

Title:**Identification of challenges to the availability and accessibility of opioids in twelve European countries: conclusions from two ATOME six-country workshops****Authors:**

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Abstract

Access to many controlled medicines is inadequate in a number of European countries. This produces deficits in the treatment of moderate to severe pain as well as in opioid agonist therapy. To elaborate the reasons ~~effor~~ for this inadequacy, the **work plan of the** Access to Opioid Medication in Europe (ATOME) project included two six-country workshops. ~~These workshops included to conduct a~~ national situational analysis, ~~and to elaborate~~ tailor-made recommendations for improvement and ~~drafts of~~ action plans for their implementation. ~~In total, Eighty-four~~84 representatives of the national Ministries of Health, national controlled substances authorities, experts representing regulatory and law enforcement authorities, ~~and~~ leading healthcare professionals, ~~and patient representatives~~ from thirteen European countries participated in ~~either one~~ of the workshops. ~~The delegates utilized break-out sessions to identify key Common challenges that could be identified during the ATOME workshops were a number of~~ opioid accessibility in their country ~~in the domain~~level of knowledge and educational, regulation and ~~ory,~~ legislation, ~~as well as public awareness~~ and training barriers that limit opioid prescription. ~~In addition short validity and bureaucratic practices resulting in an overregulation impeding availability of some essential medicines.~~ In relation to opioid agonist therapy, stigmatization and criminalisation of people who use drugs remained the major impediment to increasing programme coverage. The ~~challenges identified during outcomes of~~ the workshops were ~~the basis for further used to inform subsequent dissemination and implementation~~ activities in the ATOME project, and in some countries already ~~theserved as a~~ stepping stone for the first changes in regulations and legislation.

Identification of challenges to the availability and accessibility of opioids in twelve European countries: conclusions from two ATOME six-country workshops

Background

With the exception of some Western industrialized countries, access to many controlled medicines is inadequate around the world [1,2]. The World Health Organization (WHO) estimates that approximately five billion people live in countries with low or no access to controlled medicines [3] and insufficient access to treatment for moderate to severe pain is reported in more than 150 countries. In 12 countries of the European Union (EU), opioid analgesic consumption is described as 'low to very low' [4].

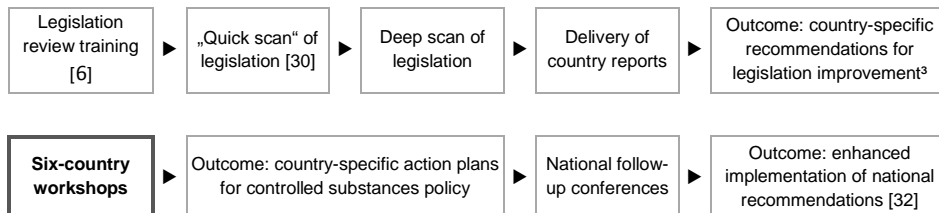
In addition to pain management, opioids are also needed ~~for-in the treatment of opioid dependence, mainly substitution programmes like the~~for opioid agonist therapy (OAT) ~~for drug users~~. Access to OAT in the EU varies dramatically. In some Central and Eastern European countries, less than 10% of people who would benefit from opioid agonist therapy are reached. Where harm reduction programmes exist, access is impeded by lengthy waiting lists, strict admission criteria, and lack of evidence-based standards for provision and quality of care; those at the greatest risk of exclusion are women, young people and migrants [5].

The European Commission's 7th Framework programme funded the *Access to Opioid Medication in Europe* (ATOME) project (2009-2014, www.atome-project.eu). Its objective was to improve access to opioids in 12 European countries (~~Figure 1~~) where there has been statistical evidence of low per capita morphine consumption at the time of the project submission (09.2009): Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia, Serbia and Turkey.

The work plan of the ATOME project (Figure 1) included two international six country-workshops as the foundation of subsequent activities directed at improving national policies related to opioid access. This article aims to describe the main challenges to opioid availability and accessibility identified during these two workshops and the recommendations for improving access to opioids that were made by the participants of the workshops.

Methods

Figure 1: ATOME work plan-map



~~As a part of this project two international six country-workshops were organised. Country teams had been composed at the outset of the work programme to ensure country-specific relevance and applicability of the project activities; the teams included representatives of the national Ministries of Health; national controlled substances authorities; experts representing regulatory and law enforcement authorities; leading healthcare professionals; and patient representatives. The six-country workshops were held in Bucharest, Romania in September and November 2011, with the purpose to 1) assist expert delegations to undertake national situational analyses, 2) disseminate tailor-made recommendations to their national governments for improving the accessibility, availability and affordability of controlled medicines and 3) plan how to implement these improvements. with the aim to undertake national situational analysis, make tailor-made recommendations for improvement and develop action plans to implement these recommendations. This article aims to describe the main challenges to opioid availability and accessibility that were identified during these two workshops and the recommendations for improving access to opioids that were made by the participants of the workshops.~~

Methods

~~Two six country-workshops were organized in Bucharest, Romania in September and November 2011, with the purpose to:~~

- ~~(1) assist expert delegations to undertake national situational analyses~~
- ~~(2) disseminate tailor-made recommendations to their national governments for improving the accessibility, availability and affordability of controlled medicines~~
- ~~(3) plan how to implement these improvements.~~

~~Additionally, awareness about tools and resources was intended to be raised.~~

~~The guiding principle of each workshop was t[The principle of balance in national opioid policy, i.e. the obligation of n each government to ensure availability and~~

accessibility of opioids while preventing abuse and diversion was the guiding principle in both workshops. The workshops were designed as two-and-a-half day events with a combination of lectures from international experts (total duration: 5,5h) and discussion groups where the to analyze the national situation was analyzed regarding access to opioids, identify identify potential problems, and decide on further action steps to improve the situation (total duration: 8h) were prepared. Representatives from the ATOME consortium and the workshop faculty assisted the group work as facilitators. The country teams presented the outcomes of their group work in plenary, followed by a discussion and feedback from the other delegations (total duration: 3,5 hours). Tools such as the WHO checklist for national situation analysis [7]; a case example of a patient in order to discuss the national situation in a problem-based manner; and a strategic action planning worksheet were used in the discussion groups in order to guide the process of tailoring country-specific solutions. Material relevant to the accessibility and availability of opioids, such as scientific articles or position papers, was provided to participants prior to the workshop. ~~The country teams presented the outcomes of their group work in plenary. Tools such as the WHO checklist for national situation analysis [8]; a case example of a patient in order to discuss the national situation in a problem-based manner; and a strategic action planning worksheet were used in the discussion groups in order to guide the process of tailoring country-specific solutions. The results of this article have been were condensed from the country team team's teams' presentations, action plans and minutes from the group work sessions. The workshops were as evaluated by a pre- and post-workshop questionnaire.~~

Results

Participants

In total, 39 representatives from Bulgaria, Cyprus, Greece, Turkey, Serbia and Slovenia attended the first workshop, and 45 people delegates from Estonia, Hungary, Latvia, Lithuania, Poland and Slovakia attended the second one. Ukraine (which was not one among of the target countries) sent observers to the second workshop. Participants forming the country teams were representatives from the national Ministries of Health, national controlled substances authorities, experts representing regulatory and law enforcement authorities; and leading healthcare professionals.

The national delegations utilized break-out sessions to analyse country-specific key challenges to opioid accessibility and to elaborate strategic action plans for improvement, which were subsequently presented and discussed in plenary.

Identified Key challenges

Lack of education, excessive regulations relating to the prescribing of opioids, “opiophobia” – fear from opioids and lack of reimbursement were

The most frequently identified as challenges to concerning access to opioids by 50-75% of the country teams, see (Table 1), during the ATOME workshops are:

Table 1 shows the most frequently identified challenges and recommendations for improvement made

The most frequently lack of education (identified by 9 country teams); excessive regulations relating to the prescribing of opioids (identified by 8 country teams); “opiophobia” (identified by 7 country teams); lack of reimbursement (identified by 6 country teams); lack of knowledge about opioids amongst patients, their family and society; lack of recognition of pain management; limitations to the formulary availability of opioids; excessive regulations relating to storage and dispensing of opioids; lack of opioid legislation/inappropriate legislation; and treatment of pain in non-cancer patients (identified by 5 country teams). All challenges that were highlighted/identified challenges during the workshops are presented below and in Table 1, followed by recommendations for improvement made by the participants, on how to deal with these challenges. The names of the countries mentioned in the following paragraphs can be seen as exemplary, because the suggestions may relate have been given by one or more countries during the workshops but can it can be assumed to be applicable to many other countries as well.

Lack of education and training on opioid medicines and their use:

Lack of education and inadequate and inconsistent training of physicians in pain management results in a lack of knowledge regarding the correct dosage of opioids. Where education initiatives exist, they are usually subsumed within the training of other medical specialties and are often only of a few hours duration. In consequence many general practitioners lack expertise in prescribing opioids and usually refer this responsibility to oncologists. This may hamper access to opioid medicines for patients.

To overcome the challenge regarding the lack of opioid education and training initiatives for healthcare professionals, delegates from Cyprus suggested an obligatory examination for that all doctors should be required by the Head of Pharmaceutical Services/Medical Council to pass an examination regarding relating to opioid prescribing. For Estonia and Hungary it was recommended by participants from the countries to improve opportunities for Continuing Medical Education in the area of pain management, whilst Hungarian delegates recommended that physicians should also be taught practical skills in how to apply the pharmacotherapy of pain. In Serbia there is a need for education/training sessions and opioid workshops amongst regulatory authorities that stress access to pain relief as a ‘human right’. Workshop participants from Slovenia recommended developing a network to educate, train and support all members of the multidisciplinary team in prescribing.

Lack of knowledge about opioids amongst patients, their family and society

There is a lack of public awareness about opioids was explicitly mentioned by seven country teams. This involves fears and beliefs amongst patients and their

families, ~~as well as~~ and the general public. In addition attitudes and beliefs amongst the public in relation to opioids involve much misinformation and misunderstanding in the general public. Many medical professionals are afraid of prescribing opioids. This was explicitly mentioned by seven country teams. Societal misconceptions about opioids lead to negative side effects such as the perception that suffering is normal, heroic or necessary. Negative stereotypes about opioids (e.g. labelling opioid medicines as “narcotic drug” or “poison”) and fears about tolerance amongst patients and their families reinforce this problem. In some countries, e.g. Lithuania, there was a perception that national policy discourse or the societal rhetoric around opioids even increases reluctance among general practitioners to provide pain management.

Lack of recognition of pain management

Five country teams reported that chronic pain is often neither recognised nor acknowledged by healthcare professionals and a sceptical attitude towards pain treatment is reported among many physicians. Specialists of other disciplines other than oncology do not always recognise the need for pain management. In some countries, e.g. Lithuania, there was a perception that national policy discourse or the societal rhetoric around opioids even increases reluctance among general practitioners to provide pain management.

Treatment of pain in non-cancer patients

Five countries reported that pain management for non-cancer patients is poorly organised. In some countries opioids are usually limited for use in terminal cancer. Access to palliative care for non-cancer patients is a challenge in many countries; for example it was reported from Latvia that opioids are not reimbursed for patients with non-oncological diseases except for patients suffering from HIV/AIDS.

Lack of reimbursement (particularly for non-cancer patients)

The costs of opioids, described as very high in many countries, are not always covered by government funding appropriate statutory funding schemes. This was described as a challenge by six country teams. Particularly for people suffering from acute or chronic conditions due to non-oncological diseases this is a problem since chronic non-cancer pain in some places is not recognised as a medical condition, which makes reimbursement impossible. For people with low or no income, this may mean that they will not have access to the medicines they need.

Limitations to the available range of opioids

Lack of choice of opioids such as injectable morphine, slow-release oral morphine, buprenorphine and methadone was highlighted as one of the challenges in 5 countries. As an example, in Slovenia not all medicines from the WHO essential medicines list were available. Even though a proposal for a new list had been drafted at the time of the workshop, there was concern that it will not be adhered to by the pharmaceutical industry.

Pharmaceutical company reluctance to manufacture opioids

In some smaller countries pharmaceutical companies have little interest in procuring opioids as there is only a rather small market where cost of procurement and projected incomes are disproportional. This challenge was reported by three country teams.

Excessive regulations relating to the prescribing of opioids

Physicians often are reluctant to prescribe opioids due to excessive bureaucracy, as described highlighted by eight country teams. Barriers such as special prescription forms that need to be stored with special security measures, restrictions regarding the authorisation to prescribe (e.g. only designated medical specialties), excessive reporting requirements of opioid prescriptions, and complicated administrative requirements for filling out the prescriptions may result in a reluctance to prescribe opioids for patients in medical need. Other reported challenges to the availability of opioid medicines are a limited prescription validity in combination with restrictions regarding the maximum amount of opioids to be prescribed. In addition it was reported that fear of prosecution if the patient should die deters physicians from prescribing opioids. This may as well result in a lack of experience in prescribing amongst family practitioners. Excessive regulation may also affect provision of opioids in home care settings.

Excessive regulations relating to storage and dispensing of opioids

Five country teams reported that not all pharmacies are allowed to store opioids and that special storage conditions are required. Extensive bureaucracy relating to the dispensing of opioid medicines often results in a delay in the commencement of treatment with these medicines. Fear of prosecution may also deter medical practitioners from prescribing or dispensing opioids, such as in Greece, where prosecution of pharmacists for minor opioid offences is common so many pharmacies refuse to dispense morphine.

Lack of opioid legislation/inappropriate legislation

A lack of legislation related to the use of opioids, the lack of education that would be necessary to work with opioids and an outdated opioid terminology impede an adequate supply. Complicated legislation structures such as the involvement of three separate Ministries make changes in the opioid legislation extremely difficult. This challenge was reported by five country teams.

Focus on suppression rather than availability of opioids

Government agencies and committees tend to focus more on prevention of diversion and misuse rather than medical availability of opioids. National governments have little recognition that opioids are necessary for pain relief or that it is their obligation to ensure adequate availability of opioid medicines. This was reported by three country teams.

Other challenges to the availability and accessibility of opioids identified at the workshops

Other challenges identified during the workshops were difficulties in accessing opioids out-of-hours – particularly in rural areas because not all pharmacies stock opioids; an unequal geographical distribution of pain services due to financial reasons and a lack of trained specialists; or that patients not registered with a general practitioner or not admitted to hospital may not be able to get access to opioids.

National approaches to solution

To ~~approach the~~ develop national action plans the country teams completed so called strategic planning worksheets in group work (see Table 2).

Table 2 Strategy planning worksheet – example education

<u>What?</u>	<u>A. State the problem</u>	<u>Education</u>
<u>Why?</u>	<u>B. State the underlying reason(s) for the problem</u>	<u>No standard training in opioid analgesia in the basic curriculum in physicians and other health care professionals</u> <u>No comprehensive continuing education and training of executives involved with the subject</u>
<u>What?</u>	<u>C. State the objective(s) that would address the problem. Which objectives are top priorities</u>	<u>Inclusion of PC and opioid management in the basic training of physicians and paramedics</u> <u>To overcome opiophobia</u>
<u>How?</u>	<u>D. What action steps are needed to achieve the objective?</u>	<u>Target population of education :</u> <u>Physicians, Nurses, Social workers, Pharmacists, Patients and Families, Public</u>
<u>Who?</u>	<u>E. List those who have the authority and/or responsibility to take the necessary action.</u>	<u>Ministry of Education</u> <u>Ministry of Health</u> <u>Ministry of Justice</u>
<u>When?</u>	<u>F. Timeline for completion of action steps</u>	<u>September 2011-October 2012</u>
<u>How Much?</u>	<u>G. What technical and financial assistance will be needed to achieve each objective</u>	<u>1. Ministry of Health</u> <u>2. Ministry of Education</u> <u>3. Pharmaceutical Companies</u>

Process observation made during both events by representatives of the ATOME consortium confirmed the particular benefit of the workshop method. The six-country workshops had brought together stakeholders from different areas who usually would not have the opportunity to exchange and share their perspectives. This also resulted in concrete positive effects such as in one country clarification of misunderstandings about the legal restrictions and unawareness of regulatory leeway regarding methadone prescription for pain treatment (Cyprus).

Workshop evaluation

~~44%~~ ~~Fortyfour~~Forty-four percent (n=37) of the 84 ~~A total of 37 participants completed both pre- and post-workshop questionnaires~~ participants completed both pre- and post-workshop questionnaires, see Table 32. ~~;-35~~ ~~Thirtyfive~~Thirty-five of the 37 ~~respondents (95%)~~ reported that their knowledge about accessibility of controlled medicines 'had been enhanced' by attending the workshop; and 21 (57%) reported that their attitudes in relation to the accessibility of controlled medicines 'had been changed' by attending the workshop.

~~Respondents made suggestions in the questionnaire, suggestions were made to improve the situation; countries mentioned here can be seen as exemplary; the suggestions are likely to relate to other countries as well.~~ Raising public awareness about the beneficial effects of opioids to reduce the fear of prescribing opioids ~~medicines~~ was suggested by several teams. Concrete measures were proposed, such as the initiation of social campaigns ~~counteraction~~to counteract myths and stereotypes about opioids (-Poland, Serbia, Slovakia and Turkey), or raising pressure from professional organisations, trade unions, patient organisations and professional bodies to influence political will and ensure adequate reimbursement of opioids (Hungary).

~~The acknowledgement of chronic pain as a clinical problem was deemed of paramount importance (highlighted by a delegate from Bulgaria), and the development of policy guidelines in pain management in collaboration with the Ministry of Health to overcome barriers relating~~related to excessive regulations was proposed by a representative from Cyprus.

~~In the questionnaire, suggestions were made to improve the situation. Raising public awareness about the beneficial effects of opioids to~~ ~~In the questionnaire section for possible improvements several recommendations have been made by the country teams. In relation to reduce the fear of prescribing opioids was suggested by the Estonian team, Estonian team members, recommended that public awareness about the beneficial effects of opioids should be raised on a regular basis in order to~~

~~change attitudes. Poland, Serbia, Slovakia and Turkey suggested the initiation of that social campaigns counteracting myths and stereotypes about opioids should be initiated. Participants from Hungary recommended raising pressure from professional organisations, trade unions, patient organisations and professional bodies to influence political will and ensure adequate reimbursement of opioids.~~

~~To address the challenges associated with the lack of reimbursement for opioids, participants from Hungary recommended that the only way that opioids can be adequately reimbursed is through pressure from professional organisations, trade unions, patient organisations and professional bodies in order to influence political will. Bulgaria highlighted the need to acknowledge chronic pain as a clinical problem. Participants from Cyprus suggested the development of policy guidelines in pain management in collaboration with the Ministry of Health to overcome barriers relating to~~

~~To ease the challenges from excessive regulations, related to storage and dispensing of opioids, Cyprus suggested that challenges to a lack of opioid legislation or inappropriate legislation could be overcome by developing policy guidelines in pain management in collaboration with the Ministry of Health.~~

Discussion

The results of the workshops ~~demonstrate underline~~ that lack of access to opioids is ~~a~~ multifactorial ~~field~~ in nature. Barriers exist on numerous levels which are interlocked and partially reinforced by each other. ~~A strength of these workshops was therefore that~~ ~~For this reason~~, stakeholders representing as many relevant fields as possible in relation to access to opioids were addressed ~~by this workshop~~.

Common challenges identified during the ATOME workshops were a number of educational, regulatory, legislative and training barriers that limit the ability of both physicians and nurses to prescribe the necessary doses of opioids to patients. ~~A number of publications have been produced by the European Association for Palliative Care (EAPC)[9,10] to overcome these challenges. These findings are in line with the main barriers to opioid accessibility reported in previous publications by leading researchers in the field [11, 12, 13, 14].~~

~~Other~~ frequently reported challenges ~~were~~ related to short validity of prescriptions and excessive bureaucratic practices when prescribing. Similar results have been identified in the legislation analysis by Utrecht University during the ATOME project as well as ~~in~~ the individual country reports. The issue of overregulation of opioids was also reviewed by Cherny, *et al.*, [15,16,17] who reported on some elements of the legal and regulatory barriers to opioid availability and accessibility throughout Europe and the world. Unduly restrictive legislation that limits the distribution, prescription, dispensation, and use of opioids has been described by Joranson and Ryan [18] and Human Rights Watch [19]. These authors agree that in most cases ~~the problem is it is~~ not the lack of availability of opioids in the country, but rather the combination of many bureaucratic and legislative regulations that impede opioid prescription and

dispensing. Many medical professionals, ~~especially~~ particularly family doctors, appear to be afraid of prescribing opioid medications, often related to these regulatory barriers [20]. Lynch, *et al.*, [21] reported complicated procedures relating to the prescription of opioids in the countries of Central and Eastern Europe and Commonwealth of Independent States, where it was very difficult to obtain a license to prescribe opioids.

Limited knowledge about opioid analgesics was reported in a number of countries in Western Europe [22], where lack of professional knowledge about the prescription of strong opioids may result in reluctance on the part of physicians to prescribe them. The relevance of such challenges to a plethora of diverse socio-cultural, economic, educational and health policy settings should be fully and adequately considered.

Next to establishing national, regional, or local under- and postgraduate education opportunities for healthcare professionals, the availability of guidance papers/guidelines or other guidance can be a possible/feasible way to address unawareness and misinformation, such as the evidence-based guidelines by the European Association for Palliative Care (EAPC) on the use of opioid analgesics for the treatment of cancer pain [23ref.].

In relation to opioid agonist therapy, stigmatization and criminalization of people who use drugs remain the major impediment to increasing programme coverage, particularly in prison settings. This manifests a lack of interest among policy makers to invest in evidence-based harm reduction approaches, despite the proven effectiveness of these programmes in preventing HIV transmission. Fear of arrest and police harassment among drug users may deter many from accessing these services [5].

The aims of the workshops to assist the country teams to analyse their national situation~~al~~, disseminate country-specific national action plans and raise the awareness about tools and resources have been realized. The challenges reported in the workshops have been analyzed and have been considered in subsequent steps of the programme such as the national follow-up conferences. ~~Participants' feedback included some criticism on the schedule (too full); or that a longer meeting time or repeated events over a period of time might have provided better outcomes. However, nearly all participants reported that their expectations for the workshop had been met.~~

Limitations

There are a number of limitations associated with this paper. First of all, the selection of experts and participants attending the workshops was a potential source of bias as their views may not represent the situation in were subjective and isolated, they cannot be presumed to be completely representative of the countries concerned. However, the participants (ATOME country team members) were carefully selected to ensure that as many relevant fields as possible in relation to access to opioids were represented. This is crucial as improving access to opioids requires a multilevel approach since it is the outcome of a complex interaction of

national legislation, policies and regulations, education, economy/finance, healthcare practice, attitudes, and social norms. In addition, close collaboration with the country teams during all phases of the ATOME project, including the workshops, ensured ownership of the proposed strategies which is an important prerequisite for successful implementation. ~~Therefore, stakeholders representing as many relevant fields as possible in relation to access to opioids were invited to these workshops. The setting was prepared to ensure that the situational analysis, the identification of problems, and proposal of solutions were developed by the national stakeholders themselves.~~

~~In a~~ Addition, there may also have ~~There may have~~ been some unintended negative effects during the workshops – for example the fact that data-challenges provided reported by participants or country teams could potentially have been inflated suppressed by competitive tendencies between neighbouring countries. However, the invitation of six different countries to each workshop was also believed to facilitate exchange, reduce stigma, and enhance the creative development of solutions by learning from models in other countries, since many countries do encounter similar problems.

Importantly, the challenges identified during each workshop only reflect what was explicitly discussed; this does not necessarily mean that the respective issues do not also apply to other countries– the barriers identified are not exclusive to the countries that reported them.

~~Similar w~~ Workshops with similar setup have been used to compare the development of health care policy across both countries and regions and have come to similar results; most notably, those undertaken by the Open Society Foundations *International Palliative Care Initiative* and regional or national palliative care associations such as the *African Palliative Care Association (APCA)* [24,25,26] and the *International Association for Hospice & Palliative Care (IAHPC)* [27]. The international comparison of barriers as well as the possibility of establishing new contacts in a similar field of expertise seems to be a fruitful way of resolving widespread difficulties.

~~Importantly, the challenges identified during each workshop only reflect what was explicitly discussed; this does not necessarily mean that the respective issues do not also apply to other countries– the barriers identified are not exclusive to the countries that reported them.~~

Conclusion

The participants of the country teams made use of the two six-country workshops to identify key challenges to access to opioids in their country and to elaborate tailor-made strategic action plans for improvement. Findings from the country workshops reported here were triangulated with outcomes from related activities in the ATOME project, most importantly the recommendations resulting from the in-depth analysis of

legislation [30]. The results of these workshops therefore delivered an important contribution to a comprehensive analysis and informed the subsequent work of the country teams during a series of national follow-up conferences, as well as the development of tailor-made recommendations and solutions for each of the twelve participating countries [29]. These recommendations could serve as guidance for other countries in the world as well.

The WHO resolution on strengthening Palliative care, which has been adopted at the World Health Assembly in May 2014 in Geneva [28] gives hope that a global improvement of pain treatment gets to the focus of politicians and health care decision makers. As to the further~~The action steps resulting from the identified challenges the ATOME programme developed~~with tailor-made solutions for each of the twelve participating countries that could account~~could set an example for other countries in the world as well~~ that want to improve access to controlled medicines following the WHO resolution [29].

~~Many The challenges to access to opioids were identified during the workshops. These challenges, as well as key topics from the national action plans developed in the two workshops were used to inform the work of the country teams during a series of national follow up conferences. Importantly, legislation and regulations concerning the use of controlled medicines have been analysed in depth by Utrecht University as part of the ATOME project [30]. Findings from the country workshops reported here, the results of the legislation review and the results of the national follow-up conferences have been used for triangulation. Finally, a report on the findings in each participating country has been compiled and will be presented to the national health ministries.~~

~~The WHO resolution on strengthening Palliative care, which has been adopted at the World Health Assembly in May 2014 in Geneva [31] gives hope that a global improvement of pain treatment gets to the focus of politicians and health care decision makers. As to the further steps resulting from the identified challenges the ATOME programme developed tailor made solutions for each of the twelve participating countries that could account for other countries in the world as well [32].~~

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Table 1: challenges concerning access to opioids identified by the country teams

<u>Identified challenge</u>	<u>No. of country teams</u>	<u>Recommendations elaborated among the country teams</u>
<u>Lack of education:</u> Inadequate training of physicians in pain management. Many general practitioners therefore refer the prescription of opioids to oncologists resulting in underprescription.	9	Implement opioid prescribing examination, improve education in the field of pain management, educate regulatory authorities to underline that access to pain relief is a human right, and develop a network to educate multidisciplinary teams in prescribing.

<p><u>Lack of knowledge about opioids amongst patients, their family and society:</u></p> <p>Fears and beliefs as well as mis-information and misunderstanding. Perception that suffering is normal, necessary or heroic. Negative stereotypes about opioids (“drugs”) reinforce the fear of patients and physicians.</p>	<p>7</p>	<p><u>raise public awareness about the beneficial effects of opioids</u></p>
<p><u>Lack of recognition of pain management:</u></p> <p>Chronic pain and other non-oncological diagnoses are often not being recognised by healthcare professionals.</p>	<p>5</p>	<p><u>develop policy guidelines in pain management in collaboration with the respective ministry, recognise/acknowledge chronic pain and pain of non-cancer as a clinical problem (with an ICD code if possible)</u></p>
<p><u>Lack of reimbursement:</u></p> <p>Due to high costs opioids are not being reimbursed for acute or chronic conditions. The lack of recognition of chronic non-cancer pain as a medical condition makes reimbursement impossible.</p>	<p>6</p>	<p><u>achieve adequate reimbursement through pressure from professional organisations, trade unions, patient organisations and professional bodies in order to influence political will</u></p>
<p><u>Limitations to the available range of opioids:</u></p> <p>Lack of choice of opioids such as injectable morphine, slow-release oral morphine, buprenorphine and methadone.</p>	<p>5</p>	<p><u>bring the revised WHO list of essential medicines to the adherence of government representatives and the pharmaceutical industry</u></p>
<p><u>Pharmaceutical company reluctance to manufacture opioids:</u></p> <p>Some pharmaceutical companies have little interest in procuring opioids as there is only a small market where cost of procurement and projected incomes are disproportional.</p>	<p>3</p>	<p><u>establish a reliable supply of slow-release oral morphine (if needed via import) and improve access to immediate-release opioids</u></p>

<p><u>Excessive regulations relating to the prescribing of opioids:</u></p> <p><u>Special prescription forms that need to be stored with special security measures, restrictions regarding the authorisation to prescribe, excessive reporting requirements of opioid prescriptions, complicated administrative requirements for filling out the prescriptions and limited prescription.</u></p>	8	<p><u>e-prescription forms should be introduced to enable every physician to prescribe opioids without having to complete a special prescription form</u></p>
<p><u>Excessive regulations relating to storage and dispensing of opioids:</u></p> <p><u>Not all pharmacies are allowed to store opioids and special storage conditions are required.</u></p>	5	<p><u>special licensing for dispensing opioids should be abolished, and all pharmacies should be legally obliged to dispense them</u></p>
<p><u>Lack of opioid legislation/ inappropriate legislation:</u></p> <p><u>Lack of legislation and outdated terminology impede an adequate supply.</u></p>	5	<p><u>revise legislation with the aim of addressing fears and myths relating to the use of opioids</u></p>
<p><u>Focus on suppression rather than availability of opioids:</u></p> <p><u>Government agencies tend to focus more on prevention of diversion and misuse rather than medical availability of opioids and have little recognition that opioids are necessary for pain relief.</u></p>	3	<p><u>education/training sessions and opioid workshops amongst regulatory authorities that stress access to pain relief as a 'human right'</u></p>
<p><u>Other challenges identified:</u></p> <p><u>Difficulties in accessing opioids out-of-hours (rural areas) and a lack of trained specialists.</u></p>	1	<p><u>all pharmacies should be permitted to stock opioids</u></p>

Table 3: Extract of results from the post-workshop questionnaire

1.	What was the most valuable aspect of the workshop?
	<u>Opportunity to collaborate with the government on a project</u>
	<u>Exchanging information with other countries</u>
	<u>Meeting people working in the same field in other countries</u>
	<u>Experience of other countries and recommendations</u>
	<u>I was able to convince my country team and raise awareness especially in the Ministry of Health</u>

	<u>Country action plans gave a good overview of the problematic situation</u>
<u>2.</u>	<u>What was the least valuable aspect of the workshop?</u>
	<u>Too hard working the whole day requiring full concentration</u>
	<u>Too crowded schedule was so exhausting – one more day would be needed to improve the quality of work</u>
	<u>Too much time is spent on the action plan</u>
<u>3.</u>	<u>Please write down any additional comments or suggestions</u>
	<u>It would be useful to know the opinions of authorities for restrictions if these are not due to financial problems</u>
	<u>Everything was well organized; maybe more teaching, films, case examples can be included in the programme</u>
	<u>Good balance of theory and information and practical work</u>
	<u>'Report of status of...' should be prepared before the workshop</u>