

## **Alcohol Policymaking in the Context of a Larger Europe; Bridging the Gap**

**FIRST EUROCARE CONFERENCE, WARSAW, POLAND, 16-19 JUNE 2004**

### **TOWARDS A COMPREHENSIVE TREATMENT STRATEGY**

#### **THE ROLE OF PRIMARY HEALTH CARE (GENERAL PRACTICE)**

**Kaija Seppä, University of Tampere and Tampere University Hospital**

Excessive alcohol consumption with its consequences is a multi-professional problem. Social workers meet excessive drinkers when their economical situation is problematic, police when they have difficulties in obeying the law and health care workers when alcohol has deteriorated their health. The struggle whether excessive consumers are sinful, criminals, pitiful or sick goes on; to which discipline - if any - these people belong?

Inside health care the tradition is that they are treated only when necessary; i.e. if drinking has led to severe somatic complications. The cause, drinking problem, is left for 'someone else'. Even if alcoholism is defined as a psychiatric disease only life-threatening conditions (delirium tremens) are treated inside psychiatric wards. Primary health care is busy with manifold medical tasks, lack of money and personnel. In this framework reframing the understanding of primary health care's role in preventing alcohol-related harm is a huge challenge and a huge possibility when promoting public health.

#### ***1. The preventive role of primary health care***

Prevention is the best way in reducing the suffering due to different diseases. Even if everybody's final destiny is a mortal disease – usually cancer or cardiovascular event - much can be done to postpone the outbreak and increase the quality of life by preventive means. Prevention in the case of alcohol, could totally eliminate the unpleasant consequences and be a powerful weapon especially here.

Among the medical disciplines especially academic general practice (family medicine) has taken the preventive role. This has, in case of alcohol, been supported by the diagnostic classification (ICD-10), where the World Health Organization included, in addition to acute intoxication and dependence, the category 'harmful use' (those who have already incurred alcohol-related damage) in 1992. Further, knowledge of risks in relation to high cholesterol and high blood pressure has promoted conversations also about risky (=hazardous; beyond safe limits) drinking. For example in Finland, it is included in law that health care (not only social) has the responsibility to treat addictive disorders. In spite of these legislative and academic efforts, primary health care staff has been slow and reluctant in taking the preventive role. Reframing alcohol-related harm into a clinical diagnostic concept, not a behavioural one may, even if slowly, be accepted by general practitioners.

Those primary health care GPs and nurses who say that for example heavy drinkers are not the ones they should deal with, are pleased with the discussion around medicalisation. The solution is simple – alcohol is a many-faceted phenomenon, but when it deteriorates health it is straightforward that this part of this phenomenon

belongs to health care. Another excuse not to raise the alcohol issue is the belief that patients do not want advice on alcohol. In a recent 'Editor's choice' Richard Smith (BMJ 2004;328, 14 February) wrote that it is abusing patients by denying them choice. Also here, heavy drinkers need choices to be able to make their decisions; they have the right to know.

## **2. What is Brief intervention (BI)?**

Brief intervention includes alcohol consumption assessment, information on health hazards and short, individual counselling related to current drinking levels. A good tool in detecting the problem is the ten-item AUDIT questionnaire (Alcohol Use Disorders Identification Test) developed by WHO multinational study group (Saunders et al 1993). The goal group are non-dependent drinkers. The goal is non-problem drinking, not necessarily non-drinking and the goal is preferably set in collaboration with the patient, aiming at realistic goals. The counselling includes motivational components and its essential content is 'FRAMES' (Feedback – Responsibility – Advice – Menu – Empathy - Self-efficacy). All this takes place in a health care setting by nurses or physicians, incorporated inside a normal clinical work.

## **3. What is the evidence?**

Hitherto more than 10 000 subjects have been included in randomised controlled brief intervention studies and several systematic reviews and meta-analyses have been published.

The first systematic review was published by Bien et al (1993). They included studies from different levels of health care with heterogeneous outcomes and including also quality scores. The results favoured the effectiveness of brief intervention versus control condition (effect size 0.38), whereas the mean pooled effect size for brief interventions versus extended treatment was negligible (.06). The review by Bien et al. was not a formal meta-analysis, neither did it separately analyse the possible differences in the effectiveness between different settings.

Kahan et al (1995) developed quality scores to assess internal and external validity of individual studies. Even if not a quantitative meta-analysis, also this review ended up with the conclusion that brief interventions are effective. The specific emphasis in this review was in health care.

The first formal meta-analysis of BIs in health care settings was published by Wilk et al (1997). Eight studies with quality scores from different health care levels were included giving an OR 1.95 favouring intervention (95% CI OR: 1.7-2.3) and no apparent heterogeneity between the studies. Subgroup analyses showed trends for a greater likelihood of moderate drinking following interventions with more than one session versus just one session, for females versus males, and for interventions delivered in inpatient versus outpatient medical settings but none of these comparisons was statistically significant.

SBU (Salaspuro 2001) included 27 Randomised controlled studies from primary health care and hospital settings. Nineteen of these studies ended up with positive and eight with negative results. At follow-up there were 31% non-risk consumers in

the treatment and 19% in the control groups. This is the first systematic review where NNT-figures (NNT = number needed to treat) were calculated with a mean NNT of 10.

Moyer et al. (2003) have published the largest meta-analysis to date. In this meta-analysis the target population (care-seekers and non-seekers) and the intensity of brief intervention (control condition, brief or extended intervention) were taken into account. They computed a pooled estimate combining the heterogeneous effect sizes of the individual studies. This review adds positive evidence for brief intervention compared to control conditions delivered by health care professionals to non-treatment seeking patients (effect size from small to medium) and little difference between brief and extended treatment conditions among treatment seeking patients.

All the former reviews and meta-analyses have added to the evidence, that brief intervention is effective in health care settings. Primary health care is the most important level of health care for screening, detecting, assessing, giving advice and modifying motivating. This is why it is of crucial importance to know how effective brief interventions are in primary health care settings. Three meta-analyses have focused on this.

Poikolainen (1999) took into account different exposures (brief and extended interventions) and assessed two outcome measures, e.g. alcohol consumption and serum glutamyltransferase in the seven studies which he included. The findings indicated that very brief (5-20min) interventions had significant effect sizes relative to control conditions for alcohol consumption (-70 grams per week) and gammaglutamyltransferase activity (-9.4 U/L), but estimates were not homogeneous. Extended (several visits) brief interventions had significant effect sizes for alcohol consumption (-65 grams/week) but not for GGT activity, and the effect sizes for both outcomes lacked statistical homogeneity. One significant homogeneous effect favoured extended brief interventions for alcohol consumption in female samples (-51 grams/week), but it was based on the results of only two studies. His conclusion was that more evidence is needed for the effectiveness of BI in primary health care.

Ballesteros et al. (presented in the 1<sup>st</sup> European Congress on Addictive disorders in Alicante, March 2003) also included solely randomised controlled studies performed in primary health care settings and studies applied within other health programmes were excluded (i.e. pregnancy, hypertension). They coded the several characteristics that might be related with heterogeneous results (length and intensity of BI and type of drinkers recruited) and a 4-scale quality score. The decrease in the frequency of hazardous drinkers (Odds ration and NNT) was used as an outcome measure and they analysed the intention to treat data. Thus, several studies including quantitative data (alcohol consumption and/or biochemical markers) were not included. Thirteen studies gave data for dose-effect analysis and 12 for comparison with reference categories. No evidence of a dose effect relationship was found. Generally, BIs outperformed minimal interventions and usual care (OR 1.54, 95% CI 1.26 to 1.89, NNT 12, 95% CI 8-20). The tunnel plot did not show any evidence of publication bias. The authors conclude that although indicating smaller effect sizes than previous meta-analyses their results do support moderate efficacy of brief interventions.

Ballesteros et al. (2004) have published a meta-analysis of brief interventions in primary care focusing on the effectiveness by gender. Seven studies were included

and the standardized effect sizes for the reduction of alcohol consumption were similar in men and in women as were the odds ratios of the frequency of individuals who drank below harmful levels (four studies OR for men 2.32; 95% CI = 1.78-2.93 and odds ratios for women 2.31; 95% CI = 1.60-3.17).

#### **4. What does it cost and how big are the savings?**

There is limited knowledge of the costs of brief alcohol intervention. Based on the study by McKenna et al (1996) the health care costs of an abuser are about half of those of a dependent patient (£ 632 vs. £ 1222 / 6 months). Untreated alcohol dependent people use health care services twice as much as other same-aged people and the results of treatment are better the earlier the treatment is given (Holder 1991 and 1998). Fleming et al. (2000) have studied the cost effectiveness of brief intervention. The cost of a brief intervention treatment was \$ 205 and the cost effectiveness was 5.6:1 (95% CI 0.4-11.0) when first-aid emergency visits, ward treatment costs, traffic accidents and legal costs were included. Wützke et al. (2001) counted that the cost of one BI treatment was Aus\$ 19.14-21.50 including education, marketing materials and salary costs of the staff.

In a cost-effectiveness analysis, Lindholm (1998) concluded that the crucial point is the number of people who make durable changes in their drinking. If ~1% of patients who have received counselling make lasting changes, a brief intervention is relatively cost-effective (cost of 20 000 ECU per year of life saved) and, if ~10% change, resources will be saved in health care. Providers therefore should require alcohol prevention, and also support its implementation (Lindholm, 1998 ).

We e-mailed a questionnaire survey to six GPs who are specialized to do brief alcohol intervention. Cost calculations were based on Finnish health care prices and adjusted by questionnaire results on the mean time used in screening and intervention and the extent of use of laboratory tests. A basic consultation ( $\leq 20$  minutes, including salaries, administrative costs, cleaning, rents) amounted to €53.3; an extended consultation ( $> 20$  min. or including laboratory tests or x-ray costs of equipment) = €94.8. The cost of screening all the 1600 adult patients registered to one GP and giving BI for those screened positively would make a total cost of 30 365€. An opportunistic screening done for those with alcohol-related symptoms and BI for those screened positively would make a total cost of 14 833 €. Early identification and brief intervention, especially when targeted opportunistically to the whole population, is cheap as compared to the treatment costs of alcohol-related complications (e.g. one acute pancreatitis = €30 000; according the incidence figures one is expected yearly in an area like this).

Another way of counting clarifies the real importance of systematic brief intervention in primary health care. The example, again, is Finland. About 10% of our population are heavy drinkers, this means 500 000 subjects. Almost everybody (especially heavy drinkers with several symptoms) meet their GP or a public health nurse every year. The present situation is that only 30% of the personnel use BI as part of their routine work. This means that 150 000 of the heavy drinkers meet a GP or nurse that gives them BI. If half of these heavy drinkers are motivated (n=75 000) and the treatment is successful in 10% this means that 7500 decrease their drinking to moderate. But if all

GPs and nurses would do this work, with the same assumptions on Finnish national level 25 000 heavy drinkers would decrease their drinking.

### **5. Is BI feasible?**

Even if secondary prevention of alcohol problems in health care has been proved efficacious in many studies, yet its implementation remains scarce, and its effectiveness in regular health care remains unknown.

Arborelius *et al.* (1997) found that few doctors and nurses used the prevention methods taught at a 1-day course. At a 6-month follow-up, 45 patients had been identified as problem drinkers by 22 doctors and 13 nurses. Most of these patients were serious abusers, not high consumers which was the intended target group for the course. Suggested reasons for this outcome were the difficulties of identifying high consumers and the reluctance on the part of doctors and nurses to broach the subject of alcohol. Reports from Britain indicate a similar state of affairs. A national survey of GPs in the UK found that GPs ‘... were not sure whether they should respond to excessive drinkers, did not know how to respond, and felt unsupported when they did attempt to respond.’ (Heather, 1996). In a review article, Deehan *et al.* (1998a) summarize a substantial literature that points to the reluctance of GPs to work with alcohol problems. A study from Canada found that general practitioners were reticent to ask sensitive alcohol-related questions, because they were concerned about offending their patients (Rush *et al.*, 1995 ). In a Swedish study few general practitioners and district health nurses raised the issue of alcohol with patients, made notes about alcohol in patient charts or found working with alcohol issues rewarding. The impact of a training session, where a project nurse visited all willing GPs and nurses, was limited. Although the uptake of the prevention package was high, follow-up at 3 months indicated that little use was made of the materials (Andréasson *et al* 2000).

Acknowledged barriers to alcohol prevention have been time constraints, lack of interest in prevention, uncertainty about how to detect high alcohol consumption, not knowing what is being looked for, embarrassment at asking questions, not knowing what to do if the case is uncovered, concerns about damaging doctor–patient relationship, belief that brief interventions are not effective and lack of supervision for more complicated cases.

Opposite to the common belief that patients dislike asking is the scientific evidence. Even if patients do not spontaneously raise the issue, based on several studies their attitudes are neutral or positive (>90%) towards alcohol-related questions.

The question now is, how to make BI feasible and how to engage PHC.

### **6. How to engage PHC?**

In a paper from New Zealand (Adams *et al.*, 1997), based on a questionnaire study among GPs, changes in government health policy and better skill-based training were identified as key components for a greater acceptance by GPs of the role they could play in reducing alcohol-related problems.

One encouraging example of BI dissemination comes from Australia (Gomel et al. 1998). Three marketing strategies to promote brief intervention were compared: (1) direct mail; (2) telemarketing; (3) academic detailing. Tele-marketing was found to be the most cost-effective in promoting the uptake of the brief intervention packages.

There have been suggestions that nurses could be responsible for alcohol prevention activities in primary care, with the assumption that doctors lack time for this. A number of studies support the efficacy of assigning a more active role to nurses for prevention. In practice, the tailoring of brief intervention in own organisation is worth considering – who does what and what should happen to make things go smoother. The concept of screening seems to be one of the hardest to accept among primary health care professionals. In some organisations it might be too big a step to start right away by systematic screening. Instead, asking alcohol-related questions first among a smaller, defined group might be feasible.

Practitioners often find the alcohol issue difficult, because they think that their patients might become defensive when questioned about alcohol. This might, to some extent, depend on interviewing style. Motivational interviewing is a patient-centred method employing a set of sound counselling strategies, such as open questions and reflective listening and where the advice from the practitioner is matched to the readiness of change of the patient, thereby reducing resistance (Miller and Rollnick, 1991). The method is attractive to practitioners, because it can be generalized to a wide array of behavioural problems. In reality, the issue of screening and motivational interviewing are strongly interconnected. Reluctance to screen for alcohol problems is related to uncertainty about how to proceed when problems are detected.

The most important component in a more effective strategy for secondary prevention involves attitudes among practitioners. The reasons for the present lack of interest need to be further explored and if possible counteracted. If non-obtrusive and time-efficient screening methods can be developed, counselling methods applied that reduce resistance from patients, brief treatment methods for dependent patients learned, and policy developed on the health care provider level that supports alcohol prevention, it seems reasonable that this would facilitate the adoption of secondary prevention among primary care practitioners. Education and training must take into account the attitudes and focus on strengthening GPs' and nurses' therapeutic commitment. In their study based on WHO international collaborative survey Anderson et al (2003) concluded that training and support are effective only among practitioners who initially had high role security and therapeutic commitment. Thus, alcohol-related education at medical schools should also include skills-training and discussion upon attitudes but also focus on right career choices (Anderson 2003).

Effective prevention also needs to include a policy component. The issue of alcohol prevention should be raised both with health care providers and with the professional organizations involved. From the perspective of the health care provider, alcohol prevention is a medical procedure with considerable scientific support for efficacy and potential for reducing morbidity and health care costs. Also, guidelines are needed. The European Action Plan provides an objective analysis on which to formulate relevant policies. Practical, evidence-based instructions on the content of brief interventions, published in several countries add to this information.

## **8. How to proceed – a practical example**

The aims of Finnish alcohol policy are similar to those of the European Union and the World Health Organisation, and are comprised of prevention and treatment of harm and a good availability of services. The foundations of Finnish alcohol policy lie in retail sales monopoly, age limitations and high taxation. The Finnish government has decided that, after February 2004, alcohol taxation will be reduced by 33% (spirits 44%; strong wines 40%; wines 10%; beer 32%). The aim is to reduce alcohol imports from other EU countries, especially from the future EU member state Estonia. A disintegration of preventive measures is predicted to lead to an increase in consumption and in alcohol-related harm.

Traditionally, Finnish health care took care of alcohol-related health problems but alcohol abuse itself was not considered a task for health care. The situation changed in 1987 when a law for the treatment of substance abusers was introduced. The main provision of the law is that health care, in collaboration with social and specialised care of abusers, has to take responsibility for treatment and prevention of substance abuse. In spite of this, attitudes in primary health care towards preventive and therapeutic activities have remained quite negative, despite the fact that detoxification is undertaken and somatic complications are treated in primary care.

Even if the attitudes among primary health care workers have been somewhat negative, early intervention has been considered important among policy-makers and researchers. Three doctoral dissertations in medical faculties have been undertaken to inquire into the efficacy and effectiveness of brief intervention, one in an orthopaedic setting, one as part of health check-ups and one in primary health care (Aalto 2001). The last of these was part of a wider community action project (Holmila 2000). Also, implementation of brief intervention has been promoted (Kääriäinen *et al.* 2001a,b). All this fits well with the focus on preventive cardiovascular activities in Finland.

From 1997 Finland has been involved in the WHO Phase IV BI implementation project. Reframing understanding and strategic alliances were the foundation of the implementation. A feasible model in collaboration with GPs and nurses was developed on how to do screening and brief intervention. Even if the activity among GPs and nurses to do BI did not increase, knowledge especially among nurses did. The project's success in increasing knowledge is also reflected in a decrease in training needs. Instead, attitudes and skills among the professionals did not seem to develop positively. This may have been due to positive attitudes and that were already present at the beginning of the project. Increasing motivational skills seems to be a special challenge for the future. A national survey in occupational health care showed that brief intervention activity in the demonstration project area was higher than in other parts of Finland.

For the moment the Ministry of Social Affairs and Health is committed to promoting country-wide implementation of brief intervention in primary health care. This is partly a result of the present project, partly due to earlier work in the alcohol research field but also a consequence of a fear that reduction in alcohol taxation will lead to increase in alcohol consumption and thereby to an increase in alcohol-related

morbidity and mortality. The costs of the implementation will be covered from the state budget and the work will be accomplished by project workers (six nurse-doctor pairs) in different parts of Finland. The Ministry of Social Affairs and Health co-ordinates the projects (to commence during the year 2004), organises training and produces the materials needed.

It is obvious that when money is provided nationally to brief intervention projects, it will be applied. Projects will last until 2006 which offers a sufficient perspective to make changes. There will be problems that will have to be faced. One is that Finnish primary health care is in crisis; lack of physicians generally and lack of interest in primary health care work means that the few who do work in primary care are very busy. The National Health Project, which provides money for the implementation of brief intervention, has also to confront these organizational problems. Overcoming them will hopefully lead to better future for early identification and brief intervention for hazardous and harmful drinking in Finland.

## **9. Conclusions**

Brief interventions are effective. PHC, nurses and GPs who are experts in communication skills, who know their target population and who have the possibility for continuity in care, is in crucial position to move BIs from efficacy to effectiveness. General practitioners can be engaged in the prevention of alcohol problems. Motivational skills, if adopted, would help also in many other situations. To be able to implement, time, key-persons and political goodwill are needed. Also, more good quality research including qualitative measures should be done concerning the content and target group of effective treatment as well as successful methods of implementation and sustainability of the effects. Networks are helpful, as are guidelines and continuous education and training in changing the attitudes and strengthening the therapeutic commitment of the staff. Given the BIs' preventive potential the cost-effectiveness, if systematically done, would be huge in PHC.

## **Literature**

Aalto M. Prevalence and brief intervention of heavy drinkers in primary health care: Lahti project study. Thesis. University of Tampere 2001.

Adams PJ, Powell A, McCormick R, Paton-Simpson G. .Incentives for general practitioners to provide brief interventions for alcohol problems. *New Zealand Medical Journal* 1997; 110: 291–294.

Anderson P. The risk of alcohol. What general practice can do. Thesis. Drukkerij Quickprint, Nijmegen 2003.

Anderson P, Kaner E, Wutzke S, Wensing M, Grol R, Heather N, Saunders J; Behalf of the World Health Organization Brief Intervention Study Group. Attitudes and management of alcohol problems in general practice: descriptive analysis based on findings of a world health organization international collaborative survey. *Alcohol Alcohol*. 2003; 38:597-601.

- Andréasson S, Hjalmarsson K, Rehnman C. Implementation and dissemination of methods for prevention of alcohol problems in primary health care: a feasibility study. *Alcohol Alcohol*. 2000;35:525-30.
- Arborelius E, Thakker KD, Krakau I, Rydberg U. Dilemmas in implementing alcohol-related secondary prevention in primary care using a behavioural method. *European Addiction Research* 1997;3:150–157.
- Ballesteros J, Gonzáles-Pinto A, Querejeta I, Ariño J. Brief interventions for hazardous drinkers delivered in primary care are equally effective in men and women. *Addiction* 2004;99:103-108.
- Bien TH, Miller WR, Tonigan JS. Brief interventions for alcohol problems: a review. *Addiction* 1993;88:315-36.
- Deehan A, Marshall EJ, Strang J. Tackling alcohol misuse: opportunities and obstacles in primary care. *British Journal of General Practice* 1998;48:1779–1782.
- Fleming MF, Mundt MP, French MT, Manwell LB, Stauffacher EA, Barry KL. Benefit-cost analysis of brief physician advice with problem drinkers in primary care settings. *Medical Care* 2000;38:7-18.
- Gomel MK, Wutzke SE, Hardcastle DM, Lapsley H, Reznik RB. Cost-effectiveness of strategies to market and train primary health care physicians in brief intervention techniques for hazardous alcohol use. *Social Science Medicine* 1998;47:203–211.
- Heather N. The public health and brief interventions for excessive alcohol consumption: the British experience. *Addictive Behaviors* 1996;21:857–868.
- Holder H, Longabauch R, Miller WR, Rubonis AW. The cost-effectiveness of treatment for alcoholism: a first approximation. *J Stud Alcohol* 1991;52:517-540.
- Holder HD. Cost benefits of substance abuse treatment: an overview of results from alcohol and drug abuse. *J Ment Health Policy Econ* 1998;1:23-29.
- Holmila M. The Finnish case: community prevention in a time of rapid change in national and international trade. *Subst Use Misuse* 2000;35:111-23.
- Kääriäinen J, Sillanaukee P, Poutanen P, Seppä K. Brief intervention for heavy drinkers: an action project for health care implementation. *Alcologia* 2001a;13:67-73.
- Kääriäinen J, Sillanaukee P, Poutanen P, Seppä K. Opinions on alcohol-related issues among professionals in primary, occupational, and specialized health care. *Alcohol Alcohol* 2001b; 36:141-146.
- Kahan M, Wilson L, Becker L. Effectiveness of physician-based interventions with problem drinkers: a review. *CMAJ* 1995;152:851-9.
- Lindholm L. Alcohol advice in primary health care — is it a wise use of resources? *Health Policy* 1998;45:47–56.

McKenna M, Chick J, Buxton M, Howlett H, Patience D, Ritson B. The SECCAT survey: 1. The costs and consequences of alcoholism. *Alcohol Alcohol* 1996;31:565-567.

Miller, W. R. and Rollnick, S. *Motivational Interviewing. Preparing to Change Addictive Behavior*. Guilford Press, New York 1991.

Moyer A, Finney JW, Swearingen CE, Vergun P. Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction* 2002;97:279-92.

Poikolainen K. Effectiveness of brief interventions to reduce alcohol intake in primary health care populations: a meta-analysis. *Prev Med* 1999;28:503-9.

Rush BR, Powell LY, Crowe TG, Ellis K. Early interventions for alcohol use: Family physicians' motivations and perceived barriers. *Canadian Medical Association Journal* 1995;152:863–869.

Salaspuro M: In SBU 2001. Intervention mot riskfylld alkoholkonsumtion – sekundär prevention av alkoholproblem. I *Behandling av alkohol- och narkotikaproblem. En evidensbaserad kunskapssammanställning (Brief intervention)*. SBO, Box 5650, 114 86 Stockholm, Sverige, p.31-80.

Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption-II. *Addiction* 1993;88:791-804

Wilk A, Norrman MJ, Havighurst TC. Meta-analysis of randomized control trials addressing brief interventions in heavy alcohol drinkers. *J Gen Intern Med* 1997; 12:274-83.

Wützke SE, Shiell A, Gomel MK, Conigrave KM. Cost effectiveness of brief intervention for reducing alcohol consumption. *Social Science and Medicine* 2001;52:863-870.