OVERDOSE RISK INFORMATION EU PROJECT FINAL REPORT

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In Brief: What is ORION?

The ORION project is a European funded project on developing and implementing an e-health psycho-educational tool to provide information to drug using-individuals about the risks of experiencing a drug overdose. The project was conducted in four European Union countries: Germany, Italy, Denmark and the UK. The Overdose Risk Information (ORION) tool has been designed with the aim of being easy-to use and informative to both patients and clinicians in various clinical settings across Europe. In addition, a pilot implementation of the ORION tool was conducted in the four countries to assess the feasibility of implementing the tool across various clinical settings and to assess the impact it may have on the substance misusing patients. The ultimate aim of this project is to develop a practical overdose risk assessment tool which can be developed and implemented effectively in substance misuse fields across Europe.

INTRODUCTION

'Drug overdose kills one European per hour' (European Public Health Alliance, 2008). This is an alarming but reasonably accurate reflection of the most recently reported European figures of fatal drug overdoses. This simple headline however does not account for the complex nature of overdoses and the various co-morbidities associated with both fatal and non-fatal overdoses. Non-fatal overdoses can cause a wide range of chronic morbidities, including pulmonary impairment, pneumonia and muscular impairment (Stoové et al., 2009). Overdoses may also lead to neurological damage, and the number of overdoses experienced is a significant predictor of poorer cognitive performance (EMCDDA, European Monitoring Centre for Drugs and Drug Addiction, 2012a). Currently, the risk factors and how they combine to influence the risk of fatal overdoses are not well understood.

Given these worrying facts, reducing the high prevalence of drug overdoses has become a priority across the European Union, which is reflected in the EU Drugs Strategy (2005-2012) and the EU Drugs Action Plan (2009-2012)(EMCDDA, 2012b). One key focus of the action plan is to reduce the number of drug-related deaths in Europe through implementing innovative drug prevention programmes across various healthcare settings.

Overdose prevention programmes have so far predominately focused on a combination of treatment programmes, community peer education, family support groups, supervised injecting facilities, as well as the supply of Naloxone (an opiate antagonist which can be administered by lay individuals in community settings). However, in a recent review of preventable risks of fatal overdose in heroin users, it was concluded that there is presently no single known intervention with a strong evidence base for significantly reducing overdose deaths (Frisher et al., 2012). Therefore, this review suggests that interventions need to be administered in combination to increase the effectiveness in terms of reducing the number of drug overdoses in substance misusers.

The implementation of a psycho-educational programme designed to help drug users become more aware of their overdose risk and behaviours is one way in which a variety of clinical interventions could be supplemented to provide such a combined approach. In a study conducted in the UK (London), it was found that, using psycho-educational group approaches in preventing and responding to heroin overdose can be an effective tool in helping users when it comes to managing an overdose situation (Philips et al., 2009).

The specific psycho-educational tool developed for ORION was to be an e-health intervention, using a clinical decision support framework. Clinical decision support systems themselves are not a new concept and their benefits have been demonstrated in a systematic review of seventy randomised controlled trials (Kawamoto et al, 2005). The findings indicated that 68% of the trials conducted 'significantly improved clinical practice'. Using decision support tools within a clinical setting offers an invaluable opportunity to translate a vast amount of information into effective action which can support clinicians and patients. A well designed tool offers an opportunity for professionals to support patients in making good choices about their health by translating often complex data into simple language accompanied with visual aids (Edward et al, 2002). The clinical decision tool in this project is a system that collates patient-related information and derives through an evidence-based algorithm a risk estimate for communicating to the clinician and patient in a clinical interview.

The EU policy paper "Redesigning health in Europe for 2020" (European Union, 2012) specifically calls for the increase of use of e-health programmes in healthcare settings, in order to improve clinical decision-making, treatment efficiency and to strengthen communication between healthcare professional and patients.

Within this context, the purpose of the ORION study was to develop an overdose risk information tool, which not only estimates individual overdose risks, but is also able to assist clinical staff and to educate opiate dependent individuals to become more aware of the level of their risk factors associated with potential fatal and non-fatal overdose. The overarching aim of the programme was to assess whether e-health can improve awareness and understanding in substance misusing patients, with a focus to reduce both fatal and nonfatal overdoses in this vulnerable population. The literature regarding circumstances surrounding overdose provides further evidence of the complexity of a population which, although in some instances may receive healthcare treatment for substance misuse related problems, do not necessarily change the behaviours which put them at a higher-risk of fatal overdose. This project proposes therefore to develop an e-health intervention in a clinical population which utilises a decision making process using an innovative approach to raise awareness of the factors which influence risk of fatal overdose.

DEVELOPMENT

OF THE ORION SOFTWARE

AIMS OF THE ORION SOFTWARE

The overdose risk information (ORION) software was developed to be used in various clinical settings for the treatment of opioid addiction across Europe. The software was developed with the following specific aims in mind:

> Estimate overdose risk – to estimate patient's risk of experiencing an overdose after answering a series of questions relating to their drug use and behaviour. The patient and clinician should be able to closely observe overdose risk feedback provided by the easy-to-use software, with the aim of providing health education and to increase awareness of risk factors.

> Inform healthcare professionals – the ORION e-health tool should inform healthcare professionals by providing personalised overdose risk estimates based on the behaviour of their patients. This should help the healthcare professionals in their clinical decision-making and planning of treatments and interventions for the individual patients, regardless of the clinical setting.

> Raise awareness and understanding in patients – the ORION e-health tool endeavours to raise overdose risk awareness and understanding in patients through using the software tool. The combined feedback from the software and from the clinician or healthcare professional can be used to educate patients about their potential risk of experiencing a fatal or non-fatal overdose and how their drug using behaviours contribute to this.

> Be suitable for further development – the e-health nature of the intervention was decided on the basis of EU policies calling for such developments. However, as a software product this e-health tool can easily be modified in future to be used in other settings, include other risk factors and be expanded to utilise different technological platforms, e.g. mobile phones.

REVIEW OF THE SCIENTIFIC LITERATURE

The first step in the development of the ORION software consisted of a systematic review of the existing scientific literature on overdose risk factors, which was conducted in collaboration with partners from all countries. Based on the review of the literature, as well as discussions with clinical experts from all participating sites and countries, a number of known overdose risk factors were identified for inclusion in the overdose risk information (ORION) software.

Once the risk factors for inclusion were established, a second review of the literature was conducted to establish the impact each individual factor has on overdose risk (in the form of odds ratios). This information was compiled and used in the statistical modelling of how these factors combine to influence overdose risk.

SOFTWARE DEVELOPMENT

A series of screenshots of the ORION software can be found in Appendix 1. The exact wording of the software, including introduction screen and evaluation questions (see Evaluation Methodology below) was finalised in consultation with all ORION partners at the second trans-national meeting. Once the text was finalised in English it was translated and back-translated into German, Danish and Italian to ensure consistency of the software between the countries.

The statistical modelling of the risk factors and development of the software was put to tender, which resulted in experts from Keele University being contracted to fulfil this task. The academic component of this work was completed by Dr. Martin Frisher from the School of Pharmacy at Keele University.

Once completed, the software was loaded onto 8 PC laptops (i.e. two per participating country) and delivered to the research sites.

CONTEXT ANALYSIS

Finally, prior to the data collection phase each country conducted a local context analysis of substance misuse and substance misuse services. This was completed in order to better understand the situation of differences in each participating country in terms of the extent of the substance misuse problem, service availability and local policies to address needs and associated issues.

TRAINING OF CLINICAL TEAMS

A training session was conducted at each clinical centre for staff to be conversant with the e-health tool, in its use and practical application in the clinic with recruited participants. A demonstration was featured in the training, including a discussion and provision of guidelines about communicating with the patient the information that was being displayed. In addition, the various supplementary assessments prior to the application of the e-health tool and thereafter the presentation of the overdose risk estimate(s) were explained to ensure consistent data collection to evaluate this new intervention.

The following nine risk factors (age and gender adjusted) for experiencing a drug overdose were included in the study:

DEMOGRAPHICS

Age
Gender

PROTECTIVE FACTORS

Receiving treatment
Reducing drug intake

RISK FACTORS

Injecting
Mixing drugs
Recent prison release
Using drugs alone
Previous overdose
Mental health
Life event

PILOT IMPLEMENTATION

AND EVALUATION METHODOLOGY

AIMS OF THE PILOT IMPLEMENTATION AND EVALUATION

The ORION e-health software was implemented in at least one test site per participating country. The explicit aims of the initial pilot implementation were as follows:

> **Feasibility** - To assess whether the ORION software can be used in different clinical settings across Europe, without interrupting the usual running of these clinics in terms of waiting times or consultation duration. This was examined by means of observation and feedback from the clinics

> **Evaluation** - To assess whether and how the use of the ORION software might be helpful to both patients and healthcare staff. This was established by means of qualitative feedback and interviews, as well as evaluation questions contained within the software

> **Impact** - To assess the potential impact the engagement with the ORION software has on the patients' risk awareness and self-efficacy. This was examined by means of questionnaires, which were administered to the patients both prior to and following their use of the software.

IMPLEMENTATION

The agreed target was for each country to use the ORION software with at least 40 opioid-dependent patients in two different clinical settings: outpatient/opioid maintenance treatment and inpatient/hospitalised treatment. Potential participants had to be between the ages of 18 and 55, not display any acute psychotic symptoms or severe learning difficulties and be capable of giving their informed consent to participate.

EVALUATION METHODOLOGY

All participants were given the General Self-Efficacy Scale (GSE)(Schwarzer and Jerusalem, 1995) and an Overdose Risk Awareness Questionnaire to complete prior to and after their use of the software. Changes in the participant's answers of the questionnaires are attributed to the impact of using the software.

The software itself also included three brief evaluation questions, which were designed to capture the perceived cognitive (new knowledge), behavioural (intention to change behaviour) and affective (usefulness) of the software. These three dimensions are frequently used to capture the impact of healthcare interventions (Edwards et al., 1999).

Finally, throughout the data collection period observations and comment from both staff and patients about the ORION software were noted.

ETHICAL APPROVAL

Prior to any data collection, the materials and procedures were reviewed and approved by all relevant Ethical Research Committees in the four countries (Denmark, Germany, Italy and UK) and relevant management approval was sought from all sites.

PILOT PHASE

The materials were also piloted with 10 patients of the Addiction Services in the NHS Fife (UK) to ensure that the language of the software and questionnaires was clear and could be easily completed by the eventual participants.

DATA COLLECTION AND IMPLEMENTATION PROCEDURE

All healthcare staff who went on to use the software participated in a co-ordinated training session (as previously mentioned) which described the purpose of the study, demonstrated the technical aspects of using the software and gave guidelines about the clinical discussion with the patients around the software.

The data collection period took place between July and September 2012. During this time, consecutive patients to each clinic were sent an information letter and invited to participate in the study. The majority of patients gave their consent to participate, in which case their healthcare provider used the software with the patient on their next visit.

In every case the participant was first given the General Self-Efficacy and Overdose Risk Awareness questionnaires to complete. Following this, the patient participants and healthcare provider would use the ORION software together. Both would engage with the computer and discuss the personal risk of overdose of this particular patient. Towards the end of the software, the participant completed three brief evaluation questions. After using the software the participants were asked to complete the two questionnaires again.

Finally, all participants were thanked and debriefed.

DATABASE AND ANALYSIS

The data were securely transferred to the University of St. Andrews where it was entered into a database for analysis using relevant statistical methods. The final database contains information from 194 individuals participating in the study across the four different countries.

KEY FINDINGS

IMPLEMENTATION OBSERVATIONS REGARDING FEASIBILITY

Through the implementation stage of the project, the overall feedback from the clinicians and patients involved in the study was very positive. The feedback received indicates that the ORION software did not have a negative impact on waiting or consultation times. Both patients and staff were generally enthusiastic about being involved in the study and the software was easy to use and informative for both the healthcare professionals and patients.

RESEARCH SITES AND PARTICIPANTS

A total of 194 participants took part in the study in the four countries. The numbers collected in each country are as follows:

Country	Number of participants
UK	39
Germany	99
Italy	40
Denmark	16

Of these 194 participants, 155 patients were receiving outpatient (predominantly maintenance) treatment and the remaining 39 patients were receiving inpatient treatment for their substance misuse at the time of their participation in the study.

The mean age of participants was 39 years. However, there were differences in the mean ages across the four countries:

Country	Mean age of participants
UK	33
Germany	35
Italy	40
Denmark	42

The majority of participants were male, with only 25 of the 152 participants being female. Therefore, the approximate gender ratio of participants was 1 female for every 6 males.

USING THE ORION SOFTWARE

In their overdose risk assessment, the participants were asked whether certain risk factors applied to them. When collated together, the participants' responses to these questions can give a profile of the participant group as a whole. The following table shows the percentage of participants who reported that this risk factor applies to them:

Risk/Protective* Factors'	Percent of participants this applies to
Injecting drugs	97%
Mixing drugs	58%
Recent release from prison	15%
Receiving treatment for substance misuse*	90%
Using drugs when alone	68%
Has tried to reduce drug Intake*	73%
Has had a stressful life event	51%
Has mental health difficulties	52%
Has experienced a previous overdose	23%

When given the option to review their overdose risk estimates, half of the participants made changes to their original risk assessments to see how this would change their overdose risk. On average, participants change 2.4 of these risk factors and spent an average of half a minute reviewing their changes.

Younger participants were more likely to make changes to their risk assessments ($p<0.0001$).

Finally, the use of the software did significantly increase the participants' risk awareness ratings ($p<0.0001$), but not their general self-efficacy.

EVALUATION

52% of patients said that they had learned either a little or a lot from using the ORION software

45% said that they intended to change their drug-taking behaviour as a result of using the ORION software

83% said that they found using the ORION software either a little or very useful

QUOTES FROM PATIENTS USING THE SOFTWARE

Below are some of the comments we got from the patients following their engagement with the ORION e-health software:

"After completing the questionnaire my current situation looks more positive to me".

"I found it helpful as I could understand overdose risks".

"Thank you – it was one of the most interesting things I ever did".

"It was interesting, a new thing, brief and not boring. I have learned something".

CONCLUSIONS

The ORION software has been successfully implemented in a variety of clinical treatment settings (in- and out-patient) for substance misuse in four European countries. Throughout this pilot implementation there was no indication that the use of the software caused substantial problems or disrupted the usual running of the clinics. Comments from staff suggest that the implementation was a positive experience overall for staff and patients alike.

Early indications point to the e-health software being useful for both clinical staff working in the fields of addiction as well as the patients. The staff found it useful in terms of 'opening the doors' to communication with their patients about overdose risks. The patients reported that they found the software useful and interesting.

Furthermore, the majority of patients stated that they had learned something by using the software. This is further supported by the fact that the patients' awareness of overdose risk factors was increased significantly by virtue of using the software.

Some preliminary results suggest that the software might be most useful to younger users. This may be because younger users may be more interested in the technology behind the ORION software and the fact that it is delivered on computers. This was demonstrated by the finding that younger users were more likely than older users to engage with the software by making reviewing and changing their initial risk assessment and reviewing their subsequent personalised overdose risk feedback. Furthermore, comments from users suggest that younger users might not have as much knowledge and experience about overdose risks than their older counterparts, and might hence benefit more from using the software.

RECOMMENDATIONS

Based on the promising early results of the implementation of the ORION software, further research should be conducted to further examine how the impact of the software could be maximised. Such research could include projects which seek to:

> Establish whether patients utilise the information they learned to change their drug taking behaviour and reduce their overdose risks.

> Establish the degree to which the software accurately predicts overdose risk.

> Establish how the interaction between healthcare staff and patients while using the software influences the impact of the software and how this can be maximised.

Furthermore, the very e-health nature of the ORION tool lends itself to further developments and wider dissemination, which could include the following:

> Wider dissemination of the ORION software into substance abuse treatment settings across Europe. This would require translation of the software into more languages as well as on-going monitoring of impact.

> Expansion of the ORION software to include more risk factors and address more drug taking behaviours, e.g. those related to the use of other, non-opioid drugs.

> Further developments of the software to other platforms, e.g. utilising mobile technology.

REFERENCES

> European Public Health Alliance (EPHA, 2008) Drug Overdoses Kills One European Per Hour. Available:

http://www.epha.org/spip.php?article3317

> European Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 2012a). Preventing opioid overdose in Europe: A critical assessment of known risk factors and preventative measures. Available:

http://www.emcdda.europa.eu/attachements.cfm/att_190074_EN_Preventing%20overdose%20report_final.pdf

> European Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 2012b). The state of the drug problem in Europe: Annual report 2012. Available:

http://www.emcdda.europa.eu/attachements.cfm/att_190854_EN_TDAC12001ENC_.pdf

> Euroepan Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 2012c). EU Drugs Strategy (2005-2012). Available:

http://www.emcdda.europa.eu/html.cfm/index6790EN.html

> European Union (2012) Redesigning health in Europe for 2020: eHealth Task Force Report. Available:

http://www.eu-patient.eu/Press/News/Report-Redesigning-health-in-Europe-for-2020-/

> Kawamato, K., Houlihan, C.A., Balas, E.A., Lobach, D.F. (BMJ, 2005), 'Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success'. BMJ 330 (7494) 765.

> Phillips, Peter, Glover, Chris, Allan, Teresa and Khoo, Mary Ellen (2009) 'Using a group approach to preventing heroin overdose in North London', Drugs: education, prevention and policy.

> Stoové, M.A., Dietze, P.M. and Jolley, D. (2009), 'Overdose deaths following previous non-fatal heroin overdose: record linkage of ambulance attendance and death registry data', Drug and Alcohol Review 28, pp. 347–52.

ORION PARTNERS

The University of St. Andrews (UK) comprises 16 academic schools, including the Medical School, which was reformed in October 2002 and includes 60 academic staff, research fellows, and research assistants and a large group of honorary clinical academic staff, who contribute to teaching. University of St. Andrews is the ORION project coordinator.

University of Milano Bicocca (IT) is a young, dynamic and multidisciplinary university, which has created an extensive network including many world-famous universities, research centres, and top corporations. It's Department of Neurosciences and Biomedical Technologies is a partner in the ORION project.

The LVR-Hospital Essen (DE), formerly Rhine State Hospital Essen, is a Hospital of the University of Duisburg-Essen. The LVR-Hospital was founded in 1974, and provides psychiatric inpatient and outpatient care. In 2004 the Department of Addictive Behaviour and Addiction Medicine was established. The University Hospital Essen consists of several departments focusing on basic (theoretical) and practical medicine."

Aarhus University Hospital (DK) consists of four university teaching hospitals, including the Psychiatric Hospital. The hospital includes a 24-hour emergency unit, two psychiatric units, a geronto-psychiatric unit, and a forensic unit, as well as six community psychiatric centres and six units for specialised psychiatry. The Psychiatric Services assume responsibility for graduate and undergraduate medical training and include a research centre (WHO Collaborating Centre) and a staff education and training department.

Synergia (IT) is an Italian social research, training, and consulting firm that has operated since 1989 in the field of social and health policy. Synergia has developed hundreds of research projects for the public sector, private companies, and third sector on local, national, and European levels—deploying solid scientific expertise with a strong commitment to operating efficacy and timely delivery.

Business Solutions Europa (UK) is a dynamic European affairs consultancy with offices in UK and Brussels. Its goals are to "bring Europe closer to the needs of Europeans" by facilitating dialogue and the exchange of information with key institutions and actors and helping to develop ideas and European projects. Business Solutions Europa is involved in a number of European public health communication projects and advises on these matters public and private organizations across Europe.

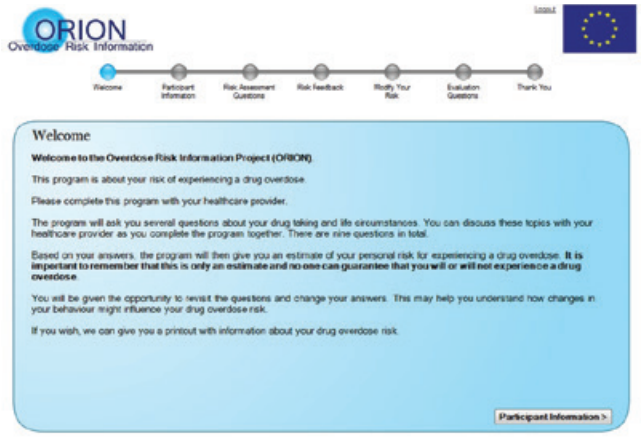
COLLABORATORS AND SERVICE UNITS INVOLVED IN ORION

Azienda ospedaliera San Gerardo
Addition Services, NHS Fife
Regione Lombardia (ASL Monza and Brianza)
School of Pharmacy, University of Keele
Department of Psychiatry, University of Dundee

APPENDICES

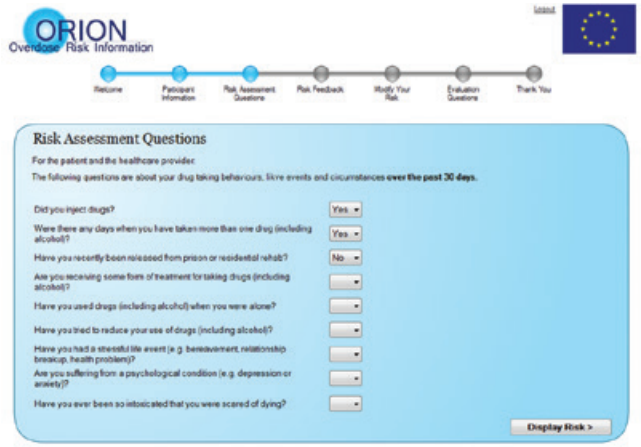
ORION SOFTWARE SCREENSHOTS

The information in Appendix 1 provides a series of snapshots of the most important aspects of the ORION software tool which patients participating in the study would see.



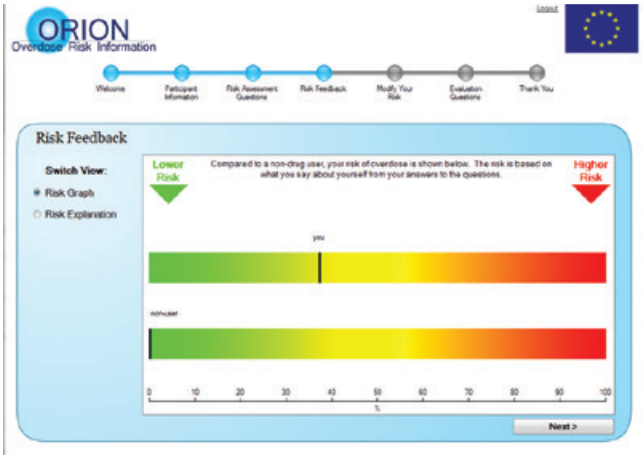
A1.1 Welcome Screen

The welcome page enables the participant to read the summary of the study and allows the patient to discuss the questions and answers with the healthcare provider.



A1.2 Overdose Risk Questions

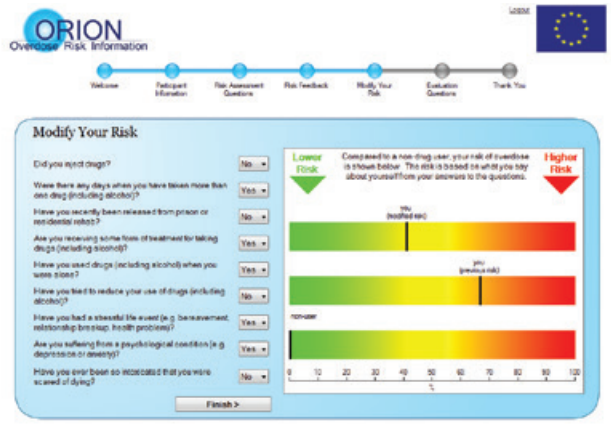
The patient is then asked about information about their overdose risk factors. This is done in the form of 9 questions with yes/no answers.



A1.3 Overdose Risk Feedback

The risk feedback screen shows the drug user his or her individual risk of experiencing a drug overdose in comparison to a non-drug user. The risk is shown on a scale of 0-100 where 0 = lowest risk and 100 = highest risk of experiencing a drugs overdose.

APPENDICES



A1.4 Modifying risk

Participants can modify their risk by reviewing the original risk assessment questions and changing their answers. As they change the answers the graphic display of their overdose risk changes to reflect the new overdose risk. By changing the Yes/No answers to the question the participant will either increase or decrease their risk of experiencing from an overdose.

A1.5 Evaluation questions

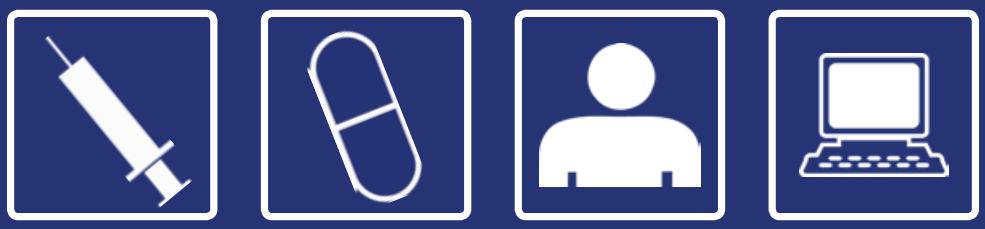
Finally, participants were asked to evaluate the software on three simple dimensions – whether or not they learned something, intend to change their drug taking behaviour and whether or not they found the software useful in some way.

DISCLAIMER:

The views expressed in this brochure are purely the authors' own and do not reflect the views of the European Commission.

For more information:

http://www.orion-euproject.com



ORION Project, 2013