

Expert Opinion

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System of Objectified Judgement Analysis (SOJA) as a tool in rational and transparent drug-decision making

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Drug selection should be a rational process that embraces the principles of evidence-based medicine. However, many factors may affect the choice of agent. It is against this background that the System of Objectified Judgement Analysis (SOJA) process for rational drug-selection was developed. This article describes how the information on which the SOJA process is based, was researched and processed.

Keywords: drug selection, evidence-based medicine, matrix models, SOJA

Expert Opin. Pharmacother. (2007) 8(Suppl.1):S5-S14

1. Introduction

Decisions have to be made many times a day by every individual. Most of these are relatively simple and the consequences of the choices that are made are often confined to the person in question. However, the choices are more complex and the decisions may have consequences for others who will have to accept the selections that have been made. In such cases, it is desirable that the selection process is fully transparent and that all others feel that they have been involved. This is the case for drug selection. Although almost everyone will agree that drug selection should be a rational process that embraces the principles of evidence-based medicine, many other factors may affect the choice of agent. It is against this background that the System of Objectified Judgement Analysis (SOJA) process for rational drug selection was developed. This article describes how the information on which the SOJA process is based, was researched and processed. Table 1 summarises the various factors that may play a role in the decision-making process of individual physicians. Some of these factors have been discussed in more detail in the Introduction paper of this supplement [1].

2. SOJA method

In the SOJA method, selection criteria for a given group of drugs are prospectively defined and the extent to which each individual drug fulfils the requirements for each criterion is studied. Each criterion is given a relative weight (i.e., the more important a given selection criterion is considered to be, the higher is the relative weight given to that criterion. Both the relative scores for each drug for each selection criterion and the relative weight of each criterion are determined by a panel of experts in this field.

The properties of all drugs are compared to the hypothetical 'ideal' drug from that group, which is assigned the full relative weight for each criterion. This drug will be 100% effective in all patients, have optimal effects in terms of clinically relevant end points and quality of life, have no side effects, is given once daily,

Table 1. System of Objectified Judgement Analysis (SOJA) decision-making criteria and influencing factors.

Decision-making criteria or influencing factors	Effects
Emotional criteria	Positive or negative personal experience with a drug or company (e.g., severe side effect, good relationship with representative or recent congress attended).
Personal financial criteria	Payment to prescribe or dispense (sometimes disguised: e.g., post-marketing surveillance studies).
Unconscious criteria	Influenced by awareness-raising and marketing.
Professional colleagues, specialists, pharmacists	Good relationships favour consensus-building on the issues of drug selection and other pharmacological items.
Literature	Objective information sources (e.g., Farmacotherapeutisch Kompas [FK], Geneesmiddelenbulletin [Gebu] in The Netherlands; the Drug and Therapeutics Bulletin, Clinical Evidence in the UK); evidence-based medicine; experience and cost are the most important criteria.
Consensus meetings/national guidelines	Compliance may be low as most prescribers are not involved in the decision-making process.
Government/health insurance companies	Efforts usually focused on cost-containment.
The patient	Increasingly well-informed because of Internet. Today, a patient can focus on one disease, although a doctor must focus on many.

shows no drug interactions, is well documented and has a low acquisition cost. The scores for the other drugs on each selection criterion are expressed as a percentage of the relative weight for that criterion. One drug may therefore score 70% on efficacy, 80% for side effects, 100% for dosage frequency, 30% for drug interactions and 20% for cost, as compared in each case with the 'ideal' drug that is used as a reference.

In the published SOJA scores, 1000 points are divided over the criteria that are considered to be relevant for a particular group of drugs. In the interactive program, the scores for each drug have been determined by a group of experts and the user is free to assign his own relative weight to each criterion using any scale he wishes. The program then computes the ranking scores for the drugs in the group.

3. Rational selection criteria in the SOJA method

3.1 Clinical efficacy

The clinical efficacy of a drug is, by definition, an important selection criterion. The relative efficacy of one drug (compared with other agents from the same drug group) may be determined from double-blind, randomised, comparative studies. However, these studies have their limitations. Usually only 'ideal' patients are studied, who do not have co-morbidities, who have good renal and hepatic function and whose compliance is likely to be good. Often, numerous exclusion criteria are applied and the results from these trials are not necessarily valid in 'real life'.

Another important aspect of these studies is that many times double-blind, double-placebo studies do not use the original

formulations of both drugs as this would mean that both pharmaceutical companies involved would need to cooperate to supply both the original formulations and matching placebos. This rarely occurs, and usually, the comparator drug is given as a capsule. The impact of this formulation-change on pharmacokinetics and pharmacodynamics is almost never investigated.

So far, most comparative studies, such as those between angiotensin converting enzyme (ACE) inhibitors, antiemetics, β -blockers, calcium antagonists, hypnotics, antidepressant drugs, non-steroidal inflammatory drugs (NSAIDs), histamine H₂ receptor antagonists and proton pump inhibitors show very similar clinical efficacy. Exceptions to this 'rule' are higher clinical efficacy of proton pump inhibitors versus histamine H₂ antagonists in reflux oesophagitis, and the stronger LDL-cholesterol-lowering effect of atorvastatin and rosuvastatin over other statins [1,2]. Clinical efficacy, although it is considered to be the most important selection criterion by almost all doctors and pharmacists, is therefore not always a discriminating factor for drug selection!

Another limitation of clinical studies is the fact that resistance rates of bacteria to antibiotics may show large variations from country to country. Results from comparative studies between amoxicillin and a broad spectrum antibacterial agent in bacterial bronchitis from the Netherlands (which has a relative low resistance rate) are not necessarily valid for Southern Europe (where resistance rates are much higher) and vice versa.

The numbers of patients in most clinical studies are insufficient to demonstrate equal efficacy with an acceptable beta error. It is of importance to study the scientific 'evidence' of clinical efficacy in a critical way. Sometimes the results from consensus conferences are somewhat modified

by pharmaceutical companies to make them more suitable for promotion of a certain drug.

With these limitations in mind, clinical efficacy remains an important selection criterion.

3.1.1 Parameters to predict clinical efficacy

As clinical studies have their limitations, it is important to look for other criteria that may have a predictive value for therapeutic outcome. This has been done for example with regard to antibiotics by introducing the ratio between the area under the serum concentration time curve (AUC) and the minimal concentration which is inhibitory to 90% of isolates (MIC₉₀) in the case of the SOJA score for fluoroquinolones. This pharmacodynamic parameter has good predictive value for the clinical efficacy of fluoroquinolones, as has been demonstrated both in animal and clinical studies.

Another example is the introduction of the 'probability of hitting' in case of the SOJA score for antibiotics in lower respiratory tract infections. In this case, the pathogens usually encountered in these infections and the actual resistance rates for each individual antibiotic are examined. In some cases, large differences are observed between these two parameters, whereas no differences were found in small scale comparative clinical studies. The criterion 'probability of hitting' is country- and sometimes even region-specific, as large differences in the susceptibility to antibiotics are observed.

3.2 Effects on clinically relevant end points

Besides the results of double-blind comparative studies comparing, for example, the antihypertensive effects of two drugs, the demonstrated effects on clinically-relevant end points or outcomes are also taken into consideration. It may be interesting to show that a drug has strong antihypertensive efficacy, but the reason to administer these drugs is to prevent cardiovascular morbidity or mortality. These effects are important discriminating factors between drugs from the same pharmaceutical class. For the statins, the clinical evidence for atorvastatin, simvastatin and pravastatin is much stronger than that of rosuvastatin (despite the strong cholesterol-lowering effects of rosuvastatin); the same is true for ramipril in comparison with most other ACE inhibitors [3,4]. This criterion is added to a SOJA score as soon as some evidence for any drug becomes available.

In case of the statins, the effects of the various statins on cardiovascular morbidity in primary prevention, secondary prevention and diabetes patients are judged separately. The effects on cardiovascular mortality are discussed in the article, but not weighted, because the studies with the newer drugs (atorvastatin and rosuvastatin) are not powered to show an effect on mortality. If mortality was taken into consideration, this would introduce a bias against these newer statins.

The data on clinically relevant end points are collected per drug. It is for the user of the interactive programme to decide whether he considers the effects on clinically relevant end

points to be a class effect (relative weight zero) or that he is not convinced that this is a class effect. In case of the latter, a high relative weight will usually be assigned to this criterion.

3.3 Incidence and severity of side effects

The incidence and severity of side effects is also an important selection criterion for all pharmacotherapeutic groups. However, it is not easy to create a scoring system for the rate and extent of side effects.

The overall incidence of adverse reactions observed in double-blind comparative clinical studies is used for calculation of the score in all SOJA papers. It remains difficult to create a truly 'objective' score. Consider the following example: three drugs may have the same incidence of adverse reactions; the first drug causes headache in 10% of patients, the second one heartburn in 10% and the third results in 10% skin reactions. In the authors' scoring, the differences between these individual 'mild' side effects were ignored and only the overall incidence rate was used for calculation of the score.

In some cases, severe, or even life-threatening side effects may be observed. These must be scored separately from the scoring of mild side effects. This has been done for antibiotics for lower respiratory tract infections, such as cotrimoxazole, which may cause Stevens-Johnson syndrome. For antirheumatic drugs, the risk of severe gastrointestinal reactions was scored separately from side effects, as were the results from endoscopic studies investigating the effects of NSAIDs on the gastric mucosa. Although only marginal differences were found in the overall incidence of side effects, significant differences were found between NSAIDs in the latter two criteria, but these are usually only relevant in high-risk patients.

The safety of drugs in case of overdosage was a criterion specific to drugs with an increased risk of intentional overdosage, such as antidepressant drugs and hypnotics. Large differences were found in the relative toxicities of antidepressant drugs after overdosage, the classical tricyclic antidepressants being much more toxic than the newer agents, such as selective serotonin uptake inhibitors (SSRIs) and venlafaxine. No relevant differences were found in the relative toxicities of benzodiazepine hypnotics, zolpidem and zopiclone, with the exception of flunitrazepam, which is slightly more toxic than the other agents.

3.4 Dosage frequency

In general, once-daily administration is patient-friendly and optimises patient compliance with drug therapy. The differences between once-daily and twice-daily administration are small in terms of patient compliance, but this does fall rapidly with increasing dosage frequency. The rating used in all SOJA scores is shown in Box 1.

The importance of this criterion concerning its effect on patient compliance is higher in case of long-term treatment of asymptomatic hypertension (ACE inhibitors, β -blockers,

Box 1. The rating used for obtaining a system of objectified judgement analysis (SOJA) score based on dosage/frequency of administration of a drug.

Frequency	Score
Once daily	100%
Once or twice daily	90%
Twice daily	80%
2 – 3 times daily	60%
3 times daily	40%
4 times daily	10%

calcium antagonists) than for short-term treatment of infections. On the other hand, it is likely that a missed day of treatment for a serious infection may be of greater importance than a missed day of treatment in hypertension.

The same scoring is not necessarily valid in all countries. In Japan, it is considered that 3 times daily dosage is optimal and that once daily administration is considered a disadvantage by most prescribers. Besides, it must be taken into account that if a patient forgets one dose at once-daily administration, this has a much greater effect on compliance than forgetting one out of four daily doses.

3.5 Drug interactions

Drug interactions will actually occur in a small minority of patients, but are of importance from a formulary point of view in order to reduce the incidence and severity of these interactions. They may also limit the number of other drugs that can or should be added to the formulary.

For some pharmacotherapeutic groups, interactions are of greater importance than others. Few clinically relevant drug interactions are observed with angiotensin II antagonists and ACE inhibitors, whereas it is a distinguishing factor for drugs such as statins (simvastatin and lovastatin), histamine H₂ receptor antagonists (cimetidine), antibiotics (fluoroquinolones, tetracyclines, macrolides) and antidepressant drugs (SSRIs, tricyclic antidepressants, moclobemide) [2-5]. The effects of interactions with fluoxetine may persist for many weeks after stopping the treatment, due to the long half-life of its metabolite.

The relative weight that has been assigned to this criterion is therefore higher in the case of antidepressant drugs than in the case of ACE inhibitors or angiotensin II blockers. The score for each individual drug depends on the frequency and severity of drug interactions and will be close to 100% for those drugs that do not show any relevant drug interactions (such as betalactam antibiotics), whereas drugs that demonstrate a high incidence and severity of drug interactions (e.g., fluoxetine, erythromycin, cisapride) have a low score for this criterion.

3.6 Cost

As the financial resources available for healthcare are not infinite and an increasing demand on these resources is expected in the near future (due to the fact that the population is getting older), the cost factor is an important selection criterion for all groups of drugs.

It is important to realise that the actual acquisition cost contributes to the total cost of treatment to differing extents. Ideally, pharmacoeconomic assessment of the total cost of treatment for each individual drug should be taken into account. Unfortunately, such data are very scarce, and pharmacoeconomics was used as a selection criterion for antidepressant drugs and NSAIDs. For statins, the cost per percent point LDL lowering effect was used for comparison of the drugs and for reflux oesophagitis, the cost per cured patient was used for calculation of the score.

If pharmacoeconomic data become available for more groups of drugs, these data will be used together with acquisition cost. An important factor to bear in mind is that the results of pharmacoeconomic evaluations may be highly dependent on the healthcare systems in different countries. A shorter duration of hospitalisation may be an important pharmacoeconomic advantage in the US, whereas it is much less so in the Netherlands.

For all other groups of drugs, these data are incomplete or even absent. Therefore, acquisition cost was taken into consideration for all groups of drugs.

For all SOJA scores, the official prices were taken into account for calculation of the score. The user of the method may also enter the actual acquisition cost for the hospital in question and recalculate the relative scores for each individual drug for this criterion, as significant discounts can be given to large hospitals.

It is also important to consider the effects of hospital formularies on the cost of drugs outside the hospital. Very large discounts are given to hospitals on several drugs (in the Dutch situation, e.g., in cases of pantoprazole and esomeprazole). This is done with the aim of including these drugs in the hospital formulary and 'earning back' the money outside the hospital, because of the relatively low turnover in hospitals in comparison with the large-scale community use of these drugs. Therefore, both the 'realistic cost' to the hospital in question and the 'official cost' in the community setting should be taken into account.

3.7 Documentation

Documentation is split into four subcategories: i) the number of comparative studies; ii) the number of patients in these studies; iii) the number of years on the market; iv) the number of patient-days worldwide. Each of these subcategories accounts for 25% of the total documentation score.

The first two subcategories are indicative of the overall clinical documentation of the drugs in randomised controlled clinical studies. A large number of clinical studies that include significant numbers of patients leave no doubt about

the clinical efficacy and safety of a drug in the studied population. The latter two criteria are indicative of the overall clinical experience with the drug. These subcategories may introduce a bias in favour of older drugs, but this is done intentionally. The safety of a newly-introduced drug cannot be guaranteed from the results of clinical studies in which only a relatively small number of patients were included and most patients at risk for the development of adverse reactions (e.g., patients with diminished renal function) were excluded. Both the number of patients who have been treated on a worldwide basis and the period for which a certain drug has been available are of importance, as it often takes time for all possible adverse reactions to occur.

A short description of scoring details for each subcategory appears below.

- The number of double-blind comparative studies: of the maximum possible score, 5% is assigned for each study on a specific drug. As a result, the score for 20 studies is 100%.
- The number of patients in these studies: for every 10 patients participating in these studies, 1% of the maximum score was assigned. As a result, the score for 1000 patients is 100%.
- The number of years on the market: every year a certain drug has been on the market represents 10% of the score. If a drug has been on the market for at least 10 years, the score is 100%.
- Number of patient-days worldwide: every 1 million patient-days of experience represents 1% of the score. If the number of patient-days of experience exceeds 100 million, the score is 100%.

3.8 Pharmacokinetics

A large number of pharmacokinetic parameters may be taken into account for drug-decision making. These include absorption, bioavailability, variability of the serum concentration, effect of food on absorption, volume of distribution, tissue concentration, protein binding, clearance, AUC, extent of renal excretion, extent of metabolism, activity of metabolites, elimination half-life and so on.

The relationship between most of these criteria and clinical efficacy or tolerability is doubtful. In most SOJA scores, a relatively low weight was given to pharmacokinetic criteria. Most scores use variability of the serum concentration (coefficient of variation of the AUC) as a pharmacokinetic criterion.

3.9 Pharmaceutical aspects

Pharmaceutical aspects were taken into account in several SOJA scores. For some groups of drugs, it is an advantage that the drug can be given both orally and parenterally. This was scored in the cases of fluoroquinolones and proton pump inhibitors. For the other pharmaceutical groups, such as hypnotics and β -blockers, this was not considered clinically relevant.

A liquid or dispersible formulation may offer an advantage in several groups of drugs; this was used as a criterion in case of NSAIDs and antibiotics in lower respiratory tract infections. It was not used as a criterion for antidepressant drugs, as a liquid formulation may actually increase the risk of intentional overdosage of the drug.

The number of tablet strengths was used as a criterion in most scores.

In all cases, pharmaceutical aspects were given a relatively low weight of 2–4% of the total to be assigned to all criteria together. A higher weight should be given to these criteria when a SOJA score is made for a nursing home, in which the availability of a liquid dosage form may be an important criterion.

3.10 Group-specific criteria

In some SOJA scores, selection criteria which are specific for that pharmaceutical group were used. Development of resistance was taken into consideration for all scores involving antibiotics. In the score for inhaled corticosteroids, various aspects of the inhalation device were taken into consideration, as was the patient preference concerning devices. In the case of antihypertensive drugs, the trough-to-peak ratio of the antihypertensive effect was taken into consideration.

The number of approved indications was included as a criterion for most groups of drugs as these may have more than one application in the hospital setting.

A list of available interactive programmes is presented in **Box 2**.

4. Pharmaceutical marketing

The pharmaceutical industry spends at least \$5000 per physician each year on direct marketing. This money would not be spent if it did not result in increased drug sales. Many problems of medication misuse stem from pharmaceutical marketing. In relation to the pharmaceutical industry, ethical codes govern the information/detailing that they can provide to both physicians and pharmacists. On the other hand, there are no ethical codes that force these companies to tell the 'whole truth'. Companies will always pick that part of the 'truth' that is favourable to their product.

An important step in preserving the doctors' integrity is to explain to them at undergraduate and postgraduate levels how pharmaceutical marketing works. This will help to make them understand that all doctors and pharmacists are influenced by marketing. Doctors and pharmacists must be taught to look at advertisements critically.

If one wants to stimulate the use of certain drugs that are not included in the evoked sets, prescribers have to be convinced that it is important to change their prescribing behaviour. However, this is not likely to be achieved by the use of scientific literature. The use of decision-making models, preferably interactive programs, may be much more effective in obtaining better (different and more effective) prescribing behaviour. The SOJA method may be a valuable

Box 2. Available system of objectified judgement analysis (SOJA) programs.

Angiotensin converting enzyme (ACE) inhibitors in hypertension
 Angiotensin II blockers in diabetic nephropathy
 Angiotensin II blockers in hypertension
 Antidepressant drugs
 Antiemetics in oncology
 Antiemetics in surgery
 Antiherpes drugs
 Antipsychotics in schizophrenia
 Benign prostatic hyperplasia
 Bronchodilators, long acting
 Calcium antagonists in hypertension
 Combinations of bronchodilators and corticosteroids
 Erectile dysfunction
 Inhaled corticosteroids
 Low molecular weight heparins
 Nasal corticosteroids
 Onychomycosis
 Opiates in cancer pain, long acting
 Osteoporosis
 Reflux oesophagitis
 Statins
 Triptans

tool in this respect, as the user of this method is forced to consider facts and objective truth (information possible closer to the 'whole truth') in the decision-making process.

5. Expert panel

The expert panel should be as independent as possible. Despite the fact that the SOJA process is fully transparent, manipulation is not always easy to detect.

Therefore, a highly standardised procedure is used in the creation of a new manuscript:

- Literature searches on Medline, Embase, and Cochrane databases and searches for review articles in relevant publications.
- Consultation of European Medicines Agency (EMA) scientific reports, National Institute for Health and Clinical Excellence (NICE) guidelines.
- On the basis of such sources (as above), the most relevant publications are obtained.
- Creation of the SOJA scores by the authors.
- In order to minimise bias, from whatever source, all final manuscripts are sent to experts on the topic in question, the

organisation of general practitioners, an editorial board, and to all pharmaceutical companies active in that field. This is in order to conduct a check on scientific correctness and completeness of the presented data.

The first draft is written by Robert Janknegt, in order to obtain a standardised judgement of the available literature. A panel of experts, with specific knowledge on the topic in question, judges the first draft of the manuscript on scientific correctness and completeness with respect to the following questions: are all relevant double-blind studies included; are the conclusions justified; are major limitations of the studies discussed; is there any relevant information on the subject that is missing? The expert panel also critically judge the relative scores assigned to each individual drug for each criterion, and adjust these when necessary.

The whole process from scratch to the final manuscript takes, on average, ~ 1 year.

6. Discussion

6.1 Advantages of SOJA

The main advantage of the SOJA method is that all emotional, financial and other non-rational selection criteria are excluded and that drug-decision making is based solely on rational criteria. The use of the interactive SOJA programme makes the decision process fully transparent as the criteria and weightings on which the decisions are based are obvious to all. The use of this method for drug decision-making greatly aids discussion in formulary committees, as it enables the debate to be much more focussed. It is important to avoid the risk of formulary decisions being based on a single criterion, such as cost. This is only allowed if all other selection criteria do not yield any differences. If the interactive programmes are used, each member of the committee may enter his own relative weight to each criterion, and thereby, actively participate in the decision-making process.

In general, new drugs will have a lower score for documentation due to the fact that clinical experience with these agents is limited. New drugs must have major advantages over the other criteria to overcome the lower score for clinical experience.

The most important difference between SOJA and expert consensus guidelines is that the SOJA method is interactive, allowing active participation of the user of the method instead of simple adherence to a guideline prepared by others. An interesting feature of SOJA is that it combines the advantages of the 'top-down' and 'bottom up' methods of decision-making. The high quality 'top-down' contents of the programme (judgement of the drugs based on a thorough study of literature) are combined with the high compliance of the 'bottom-up' decision-making process as the final decision is made by the formulary committee and not by the authors of the score.

The SOJA score is based on decision-making processes in economics, such as 'vendor rating'. The simplest method is known as 'linear averaging method' or 'weighted factor score method'.

The SOJA score should be used as a formulary decision-making model, and not for drug decision-making in treating individual patients, as only drug-related selection criteria are taken into account, whereas patient-related factors (such as previous reaction to the drug in question, age, renal or hepatic function, comorbidity, gender and so on) will play an important role in the individual patient.

The relative scores for each drug for each selection criterion were determined by a panel of experts in this field, on the basis of an extensive literature study. For the determination of the relative weight of each criterion, data on the importance of these criteria to prescribers and pharmacists were used, if these were available, or the relative weight was assigned by the panel of experts. However, the relative weight that is assigned to each criterion will always be a subject of discussion. To overcome this problem, the programs are available in an interactive format on the Internet at www.sojaonline.com. In the near future, a UK-specific website will be available. Box 3 contains a list of published articles on SOJA.

6.2 Limitations of SOJA

The SOJA method also has its limitations. It is time-dependent. Documentation on most products is still increasing and the score for this criterion will therefore change continuously. New products are introduced and prices are also subject to change. The views of the relative importance of each selection criterion are open to change as well. The patterns of bacterial resistance may change over time. Regular updates of published SOJA scores are therefore necessary and updates of the interactive programme are made available through the Internet. The programmes are updated with new literature every 3 months and prices are updated every month.

It is important to stress that the SOJA method is not an objective method. All judgements are by definition subjective! There will usually be agreement on the fact that drug 'A' has a lower incidence of side effects than drug 'B', which can be proven in clinical trials. However, any assessment on the importance of the observed difference is subjective. The interpretation of the data has been sent to the other authors in order to reduce subjectivity. Before publication, peer reviewers (about 5) also look critically at these data.

A sensitivity analysis is necessary to investigate whether the choice is really based on all criteria. If one criterion is eliminated and this results in a major change in the rankings of the drugs, the choice is largely based on that criterion. This can easily be performed with the interactive program.

6.3 Applications of SOJA

The major advantage of SOJA is that the discussion on, for example, the relative importance of cholesterol-lowering

properties or a proven effect on cardiovascular morbidity becomes very concrete because the user of the method must assign his or her own relative weight to each criterion. The vast majority of the users (many hundreds of physicians and pharmacists in the Netherlands and in Northern Ireland) assign a high weight to both efficacy and documented effects on clinically relevant end points.

In practice, the results of interactive SOJA sessions are highly predictable. Almost all prescribers will assign a high weight to criteria such as clinical efficacy, documented effects on clinical end points, safety and dosage frequency. Pharmaceutical factors, pharmacokinetics and acquisition cost are usually given a low relative-weight. Drugs that score well on the most important criteria will therefore show a high score for almost all users. This makes the programme suitable for use in national, regional, local or hospital formulary committees. The scores of each individual user can be presented and compared with the overall results.

During interactive sessions, a usual comment is that the SOJA method may inhibit the introduction of innovative drugs because documentation is also taken into account. This is only partly true. If a new drug has no advantages concerning the most important criteria (as described above), it will almost certainly show a low score because of its poorer documentation and usually higher acquisition cost. In this case, this is not an innovation but just a 'me too' drug. If a new drug has major advantages concerning efficacy, safety or dosage frequency, this may result in a relatively high score. This is a true innovation. It should be kept in mind that the true innovators are the oldest drugs in a class.

It is important that a broad panel of experts is involved in the preparation of a SOJA score to ensure that it is of the highest quality. The literature is obtained by a Medline search, collection of data from the Cochrane library and collecting references from review articles on the topic in question. The literature is screened by the authors and the pharmaceutical companies involved are asked for additional information on their drug.

As stated before, all judgements, even those that are highly and prospectively structured, are by definition subjective. This means that when SOJA is used by experts on the subject in question, these users are likely to disagree on at least some of the judgements of the expert panel. Therefore, the InforMatrix method was introduced. In this method, the user has to judge both the criteria, as well as the properties of the individual therapy options. This method is described in detail in the paper by Brenninkmeijer *et al.* on InforMatrix, which is also included within this supplement [7].

Therefore, the SOJA is most useful for general practitioners and pharmacists who are not specialists in the given subjects. The SOJA method allows them to make a rational and transparent drug selection with minimal efforts.

Box 3. Published English language articles on system of objectified judgement analysis (SOJA).

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* The first international publication on the methodology of the SOJA technique.

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7. Applications of SOJA in Northern Ireland

The SOJA score is country-specific as many criteria are country specific (number of approved indications, number of formulations, resistance patterns, available drugs, dosage, dosage frequency and cost). If a score is to be used in other countries, it is important that the contents of the article are critically reviewed by a panel of experts from that country.

In Northern Ireland, SOJA has been implemented as part of the Safe Therapeutic Economic Pharmaceutical Selection (STEPS) project, which takes into account all the available literature as per the SOJA method, with appropriate weightings being decided by a local expert group. This process covers both primary and secondary care, and so a

questionnaire is sent to all relevant pharmaceutical companies to complete the evidence base for adjudication. Furthermore, a risk assessment of packaging and labelling is also carried out as a second step. The acquisition cost is only considered for those products that score sufficiently in the first two steps, which assure efficacy and safety. In relation to the secondary care sector, a contract is put in place for the selected products. The products, together with appropriate guidance, are then to encompass 70% of the prescribing for that class in Northern Ireland for both primary- and secondary-care sectors. In relation to the information cascade to all healthcare practitioners, interactive sessions are used to both inform and educate all those concerned regarding the process; and this is driven regionally by relevant expert panels drawn

from both primary and secondary care. (For more detail, see [8].

The costs of the development and maintenance of the different SOJA programmes in the UK are easily covered by the major cost savings achieved for drug classes like the statins and proton pump inhibitors.

8. Conclusions

Drug selection processes in either formulary or other drug committees are often neither transparent nor based solely on rational selection criteria. The SOJA method provides a model to facilitate rational and evidence-based drug selection. With specific computer applications, the SOJA method can be used by all formulary committees as a dynamic model

for drug selection, thereby limiting the role of emotional, personal, financial and unconscious selection criteria.

Some of the programmes are now made specific for the UK situation and are available at no cost to the user. One of the purposes of this paper is to facilitate discussion on the use of decision making models in other countries. The authors would appreciate contacts with individual prescribers and pharmacists. They can test any of the programmes mentioned in **Box 2** on www.sojaonline.com and comment on its contents. In the near future, a UK-specific website will be available. All correspondence can be directed to the e-mail address of the first author. Based on received comments, specific adaptations to the programme will be made to adjust it to continuously improve the quality of the decision-making process.

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