. *British Medical Journal*. **346**:f2678.
14. Smith KA, Rudmik L (2014). Impact of continued medical therapy in patients with refractory chronic rhinosinusitis. *International forum of allergy & rhinology*. **4**(1),34-8.
15. Hopkins C, Rimmer J, Lund, V.J (2014). Does time to endoscopic sinus surgery impact outcomes in Chronic Rhinosinusitis? Prospective findings from the National Comparative Audit of Surgery for Nasal Polyposis and Chronic Rhinosinusitis. ePub available online at *Rhinology International Journal* in advance of publication.

16. Hopkins C, Andrews P, Holy CE (2014). Does time to endoscopic sinus surgery impact outcomes in chronic rhinosinusitis. *Rhinology*. ePub available online at *Rhinology International Journal* in advance of publication.

1. Diagnostic criteria should include two or more persistent symptoms for at least 12 weeks, one of which should be nasal obstruction and/or discharge, and/or facial pain/pressure or anosmia. Severity of symptoms should be assessed using a 10-point visual analogue scale to categorise the disease into mild or moderate/severe. Anterior rhinoscopy should be performed to exclude neoplasia or diagnose large polyps. Allergic rhinitis and asthma should be looked for and managed appropriately.
2. Patients with suspected malignancy should be referred urgently using the 2 week wait referral pathway
3. Plain sinus x-rays should not be used
4. All patients should be offered saline irrigation and intranasal corticosteroids. Antibiotics are not recommended. If large polyps are visible, oral prednisolone for 5-10 days, followed by topical nasal steroid drops for 4 weeks, may be used.
5. Patients with moderate/severe symptoms, despite three months of topical therapy, or those with large polyps that have not responded to four weeks of treatment, should be referred for a specialist opinion. For those with mild symptoms, medical treatment may be continued in primary care
6. Patients should be provided with written information and actively engaged in their treatment decisions.

**Figure 1; Rhinosinusitis Commissioning guide, Primary Care referral pathway<sup>1</sup>**

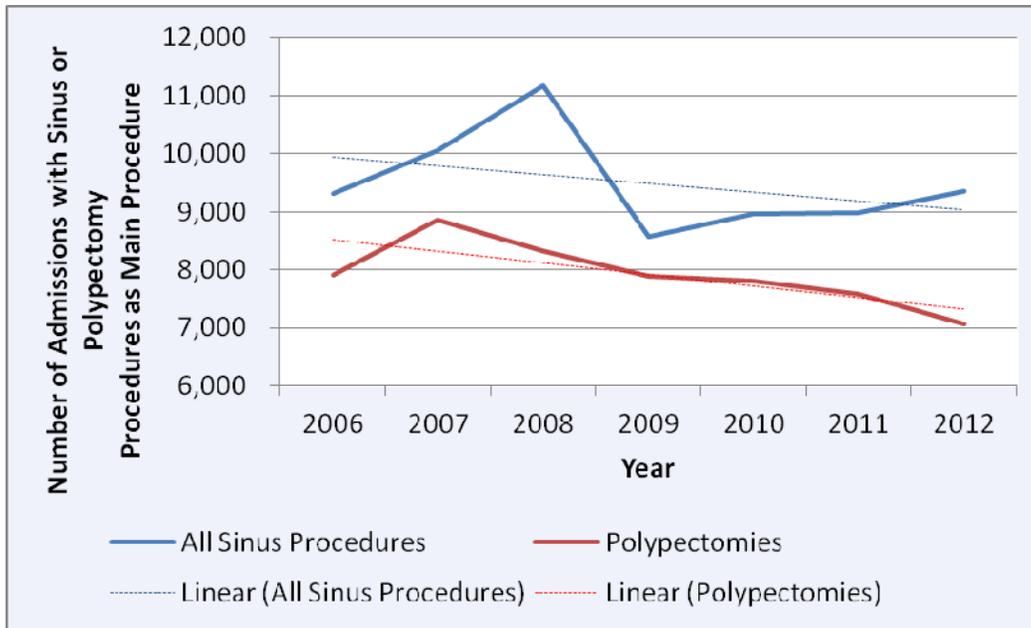


Figure 2; declining rates of admission with polypectomy or sinus surgery, listed as primary procedure, on the Hospital Episode Statistics (HES) Website

RCS guidance	Kernow	Wokingham	North Hampshire	Barnet	Bury	Haringey	Islington
Clinical symptoms >12 weeks	No	No	no	yes	Yes	Yes	No
Severity using VAS scores	No	Advise SNOT 22	no	no	no	No	No
Anterior rhinoscopy findings	No	no	no	yes	<i>Along with facial palpation</i>	Yes	No
Manage allergic rhinitis and asthma	no	no	no	no	no	No	No
Red flag symptoms	yes	yes	no	yes	no	Yes	Yes
Use Nasal saline irrigation	yes	yes	yes	yes	yes	Yes	No
Use intranasal steroids	yes	yes	yes	yes	yes	Yes	Yes
Antibiotics not recommended	<i>Recommend use – details not given</i>	<i>Recommend use – details not given</i>	<i>3 months of a macrolide</i>	no	<i>Recommend use– details not given</i>	No	No
If nasal polyps- single course of oral steroids for 10/7, followed by nasal drops	Yes	<i>Yes; but to be repeated three times at three monthly intervals prior to referral</i>	<i>Yes; but to be repeated at three monthly intervals</i>	no	no	No	No
Refer to secondary care if moderate/severe symptoms after	No	no	<i>Yes, after one year</i>	Yes, after three months	Yes – no time-frame given	Yes, after three months	Yes, after three months

<b>three months of treatments</b>							
<b>Do not use sinus x-ray</b>	<i>They suggest G.Ps arrange a CT scan for polyps</i>	no	no	no	yes	no	no
<b>Age/sex standardized activity (100,000 population)</b>	27.4	27.0	16.9*	24.6	24.9	15.7*	19.9

**Table 1; Summary of CCG PoLCE policy findings and their compliance with the RCS advanced surgical standards and ENT-UK commissioning guide; 2013**

**Appendix 1;**

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Clinical Commissioning Groups

Barnet	Basildon and Brentwood
Bassetlaw	Bedfordshire
Blackpool	Bury
Calderdale	Cambridgeshire and Peterborough
Cannock Chase	Castle Point and Rochford
Coastal West Sussex	Croydon
Cumbria	Dudley
East and North Hertfordshire	East Leicestershire and Rutland
East Riding	East Staffordshire

East Surrey	Eastbourne, Hailsham and Seaford
Gloucestershire	Great Yarmouth and Waveney
Haringey	Harrow
Hillingdon	Islington
Kernow	Kingston
Leicester City	Liverpool
Luton	Mid Essex
Newbury and District	North and West Reading
North East Lincolnshire	North Hampshire
North Somerset	North Staffordshire
North Tyneside	Oldham
Oxfordshire	Portsmouth
Rotherham	Sandwell and West Birmingham
Shropshire	Somerset
South East Staffordshire and Seisdon Peninsular	South Gloucestershire
South Reading	Stafford and Surrounds
Stoke on Trent	Wakefield
Wandsworth	Warrington
Warwickshire North	West Cheshire
West Leicestershire	Wokingham