

EU-Dap Final Conference
Lisbon 15-17 December 2005

RATIONALE AND STUDY DESIGN

Roberta Siliquini

OED Regione Piemonte



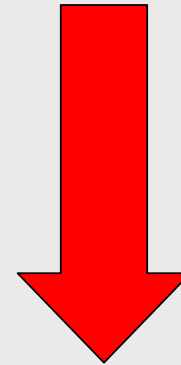
► in almost all schools in Europe an intervention against drugs is carried out each year... but

► ... they are never evaluated

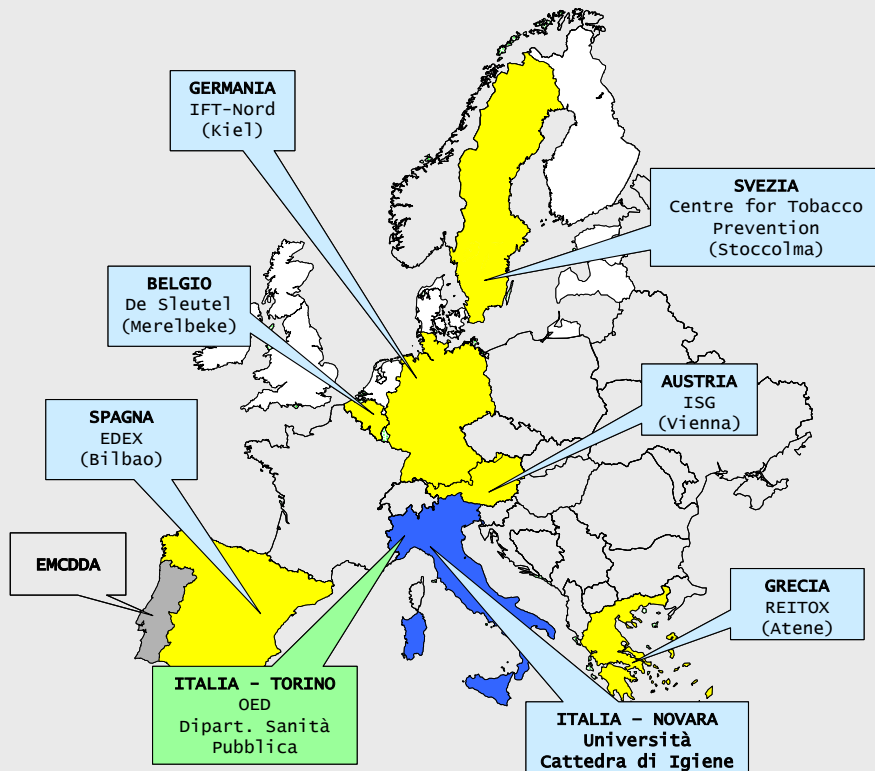


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1. Is not acceptable that an intervention carried out on healthy population could cause harm
2. No information is given about risk factors and natural history



CONTRIBUTE TO THE PRODUCTION OF EVIDENCE
CONCERNING THE EFFECTIVENESS OF DRUG
PREVENTION PROGRAMME



- a complex intervention*
- aimed either to curb initiation with drugs*
- or to delay transition from experimental to addiction*
- of tobacco, alcohol, cannabis and other drugs*

CONTRIBUTE TO THE PRODUCTION OF EVIDENCE
CONCERNING THE EFFECTIVENESS OF DRUG
PREVENTION PROGRAMME



A rigorous evaluation...

- x A control group
- x A random assignment of subjects
- x A standardized intervention
- x A standardized evaluation tool
- x A continuous monitoring process

Control
Basic intervention
Basic intervention + peer
Basic intervention + parents



A rigorous evaluation...

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CLUSTER RANDOMIZED STUDY

Study base and study population

x 12-14 years old adolescents

- age of students must be under the modal age of prevalence
- the prevalence at the first year of follow up
- the probability to stay 2 years or more in the same school

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× Inclusion of schools criteria

- have at least two classes
- to be a 'normal school'
- willingness to be included in the study with at least 2 classes
- not strong prevention packages already carried out

Sample size

INTERCLASS CORRELATION COEFFICIENT

ρ

From others study ICC = 0.06-0.015

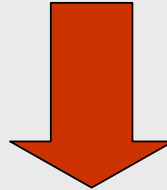
INFLATION FACTOR = $1+(m-1) \rho$

Sample size

- Commonly employed values for statistical test
 $\alpha = 0.05$ power = 0.80
- Intervention effect corresponding to RR = 1.5
- Class size = 20

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15 schools for each center (30 for Torino and Stockholm)
a ratio of 3 (intervention): 2 (controls)
6600 students

Random assignment

List of the area school meeting base population criteria

Exclusion of schools not meeting criteria

Stratification in 3 strata according to social class

Extraction (by chance) of the schools in each strata

Contact of headmaster and agreement

Random allocation to study arms

NUMBER OF SCHOOLS RANDOMISED AND DROPPING OUT AFTER RANDOMISATION, BY STUDY ARM AND CENTER

Centres	Study arm								Total	
	Basic		Parent		Peer		Controls			
	Rand.	Drop out	Rand.	Drop out	Rand.	Drop out	Rand.	Drop out	Rand.	Drop out %
Italy/Torino	6	1	6	0	6	1	12	0	30	6.7
Spain/Bilbao	3	2	3	2	3	1	6	0	15	33.3
Germany/Kiel	3	0	3	0	3	0	6	0	15	0.0
Belgium/Gent	5	3	5	3	4	2	8	1	22	40.9
Sweden/Stockholm	6	1	6	1	6	2	10	1	28	17.9
Greece/Thessaloniki	3	0	4	0	3	0	7	0	17	0.0
Austria/Vienna	3	0	3	2	3	1	8	0	17	17.6
Italy/Novara	3	2	2	0	3	0	5	1	13	23.1
Italy/L'Aquila	3	0	3	0	1	0	6	0	13	0.0
Total	35	9 (25.7%)	35	8 (22.9%)	32	8 (21.9%)	68	4 (4.4%)	170	27 (15.9%)

Evaluation tool

x Pre-post questionnaire

- Self completed (october-december 2004-2005)
 - Self completed at the end of the scholar year
 - Foreseen a follow up at 2-3-5 years
-
- most of the questions come from EDDRA bank
 - about 1 hour for filling it

Evaluation tool

x Pre-post questionnaire

Social environment
Own substance use
Knowledge and opinion about substances
Substances use in the nearest environment
Family and social environment
School environment and climate
Problems and skills

Evaluation tool

x Pre-post questionnaire

- Self completed (october-december 2004-2005)
- Self completed at the end of the scholar year
- Foreseen a follow up at 2-3-5 years

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- Anomynous but allowing the linkage between pre and post test

SELF-GENERATION SHEET FOR THE ANONYMOUS CODE

Name	<input type="text"/> <input type="text"/> <input style="background-color: cyan;" type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<div style="background-color: cyan; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="background-color: darkblue; width: 20px; height: 20px; margin: 0 auto;"></div>										
Surname	<input type="text"/> <input type="text"/> <input style="background-color: lightblue;" type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<div style="background-color: lightblue; width: 20px; height: 20px; margin: 0 auto;"></div>										
Birth date (dd/mm/yyyy)	<input type="text"/> <input style="background-color: pink;" type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<div style="background-color: pink; width: 20px; height: 20px; margin: 0 auto;"></div>										
Mother's name	<input type="text"/> <input style="background-color: yellow;" type="text"/> <input type="text"/> <input style="background-color: orange;" type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<div style="background-color: orange; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="background-color: yellow; width: 20px; height: 20px; margin: 0 auto;"></div>										
Father's name	<input type="text"/> <input type="text"/> <input style="background-color: lightgreen;" type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<div style="background-color: lightgreen; width: 20px; height: 20px; margin: 0 auto;"></div>										
Paternal Grandmother's name	<input type="text"/> <input style="background-color: lightblue;" type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<div style="background-color: lightblue; width: 20px; height: 20px; margin: 0 auto;"></div>										
Your eyes colour	<table border="1" style="margin: 0 auto; border-collapse: collapse;"> <tr> <td style="background-color: red; color: white; padding: 2px;">G</td> <td style="background-color: red; color: white; padding: 2px;">B</td> <td style="background-color: red; color: white; padding: 2px;">L</td> <td style="background-color: red; color: white; padding: 2px;">U</td> <td style="background-color: red; color: white; padding: 2px;">R</td> </tr> <tr> <td style="text-align: center; padding: 2px;">Green</td> <td style="text-align: center; padding: 2px;">Brown</td> <td style="text-align: center; padding: 2px;">Black</td> <td style="text-align: center; padding: 2px;">Blue</td> <td style="text-align: center; padding: 2px;">Grey</td> </tr> </table>	G	B	L	U	R	Green	Brown	Black	Blue	Grey		<div style="background-color: red; width: 20px; height: 20px; margin: 0 auto;"></div>
G	B	L	U	R									
Green	Brown	Black	Blue	Grey									

QUESTIONNAIRE
on attitudes, use, facts
on non-nutritional substances



Questionnaire evaluation

x Pilot study

- September 2004, coordinated by Stockholom center
- Participants: Greece, Italy (Torino, Novara), Spain, Sweden
- Objectives:
 - test the application of the link algorithm
 - test-retest reliability of the algorithm
 - Test of the anonymous link procedures
 - Test- retest reliability of the questionnaire form
 - General acceptance of the questions
 - Test of cost-efficiency of input options

Questionnaire evaluation

EUDAP pilot study: participants by centre

CENTRE	Anonymous code generation (AC)		Anonymous code link ¹ (AL)	
	CLASSES	STUDENTS	CLASSES	STUDENTS
	N.	N.	N.	N.
Italy 1/Turin	3	63	4	84
Italy 2/Novara	4	85	4	84
Spain/Portugalete	2	28	2	40
Sweden/Stockholm	2	46	3	55
All centres	11	222	13	263

Questionnaire evaluation

EUDAP pilot study: proportion of successfully linked anonymous code by number of digit

Centre	Digits included in the link procedure				
	All 9 digits	Eight digits: - Eye colour	Seven digits: - Grand-mother's name	Six digits: -Father's name	Five digits: - 4 th character of mother's name
Italy 1	71.4	75.0	78.6	80.9	82.1
Italy 2	58.3	61.9	77.4	77.4	79.8
Spain	42.5	45.0	57.5	60,0	65.0
Sweden	43.6	49.0	61.8	69.0	70.9
All centres	57.0	60.8	71.5	74.1	76.4



Process monitoring

OSSERVATORIO



- Process Monitoring -
- DE V2.2 -



eudap@oed.piemonte.it

OSSERVATORIO



EU-DAP - European Drug Addiction Prevention - DE V2.2

Help Exit

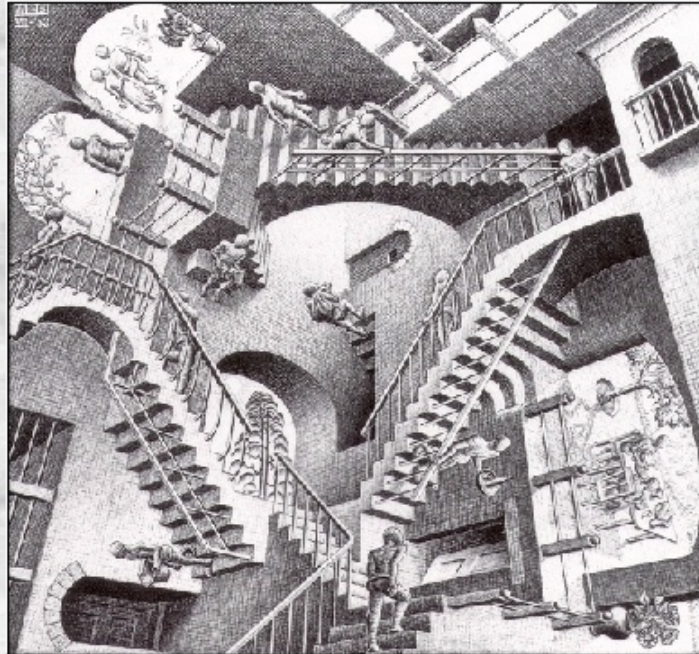


- Process Monitoring - DE V2.2 -

"Unplugged" Base Program	ANNEX1	ANNEX2	Parents' Meeting Program
"Unplugged" P2P Program	ANNEX3	ANNEX4	Control Classes Programs
Teachers' Training	ANNEX5	ANNEX6	Teachers' Training Ass.
Questionnaire Survey	ANNEX7	ANNEX8	Drop-out of Trial Units

EpiData 3.0

eudap@oed.piemonte.it



Elaborazione e organizzazione

G. Luca Cuomo

OED 2004, Piemonte/Italy

AutoPlayer ottimizzato per VGA 800x600

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