

# Safe Therapeutic Economic Pharmaceutical Selection (STEPSelect): development, introduction and use in Northern Ireland



**Professor  
Mike Scott  
PhD**



**Professor  
James McElroy  
PhD**



**Robert  
Janknegt  
PharmD, PhD**

**Jill Mairs, BSc, PhD  
Rob Brenninkmeijer, PharmD**

**P**harmaceutical care faces great challenges due to ever increasing drug costs, increasing numbers of adverse events, poor adherence, medication errors and inadequate communication across the primary/secondary care interface. The recent global economic crisis has resulted in increased awareness of the costs and outcomes of pharmaceutical care.

In Northern Ireland an integrated medicines management project was undertaken which has achieved significant patient benefits including reduced length of stay in hospital, reduced re-admission rate, a more accurate medicine history and an improved discharge process [1]. One of the key issues identified as part of this work was the problem of a lack of product standardisation

**The implementation of a new model for drug selection in Northern Ireland has improved the quality of prescribing, safety and reduced costs.**

between the primary and secondary care sectors. This causes significant problems for elderly patients who constitute over two-thirds of emergency admissions to hospital. Whilst there had been a joint prescribing formulary within the area where the work was undertaken, this did not effectively address the problem due to the inherent difficulties with such systems. It was clear that a more robust method was needed to address this issue, utilising some form of medicine selection model. A rational and transparent model for medicine decision-making for formulary inclusion purposes has been developed in The Netherlands, namely the System of Objectified Judgement Analysis (SOJA) [2]. This system was used in the Safe Therapeutic Economic Pharmaceutical Selection (STEPSelect) project.

## Method development

The aim was therefore to develop a system which would:

- allow medicine selection within a medicine class across a wide range of indications
- give clinical efficacy and safety primacy over cost
- be suitable for the development of user-friendly and easily accessible guidance which would standardise cost-effective prescribing across both primary and secondary care.

## Procurement in secondary care

The procurement of pharmaceutical products for secondary care is carried out on a rolling three year basis, to which all of the hospital trusts contribute. The tender is carried out using the approved names of all the requisite products, with estimated volumes being submitted for these agents. However, whilst this system is robust and effective there are deficiencies, namely:

- lack of a primary care element/consideration in the process
- significant disparity between primary and secondary care prescribing and consequently no integration
- the use of the approved name of each individual agent within a therapeutic class resulted in prices being submitted for each of these products, however, there was no mechanism to effectively compare them on a therapeutic evidence-derived, more competitive basis, thus leading to less than optimal healthcare resource use.

## Procurement in primary care

In the primary care sector, the National Health Service (NHS) list price is set under the Pharmaceutical Price Regulatory Scheme (PPRS) by the Association of the British Pharmaceutical Industry (ABPI) and the government. This ensures that there is a balance between the price to the NHS and the profitability of the industry in the UK, in order to promote research and development and thus the production of new agents which can further improve patient care. The price paid by the Central Services Agency (which remunerates community pharmacists) for any given product is laid down by the medicine tariff, with the community pharmacist supplying the most cost-effective product which they can procure.

Therefore, it can be seen that there is a lack of integration between the sectors in terms of product use. This results in problems for patients, in not only obtaining optimal benefit from their therapy, but also increased occurrence of medicine-related adverse effects. This product mismatch mitigates against the development and maintenance of a robust, high quality, integrated approach to medicine selection, which is actively promoted as a system to enhance high quality, safe and effective patient care.

## STEP – Select methodology

- STEP I Clinical evaluation
- STEP II Risk assessment
- STEP III Budgetary impact analysis
- STEP IV Final procurement selection

### STEP I – Clinical evaluation

The basis for Step I, the clinical evaluation aspect, was based on the SOJA system. In the SOJA method, rational and standardised selection criteria for a given group of medicines are prospectively defined and the extent to which each individual medicine fulfils the requirement for each criteria studied. Each criterion is given a relative weight determined by an expert panel in this area. The more important a criterion is judged, the higher the relative weight for this criterion. Next, the properties of all agents within a therapeutic class are compared against the hypothetical 'ideal' medicine for this group and each product is given a percentage of the score of the 'ideal' medicine. A detailed description of the methodology is provided elsewhere [2, 3]. The draft scoring system arrived at by the expert panel was then circulated to secondary care consultants in Northern Ireland with an interest in the specific therapeutic area, key decision makers, including general practitioners with special interests in pharmacotherapy in primary care, specialist clinical pharmacists, primary care prescribing advisors, other specialist healthcare professionals and the ABPI. They were asked to comment on the scientific correctness and completeness of the manuscript.

The final part of this step was to send the matrix to all relevant pharmaceutical companies to complete together with any additional evidence not already identified. The companies were made aware of the implications of the process. It was envisaged that within any given therapeutic area at least 70% of the prescribing of the products in that particular class will be constituted by the agents selected at the end of the process. Acquisition cost was not taken into account as a criterion during this step, to allow a pre-selection of drugs on quality aspects only. At the end of STEP I only products which have satisfactorily met the clinical evaluation criteria as described will proceed to STEP II.

### STEP II – Risk assessment

The second phase of the evaluation process

focused on factors which could impact upon the safe use of the various products during routine use by patients. The process was divided into two separate but related elements:

#### *Critical information*

This includes labelling (English language products only), packaging, storage conditions, blisters and patient information leaflets.

#### *Added value*

This includes: calendar packs, EAN barcode, pack size, tablet/capsule colouring and marking, and label instruction space. Initially, a proforma, developed by the Northern Ireland Regional Medicines Governance Team, was used to score the information received for the elements identified in this step. This has now been superseded by the use of a modified version of the 'Quality Assurance and Risk Assessment of Licensed Medicines' for the NHS, as well as taking account of the 'National Patient Safety Agency Purchasing for Safety'.

Product lines were only accepted if they met the criteria set out in the critical information step. The product lines related to those medicine entities which had progressed from the clinical evaluation step, and then passed the risk assessment step (combined scores) were included in the budgetary impact analysis step.

### STEP III – Budgetary impact analysis

In this phase the costs of each available strength of each individual product was determined and related to the Defined Daily Dose (DDD), as laid down by the WHO, in order to estimate the expected overall costs of each of these drugs. This was carried out to ensure that true cost comparisons were calculated, as the equivalent DDD varies from one therapeutic agent to another. The total costs were calculated on the tendered price for secondary care and the current NHS price as set by the PPRS, for primary care as appropriate.

### STEP IV – Final procurement selection

The expert panel then decided, on the basis of the budgetary impact analysis, which of

the products that had passed Steps I and II should be recommended to constitute 70% of the requirement for that therapeutic class. The rationale for a 70% target was to ensure that there was sufficient scope to enable the treatment of both more complex (mainly in secondary care) and well-stabilised (chiefly in primary care) patients to be accommodated, thereby ensuring that all patients can be treated optimally.

### Regional system

The initial project was carried out on a pilot basis within one area of Northern Ireland but has now been adapted in the light of learning points to become the regional system. It has also been renamed STEP-Select. Regional expert groups have been set up for each class being considered and will remain as permanent standing groups. This is due to the dynamic nature of the work, where there will be an ongoing requirement to maintain and develop product selection in the light of both new clinical information and new products. All SOJA productions are updated several times per year. In addition the process has been sped up by the development of electronic tools and e-sessions to maximise involvement in the process for practitioners.

Guidance will also be produced to complement the final product selection, thereby enhancing safe and effective product utilisation, chiefly for the primary healthcare sector. This guidance takes the form of a single A4 sheet reflecting both the outcomes of the selection process and the key information points to assist with optimal prescribing. Further, it is the intention that this guidance will also be incorporated into an electronic prescription system, which will greatly facilitate the implementation process.

The fact that this process is linked to the procurement process ensures full compliance with all European regulations, which is critical to emphasise the robust, transparent, objective nature of the system. In addition, the process is also linked to the general practitioners quality and control framework and prescribing incentive scheme, thereby giving a very coherent process which is owned, and indeed, driven by the major stakeholders such as consultants,

general practitioners, with full support from the relevant specialist clinical pharmacists. The deliberations of the various expert groups will be formatted in interactive decision matrices on [www.stepselect.com](http://www.stepselect.com), which will be accessible to all registered healthcare professionals in Northern Ireland. Selected productions will also be accessible to tendering manufacturers. These matrices will be updated regularly in order to ensure that they remain current in the light of the rapidly changing products available and therefore fit for purpose as a dynamic up-to-date aid to safe and effective prescribing.

The savings achieved with STEPSelect are considerable. This process is an integral part of a comprehensive eight component programme, namely Pharmaceutical Clinical Effectiveness (PCEP). The programme itself was initially financed by the Department of Health, Social Services and Public Safety (DHSSPS), as part of the whole PCEP. Over the last four years, savings of the order of GBP 100 million (Euros 115 million) in total have been achieved. With specific respect to STEPSelect, it is estimated to have contributed of the order of GBP 20 million (Euros 23 million), i.e. approximately GBP 12 (Euros 14) per capita per year. As a large number of SOJA and InforMatrix programmes are available, the STEPSelect project can be applied to other medicine classes as well, thereby potentially increasing the expected annual savings to well over GBP 20 (Euros 23) per capita per year.

## Conclusion

The system has now been used for statins, proton pump inhibitors, angiotensin receptor blockers, ACE inhibitors, selective serotonin reuptake inhibitors, and wound dressings, with a comprehensive programme of work underway to cover the range of classes of products required, including medical and surgical devices. The system has improved the quality of drug selection as evidenced by the relative use of the selected agents in any particular therapeutic class, in conjunction with a concise guidance note. This should, potentially, also improve safety since the guidance sheet or flow chart will highlight those agents that say, for example, have good evidence for use in patients with renal problems. At the same

time it has reduced costs considerably, in other words, Safety + Quality = Improvement and Efficiency (S + Q = I + E). The system has the potential to be applied in other countries or regions.

## Authors

Professor Mike Scott, PhD, MCPP, FPSNI  
Head of Pharmacy and Medicines Management  
Antrim Hospital, Northern Health and Social Care Trust  
45 Bush Road  
Antrim BT41 2RL, Northern Ireland  
[drmichael.scott@northerntrust.hscni.net](mailto:drmichael.scott@northerntrust.hscni.net)

Robert Janknegt, PharmD, PhD  
Hospital Pharmacist and Clinical Pharmacologist  
Orbis Medisch Centrum  
1 Dr H van der Hoffplein  
6162 BG Sittard-Geleen, The Netherlands  
[r.janknegt@orbisconcern.nl](mailto:r.janknegt@orbisconcern.nl)

Jill Mairs, BSc, PhD, MPA, MCIPS  
MPSNI  
Regional Pharmaceutical Procurement Pharmacist  
Northern Health and Social Care Trust

Whiteabbey Hospital  
Doagh Road  
Newtownabbey BT37 9RH, UK

Professor James McElnay  
Pro-Vice Chancellor  
The Queens University of Belfast  
Belfast BT7 INN, Northern Ireland

Rob Brenninkmeijer, PharmD  
Pharmacist  
Digitalis BV, Amsterdam, The Netherlands  
Digitalis Medicines Management, Dublin  
Ireland

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## Summary of key elements of the STEPSelect approach

- Evaluation of all available evidence relating to efficacy, evidence, safety, tolerability, ease of use, medicine interactions and experience.
- Continuous updating of relevant new literature to ensure that the products with the best evidence continue to be used to produce optimal patient outcomes.
- The information is available in an interactive matrix model to allow the determination of the personal preference based on the weighting of the selection criteria.
- Various interactive tools are available to allow involvement of a large number of general practitioners, clinicians and pharmacists in the selection of the optimal medicines.
- The top 3–4 medicines are selected within a class based on the weightings assigned by the panel. Acquisition cost is not taken into consideration at this stage, allowing a preselection of medicines on quality aspects only.
- Risk assessment of the packaging to minimise difficulties for patients in safely and optimally using their medicines.
- Reduced medicine costs due to the fact that of all of those products that meet the evidence and safety as outlined, the most cost effective are then selected to deliver the desired outcomes at minimised cost to the health service.
- A concise evidenced-based guidance sheet or flow chart, as appropriate, to assist in the use of the products, thereby optimising therapy but with tailoring based on patient-specific characteristics.
- Flexibility is built into the process as it does not demand 100% compliance with the product selections, rather a percentage that will cover the majority of patients (70–80% depending on the group), thereby allowing more complex at one end, or stabilised patients to be effectively managed.
- Integration of prescribing between primary and secondary care, as this present lack of standardisation is a risk factor for patient care.
- The new procurement model also allows for a radical redesign of the drug tariff based upon safety, efficacy and economy. The drug tariff effectively represents the price of products in primary care, incorporating PRS pricing as agreed by the Government and the pharmaceutical industry for branded agents only, but also determines whether or not an agent is available to be prescribed by a general practitioner.
- The achieved savings are available to the DHSSPS, who then arbitrate as to the best use of the additional funding for the population, with significant reinvestment in pharmaceutical care to further optimise therapy and to pay for new expensive drugs, which have been demonstrated to produce significant patient benefit.