INVITED SPECIAL ARTICLE

SCIENCE, PRACTICE AND PATIENT NEEDS: THE WORK OF THE PLINIUS MAIOR SOCIETY

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Abstract — The Plinius Maior Society is a European multinational, multidisciplinary group of clinicians and researchers in the alcoholism field, which strives for a comprehensive care concept in the management of alcoholism and alcohol-related problems. The Society, using evidence-based medicine, has developed a set of protocols, in the forms of guidelines, flow-charts, leaflets and booklets, for use as tools in research on and treatment of alcohol dependence, with a view to standardize clinical research procedures and to bridge the gap between the alcoholism researcher, practitioner and patient. These protocols or tools have been subjected to a review process during their preparation, and further comments on their validity will be integrated in their updates. Seven protocols have so far been developed, two of which, ‘Guidelines on Evaluation of Treatment of Alcohol Dependence’ and ‘Detection and Management of Patients with Psychiatric and Alcohol Use Disorders’, are aimed at the clinical researcher and specialists, whereas three others [in the form of decision trees (flow-charts)] are aimed at the general practitioner and other primary health care providers. These are entitled ‘Alcohol Risk Assessment and Intervention in Primary Care’, ‘Withdrawal from Alcohol at Home’ and ‘Brief Intervention in Patients with Alcohol-Related Problems’. The remaining two tools are booklets aimed at the patient, one to support initiatives for detection of drinking problems and primary intervention, namely ‘Do you have this Problem? Discuss it with your Doctor!’; and the other to assist the patient in relapse prevention after the early stages of treatment, namely ‘On the Way to Recovery’. The protocols for the general practitioners and patients have so far been produced in seven European languages, and, as with the Guidelines, feedback from target users will be collected and incorporated in future updates. The Society continually seeks to consider areas of clinical importance for its work and, as it enters the new millennium, it hopes to address and make a significant contribution to the most pressing problem in the management of alcohol dependence, namely relapse.

INTRODUCTION

Despite considerable progress towards standardization and harmonization in alcoholism treatment and research, difficulties in international comparison of methodology and results remain an important obstacle in communication, dissemination, exchange and validation of scientific and clinical experience. Differences in medical schools and psychiatric teaching, in health provider systems and in culture and language all contribute to the lack of standardization. The close proximity of the European countries offers an important advantage for sharing experience and developing common approaches and strategies. Recognizing these differences, 13 clinicians and researchers from 11 European countries (Austria, Belgium, France, Germany, Italy, The Netherlands, Portugal, Spain, Sweden, Switzerland and the United Kingdom) met for the first time in 1991 to agree on future procedures and address these issues, and to work towards finding common denominators to standardize research and treatment of alcoholism in Europe. They formed a working group and decided to call it the ‘Plinius Maior Society’, after Pliny the Elder, physician and philosopher (AD 23–79), who recorded some of the earliest clinical symptoms of alcoholism known in medical history. Four additional members have since joined, making a current total of 17 members (see Table 1).

AIMS AND OBJECTIVES

Striving towards a comprehensive care concept for the management of alcoholism, a major objective of the Plinius Maior Society is to contribute towards daily implementation of evidence-based information in the treatment of alcoholism. The Society acknowledged the general need to compare results and treatment approaches across the various European cultures and their diverse medical practices, and to identify specific needs of information transfer to health providers and patients. In achieving these objectives, the Society therefore envisages the need to discuss differences and to produce a consensus view, and, in doing so, it hopes to contribute significantly towards bridging the gap between the researcher, the health provider and the patient. Bridging this gap also applies differences between basic scientific research and clinical research and

Table 1. Current members of the Plinius Maior Society

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<tr>
<th>Name</th>
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<tr>
<td>Jean Ades</td>
<td>Colombes</td>
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<td>Abdulla Badawy</td>
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<td>Wales, UK</td>
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<td>Jose Barrias</td>
<td>Porto</td>
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<td>Mats Berglund</td>
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<td>Jacques Besson</td>
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<td>Stefan Borg</td>
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<tr>
<td>Jonathan Chick</td>
<td>Edinburgh</td>
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<td>Otto Lesch</td>
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<td>Peter Geerlings</td>
<td>Amsterdam</td>
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<td>Nicholas Moore</td>
<td>Bordeaux</td>
<td>France</td>
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<td>Francois Paille</td>
<td>Nancy</td>
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<td>Isidore Peli</td>
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<td>Flavio Poldrugo</td>
<td>Trieste</td>
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<td>Alicia Rodriguez-Martos</td>
<td>Barcelona</td>
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<td>Henning Sass</td>
<td>Aachen</td>
<td>Germany</td>
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<td>Paul Verbanck</td>
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<tr>
<td>Jan Walburg</td>
<td>Amsterdam</td>
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practice in the alcoholism field, and the Society is also committed to achieving this goal through high-quality, state-of-the-art, multidisciplinary research by example. Throughout its approaches and activities, the Society subscribes to the widely accepted concept that alcohol dependence is a disease, as enunciated in the tenth edition of the International Classification of Diseases [World Health Organization (WHO), 1992].

PROCEDURES

The Society meets three times a year at different European locations. Important issues in clinical practice or research are identified and discussed with the aim of developing relevant protocols or tools based on critical appraisal of evidence from the literature and the Society’s own consensus. Over the past 8 years, several topics have been identified, for which six different protocols or tools have been developed. These tools consist of guidelines, flow-charts, leaflets or booklets. Once the need for considering a specific topic has been established, all members begin the task by reviewing the relevant literature. The outcomes of literature reviews and the members’ own experiences and views are then presented and discussed during plenary sessions, and a consensus on contentious issues is sought during these sessions. The contention here is almost invariably due to differences in medical and treatment approaches, in national health systems, in philosophies and cultural perceptions and even in idiomatic language utilization. Once full consensus is reached on all issues, members then divide into smaller working groups to draft subcomponents of the relevant guideline, flow-chart or document under preparation. A second plenary session would then follow to discuss the drafted component and again reach consensus. Normally at the next meeting, the draft document would be reviewed, corrected and finally approved by all members.

All master (original) documents are drafted in English. The Society has, however, developed a concurrent lateral language assessment procedure, during which each member would consider potential future translation difficulties, already identified during the drafting phase of the English text. Relevant suggestions or alterations would then be made at this stage, i.e. before finalizing the agreed English version. This helps to avoid the return of the master English document for renewed discussion, and ensures that translations do not deviate significantly from the agreed master text. Once the English master document has been accepted by all members, translations are made, either by the members themselves or by professional translators, in which case the relevant member would review and certify the translation as a true interpretation of the master document. When documents or leaflets are destined for patients or the public, the translated documents are also submitted to lay writers, journalists or the like to be reviewed and, if necessary, adapted to be more reader-friendly. If changes are recommended by the lay writer, each member would accept or reject such changes in his or her mother tongue according to his/her own discretion and in accordance with the agreed meaning in the English version.

As a rule, the material is then submitted in small samples (10–50 individuals) of the target readership (clinicians, researchers or patients) in the different European countries of the members for review and comment. Additionally, where appropriate, the material is also submitted to the WHO Office for Europe for review and/or approval. Once all comments have been received and discussed, a final version in each language is printed. The Society decides on appropriate methods of distribution and would normally seek and sponsor the collaboration of local or national health authorities in the distribution of the material.

TOOLS

Seven tools have been developed so far: one aimed at clinical researchers, three at general practitioners and other primary health care providers, two at patients and one at specialists.

Tools for clinical researchers

The first publication appeared in 1994 and was entitled ‘Guidelines on Evaluation of Treatment of Alcohol Dependence’ (Plinius Maior Society, 1994). It consisted of 23 short chapters discussing topical issues related to study design, patient description, interventions, outcome measurement, statistical analysis, economic and ethical aspects in clinical research on alcoholism (Table 2). Some of the subjects covered included translation and cross-cultural requirements for validation of instruments, screening, diagnosis, therapy, compliance, mortality and other aspects. The approach of each chapter was to summarize briefly both straightforward and more contentious issues and then to develop for both types of issues

Table 2. Guidelines on evaluation of treatment of alcohol dependence: table of contents

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<td>1.2</td>
<td>Translation and cross-cultural validation of instruments</td>
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<td>Patient description</td>
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<td>2.2</td>
<td>Diagnostic criteria for dependence</td>
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<td>2.3</td>
<td>Drinking behaviour and adverse consequences</td>
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<tr>
<td>2.3.1</td>
<td>Description</td>
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<td>2.3.2</td>
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<td>Biological markers</td>
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<td>2.5</td>
<td>Psychiatric problems associated with alcohol abuse</td>
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<td>2.5.1</td>
<td>A scale for psychiatric health problems</td>
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<td>Social environment</td>
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<td>Physical health</td>
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<td>3.4</td>
<td>Assessment of programme delivery</td>
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<td>4.</td>
<td>Outcome measures</td>
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<tr>
<td>4.1</td>
<td>Outcome measurement methodology</td>
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<tr>
<td>4.2</td>
<td>Compliance with treatment as a measure of outcome</td>
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<td>4.3</td>
<td>Biological tests in outcome assessments</td>
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<td>4.4</td>
<td>Mortality and morbidity</td>
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<td>5.</td>
<td>Statistical analysis</td>
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<td>6.</td>
<td>Economics</td>
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<td>7.</td>
<td>Ethics</td>
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<tr>
<td>Appendix: Chart of use of assessment instruments</td>
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Fig. 1. 'Alcohol risk assessment and intervention in primary care'.
WITHDRAWAL FROM ALCOHOL AT HOME
A doctor's care makes this a safe procedure in moderate alcohol dependence

OBJECTIVE
To facilitate commencement of abstinence from alcohol in the patient's own environment by reducing severe discomfort and alcohol craving while preventing the development of medical complications, in particular delirium tremens or withdrawal fits.

INDICATIONS FOR HOSPITAL REFERRAL
- Home environment unsupportive to abstinence from alcohol
- Past history of withdrawal fits or delirium
- Polydrug abuse
- Very severe tremor & tachycardia already developed
- Disorientation or hallucinations already developing
- Suicide risk
- Jaundice, established liver cirrhosis, other signs of poor physical health or severe malnutrition
- Failure to detoxify at home
- Clear patient preference

WHEN IS MEDICATION NOT NEEDED?
If the patient reports neither recent withdrawal symptoms nor recent drinking to prevent withdrawal symptoms and consumption less than 15 units per day, cessation of alcohol is unlikely to be complicated. If the patient is sober and has no withdrawal symptoms medication is unlikely to be needed.

IF MEDICATION IS NEEDED
A sedative with anticonvulsant action is prescribed, with large doses given in the first 24 hours and gradual reduction to zero over 4 to 10 days maximum. Customs vary between countries. In the UK, most commonly used is diazepam (40-60 mg in the first 24 hours) or chlordiazepoxide (80-120 mg in the first 24 hours). The larger doses are given at bedtime.

EXAMPLE OF DOSAGE REGIMEN
FOR MODERATE ALCOHOL DEPENDENCE:
CHLORDIAZEPoxide

<table>
<thead>
<tr>
<th>Time</th>
<th>07.00</th>
<th>13.00</th>
<th>18.00</th>
<th>23.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>40 mg</td>
<td>40 mg</td>
<td>40 mg</td>
<td>30 mg</td>
</tr>
<tr>
<td>Day 2</td>
<td>20 mg</td>
<td>20 mg</td>
<td>20 mg</td>
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<td>Day 3</td>
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<td>Day 4</td>
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<td>Day 5</td>
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<tr>
<td>Day 6</td>
<td>10 mg</td>
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NB: Specific drug and dosage may vary according to patient’s needs and physician’s preference

INSTRUCTIONS TO PATIENT
You have agreed to stop drinking. This program will help achieve this safely at home. Remember that taking alcohol and medication together could be dangerous.

Avoid stress: look after yourself, do relaxing things.

Sleep: you will find it difficult to get off to sleep for the first week. The capsules will help this but sleep may still be disturbed.

Meals: take small regular meals.

Fluid: drink water, milk, fruit juice, but very large amounts are not necessary (2 litres per day is sufficient). Tea and coffee contain caffeine which disturbs sleep.

Phone your doctor, nurse or clinic if you have any concerns or urge to drink.

Fig. 2. ‘Withdrawal from alcohol at home’.
respectively simple or consensus guidelines agreed by all members. The readership target of this publication are clinical researchers in the field of alcoholism and so far over 2500 copies of the Guidelines have been distributed worldwide. The Guidelines have so far been produced in English, French, Portuguese and Spanish.

Tools for general practitioners and other primary health care providers

Alcohol risk assessment and intervention in primary care. The Society agreed that certain primary care barriers constitute an important problem in the care of the alcoholic patient. It therefore produced in 1995, in consultation with the WHO, a one-page flow chart (decision tree) entitled as above (Fig. 1). This is a useful instrument in the form of a one-page plastiﬁed ﬂow chart, which primary care physicians and health care providers could easily use on a daily basis. It summarizes detection and primary intervention in eight steps, and suggests when intervention is necessary and how to approach cutting down or complete abstinence from alcohol.

Withdrawal from alcohol at home. Withdrawal from alcohol often needs to be managed by medical practitioners who are not in direct liaison with specialized alcoholism treatment centres. This situation will become more prevalent as disease awareness and willingness to treat alcohol-dependent patients improve. Therefore, another one-page ﬂow chart for physicians was developed during 1996 to address this need. Entitled ‘Withdrawal from Alcohol at Home’ (Fig. 2), it explains briefly if and when hospital referral is indicated, as well as whether medication is needed, what prescription practices are suggested, what supervision is necessary and what instructions should be given to the patient during this critical acute withdrawal period.

Brief intervention in patients with alcohol-related problems. In addition to withdrawal, or once withdrawal has been achieved, patients may need to receive medical intervention and/or psychosocial support. Although such support is usually well-deﬁned in specialized centres, this may be a concern for the family physician. The Society therefore produced a third one-page ﬂow chart for health providers in primary care to demystify and introduce brief psychosocial support to the general practitioner (Fig. 3). This ﬂow chart introduces the concept of brief intervention according to the stages of change as developed by Prochaska and DiClemente (1985), starting with pre-consideration, then contemplation, decision-making and ﬁnally action. Patients who are not ready for change are advised to return within 3 months and critical cases are referred to specialized centres. All the above three tools have so far been produced in Dutch, English, French, German, Italian, Portuguese and Spanish.

Tools for alcohol-dependent patients

Do you have this health problem? Discuss it with your doctor! As a complement to the tools for clinicians, the society has also developed a small one-page folded leaflet for patients to support initiatives for detection of drinking problems and primary intervention. The leaflet (Fig. 4), entitled ‘Do you have this health problem? Discuss it with your doctor!’, is intended as a waiting room or random pick-up document, which, in an informative and non-judgmental way, encourages patients to discuss with their doctor any doubts they may have about their drinking behaviour. The leaflet follows the same structure as the primary intervention ﬂow-charts and could simultaneously serve as additional information which the physician may want the patient to read before making a joint decision on the necessary intervention. It also discusses self-assessment, decision-making, differences between cutting-down and stopping drinking, and how to maintain self-control.

On the way to recovery. During the interactions with physicians in the ﬁeld, the Society identiﬁed the need for a brief but informative patient booklet to assist the patient in relapse prevention after the early stages of treatment. A booklet entitled ‘On the Way to Recovery: Relapse is not the End …’ was produced, aimed at explaining in a simple and patient-friendly style the nature of alcohol dependence, the patterns of recovery, situations of risk, what happens in the brain, how to cope with relapse, how to keep it up over a long time, how medication may help and how people around the patient may help or sometimes make things worse. Although some countries or regions have one or more equivalent publications, others have found the Society booklet useful as it stood, or if adapted for local purposes. As is the case with the material aimed at the clinician, the patient information leaflet and booklet have also been produced in Dutch, English, French, German, Italian, Portuguese and Spanish.

Tools for specialists

Detection and management of patients with psychiatric and alcohol use disorders. The society recently completed a one-page ﬂowchart for psychiatrists faced with patients presenting underlying alcohol disorders (in press). It offers practical guidance for early detection, brief intervention and management of alcohol and drug interactions, with a few notes on pharmacotherapy. Emphasis is placed on alcohol problems in cases of alcohol-induced mental disorder, while comprehensive case management is recommended for patients with a dual diagnosis.

PUBLICATIONS RELATED TO THE WORK OF THE SOCIETY

Various aspects of the activities of the Society, mainly those related to the Guidelines for clinical researchers, but also to the other subsequent activities, have been addressed in individual publications by various members of the Society. These publications are included in the references at the end of this article.

SYMPOSIA AND COMMUNICATIONS OF ACTIVITIES OF THE SOCIETY

The Plinius Maior Society has organized a number of symposia and other meetings either alone or in conjunction with other learned societies and organizations. From the data in Table 3, it can be seen that 16 such activities took place, starting in 1990, before the formation of the Society, with the symposium held by what was known as the GSA (contact) group, and ending in 1999 with the WPA in Hamburg.
BRIEF INTERVENTION IN PATIENTS WITH ALCOHOL-RELATED PROBLEMS

If you suspect some alcohol problem in your patient, invite him/her to discuss it and propose the possibility of change in a few consultations.

FIRST VISIT: PRE-CONTEMPLATION
Target: the patient becomes willing to discuss the problem
Means: open ended questions, non-judgmental attitudes

SECOND VISIT: CONTEMPLATION
Target: assessment of the alcohol problem
Means: screening tests (e.g. AUDIT), laboratory tests, physical examination

SAME OR NEXT VISIT: DECISION AND ACTION
Target: stop, reduce or stabilize alcohol consumption
Means: information, FRAMES (see over)

PATIENT NOT READY OR DOUBTFUL
- Give information to patient
- Keep contact

PATIENT READY FOR CHANGE
- Self-monitor with diary
- Give information to patient
- Follow-up in 2 weeks

READY TO REDUCE DRINKING
- Acute withdrawal with or without medication

READY TO STOP
- Follow-up: 2 weeks or more
- Maintain abstinence

SUCCESSFUL?

NO
- Referral

YES
- Follow-up: 2 weeks or more
- Follow-up within 2 weeks

END OF BRIEF INTERVENTION - KEEP CONTACT
Consider one year reassessment

Fig. 3. ‘Brief intervention in patients with alcohol-related problems’.

The flowchart is based on the STAGES of CHANGE, developed by Prochaska and DiClemente. The duration of each phase can vary between patients. However, when the patient has experienced stability for 15 months the prognostic is favourable.

Note: Discussion with patients who are visibly intoxicated is seldom useful. Arrange appointment when patient is more sober.

Well recognized elements of motivational support are listed below, using the example of FRAMES:

F - Feedback: Give patient personal feedback concerning his individual status. Give detailed information about e.g. the patient's physical improvement in the blood-picture, liver function, psychological and social conditions with additional neutral information about the consequences of alcohol abuse.

R - Responsibility: The patient is and stays responsible for himself. Emphasize freedom of choice and personal responsibility for change.

A - Advice: Give clear recommendations or advice on the need for change with a supportive and concerned, rather than authoritarian, style.

M - Menu of Change: Provide a menu of options for your patient, allowing him to choose the one that is most suitable or appealing. Make concrete agreements with the patient: he will try to stop, or reduce, or stabilize the drinking. Fix a follow-up date.

E - Empathy: Use a style that is empathic, reflective, warm and supportive - not condemning. This increases the willingness of your patient to consider change.

S - Self-Efficacy: Try to reinforce the self-confidence of your patient, his expectation that he can actually achieve change.

Brief intervention has been shown to be more effective than no intervention in reducing drinking and/or alcohol problems in 15 randomized controlled trials in hospital and primary care, a finding which is confirmed in meta-analysis of such trials.


See also Flowchart "Withdrawal from Alcohol at Home", The Plinius Major Society

The Plinius Major Society is a multidisciplinary group of European Clinicians and Researchers working towards an integrated care model for alcohol problems

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Many disorders are potentially caused by alcohol. You may also be concerned. Even low quantities interact with diseases and medications. Help your doctor to discuss it.

Fig. 4. ‘Do you have this health problem? Discuss it with your doctor!’.
GENERAL DISCUSSION, COMMENTS AND FUTURE PERSPECTIVES

The long-term aim of the Plinius Maior Society, as embodied in its charter, is to improve the quality of health care in the area of alcohol dependence: ‘We are a European Society of clinicians and researchers striving at the comprehensive care concept for the management of alcohol disease. We endeavour to promote and advance our understanding of preventive, therapeutic and research aspects of alcoholism through exchange and dissemination of information and through joint research and assessment of methodological and related matters, with emphasis on multidisciplinary interaction between clinical, psychosocial and basic sciences.’ The Society has therefore taken an important initiative to identify particular needs in the research and treatment of alcoholism and by way of European consensus produced information pieces over the past 7 years. In recognizing the need to promote and facilitate the management of alcohol dependence, the Society identified targets for such promotion and action at three levels: (1) political decision-makers involved in defining national or international alcohol policies; (2) specialized centres or institutions for the treatment of severe alcohol dependence or somatic complications; (3) primary care providers who identify and ensure first-line management of alcohol-related problems.

The political agenda concerning the management of alcoholism and alcohol-related disorders is in the realm of national health ministries or international bodies such as the European Commission Directorate General (EC DG-V) or WHO with input from national or international scientific societies. Acting on this would require a conviction that the present policies are not appropriate, a demonstrable political clout, and a mastering of the financial aspects of decision and policy-making, none of which applies to the Society. An important new mission identified by the Plinius Maior Society is to analyse how the different national health systems in Europe could contribute to improving purchaser/provider interaction in alcoholism.

Specialized units in the field of alcohol dependence are knowledgeable in all aspects of management options, and conduct more research in the field. Proper methodologies should be used in the design, conduct and analysis of clinical studies in alcohol dependence. This was the objective of the Society’s first product ‘Guidelines on Evaluation or Treatment of Alcohol Dependence’. It included items on patient classification to ensure applicability, intervention description for reproducibility and outcome measures to judge the relevance of results. As far as possible, the instruments or methods chosen were standard validated tools based on scientific evidence. When such evidence did not clearly exist, the guideline recognized this and suggested further validation. These recommendations are destined for researchers, so that the effects of studied interventions can be understood, compared and compiled to provide adequate disease management guidelines. The guidelines were published in a journal for easy reference and distributed as reprints in symposia organized by the Society and through various professional and scientific organizations. Use of and compliance with these guidelines is being evaluated, and an update is presently underway.

At the other end of the spectrum are the general practitioners and primary health care providers, who are at the forefront of diagnosis and capable of initiating early intervention, but often
do not recognize alcohol-related problems or feel unsure how to cope with them before major social, psychiatric or somatic disorders justify or necessitate referral to a specialized unit. Feedback from general practitioners on the first flow chart (‘Alcohol Risk Assessment and Intervention in Primary Care’) led to the corresponding patient leaflet. Since the possibility of home detoxification had been suggested, a relevant guideline was requested, and another on brief intervention. A parallel patient leaflet was produced for home detoxification. The third patient document, the booklet on coping with relapse, is not directly related to brief intervention, but does cover different aspects of alcoholism, and especially its treatment, and, in this respect, can be considered as the companion patient-oriented tool to the general practitioner brief intervention chart.

A major advantage of the method used by the Society to produce these tools is that of achieving cooperative consensus crystallizing the life-long experience of the members and their respect, can be considered as the companion patient-oriented patient leaflet was produced for home detoxification. The third home detoxification had been suggested, an relevant guideline led to the corresponding patient leaflet. Since the possibility of achieving cooperative consensus crystallizing the life-long experience of the members and their respect, can be considered as the companion patient-oriented tool to the general practitioner brief intervention chart.

Acknowledgements — The Plinius Maior Society is supported by an unrestricted educational grant from Groupe LIPHA, SA.

REFERENCES


