

Behavioral Counseling Interventions in Primary Care To Reduce Risky/Harmful Alcohol Use by Adults: A Summary of the Evidence for the U.S. Preventive Services Task Force

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Background: Primary health care visits offer opportunities to identify and intervene with risky or harmful drinkers to reduce alcohol consumption.

Purpose: To systematically review evidence for the efficacy of brief behavioral counseling interventions in primary care settings to reduce risky and harmful alcohol consumption.

Data Sources: Cochrane Database of Systematic Reviews, Database of Research Effectiveness (DARE), MEDLINE, Cochrane Controlled Clinical Trials, PsycINFO, HealthSTAR, CINAHL databases, bibliographies of reviews and included trials from 1994 through April 2002; update search through February 2003.

Study Selection: An inclusive search strategy (*alcohol** or *drink**) identified English-language systematic reviews or trials of primary care interventions to reduce risky/harmful alcohol use. Twelve controlled trials with general adult patients met our quality and relevance inclusion criteria.

Data Extraction: Investigators abstracted study design and setting, participant characteristics, screening and assessment proce-

dures, intervention components, alcohol consumption and other outcomes, and quality-related study details.

Data Synthesis: Six to 12 months after good-quality, brief, multicontact behavioral counseling interventions (those with up to 15 minutes of initial contact and at least 1 follow-up), participants reduced the average number of drinks per week by 13% to 34% more than controls did, and the proportion of participants drinking at moderate or safe levels was 10% to 19% greater compared with controls. One study reported maintenance of improved drinking patterns for 48 months.

Conclusions: Behavioral counseling interventions for risky/harmful alcohol use among adult primary care patients could provide an effective component of a public health approach to reducing risky/harmful alcohol use. Future research should focus on implementation strategies to facilitate adoption of these practices into routine health care.

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Alcohol misuse, including risky and harmful drinking, alcohol abuse, and dependence, is associated with numerous health and social problems and with more than 100 000 deaths per year (1). Risky drinkers consume alcohol above recommended daily, weekly, or per-occasion amounts. Harmful drinkers experience harm associated with their alcohol use but do not meet criteria for alcohol abuse or dependence (2). Persons who misuse alcohol have elevated risks for a host of health problems (3–6), including violence-related trauma and injury (4). Most individuals who consume alcohol do so in moderation and without adverse consequences, however, and observational research suggests light or moderate use may be beneficial for some people (7–20).

The assumption underlying brief behavioral counseling interventions in primary care is that, for identified risky or harmful drinkers, reducing overall alcohol consumption or adopting safer drinking patterns (that is, fewer drinks per occasion and not drinking before driving) will reduce the risk for medical, social, and psychological problems (21). Little experimental evidence supports this assumption, and most epidemiologic evidence relates health outcomes to existing drinking behaviors rather than to changes in drinking behaviors. Cross-sectional and cohort studies have consistently related high average alcohol consumption to short- or long-term health consequences (4, 22). A meta-analysis of studies examining the association between all-cause mortality and average alcohol consump-

tion found that men averaging at least 4 drinks per day and women averaging 2 or more drinks per day experienced significantly increased mortality relative to nondrinkers (23). Studies also relate heavy per-occasion alcohol use (“binge drinking”) to acute injury risks and alcohol-related life problems (4, 22). Injury rates are higher for binge drinkers who consume 5 or more drinks on one occasion as infrequently as 3 to 6 times per year, even when average intake is not excessive (24).

In the United States, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has proposed epidemiologically based alcohol use guidelines to limit risks for short- and long-term drinking-related consequences by establishing age- and sex-specific recommended consumption thresholds (25). Maximum recommended consumption is 1 or less standard drink per day for adult women and for anyone older than 65 years of age and 2 or fewer standard drinks per day for adult men. These guidelines do not apply to persons (such as adolescents, pregnant women, and persons with alcohol dependence or medical conditions or medication use) for whom alcohol intake is contraindicated, or to circumstances (driving) in which no consumption is considered safe.

Primary care clinicians commonly see patients with a range of alcohol-related risks and problems. In Wisconsin, about 20% of primary care patients were found to exceed NIAAA guidelines and to qualify as risky drinkers (26). Across multiple primary care populations, 4% to 29% are

risky drinkers, 0.3% to 10% are harmful drinkers, and 2% to 9% exhibit alcohol dependence (27). Prevalence of these forms of alcohol misuse generally is higher in males and younger persons of all races and ethnicities (28).

The NIAAA and others encourage physicians to identify patients with alcohol-related risks or problems and to provide office-based brief interventions or referrals as needed (25, 29, 30). In everyday practice, screening and screening-related assessment procedures are necessary to identify the range of alcohol users in order to offer appropriate treatment (31, 32). Even so, few primary care clinicians use recommended screening protocols or offer treatment (33).

To assist the U.S. Preventive Services Task Force (USPSTF) in updating its 1996 recommendation (34), the Oregon Evidence-based Practice Center systematically reviewed the evidence on primary care-based behavioral counseling interventions for risky/harmful alcohol use; systematic evidence reviews and meta-analyses since the last USPSTF report (35–39) did not adequately address the key questions posed by the USPSTF. This review was exempted by the Institutional Review Board at Kaiser Permanente Northwest (FWA 00002344-IRB 00000405). Our review addressed the following questions:

1. Do behavioral counseling interventions in primary care reduce risky or harmful alcohol use? What are elements of effective interventions? Do such interventions improve health outcomes?
2. What methods were used to identify risky/harmful drinkers for behavioral counseling interventions in primary care?
3. What adverse effects are associated with interventions addressing risky/harmful drinkers in primary care?
4. What health care system influences are present in effective interventions for risky and harmful drinkers in primary care?

METHODS

We concentrated our review on the program elements of brief primary care interventions for risky and harmful drinkers and their effects on alcohol use, health outcomes, and intermediate alcohol-related outcomes. **Appendix Figure 1** shows the analytic framework and key questions guiding the entire systematic evidence review. Methods not described in this section appear in the Appendix, **Appendix Figures 2 and 3**, and **Table 1**. All Appendix material is available at www.annals.org.

Definitions

No consistent definitions for the drinking patterns that should be the focus of primary care interventions are available from existing guidelines or research; however, it is commonly held that less severe alcohol problems are appropriate for brief interventions in primary care, whereas more severe problems need specialty addiction treatment (41). We adapted the following definitions from a recent

Table 1. Criteria for Grading the Internal Validity of Individual Studies*

Randomized, controlled trials:
Adequate randomization, including concealment and equal distribution of potential confounders among groups
Maintenance of comparable groups (includes attrition, crossovers, adherence, contamination)
Important differential loss to follow-up or overall high loss to follow-up
Equal, reliable, and valid measurements (includes masking of outcome assessment)
Clear definition of interventions
Important outcomes considered
Intention-to-treat analysis

* The Methods Work Group of the U.S. Preventive Services Task Force developed a set of criteria to determine how well individual studies were conducted (internal validity) (40). The Task Force defined a 3-category rating of “good,” “fair,” and “poor” based on these criteria. In general, a good study meets all criteria well. A fair study does not meet, or it is not clear that it meets, at least one criterion but has no known important limitation that could invalidate its results. A poor study has important limitations. These specifications are not meant to be rigid rules but rather are intended to be general guidelines; individual exceptions, when explicitly explained and justified, can be made.

systematic review of primary care screening for alcohol problems (2). *Risky or hazardous drinkers* are at risk from consumption that exceeds daily, weekly, or per-occasion thresholds (other terms further distinguish risky/harmful users who exceed longer-term thresholds—“high-average” or “heavy users”—from “heavy occasional” or “binge” drinkers, who exceed per-occasion thresholds). *Harmful drinkers* experience physical, social, or psychological harm from their above-threshold alcohol use without meeting criteria for dependence. *Alcohol-abusing/dependent drinkers* continue to use alcohol despite significant negative physical, psychological, and social consequences (42); generally meet criteria for abuse or dependence as outlined in the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (43); and are candidates for specialty addiction treatment. Our review focuses on studies oriented toward the risky/hazardous/harmful category, which we refer to as “risky/harmful” drinkers. Fiellin and colleagues (2) similarly divide the literature on screening instruments for alcohol problems into studies that focus primarily on risky, heavy, or harmful drinking and studies that focus on detecting alcohol abuse or dependence.

Among the brief intervention studies targeting risky/harmful drinkers selected for this review, we classified intervention groups into 1 of 3 levels of intensity: 1) “very brief interventions” had 1 session, up to 5 minutes long; 2) “brief interventions” had 1 session, up to 15 minutes long; and 3) “brief multicontact interventions” had an initial session up to 15 minutes long, plus follow-up contacts.

We used the definition of primary care recommended by the Institute of Medicine (44) (see Inclusion and Exclusion Criteria in the Appendix) to identify relevant medical settings for our review.

Inclusion and Exclusion Criteria

We included English-language reports of randomized or nonrandomized controlled clinical trials of nondependent drinkers 12 years of age or older who received a primary care behavioral counseling intervention primarily to reduce alcohol intake. We excluded studies based in hospitals or emergency departments, specialty addiction treatment settings, behavioral health departments, and schools or community agencies without health clinics. We also excluded studies among comorbid patient populations because of limited generalizability to primary care. We excluded studies rated as having poor quality, as described below.

Search Strategy

We identified 5 recent systematic reviews addressing primary care brief interventions to reduce risky/harmful alcohol use (35–39) and 3 addressing screening (2, 45, 46) from the Cochrane Database of Systematic Reviews and Database of Research Effectiveness (DARE). Relevant trials were identified from searches of MEDLINE, Cochrane Controlled Clinical Trials, PsycINFO, HealthSTAR, and CINAHL databases (1994 to April 2002), reference lists of systematic reviews, the USPSTF 1996 recommendation (34), and experts. We conducted separate searches in MEDLINE and PsycINFO from 1994 through April 2002 to identify any literature on harms related to alcohol screening, screening-related assessment, or intervention. None was found. The Appendix contains further search strategy details, along with information on our abstract and article review processes. We used USPSTF internal validity criteria (40) (Table 1), supplemented by specific quality criteria addressing study randomization, attrition, and intention-to-treat analyses from the Cochrane Drug and Alcohol Group (CDAG) (47) (Appendix Figure 3), to grade the quality of trials that met inclusion and exclusion criteria. We assigned each study's final quality rating according to investigator team consensus. Minimal to no attrition, nondifferential attrition, and replacement of missing values in the outcome analyses were key features of trials rated good quality. Studies receiving a consensus rating of poor quality ($n = 27$) were excluded from the review (Appendix Table 2). Major quality problems included nonrandom assignment, noncomparable baseline conditions, attrition rates greater than 30%, and inadequate or unavailable alcohol consumption outcomes. Seventeen studies met final setting and quality criteria (although 1 did not have study results available in time for our review) (48). Twelve of the 16 reviewed studies addressed nonpregnant adults and are the basis of this report. The others addressed pregnant women ($n = 3$) and adolescents ($n = 1$) and are reviewed elsewhere (41). A database search update through February 2003 revealed no new trials.

Data Abstraction

For all 12 included studies, 1 author abstracted relevant information using data abstraction forms. The Appen-

dix describes the data abstraction. A second author checked all data in the final evidence tables.

We examined intervention groups ($n = 15$) from included studies ($n = 12$) by levels of intensity and use of 5 key intervention components (feedback, advice, goal-setting, further assistance, and follow-up) identified from previous research (25, 31, 34, 49). We recorded 3 commonly reported alcohol use outcomes that measured different but comparably important improvements in alcohol use at the end point nearest to 12 months' follow-up: 1) mean drinks per week or the reduction in mean drinks per week (follow-up minus baseline); 2) percentage of participants without binge drinking (usually defined as ≥ 5 drinks per occasion); and 3) percentage of participants achieving recommended drinking levels or patterns (as defined by the study). Where possible, we converted alcohol outcomes into consistent measures across studies and conveyed final results as "net" (that is, intervention minus control); the Appendix further describes our calculations. We did not undertake a quantitative synthesis of alcohol outcomes because of the lack of a clearly superior measure among the 3 alcohol use outcomes available and because of our judgment, supported by that of the USPSTF, that a qualitative synthesis that includes all outcomes would be most informative. Graphs displaying trial results by alcohol use outcome, with sex subgroups (where available), can be accessed elsewhere (41).

Role of the Funding Source

This research was funded by the Agency for Healthcare Research and Quality (AHRQ) under a contract to support the work of the USPSTF. The USPSTF members participated in the initial design and reviewed interim results and the final evidence review. The AHRQ had no role in study design, data collection, or synthesis, although AHRQ staff reviewed interim and final evidence reports and distributed the initial evidence report for external content review by 11 outside experts, including representatives of professional societies and federal agencies. The subsequently revised systematic evidence review on which this manuscript is based is available at www.ahrq.gov/clinic/serfiles.htm (41).

DATA SYNTHESIS

Characteristics of Behavioral Counseling Intervention Trials Reviewed

Table 2 and Appendix Table 3 detail the 12 trials of primary care interventions for risky/harmful alcohol use. Seven trials (50–56) were judged good quality, and the rest were fair (57–61). All were randomized, controlled trials conducted in multiple primary care practices (ranging from 3 to 47 practices per study), except for 1 controlled clinical trial (57). All but 3 trials (51, 54, 59) involved more than 300 participants. The studies examined drinking outcomes after at least 12 months of follow-up, except for 1 with

Table 2. Components of Interventions and Alcohol Outcomes among Adult Alcohol Intervention Trials, by Intervention Intensity*

Intervention Condition†	Population	Setting/Duration	Intervention	Outcomes	Study Quality
Very brief intervention conditions					
Richmond et al. (61)‡	378 adults age 18–70 y; baseline mean alcohol consumption: 38.5 drinks/wk	40 Australian primary care practices (119 physicians) Outcomes assessed at 12 mo	Group 1: alcohol assessment placed on chart before visit (n = 93) Group 2: Same as group 1 plus 5-min physician advice and self-help manual (n = 96)	Group 1 Mean drinks/wk§: 21.5 (women); 36.2 (men) Not bingeing: NR Moderate/safe drinking: 21.5% Group 2 Mean drinks/wk: 24.2 (women); 39.3 (men) Not bingeing: NR Moderate/safe drinking: 22.9% (P = NS)	Fair: nonrandom assignment, control follow-up not assessed, contamination between interventions, baseline differences not controlled for in all analyses
WHO Brief Intervention Study (58)¶¶ (group 1)	1559 adults age 18–70 y; baseline alcohol consumption: NR	Various outpatient medical settings in 8 countries, including United States Outcomes assessed at an average of 9 mo	Group 1: 5-min clinician advice	Group 1 Mean drinks/wk: NR Not bingeing: NR Moderate/safe drinking: 43% (women); 43% (men) Control group Mean drinks/wk: NR Not bingeing: NR Moderate/safe drinking: 35% (women) (P = NS); 35% (men) (P < 0.05)	Fair: possible noncomparable groups at baseline and follow-up, potential contamination across intervention conditions
Brief intervention conditions					
Anderson and Scott (54)	154 men age 17–69 y; baseline mean alcohol consumption: 52 drinks/wk	8 primary care group practices in United Kingdom Outcomes assessed at 12 mo	10-min clinician advice	Intervention group Change in mean drinks/wk: –15.7 Not bingeing: 77.50% Moderate/safe drinking: 17.50% Control group Change in mean drinks/wk: –9.2 (P = 0.06) Not bingeing: 60.81% (P < 0.05) Moderate/safe drinking: 5.41% (P < 0.05)	Good: relatively high attribution levels (31% and 39%), but baseline-forward-replacement of missing values analysis reported
Maisto et al. (60)¶¶ (group 1)	301 adults age ≥21 y; baseline mean alcohol consumption: 5.5 drinks/drinking day	12 primary care clinics in the United States Outcomes assessed at 12 mo	Group 1: 10- to 15-min advice from research staff	Group 1 Change in mean drinks/drinking day: –0.79 Change in mean drinks/wk: –8.3 Not bingeing: NR Moderate/safe drinking: NR Control group Change in mean drinks/drinking day: –0.85 (P = NS) Change in mean drinks/wk: –3.6 (P = NS) Not bingeing: NR Moderate/safe drinking: NR	Fair: high attribution (23%) without addressing loss to follow-up, unclear blinding, potential contamination between groups
Nilssen (57)¶¶ (group 1)	338 participants age 12–62 y (mean, 42 y); baseline alcohol consumption: NR	Residents of Tromsø, Norway Outcomes assessed at 12 mo	Feedback given about biological assay results at study-initiated visit	Group 1 Mean alcohol consumption, g/d: 15.6 Not bingeing: NR Moderate/safe drinking: NR Control group Mean alcohol consumption, g/d: 39.2 (P < 0.001) Not bingeing: NR Moderate/safe drinking: NR	Fair: unclear allocation concealment, blinding of outcome assessment, possible noncomparable groups at baseline and follow-up
Scott and Anderson (59)	72 women age 17–69 y; baseline mean alcohol consumption: 35.3 drinks/wk	8 primary care group practices in United Kingdom Outcomes assessed at 12 mo	10-min clinician advice	Intervention group Change in mean drinks/wk: –11.6 Not bingeing: 87.9% Moderate/safe drinking: 27% Control group Change in mean drinks/wk: –10.0 (P = NS) Not bingeing: 84.6% (P = NS) Moderate/safe drinking: 26% (P = NS)	Fair: noncomparable groups at baseline, unclear allocation concealment, possible contamination of controls, inadequate power

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Table 2—Continued

Intervention Condition†	Population	Setting/Duration	Intervention	Outcomes	Study Quality
Senft et al. (56)	516 adults age ≥21 y; mean baseline alcohol consumption: 16.5 drinks/wk	3 primary care clinics in an HMO in the United States	30-s clinician advice plus 15-min motivational interview with study counselor	Intervention group Mean drinks/wk: 13.1 Not bingeing: 77% Moderate/safe drinking: 80% Control group Mean drinks/wk: 14.9 (P = NS) Not bingeing: 77% (P = NS) Moderate/safe drinking: 73.1% (P = 0.07)	Good: although high attribution (20%) (and differentially greater in intervention group), baseline-forward-replacement of missing values showed no effect on results
WHO Brief Intervention Study (58)¶ (group 2)	1559 adults age 18–70 y; baseline alcohol consumption: NR	Various outpatient medical settings in 8 countries, including United States Outcomes assessed at an average of 9 mo	Group 2: 15-min advice from health care provider	Group 2 Mean drinks/wk: NR Mean cL alcohol/d: males, 5.18; females, 3.39 Not bingeing: NR Moderate/safe drinking: males, 43%; females: 39% Control group: Mean drinks/wk: NR Mean cL alcohol/d: males, 6.29 (P < 0.001); females, 3.80 (P = NS) Not bingeing: NR Moderate/safe drinking: males, 35% (P < 0.05); females, 35% (P = NS)	Fair: possible noncomparable groups at baseline and follow-up, potential contamination across intervention conditions
Brief multicontact intervention conditions					
Curry et al. (50)	307 adults; mean age, 48.2 y; baseline alcohol consumption: 14.9 drinks/wk	Patients of 23 clinicians in an HMO in the United States Outcomes assessed at 12 mo, adjusted for missing data	≤5-min motivational clinician message, self-help manual, and up to 3 phone calls from research health educator	Intervention group Mean drinks/wk: 10.6 Not bingeing: 86% Moderate/safe drinking: 57% Control group Mean drinks/wk: 10.6 (P > 0.2) Not bingeing: 81% (P > 0.2) Moderate/safe drinking: 43 (P = 0.048)	Good: high, differential attribution (34% and 22%) addressed by multiple imputation procedure
Fleming et al. (53)	774 adults age 18–65 y; mean baseline alcohol consumption: 19.1 drinks/wk	17 primary care practices in the United States Outcomes assessed at 12 mo	2 brief clinician visits, each followed by phone call from nurse	Intervention group Mean drinks/wk: 11.5 Not bingeing: 52% Moderate/safe drinking: 84.7% Control group Mean drinks/wk: 15.5 (P < 0.001) Not bingeing: 31.7% (P < 0.001) Moderate/safe drinking: 68.9% (P < 0.001)	Good: low attribution (10%, slightly differential between groups), baseline-forward-replacement of missing values
Fleming et al. (51)	158 adults age ≥65 y; mean baseline alcohol consumption: 16 drinks/wk	24 primary care practices in the United States Outcomes assessed at 12 mo	Two 10- to 15-min clinician visits, each followed by phone call from nurse	Intervention group Mean drinks/wk: 9.9 Not bingeing: 69.2% Moderate/safe drinking: 84.6% Control group Mean drinks/wk: 16.3 (P < 0.001) Not bingeing: 50.8% (P < 0.025) Moderate/safe drinking: 65.7% (P < 0.005)	Good: all criteria met
Maisto et al. (60)¶ (group 2)	301 adults age ≥21 y; baseline alcohol consumption: 5.5 drinks/drinking day	12 primary care clinics in the United States Outcomes assessed at 12 mo	30- to 45-min motivational session with research interventionist plus two 15- to 20-min booster sessions	Group 2 Change in mean drinks/drinking day: −0.64 Change in mean drinks/wk: −5.5 Not bingeing: NR Moderate/safe drinking: NR Control group Change in mean drinks/drinking day: −0.85 (P = NS) Change in mean drinks/wk: −3.6 (P = NS) Not bingeing: NR Moderate/safe drinking: NR	Fair: high attribution (23%) without addressing loss to follow-up, unclear blinding, potential contamination between groups
Nilsen (57)¶ (group 2)	338 participants age 12–62 y (mean, 42 y); baseline alcohol consumption: NR	Residents of Tromsø, Norway Outcomes assessed at 12 mo	Feedback given about biological assay results at study-initiated visit; participants invited to repeat visits with laboratory tests until γ-glutamyltransferase level normalized	Group 2 Mean alcohol consumption, g/d: 13.5 Not bingeing: NR Moderate/safe drinking: NR Control group Mean alcohol consumption, g/d: 39.2 (P < 0.001) Not bingeing: NR Moderate/safe drinking: NR	Fair: unclear allocation concealment, blinding of outcome assessment, possible noncomparable groups at baseline and follow-up

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Table 2—Continued

Intervention Condition†	Population	Setting/Duration	Intervention	Outcomes	Study Quality
Ockene et al. (52)	530 adults age 21–70 y; mean baseline alcohol consumption: 18.9 drinks/wk	4 primary care sites (93 clinicians) in the United States Outcomes assessed at 6 mo	5- to 10-min tailored consultation with clinician plus follow-up visit	Intervention group Change in mean drinks/wk: –6.0 Not bingeing: 31% Not bingeing and moderate/safe drinking: 38.7% Control group Change in mean drinks/wk: –3.1 (P = 0.003) Not bingeing: 26% (P = NS) Not bingeing and moderate/safe drinking: 28.3% (P < 0.05)	Good: met all criteria
Wallace et al. (55)‡	909 adults age 17–69 y; mean baseline alcohol consumption: 35.1 (females) and 62.2 (males) drinks/wk	47 group practices in England and Scotland	1 or 2 visits with clinician with up to 5 visits as needed	Intervention group Mean drinks/wk: females, 23.6; males, 44.0 Binge/heavy episodes: NR Moderate/safe drinking: females, 47.7%; males, 43.7% Control group Mean drinks/wk: females, 30.4 (P < 0.05); males, 55.6 (P < 0.001) Binge/heavy episodes: NR Moderate/safe drinking: females, 29.2% (P < 0.05); males, 25.5% (P < 0.001)	Good: met all criteria

* HMO = health maintenance organization; NR = outcome not reported; NS = reported as non-statistically significant in study; WHO = World Health Organization.
 † Includes 15 intervention conditions from 12 studies. Multiple intervention groups from Maisto (60), Nilssen (57), and WHO (58) are further detailed in Appendix Table 3. Intervention definitions: “very brief” interventions include up to 5 minutes at initial contact with no follow-up contacts; “brief” interventions include up to 15 minutes at initial contact with no follow-up contact; “brief multicontact” interventions include up to 15 minutes at initial contact with multiple follow-up contacts.
 ‡ This study contributed 2 minimal intervention conditions, designated here as group 1 and group 2.
 § Mean drinks per week was reported as change scores from baseline for Ockene (52), Anderson and Scott (54), Maisto (60), and Scott and Anderson (59). Two studies—Nilssen (57) and WHO (58)—did not report mean drinks per week but did report average daily consumption measures, with some statistically significant between-group differences (Appendix Table 3).
 ¶ Trial results considered in 1996 U.S. Preventive Services Task Force recommendation for screening to detect problem drinking.
 ¶¶ This study reported 2 intervention conditions—designated here as group 1 and group 2—and 1 control.

6-month results (52) and 1 with at least 9 months of follow-up (58).

About one third of study participants were women; the exceptions were some older international studies that did not target women (54, 57, 58). Adults 65 years of age or older were included in 9 trials (50, 52, 54–56, 58–61) and were specifically targeted in another (51). Rates of participation of nonwhite persons were not reported in many older international studies and were low (4% to 27%) where reported in recent U.S. studies (50, 52, 53, 56).

The trials generally targeted risky or harmful drinkers or both and excluded known or suspected dependent drinkers, using variable criteria. However, more recent studies (those published after 1996) were more likely to include binge drinkers in addition to persons with high average consumption. These studies tended to define lower thresholds for risky weekly or average use and often excluded heavier drinkers who were at a lower threshold of average use or had any evidence of dependence or abuse. Generally, thresholds for risky alcohol consumption were lower for women than men. More details on inclusion and exclusion criteria applied within each trial are available in Appendix Table 3 and in the full evidence report (41).

On the basis of our definitions, 2 studies evaluated very brief interventions (58, 61), 6 evaluated brief interventions (54, 56–60), and 7 evaluated brief multicontact interventions (50–53, 55, 57, 60). Twelve of the 15 inter-

ventions were delivered all or in part by the patient’s usual primary care physician. Four of these used physicians to deliver initial and repeated intervention contacts (52, 55, 59, 61), whereas others used health educators and counselors (50, 56) or clinic nurses (51, 53) for some contacts.

Effectiveness of Behavioral Counseling Interventions on Risky/Harmful Alcohol Use

All 7 trials testing brief multicontact behavioral counseling interventions (50–53, 55, 57, 60) reported mean drinks per week or average daily consumption outcomes. Five studies (50–53, 55) reported the proportion of participants with safe or moderate alcohol use. Four studies reported the proportion of participants not bingeing (50–53). Six of these trials (50–53, 55, 57) reported a significant effect on at least 1 drinking outcome (Table 2). The seventh fair-quality study, delivered entirely by research personnel outside the clinical setting, found no significant effect on mean drinks per week, the only outcome measure it reported (60). Four good-quality trials (51–53, 55) reported that weekly drinking was reduced 13% to 34% more in intervention groups than in controls (that is, 13% to 34% net reduction), resulting in 2.9 to 8.7 fewer mean drinks per week at follow-up in intervention compared with control participants (data shown elsewhere) (40). One fair-quality brief multicontact intervention significantly reduced mean daily alcohol consumption (57), while 1 good-

quality trial did not significantly change average use (50). All 5 good-quality trials (50–53, 55) found significant effects on recommended or safe alcohol use, resulting in 10% to 19% more intervention participants than controls reporting recommended or safe drinking patterns (data shown elsewhere) (41). Two of 4 good-quality trials reported significantly reduced binge drinking (51, 53). In trials with at least 49% binge users in the study sample at baseline (51–53), binge drinking remained fairly common (31% to 69%) among intervention participants after intervention.

Of the 8 trials testing very brief interventions (58, 61) or brief interventions (54, 56–60), all reported mean drinks per week or average daily consumption outcomes. Six intervention groups from 5 studies (54, 56, 58, 59, 61) reported the proportion of participants with safe or moderate alcohol use; 3 reported the proportion not bingeing (54, 56, 59). Statistically significant results were limited to 3 studies (54, 57, 58), although results tended to favor intervention groups over control groups. One fair-quality very brief intervention (58) improved daily alcohol intake and the proportion of participants drinking moderately among males only. This result may have been due to limited power given the relatively small number of females in the study, or the very brief intervention could have been contaminated—interventionists also delivered a brief intervention protocol (which similarly improved outcomes in males) as part of the same study. A trial testing both brief and brief, multicontact interventions found an average intake effect for both, although potential for contamination was not clear (57). A good-quality brief intervention targeting males significantly improved the proportion with safe or moderate use and the proportion not bingeing (54).

All interventions that showed statistically significant improvements in alcohol outcomes of any intensity included at least 2 of 3 key elements—feedback, advice, and goal-setting. Since most effective interventions were multicontact ones, they also provided further assistance and follow-up. A few also reported tailoring intervention elements to each participant (50, 52).

We found no consistent differences between women and men in the effectiveness of interventions, particularly brief multicontact interventions (data displayed and discussed in detail elsewhere) (41). One intervention that targeted older adults (51) appeared as effective as or more effective than a similar intervention in younger adults (53).

Effectiveness of Behavioral Counseling Interventions on Health and Related Outcomes

About half of intervention studies reported morbidity-related outcomes, such as problem scores (54, 58, 59, 61), psychological scores (54, 59), and lifestyle improvements or reduced accidents and injuries (51, 53, 54). In 2 of the 4 studies examining problem scores, those in all groups generally improved, with no differences between intervention and control groups at follow-up (54, 61). The other 2 studies showed no changes from baseline to follow-up

within or between groups (58, 59). With other outcomes, studies generally found no improvement or similar improvements in interventions and controls over the duration of the trials (51, 53, 54, 59). Of the 5 trials that examined health care utilization (53, 54, 56, 59), only 1 found reduced self-reported hospital days at 12 months (53). In a study evaluating brief interventions and brief, multicontact interventions (60), quality-of-life measures, including those related to alcohol-related problems, improved among the subset of intervention and control participants who reduced drinking by at least 20% (62).

We identified 4 reports of long-term health outcomes following 3 intervention trials (63–66). In 1 good-quality brief multicontact intervention trial (53), fewer hospital days were self-reported by the intervention group than controls after 48 months (429 vs. 664 days; $P < 0.05$), and there was a trend toward reduced all-cause mortality in intervention participants compared with controls (3 vs. 7 deaths; $P > 0.10$) (64). However, other morbidity-related outcomes did not significantly differ between groups. Significantly greater reductions in alcohol use among intervention participants compared with controls were maintained at 48 months.

In a second study, a brief single-contact intervention had no long-term effects on morbidity, mortality, or alcohol consumption at 10-year follow-up (66).

The third study (65), an intensive population-based intervention that alternately enrolled annual cohorts in screening and nonscreening study groups over many years, reported health outcomes but not alcohol consumption outcomes (the Malmö Screening and Intervention Study). Men age 32 to 37 years who were invited to participate had significantly lower total mortality rates (24/100 000 person-years) than noninvited controls (30/100 000 person-years) ($P < 0.02$) and had significantly reduced alcohol-related mortality after 3 to 21 years (65). In a nested, randomized, controlled trial within the Malmö Study, men age 45 to 49 years with elevated serum γ -glutamyltransferase levels who were randomly assigned to control groups had more alcohol-related deaths after a median of 13 years (relative risk, 2.0 [95% CI, 1.1 to 3.7]; $P = 0.026$) than those assigned to intensive intervention (63). Since this trial did not report alcohol use outcomes and it selected drinkers on the basis of confirmed elevations in serum γ -glutamyltransferase levels, participants may have been more severely affected than in other studies we reviewed.

Methods Used To Identify Risky and Harmful Alcohol Users

In the 12 trials reviewed, methods to identify alcohol users appropriate for brief interventions in primary care (Table 2, Appendix Table 3, and Table 11 from the systematic evidence review [41]) typically included screening (identifying patients with probable risky/harmful alcohol use) and screening-related assessment (confirming screening results and distinguishing patients suitable for brief

interventions from those needing specialty care referral). Screening typically involved self-administered questionnaires or brief interviews to assess average quantity or frequency and binge use. In recent U.S. studies (50–53, 56, 60), about 8% to 18% of patients screened “positive,” and about half of these remained eligible for primary care intervention after assessment (data shown elsewhere [41]). Processes to identify patients were generally embedded, at least initially, within assessment of other behavioral health risks. Screening and assessment steps included an added respondent burden for research; however, this burden applied equally to intervention and control participants in all but 1 study (57). Many of the trials we reviewed used validated screening instruments (CAGE [4-item screening questionnaire to detect alcoholism], AUDIT [alcohol use disorders identification test—10-item instrument for risky/harmful use]) that have been shown to have reasonable-to-good test performance among primary care populations (2, 45, 46). Test performance is summarized elsewhere (41). Validated instruments were used alone (for example, AUDIT) or in combination (CAGE plus standardized questions on quantity and frequency) to detect patients with at-risk or harmful drinking, or alcohol abuse or dependence. Research personnel generally provided all or most of the screening and assessment for participants. Screening and assessment steps for each study, and their yields, are examined in greater detail elsewhere (41).

Adverse Effects of Screening and Intervention

We found no research that addressed adverse effects associated with alcohol use screening or assessment, or with behavioral counseling interventions for alcohol use. Three good-quality intervention trials reported greater dropout rates among participants receiving alcohol interventions than among controls (50, 55, 56), while 1 good-quality trial reported higher dropout among controls (54). Differential dropout rates did not affect outcomes since they were addressed analytically; however, dropout may indicate discomfort or dissatisfaction with the intervention, among other plausible explanations. These findings occurred in a minority of trials and cannot be explained with the available data.

Health Care System Supports and Influences

In all 12 trials, additional staff or systems support were required to provide screening and assessment services and, in some cases, intervention support. To identify potential study participants for screening and assessment, 2 studies used systems that highlight upcoming appointments (50, 52), while others used practice registries (54, 55, 59). In nearly every study, research staff conducted the screening and assessment outside the routine care encounter. Most of these processes took more than 30 minutes, although time estimates also include research-related procedures.

Provider training sessions, reported in many studies (50, 52–54, 58, 59, 61), ranged from 15 minutes to 2.5 hours. Several recent studies reported both initial and on-

going training (52, 53). Only 3 studies reported using incentives for participating providers or patients (51, 53, 60). Besides usual care physicians, studies also used research staff (50, 56, 58, 60) or nonphysician health care staff (51, 53) to deliver some or all of the intervention. Research staff often performed important support functions, such as prompting the provider and supplying intervention materials to the chart (50, 52, 56, 60). None reported using electronic medical record support.

DISCUSSION

Summary of Research Findings

We found that good-quality brief multicontact behavioral counseling interventions reduced risky and harmful alcohol use by primary care patients for several alcohol outcomes. A recent meta-analysis that included 7 of the 12 trials we examined reported pooled estimates for the proportion drinking sensibly at follow-up, an absolute risk reduction of 10.5% (CI, 7.1% to 13.9%), with a number needed to treat for benefit of 10 (CI, 7 to 14) (67). We found similar results (ranging from 10% to 19% more intervention participants than controls achieving safe or recommended drinking levels) among studies providing brief multicontact interventions. We examined other equally relevant alcohol outcomes and found that good-quality brief multicontact intervention trials also reduced weekly drinking 2.9 to 8.7 mean drinks per week more than in controls (13% to 34% net reductions) but had inconsistent effects on binge drinking. Very brief or brief single-contact interventions were less effective or ineffective in reducing risky/harmful alcohol use. This finding contrasts with the significant results seen for very brief and brief tobacco interventions among adults in primary care and other medical settings (68). Effective interventions generally included advice, feedback, goal setting, and additional contacts for further assistance and support, although available evidence cannot clearly distinguish higher-intensity intervention effects from intervention components. The elements in effective interventions were generally consistent with the 5 A's (assess, advise, agree, assist, arrange) approach to behavioral counseling interventions adopted by the USPSTF (69).

Earlier intervention studies and reviews raised concerns that women either might not be as responsive to brief interventions as men or might be so responsive to screening alone that brief intervention would not confer much additional benefit. Our results are consistent with recent reviews that found no important sex differences in outcomes of brief interventions (31, 36, 38). Primary care interventions also appear effective in older as well as younger adults, according to the results from a trial targeting older adults (51) and inclusion of older adults in most trials reviewed.

Less is known about the direct effects of risky/harmful alcohol use interventions on morbidity and mortality than

on alcohol intake. Mortality benefits were seen primarily in 1 extended intensive intervention (with repeated contacts up to 5 years) among more severely affected drinkers (65). It is not clear whether mortality benefits will be seen with less severe drinkers undergoing the less intensive interventions typical of studies reviewed here. Since most favorable mortality outcomes were seen only in males or younger males, mortality benefits may accrue primarily to specific subgroups, and their demonstration may require 4 or more years of follow-up. Results were mixed for morbidity measures, and future research is clearly needed; primarily null findings may reflect lack of an effect, reduced power for secondary analyses, or insufficient measures.

Patients were identified for intervention by methods including standardized screening instruments such as AUDIT and CAGE (to detect alcoholism but not risky drinking) that have been shown to perform adequately in primary care populations (2, 45, 46). The 2-step strategy used in trials approximates the NIAAA-recommended approach, in which all patients identified as alcohol drinkers are asked about usual quantity and frequency of drinking, maximum drinks per occasion in the past month, and the 4 CAGE screening questions (wanting to Cut down on drinking, people Annoying you by criticizing your drinking, feeling Guilty about your drinking, and having an "Eye-opener" drink upon arising in the morning) (30). The second step is a confirmatory clinical assessment that also considers specific alcohol problems and dependence.

If primary care clinicians appropriately use these validated screening instruments in conjunction with clinical assessment and judgment, they are likely to identify patients in their practices who are similar to trial participants. Screening and assessment steps were not tested as part of the clinical protocol in these studies, however, and most interventions involved contact with research personnel to determine study eligibility. We found that at least 8% to 18% of general primary care patients would be candidates for brief interventions (screen positives), with at least half remaining eligible after completing the assessment step; according to available data, active refusal rates should be fairly small (41). In the recent meta-analysis of many of the same studies, a similar proportion (9% [range, 3% to 18%]) of patients screened positive, but estimates for the proportion remaining after the assessment step were much lower than ours (67). The authors used their lower estimate of the final screening yield to calculate a benefit for screening and intervention of 2 to 3 per 1000. They have been criticized, however, for such issues as equating the screening yields from recruitment for intervention efficacy trials with those that would result from usual care screening (70); other concerns about this meta-analysis have also been discussed (71–75).

Implications and Future Research Recommendations

Considerable work is needed to implement screening and brief intervention for risky/harmful alcohol use as part

of routine practice, and more research is needed on effective strategies and supports for adoption of these services by physicians and health plans. While brief or very brief interventions may be more easily incorporated into routine primary care, effectiveness of risky/harmful alcohol use interventions probably depends on multiple contacts over time. Most primary care physicians report asking about alcohol use, but far fewer use recommended screening protocols (33) or prefer physician counseling as the means to address risky/harmful users (76). Current research points the way to persuading physicians to accept screening and intervention materials (77) and to providing training that increases screening and intervention activities (78). Prompting untrained physicians with alcohol screening results and simple treatment recommendations yields mixed results in terms of alcohol advice and discussions or patient drinking behaviors (48). Given the system supports provided for most trials, those seeking positive results from these interventions in real-world clinical practice will probably require similar support, such as 1) commitment to planning; 2) allocation of resources and staff to consistently identify risky/harmful alcohol-using patients; and 3) delivery resources (such as clinician training, prompts, materials, reminders, and referral resources).

Trials are needed to examine the direct effects on alcohol use, mortality, and morbidity (including quality of life, mental health, and social functioning) of screening followed by interventions for risky/harmful alcohol use and to report possible harms associated with screening, assessment, and brief intervention. Future intervention research should more directly target screening, interventions, and outcome measures to address binge use. Future research is also needed to establish possible cost savings (79) or cost-effectiveness (80) for these interventions.

Limitations of Our Review

We did not quantitatively summarize study trial results; however, our findings are generally consistent with findings from meta-analyses of brief interventions on alcohol consumption in primary care (36–38, 67).

Our review primarily addressed the effect of behavioral counseling interventions on patients identified as risky/harmful alcohol users and did not systematically address the performance of screening tests to identify these patients. We relied on the previous USPSTF recommendation and intervening systematic reviews by others for our conclusions about screening tests. We judged that methods to identify patients for the intervention trials and validated, feasible primary care screening tests (when coupled with clinical assessment) are sufficiently similar, after removing the burden imposed by research, although we did not test this assumption by this review.

The alcohol use outcomes relied on self-report, with occasional collateral verification, since there are no good objective measures of changes in alcohol use (81). Self-report of alcohol use has been found to be as accurate as or

more accurate than other measures if collected carefully, such as when elicited as part of a general health assessment by nonclinical personnel outside the clinical setting (82). Given that these conditions were often met in the trials reviewed and that we relied on finding net improvements in alcohol consumption patterns, we believe that self-reported alcohol consumption is a reasonable basis for the findings in this report.

We did not address health care interventions in settings other than primary care. Other settings, such as the emergency department or trauma units, may offer other important health care opportunities to address problematic alcohol use in patients.

Publication bias may also have affected our results. Although we located many unpublished or prepublished studies, we cannot be certain that we located all negative studies.

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