Introduction

School-based prevention is advocated as a necessary component of universal prevention and health promotion.1 In particular, schools provide convenient settings for the conduction of programmes aimed at preventing tobacco, alcohol and drug use, primarily because of their institutional contacts with the population group at highest risk of onset.2 Yet, the extensive formal evaluation of curricula into the complex setting in which teachers operate brings considerable variation in the extent of delivery, particularly in relation to interactive components.8,9 Besides, it has been demonstrated that low implementation fidelity results in smaller or no effects on behavioural outcomes and programme mediators compared with full compliance.10 Therefore, it is crucial to understand the nature of the obstacles to implementation fidelity in the school setting.11

The question of why and how a school programme is or is not implemented as intended has been addressed in quite a few studies. Key elements to successful implementation include factors operating at the school level, such as standardization of programme materials and methods,8,12–15 integration into school routines,12,13,15,16 high quality training, supervision of implementation,12 school and community organizational capacity as well as stability in terms of resources and personnel,12,15,16 local planning and involvement in decisions about implementation, support from the principal, school size and area urbanization.15,16 However, implementation can vary considerably even within a single school, for instance, because of class-related characteristics first and foremost, teachers’ motivation, positive attitude towards the programme,8 self-efficacy in the delivery17 and experience.8,18 Moreover, social processes that occur in a given class group may be at play.19 Despite this suggestion, important potential determinants of implementation at the class level, such as group behaviours and students’ connectedness,13 have been addressed in comparatively few studies. Mihalic et al.13 reported that misconduct in the class during sessions was a strong predictor of low-level implementation of the programme. Domitrovich et al.20 suggested that a class environment characterized by peer or teacher–student conflict may negatively
influence programme implementation. Botvin\textsuperscript{11} cited classroom overcrowding as well as classroom management and disciplinary problems as examples of potential barriers to fidelity. Curiously, problem behaviours in the class, such as substance use and violence, have not been studied as predictors of implementation. Theoretically, the presence of these problems may both enhance teachers’ determination to conduct a preventive programme and undermine the success of his or her effort.

To shed lights on the potential impact of class characteristics on quantitative aspects of implementation of a preventive programme, we conducted a secondary analysis of the European Drug Addiction Prevention (EU-DAP) trial.\textsuperscript{21} The curriculum evaluated in this trial achieved modest albeit prolonged effects on alcohol problematic drinking and illicit drugs use,\textsuperscript{22,23} but was conducted in its entirety by about half of the teachers,\textsuperscript{24} thus providing a wide range of implementation completeness and fidelity.

**Methods**

**Experimental design and sample**

EU-DAP was a cluster randomized controlled trial (ISRCTN 18092805) among students attending junior high school in seven European countries: Austria, Belgium, Germany, Greece, Italy, Spain and Sweden, represented by nine regional centres.\textsuperscript{21} The research protocol complied with the ethical requirements foreseen at the respective study centres.

In total, 170 schools were selected and randomized to the experimental or control conditions.

Students in the intervention group ($n = 3547$ at baseline in 78 schools) participated in the preventive programme Unplugged, consisting of 12 units of one scholastic hour targeting adolescents’ substance use and constitute the study population in this analysis. This new curriculum is based on a Comprehensive Social Influence model\textsuperscript{25} and focuses on enhancing interpersonal and intrapersonal skills, using highly interactive teaching methods, such as small-group work, discussions, role-plays and group games. Sessions on normative education and information on substances are also provided. Ordinary classroom teachers delivered the sessions for 3 months, after attending a 3-day course in interactive teaching techniques. The implementation protocol was carefully standardized.

Detailed information regarding the study design and population,\textsuperscript{21} as well as the curriculum theory base and content,\textsuperscript{24} has been previously published.

**Data collection and measures**

**Assessment of implementation fidelity**

A monitoring system for the programme implementation was developed as part of the process evaluation in the trial and can be consulted at the European Monitoring Centre for Drugs and Drug abuse (EMCDDA, http://www.emcdda.europa.eu/html.cfm/index 5109EN.html). Class teachers were requested to fill in a structured report immediately after delivering each unit. The form requested information on multiple dimensions of implementation. Adherence to the manual-based instructions was assessed by recording whether each of the activities in a given unit was implemented. Information was also recorded on the actual duration of the unit, as the allotted time should in principle not exceed one school hour (usually 50 minutes). Study outcomes were the following dimensions of the programme implementation at the class level:

(i) Curriculum completeness: proportion of units implemented (at least partially) of the total number of units of the curriculum, dichotomized into ‘All units implemented’ vs. ‘No’.

(ii) Application fidelity: proportion of units conducted as intended, i.e. encompassing all activities described in the manual, of the number of units actually delivered, dichotomized into ‘At least half of the units delivered as intended’ vs. ‘No’.

(iii) Duration: average number of minutes actually required to complete a standard unit.

(iv) Use of role-play: an indicator related to the three activities of this interactive component of the curriculum, dichotomized into ‘All role-play activities implemented’ vs. ‘No’.

**Assessment of predictors of implementation**

We used a self-administered anonymous paper-and-pencil questionnaire to collect baseline information from the students on their substance use, demographic and psychosocial characteristics. The standardized questionnaire (available on the EMCDDA website: http://www.emcdda.europa.eu/html.cfm/index4872EN.html) was administered in the classrooms, without teachers’ participation and after ensuring confidentiality. Most questions were retrieved from the ‘Evaluation Instruments Bank’ (http://eib.emcdda.europa.eu/), in 2004.

From the questions assessing substance use,\textsuperscript{23} we derived three binary indicators of ‘any cigarette smoking’, ‘any cannabis use’ and ‘any episode of drunkenness’ in the past 30 days, respectively. Further, students were asked whether they would expect to improve their grades by the end of the school year. Answering ‘yes’ or ‘probably yes’ was used as indicator of positive academic expectations. School liking was investigated by asking students how they felt about school at the moment. Answering ‘I like it a lot/a bit’ was used as indicator of school liking. Connectedness to the class was assessed by asking the students to rate their agreement with five statements about the relationships in the class (‘The students in my class enjoy being together’, ‘Most of the students in my class are kind and helpful’, ‘Other students accept me as I am’, ‘How I do in school matters a lot to me’ and ‘I have great respect for what my teachers tell me’). The responses were rated on a 4-point Likert scale ranging from strongly disagree to strongly agree (Cronbach’s alpha = 0.69) and then averaged to yield an individual mean score. At least three items had to be completed for a mean score to be computed.

**Statistical analysis**

Class was chosen as the unit of analysis. Accordingly, information collected at the student level was aggregated at the class level. The following class-level variables were considered as potential predictors of implementation: gender composition (percentage of boys), mean age in years, size (number of students in a class who participated in the baseline survey), proportion of students reporting any substance use (past 30 days prevalence of any cigarette smoking, cannabis use or drunkenness), average score for connectedness to class as well as proportion of students with positive academic expectation and school liking. The ‘connectedness to class’ index was transformed to range from 0 in case of total disagreement to 10 in case of maximum agreement (mean = 5.2, SD = 1.8, skewness = −0.1 and kurtosis = 3.5). These variables were used on a continuous scale in the regression analysis, whereas, for the purpose of descriptive analyses, all variables but age were dichotomized as potential predictors (above/below the median).\textsuperscript{30} The ‘substance use (past 30 days prevalence of any cigarette smoking, cannabis use or drunkenness)’ variable was dichotomized as a binary indicator (‘any episode of drunkenness’ in the past 30 days, respectively). Further, students were asked whether they would expect to improve their grades by the end of the school year. Answering ‘yes’ or ‘probably yes’ was used as indicator of positive academic expectations. School liking was investigated by asking students how they felt about school at the moment. Answering ‘I like it a lot/a bit’ was used as indicator of school liking. Connectedness to the class was assessed by asking the students to rate their agreement with five statements about the relationships in the class (‘The students in my class enjoy being together’, ‘Most of the students in my class are kind and helpful’, ‘Other students accept me as I am’, ‘How I do in school matters a lot to me’ and ‘I have great respect for what my teachers tell me’). The responses were rated on a 4-point Likert scale ranging from strongly disagree to strongly agree (Cronbach’s alpha = 0.69) and then averaged to yield an individual mean score. At least three items had to be completed for a mean score to be computed.

Results are based on data provided in the implementation forms returned by the teachers, where non-returned forms yielded missing
values for the corresponding information. Missing data were handled by means of multiple imputation\textsuperscript{28} as well as assuming they were all indicative of absence of implementation. Finally, we repeated the analysis including only classes that provided the monitoring forms for all the units (listwise deletion).

**Results**

The study sample consisted of 173 classes, of which 103 (60\%) complied with the monitoring system providing information on all the units, 61 (35\%) returned the forms partially and nine (5\%) classes did not return the monitoring form for any unit. Therefore, although information on predictors collected at the student level and then aggregated at the class level was always complete, missing data affected implementation indexes (outcomes). Specifically, one-third of the classes lacked information on programme completeness and use of role-play. Information on application fidelity and duration was missing each for 5\% of the classes.

Overall, half of the classes (n = 87) implemented all the units in the curriculum. Only 43\% (n = 74) of the teachers succeeded in completing all the planned activities in at least half of the units they delivered, whereas the role-play was actually used each time this activity was foreseen in the programme in 54\% of the classes. The average duration of a unit was 62 min (SD = 18). The distribution of the indexes of implementation varied among the regional centres and among areas of different socio-economic levels (table 1).

Table 2 describes the distribution of the implementation indexes by class-level predictors.

Curriculum completeness and use of role-playing were more frequent in classes with mean age of students 12 years, size above the median of the sample (n = 22), proportion of males and of drug use below the median and with proportion of connectedness, school liking and positive academic expectations above the median. Apart from class size, the same was observed for application fidelity. Also, time for unit completion tended to exceed the allotted time in classes with mean age >12 years.

In multilevel regression models, mutual adjustment for all the potential predictors did not yield estimates that were fundamentally different from the crude ones; therefore, the latter are presented in table 3. The level of implementation was not affected by mean age, prevalence of positive academic expectation or prevalence of school liking. On the other hand, each of the other class-level predictors resulted significantly associated with an implementation index. Each additional student in the class was associated with a 10\% decrease of the odds to implement completely at least half of the units, and for each 10 percentage points increase in the proportion of boys, the duration of a unit was on average 2 min shorter. One-unit increase in substance use prevalence was associated with a 20\% decrease in the odds of completing the curriculum. Finally, for each unit increase in connectedness score, classes had a 50\% increased odds of using role-play.

The results obtained from the analyses on imputed data and from the analyses carried out under the assumption of no implementation in case of unreturned form did not differ from those based on the original data set (data not shown). The listwise deletion led to an important reduction in the sample size, with no statistically significant relationship detected (data not shown).

**Discussion**

This secondary analysis of an experimental evaluation of a substance use prevention programme in schools of seven European countries showed that some class characteristics might predict the level of programme implementation.

Expectedly, class size was inversely related with application fidelity, an increasing proportion of girls in the classroom resulted weakly associated with longer sessions. Among the structural factors, age did not appear to play an important role. Prevalence of substance use at baseline was a strong negative predictor of curriculum completeness, whereas class-level students’ connectedness to their class showed a clear and positive impact on the use of the most interactive component of the curriculum, i.e. role-play. Most of these results were in the anticipated direction and were consistent with several previous studies that reported rates lower than expected and wide variation in implementation of school

**Table 2 Proportions (%) of the implementation indexes, by class-level predictors**

<table>
<thead>
<tr>
<th>Class characteristic</th>
<th>Curriculum completeness</th>
<th>Application fidelity</th>
<th>Use of role-play</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All 12 units delivered</td>
<td>At least half of the units delivered as intended</td>
<td>Average minutes per unit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Gender composition (% of boys)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above the median</td>
<td>44</td>
<td>39</td>
<td>44</td>
<td>57</td>
</tr>
<tr>
<td>Below the median</td>
<td>57</td>
<td>46</td>
<td>64</td>
<td>66</td>
</tr>
<tr>
<td>Mean age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>70</td>
<td>70</td>
<td>79</td>
<td>51</td>
</tr>
<tr>
<td>13</td>
<td>45</td>
<td>38</td>
<td>48</td>
<td>65</td>
</tr>
<tr>
<td>14</td>
<td>51</td>
<td>35</td>
<td>51</td>
<td>63</td>
</tr>
<tr>
<td>15</td>
<td>31</td>
<td>38</td>
<td>38</td>
<td>69</td>
</tr>
<tr>
<td>Size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above the median</td>
<td>56</td>
<td>43</td>
<td>61</td>
<td>62</td>
</tr>
<tr>
<td>Below the median</td>
<td>44</td>
<td>43</td>
<td>47</td>
<td>62</td>
</tr>
<tr>
<td>Substance use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above the median</td>
<td>44</td>
<td>37</td>
<td>47</td>
<td>59</td>
</tr>
<tr>
<td>Below the median</td>
<td>57</td>
<td>49</td>
<td>60</td>
<td>65</td>
</tr>
<tr>
<td>Positive academic expectation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above the median</td>
<td>60</td>
<td>52</td>
<td>66</td>
<td>62</td>
</tr>
<tr>
<td>Below the median</td>
<td>40</td>
<td>33</td>
<td>41</td>
<td>61</td>
</tr>
<tr>
<td>School liking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Above the median</td>
<td>58</td>
<td>44</td>
<td>63</td>
<td>59</td>
</tr>
<tr>
<td>Below the median</td>
<td>43</td>
<td>42</td>
<td>44</td>
<td>64</td>
</tr>
</tbody>
</table>
Third, the relatively low compliance with the implementation protocol was carefully standardized, conclusions are limited to this programme only. However, given that the implementation is relatively unbiased and if a high degree of implementation improves effect-iveness, substance use prevention is likely to be less effective in the extreme case of girls-only classes, one may expect curriculum use of role-play that we observed in this study is in line with studies showing an important role of the social network context in programme implementation. For instance, in a study by Valente et al.,30 the effectiveness of tobacco prevention curricula was different based on how groups of students were assembled for programme delivery. Other studies showed that group relationships with peers can affect implementation,20,31 in particular the use of collaborative learning tasks as role-play.7 The fact that in this study class size influenced application fidelity, but not curriculum completeness and use of role-play, is not surprising. In fact, the decision whether to deliver a session is seldom based on the number of students. Class size per se is also unlikely to determine whether role-play would be implemented, given that this activity usually involves only a part of the group, whereas the remaining students act as audience. It is instead conceivable that a large class size makes it difficult to complete all the planned activities, if they should involve all students. It has also been suggested that teachers ready to meet the challenge of a new preventive programme in an effective and sustainable manner are those who have manageable demands (e.g. have moderate class sizes).32 Accordingly, classroom overcrowding has been listed among the barriers to fidelity of implementation in school-based substance use prevention.11 To the best of our knowledge, there are no previous studies on the impact of problem behaviours, such as substance use, on the implementation of preventive programmes. If the effect observed in this study is unbiased and if a high degree of implementation improves effectiveness, substance use prevention is likely to be less effective in the classes where it is most needed. Finally, gender composition did not seem to have an important impact on implementation. However, in the extreme case of girls-only classes, one may expect curriculum sessions on average 20 min longer than boys-only classes. One may speculate that attitude to active participation and in-depth reflection is more common among girls than among boys of the same age, an explanation that should be explored in adequate experimental settings.

There were some obvious limitations in this study. First, this is an investigation of a specific intervention, and therefore findings are limited to this programme only. However, given that the implementation protocol was carefully standardized, conclusions might be also applicable to similar prevention programmes. Second, the limited sample size requires a cautious interpretation of the study results. Third, the relatively low compliance with the report system led to substantial missing information for the outcome indexes. However, we comprehensively addressed this problem both by identifying possible missing value mechanisms and taking into account its implications in the analysis. The missingness mechanism was likely 'non-ignorable'.33 In fact, the probability for a form to be unreturned (i.e. the probability that an implementation index has missing data) was related to the actual implementation status. In this case, both complete case analysis, and multiple imputation lead to invalid inference.33 However, as classes who complied with the monitoring forms had better structural and social characteristics than those who did not comply, the most probable consequence of this missingness mechanism would be to bias the effect estimates towards the value expected under the null hypothesis, i.e. an underestimation of the effect modification. Moreover, we explored how our inferences varied under the assumption of no implementation for unreturned forms. Our main findings were robust to different assumptions regarding missingness. Fourth, we did not collect information on teachers’ characteristics, such as gender, age, education, experience and attitude towards the programme, important individual-level predictors of implementation. However, some studies have not confirmed teachers’ characteristics as predictors of the implementation: Stead et al.34 found few variations in delivery between teachers with or without prior expertise in drug education. Sloboda et al.35 found no correlations between provider’s age, gender, race or level of education and curriculum content coverage or use of the appropriate instructional strategy. Moreover, all teachers involved in the intervention of the EU-Dap trial attended a carefully standardized training. Finally, for integrity verification, we decided to rely on self-report of the teachers, a common practice for cost and feasibility reasons,10 rather than external observers. Although self-reports are expected to overestimate the actual implementation, we have no reason to think that social desirability would be different based on class characteristics. To assure quality of reporting, we asked the teachers to complete the forms immediately after each session, with regular and frequent dispatching to the study team.

This study suggests that classes with large size, predominantly male gender composition, scarce connectedness between students and high prevalence of substance use are likely to implement prevention programmes similar to Unplugged to a lower extent than other classes. As these characteristics may also have an impact on substance use at post-intervention, they should always be considered as potential confounders in future ‘per protocol’ analyses of experimental studies.

Our results also suggest that these class characteristics, in particular the social cohesion among students and prevalence of prevention programmes based on social influences,10 despite training of providers and standardized protocols. Research on local processes at the class level affecting teachers’ propensity to implement an innovative programme is relatively limited.29 The relationship between connectedness in the class and use of role-play that we observed in this study is in line with studies showing an important role of the social network context in programme implementation. For instance, in a study by Valente et al.,30 the effectiveness of tobacco prevention curricula was different based on how groups of students were assembled for programme delivery. Other studies showed that group relationships with peers can affect implementation,20,31 in particular the use of collaborative learning tasks as role-play.7 The fact that in this study class size influenced application fidelity, but not curriculum completeness and use of role-play, is not surprising. In fact, the decision whether to deliver a session is seldom based on the number of students. Class size per se is also unlikely to determine whether role-play would be implemented, given that this activity usually involves only a part of the group, whereas the remaining students act as audience. It is instead conceivable that a large class size makes it difficult to complete all the planned activities, if they should involve all students. It has also been suggested that teachers ready to meet the challenge of a new preventive programme in an effective and sustainable manner are those who have manageable demands (e.g. have moderate class sizes).32 Accordingly, classroom overcrowding has been listed among the barriers to fidelity of implementation in school-based substance use prevention.11 To the best of our knowledge, there are no previous studies on the impact of problem behaviours, such as substance use, on the implementation of preventive programmes. If the effect observed in this study is unbiased and if a high degree of implementation improves effectiveness, substance use prevention is likely to be less effective in the classes where it is most needed. Finally, gender composition did not seem to have an important impact on implementation. However, in the extreme case of girls-only classes, one may expect curriculum sessions on average 20 min longer than boys-only classes. One may speculate that attitude to active participation and in-depth reflection is more common among girls than among boys of the same age, an explanation that should be explored in adequate experimental settings.

There were some obvious limitations in this study. First, this is an investigation of a specific intervention, and therefore findings are limited to this programme only. However, given that the implementation protocol was carefully standardized, conclusions might be also applicable to similar prevention programmes. Second, the limited sample size requires a cautious interpretation of the study results. Third, the relatively low compliance with the implementation protocol was carefully standardized, conclusions are limited to this programme only. However, given that the implementation protocol was carefully standardized, conclusions might be also applicable to similar prevention programmes. Second, the limited sample size requires a cautious interpretation of the study results. Third, the relatively low compliance with the implementation protocol was carefully standardized, conclusions are limited to this programme only. However, given that the implementation protocol was carefully standardized, conclusions might be also applicable to similar prevention programmes.
substance use, are potentially useful indicators of the difficulties that a teacher may encounter in implementing comprehensive social influence programmes. Although the presence in a class of substance use problems may trigger the decision to adopt a prevention program, deliverers should take into consideration that it can also be a determinant of poor implementation. A sense of connectedness to school in general has in itself been demonstrated to be protective against a range of risk behaviours including risky substance use, sexual risk taking and mental health problems. Thus, efforts to build positive relationships within the classroom may be integral to the provision of effective substance education programmes. The influence of other structural factors, such as class size, may suggest that application fidelity should be targeted by specific organizational strategies such as using two or more implementation groups in a large class. Also, teachers’-led programmes may benefit from teachers’ training in class management techniques, in particular in the presence of disruptive behaviours in the students’ group.

Acknowledgements

The authors acknowledge teachers and students who volunteered in this study.

EU-Dap Study Group: Roberta Siliquini, Barbara Zunino, Luca Cuomo, Federica Vigna-Taglianti, Serena Vadrucci, Laura Vitale (Piedmont Centre for Drug Addiction Epidemiology, Turin, Italy); Karl Bohrn (Institut für Sozial und Gesundheitspsychologie, Wien, Austria), Peer van der Kreeft (De Sleutel, Gent, Belgium); Juan Carlos Melero, Laura Varona (EDEX, Bilbao; Spain); Gudrun Wiborg (IFT-Nord, Kiel, Germany); Clive Richardson (University Mental Health Research Institute, Athens, Greece); Maro Vassara (Pyxida, Thessaloniki, Greece); Maria Rosaria Galanti, Sara Sanchez (Stockholm Centre of Public Health and Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden); Gregor Burkhart (EMCDDA, Lisbon, Portugal); Fabrizio Faggiano, Massimiliano Panella (Department of Clinical and Experimental Medicine, Avogadro University, Novara, Italy); Leila Fabiani, Maria Scatigna (Department of Internal Medicine and Public Health, University of L’Aquila, L’Aquila, Italy).

Funding

This work was supported by the European Commission, European Public Health programme 2002 (grant number SPC 2002376). Additional national funding was provided by: Compagnia di San Paolo (grant number 2002-0703) and Lega Italiana per la Lotta contro i Tumori (grant number 2003 43/4) for the Novara centre; Swedish Council for Working Life and Social Research (grant number 2002-0979), Stockholm County Council (Public Health grant number LS 0401-0117) and Alcohol Research Council of the Swedish Alcohol Retailing Monopoly (grant number 07-8:1) for the Swedish centre.

Conflicts of interest: None declared.

References

27 StataCorp. *Stata Statistical Software: Release 12 College Station*. TX: StataCorp LP, 2011.