Cover Page

Title:

WayToServe Plus: In-service Professional Development Component to Improve Responsible Alcohol Service

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CLINICAL TRIALS COVER PAGE

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Responsible beverage service (RBS) training for alcohol servers is a promising intervention for reducing driving while intoxicated (DWI) by alcohol. Training, certification, and in-service contact improves professionalism and effectiveness of prevention interventions delivered by community members such as alcohol servers. This SBIR Fast-track project will develop and test an in-service professional development component to the WayToServe® online RBS training to improve the effectiveness of RBS training in order to make further gains in reducing problem alcohol behavior in communities.

2. Specific Aims

Driving While Intoxicated (DWI) is one of the most preventable public health risks in the United States. While progress has been made (21,113 DWI deaths in 1982 to 10,511 in 2018 [latest available data[2]]), DWI death rates remained relatively unchanged in 2016 and 2017.[3] While new policy and interventions are needed to reduce social, legal, medical, and economic consequences of DWI, gains are possible by increasing efficacy of existing evidence-based interventions. Among existing strategies, responsible beverage service (RBS) training[4-6] has been effective in some cases.[7] We have shown that an online RBS training, *WayToServe*®, was effective in two randomized trials, funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA; R01AA14982, R01AA016606). Onsite (bars and restaurants) and off-site (package stores) premises receiving *WayToServe* had higher rates of refusing sales to pseudo-intoxicated patrons (PiP) than control premises[11] (see **Box 1**). We are testing a culturally-tailored *WayToServe* to improve its efficacy with Spanish-speaking servers and clientele, with a grant from the National Institute on Minority Health and Health Disparities (R44MD010405).

The **goal** of this Fast-track SBIR research is to develop and evaluate an in-service professional development component to increase the efficacy of our evidence-based *WayToServe* RBS training by improving alcohol servers' professionalism and RBS skills. The **rationale** arises from literature showing that training and certification of community members improves professionalism[12] and, along with in-service contact, has boosted success of community prevention interventions.[13,14] Alcohol servers will benefit from in-service contact aimed at improving their professionalism by a) motivating them to implement RBS skills in the face of common barriers, such as pressure to sell, management disinterest or resistance, and customers' attempts to continue being served, b) receiving support for RBS from a "community" of alcohol servers, especially for servers who work in small or unsupportive premises, and c) preventing natural degradation of skills over time. **Scientific premise** derives from our research establishing the effectiveness of *WayToServe* online RBS training[11] (see **Box 1**) and preliminary survey exploring the in-service component concept (see **Box 2**).

Phase I specific aims will establish the **feasibility** of the *WayT0Serve Plus* in-service component by:
1. Developing content of in-service professional development on RBS skills with a) premises owners/ managers interviews and b) alcohol servers in California, New Mexico and Washington State trained by the *WayToServe* online RBS training through focus group discussions, and survey data.
2. Producing a prototype *WayToServe Plus* in-service professional development component in flowcharts and an initial library of social media posts, including text, graphics, and interactive elements and evaluating it for acceptability, usability, and engagement in focus groups and field pilot trial with alcohol servers in California, New Mexico and Washington State trained by the *WayToServe* online RBS training.
3. Determining feasibility of *WayToServe Plus* in-service professional development component and developing evaluation plans for Phase II research. Feasibility will be indicated by *WayToServe Plus* being acceptable/desirable to 75% of owners, managers, and alcohol servers; having specifications and prototype successfully developed; being usable (minimum 68 out of 100 on System Usability Scale[67]), engaging most servers (75% read and 50% react to a post), and improving theoretical mediators of RBS skills (d=0.2).

Milestones will be: 1) EAB-approved Phase I research plans and development of the content outline, 2) development of *WayToServe Plus* prototype, 3) evaluation of the *WayToServe Plus* prototype, and 4)

feasibility assessment of the *WayToServe Plus* in-service professional development component.

    Phase II specific aims of the SBIR research will achieve the milestones of full **production** of *WayToServe Plus* in-service component and a randomized trial testing its **effectiveness** by:

4. Producing the full *WayToServe Plus* in-service professional development component.
5. Conducting a randomized trial with 180 alcohol premises in California, New Mexico and Washington State evaluating effectiveness of *WayToServe Plus* on refusal of sales to PiP (primary outcome).

    H: Compared to premises in *WayToServe* RBS training only group, premises assigned to receive *WayToServe* RBS training plus *WayToServe Plus* will have higher rates of refusing PiP at posttest.

    The research and product is **innovative**. *WayToServe Plus* will be the first in-service professional development product for alcohol servers. The **market** is large and growing: 36 states require/incentivize RBS training and, starting in 2022, California will require RBS training. *WayToServe* was licensed by Klein Buendel, Inc. (KB), U. of New Mexico (UNM), and Pacific Institute for Research and Evaluation (PIRE) to Wedge Communications LLC (WEDGE) that has sold over 97,000 trainings in California, New Mexico, Washington State, Texas, and California. The *WayToServe* Facebook page, followed by over 20,000 alcohol servers who have completed the *WayToServe* training (http://www.facebook.com/WayToServe/), provides an innovative platform for the professional development of trained alcohol servers. *WayToServe Plus* will increase the training's effectiveness and commercial advantage for servers and corporate clients.

    The *WayToServe* team is led by Dr. David Buller and Gill Woodall, Multiple Principal Investigators, from KB. Co-Investigators are Dr. Gary Cutter (as an expert vendor) from KB and Dr. Bob Saltz from PIRE. WEDGE will provide access to *WayToServe* training to recruit alcohol servers and to *WayToServe* Facebook page to create, deliver, and commercialize *WayToServe Plus* (see **Section 9A**).

3. RESEARCH STRATEGY
3A. Significance
3A.1. Effectiveness of Responsible Beverage Service (RBS) Training

The research is significant because it may improve an effective intervention for preventing driving while intoxicated (DWI), responsible beverage service (RBS) training for alcohol servers. In 2018, there were 39,404 deaths from motor vehicle crashes (MVC) and 4.5 million people injured, costing $445.6 billion.[68] Effects of alcohol on driving impairment are well-established,[69-73] with 10,511 people killed in alcohol-impaired MVCs (29% of MVC deaths) in 2018.[2] Policy approaches to preventing alcohol-impaired driving have commonly focused on direct deterrence of drinkers who become impaired driving.[74] An alternative to direct deterrence of drivers is marketplace policies to prevent access to alcohol by persons already intoxicated. Many states have laws prohibiting sales of alcohol to visibly-intoxicated customers to reduce DWI and other harms.[9]

Another marketplace intervention that complements laws prohibiting sales to intoxicated patrons is RBS training that aims to instruct servers how to prevent intoxication by teaching drink-counting techniques, recognizing signs of intoxication, and strategies to refuse alcohol sales. Laws and training on RBS in the alcohol market is an environmental intervention to decrease opportunities for risky behavior,[8] i.e., reducing access to alcohol, consistent with a nurturing environments perspective[75] emphasizing harm reduction. They complement deterrence aimed at drivers with a targeted restriction on alcohol accessibility (i.e., refusal to sell at the specific time and place where the risk is greatest) that does not depend on decision-making by impaired persons. They can be applied to all premises, do not depend on the house policies of individual licensees to refuse sales, and reduce the ability of intoxicated customers to "shop around" to find premises that will serve.

Research on RBS training presents a mixed picture. Some studies have failed to show effectiveness of some RBS training.[76] However, reviews in 2000 and 2001 concluded that it can prevent alcohol over-service,[77] with strong management support,[1] and lower levels of apparent intoxication have been observed in premises in mandatory RBS training states.[10] A Cochrane meta-analysis[7] reported positive and negative impact. Despite questions about further research on RBS training,[78] there are reasons to continue it. First, positive outcomes of RBS have been reported.[7,79-81] Second, methodological problems limit evidence (e.g., lack of randomized trials, clear outcome variables, and effect size reporting; inconsistent/incomplete data on training implementation/ fidelity),[1,7,77] so we cannot be certain about its success. Third, most past research tested live training, despite the predominance of online technologies, which can improve training quality/fidelity (in-person trainers' instruction can vary[7]) and lower cost. Also, multi-media features can present engaging online learning activities and immersive simulations, potentially making RBS effects more predictable. Our team showed that an online RBS training, *WayToServe*®, was effective in two randomized trials in onsite (bars and restaurants) and off-site (package stores) premises[11] (see **Box 1**), which provides scientific premise for this SBIR research. Fourth, management commitment to RBS (which is not always present) can affect servers' adherence to RBS principles taught in training.[1,7] This finding provides a rationale for adding an in-service professional development component that follows on our *WayToServe* training to counter management disinterest or outright resistance.

RBS training laws across U.S. states are highly variable: 23% of serving staff are in mandatory alcohol server training states; 58% in voluntary incentivized server training states; and 19% in states with no server training laws.[82] In 2022, California will require alcohol server training for over 800,000 servers. One study[10] found lower levels of apparent intoxication in premises in mandatory training states. With variable policies, uptake of RBS training is less than optimal. Our goal is to improve our effective online server training, *WayToServe*.

3A.2. Theoretical Approach to In-service Professional Development for RBS

The proposed research is significant because theory-based professional development delivered over social media will motivate servers to implement RBS, cope with barriers, and be part of a professional community of servers that supports one another and community safety. **Diffusion of innovation theory** (DIT)[29,83] is the framework for improving *WayToServe* with in-service contact aimed at instilling professionalism. In DIT, prevention innovations like RBS must be implemented to be effective. Implementation is facilitated by making it compatible with values/needs of servers, managers, and owners, simple to use, easily accessible to try, and have observable outcomes (e.g., helping use RBS skills and overcome barriers). Compatibility and simplicity of RBS will be stressed in its content and simplicity, trialability, and observability by using popular social media. DIT, along with **social network principles,**[29] also predicts how social media content can influence. Elevated audience involvement in social media increases dissemination and impact[84] and influence involves delivering carefully-crafted content by change agents (e.g., experts) and spreading it among the community by opinion leaders (i.e., knowledgeable peers) to stimulate collective action[29] that reduces uncertainty.[30-32]

Content shared in social media results in opinions/sentiments becoming dominant by interactions among users[34-36] rather than a simple accretion of messages from isolated users.[37] Attitudes emerge from a group dynamic, not mere exposure, and can breed collective action through a process of social comparison/ identity.[29,38-40] Users compare themselves with group members[41] based on social categories and roles (e.g., female, friend, caring person, server) and conform to avoid uncertainty,[42] creating collective identity and stabilizing behavior change.[38,39] Influence of social media is also explained by **transportation theory** (TT)[85,86] and research on narratives. People's behavior is governed by stories about their lives[87,88] and risk behavior is explained by cultural narratives (e.g., young age excuses risky alcohol use). Comments/testimonials that contain personal stories can be more powerful than didactic messages and expert advice.[89] People transported into narratives often change their beliefs based on information, claims, or events depicted[90] that conform to existing cognitive schemas[91] and make narratives seem real. Persons identify with characters in a story, increasing influence.[92,93] Narratives can shift normative beliefs about risks and responses to it.[94-101]

Scientific premise is provided by literature showing training, in-service contact, and certification has improved professionalism of community members who deliver prevention services. In-service improved tobacco control and maternal health services.[12-14] In healthcare, continuous training improved hand-washing to prevent infection and barcode technology to reduce medication errors.[15] In-service contact for RBS is intended to improve servers' professionalism by a) motivating them to implement RBS skills in the face of barriers (e.g., pressure to sell, management disinterest or resistance, and customers' attempts to be served), b) providing support for RBS from a "community" of servers, especially for those in small or unsupportive premises, and c) preventing degradation of skills over time by self-enrolling into booster training. Based on our theoretical approach and preliminary data (see **Boxes 1** and **2**), in-service professional development will be delivered over social media (i.e., Facebook, Instagram, and YouTube). It will reinforce *WayToServe* training and invite user-generated content from servers that supports RBS and creates a sense of "community" among servers. We will encourage stories from other servers, have them share their RBS tips and tricks, and incorporate testimonials and videos/photos to capitalize on interpersonal/interpretive processes that sustain change.

3A.3. Summary of Significance

The proposed research is **highly significant**. Alcohol-impaired driving is very high-risk and RBS training has shown some effectiveness at preventing it. The SBIR research will show if adding continuing instruction and developing professionalism among servers improves it. **Fast-track SBIR research** is justified because:

- Acceptability, feasibility, and effectiveness of online RBS training was validated in prior trials (see **Box 1**).
- Preliminary research on *WayToServe*-trained alcohol servers (see **Box 2**) confirmed need for and interest in an in-service professional development component, informed plans for in-service topics and learning activities, and verified feasibility of delivering it through *WayToServe* Facebook page (see **Box 3**).
- Successful protocols are available from our prior RBS trials for recruitment of premises and servers, implementation of *WayToServe* training and *WayToServe Plus* on social media, assessment of RBS outcomes with pseudo-patrons, and analysis of data collected in RBS trials.
- A feasible prototype for *WayToServe Plus* and plans for full production and evaluation of this component developed in Phase I can be immediately applied in Phase II.

3B. Innovation

The major innovation in this SBIR Fast-track research is the creation of an in-service professional development component, *WayToServe Plus*, to improve effectiveness of the evidence-based *WayToServe* RBS training.

- *WayToServe Plus* will be the first RBS training that includes in-service contact promoting professional development of alcohol servers. Commercially-available RBS training, including *WayToServe,* provides a single training. States typically require that servers be retrained every 2-5 years.
- *WayToServe Plus* will fill a large gap in RBS training required/incentivized by over half of U.S. states by providing in-service training and creating a community of servers that support implementation and habituation of RBS and professionalism among servers trained by *WayToServe.*

Our experience with *WayToServe* training and its Facebook page (a community of over 20,000 trained servers; **Box 3**) and preliminary research (see **Box 2**) suggests that *WayToServe*-trained servers will engage with and benefit from in-service professional development. In Phase I, we will further confirm feasibility of *WayToServe Plus* and develop content, before full development and testing in Phase II. In 2019, most adults used social media (72%; 90% aged 18-29; 82% aged 30-49[102]) for information and peer connections[103] that can influence.[104,105] Despite some decline in user base,[106-108]

Facebook reaches a large majority of adults and is among the most popular social media (69% used it in 2019 [74% daily]; 79% aged 18-29; 79% aged 30-49),[28] including for alcohol servers (see **Box 2**). Facebook's private group feature provides control of treatment presentation to prevent contamination when testing effectiveness of *WayToServe Plus.* We will also link to in-service content posted on Instagram and YouTube, two other highly popular social media for alcohol servers (see **Box 2**).

If effective, *WayToServe Plus* will have **high impact** on a popular state DWI prevention strategy and provide a commercial advantage for *WayToServe* training. The market is large and growing (36 states require/incentives it; California will require RBS training in 2022). *WayToServe Plus* will differentiate the *WayToServe* training from its competitors, such as eTIPS and ServSafe, as the only training with in-service professional development. For corporate clients, its value-added content will ensure investment in the training maintains RBS, increasing group sales. For alcohol servers, it will provide a professional community and improve retention for renewal trainings. Under its license agreement for *WayToServe* training, Wedge Communications LLC (WEDGE) will immediately commercialize *WayToServe Plus* (see letter of support in *Section 9A*) in California, New Mexico, Washington State, Texas, and California, where it has sold over 97,000 trainings since 2012. WEDGE recently upgraded *WayToServe* to improve operability on smartphones and tablets.

**Box 1: Preliminary Studies on *WayToServe* RBS Training**
With R01 grants from NIAAA (AA14982, AA016606 PI: Woodall), we developed an effective online RBS training, *WayToServe* (https://*WayToServe*.org/).[11] It is the only commercially-available RBS training tested in randomized trials. *WayToServe* is compliant with alcohol server training requirements in New Mexico, Texas, and Washington State, where it is a state-approved RBS training in English and Spanish.

FIGURE 1: *WayToServe*® Sample Screenshots

WayToServe RBS Training: *WayToServe* teaches information <u>and</u> skills for RBS as determined by state regulations and formative research in 6 sequential modules: 1) <u>Alcohol laws</u> - What one can and must do legally as a server and penalties for non-compliance. 2) <u>Preventing service to minors</u> – Methods to identify underage patrons, e.g., checking IDs. 3) <u>Facts about alcohol</u> - Effects of alcohol, how to recognize an intoxicated patron, and standard drink and blood alcohol concentration (BAC). 4) <u>The intoxicated patron</u> – How to take an active role in refusing alcohol service to intoxicated patrons to prevent DWI and other harms. 5) <u>Responsible alcohol sales practices</u> - SERVE system, a unique drink counting method to keep patrons under 0.08 BAC driving limit. 6) <u>Alcohol and pregnancy</u> - Information about Fetal Alcohol Spectrum Disorders (FASD). Learning activities were based on principles of adult learning (i.e., learning with application and feedback[109-111] and Social Cognitive Theory (SCT; i.e., learning via modeling, practice, and feedback; see **Figure 1**).[112,113] States require servers view all content and learning activities, and pass end-of-module quizzes and final exam (at least 80% correct) to receive state certificate to serve alcohol. It takes about 3 hours to complete the training.

FIGURE 2: Results of Evaluation of Onsite WayToServe RBS Training in English
Refusal of Sale to Intoxicated Pseudo-Patrons
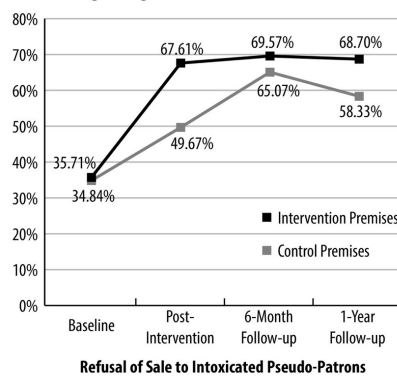
Evaluation of WayToServe Training: Two randomized trials were performed, with onsite (n=155) and off-site (n=158) alcohol premises in New Mexico, comparing *WayToServe* to usual and customary training (UC) provided by live trainers in 2 (training: *WayToServe* vs. UC) x 4 (time: baseline, immediate post-training, 6-month and one-year follow-up) design. Primary outcome was refusal of service to "pseudo-patron" buyers[114-119] who acted apparently-intoxicated (refusal to underage-appearing pseudo-patrons was assessed in Off-site Trial, too). Onsite Trial[11] had a significant main effect for training ($F_{(1,264)}=5.55$, $p=.019$) and training by time interaction ($F_{(3,792)}=2.88$, p=0.35) on refusal rates. Improvements for *WayToServe* compared to UC occurred at immediate post-training (t(288)=3.26, p<0.001) and 1-year (t(272)-1.74, p=0.002; see **Figure 2**). In Off-site Trial, there were a significant effects for training ($F_{(2,1311)}=2.87$, $p=.05$) and training by time interaction ($F_{(3,1311)}=2.72$, $p=.04$), and trend toward a difference at 1-year (*WayToServe* M=76%, UC M=68%; $t(292)=1.42$, $p=.07$). *WayToServe* improved refusals of underage pseudo-patrons, too (training $F_{(1,1024)}= 19.19$, $p=.0001$; training X time $F_{(3,1024)}=2.69$, $p=.045$; 6-months: $t(308)=2.58$, $p=.005$; 1-year ($t(101)=3.02$, $p=.001$) (see **Figure 3**).

FIGURE 3: Preliminary Results of Evaluation of Off-site WayToServe RBS Training in English
Refusal of Sales to Underage Pseudo-Patrons
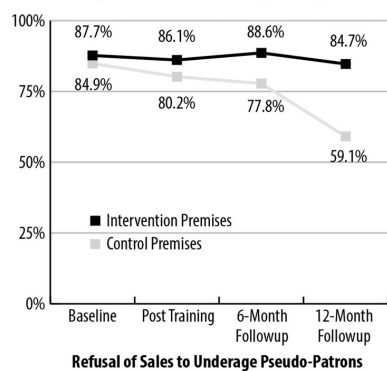
Scientific Premise: These data show that *WayToServe* training was effective at improving RBS practices. Further, its usability (M=63.73 out of 70) and servers' RBS self-efficacy (M=45.94 out of 50) remained high in dissemination. But, the Off-site Trial suggested servers will benefit from more RBS support/training. This is the goal of the proposed in-service professional development component.

3C. Research Design and Methods

The SBIR Fast-track will be completed in 3 years (see timeline in **Form F,** *Section 2.7*). Phase I protocols will be developed with External Advisory Board (EAB) in Month 1. Owners/managers and alcohol servers from onsite alcohol premises will give input on in-service professional development in Month 2 in focus group/interviews/survey. A prototype *WayToServe Plus* will be produced in Months 3-4. Acceptability, feasibility, and engagement with the prototype will be tested with alcohol servers in focus groups in Months 5-6 and in a field pilot test in Months 7-8. Phase I results will be reviewed by EAB in Month 9 for feasibility of full production and evaluation. In SBIR Phase II research, a specifications document approved by EAB will guide full production of *WayToServe Plus* (if deemed feasible) in Months 10-17; EAB will review full *WayToServe Plus* and randomized trial plans. *WayToServe Plus* will be tested for effectiveness in Months 15-36 in a randomized two-group design. All protocols will be approved by the Western Institutional Review Board (WIRB).

3C.1. Target Populations, Recruiting, and Inclusion/Exclusion Criteria

Owners/managers and alcohol servers from licensed premises selling alcohol by the drink (e.g., bars and restaurants) in California, New Mexico and Washington State will participate (see **Figure 4** for inclusion/ exclusion criteria). Onsite premises will be enrolled because Washington State requires RBS training only for onsite sales. For Phase I, alcohol servers will be selected at random from the roster of *WayToServe* trainees over the preceding 12 months to obtain newly-trained servers and those who had time to implement RBS. In 2019, *WayToServe* averaged 45 trainees per

FIGURE 4: Inclusion and Exclusion Criteria for Premises and Servers

Premises	Alcohol Servers
Inclusion Criteria	
Located in New Mexico or Washington State	19 years of age or older
Hold an active alcohol license from New Mexico Alcoholic Beverage Control or Washington State Liquor and Cannabis Board	Own/manage a licensed premises or be an alcohol server (waitress, waiter or bartender)
A bar or restaurant with full service bar	Have completed *WayToServe* RBS training (Phase I only)
	Be proficient in English
	Consent to participate
Exclusion Criteria	
Participated in our prior trials on *WayToServe* RBS training	Have a family/household member already participating in project
Have an inactive, suspended or revoked alcohol license	Younger than 19 years old (18 and younger cannot legally serve alcohol in either state)

day (~1,360 per month). In our preliminary survey (see **Box 2**), 70% of *WayToServe*-trained servers were willing to test *WayToServe Plus*. Thus, recruitment of servers is feasible.

3C.2. External Advisory Board (Month 1-9; Specific Aim 1)
The EAB will be chaired by Dr. Saltz and include Dr. Sherry Pagoto (an expert in using social media for disease prevention), and Mr. David Mosher (an alcohol industry representative). We will recruit an owner/manager and alcohol server who meet the inclusion/exclusion criteria above for the EAB. EAB will meet 6 times:
1. **Month 1:** Review plans and protocols for the SBIR Phase I research in Month 1,
2. **Month 4:** Review specifications document and prototype of the *WayToServe Plus*.
3. **Month 9:** Review Phase I results and advise on feasibility of testing *WayToServe Plus* in Phase II.
4. **Month 13:** Review all protocols for randomized trial in Phase II.
5. **Month 17:** Review fully-produced *WayToServe Plus* in-service professional development component.
6. **Month 36:** Review results of randomized trial and suggest final improvements to *WayToServe Plus.*

Milestones & Deliverables: Milestone 1: Approval of Phase I Research Procedures: In Month 1, the EAB will review and approve the Phase I research procedures. *Deliverable 1: Approved Study Protocol.*

Box 2: Survey of *WayToServe*-trained Alcohol Servers on *WayToServe Plus* Concept

In 2019-20, we surveyed 100 alcohol servers (n=50 New Mexico, 50 Washington State) who completed *WayToServe* training in past year (71% female; 36% ethnic minority; mean [M] age=33.6; 55% onsite; 48% were serving alcohol <1 year [M=4.6]) on their need for and interest in in-service professional development for RBS. Servers' most popular social media platform was Facebook at all ages, with most servers having an account and checking it several times a day (see **Table 1**). Also popular were Instagram and YouTube. Use of these 3 social media did not differ by age, gender, or type of premises (p>0.05), but YouTube is used most by servers with 2-5 years of experience (0-1 years 47.9%, 2-5 70.4%, 6+ 21.0%, p=0.004). Of the popular platforms, YouTube and Instagram have higher credibility than Facebook.

TABLE 1: Social Media Use by *WayToServe*-trained Alcohol Servers

Social Media Platform	Have Account	Use Platform	Frequency of Use			Somewhat/ Very Credible
			<1x per week	<1x per day	Several times a day	
Facebook	84.4%	70.8%	10.4%	31.3%	58.2%	27.2%
Twitter	38.5%	20.8%	20.0%	25.0%	55.0%	40.6%
Pinterest	56.7%	35.0%	47.0%	41.2%	11.8%	60.5%
Instagram	72.4%	53.0%	13.5%	36.5%	50.0%	55.7%
Linkedin	39.8%	13.3%	76.9%	23.1%	0.0%	75.9%

About a quarter of servers were not completely confident they can use RBS practices from *WayToServe*: Take steps to prevent intoxicated patron from driving (28.2% very sure), count drinks to prevent intoxication (30.9%), take other steps to prevent intoxication (28.6%; white 42.6%, Hispanic 8.0%, other 27.3%; p=0.044), recognize when patron is intoxicated (21.2%), refuse service to intoxicated

TABLE 2: Lack of Support for Responsible Sales Practices Taught in *WayToServe*

Sales Practice	Managers Do Not Support a Lot	Other Servers Do Not Support a Lot
Checking IDs to prevent sales to underage persons	15.5%	22.1%
Refusing to sell alcohol to customers who appear intoxicated	22.1%	25.0%
Talking with pregnant customers about the risks of drinking alcohol	47.9%	58.9%
Counting alcoholic drinks to keep customers from becoming intoxicated	37.9%	41.5%
Cutting off customers who are getting close to becoming intoxicated	31.2%	33.7%

patron (11.1%), and use methods from *WayToServe* (21.2%). 74.2% of servers have refused alcohol service, but fewer younger (19-24 61.8%, 25-39 90.6%, 40+ 77.3; p=0.036), Hispanic (white 82.7%, Hispanic 72.0%, other 50.0%; p=0.023), and new servers (0-1 years 60.4%, 2-5 80.8%, 6+ 100%; p<0.001) had done so (nearly all are can check IDs – 91.9% verify validity of ID; 97.0% verify age). A number of servers do not feel they have a lot of support of managers and servers for RBS (see **Table 2**) more in Washington State (managers: counting drinks: WA 36.6%, NM 13.2%, p=0.011; refusing service to intoxicated customers: WA 17.1%, NM 4.8%, p=0.048; cutting off customers close to intoxication: WA 32.6%, NM 14.0%, p=0.038; other servers: checking IDs: WA 19.1%, NM 7.0%, p<0.046; refusing service to intoxicated patrons: WA 24.4%, NM 8.9%, p=0.035).

WayToServe Plus appealed to *WayToServe*-trained servers: 73.9% were interested in ongoing information/activities to keep up-to-date and use RBS methods (20.6% a little, 26.1% somewhat, 27.2% very) and 89.4% felt they would benefit (27.4% a little, 26.3% some, 35.8% a lot). Older servers had highest interest (19-24 59.4% 25-39 72.4%, 40+ 91.7% at least a little interested; p<0.001) and benefit (19-24 81.8%, 25-39 90.0%, 40+ 100% at least a little benefit; p<0.001). 55% of servers would join *WayToServe Plus* Facebook group (20.0% a little, 19.0% some, 16.0% a lot; no age difference p=0.500) and visit it at least weekly (27.8% once a week, 15.2% several times a week, 8.8% daily). At least half of servers would be interested in and/or use various topics/features (see **Table 3**). Most servers said joining *WayToServe Plus* would make them feel like they were in a professional community (76.5%).

TABLE 3: Interest in and Likelihood of Use of *WayToServe* Plus Content

WayToServe Plus Content	Interested
Descriptions of how to use *WayToServe* methods	34.8%
Interactive activity in which they apply a *WayToServe* method and received feedback	56.1%
Story from another server about how they used a *WayToServe* method	53.0%
Unusual or humorous experience by another server	60.6%
	Somewhat/Very Likely to Use
Learning activities about *WayToServe* methods	61.9%
Share their experiences as a server	51.7%
Share their tips and tricks for using the methods learned in *WayToServe*	56.3%
Share unusual, notable, and/or humorous stories about things that happened at their premises	56.8%
Comment on posts from *WayToServe* or other servers	54.6%
Share posts from *WayToServe* or other servers on their Facebook feed	36.8%

Most *WayToServe*-trained servers (70.0%) would take part in testing in-service component. Some had privacy concerns (48.9%: WA 59.2%, NM 36.6%,p=0.002) but 63% trusted Facebook to protect personal data (less trust by new servers: 0-1 years 51.2%, 2-5 76.0%, 6+ 43.8%, p=0.016).

Scientific Premise: The results supported the need for in-service professional development and the *WayToServe Plus* component delivered through the *WayToServe* Facebook page.

- A substantial group of alcohol servers trained by *WayToServe* have room to improve their self-efficacy for RBS practices to reduce intoxication, especially younger and newer servers.
- A number of servers also do not have strong support from management and other servers for RBS and support varies by state validating our plans to test the *WayToServe Plus* in two states.

- Most servers were interested in getting in-service information and felt it would be beneficial and over half would join it through a Facebook group. Younger servers may need extra effort to recruit them.
- *WayToServe* Facebook page is a good platform to deliver *WayToServe Plus.* Facebook is the most popular social media. We also will post on Instagram and YouTube, given their popularity and credibility.
- We will emphasize interactive activities, notable, unusual, or humorous stories from servers, and tips and tricks for using RBS practices, and message features to encourage engagement, sharing, and comments.
- Ways to protect privacy of server-generated content on *WayToServe Plus* are needed.
- We should be able to recruit many servers to participate in the proposed SBIR research.

3C.3. Phase I: Formative Research on RBS Professional Development (Month 2; Specific Aim 1)
    3C.3.1. Semi-Structured Interviews with Alcohol Premise Owners/Managers: Ten owners/managers of onsite alcohol premises in California, New Mexico (n=5) and Washington State (n=5) will participate in 1-hour semi-structured interviews performed by Drs. Buller and Woodall, using KB's video conferencing software, Zoom (compensation=$75). Before the interviews, owners/managers will be sent the URL for the *WayToServe* online RBS training and instructed to review it. Owners/managers will discuss RBS policies at their premises, their support for RBS methods, perceived importance of RBS, quality of RBS methods implemented by their servers, need for ongoing training and support for RBS among their servers, and suggested content for in-service professional development for alcohol servers.
    3C.3.2. Focus Groups with Alcohol Servers: 2-hour virtual focus groups with approximately 22 alcohol servers from onsite premises in New Mexico (n=~11) and Washington State (n=~11) will be led by the Project Coordinator trained in focus group methods, using KB's video conferencing software, Zoom (compensation= $75). Servers will be recruited at random from the roster of *WayToServe* trainees in the past year. Servers will describe content and features desired for in-service professional development in RBS methods, barriers to implementing RBS and means of overcoming them, and potential utility of in-service professional development for premises and servers. They will discuss support received from premises owners/managers and other alcohol servers for RBS and its adequacy, and their experience with RBS practices, especially after receiving state-mandated RBS training. They will be asked if they have ever refused a sale, how confident they were in doing so, and techniques used to successfully/unsuccessfully refuse. Servers will be asked if they are willing to share RBS experiences or provide feedback on RBS actions to other servers on the *WayToServe* Facebook page.
Milestones & Deliverables: Milestone 2: Development of the Content Outline: Investigators and KB media developers will review results of our preliminary survey (see **Box 2**) and summaries of the formative interview and focus group results and create an initial specifications document describing all aspects of the professional development component to guide production of the prototype *WayToServe Plus*, i.e., detailed content outline and features desired by owners, managers, and servers and feasible through Facebook, Instagram, and YouTube. It will also describe technical requirements and programming plans for the component. The EAB will review and give input on the initial specifications document. *Deliverable 2: Specifications Document.*

3C.3.3 Survey of Alcohol Servers

In addition to the above focus groups, a survey will be distributed to alcohol servers at on-site premises in New Mexico (n=~15) and Washington State (n=~15). Servers will be recruited at random from the roster of *WayToServe* trainees in the past year. Servers will describe content and features desired for in-service professional development in RBS methods, barriers to implementing RBS and means of overcoming them, and potential utility of in-service professional development for premises and servers. They will discuss support received from premises owners/managers and other alcohol servers for RBS and its adequacy, and their experience with RBS practices, especially after receiving state-mandated RBS training. They will be asked if they have ever refused a sale, how confident they were in doing so, and techniques used to successfully/unsuccessfully refuse. Servers will be asked if they are willing to share RBS experiences or provide feedback on RBS actions to other servers on the *WayToServe* Facebook page.

This survey is meant to supplement the focus group data in light of the COVID-19 Omicron variant surge, not replace it.

3C.4. Phase I: Production of the Prototype *WayToServe Plus* (Months 3-4; Specific Aim 2)
A prototype of *WayToServe Plus* in-service professional development component will be produced by KB's media developers (see ***Section 8A***). The goal of in-service component is to raise servers' professionalism by:
1. increasing confidence and motivation of *WayToServe*-trained servers to implement RBS methods, with attention to ways of overcoming common barriers such as pressure to sell from managers, management disinterest or

resistance, and customers' attempts to continue being served;

2. creating a professional community of servers on *WayToServe* Facebook page that provides support to fellow servers for implementing RBS actions and serves as resources for advice/strategies to implement RBS (e.g., tips and tricks), which should be especially useful for new servers, servers in small or unsupportive premises and in the face of turnover in premises management and servers, by sharing their personal RBS experiences through user-generated comments and sharing of the posts.

3. preventing natural degradation of RBS skills and motivation over time by providing refresher instruction through text, interactive features, and videos demonstrating RBS techniques, which are based on principles of DIT (e.g., compatibility, simplicity, trialability, and observability; see *3A.2*) and SCT (i.e., modeling).

Based on formative research (see *3C.3* and **Box 2**), We will author a library of 50 Facebook posts from which a 1-month prototype will be created (see below). Posts will provide help for RBS suggested by owners/ managers, present ways to overcome barriers to implement RBS and refuse sales, describe success stories from servers; and stimulate supportive comments/feedback on RBS from other servers. To achieve high visibility on users' Facebook feed, given its revised newsfeed algorithm, we will post multiple times per week and format posts to increase user engagement (e.g., polls; true/false; activities; "fun" content).

Investigators and media developers will use agile, iterative production for *WayToServe Plus* and methods used by Drs. Buller and Pagoto (Consultant) to create an effective social media campaign in a prior studies (see Box 4). Posts will be based initially on instructional goals, DIT and SCT principles, and formative research and, later, on usability testing and field pilot test results (see *3C.5*) and be relatable, positive, entertaining, and at 4th grade reading level. Posts will be created using message grids, where each message is listed, along with theoretic principles operationalized and suggestions for graphics/weblinks to related content (e.g., videos, interactive activities, or external sources [e.g., news]). Investigators will create initial scripts for interactive exercises, based on *WayToServe* training, and short videos depicting RBS methods (e.g., ID checking, spotting intoxicated patrons, refusing sales). Interactive simulations will teach skills by presenting challenges (e.g., checking IDs; refusing sales to intoxicated patron; and counting drinks), making a choice that applies the skill (e.g., decide if ID is valid or not or to serve alcohol or not), and receiving corrective feedback. Media developers will add the multimedia elements to posts and storyboard activity/video scripts. Investigators will review all posts and scripts/ storyboards, making final adjustments, and media developers will produce interactive activities and videos. Features to elicit user-generated content will be included in posts (e.g., pose a common situation and ask for example RBS strategies, solicit stories about "most outrageous manager" or "drunkest customer," or contest for "server of the month") to create sense of "community" among alcohol servers. *WayToServe Plus* will be in English because a) nearly all social media content in the United States is in English (1.9%)[120] and b) most servers elect to complete *WayToServe* training in English (98.4% in 2019). We will incorporate Spanish posts once success of *WayToServe Plus* is established in this SBIR research.

WayToServe Plus posts (n=12) will be selected for a 1-month prototype for the field test (see *3C.5.2*) that adequately demonstrate various formats of posts (text, graphics, interactive activities, and videos) and the key professional development goals. Media developers will produce a Facebook private group with the look of the *WayToServe* Facebook page where the *WayToServe Plus* posts will be posted. Interactive activities, graphics, and videos will be posted on a custom webpage, Instagram, or YouTube, accessed via links in the Facebook posts. Some activities will function best on a webpage; Instagram and YouTube are popular social media with alcohol servers (see **Box 2**). The Project Coordinator will serve as the Community Manager and schedule posts, monitor feed, and respond to inappropriate comments. The EAB will review the prototype.

Milestones & Deliverables: Milestone 3: Development of *WayToServe Plus* Prototype: The *WayToServe Plus* prototype will contain a library of Facebook posts with text, graphics/photos, interactive activities, and videos, schedule for a 1-month field test, and updated specifications document. It will give a good sense of how the in-service component will operate and how much servers will engage with and benefit from it. *Deliverable 3: Revised Specifications Document. Deliverable 4: WayToServe Plus Library of Facebook Posts.*

Box 3: *WayToServe* Facebook Page

WayToServe Facebook page is a marketing platform, with 20,323 likes and 20,246 followers as of August 27, 2020. WEDGE posts informative, entertaining content on alcohol service (approx. 7 per week), including ads for *WayToServe* training and RBS information (e.g., BAC, mocktail recipes, holiday alcohol safety). Most posts are delivered to all states, with some geo-targeted locally. In August, 2020, 259,667 users saw a posting from *WayToServe* on their Facebook newsfeed (reach), 1913 users engaged with these *WayToServe* Facebook posts (i.e., liked, shared, or commented on a post) (engagement), and 437 users saw the last 5 Facebook posts from *WayToServe*. This use occurred without commitment or compensation; we will confirm that use will be higher by servers who enroll in a formal study testing the in-service component.

FIGURE 5: *WayToServe*® Facebook Page

3C.5. Phase I: Evaluation of Prototype *WayToServe Plus* (Months 5-8; Specific Aim 2)

The prototype *WayToServe Plus* component will be evaluated for feasibility, acceptability, usability, and engagement through focus groups with alcohol servers in Months 5-6 and a field test with alcohol servers in Months 7-8 (servers who participated in formative research [see ***3C.3***] will be ineligible).

3C.5.1. Focus Groups on Acceptability, Feasibility, and Usability (Months 5-6): Twenty alcohol servers will be recruited at random from the roster of *WayToServe* trainees (n=10 in New Mexico and 10 in Washington State; compensation=$75) to participate in focus group discussions on the acceptability, feasibility, and utility of the prototype *WayToServe Plus,* led by the Project Coordinator (10 usability testers can identify 95% of problems[121-123]). They will be presented with a description of *WayToServe Plus* and review the library of Facebook posts. For each post, servers will identify the main message (to test comprehension), indicate if it is appropriate and acceptable for alcohol servers, their premises, and their experience deploying RBS methods, report if the information will be useful to them and other alcohol servers, say whether they are likely to view, comment, or share the post, or contribute their own content on RBS methods to the Facebook page, and note what would keep them from engaging with posts (i.e., barriers to use). Investigators and KB production staff will revise the *WayToServe Plus* based on this feedback and before field testing (see ***3C.5.2***).

3C.5.2. Field Pilot Test of Prototype *WayToServe Plus* (Months 7-8): A field pilot test of a 1-month prototype of *WayToServe Plus* will be conducted with 100 alcohol servers (n=50 New Mexico; n=50 Washington State; compensation=$100) recruited when completing *WayToServe* training and randomized to *WayToServe Plus* (n=50) or untreated control (n=50). Servers in *WayToServe Plus* group will "follow" a *WayToServe Plus* Facebook private group, administered by the Project Coordinator that has the look of the *WayToServe* Facebook page but messages will be viewable only to group members. Project Coordinator will post 3 *WayToServe Plus* posts per week for 4 weeks (n=12 posts), along with normal posts by WEDGE's marketing staff. Servers' engagement with *WayToServe Plus* will be recorded – number of times posts are viewed, reacted to, and commented on, and user-generated content posted such as personal experiences with refusing sales to intoxicated patrons or entry by minors. After 4 weeks, servers will complete a posttest in KB's Qualtrics online survey software assessing acceptability/appropriateness of *WayToServe Plus* in-service component for servers and premises, and their experience using RBS methods, usability of *WayToServe Plus* on validated System Usability Scale (SUS),[124-126] utility of in-service posts, and perceived self-efficacy and response-efficacy (for keeping community safe) for RBS methods. Servers will be asked how willing they are to use *WayToServe Plus* in the future and how they would improve it and make it more engaging.

Ten alcohol servers in the field test sample (n=5 New Mexico; 5 Washington State; compensation=$50) will be randomly selected for a semi-structured interview on reactions to *WayToServe Plus* prototype. The Project Coordinator, using video conferencing, will probe for in-depth input on whether the in-service component was appropriate, acceptable, and useful for themselves, their premises, and their RBS methods, what made them engage with the posts or not, and how the in-service component could be improved and made more engaging.

Milestones and Deliverables: Milestone 4: Evaluation of the Prototype: Reports will be prepared on the usability and field test findings in Month 9 that describe overall usability, valued parts of the prototype, ways to improve the in-service component in Phase II (i.e., solutions to remaining problems planned for Phase II production), engagement with the prototype, and barriers/willingness to use *WayToServe Plus*. KB media developers will update the specifications document for full production of *WayToServe Plus* in Phase II. For planning the evaluation of *WayToServe Plus* in Phase II,

reports will summarize recruitment and follow-up rates in the field test. *Deliverable 5: Evaluation Reports; Deliverable 6: Revised Specifications Document.*

Box 4: Previous Technology Intervention Development and Testing

Drs. Buller and Woodall and KB media developers are experienced with technology interventions, including on adolescent smoking,[127] dietary change,[128] risky drinking,[129] risky sexual behavior,[130] and HPV vaccine uptake,[131] as well as the *WayToServe* training. Scientific premise for delivering *WayToServe Plus* over social media is provided by past research by Drs. Buller and Pagoto (Consultant). They tested a social media campaign to prevent indoor tanning (IT) by adolescent girls in a randomized trial (R01CA192652; see **Figure 6**).[132] Mothers (n=869) with teen daughters were enrolled. Relevant to the SBIR Fast-track research, mothers received either intervention or control social media campaign by joining Facebook private groups, to control treatment condition and prevent contamination. IT messages were posted 3-4 times per week over 12 months (~185 posts each; 87% stayed in groups for 12 months). Follow-up was high (72.4% at 12-months; 78.9% at 18-months). At 12-months, the social media campaign reduced mothers permissive toward daughters' IT (p<0.05) and IT intentions (p<0.05) and increased communication with

FIGURE 6: Sample Posts from *Teen Health Chat*

daughters about avoiding IT (p<0.05). Dr. Pagoto used social media in 3 studies of successful social media weight loss interventions (R21DK098556, K24HL124366, KL2TR000160, U01HL105268)[133-135] and 5 ongoing studies of weight loss interventions (R01DK103944-01A1, R01CA192652, R01HL122302, K24HL124366, R21CA226133). Drs. Buller and Pagoto are collaborating on a family-based Facebook intervention on skin cancer prevention (R01CA221854; S. Manne, PI).

   Scientific Premise: We created theory-based social media campaigns that improved health behaviors. We have protocols to develop social media messages, recruit and retained multi-ethnic adults, and deliver, track, and analyze social media messages using Facebook private groups to achieve experimental control. The SBIR Fast-track research will leverage this experience to create, deliver, and test *WayToServe Plus*.

3C.6. Phase I: Data Management and Analysis

Qualitative analysis of interviews, focus groups, and survey data will rely on constant comparative analysis[136] and methods by Krueger and Casey.[137] Atlas-ti[©] software will be used to assign codes to categorize themes and opinions. To identify problems that impact $\geq$10% of users in usability testing[138,139] with a 90% chance of detection (log(1-.90)/log(1-.10)), 21 participants are needed. For field pilot test, we will enroll 25 servers per state per condition (n=50 *WayToServe Plus*; n=50 control). Control sample will allow us to estimate follow-up rates in both conditions for Phase II randomized trial. Data from field pilot test of prototype *WayToServe Plus* will be stored in KB's secure servers, with data management and analysis supervised by Dr. Cutter, Project Biostatistician and Ms. Lucia Liu, Biostatistical Manager, using quality assurance protocols and SAS software. Servers' pre-post change in theoretic mediators of RBS (i.e., self- and response efficacy) will be compared between *WayToServe Plus* and control, using Fisher's exact test and t-tests (intention-to-treat), to show potential effectiveness (for proportions of 35% to 50%, differences of about 25% can be detected with 80% power; for continuous outcomes, power is >80% for effects sizes >0.55 sd). Comparisons on server demographics and premises characteristics will be done using χ^2, t-tests, and correlations. Usability of (ratings on SUS) and engagement with in-service component (i.e., viewing; commenting; and contributing posts), evaluations of its content, and barriers and willingness to use it will be collected and analyzed. Analyses will include descriptive statistics and regression analyses, using intention-to-treat analyses and sensitivity analyses adjusting for covariates and levels of adherence. All tests will be at 2-tailed p=0.05.

3C.7. Appraisal of Feasibility of *WayToServe Plus* and Phase II Plan (Month 9; Specific Aim 3)

The EAB will meet in Month 9, review Phase I findings, and advise on feasibility of *WayToServe Plus*. Feasibility is indicated by a) *WayToServe Plus* being acceptable and desirable to 75% of owners/managers and servers, b) *WayToServe Plus* specifications and prototype being developed, c) *WayToServe Plus* prototype being acceptable, usable (minimum 68 out of 100 on SUS[67]), and engaging (75% of users view and 50% react to a post [e.g., like; comment]), and d) *WayToServe Plus* influencing theoretic mediators (at least small effect sizes, Cohen's d=0.2). They will provide input on specifications document, ways to improve *WayToServe Plus* and research design and implementation procedures for

evaluating *WayToServe Plus* in Phase II.

Milestones and Deliverables: <u>Milestone 5: Feasibility Assessment:</u> The EAB will review Phase I outcomes and advise on feasibility of the full *WayToServe Plus,* its specification document, and research plans for SBIR Phase II research. A feasibility report will contain Phase I findings, decision on feasibility of *WayToServe Plus* and plans for Phase II research. *Deliverable 7: Phase II Plan and Final Specifications Document.*

3C.8. Scientific Rigor and Limitations in Phase I
State-of-the-art research methods, pre-defined protocols, diverse samples from two states, and established measures (e.g., SUS) will ensure **scientific rigor** of the SBIR Phase I research. Small samples are a limitation but typical for qualitative research; sample in field pilot test is moderate in size and provides adequate precision and will identify problems to create a usable in-service component. The control sample is designed to test for statistical differences in effect moderators, serve as a calibration sample to test acceptability of control condition, and estimate follow-up rates for Phase II randomized trial that will test *WayToServe Plus*.

3C.9. Overview of Phase II Research and Timeline
SBIR Phase II research will include full production of *WayToServe Plus* in-service professional development component (Months 10-17) and a randomized 2-group field trial testing its effectiveness (Months 15-36), in a 27-month timeline (see ***Section 2.7*** in **Form F**). The target population (see ***3C.1***) is owners, managers, and alcohol servers working in state-licensed premises for onsite sale of alcoholic beverages in California, New Mexico and Washington State. These two states require servers to complete state-approved RBS training such as *WayToServe* and be certified to serve alcoholic beverages to work as an alcohol server (and renew every 3 years in New Mexico or 5 years in Washington State). Investigators and media developers at Klein Buendel (KB) will produce the *WayToServe Plus* in-service component, using Phase I specifications, content outline, and prototype (see ***3C.4*** and ***3C.5***). The randomized trial will be performed, starting in Month 15, with intervention and assessment concluding in Month 32 and outcome analyses completed by Month 36. The EAB will meet in Month 13 to approve trial protocols, in Month 17 to review the *WayToServe Plus* in-service component, and in Month 36 to review trial outcomes (see ***3C.2***). All Phase II procedures will be approved by the WIRB. Premises with participants in Phase I research will be ineligible for Phase II randomized trial.

3C.10. Phase II: Production of *WayToServe Plus* (Months 10-17; Specific Aim 4)
Investigators and media developers will author a library of ~160 Facebook posts for *WayToServe Plus* in-service component, planning to post 3 posts per week in a year (currently WEDGE posts 7 posts per week to *WayToServe* Facebook page, see **Box 3**), along with interactive activities and short videos. We will draft posts and script/storyboard activities/videos using methods from Phase I (see ***3C.4***). Prototype *WayToServe Plus* will be a starting point for the complete library of in-service posts (see ***3C.4***), with changes suggested by usability testing, server reactions/engagement in field pilot test, and EAB at the end of Phase I. To achieve high visibility on users' Facebook feed, with its revised algorithm which downgrades posts that get low engagement, we will format posts to be engaging (e.g., polls; true/false; activities; "fun"). To increase relevance, posts will address barriers/facilitators and contain ethnically-diverse images from KB's *Real Health Photos* stock art library that improves identification and impact.[140] Frequency of posts will meet standards of repetition.[141] Half of posts will be created before launch of *WayToServe Plus*; the other half during the intervention to leverage news items/current events for relevance. In our previous social media campaign, after 6 months, participant engagement declined,[142] indicating topic fatigue. We will monitor engagement/comments for evidence of fatigue, adjust post schedule, add videos/images for salience, and link to current events for engagement.[84,143,144] Using these methods, 86% of mothers stayed in private groups in our past social media campaign (**Box 4**). EAB will review the library of posts, activities, and videos, suggesting final changes.

Milestones and Deliverables: <u>Milestone 6: Production of *WayToServe Plus* In-service Component</u>. *Deliverable 8: Fully-produced WayToServe Plus. Deliverable 9: Randomized Trial Evaluation Plan.*

3C.11. Phase II: Experimental Design for Randomized Trial (Months 15-36; Specific Aim 5)
We will test *WayToServe Plus* in-service component's ability to increase refusal of service to intoxicated patrons in a randomized trial (see timeline in ***Section 2.7***, **Form F**). A two-group randomized field trial (*WayToServe* training only [comparison control] v. *WayToServe* training plus *WayToServe Plus* in-service component [intervention]) with 2 assessment rounds (Baseline and Posttest [12-months post-randomization]) will yield a 2 (treatment) x 2 (assessment time) factorial design, with 4 assessments per alcohol premises (2 per round; see **Figure 7**). State-licensed onsite alcohol premises (n=180) in California, New Mexico and Washington State will be randomly-selected from publicly-available

lists, stratified by location (metro areas [Albuquerque, Seattle; n=110] v. small towns/ rural areas [n=50] within 1-day drive of metro areas for feasible assessment) and assessed for refusal of alcohol service to visibly-intoxicated patrons, using pseudo-intoxicated patron (PiP) protocol (see **3C.14**; primary outcome) at baseline (Months 15-17) (10 premises per state will be selected to replace any closed businesses). Using a custom-written program, project biostatistician will randomly assign n=80 premises to *WayToServe* training plus *WayToServe Plus* after baseline in Month 18, stratified by state and location. Remaining premises (n=80) will receive *WayToServe* training only. All premises will be recruited to have all servers complete *WayToServe* training. Servers in intervention group will be accepted into a Facebook private group after *WayToServe* training to receive in-service component with ~3 posts per week for 12 months (Months 18-29; n~160 posts total). In a prior trial, a social media campaign at this frequency over a year was effective (retention= 86%; see **Box 4**). In Months 30-32, all premises will be posttested with PiP assessments (<u>blind to condition</u>). Analyses will test the **hypothesis**:

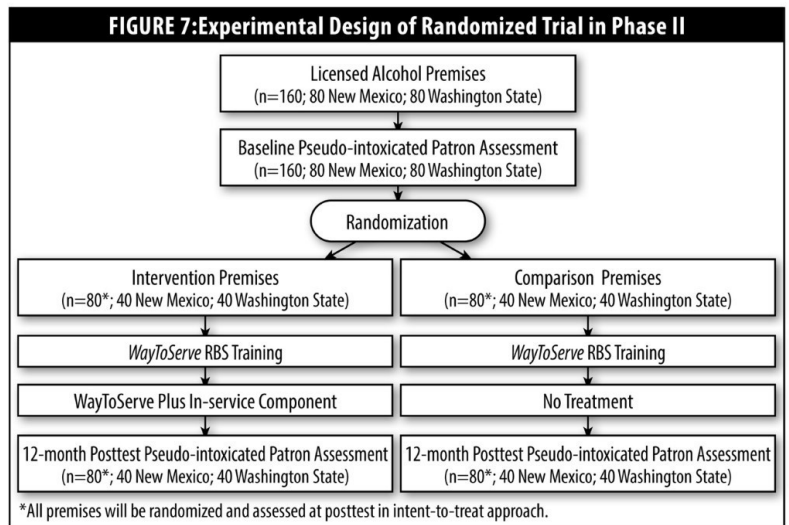**H:** Compared to premises in *WayToServe* RBS training only group, premises assigned to receive *WayToServe* RBS training plus *WayToServe Plus* will have higher rates of refusing PiP at posttest.

In our prior research, uptake of training in alcohol premises affected refusal rates,[145] so we will test the **research question** of whether uptake of the *WayToServe* training and of *WayToServe Plus* improves PiP refusal rates. PiP assessment teams will also record characteristics of alcohol premises to be analyzed as effect modifiers of *WayToServe Plus*. The design will blind premises and alcohol servers to all PiP assessments, protecting against compensatory increases in refusal rates. Project staff, except Community Manager and Project Coordinator, also will be blind to experimental condition.

3C.12. Implementation of *WayToServe* RBS Training

Following baseline, all 180 premises will be contacted and recruited to the trial (premises compensation= $250 for intervention group and $150 for control group). Managers will provide a list of all servers, who will be registered by project staff on *WayToServe* training and provided with a user ID that will track use and link it with premises. See **Box 1** for description of *WayToServe* RBS training. Servers will complete consent form and profile at their first login. They will be asked to complete the training within 4 weeks from registration; email and text reminders will be sent to those who do not login within 1 week (compensation= $35 from research team and new server training certificate from NMABC or WSLCB free of charge). *WayToServe* will remain available to premises throughout the trial; managers will report new hires so project staff can register them and they can complete the training. Drs. Buller and Woodall have successful protocols for recruiting premises: Over 400 onsite and off-site licensed premises were enrolled in the 3 trials evaluating *WayToServe* (English) and *WayToServe Español* (Spanish) training (see **Box 1**). After baseline assessment, we will call the premises

FIGURE 7: Experimental Design of Randomized Trial in Phase II

Licensed Alcohol Premises (n=160; 80 New Mexico; 80 Washington State)

Baseline Pseudo-intoxicated Patron Assessment (n=160; 80 New Mexico; 80 Washington State)

Randomization

Intervention Premises (n=80*; 40 New Mexico; 40 Washington State) — *WayToServe* RBS Training — WayToServe Plus In-service Component — 12-month Posttest Pseudo-intoxicated Patron Assessment (n=80*; 40 New Mexico; 40 Washington State)

Comparison Premises (n=80*; 40 New Mexico; 40 Washington State) — *WayToServe* RBS Training — No Treatment — 12-month Posttest Pseudo-intoxicated Patron Assessment (n=80*; 40 New Mexico; 40 Washington State)

*All premises will be randomized and assessed at posttest in intent-to-treat approach.

management and arrange a meeting, where we will describe participation and obtain agreement for all servers and managers to participate in the study. We will appeal to the value-added benefits of server training to reduce violations, citations, and lawsuits. Based on our previous evaluations of *WayToServe*, we expect 80% of premises to agree to use *WayToServe* training (n=128 premises) and 80% of servers to complete the training (n=1024, assuming 10 servers per premises). Premises that decline will be recorded and scheduled for post assessments in intention-to-treat approach.

3C.13. Implementation of *WayToServe Plus* In-service Professional Development Component

The project biostatistician will randomize half of the premises to join *WayToServe Plus* following the baseline survey. Intervention-group trainees will be instructed to "friend" the Community Manager for the *WayToServe* Facebook page at the end of *WayToServe* training (compensation=$50). In-service component will be implemented through a Facebook private group that has the look and feel of the *WayToServe* Facebook page (see **Box 3**). Group members can comment and react to posts, but not share them on their own feed, so other Facebook friends cannot see private group or posts.

Based on current social media marketing advice for new Facebook algorithms, the Community Manager will post *WayToServe Plus* messages ~3 times per week (and post messages from *WayToServe* Facebook page the other 4 days) to achieve effective reach,[141,146-148] scheduling posts in advance on Buffer software.[149] Orientation to private groups will be self-explanatory. Alcohol servers in our preliminary survey (see **Box 2**) said they would check in-service component weekly, but not likely daily. In our past project (see **Box 4**), participants were adept at using Facebook private group and most commonly viewed posts at 8-9 am and 7-8 pm ET. The Community Manager will stress respect for others as a ground rule and monitor all comments and correct inappropriate/unfavorable/ bullying comments or misinformation, using a moderator guide that provides ways to respond while maintaining credibility (no bullying was observed in our past studies). If an alcohol server leaves the group, they will be contacted to see why; in our past project, 121 (13.7%) participants left groups (see **Box 4**). In the comparison group, servers will "follow" the *WayToServe* Facebook page where daily posts are focused on marketing *WayToServe* training (see **Box 3**).

3C.14. Primary Outcome: Pseudo-patron Assessment of Alcohol Service to Intoxicated Patrons

Primary outcome measure, refusal rate of alcohol service to apparently-intoxicated patrons, will be obtained via a pseudo-intoxicated patron (PiP) assessment. Confederate buyers will feign intoxication and record if servers agree to serve them an alcoholic beverage. PiP protocol presents a server with the most overt situation in which alcohol service should be refused, (i.e., when a patron is showing clear signs of intoxication), models behavior of patrons most at risk, and is relatively low cost. Other measures have drawbacks (e.g., unpredictable prevalence of intoxicated customers for onsite observation and biases in self-reports). PiP protocol has been used in thousands of alcohol premises;[117] we have used it in over 400 premises. We will train ethnically-diverse male and female legal-age individuals (≥21) to conduct PiP assessments, <u>blind to study purpose and treatment</u>, chosen for prior acting experience and supervised by field supervisors. They will complete training from our past projects.[150-152] Signs of intoxications trained (i.e., fumbling with keys/ cash, swaying, slurred speech, and stumbling) indicate high level of alcohol intoxication,[153] provide a clear, unambiguous choice whether to serve, and are signs users learn to recognize in *WayToServe*. PiPs' intoxication performance during training will be rated by project staff. PiPs will visit two premises not in sample, perform assessment, review with supervisor, and be re-trained, if needed. They will visit other premises, until they are comfortable with protocol, agree on 95% of characteristics, and observers report buyers display intoxication cues. Procedures for each visit are:

1. Observer enters premises first, sits where they can observe the buyer, orders a non-alcoholic beverage, and records descriptive information on premises.
2. Buyer enters premises exhibiting cues of intoxication and attempt to purchase an inexpensive beer.
3. Observer notes buyer's intoxication cues, buyer-server interaction, and if buyer is served an alcoholic beverage.
4. After buyer is served or refused, buyer leaves the premises. If served, buyer pays for beverage and then leaves served drink untouched, excuses themselves for the restroom, and exits the premises.
5. Observer waits 1-2 minutes after the buyer exits and then leaves the premises.

After exiting, buyer and observer will complete buyer and observer data forms (see **Appendix A**), recording if server served an alcoholic beverage to buyer (yes v. no). Supervisors will check all forms. The observer serves as a quality control assessor of the PiP buyer's presentation of feigned intoxication by recording if the buyer displayed signs of intoxication trained. Assessment will involve 2 PiP buyer visits per premises (separated by 6 weeks) in each assessment round (baseline, posttest), one with male buyer and one with female buyer. <u>Gender has affected alcohol sales,[154,155] so we will balance PiP buyers on gender and test gender pairs</u>. Characteristics of buyer will be included as **covariates** to control variation introduced by multiple buyers (n~50). Descriptive data on premises (type – bar or restaurant; number of servers and patrons; environment [e.g., lighting, layout]) and alcohol server who interacts with PiP buyer (gender, age, and ethnicity; comments made about serving to buyer [e.g., not providing more than one drink or risk of DWI] and any other attempts not to serve requested alcoholic beverage) will be recorded in buyer/observer forms (buyers and observers had high agreement in our prior work; average Cohen's kappa=0.85).[150-152] These descriptive data will be tested as **effect moderators**.

3C.15. Process Measures of *WayToServe* Training and *WayToServe Plus* Uptake

Uptake of *WayToServe* training and *WayToServe Plus* will be recorded. For **WayToServe training**, number and proportion of servers registered and completing it at each premises and quiz/exam scores will be recorded. Servers will complete a **Profile** with name, contact information, premises, and role (owner, manager, server).[156] For **WayToServe Plus**, servers' reactions (e.g., like, love, wow, angry, and sad) and comments to all posts will be extracted in identified

format using the Grytics app[157] (permission given in consent form; no data from their Facebook profile or personal newsfeed extracted). Two trained research assistants will code reactions/ comments as pro-, neutral, or anti-.[158] Facebook no longer displays views in private groups larger than n=250. After posttesting, intervention premises owners/managers (n=20; 10 per state) will be selected at random for **interviews** about *WayToServe Plus*, e.g., compatibility with premises RBS policies/practices, helpful features, server engagement, suggested improvements, and problems/barriers (compensation=$75).

3C.16. Data Management
Databases will be linked by a standard database structure and checked by sophisticated data editing/quality assurance methods. A random sample of 10% of manually-entered forms will be double entered; if error rate exceeds 1%, all forms will be double entered. Databases for PiP buyer/observer forms and process measures will be linked by a standard database structure. SAS 9.3 will be used in analyses. If missing data occur, analyses will be done a) on data collected (case-wise deletion), b) by intention-to-treat, and c) by imputation methods for missing at random data (if differential missingness is observed, by patterned mixture imputation).

3C.17. Statistical Analysis Plan
Dr. Cutter, the Project Biostatistician, will lead the analysis, working with Drs. Buller and Woodall and Ms. Liu, KB's Biostatistical Manager (who has worked with Dr. Cutter for over 10 years).

3C.17.1. Descriptive and Exploratory Analyses: Descriptive analyses (e.g., frequencies, means, SD) on refusals and premises/server characteristics will be calculated. Bivariate analyses (e.g., t-tests, χ^2) will compare premises by treatment at baseline to identify differences, mindful that intervention effects are assessed in both groups. Attributes showing treatment differences exceeding 0.25 SD will be treated as covariates in sensitivity analyses.[159] For primary analysis, there are 90 premises from intervention group (*WayToServe* training plus *WayToServe Plus*) and 90 premises from comparison group (*WayToServe* training only) (total N=180).

3C.17.2. Test of Hypothesis: PiP Refusal Rates: Primary analyses will be done using intention-to-treat. Each premises will have two attempts to refuse to serve alcohol to PiP buyers; thus, primary outcome is refusal versus not refusing at posttest (i.e., 0 or 1 v. 2 refusals), assuming that 2 refusals is clear indication intervention had the desired outcome. The hypothesis (see *3C.11*) will be tested by contrasting intervention with comparison premises. While each premises will have 2 before and 2 after PiP assessments, they will not be the same actors, but responses are clustered within premises. To simplify analysis, we will treat the premises as the unit of analysis, each scoring 0, 1, or 2 at baseline and posttest. Within intervention group, improvement in refusals is assessed using McNemar's test, a χ^2 test with 1 df computed as $(A-B)^2/(A+B)$,

FIGURE 8: Paired Outcomes of PiP Buy Attempts

Baseline	12-month Posttest		
	0 refusals	1 refusal	2 refusals
0 refusals	N_{11}	N_{12}	N_{13}
1 refusal	N_{21}	N_{22}	N_{23}
2 refusals	N_{31}	N_{32}	N_{33}

where A (green cells; **Figure 8**) and B (red cells) are off diagonal discordant pairs (A= N_{12}+ N_{13}+ N_{23}; improved) and (B= N_{21}+ N_{31}+ N_{32}; regressed). Both treatments should improve refusals. We will compare treatment groups using proportions improved (A/N) from baseline. Let us illustrate this analysis with data from our prior study on *WayToServe* training.[11] In control group (n=77 onsite premises), A=(17+9+7)=33 and B=(9+2+5)=16, χ^2=$(33-16)^2/(33+16)$=5.9, p=0.015. In intervention group (n=71 premises), A=(15+14+12)=41 and B=(4+1+3)=8, χ^2=$(41-8)^2/(41+8)$=22.2, p< 0.001. Comparing the groups, we have 33/77=42.9% (control) and 41/71=57.7% (intervention), a significant improvement in training, p=0.049. We will use a 1-tailed p-value because 1) we have no evidence that RBS intervention is harmful and 2) the question is pragmatic: can we improve *WayToServe* training? Failure to reject the null hypothesis H_0: $P_{wts} \geq P_{wts+}$ v. H_0: $P_{wts} < P_{wts+}$ is in itself the decision not to implement *WayToServe Plus*.

Additional analyses will enable adjustment for covariates using a repeated measures model with PROC GENMOD. Risk difference can be estimated using Margins or NLMeans macro, or by modeling the event probability directly. We will use hierarchical modeling, because observations (PiP buyer attempts) are nested within premises (Level II).[160] Level I outcome measures are binary (e.g., refused v. not refused), so a logit link function will be used. The Level I model will include measurement point (baseline, posttest) as a fixed effect and an error term as a random effect. Level II will include treatment condition and premises characteristics as covariates. Sensitivity analyses will test covariates in *3C.14* to ensure that results are not due imbalances.

3C.17.3. Exploratory Research Questions: Effect of *WayToServe* training and *WayToServe* Plus in-service component **uptake** (see process measures in *3C.15*) will be tested as a dose effect on PiP refusal rate. Uptake of training will be assessed in both treatment groups; uptake of the in-service component will only be available in the intervention group.

Dose-responses will be test as a simple covariate in the outcome models Receiver operator curve analysis[161] will detect if certain uptake is clearly effective rather than just incremental. Potential **effect moderators** collected on alcohol servers, PiP buyers, and premises (see *3C.14*), and state, will be tested within a regression framework using interaction terms of potential moderators with experimental condition, adjusted for multiple comparisons using a bonferroni correction. The differences associated with these moderators will need to be large to be detected. As ancillary tests, a 2-tailed p-value of 0.05 will be used.

   3C.17.4. Statistical Power Analysis: For comparison of *WayToServe* training plus *WayToServe Plus* in-service component to *WayToServe* training only with the analysis approach in *3C.17.2*, the final sample has n=90 premises in each group (n=180total), with two assessments rounds (baseline and posttest). The primary analysis will be to estimate the reduction (difference) in proportion of alcohol service (i.e., refusals: 0, 1, or 2) that occurred in the 2 PiPs per round and its 95% CI. Difference is expected to be a function of both training (both treatment groups) and in-service component (intervention group only). Our prior onsite trial showed an estimated 57.7% improvement for *WayToServe* training (see illustration of our approach to primary outcome analysis in *3C.17.2*), but to be conservative we assume 50% to 55% (+10-15% in refusals). We expect that *WayToServe Plus* in-service component will increase refusal rates by another 20% to 70% to 75%. In the minimum difference, we will be comparing 75% in *WayToServe Plus* group to 55% in *WayToServe* training only group. A sample size of 70 per group provides 80% power with a 1-sided Type I error of 5%. To provide a buffer on the necessary improvement as not all premises will use *WayToServe* training and intervention servers will not view all *WayToServe Plus* posts, we plan to have 80 premises per group.

Milestones and Deliverables: Milestone 7: Implementation and Randomized Trial Evaluation. *Deliverable 10: Final Report on Evaluation of WayToServe Plus In-service Professional Development Component.*

3C.18. Strengths, Weaknesses, and Overall Impact of Proposed Research
There are number of **strengths**. *WayToServe Plus* is based on effective RBS models. Randomized trial design is rigorous with adequate statistical power. PiP protocols provide objective measures. We avoided potential **weaknesses**. Blinding will reduce bias by not revealing the PiP assessments to owners, managers or servers; IRB-approved debriefing will be used. *WayToServe* training, social media development and delivery methods, and assessment protocols are already developed. The research will have **very high impact**. Intervention targets a frequent, highest-risk situation, alcohol intoxication, that if alcohol service continues produces dangerous impaired driving. In-service component can be immediately deployed with *WayToServe* training.

Eligibility Criteria
Licensed Alcohol Premises:
Inclusion Criteria:
- Located in California, New Mexico and Washington State
- Hold an active alcohol license from New Mexico Alcoholic Beverage Control or Washington State Liquor and Cannabis Board
- A bar or restaurant with full service bar

Exclusion Criteria:
- Participated in our prior trials on *WayToServe*® RBS training
- Have an inactive, suspended or revoked alcohol license

Alcohol Servers:
Inclusion Criteria:
- 19 years of age or older
- Own/manage a licensed premises or be an alcohol server (waitress, waiter or bartender)
- Have completed the *WayToServe* responsible beverage service training (Phase I only)
- Be proficient in English
- Consent to participate

Exclusion Criteria:
- Have a family/household member already participating in project
- Younger than 19 years old (18 and younger cannot legally serve alcohol in either state)

Age Limits
Minimum Age: 19
No maximum age

Inclusion of Individuals Across the Lifespan:
   Children will not be included in the proposed research because state laws prohibit individuals under age 19 from serving alcohol in licensed premises in California, New Mexico and Washington State. Adults aged 18 will be excluded because they cannot legally sell alcoholic beverages in California, New Mexico and Washington State. There is no maximum age limit for participants. Age of all participants will be collected when enrolled in the research.

Inclusion of Women and Minorities:
   We will recruit owners/managers and alcohol servers in on-site alcohol sales premises in California, New Mexico and Washington State at rates that reflect the gender and race/ethnic distribution in that workforce, based on our experience with *WayToServe* training and preliminary survey of *WayToServe*-trained alcohol servers.
   Combined the population of the two states: 59% of are female. Also, 80% are white, 4% Black/African American, 4% Asian, 0% Native Hawaiian or Other Pacific Islander, 2% American Indian/Alaska Native, and 10% more than one race. Of these, 20% are Hispanic. No exclusions will be made based on gender or race/ethnicity. The research team has experience in prior responsible beverage service (RBS) training research working with owners, managers, and servers in on- and off-site alcohol sales premises and we do not anticipate any difficulties in recruiting female and racial/ethnic minority participants.
   During the recruitment process, the Project Coordinator will screen for participants using IRB-approved protocols for screening based on gender, race, and ethnicity. If the Project Coordinator finds that we are over-recruiting a particular gender or racial or ethnic group, relative to our anticipated inclusion rate, we will place them on a waiting list until we have recruited an adequate number of targeted participants.

Recruitment and Screening:
   Human Subjects oversight will be conducted by the Western Institutional Review Board (WIRB; DHHS IRB Reg. No.

IRB0000053; FWA No. 00003715). All subject materials (including recruitment materials, consent forms, and interview and discussion questions, protocols, measures, and data management procedures will be approved by the IRB prior to study implementation. Project staff will provide participants with IRB-approved consent forms that will describe the purpose of the project, risks and benefits, and selection criteria. Project staff will provide participants with copies of their signed IRB-approved consent forms that will describe the purpose of the project, risks and benefits, and selection criteria. Participants will be informed that they have a right to withdraw from the study at any time and there will be no penalty for non-participation.

For the Phase I formative research, owners and managers of licensed alcohol premises will be recruited from publicly-available lists from New Mexico Alcoholic Beverage Control (NMABC) and Washington State Liquor and Cannabis Board (WSLCB). Participants for the focus groups (n= ~22), online survey (n= ~30), usability focus groups (n=20), and field pilot test (n=100) will be recruited from adults who complete the *WayToServe* responsible beverage service (RBS) training in New Mexico or Washington State. Adults will be recruited through email and written invitations, with telephone follow-up for owners/managers.

For Phase II randomized trial, licensed alcohol premises will be recruited from publicly-available lists from NMABC and WSLCB. All of premises will be assessed with pseudo-intoxicated patron (PiP) assessment protocols without informing premises management (i.e., premises and staff are blind to assessment), because the PiP teams observe public behavior by alcohol servers (i.e., willingness to serve alcoholic beverage). This blinding should avoid the threat of compensatory behavior by premises and servers (i.e., increased refusal rates) due to study participation. Alcohol servers who encounter the PiP teams when they attempt to purchase an alcoholic beverage will be enrolled in the study. We will inform premises of the PiP assessments at the conclusion of the study, provide them with debriefing information, and permit them to withdraw. After baseline PiP assessents, Drs. Buller and Woodall will contact premises owners/managers by email and telephone and invite them to participate. They will schedule a meeting at each premises to explain the study and obtain a list of alcohol servers to be registered on the *WayToServe* training. Owners/managers will be provided unique codes for alcohol servers to access the *WayToServe* training online. This code will track each server's use of the training and associate it with the premises. All alcohol servers at a participating premises will be invited to complete the *WayToServe* training. They will enter the training using a user code and complete a consent form and profile. They will be sent reminders to login and complete the training. Alcohol premises will be randomized to experimental condition, using a customized program prepared by the project biostatistician following completion of the baseline assessment, and alcohol servers in intervention premises will "friend" the Project Coordinator to be joined to the *WayToServe Plus* Facebook private group when they complete the *WayToServe* training. Servers in premises randomized to the *WayToServe* training only comparison group will follow the *WayToServe* Facebook page. In Year 3, KB staff will perform the posttest PiP assessment of all the premises in both treatment groups (blind to condition) at 12-months post-randomization. Finally, an owner/manager at 20 participating intervention premises will be recruited to complete a semi-structured interview on the *WayToServe Plus*, as part of process measures.

Retention and Adherence:

For the formative focus groups, online survey, semi-structured interviews, and usability focus groups in Phase I, the length of time that participants are expected to remain in this study is approximately two hours. The formative field pilot test participants in Phase I will participate in the Facebook private groups, Qualtrics online survey, and semi-structured interviews (n=10 participants selected at random) over 4 weeks. To promote participation and retention, Phase I participants will be compensated for their time participating (focus groups=$75, online survey=$25, semi-structured interviews=$75, usability focus groups=$75, field pilot test=$100, field pilot test semi-structured interviews=$50).

For the randomized trial in Phase II, the length of time that participants are expected to remain in this study is up to 17 months. Participant retention and compliance with study procedures are paramount concerns and we will implement retention protocols from our prior trials on *WayToServe* RBS training and social media interventions. We will make expectations of the project activities very clear during this telephone and email contact. Locator information will be collected from owners, managers, and servers upon enrollment, including their physical address, email address, home, work, and mobile telephone numbers, and the addresses and phone numbers of a person who can always reach them. KB project staff will provide unique codes for alcohol servers to access the *WayToServe* training online, track each server's use of the training, and associate it with the premises. Participants can withdraw at any time, so steps will be used to minimize

dropouts to ensure high internal validity. If a participant drops out of the private Facebook group, project staff will contact them to determine if they did so intentionally and if so, why. Participant progression will be tracked. As compensation, premises will receive $250 for intervention group and $150 for control group, servers who complete the *WayToServe* training will receive an alcohol server training certificate registered with NMABC or WSLCB and $35, and servers who join the *WayToServe* Plus Facebook private group will receive $50. *WayToServe* training will be available to the premises throughout the trial. We will select an additional 10 licensed premises as replacements for any that are discovered to be out-of-business at the baseline assessment. From prior experience in our *WayToServe* training and social media intervention trials, we are confident that we can obtain, engage, and retain a sample of high quality and generalizability.

PROTECTION OF HUMAN SUBJECTS
Risks to Human Subjects
Human Subjects Involvement, Characteristics, and Design:
   The subject population for this study will be owners/managers and alcohol servers from premises licensed to sell alcohol by the drink (e.g., bars and restaurants) in California, New Mexico and Washington State.

Study Procedures:
   Formative Semi-Structured Interviews (n=10 alcohol premise owners/managers): Participants will take part in one-hour semi-structured interviews performed by Drs. Buller and Woodall, using KB's video conferencing software, Zoom. Before the discussions, owners/managers will be sent the URL for the *WayToServe* online RBS training and instructed to review it. Owners/managers will discuss RBS policies at the premises, their support for RBS methods, the perceived importance of RBS, quality of RBS methods implemented by their servers, need for ongoing training and support for RBS among their servers, suggested content for in-service professional development for servers, and willingness to pay for *WayToServe Plus*. Five participants will be from California, New Mexico and five from Washington State. Participants will be compensated $75 for their time.
   Formative Focus Group (n=~22 alcohol servers): Focus groups will be led by the Project Coordinator trained in focus group methods, using KB's video conferencing software, Zoom. Servers will be recruited at random from the roster of *WayToServe* trainees in the past year. Participants will describe content and features, servers' desire for in-service professional development in RBS methods, barriers to implementing RBS methods and means of overcoming them, potential utility of in-service component for premises and servers, and willingness to pay for *WayToServe Plus*. They will discuss the support they receive from premise owners/managers and other alcohol servers for RBS and its adequacy and their experience with RBS practices, especially after receiving state-mandated RBS training. They will be asked if they have ever refused a sale, how confident they were in doing so, and the techniques used to successfully or unsuccessfully refuse a sale. Servers will be asked if they would be willing to share RBS experiences or provide feedback on RBS actions to other servers on the *WayToServe* Facebook page. Approximately 11 participants will be from New Mexico and approximately 11 from Washington State. Participants will be compensated $75 for their time.
   Formative Online Survey with Alcohol Servers (n=~30 alcohol servers): This survey will be conducted through KB's Qualtrics online survey software. Servers will be recruited at random from the roster of *WayToServe* trainees in the past year. Participants will describe content and features, servers' desire for in-service professional development in RBS methods, barriers to implementing RBS methods and means of overcoming them, potential utility of in-service component for premises and servers, and willingness to pay for *WayToServe Plus*. They will discuss the support they receive from premise owners/managers and other alcohol servers for RBS and its adequacy and their experience with RBS practices, especially after receiving state-mandated RBS training. They will be asked if they have ever refused a sale, how confident they were in doing so, and the techniques used to successfully or unsuccessfully refuse a sale. Servers will be asked if they would be willing to share RBS experiences or provide feedback on RBS actions to other servers on the *WayToServe* Facebook page. Participants will be compensated $25 for completing the survey.
   Usability Focus Group (n=20 alcohol servers): Twenty alcohol servers will be recruited at random from the roster of *WayToServe* trainees (n=10 in New Mexico and 10 in Washington State) to participate in virtual focus group discussions on the acceptability, feasibility, and usability of the prototype *WayToServe Plus* led by the Project Coordinator and using KB's video conferencing software, Zoom. Participants will be presented with a scenario describing the *WayToServe Plus*

and review the library of Facebook posts for this component. For each post, servers will identify the main message (to test comprehensibility), indicate if the content is appropriate and acceptable for alcohol servers, their premises, and their experience implementing RBS methods, report if the information will be useful to them and other alcohol servers, say whether they are likely to view, comment, or share the post, or contribute their own content on RBS methods to the Facebook page, and note what would keep them from engaging with posts (i.e., barriers to use). Participants will be compensated $75 for their time. Investigators and KB production staff will revise the *WayToServe Plus* based on this feedback and before field testing.

Field Test of Prototype (n=100 alcohol servers): Participants will be recruited when they complete the *WayToServe* training. Participants (n=50 New Mexico; n=50 Washington State) will be randomized to *WayToServe Plus* or untreated control group. Servers in the *WayToServe Plus* group will be instructed to "follow" a *WayToServe Plus* Facebook private group, administered by the Project Coordinator (alcohol servers will be added by "friending" the Project Coordinator). It will have the look of the *WayToServe* Facebook page but the messages posted in this group will be viewable only to group members (i.e., study participants). The Project Coordinator will post three *WayToServe Plus* posts per week for 4 weeks to the private group (n=12 posts), along with normal posts by WEDGE's marketing staff. Alcohol servers' engagement with *WayToServe Plus* will be assessed by recording number of times a post is viewed and commented on, and the number of posts made by alcohol servers (i.e., user-generated content such as personal experiences with refusing sales to intoxicated patrons or entry by minors). After 1 week, servers will complete a post-survey via a link to KB's Qualtrics online survey software. It will assess acceptability/appropriateness of the in-service professional development component for alcohol servers, their premises, and their experience implementing RBS methods, the usability of the in-service component on the validated System Usability Scale (SUS), utility of the in-service posts to them, and perceived self-efficacy (confidence in practicing RBS) and response-efficacy (effectiveness of RBS methods for keeping community safe) for RBS methods. Servers will be asked how willing they would be to use the *WayToServe Plus* in the future and how they would improve the component. It will assess acceptability/appropriateness of the in-service professional development component for alcohol servers, their premises, and their experience implementing RBS methods, the usability of the in-service component on the validated SUS, utility of the in-service posts to them, and perceived self-efficacy (confidence in practicing RBS) and response-efficacy (effectiveness of RBS methods for keeping community safe) for RBS methods. Servers will be asked how willing they would be to use *WayToServe Plus* in the future. All participants will be asked how they would improve the component and make it more engaging, in open-ended questions. Participants will be compensated $100.

Ten alcohol servers in the field test sample (n=5 New Mexico; 5 Washington State) will be randomly selected for a semi-structured interview on reactions to *WayToServe Plus* prototype. The Project Coordinator, using video conferencing, will probe for in-depth input on whether the in-service component was appropriate, acceptable, and useful for themselves, their premises, and their RBS methods, what made them engage with the posts or not, and how the in-service component could be improved and made more engaging. Participants will be compensated $50.

Randomized Trial (n= 180 state-licensed onsite alcohol premises): The *WayToServe Plus* in-service component's ability to increase refusal of service to intoxicated patrons will be tested in a randomized trial. A two-group randomized field trial (*WayToServe* training only [comparison control] v. *WayToServe* training plus *WayToServe Plus* in-service component [intervention]) with 2 assessment rounds (Baseline and Posttest [12-months post-randomization]) will yield a 2 (treatment) x 2 (assessment time) factorial design, with 4 assessments per alcohol premises (2 per round). Using a custom-written program, project biostatistician will randomly assign n=80 premises to *WayToServe* training plus *WayToServe Plus* after baseline in Month 18, stratified by state and location. Remaining premises (n=80) will receive *WayToServe* training only. All premises will be recruited to have all servers complete *WayToServe* training. Servers in intervention group will be accepted into a Facebook private group after *WayToServe* training to receive in-service component with ~3 posts per week for 12 months. In Months 30-32, all premises will be posttested with PiP assessments (blind to condition).

Following baseline, all 180 premises will be contacted and recruited to the trial (premises compensation= $250 for intervention group and $150 for control group). Managers will provide a list of all servers, who will be registered by project staff on *WayToServe* training and provided with a user ID that will track use and link it with premises. Servers will complete consent form and profile at their first login. They will be asked to complete the training within 4 weeks from registration; email and text reminders will be sent to those who do not login within 1 week (compensation= $35 from

research team and new server training certificate from NMABC or WSLCB free of charge). *WayToServe* will remain available to premises throughout the trial; managers will report new hires so project staff can register them and they can complete the training.

The project biostatistician will randomize half of the premises to join *WayToServe Plus* after completing the *WayToServe* training. Intervention-group trainees will be instructed to "friend" the Community Manager for the *WayToServe* Facebook page at the end of *WayToServe* training (compensation=$50). In-service component will be implemented through a Facebook private group with the look and feel of the *WayToServe* Facebook page. Group members can comment and react to posts, but not share them on their own feed, so other Facebook friends cannot see private group or posts. Based on current social media marketing advice for the new Facebook algorithms, the Community Manager will post ~3 times per week to achieve effective reach (another 4 posts per week will be posted from the *WayToServe* Facebook page),[256,295-297] scheduling posts in advance on Buffer software[298] so they appear on a reliable schedule. Orientation to private groups will be self-explanatory.

Study Materials:

Data from interviews, focus groups, online surveys, and the field pilot test will be collected in the form of handwritten notes, video and audio recordings, computer files, transcriptions, and surveys. Transcripts of the recorded focus group and interview discussions will be analyzed via Atlas-ti[©] content and thematic analysis software to identify consistent and recurrent content and themes in response to discussions. Data gathered from the formative online survey with alcohol servers will be collected using KB's Qualtrics online survey software, and analyzed using various quantitative methods to confirm and/or learn more about the themes identified in the aforementioned focus group and interview discussions. Data gathered from the usability focus group will be summarized in notes by research staff to identify usability problems. Data gathered from the randomized trial will be collected via pseudo-intoxicated patron (PiP) assessments. Registration on and progress through the WayToServe RBS training will be tracked by the training's backend SQL database, along with scores on quizzes/final exam. Users' engagement with the *WayToServe Plus* will be assessed by recording number of reactions and comments to a post, and posts made by alcohol servers with user-generated content. All data will be obtained specifically for research purposes. Data will be kept confidential and anonymous. Access to all data will be limited to the Principal Investigator (PI), Co-Investigator, specific project staff, and consultants. All data will be kept in locked files and secure computer servers.

Potential Risks:

The potential risks to participants are minimal, mainly social or psychological. Focus group, interview, and survey participants may be hesitant or uncomfortable responding to questions about alcohol service in licensed establishments and methods to prevent sales to intoxicated patrons and minors. Participants in the usability testing and field pilot test may not feel comfortable responding to questions about their opinions on appeal, ease of understanding, usability of, and engagement with the *WayToServe Plus* in-service professional development component. Owners/managers/clerks in the randomized trial will participate anonymously and passively in the PiP assessments and the data from these measures on individual stores and persons will be kept confidential and not shared with state regulators, other premises, or anyone outside the KB research team. Data on specific servers will not be reported to the premises. In any group-based intervention, participants breaking confidentiality is a possibility and risks revealing private communication by and information about other participants to individuals outside the study. This is considered a minimal risk. We will add it to the consent forms and warn participants against making such disclosures when joining the trial and the Facebook private group. There is a risk that some randomized trial participants may experience hostile communication or "cyberbullying." Participants may choose to not answer questions, as required the by WIRB. Any public release of the data will be in aggregate form, summarizing across groups of premises and individuals. These methods reduce the risk to trial participants. All individual responses collected in this project will not be shared with anyone except KB project staff. Participants will be allowed to withdraw at any time if they are uncomfortable with aspects of the research. No additional data will be collected from participants who decide to withdraw; however, the information collected prior to withdrawal will remain in the study.

ADEQUACY OF PROTECTION AGAINST RISKS

Informed Consent:

Human Subjects oversight will be conducted by the WIRB (DHHS IRB Reg. No. IRB0000053; FWA No. 00003715). All subject materials (including recruitment materials, consent forms, survey questions, interview questions, protocols and measures) and data management procedures will be approved by the IRB prior to study implementation.

Since the Phase I formative research activities will be conducted using KB's video conferencing software, Zoom, participants will be presented with an online IRB-approved consent statement. Participants will then click on a button that indicates whether they consent to participate. Similarly, for the field usability test, field pilot test, and the randomized trial, participants will be presented with a written consent statement and participants will click on buttons that indicate whether they consent to participate. The consent statements will describe the purpose of the project, risks and benefits, and selection criteria. Participants will be given an opportunity to ask questions and have them answered. Participants will have the option to print or save the consent statement.

All participants will be informed that their consent to participate is completely voluntary and that they will be able to skip over any questions that make them feel uncomfortable. Responses to survey, interview, focus group, or field pilot test questions will not reasonably place participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Participants will be informed that thei responses will be confidential, they have a right to withdraw from the study at any time, and there will be no penalty for non-participation.

All data management, analysis and reporting activities will be conducted by KB staff. All notes and printed data collection forms will be stored in locked cabinets; all electronic data files will be stored on secure network servers behind computer firewalls, with routine backup. No clinical data will be captured. All data coding, data entry, analysis and reporting activities will be conducted by KB. All identifiers for participants will be stored in secure files and behind computer firewalls at KB. Participant names and study identification numbers will be recorded and stored separately from the research data files. Data forms will be labeled only with participant identification number. Results of analyses will be shared in aggregate form only. No additional data will be collected from participants who decide to withdraw; however, the information collected prior to withdrawal will remain in the study.

Protection Against Risk:

To minimize potential psychological risks, staff, facilitators, and interviewers will establish ground rules for discussion that includes an open, non-evaluative exchange of comments and ideas. All data collection forms and surveys will be IRB-approved and administered under the supervision of senior project staff. Participants will be told that they do not have to answer any questions that make them uncomfortable and can terminate their participation at any time they wish. Notes, surveys, video recordings, transcripts, and data will be confidential, accessible only by research personnel. Data forms and computer records will be labeled only with participant identification number. Participant names and study identification numbers will be recorded and stored separately from the research data files. Focus group participants will be asked to use first names only during focus groups.

IRB-approved survey instruments and surveying procedures will be carried out under the supervision of project staff. Survey questions will be de-identified before being submitted for analysis and the Project Coordinator will remove any references to individual names or identifier data. Responses to survey questions would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. The data collected on this project will be obtained with the "use of educational tests, survey questions and interview procedures."

All data collection forms for the PiP assessment will be reviewed and approved by WIRB and used under the supervision of Investigators and the Project Coordinator. In our past trials testing WayToServe RBS training, the IRBs approved selecting and assessing alcohol premises with pseudo-patron protocols without informing premises management (i.e., premises were blind to assessment), ruling it was an assessment of public behavior. Thus, all alcohol premises and alcohol servers in the randomized trial will be blind to all PiP assessments at baseline and posttest. In our past trials, the IRBs required us to disclose the premises' participation at the end of the study. We will inform premises at the conclusion of the study, provide them with debriefing information, and permit them to withdraw. To minimize potential psychological risk, we will make it very plain that data collected as part of the research study will not be available to law enforcement and the project will receive a Certificate of Confidentiality from NIH.

The prototype *WayToServe Plus* in-service professional development component and databases will be hosted on KB's state-of-the-art web server farm. To minimize the risk to participant data privacy and protection through the Internet, KB programmers will monitor and maintain all programs and databases and use an established protocol for participant cyber safety and security. KB is HIPAA complaint and maintains vigorous technical safeguards which are built into KB's IT system to protect information and to control access to it.

To reduce risks to participants in the randomized trial, servers in intervention group will be invited to a private Facebook group. In private groups, only members can view posts and there is no option to "share" content onto one's main profile page. This will keep content only accessible via the group. Only the group administrator can invite people to the group. At the outset of the study, alcohol servers will be asked to keep all discussion in the group confidential. Servers will be informed as to the nature of the privacy settings (e.g., all participants can see their posts in the group). They will also be reminded to update their personal Facebook page privacy settings if they want to protect against other participants inspecting their personal pages. As in face-to-face groups, participants will know each other's names and be exposed to any information that group members wish to share with each other. In the same way we ask participants to keep all group discussions confidential for in-person groups, we will do so for Facebook discussions.

Data will be hosted on KB's state-of-the-art web server farm. To minimize the risk to participant data privacy and protection through the Internet, KB programmers will monitor and maintain all programs and databases and use an established protocol for participant cyber safety and security. KB is HIPAA complaint and maintains vigorous technical safeguards which are built into KB's IT system to protect information and to control access to it. All participant information will be protected using 128-bit SSL encryption. All Internet information must travel through KB's CISCO ASA 5505 firewall using ASA software version 9.0(2) encrypted 3DES-AES. Traffic then moves to KB's web server. This server is a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows Hyper-V Operating System. The virtual web server uses Windows 2008 IIS Web server software. User click stream data is collected using Webtrends and is saved to our SQL server. Enrollment data is transferred to our SQL server (Windows Server 2008) which uses MS SQL server 2008 R2 database software. This machine is also a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows Hyper-V OS and has no access to the Internet. When a participant is directed to take a survey, their computer is linked to a third server in our system which is also a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows Hyper-V OS. This server runs Qualtrics survey software. All network traffic is sent from the CISCO firewall to a Syslog server using Manage Engine Firewall Analyzer 7 software. Login and network activity are required and monitored by Windows servers to an event viewer. Servers are kept in a locked room on site. All files are secured locally using MS NTFS. All traffic between servers and PCs on the LAN are digitally signed communications. Each local machine has a built-in operating system firewall. Data from the Qualtrics survey software are exported for data analysis by local machines which are also behind KB's firewall. Access to this exported data by outside sources is done using File Transfer Protocol (FTP) protected by Secure Socket Layer (SSL). SQL databases are protected by the built-in security of MS Active Directory. Data is backed up using a Quantum SuperLoader 3 tape library using LT04 tapes that contain 800 GB/1.6 TB of info (depending on compression used). The device holds 16 tapes. The backup software used by KB is Symantec Back-up Exec. 2012. Daily backups are incremental and tapes are recycled weekly. Weekly backups are done every Friday and are recycled every six weeks. Monthly backups are done on the last Friday of each month and are full backups of all data. These monthly tapes are stored in a secure offsite facility and are never recycled.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO PARTICIPANTS AND OTHERS:

The research literature shows that training and certification of community members in prevention activities improves professionalism and along with on-going in-service contact has boosted effectiveness of community-based interventions. Alcohol servers may benefit from ongoing in-service contact aimed at improving their professionalism by a) motivating them to implement the RBS skills in the face of common barriers such as pressure to sell, management disinterest or resistance, and customers' attempts to continue being served, b) providing support for RBS actions from a "community" of alcohol servers, especially for servers who work in small or unsupportive premises, and c) preventing natural degradation of skills over time by having them self-enroll into booster training on RBS methods. Potential benefits for all participants will be the knowledge that one has helped in development of an important prevention

intervention that may be used on a national basis to reduce the number of alcohol-related problems, including driving while under the influence of alcohol.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify participants. At most, the website will include a summary of the results. This website can be searched at any time.

IMPORTANCE OF THE KNOWLEDGE TO BE GAINED:

We are proposing the development of an innovative online RBS in-service professional development program that has the potential to increase the efficacy of existing evidence-based RBS training. The sale of alcohol to patrons who are either on the verge of intoxication or already are intoxicated, and the consequent instances of DWI and related crashes, injury, and death, remain a very serious and preventable public health issue, among the most serious in the United States. Among interventions that can be used to prevent DWI and its consequences, RBS training holds promise as we have demonstrated in our previous R01 funded research with alcohol servers in onsite (by the drink) and off-site (package) alcohol sales premises. Interventions that intervene at the point of alcohol consumption before a drinker becomes intoxicated and attempts to drive such as RBS training, rather than after they reach intoxication and attempt to drive (e.g., roadside checkpoints or ignition interlock devices), can be an important part of multi-component interventions that also include premises management training and environmental policies and are seen as positive by many alcohol servers who wish to provide alcohol in careful, responsible ways that keep their customers safe.

Data and Safety Monitoring Plan:

A data and safety monitoring plan will be implemented for this project, following well-established procedures. We will not set up an independent Data Safety and Monitoring Board because this study is very low risk, does not include use of therapeutics, and psychological risk is not anticipated. A total of 152 alcohol servers and 10 owners/managers of licensed alcohol premises will be enrolled in Phase I formative research. Also, 180 licensed alcohol premises in California, New Mexico and Washington State will be enrolled in the randomized trial and assessed for refusal of sales to pseudo-intoxicated buyers, using a PiP assessment protocol. Alcohol servers from participating premises (up to n=1600, 10 per premises) will complete the *WayToServe* RBS training and servers (n=800) assigned to the intervention group will use the *WayToServe Plus* in-service professional development component. Finally, an owner/manager at 20 intervention premises will complete a semi-structured interview on the use of the *WayToServe Plus* in-service component.

The progress of the research will be monitored monthly by the Multiple PIs, Co-Investigator, Project Coordinator, and Project Biostatistician. We will maintain strict confidentiality of participants in the project's registration system, provide only ID numbers in data files, and ensure quality control using standard data management routines. A serious adverse event will be any problems that cause the project to be "banned" from a premises; critical events will be reviewed by the Investigators to ensure that project methods have not been intrusive or disruptive. Compliance with data collection protocols, including the PiP assessment protocol, will be monitored throughout data collection by the Investigators and Project Coordinator. The data management staff at KB will examine the quality of data input throughout the data collection period following standard quality control and assurance procedures (e.g., double entry of hard-copy coded data; detection and estimates of keystroke errors, identification of systematic mistakes in coding or responses; range checks). Analyses of the data will be performed by Dr. Cutter and Ms. Liu, at the conclusion of the baseline data collection periods to assess distributional assumptions and the success of randomization.

Annual reports on data safety and monitoring will be submitted to WIRB. Dr. Buller, Contact Multiple PI and the Project Coordinator are responsible for reporting all adverse events to WIRB. Only Grade 1 events are expected on this trial. Thus, adverse events will be reported annually, as required by Department of Health and Human Services. This report will be reviewed by WIRB. Any action taken by WIRB or project investigators resulting in a temporary or permanent suspension of the trial will be communicated immediately by Dr. Buller, Multiple PI to the NIH program officer.

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