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

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A number of medicine selection methods have been used worldwide for formulary purposes. In Northern Ireland, integrated medicines management is being developed, and related projects have been carried out. This paper deals with the description of the STEPS (Safe Therapeutic Economic Pharmaceutical Selection) programme. The paper outlines the development of STEPS and its application as an element of a cost-effective medicines-management process in Northern Ireland.

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1. Introduction

Pharmacy is the healthcare profession that has the responsibility for ensuring safe, effective and rational use of medicines, and, consequently, plays a vital role in the delivery of healthcare worldwide [1]. The present healthcare system faces great challenges due to the increasing numbers of adverse events, poor adherence, increasing numbers of medication incidents and inadequate communication across the primary/secondary care interface. Furthermore, expenditure on medicines is the second largest cost in healthcare. At present, of the order of £400 million is being spent per annum by the Health and Personal Social Services (HPSS) on medicines, accounting for 12% of the whole healthcare budget within Northern Ireland.

The National Health Service (NHS) plan set out the challenge to pharmacy in the document 'Pharmacy in the Future – Implementing the NHS plan to meet the changing needs of patients' [2]. To acheive this, pharmacy needs to make sure that patients can obtain medicines or pharmaceutical advice early, make sure that patients get more support in using their medicines, and give patients the confidence that they are receiving a good service when they consult a pharmacist. Recommendations have been produced by the National Audit Commission Report in the 'A Spoonful of Sugar' [3] article and the Department of Health 'An Organisation with a Memory' [4] report, in an attempt to ensure that there is integrated best practice across the continuum of activity that is 'medicines management'.

Medicines management is not a new concept. It has been defined by the Audit Commission as '*Encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care*' [3]. It includes all aspects of medicinal use, from the prescribing of medicines, to the ways in which medicines are taken or not taken by patients [5]. Medicines management involves the systematic provision of medicines therapy through

a partnership of effort between patients and professionals to deliver best outcomes at minimal cost [6]. The quality use of medicines is a key factor in achieving future health outcomes [7].

It is widely recognised that accurate and timely exchange of information across the primary/secondary care interface is crucial to seamless pharmaceutical care, which is an integral part of medicines management. It is essential that a holistic approach is taken to medicines management, rather than the present, fragmented, sector-specific system.

In Northern Ireland, an Integrated Medicines Management (IMM) project was undertaken. This project 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 [8].

One of the key issues identified as part of this work was the problem of a lack of product standardisation between the primary and secondary care sectors, which causes significant problems for elderly patients (who constitute over two-thirds of emergency admissions to hospital). Although there had been a joint prescribing formulary within the area where the work was undertaken, this did not effectively address the problem. It was clear that a more robust method was needed to address this issue, using some form of medicine-selection model.

A number of medicine selection methods have been used worldwide for formulary purposes. For example, Comparative Utilisation of Resources Evaluation (CURE) is a flexible model that was developed by a multinational pharmaceutical company [9]. Formulary analysis, which was developed and used in Sheffield (UK), is a hospital-specific method where a number of selection criteria set for different groups of medicines were developed as a comparison framework [10].

However, over the last 20 years, Janknegt and colleagues in the Netherlands have developed a model for medicine decision-making for formulary inclusion purposes, namely, the System of Objectified Judgement Analysis (SOJA) [11].

In this method, selection criteria for a given group of medicines for one indication are prospectively defined, and the extent to which a medicine fulfils the requirements for each criterion is determined. This is discussed in detail in this supplement in another article [??].

2. Method development

The aim was to develop a system that would:

- allow medicine selection within a medicine class across a range of indications
- give clinical efficacy and safety dominance over cost
- be suitable for the development of formularies that would standardise cost-effective prescribing across both primary and secondary care.

The IMM highlighted that the lack of integrated product use was a significant deficiency in the existing medicines management processes due primarily to:

- different choices of agents within a therapeutic class
- different generics and parallel imports being used in primary care.

This inevitably leads to confusion with regard to medicines that patients should be taking, and can result in omission of products or indeed duplication of product use with potentially far reaching consequences. This is particularly problematic for the elderly who constitute an ever increasing proportion of the population and in excess of two-thirds of hospital admissions.

2.1 Procurement in secondary care

Procurement of pharmaceutical products for secondary care is carried out on a rolling, 3-year basis, to which all Trusts (health and social care organistions reponsible for the provision of both health and social care for both the acute and community sectors) contribute. The tender is carried out using the approved names of all the requisite products with estimated volumes being submitted for these agents. The bids are subsequently assessed by a pharmacist advisory panel representing each of the participating Trusts. On completion of the assessments, recommendations are then made to the Pharmaceutical Contracting Executive Group, which consists of the Director of Pharmacy of each Trust, being a subcommittee of the Trust Chief Executives, who then authorise the letting of the contracts.

This process has worked well and achieved significant savings for the secondary care sector. For example, in the 2004 – 2007 contract period, savings of > £2 million were achieved, representing a reduction in expenditure, taking into account the underlying effect of therapeutic inflation on medicines costs to the health service, of 7.6%. The robustness of this process has been validated by demonstrating the fact that 87.2% of all pharmacy procurement complies with the Audit Commission's definition of good procurement practice [12].

Although this system is robust and effective, there are certain deficiencies:

- lack of a primary care element/consideration in the process
- significant disparity between primary care and secondary care prescribing.
- approved name contracts as all products in a class would be requested, but with no mechanism to consider therapeutically equivalent entities.

2.2 Procurement in primary care

In the primary care sector, general practitioners write a prescription for the agents required by their patients (the items must be prescribable, i.e., on the medicine tariff, which not only dictates those products that will be reimbursed on the Health Service, but also sets the price at which the

product will be remunerated). The prescription is then dispensed by the community pharmacist. Both professionals are independent contractors, and no contracting is undertaken in the manner of the system described above for secondary care. The NHS list price is set by the Association of the British Pharmaceutical Industry (ABPI) and the Government, to ensure 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, leading to the production of new agents that can further improve patient care. The price paid by the Central Services Agency for any given product is laid down by the medicine tariff with the community pharmacist, supplying the most cost-effective product that they can procure.

Therefore, there is an apparent lack of integration between the sectors in terms of product use, with resultant problems for patients in not only obtaining optimal benefit from their therapy, but also increased use of medicine-related adverse effects. This product mismatch mitigates against the development and maintenance of a robust quality joint formulary, which is actively promoted as a system to enhance high quality, safe and effective patient care.

3. Pilot scheme

In light of the significant disparities in the present procurement and medicine selection processes between primary and secondary care, it was agreed that a pilot scheme be put in place in one of the Health Boards in Northern Ireland. The Board represents approximately 25% of the population. The pilot was undertaken in three stages based on the potential problems that might be encountered as a result of existing structural and procedural requirements relating primarily to European procurement law, and remuneration system for community pharmacists.

Thus, the three stages were:

Stage I – branded generics
Stage II – therapeutic tendering
Stage III – 'generic' generics

- Stage I
  Agreement was reached via the Northern Area Prescribing Forum, which represents all key stakeholders in the area (consultants, general practitioners, hospital and community pharmacists and prescribing advisers) with regard to the use of seven branded generic products that, on the basis of reviewed evidence, were concluded to be equivalent from a clinical efficacy viewpoint. The products are listed in **Table 1**.

In terms of implementation in primary care, prescribing advisers and prescribing support assistants actively promoted and implemented the change with general practitioners. Community pharmacists were also key players in this process with regard to availability and stock management. For secondary care, appropriate contractual arrangements were put in place by the Regional Pharmaceutical Procurement Unit. The IMM team of pharmacists and pharmacy technicians ensured that the agreed products were utilised in hospital and detailed on discharge. This information is vital for general practitioners in order to ensure that there is consistency in medicines required by the patient. Consultants agreed that substitution could also be carried out by this team, if appropriate.

This process proved to be very effective in achieving the goal of product standardisation and the removal of this risk factor for patients in terms of their movement between sectors. The success of the implementation process, as used for product standardisation in order to enable optimisation of methodology for the later stages of therapeutic tendering and generics, is reflected in the following data.

In the pilot Board area, the current percentage of the products standardised is in the range of 40 – 50% of market share compared with 4 – 11% in the last Board area to commence the process. In financial terms, the achievement of 80% compliance with the preferred products will achieve an efficiency gain of £3.5 million. Thus, the process can clearly be seen to work. Considerable experience was also gained in the differing elements that needed to be managed in order to obtain ownership of the process by all of the stakeholders.

Before discussing stage-two related to therapeutic tendering, in relation to the implementation of stage-three, the methodology will be as for stage one, except that there will be the requirement to gain full support from community pharmacists in terms of appropriate product use and substitution, as part of a community medicines-management programme. This will ensure that patients will always receive the agreed generic product from their community pharmacy, in line with the appropriate recommendations.

- Stage III
  Following on from the work carried out with the branded generics, the STEPS process was developed [13] incorporating a therapeutic tender to ensure that there was full compliance with the requisite European Union procurement legislation. As a proof of concept project, angiotensin converting enzyme (ACE) inhibitors were selected as the medicine class for this purpose. This requires there to be clear identification of the procurement group making the selection, in addition to defining the criteria against which all of the competing products will be assessed. This, therefore, facilitates a robust and transparent process.

4. STEPS methodology

4.1 STEP I: clinical evaluation

The basis for Step I (the clinical evaluation aspect) was predicated on the SOJA system developed by Janknegt and colleagues in the Netherlands [11]. In the SOJA method, selection criteria for a given group of medicines are prospectively developed, and

Table 1. Agreed branded generics for product standardisation.

Current product	New product
Calcichew, Shire	Adcal, ProStrakan
Imdur, Astra Zeneca; Elantan LA, Scharwz	Isotard XL, ProStrakan
Adalat LA, Bayer	Coracten XL, Celltech
Gaviscon, Reckitt-Benckiser	Peptac, Ivax
Nitrate patches, Deponit (Scharwz), Minitran (3M)	Nitrodur, Schering-Plough
Proctosedyl preparation, Aventis Pharma	Uniroid preparation, Chemidex
Diltiazem brands, various brands	Slozem, Merck

the extent to which each individual medicine fulfils the requirement for each criteria is studied. Each criterion is a given relative weight determined by an expert panel in this area.

The properties of all agents within a therapeutic class are effectively compared against the hypothetical 'ideal' medicine for this group. In the process, 1000 points are divided across all of the relevant criteria for that class. The methodology is summarised here, but is described fully elsewhere in this supplement [??].

A comprehensive literature survey was carried out covering all the major databases, Cochrane reviews, Embase and so on. An expert panel then reviewed the results of the literature survey, and then identified the key selection criteria, such as clinical efficacy, licensed indications, lack of adverse effects and published evidence. The criteria were then weighted as per their relative importance to the overall selection, with a maximum of 1000 points being available for distribution across the criteria. In relation to the best published evidence, there were sub-criteria based on the hierarchy of evidence of studies (with randomised controlled trials scoring highest), quality of journal in which the studies were published (scored according to the impact factor of the journal), and finally, number of years on the market.

The draft scoring system arrived at by the expert panel was then circulated to all secondary care consultants in Northern Ireland with an interest in the specific therapeutic area, key decision makers (including GPs with special interests in primary care), the ABPI, the British Generic Manufacturing Association (BGMA) and the Parallel Pharmaceutical Distribution Industry (PPDI). These decision makers were asked to comment on the allocation of the scores, and to amend, delete or add new criteria if considered appropriate. Responses were anonymous in terms of individuals, but were known by speciality (e.g., cardiologist, nephrologist, general practitioner). The data gathered as a result of this consultation were analysed statistically to yield the final scoring system.

The last part of this step (Step I) was to send the matrix to all relevant pharmaceutical companies (i.e., all who manufacture and supply the products within the relevant therapeutic class). Companies were then asked to complete the matrix for their product as well as provide a hospital price (and the current NHS price) in primary care, as set under the Prescription Price Regulatory Scheme (PPRS). In addition, the companies were also asked to provide a sample of their packaging, which is input required for STEP II.

The companies were also made aware of the implications of the process, which were that it was envisaged that within the 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. To support the correspondence, a briefing session was held with all the relevant companies, thereby enabling any queries regarding the process to be addressed. At the end of STEP I only products that have satisfactorily met the clinical evaluation criteria as described above will proceed to STEP II.

4.2 STEP II: risk assessment

The second phase of the evaluation process focused on factors that could affect safe use of the various products during routine use by patients.

The process was divided into two separate but related elements:

1. Critical information

- labelling
- packaging
- storage conditions
- blisters
- patient information leaflets.

2. Added value

- calendar packs
- European Article Number (EAN) barcode
- pack size
- tablet/capsule colouring and marking
- label instruction space.

A pro forma developed by the Northern Ireland Regional Medical Governance Team was used to score the information received for the elements identified in this step.

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 that had progressed from the clinical evaluation step, and which passed this risk assessment step (combined scores), were then included in the budgetary impact analysis step.

4.3 STEP III: budgetary impact analysis

This entails looking at the impact of the use of the agents in a therapeutic class on the complete healthcare economy that is both primary and secondary care. This is of key importance, as the product selection is to inform a joint formulary to yield safe and cost-effective therapy for the population. The first

phase within this step was to profile the overall usage into defined daily doses (DDD), as laid down by the World Health Organisation. The current total annual usage of the therapeutic class is calculated for both primary and secondary care, with the resultant figure being converted into DDDs. The DDDs are then profiled into regular fractions of DDDs according to the strengths available.

On completion of this calculation, comparisons could then be made between the products that had passed Steps I and II. Having calculated the minimum quantities of each individual product line that would be required to meet the profiled DDD requirements over a 1-year period, the cost for each product-line to meet the estimated volumes was calculated (based on both the tendered price for secondary care and the prevailing NHS price set under PPRS).

4.4 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 (mostly in secondary care) and well stabilised (mostly in primary care) patients to be accommodated.

5. Regional system

The initial project was carried out on a pilot basis within one area of Northern Ireland, but has now been adapted to become the overall Regional system.

The system still comprises the four steps as described. However, there is a regional steering group, comprising all the key stakeholders that oversee the process for both primary and secondary healthcare sectors. The group also has representation from the pharmaceutical industry in order to facilitate and ensure that the process works smoothly, robustly and transparently from this perspective, as the aim is to ensure that patients have access to the most safe, effective and economic products for their disease state or states. In addition, regional expert groups have been set up for each class that is being considered, and they will remain as permanent standing groups. This is due to the dynamic nature of this work, where there will be an on-going requirement to maintain and develop product selection in the light of both new clinical information and new products.

In the early part of the process, only SOJA was used as a tool for rational decision-making. Later on, another tool was also used as part of the process, namely, InforMatrix. This method was developed in the early 1990s, and is a decision analysis matrix technique [14]. The technique comprises six selection criteria: efficacy, safety, tolerance, ease-of-use, applicability and cost. The model is very useful when there is insufficient data to set up a clinically sound SOJA score. It also has the added benefit of getting much greater participant ownership of the process, as much more individual input is required. This is important in terms of adoption of the process. The InforMartix technique is discussed in much more detail elsewhere in this supplement [15,16].

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 will also be incorporated into an electronic prescription system, which will facilitate the implementation process.

In addition, the process will be linked to the secondary sector contracting process, to the general practitioners' quality and outcomes framework, thereby giving a very coherent process that is owned and indeed driven by the prime stakeholders (consultants and general practitioners) with full support from the relevant specialist clinical pharmacists.

The deliberations of the various expert groups will be put on a STEPS-specific website, which will be accessible to all healthcare professionals in Northern Ireland to inform their practice. This will be updated regularly in order to ensure that it will retain currency in the light of the rapidly changing products available, and therefore, be fit for purpose as a dynamic up-to-date aid to safe effective prescribing.

In terms of efficiency gain to the Department of Health Social Services and Public Safety (DHSSPS) in Northern Ireland, the initial product standardisations are on track to achieve savings of £3.5 million per annum.

The savings achieved with the STEPS process are even greater: The minimum efficacy gains from statins and proton-pump-inhibitors will be in the region of £7.7 and 5.5 million per year, respectively. The savings for the selective serotonin re-uptake inhibitors are likely to be £2.0 million, ACE inhibitors: £0.7 million and angiotensin receptor blockers: £1.5 million, while the wound dressings scheme will generate an efficiency gain of the order of £1 million, per annum. The savings per capita on these classes alone amount to £10 per capita per year, with investments that are only a fraction of the savings. Initial results show even greater savings.

As a large number of SOJA and InforMatrix programmes are available, the STEPS project can be applied to a number of other medicine classes as well, thereby increasing the expected annual savings to well over £20 per capita per year. It is to be expected that the implementation of the electronic prescription system will further enhance the efficiency gains.

In relation to secondary care, the Regional Pharmaceutical Procurement Unit will undertake all the necessary work with regard to all the stages of the procurement process.

6. Supporting infrastructure

6.1 Integrated medicines management

This system is now the regional system in Northern Ireland, and has significantly enhanced patient care in terms of optimising their medicinal use. The system entails the full

Box 1. Key elements of the STEPS approach.

1) Evaluation of all available evidence relating to efficacy, evidence, safety, tolerability, ease of use, medicine interactions and experience.
2) Continuous updating of all relevant new literature to ensure that the products with the best evidence continue to be used to produce optimal patient outcomes.
3) The above information is available in an interactive matrix model to allow the determination of the personal preference based on the weighting of the selection criteria.
4) Various tools are available to allow involvement of a large number of general practitioners, clinicians and pharmacists in the selection of the optimal medicines.
5) The top 2 – 4 medicines are selected within a class based on the weightings assigned by the panel. Acquisition cost is not taken into consideration, allowing a preselection of medicines on quality aspects only.
6) Risk assessment of the packaging to minimise difficulties for patients in safely and optimally using their medicines.
7) 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.
8) Evidence-based guidelines to facilitate use of the products for specific disease conditions based on the assimilated and assessed data.
9) 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.
10) Integration of prescribing between primary and secondary care as this present lack of standardisation is a risk factor for patient care.
11) The new procurement model also allows for a radical redesign of the medicine tariff based upon safety, efficacy and economy.
12) In relation to GPs, the new system is linked to the presently existing prescribing incentive scheme, again ensuring optimal prescribing and, taken with the guidance, could be used to link targets to outcomes in the future.

involvement of both pharmacists and pharmacy technicians in the management of patients and medicines. This involves the achievement of an accurate admission medication history for patients being admitted to hospital using all available sources: general practitioner letter, patients own medicines, patient/carer information, community pharmacist medication record and the record held on the general practitioner computer system. This enables an accurate history to be obtained. During the in-patient stay, medicines are routinely monitored to ensure safe and effective use. Patients are also counselled about their medicines with full discussion of any issues regarding their use, as well as any changes that have been made to their regimen prior to admission. At discharge, the pharmacist completes the discharge letter detailing all required medicines together with any changes and the reasons for them, and forwards this to the general practitioner and the nominated community pharmacist, so that there is a seamless transfer of care. This system then ensures the use of the most efficacious medicines, as determined by the STEPS process, to be confirmed, including switching, as appropriate. There are a comprehensive suite of standard operating procedures that underpin this whole process and ensure uniformity. This will be further enhanced by the introduction of independent prescribing for pharmacists. Thus, the STEPS process together with the IMM system combine to bring about a comprehensive scheme that achieves the goal of safe, effective, economic patient care with regard to medicines use.

Furthermore, an electronic system for recording pharmacist interventions has been developed for use with wireless personal digital assistants that also records diagnosis, demographics, has links to the laboratory system as well as web-based databases, such as e-BNF, in addition to access to all local guidelines, thereby enabling use at the patients' bedside. This, again, supports the STEPS process. This new way of working also involves the community pharmacist much more as a medicines expert, ensuring comprehensive optimal medicines management and integrating more closely both with hospital pharmacist colleagues and general practitioners. The key elements of the STEPS approach are summarised in Box 1.

7. Conclusion

The STEPS process has now become the regional system for the robust transparent and rational selection of pharmaceutical products, incorporating elements of both SOJA and InforMatrix in the approach.

The system has now been used for statins and proton pump inhibitors, angiotensin receptor blockers and selective serotonin re-uptake inhibitors, with a comprehensive

programme of work underway to cover the range of classes of products required. In addition, the process has been successfully applied to wound dressings, and is also to be adapted to use with medical and surgical devices as part of the DHSSPS Pharmaceutical Clinical Effectiveness Scheme, operating under the umbrella of the PSIP. The linkage of STEPS to the IMM scheme, together with the repeated dispensing and generic substitution projects in primary care, show the value of a truly integrated approach to achieving pharmaceutical clinical effectiveness.

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