Is Our South East London Area Prescribing Committee Working To Best Practice, Or Could We Be Even Better?

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Summary

This paper:

- outlines our collaborative partnership across all local stakeholders
- describes the formal annual work plan
- summarises our funded resources that are available to support the groups
- offers our model of a safe, consistent approach to medicines use in South East London
- seeks view on whether the model could be improved.

Introduction

As in all health communities, there has been considerable change in the NHS in South East London (SEL) in recent years, but alongside the transformation of services there remains the need to continually ensure medicine use is both clinically and cost effective. The primary care spend on medicines across the six boroughs in SEL is approximately £200m, with an estimated additional Clinical Commissioning Group (CCG) cost of approximately £17m for high cost drugs (i.e. 'Payment by Results' excluded drugs) for 2015/16.

At times of reorganisation, personnel move on, often taking with them organisational memory. The SEL Area Prescribing Committee (APC) ensures that there is an ongoing consistency for decision making at times of such change. It is the result of a commitment from all CCG clinicians and medicines optimisation teams, as well as from colleagues in provider organisations, to ensure medicine use remains safe and consistent across the area covered, despite the significant changes in the NHS locally. Attendance at all meetings is good and clinicians have prioritised their involvement. The SEL APC aims to provide a consistent, high quality approach to clinical decision making about medicines across the local health economy.

The aim of this article is to explain our current SEL APC model and to understand if we are providing and implementing best practice for our patients and clinicians, compared to other APCs across the country. Pharmacy Management have offered to assist in this by conducting a survey of local APC arrangements and disseminating the outcomes so that additional ideas can be incorporated as appropriate at a local level. The outcomes from the survey could also contribute to a new document showcasing current best practice for APCs.

The South East London Area Prescribing Committee

This was established in February 2013. It is a forum where each CCG, Acute Trust and Mental Health Trust in SEL has signed up to jointly discuss and agree pertinent medicines issues. The Committee represents a partnership of NHS organisations involving six CCGs, three Acute Trusts and two Mental Health Trusts in SEL, with a nominated Lead Clinician and Lead Chief Officer identified from within the SEL CCGs .

There are strong links with the Health Innovation Network (South London) to support work in the medicines elements of diabetes.

Support and leadership from the Chairs and Vice-Chairs and the Chief

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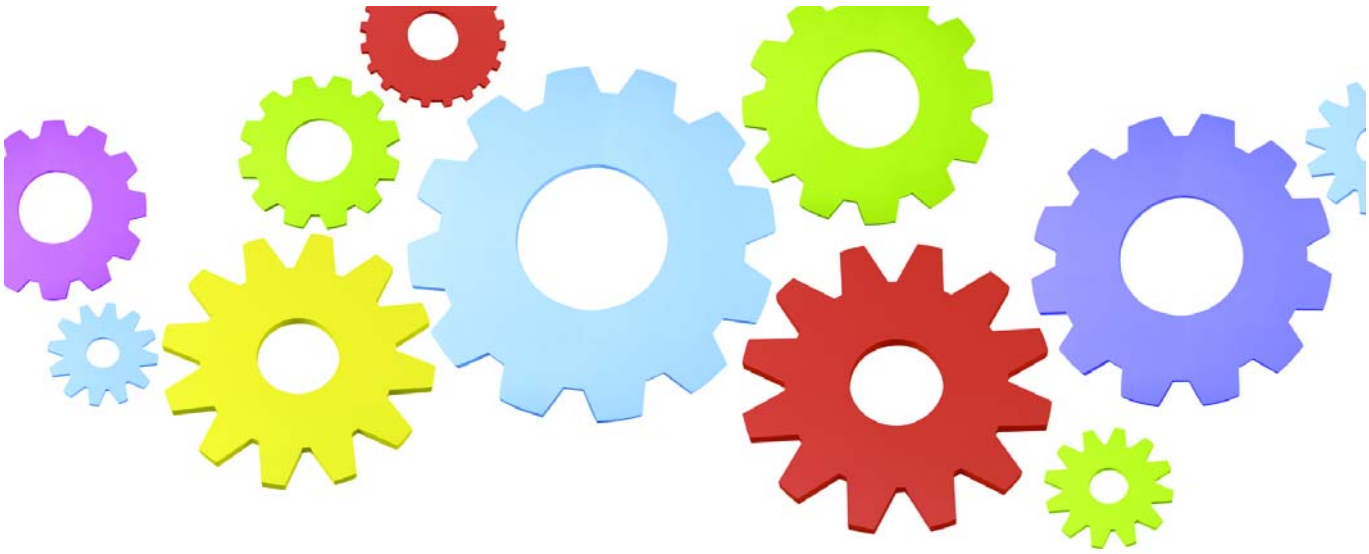

The APC is a partnership of local organisations

Officer (from a variety of SEL organisations) has been invaluable. Although membership of the committee is large and varied, commitment to making it successful is high across both commissioners and providers. Many members describe their enjoyment at participating in the APC. GPs are positive about the outputs of the APC, reporting that it offers consistency and reduces inappropriate requests.

The Committee has the following remit:

- To provide a collective clinical leadership committee to ensure co-operation and consistency of approach to medicines optimisation across SEL.
- To enable clinicians, providers and commissioners to work together to ensure that patients have safe and consistent access to medicines in the context of care pathways which cross multiple providers.
- To advise on implementation of best practice around medicines, including NICE guidelines and technology appraisals, to encourage rapid and consistent implementation.
- To enable local NHS stakeholders and clinicians to exert a population approach to the prioritisation, improvement and development of healthcare delivery related to medicines.

The SEL APC uses a prioritisation approach, taking account of the financial position of its constituent organisations, when considering any new application that is outside of the NICE Technology Appraisal (TA) process. Any decision for change from the APC needs consideration of where funding will be found; this may be from new money, the need to disinvest or a change to the current pathway.

National guidance on APCs

In 2000, the National Prescribing Centre produced a document entitled 'Area Prescribing Committees - maintaining effectiveness in the modern NHS' but, with the national NHS transformation, this is no longer current or readily available.

In 2003, following another NHS reorganisation, an article was published in the Pharmaceutical Journal,[1] in which the author asked: 'Area Prescribing Committees - what is their role in the new NHS?' He went on to discuss how one APC was adapting to the changing National Health Service, similar to what the SEL APC describes here.

In 2012, NICE published 'Developing and updating local formularies (MPG1)' which provides good practice recommendations for the systems and

processes needed to ensure that NHS organisations develop and update local formularies effectively and in accordance with statutory requirements.[2] This goes some way to advising on the membership, governance and outputs of an APC.

The remit of our SEL APC is far wider than just formulary inclusion. Along with clinical effectiveness, we also consider funding, commissioning of both drugs and services and the overall budgetary impact across our whole health economy.

Current SEL Prescribing Committees

In SEL we have two main committees - the APC and New Drugs Panel (NDP). These are supported by a set of time-limited subcommittees, together with other prescribing groups.

Area Prescribing Committee (APC)

This strategic committee meets every 12 weeks. It reports and is accountable to the SEL Commissioning Strategy Committee (CSC). It is advisory to the SEL CCGs, who have agreed inclusion of its recommendations into the SEL collaborative commissioning agreement, which will uphold the APC recommendations, unless very exceptional circumstances prevail.

The committee has Terms of Reference (ToR) which are reviewed, agreed and updated annually and presented as part of the APC Annual Report to the SEL (CSC). These ToR set out the governance and remit of the SEL APC (including the NDP, see below). The ToR are included in the SEL collaborative commissioning agreement.

Our APC continually reviews its decision making processes based on the DH guiding principles and best practice as defined by NICE.

The APC is the single point of entry for new medicines or new indications for medicines (i.e. not devices or interventions) in all the following situations where:

- the cost impact assessment (including both medicines and activity costs) is likely to be significant to our local health economy
- the intervention is likely to have a high impact for the needs of the population
- a major change in the care pathway or model of care is required
- there is likely to be a high risk of challenge to decision making and a SEL wide approach would reduce this risk.

The APC also advises on best adoption and implementation in line with NICE where primary care or commissioned medicines are subject to a new NICE technology appraisal.

Core membership and partner organisations

Nominated representatives are responsible for ensuring two way reporting, implementation and feedback to the APC via relevant committees such as the Drugs and Therapeutics Committees in the member organisations.

The Chair of the SEL APC is currently a CCG chair (GP) and is nominated by the CSC; the tenure of the Chair is two years with the possibility of a further two years.

A Chief Officer, who is a manager not a clinician, regularly attends meetings, broadening the discussions but also closing protracted deliberations thus ensuring that the meetings remain focussed. He brings a different dimension compared to the clinicians and provides a valuable link to other SEL work (e.g. health innovation and transformation work), which otherwise may not be apparent to the members.

Each of the partnership organisations nominates one GP/Consultant and one Pharmacist member; a consultant in Public Health and the Director of Medicines Information from Guy's and St Thomas' NHS Foundation Trust (GSTfT) complete our core membership. The CCG Chief Pharmacists have regular teleconferences; it is their responsibility to ensure we have a collaborative APC.

Each member is the representative of a 'constituency' (e.g. organisation) and is accountable to the constituency for ensuring that their representation reflects their view. Members are responsible for ensuring representation - if they cannot attend a deputy must be arranged or comments given to the Chair in advance of the meeting. An attendance rate of below 50% is flagged to the Chair for consideration of any action to be taken.

Any potential conflicts of interest are declared and recorded. A report is made available for public scrutiny. In the case of committee members, if appropriate, they may be asked to leave the room during the decision making process if a potential conflict of interest arises.

Where appropriate the committee invites and actively seeks the views of appropriate consultant and/or service leads for specific issues in order that decisions are made with full acknowledgement of specialist expertise and reflect the need of the local health economy.

Engagement with clinical groups and networks, especially if a formulary decision needs specific knowledge and expertise or has direct implications for a clinical practice area, is undertaken as required with:

- patients or patient representative groups e.g. for our diabetes and inflammatory bowel disease pathways
- local people and communities
- local clinical specialists
- relevant manufacturers of medicines, for example, when the company can offer additional evidence and insight that can assist with decision-making
- other relevant decision-making groups.

It is ensured that stakeholder engagement is proportionate to the type of decision being made and the medicine being considered.

The SEL APC is fortunate to have local input and membership from the Regional Medicines Information Centre, based at GSTfT, which is one of the core member Trusts. They provide active support to the APC's horizon scanning, NICE implementation and the NDP new medicines evaluation processes.

In attendance at our APC

The following are in attendance:

- NHS England (NHSE) London Area Team has membership of the Committee to provide communication and alignment on the management of the specialist drugs they commission. Attendance has been challenging, due to their small team, but with the recent recruitment of an embedded Medicines Optimisation Pharmacist it is hoped this will be addressed going forwards.
- South East London Commissioning Support Unit (CSU)
- Specialised commissioning, NHSE
- Consultant Pharmacist, cardiovascular disease
- A Community Pharmacist, nominated by South London Local Education and Training Board (LETB)
- A Lay Member nominated by Healthwatch, the consumer champion for health and social care.

Other key relationships

These are:

- CCG Medicines Management Committees (formal receipt of minutes)
- Provider Trust Drug and Therapeutics Committees and Formulary Committees (formal receipt of minutes)
- Community Health Services in SEL
- Other London APCs
- SEL Individual Funding request (IFR) Panels.
- Local Medical Committee (LMCs)
- Local Pharmaceutical Committees (LPCs)
- Local Professional Networks
- Local Authority
- Patients/public
- Pharmaceutical Industry. Involvement comes from linking with the Academic Health Science Network (via our membership) and budget impact modelling for new drugs.

APC Resources

The SEL APC resources and leadership required across the partner organisations are reviewed on a regular basis by our member organisations, with the SEL CSC retaining oversight.

All six CCGs in SEL contribute to 0.4WTE business management and 0.4WTE pharmacist leadership and support time for the APC; these roles are hosted by Lambeth CCG. The pharmacist is currently seconded from one of the Acute Trusts.

Electronic papers are distributed to the members seven days before each meeting. Minutes and outputs of the Committee are published to the APC website; this is hosted by Lambeth CCG. All SEL APC partner organisations either already signpost or have committed to signposting users of their websites to the SEL APC website.

All of our member CCGs have signed up to sharing the workload of delivering and leading pieces of work on behalf of the SEL APC; this ensures every partner CCG is fully engaged in the APC's work. The SEL APC work plan ensures engagement and leadership opportunities for all of our CCGs on a rolling basis. For each work area one CCG is designated as the lead CCG and is then responsible for ensuring the agreed timescales are achieved. A supporting CGG is also identified. An update on progress against the work plan is noted as a standing item on each APC agenda. Our work plan is divided into broad pathway reviews and narrower therapeutic or project areas.

Outputs of the SEL APC in 2014/2015

- Reviewed, consulted on and approved 17 guidelines/pathways.
- Consulted on, agreed and published a red list for SEL (drugs suitable for hospital only prescribing).
- Reviewed, consulted on and approved four shared care/transfer of care guidelines.
- Received and resolved one appeal against a 'grey' (not for prescribing) decision.
- Regularly forward planned for NICE technology appraisals.
- Withdrew one shared care guideline following publication of NICE clinical guideline not supporting the treatment.
- Undertook a horizon scanning exercise with SEL Trusts to assist with planning for the APCs 2015/16 work plan.
- Consulted on, agreed and issued a position statement on the commissioning of the biosimilar infliximab.
- The SEL APC co-ordinated a response on behalf of six SEL CCGs to a national campaign, led by NHS Clinical Commissioners, seeking support for a national solution to the use of unlicensed intravitreal bevacizumab for wet age-related macular degeneration. The process used to reach a consensus decision across SEL to support the campaign demonstrated just how well engaged SEL APC members are.
- The NDP considered and made decisions for 18 new medicine submissions and issued 17 recommendations for these medicines, with only one deferred. Of the 18 submissions, approximately 80% resulted in recommendations for approval (categorised as either red or amber or green).

New Drugs Panel

The NDP meets every four weeks as an active working group of the APC. It provides a strong focus on quality and prioritisation and reporting to and advising the APC on the entry of new medicines into our local health economy, in line with the principles outlined in the APC ToR. The Panel assesses new medicines for prescribing within SEL where these are intended to be prescribed in primary care or commissioned by CCGs. NDP recommendations require ratification by the APC; this is usually via Chair's action when a full consensus has been reached; otherwise (or if a decision is likely to have significant implications) a full circulation to the APC for ratification is undertaken.

The NDP has Joint Chairs - a CCG GP Lead and a Trust Consultant, who are recruited from the membership of the APC.

The NDP liaises closely with the local Acute Trust Joint Formulary Committee via its membership.

The NDP is supported by Formulary Pharmacists in the member Acute and Mental Health Trusts, member CCG Medicines Management Teams and GSTfT Medicines Information, who provide triage and horizon scanning.

APC Subcommittees

Pathway Groups

These take between 6-12 months to fully develop a pathway, ensuring all stakeholders are involved. An example completed in 14/15 is the Inflammatory Bowel Disease (IBD) pathway group. This was a short-life working group of the APC, which brought together key stakeholders across SEL to develop comprehensive disease management pathways for IBD (Crohn's disease and ulcerative colitis). The pathways cover the treatment of IBD from diagnosis to the use of the more complex biologic agents.

The final pathways are an example of real clinical commitment and engagement with all partners working together to achieve consistency and improve the patient experience. As part of the development process, the working group held a valuable and successful patient engagement event to identify where in the pathway quality improvements could be made. A second event is being planned to present the finalised pathway to patients.

This work resulted in a potential increase in cost (~£158K/100,000 population) relating to two recommendations arising from the IBD biologics pathway. However, these costs have been offset locally by efficiencies in the pathway such as the use of dose banding, dose optimisation and cost effective choices of medicines across the pathway. Contract monitoring will be agreed with the Trusts and implemented for this pathway with support from the SEL CSU.

The rheumatology pathway group is about to be reconvened in anticipation of the NICE MTA publication in 2015.

Task and Finish Groups

These work to a set timetable.

A number of cardiovascular guidelines were approved by the SEL APC in 2014/15. These were co-ordinated by the Consultant Cardiovascular Pharmacist for South London and provide common guidance across SEL for a number of indications, including:

- a position statement on stroke prevention in atrial fibrillation
- an algorithm to guide choice of novel anticoagulant agents for stroke prevention in AF
- a summary of the available antiplatelet options in cardiovascular disease
- guidance for managing uncomplicated hypertension.

Other prescribing groups

Trust Prescribing Committees

The local Trusts retain a Joint Formulary Committee which considers new drugs and changes of use of existing drugs which are used only within hospitals and are not subject to any specific commissioning arrangements. Individual Trusts also maintain Drug and Therapeutics Committees/Prescribing Committees within their organisations.

Borough Committees

These six committees consider local CCG priority items and most have Local Authority and Community Pharmacy membership; these do not formally work collaboratively but aim to avoid postcode prescribing and APC minutes are ratified by these committees.

Work Plan for the SEL APC and its subcommittees

The APC develops a work plan with specific objectives which is reviewed regularly and formally on a 12 monthly basis; this assesses the outputs of the APC against the benefits identified during a scoping exercise we undertook in 2012, which were:

"The NDP . . . provides a strong focus on quality and prioritisation . . . advising the APC on the entry of new medicines into our local health economy . . ."

- an ability to assess medicines use across the whole care pathway and move beyond a simple assessment of one drug against another
- a forum where a decision can be made about appropriateness of prescribing in different settings so that prescribing can take place in the right place. Shared care guidelines would be included in this
- the costs of medicines can be assessed as part of the managed entry process, which can also incorporate a local reality check on NICE drugs and possible phased implementation of new medicines
- the APC would be able to work in the 'grey areas' i.e. clinical consensus can be gained where there may not be strong evidence for a medicine or there is a complex risk vs. benefits balance to be struck
- reduce bureaucracy associated with management of Payment by Results excluded (PBRe) drugs and IFRs
- transparency of Quality, Innovation, Productivity and Prevention (QIPP) savings – the APC could be explicit about potential shifts between medicines spend and subsequent investment or disinvestment in services/activity
- mapping of local need – using public health expertise we would be able to determine likely uptake of national guidelines locally and prioritise based on our local population
- consistency of access to medicines – we would enable Trusts to ensure consistency between clinicians in prescribing or recommendations to GPs to prescribe
- forecasting local spend on drugs and potential QIPP initiatives (using our local Medicines Information expertise to distil national horizon scanning information)
- management of new drugs or indications 'pre-NICE' and implementation planning
- monitoring of usage data and spend on medicines – highlighting where local uptake is higher or lower than expected.

What is the SEL APC planning for 15/16?

As part of the drug service development process for 2015/16, the APC requested local Trusts to submit horizon scanning requests for anticipated new medicines using an agreed template. Based on this exercise, the 2015/16 forecast cost pressures for SEL CCGs are likely to be around £1.3 million across SEL, although there are many large caveats on these costings and they exclude the impact from NICE technology appraisal guidance anticipated in year.

There is a section within the work plan to support the development of the APC around collaborative working to ensure that all constituent groups are given full opportunity to be aware of and be involved in pathway/therapeutic area developments.

The SEL APC has identified the following key priority areas for 2015/16:

- Continuing to manage the introduction of new medicines into our local health economy – including formulary submissions and horizon scanning.
- Development and implementation of a SEL Respiratory Prescribing Group to inform the APCs decision making process around respiratory medicines
- Improved collaborative working around the medicines optimisation mental health agenda.
- To continue to progress expert patient involvement and engagement in decision making around pathway development.

Appeals Process

Our APC received its first appeal in 2014, offering us an opportunity to review our methodology. It was resolved through a 'resubmission with further information' process rather than a formal appeal. The appeal resulted in some important learning for our Committee:

- The ToR for the SEL APC have now been updated to include grounds for appealing against decisions made by the Committee.
- The outcome letters that are sent to applicants following a new drug submission now detail the grounds for appeal and who these should be directed to.

ToRs have been developed for the appeals panel by the secretariat of the SEL Clinical Strategy Committee (CSC). The appeal panel will be supported to discharge its responsibilities administratively by the secretariat of the SEL CSC.

Any appeals against APC decisions should be directed to the CSC Chair. Appeal requests must be submitted in writing to the chair of the CSC within 30 days of the date of the decision. The appeals process gives applicants the right to appeal an APC decision if they feel that the process leading to the decision being made was not followed correctly. The Appeal Panel does not consider whether the decision was clinically right or wrong and cannot change the assessment criteria agreed by all six SEL CCGs. There are three grounds for appeal that can be considered:

- Illegality: the refusal of the request was not an option that could lawfully have been taken by the APC.
- Procedural impropriety: there were substantial and/or serious procedural errors in the way in which the process of reaching a decision was conducted.
- Irrationality: the decision was irrational in light of the information available to the Committee e.g.
  - There were any material shortcomings in the consideration of the request.
  - There was consideration of relevant factors only and no irrelevant factors.

– The decision was not reasonable taking into account all the available information and evidence.

The appeal panel will assess if the APC has followed its own processes accurately. The results of the appeal will be communicated directly to the appealing clinician and the APC who will review the decision if required. The review panel will be set up by the SEL secretariat of the CSC as required.

Proactive reviews of the APCs decision making processes will be carried out on an annual basis via scrutiny of individual examples.

Weakness/Challenges

Although we feel our SEL model has lots to offer, there is no national document to guide practice. It is difficult to understand if we are covering everything other APCs do. We would like to understand what other health care communities provide locally so that we could add to our work to improve our process.

Not all participants attend our meetings on a regular basis; we are currently exploring the use of teleconferencing facilities to understand if this would encourage attendance or promote agreement to become a member of one of the groups.

GPs can request a new addition to the Formulary, but this is very uncommon.

Lay/patient/public members are currently recruited from Healthwatch - is there an alternative?

How do we keep all participants involved e.g. Mental Health and the smaller Acute Trust?

There is a place on the committee for a nominated Community Pharmacist, but currently there is no member - how do we get engagement from this sector?

Bordering CCGs - we know there are inconsistencies which could result in postcode prescribing.

We do not provide training for our members but this may be particularly useful for lay/patient members.

Are the recommendations and guidelines we develop helpful and are they being used? We have developed a local survey which will hopefully provide an answer.

Succession planning for members and Chairs needs to be more robust.

What next?

The benefits of the local Primary Care investment in a Consultant Cardiovascular Pharmacist are evident from the outputs achieved in this therapeutic area. The appointment to a Consultant Respiratory Pharmacist post will allow similar achievements going forwards and the recent work to develop a diabetes post should provide similar benefits.

Our SEL APC is dynamic and continuously evolving to support the needs of an ever changing NHS, but we would welcome constructive comments on how we can make it even better and some help with the weaknesses/ challenges we have identified.

We have developed a local survey to send to committee members and other interested parties to understand their opinions of the current SEL APC and how we can make it better. It is hoped to publish the results and to use it to benchmark with other APCs.

It is intended to participate in the proposed Pharmacy Management survey to understand the national picture for APCs and to determine how they might have changed since 2013 and development of an updated document to demonstrate what makes an effective APC.

Declaration of interests

- None

Acknowledgment

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