Chapter 26
Strengthening Prevention Science to Ensure Effectiveness of Intervention in Practice: Setting up an International Agenda

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Introduction

Primary prevention is the public health activity dedicated to prevent the occurrence of disease and promote health (Last, 2006). It can act by reducing exposure to well-known risk factors at the environmental level (e.g., air pollution, occupational exposure to chemicals, asbestos ban) by increasing individual biological defences (such as immunization) or act at the individual level to change risky behaviors.

There are deep differences in these three approaches to primary prevention: the first mainly addresses eliminating risk factors from the environment through regulatory interventions at a national or international level. The second and the third work on different and complex individual mechanisms. This contribution focuses on the third approach: the prevention and change of risky behaviors.

Psychological and Social Mechanisms of Prevention of Risky Behaviors

Interventions focused on the third approach usually target psychological and social factors that are recognized to be related to risk behaviors; such factors are usually the mechanisms through which interventions are designed to modify problematic behaviors. For example, parenting behaviors, such as communication, setting rules, and providing warmth and emotional support, have an inverse association to the development of high-risk behaviors of adolescents, such as alcohol and substance

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use, delinquency, and school dropout (Velleman, Templeton, & Copello, 2005). On the basis of these associations, interventions that intend to reduce substance use may want to focus on changing the type of communication and relationship between parents and children, and this in turn would reduce the risk of problematic outcomes during adolescence. Personal competencies, such as decision making, self-control, self-reinforcement, substance-specific assertiveness, attitude against the use of alcohol and drugs, and normative expectations, also are negatively associated with drug use during adolescence (Botvin, Malgady, Griffin, Scheier, & Epstein, 1998; Griffin, Botvin, Scheier, Epstein, & Doyle, 2002; Willis, Baker, & Botvin, 1989). Thus, many interventions have focused on the enhancement of such competences to diminish the occurrence of engagement in high-risk behaviors.

Unexpected Effects of Prevention Programs and Possible Explanations

In spite of the existence of clear theories about what are the psychological processes that should be targeted to make interventions work, an appropriate translation of this knowledge into practice cannot always ensure the success of the program. There are several examples of theory-based intervention programs that produced counterintuitive effects. Among those that adopted rigorous methods, the US National Youth Anti-Drug Media Campaign during the years 1998–2004 and the "Take Charge of Your Life" program for drug, tobacco, and alcohol prevention both were based on social influence theory, which is shown to be fundamental to most effective interventions (Tobler, 2000). Nevertheless, they produced, respectively, a substantial increase in the use of cannabis among adolescents exposed to television advertising (Hornik, Jacobsohn, Orwin, Piesse, & Kalton, 2008) and an increase in the risk of tobacco and alcohol use and binge drinking (Sloboda et al., 2009) among those who had not used tobacco or alcohol at baseline, when they were 12–13 years old.

Outside of the field of substance prevention, the examples are similar. The Spark study suggested that an intervention for the promotion of physical activity in elementary schools, aimed at reducing the risk of obesity, significantly increased body mass index among students of both intervention groups compared to controls 18 months after the intervention (Sallis et al., 1993). The Postponing Sexual Involvement curriculum, widely implemented in the USA and evaluated in California by a randomized study, determined the increase of intercourse, the number of sexual partners, and the number of sexually transmitted diseases (nonsignificant) as well as the number of of pregnancies ($P < 0.05$) among intervention groups, both of which were led by peers and adults (Kirby, Korpi, Barth, & Cagampang, 1997).

There are several possible reasons for these failures, ranging from theory to implementation. In the following, we attempt to group these reasons into five broad categories.

Bad Theory

Theories in psychological and sociological fields usually are based on longitudinal studies that attempt to establish temporal associations between factors even though they cannot claim causality. Sometimes interventions are grounded on theories that do not have another empirical base. For instance, one of the first interventions to reduce substance use among youth was aimed at increasing knowledge about substance use. The underlying theoretical framework was the information-dissemination theory that postulates a decrease of substance use as a consequence of the acquisition of knowledge about negative effects of drug use. However, it was found to be ineffective in experimental studies even though it was, in fact, able to increase knowledge of the consequences of substance use (Botvin, 1990).

Experimental evaluation studies can be considered as experiments that can test the validity of a theory. As claimed by Claude Bernard (1865) 150 years ago in his *Introduction to Experimental Medicine*, "when we meet a fact which contradicts a prevailing theory, we must accept the fact and abandon the theory, even when the theory is supported by great names and generally accepted."

This case of program failure is quite common in different contexts; for example, programs that involved organized visits to prison facilities by juvenile delinquents or children at risk of becoming delinquent and were designed to deter participants from committing future offenses by providing first-hand observations of prison life failed to prove their effectiveness. A systematic review of seven randomized trials found that this approach not only fails to deter crime but also actually leads to more offending behavior (Petrosino, Turpin-Petrosino, & Buehler, 2004), with an odds ratio of 1.68 (95 % confidence interval, 1.20–2.36).

Intervention Is Unable to Affect Target-Mediating Factors

Sometimes the proposed activities might be inappropriate to target and modify the factors associated with the risk behaviors, namely the mediating factors of the intervention (e.g., psychological factors that explain the risk behavior). When a lack of effect on mediating factors occurs together with a lack of effect on the targeted behaviors, one can argue that the intervention does not include the appropriate activities necessary to target the appropriate factors.

Intervention Targets the Wrong Mediating Factors

Sometimes the intervention can indeed modify the targeted mediating factors, but mediation analysis can reveal that those factors are not, in fact, mediators of the final outcomes. For example, Botvin, Griffin, Diaz, and Ifill-Williams (2001), in

their school-based intervention to prevent drug use, found effects on many expected mediators. However, only a few of them were found to be related to the change of the outcome (e.g., substance use).

Implementation Failure

A program also may fail because of poor program implementation. Interventions are usually constituted of components (e.g., a series of role-plays that simulate real-life situations) that are aimed at modifying specific factors (e.g., refusal skills), which in turn are expected to change the final outcome. When implementation failure occurs, it is likely that the program components were not correctly implemented. For example, it might have not been possible for some teachers to deliver all of the program contents. If a program is not implemented as intended, no conclusion can be drawn about its theoretical validity and efficacy.

Good Theory but Sensitive to the Context

Finally, sometimes moderator mechanisms may influence the relationship between mediating factors and the target behavior, resulting in an intervention's lack of effect. In other words, psychological factors may interact with many other social or contextual factors and may result in negative outcomes. For instance, peer-training programs, even when they target well-established mediators, obtained iatrogenic effects if implemented among a group of high-risk youth (Dishion, McCord, & Poulin, 1999). As Dishon and colleagues (1999) argued, high-risk youth in the group influenced each other into a "deviancy training" that resulted in an increase in deviant behaviors after the intervention. This suggests that even when an intervention targets the right mediators, moderator factors might intervene and cause null or iatrogenic effects.

In sum, the complexity of psychological pathways and their interaction with context may complicate the identification of the right mediators to target and the activities that are aimed at modifying those mediators. Rigorous scientific standards for the evaluation of prevention interventions should include a continued process of assessment of the robustness of the theory and of causal relationships, taking into account psychological and social processes that may act as moderators.

Need for Evaluation of Prevention Interventions

In the previous sections we discussed the fact that prevention interventions target complex and delicate psychosocial mechanisms that are expected to be determinants of problematic behaviors. However, we also showed that preventive

interventions provide unique opportunities to test empirically theories of human behavior through experimental designs. This calls for a rigorous evaluation of both the intervention effects and the mediator and moderator mechanisms that are responsible for those effects. The need for a rigorous evaluation process is shared with other fields that deal with individual well-being and health as well, for example, pharmacology, but with deep differences in implementation. As David Sackett (2002) wrote a few years ago in his polemic article "... surely the fundamental promise we make when we actively solicit individuals and exhort them to accept preventive interventions must be that, on average, they will be the better for it. Accordingly, the presumption that justifies the aggressive assertiveness with which we go after the unsuspecting healthy must be based on the highest level of randomized evidence that our preventive manoeuvre will, in fact, do more good than harm. Without evidence from positive randomized trials (and, better still, systematic reviews of randomized trials) we cannot justify soliciting the well to accept any personal health intervention."

In spite of these premises, it is highly likely that the great majority of prevention activities provided in practice have never been evaluated. For example, according to the 2013 report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the effectiveness of prevention programmes is rarely evaluated in Europe, although "A small shift has [..] been noted towards the use of positively evaluated universal prevention approaches in schools" (EMCDDA, 2013). Most European prevention interventions are built upon untested theoretical assumptions and individual experience/perception, and all European countries have experienced a low level of evaluation activity, with few exceptions, according to the opinion of an expert panel (EMCDDA, 2014a). In Italy, for example, the proportion of evidence-based prevention interventions targeting youth for the prevention of tobacco smoking, alcohol abuse, and the promotion of a healthy diet and safe sexual activity is probably less than 1 % (Coffano, 2009). Even if in the USA evaluation of effectiveness of prevention interventions seem to be more common (Gandhi, Murphy-Graham, Petrosino, Chrismer, & Weiss, 2007), prevention is far from the standards of many others field of medicine.

The situation is even worse when it comes to understanding why those interventions are effective. Indeed, there are a very limited number of studies that show mediating mechanisms, as Sandler, Schoenfelder, Schoenfelder, and MacKinnon (2011) observed in a review of mediators of family-based interventions. This gap in our knowledge translates into a failure in our understanding of why and how interventions work and thus difficulty in transferring the effective intervention to other contexts.

International Procedures to Disseminate Evidence-Based Prevention Programs

The diffusion of effective, evidence-based practices in the field of prevention is still limited. However, a formal process aimed at restricting the use of interventions to those with evidence of effectiveness is currently lacking. No procedures are currently in place for prevention interventions that are similar to those used in other health areas, such as the approval of medications used by the Food and Drug Administration (FDA; http://www.fda.gov) and the European Medicines Agency (http://www.ema.europa.eu).

Nevertheless, some interesting experiences are worth mentioning. In the field of mental health and substance abuse, for example, the EMCDDA established the Best Practice Portal (BPP) to respond to the 2009–2012 EU drugs action plan (EMCDDA, 2014b). The BPP summarizes evidence gathered from systematic reviews (mainly the Cochrane Library) assessing the effectiveness of drug-related prevention interventions. The BPP contains available evidence regarding specific activities or interventions aiming to prevent and treat drug abuse and reduce harm caused by drug abuse (EMCDDA, 2014b). The BPP includes only general programs categories instead of specific program names (e.g., "comprehensive family-oriented prevention for cannabis use"), scored with the GRADE evidence assessment system (Guyatt et al., 2008) to determine the level of impact on patients, from "beneficial" to "evidence of ineffectiveness" (Bo, Allara, & Ferri, 2011).

In the USA, comprehensive best-practice lists of evidence-based prevention programs are regularly updated by governmental or academic agencies, particularly in the fields of mental health, drug abuse, and violence (Gandhi et al., 2007). Prominent lists are the List of Exemplary and Promising Prevention Programs, run by the US Department of Education, in which interventions are selected using criteria such as evidence of efficacy, quality of the program, educational significance, and usefulness to others (http://www2.ed.gov/admins/lead/safety/exemplary01/exemplary01.pdf); the National Registry of Evidence-based Programs and Practices, run by the Substance Abuse & Mental Health Services Administration, lists programs that are reviewed and rated by independent reviewers, describing them in light of the quality of the evaluation research and readiness for dissemination (http://nrepp.samhsa.gov/).

We were able to find only a small number of similarly advanced experiences in other fields of prevention. The US Centers for Disease Control and Prevention, for example, runs the Compendium of Evidence-based HIV Prevention Interventions (http://www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm) that brings "science-based, community, group, and individual-level HIV prevention interventions to community-based service providers and state and local health departments." It presents best evidence interventions and promising-evidence interventions, classified according to the evaluation quality and effect size of interventions. The California Evidence-Based Clearinghouse for Child Welfare (http://www.cebc4cw.org/) provides interventions to prevent mental health disorders such as depression, anxiety, and neglect for adults, children, and families.

The classification of interventions is based on the level of research support available. The Office of Juvenile Justice and Delinquency Prevention (Model Program Guide contains interventions designed to prevent at-risk behaviors spanning from "academic problems" to "aggression/violence" and "gang activity." A similar project is carried out by the University of Colorado's Blueprints for Violence Prevention (Center for the Study and Prevention of Violence, Institute of Behavioral Science; http://www.colorado.edu/cspv/blueprints/).

We also found one lists of studies: the Washington State Planning Group's Effective Intervention and Strategies Document (http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/Prevention/Interventions.aspx), that annually review and update a list of effective HIV prevention programs.

Unfortunately the lists vary as to which programs are classified as effective and which are not. And, at least in the field of drug abuse, the lists vary considerably as to the evidence needed for inclusion, the use of independent assessors, the required length of follow-up duration, as well as issues such as outcome reporting bias and generalizability of programs (Gandhi et al., 2007). Table 26.1 compares the criteria for program classification adopted by the seven lists reviewed by Gandhi (2007) together with those of the EMCDDA's BPP (2014b).

In this panorama, characterized by large variability in the definition of quality standards, the work of Flay et al. (2005) deserves special mention. On behalf of the Society for Prevention Research, standards of evidence for prevention interventions were developed that should be considered a reference for reviews of prevention programming. Three different sets of standards are described: (1) efficacy, the utility of the intervention under ideal conditions; (2) effectiveness, the efficacy under real-world conditions; and (3) readiness for dissemination. The article presents a detailed list of standards for all three situations regarding the quality of outcomes, measurements, study design, and statistical analysis; the establishment of minimum duration of effects; and the role of replication, generalizability requirements, and related issues.

Despite the effort of these agencies, especially from the USA, a unique, harmonized, mutually accepted international system to process and classify evidence on prevention and that is available to decision makers is still lacking. Such a system could (a) facilitate adoption of effective, evidence-based interventions; (b) reduce dissemination of untested and harmful interventions; and (c) assist decision makers in dispersing public and private money more efficiently.

Intrinsic Limits of Current Procedures for the Improvement of Evidence-Based Prevention: Ingredients Versus Programs

Although useful, the procedures and systems described earlier do not ensure an adequate level of dissemination of effective interventions nor a reduction in the delivery of ineffective ones. This is mainly because of the intrinsic characteristics of the procedures. First, they suggest that programs be adopted voluntarily, without

Table 26.1 Criteria used in evidence-based lists to classify prevention interventions. This table is partly based on work by Gandhi et al. (2007), with the addition of BPP EMCDDA (2014b)

List	Criteria							
	Evidence of efficacy	Quality of evaluation	Quality of program goals	Quality of program rationale	Quality of program content and appropriateness	Quality of program implementation methods	Educational significance[a]	Usefulness/ replicability
Blueprints	Yes	Yes	Yes	N/A	N/A	N/A	N/A	Yes
Drug strategies: making the grade	Yes	Yes	Yes	N/A	N/A	N/A	N/A	N/A
ED list	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Maryland report	Yes	Yes	N/A	N/A	N/A	N/A	N/A	N/A
NIDA guide	Yes	Yes	N/A	N/A	N/A	N/A	N/A	N/A
SAMHSA National Registry of Evidence-Based Programs and Practices	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Youth violence: a report of the surgeon general	Yes	Yes	Yes	N/A	N/A	N/A	N/A	Yes
EMCDDA best practice portal	Yes	Yes	Yes	No	Yes	Yes	No	No

EMCDDA European Monitoring Center for Drugs and Drug Abuse, *NIDA* National Institute on Drug Abuse, *SAMHSA* Substance Abuse and Mental Health Services Administration, *ED* US Department of Education, *N/A* not available

[a]The application describes how the program is integrated into schools' educational missions

any incentive or disincentive. Their use relies mainly on the authoritativeness of the agency that maintains the lists, and this quality varies widely across countries, regions, and probably social conditions.

A further limitation undermines the above-described procedures: the oversimplification of program evaluation. In a recent editorial, Heneghan noticed, disappointingly, that the current evidence of effectiveness of counseling and education to change behavior in order to prevent cardiovascular diseases does not show an effect in general populations. One of the reasons put forward to explain this observation is that considerable variation often occurs in the components of the interventions (Heneghan, 2011). This is a basic characteristic: interventions aimed at changing risky behaviors are usually complex and have multiple components. In a recent review of the content of effective substance abuse prevention programs, Hansen, Dusenbury, Bishop, and Derzon (2007) identified 23 distinct content areas in 48 programs. The average program addressed 8.5 content areas. Moreover, they noticed that most programs are an amalgam of approaches and content areas that are independent of formal theories. The review also showed that programs are not truly driven by theory and do not adhere consistently to a theory's tenets. On the other hand, Noar and Zimmerman (2005) demonstrated that there is a large overlap among theories commonly used as the basis for interventions. To our knowledge, similar analyses of prevention program content are not common in other fields of prevention, but, presumably, the above reasoning can be extended to those domains.

Thus, disappointingly, what we know about the effect of prevention programs is just the total effect, and it is impossible to disentangle the role of specific components or theories. This makes it impossible to isolate effective components from those programs that are ineffective or even iatrogenic, even if this could be highly important for the elaboration of new programs.

Examples of Frameworks for the Evaluation and Approval of Complex Interventions

A framework that is useful for explicitly addressing the evaluation of complex interventions (MRC, 2000; Campbell et al., 2000) outlines four phases that would help define the "active ingredients" of prevention interventions. In addition to the "preclinical" or theoretical phase, which must frame the conjectural basis of the effectiveness of the intervention, the four phases include the following: (a) *Phase I, or modeling*: This phase involves delineating an intervention's components and how they interrelate and how active components of a complex package may relate to either surrogate or final outcomes. It may also include qualitative testing through focus groups, preliminary surveys, case studies, or small observational studies. (b) *Phase II, or exploratory trial*: In this phase the evidence gathered thus far is put to the test, with the possible use of experimental designs, varying different components to see what effect each has on the intervention as a whole. This phase

could permit the testing of alternative forms ("doses") of an intervention. (c) *Phase III, or main trial*: This involves a randomized controlled trial to evaluate the main effect a complex intervention. (d) *Phase IV, or long term surveillance*: This phase consists of a separate study to establish the long-term and real-life effectiveness of the intervention. The broader applicability of an intervention outside of a research context may be tested, and rare or long-term adverse events are identified. This stage is likely to involve observational designs.

This framework addressed many issues that seem to be essential to prevention interventions. For example, the preclinical phase focuses on the identification of the "active ingredients" of the intervention; besides the component of the intervention, included in this concept are all the other factors that can affect its effectiveness, such as the characteristics of the patient, the skill level of providers, the method of delivery, frequency, duration, and timing. Although the exploratory phase is explicitly targeted to "consider variants of the intervention and their possible effects on outcomes," it fails to answer the main question: Which ingredients work and which do not work?

Several years after this framework was introduced, Collins, Chakraborty, Murphy, and Strecher (2009) suggested a way to tackle the challenge of assessing the effects of single program components and their combinations. They proposed adopting a phased experimental approach – essentially a randomized trial using a factorial design to test separately each active component identified in the previous phases of the process. Factorial designs can clearly help to evaluate separately several components and identify possible interactions. However, it cannot be the solution in the field of prevention because the number of active ingredients to be tested is overwhelming; following the review by Hansen et al. (2007), an average number of 8.5 components per intervention have to be tested across, for example, different dosages and methods of delivery.

The oldest and most comprehensive framework for developing and evaluating health technologies is one dedicated to the approval of medications. In both the USA and Europe there are official agencies responsible for the authorization and licensing of drugs: the US FDA and the European Medicine Agency (EMA), respectively (Fig. 26.1). Although formal approval pathways are slightly different for the two agencies, the processes are similar. Once biochemical research indentifies a new candidate molecular target and screens thousands of chemical compounds to generate promising molecules with desirable properties, four steps have to be accomplished to apply for approval of a new drug: preclinical testing and three clinical trials phases (Pharma, 2011). Preclinical testing consists of laboratory (in vitro) and animal (in vivo) testing performed to determine the drug's safety profile (Pharma, 2007). Clinical trials then determine whether a potential drug can safely and effectively treat a targeted disease in humans and consist of three phases. Phase 1 involves 20–100 healthy volunteers and aims to study the drug's pharmacokinetics and pharmacodynamics to determine the dosage and safety of the candidate new drug. This phase is similar to the preclinical testing but involves humans and not laboratory studies or animal testing. Phase 2 involves 100–300 patient volunteers to be studied for about 2 years to evaluate the drug's effectiveness and short-term side effects. Finally, during Phase 3, 1,000–3,000 patient

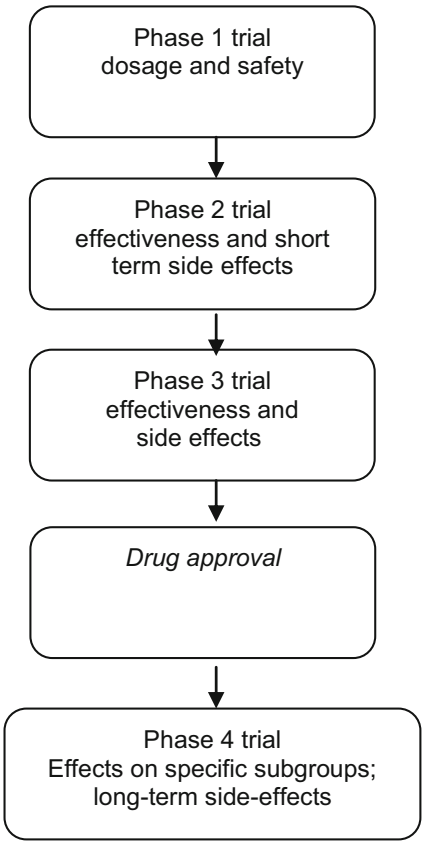

Fig. 26.1 The process of approval of drug medicines adopted by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA)

volunteers are involved to verify the drug's effectiveness and monitor adverse long-term effects. Phase 3 trials are both the costliest and longest trials, and they sometimes involve hundreds of sites in the around the world. After the third phase is completed, the drug manufacturer applies for EMA and/or FDA approval. In Europe drug licensing may happen through a centralized or a decentralized (or "mutual recognition") system (http://www.ema.europa.eu).

When a drug receives marketing authorization, the manufacturer may apply to market its drug in each individual country. After this last step, the product is available for doctors to prescribe.

In the USA, after completing clinical trials, the company sends the FDA a New Drug Application, which contains all the preclinical and clinical information obtained during the testing phase (http://www.fda.gov).

Once a drug is approved, it can be marketed (Lipsky & Sharp, 2011). Where the product is marketed and sold, and as a much larger number of patients begin to use the drug, drug manufacturers are required to monitor drug safety and submit periodic reports, including cases of adverse events, to the FDA and/or EMA. In addition, a company may be required to conduct additional studies on an approved

drug in "Phase 4" trials: these studies can be set up to evaluate long-term safety or how the new medication affects a specific subgroup of patients.

The Medical Research Council (2000) framework acknowledges parallels in the sequence of steps usually required in the evaluation of drugs from initial preclinical research through surveillance after marketing. However, it also stresses that such parallels and analogies in no way imply that the evaluation of prevention programs is like that of a new drug because of the numerous differences and levels of complexity.

International Perspective and the Role of International Societies

In the USA the establishment of the Society for Prevention Research (SPR) has had a remarkable impact on the development of the field of prevention science. Founded in 1991, the SPR's scope has broadened over the years, together with an increase in the number of its collaborations with varied federal US funding agencies such as the National Institute on Drug Abuse, the National Institute of Mental Health, and others (http://www.preventionresearch.org/about-spr). In 2010, the European Society for Prevention Research was founded. Among its purposes is the promotion of high-quality intervention assessment studies in Europe (http://www.euspr.org). A similar experience is being led in the Middle East and is forming the basis for the establishment of a new pan-Arab agency for drugs monitoring and prevention, the Arab Research, Resource and Information Center on Drug Prevention.

There are other international experiences that provide a glimpse into the potential of international collaboration in the field of prevention. The US-EU Cross-National Study on Variation of Receptivity to Substance Abuse Prevention Interventions is an opportunity to explore international differences and factors affecting program effectiveness focusing on the EU-Drug Abuse Prevention study (EU-DAP) and the Adolescent Substance Abuse Prevention Study (ASAPS). Both of these studies consist of large longitudinal, randomized, controlled trials conducted in Europe and in the USA, respectively, assessing comparable preventive interventions implemented among similarly aged populations. The current in-depth analysis being carried out by both study groups will contribute to an understanding of the role that program context plays in determining the effect of an intervention (Brown et al., 2013).

Another example is ALICE RAP (Addiction and Lifestyles in Contemporary Europe—Reframing Addictions Project): this new dynamic transdisciplinary EU project aims to help policy makers to "re-think and re-shape" current and future approaches to the huge human and economic costs of addictions and risky lifestyles in Europe. ALICE RAP aims to critically examine and analyze currently fragmented research and strengthen scientific evidence to inform a new dynamic

platform for public and political debate on current and alternative approaches to addictions (http://www.alicerap.eu).

The vitality of the research arena gives hope as to the role that research will play in strengthening the evidence base for prevention; in particular, the capacity of research networks to work and think together, share objectives, and study results, such as the ALICE RAP and SPR experiences, is a requirement for any new advancement in prevention science.

A Proposal for a Four-Pillar System of Approval of Intervention Programs

In the previous sections we argued that there are basic conditions to moving forward in the prevention field: fostering prevention science and raising the field's scientific standards. This should include, and be hastened by, setting up a formal process for the approval of prevention interventions analogous to that of medicines. This process, based on evidence of effectiveness and safety, should have some peculiarities and be based on the following pillars:

1. *A formal process of approval*. The process should be administered by agencies recognized at an international level. The whole process should lead to the release of a certification of effectiveness and safety. Single countries could give priority to certificated programs in health planning or could, once the number of certified programs is sufficient to cover all the needs of prevention, consider making certification compulsory to program delivery.
2. *A three step evaluation process*. (1) Measure the effect of any single intervention component on specified/related mediators of the target behavior through an experimental study. This would allow shorter follow-ups and smaller sample sizes. This step should also address the effective dose through testing, when appropriate, different frequencies or durations of interventions, as well as testing combinations of interventions. For single-component programs, the evaluation should be limited to effective dose evaluation. (2) Conduct a randomized controlled trial with a rigorous design and appropriate sample size to evaluate the full program in an appropriate and generalizable population. As an alternative, a meta-analysis of smaller trials could also be considered. After this step the certificate could be released. (3) Require replicability, in particular in different contexts, to assess the generalizability of results and the safety of the intervention. Replication of the original program or of modified versions is always recommended, especially if conducted by different groups of researchers (Valentine et al., 2011). Evaluating versions adapted for other languages or cultures also is recommended and should be submitted to the process to upgrade the certification (Fig. 26.2).
3. *Transparency and publication of all documents*. This aspect is of particular relevance for the documentation of the program itself and for its dissemination.

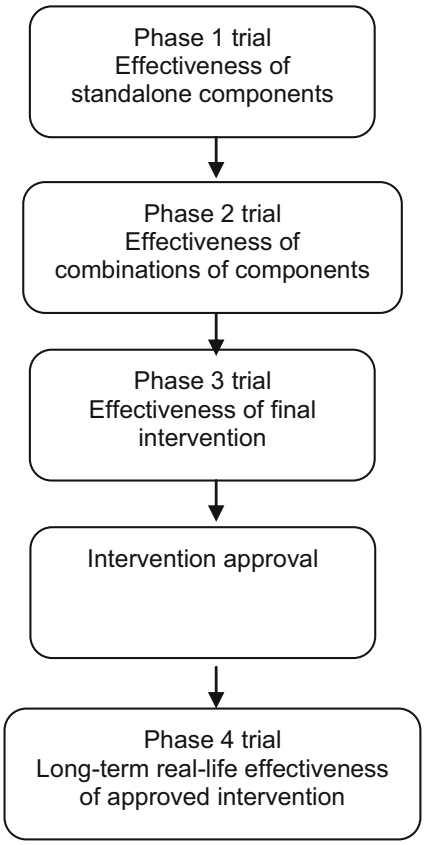

Fig. 26.2 Proposal for an approval process of prevention interventions

The level of documentation must be such that it enables replication with a high level of fidelity. The evaluation of single components is particularly important to allow other program developers to use effective components to build new programs from already validated components.

4. *International cooperation*. The establishment of standards of evidence for the approval of prevention programs requires international cooperation and consensus to develop a process accepted by researchers and practitioners. Large consensus and a high level of adherence, especially from developers and researchers, is needed since the impact of such a process on prevention practice can only occur once the number of programs and their ingredients can satisfy practitioners. This is one of the main challenges of this presented proposal.

Conclusions

The scientific content of prevention interventions and programs are still underconsidered and underused. Despite many commendable experiences, systems currently adopted by public agencies and scientific societies to ensure the effectiveness of prevention interventions adopted in clinical practice do not seem to have reached their principal aim, and a large part of prevention interventions found in practice, at least in Europe, do not have the minimal requirements to ensure that disseminated programs are effective, or at least safe.

Prevention scientists and professionals have to foster prevention science to promote the dissemination of effective intervention and to develop advanced methods for the evaluation of mechanisms and effects of prevention interventions. Among the possible items on the agenda of prevention science, we propose international cooperation to design and carry out a system of approval of prevention interventions that are able to target this objective. This chapter summarizes some proposals already presented by the scientific community and delineates the characteristics of a possible process used at an international level.

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