Availability and Accessibility of an Essential Medicine.

Key Issues Around Opioid Pain Relief for Palliative Care in Georgia

Sandra Elisabeth Roelofs

B.A., MSc. London School of Hygiene and Tropical Medicine (LSHTM)

University of Georgia, Head of International Public Health Program, Tbilisi, Georgia

Summary

Background. Opioids are a mainstay for the alleviation of medium-strong pain. Nevertheless, if opioids are taken inappropriately, they have the ability to induce dependence on them. Their manufacture, import, distribution, prescription, stocking, dispensing and administering are therefore subject to (international) control mechanisms. Unfortunately, opioid control often impedes its access for medical purposes.

This study explored barriers to opioid access in Georgia, an Eastern-European country that to some extent introduced opioid-related legislative changes. The study's aim was to identify issues around impediments to accessing opioid pain relief and recommend ways to overcome these barriers. The specific objectives were fourfold:

- 1) get an overview of the existing knowledge base around barriers to opioid access;
- 2) critically review the present legislation/policies in the field of medical opioid control/use;
- 3) seek expert opinion of relevant stakeholders;
- 4) provide recommendations.

Methodology. A mixed methods approach with data triangulation was selected: literature review, background documentary analysis and a subsequent focus-group discussion (FGD). Data analysis took place through categorizing/indexing and subsequent coding/charting. Ethical approval was obtained from both LSHTM and the National Center for Disease Control and Public Health in Georgia. Results.

- Thirty-six publications were identified for data extraction. A common concern is that despite advanced medical knowledge on pain, access to safe and rational use of opioid analgesics remains problematic.
- The administrative frame in which opioid access in Georgia is regulated showed certain ambiguities/inconsistencies.
- -- FDG main insights per barrier type:

საბაზისო სამედიცინო დახმარების შესაძლებლობა და ხელმისაწვდომობა.

საქართველოში პალიატიური მზრუნველობის მიზნით ოპიოიდური ტკივილის შემსუბუქების ძირითადი საკითხები

სანდრა ელისაბედ რულოვსი

B.A., MSc. ლონდონის ჰიგიენისა და ტროპიკული მედიცინის სკოლა (LSHTM) საქართველოს უნივერსიტეტი, საერთაშორისო საზოგადოებრივი ჯანდაცვის პროგრამის ხელმძღვანელი, თბილისი, საქართველო

რეზიუმე

შესავალი: ოპიოიდები წარმოადგენენ ბირითად გამაყუჩებელ საშუალებას საშუალოდან ძლიერი ინტენსივობის ტკივილის მართვისას. თუმცა, ოპიოიდების არასწორმა გამოყენებამ შეიძლება განავითაროს მათდამი დამოკიდებულება. ოპიოიდების წარმოება, იმპორტი, დისტრიბუცია, დანიშნვნა, შენახვა, გაცემა და გამოწერა ექვემდებარება (საერთაშორისო) კონტროლის მექანიზმებს.

სამწუხაროდ, ოპიოიდების კონტროლი ხშირად

ხელს უშლის სამედიცინო მიზნებისთვის მათ გამოყენებას. კვლევისას შესწავლილი იქნა ოპიოიდების ხელმისაწვდომობაში არსებული ბარიერები აღმოსავლეთ ევროპის ქვეყანაში - საქართველოში, სადაც გარკვეულწილად განხორციელდა ოპიოიდების მოხმარებასთან დაკავშირებული საკანონმდებლო ცვლილებები. კვლევის მიზანს წარმოადგენდა ოპიოიდური ტკივილგამაყუჩებელი მედიკამენტების ხელმისაწვდომობის ხელისშემშლელი ფაქტორების დადგენა და რეკომენდაციბის მოძიება ამ პრობლემების გადასაჭრელად. დასახული იყო ოთხი კონკრეტული მიზანი:

- 1) ოპიოიდების ხელმისაწვდომობაში არსებული ბარიერების შესახებ არსებული ცოდნის მიმოხილვა;
- 2) სამედიცინო მიზნეზით ოპიოიდეზის გამოყენეზის მარეგულირებელი კანონმდეზლოზის/პოლიტიკის კრიტიკული განზილავა;
- 3) შესაბამის სფეროში დაინტერესებული/ ჩართული მხარეების ექსპერტული მოსაზრების მოძიება;
- 4) რეკომენდაციების შემუშავება. მეთოდოლოგია: შეირჩა მონაცემათა შეგროვების შერეული მეთოდი "მონაცემთა ტრიანგულაციის გზით" - ლიტერატურის მიმოხილვა, მირითადი დოკუმენტების განხილვა და შემდგომ ფოკუს-ჯგუფში დისკუსია (FGD). მონაცემთა

- I) lack of knowledge: myths and misconcep tions, e.g. morphine mostly administered at final stage of life establishing an apparent causal relationship between inception of morphine and death:
- II) issue of side-effects: prudence leading to underdosage, NSAID pharma-lobby;
- III) fear of dependence and tolerance: opiophobia delaying inception of opioid treatment;
- IV) healthcare system barriers: police stations' role in dispensing opioids, limited opioid formularies, lack of palliative care specialists, governmental reluctance to promote medical use, difference urban-rural service provision;
- V) legislation: issue of prescribers, legislative inconsistencies.

Issues to be addressed based on key findings:

- Access to opioids as it remains problematic and the barriers are interrelated, occur often simultaneously;
- Implementation of the reformed legislation, which is weak;
- Pharma-lobby for NSAIDs which hinders medical use of opioids;
- Knowledge base needs to be strengthened;
- · Lack of time (physicians);
- Opioid formulary availability should be expanded;
- Governmental support to integrate palliative care in Universal Health Coverage (UHC) needs strengthening.

Conclusions, Significance of work. From the EE-CA-related literature and the FGD it became clear that the 'war on drugs' is still waging in Georgia, Armenia, Ukraine and Russian Federation, despite the fact that certain legislative changes have been pursued and partly implemented.

The FGD yielded new insights on barriers: increasing NSAID pharma-lobby, lack of time for physicians to keep abreast of legislative changes and progress in pain management. The study also clearly showed that barriers to opioid access occur concurrently and are often synergizing.

The recommendations of this research are relevant and timely as Georgia has taken the road towards UHC. In 2014, the World Health Assembly adopted a resolution on 'Strengthening of palliative care as a component of comprehensive care throughout the life course', seen as the ethical responsibility of health systems.

Keywords: opioids, controlled substances, palliative care, pain relief medication, drug control

ანალიზი მოხდა კატეგორიზაცია/ინდექსაციის და შემდეგ მათი კოდირებისა და დაჯგუფება - ილუსტრირების გამოყენებით. ეთიკური განხილვა-გამართლება მოპოვებლი იქნა როგორც ლონდონის ჰიგიენის & ტროპიკული მედიცინის სკოლიდან (LSHTM- დან), ასევე საქართველოს დაავადებათა კონტროლისა და საზოგადოებრივი ჯანდაცვის ეროვნული ცენტრიდან. შედეგები: მონაცემების მოსაპოვებლად მოხდა 36 პუბლკაციის განხილვა. საერთო პრობლემად გამოვლინდა ის ფაქტი, რომ მიუხედავად არსებული თანამედროვე სამედიცინო ცოდნისა ტკივილის შესახებ, ოპიოიდური ანალგეტიკების უსაფრთხო და რაციონალურ გამოყენებაზე ხელმისაწვდომობა კვლავ პრობლემური რჩება. ადმინისტრაციულმა ჩარჩომ, რომლის ფარგლებშიც რეგულირდება ოპიოიდების ხელმისაწვდომობა საქართველოში, გამოავლინა გარკვეული შეუსაბამობები და წინააღმდეგობები. ბარიერის ტიპის მიხედვით ფოკუს ჯგუფის მირითადი შეხედულებები:

I) ცოდნის ნაკლებობა, მითები და არასწორი წარმოდგენები, მაგ. ვინაიდან მორფინს ძირითადად ნიშნავენ სიცოცხლის ბოლო ეტაპზე, ეს წარმოქმნის აშკარა კავშირს მორფინის მიღებასა და სიკვდილს შორის; II) გვერდითი მოვლენების მიმართ შიში და სიფრთხილე, რაც იწვევს არაადეკვატურ დოზირებას, არასტეროიდული ანთების საწინააღმდეგო საშუალების ფარმაკოლოგიური ლობირება;

III) დამოკიდებულების განვითარების და ტოლერანტობის შიში: "ოპიოფობია" - რაც იწვევს ოპიოიდებით დაგვიანებულ მკურნალობას;

IV) ჯანდაცვის სისტემის ბარიერები: პოლიციის განყოფილებების როლი ოპიოიდების გაცემაში, ოპიოიდების შეზღუდული ფორმულაციები, პალიატიური მზრუნველობის სპეციალისტების ნაკლებობა, სახელმწიფოს მხრიდან ოპიოიდების სამედიცინო გამოყენებაზე დაბრკოლება, განსხვავება ურბანულ და სოფლის მომსახურებებს შორის;
V) კანონმდებლობა: დანიშვნის საკითხის პრობლემურობა, საკანონმდებლო

სარეკომენდაციო მიმართულებები ძირითადი დასკვნების მიხედვით:

- ოპიოიდურ მედიკამენტების ხელმისაწვდომობა, რადგან ის პრობლემატური რჩება და ბარიერები ურთიერთკავშირშია და ხშირად ერთდროულად იჩენს თავს;
- · სამართლებრივი რეფორმების განხორციელება სუსტია;
- ანთების საწინააღმდეგო საშუალებებზე

Abbreviations:

EECA	Eastern Europe and Central Asia
FGD	focus-group discussion
INCB	International Narcotics Control
	Board
LMIC	low- and middle-income countries
MoH	Ministry of Labor, Health and Social
	Affairs of Georgia
NCD	non-communicable disease
NSAIDs	non-steroidal anti-inflammatory
	drugs
OSGF	Open Society Georgia Foundation

financed and managed to foster health equity and to protect citizens against financial hardship due to health expenses

universal health coverage: a system

in which healthcare services are

Some of the terms I use surrounding the use of controlled medications might be considered archaic, incomplete, discriminatory) but I use them as they are generally understood or referred to in literature and they are not intended to cause offense.

Introduction.

UHC

Opioid substances like morphine and codeine are a mainstay for the alleviation of medium and strong pain. Nevertheless, if taken inappropriately, they have the ability to induce dependence on them.. Their manufacture, import, distribution, prescription, stocking, dispensing and administering are therefore subject to (international) control mechanisms.

Unfortunately, opioid substance control often impedes its access for medical purposes, substantiated by statistics from the International Narcotics Control Board (INCB) and World Health Organization (WHO): INCB highlights that at least 80% of the world's population living in low- and middle-income countries (LMIC) consume less than 10% of the total reported global opioid consumption (INCB, 2011). WHO reports that 83% of the world's population live in countries with low or non-existent access to controlled medicines (WHO, 2015). Time is pressing, as in addition to the heavy burden of un(der)treated pain, LMICs are disproportionally affected by the observed global trend of increasing prevalence of NCDs (Bollyky et al., 2014). The absolute number of suffering patients encountering barriers is therefore expected to rise further.

This study explored barriers to opioid access in Georgia, an Eastern-European country that started –in 2007– to introduce opioid-related

ლობირება ფარმაკოლოგიური კომპანიების მხრიდან ხელს უშლის ოპიოიდების გამოყენებას სამედიცინო მიზნით;

- ცოდნის ნაკლებობა;
- დროის სიმცირე (ექიმეზი);
- ოპიოიდების ფორმულაცების ნაკლებობა;
- საყოველთაო ჯანდაცვაში პალიატიური მზრუნველობის ინტეგრირებსთვის სახელმწიფო მხარდაჭერის ნაკლებობა.

დასკვნა:

კვლევის მნიშვნელობა: აღმოსავლეთ ევროპის ქვეყნებში ხელმისაწვდომობასთან (EECA)

- დაკავშირებული ლიტერატურიდან დაფოკუს ჯგუფის დისკუსიიდან ცხადი გახდამიუხედავად იმისა, რომ განხორციელდა
- გარკვეული საკანონმდებლო ცვლილებები და ნაწილობრივ კიდევაც დაინერგა,,,ნარკოტიკების წინააღმდეგ ომი" კვლავ მიმდინარეობს საქართველოში, სომხეთში, უკრაინასა და რუსეთის ფედერაციაში.

ფოკუს ჯგუფის დისკუსიამ ახალი კუთხით გამოავლინა ბარიერები: ანთების საწინააღმდეგო საშუალებებზე ფარმაკოლოგიური კომპანიების მხრიდან ლობირების გაზრდა, ექიმების დროის ნაკლებობა, რათა გაეცნონ საკანონმდებლო ცვლილებებს და პროგრესს ტკივილის მართვის შესახებ. კვლევამ ასევე ნათლად გამოავლინა, რომ ოპიოიდების ხელმისაწვდომობის სხვადასხვა ბარიერები ერთდროულად გვხვდება და ხშირად ამას სინერგიული ხასიათი აქვს.

კვლევის რეკომენდაციები შესაბამისი და დროულია, რადგან საქართველომ აიღო გეზი საყოველთაო (უნივერსალური) ჯანდაცვისკენ. 2014 წელს ჯანდაცვის მსოფლიო ასამბლეამ მიიღო რეზოლუცია "პალიატიური მზრუნველობის გამლიერება, როგორც ყოვლისმომცველი ზრუნვის კომპონენტი მთელი ცხოვრების მანძილზე" და განიხილება, როგორც ჯანმრთელობის სისტემების ეთიკური პასუხისმგებლობა.

საკვანბო სიტყვები: ოპიოიდები, კონტროლს დაქვემდებარებული ნივთიერებები, პალიატიური მზრუნველობა, ტკივილგამაყუჩებელი მედიკამენტები, წამლის კონტროლი.

აბრევიატურები:

	jot.
EECA	აღმოსავლეთ ევროპა და
	ცენტრალური აზია
FGD	ფოკუს ჯგუფებთან დისკუსია
INCB	ნარკოტიკების საერთაშორისო
	კონტროლის საბჭო
LMIC	დაბალი და საშუალო შემოსავლის
	ქვეყნები
MoH	საქართველოს შრომის.

legislative changes in which I was personally involved through my work in the drug policy and palliative care sectors. These reforms did not go unnoticed: an INCB report stated: "The Board notes with appreciation that in the past few years, the Governments of a number of countries, including Georgia, [...] have introduced policy reforms aimed at ensuring adequate access to opioid analgesics" (INCB, 2011, p. 46). To systematically approach the issues around access to opioid analgesics in Georgia, a theoretical framework was conceptualized, inspired by three existing international frameworks and consisting of a classification of five types of barriers to opioid analgesics access: I) lack of knowledge and information on the part of healthcare professionals, patients and relatives; II) the issue of side-effects of opioid use; III) concern about dependence syndrome and tolerance; IV) poorly developed healthcare systems and medication supply; V) excessively strict domestic legislation or regulatory policies.

Methodology:

Aim and objectives

The aim of the study was to identify issues around impediments to accessing opioid pain relief in Georgia and recommend policies and strategies to overcome these barriers. The specific objectives were fourfold: 1) get an overview of the existing knowledge base around barriers to accessing to opioid medication in a regional context; 2) critically review the present Georgian legislation and policies in the field of medical opioid control and use; 3) seek expert opinion of relevant stakeholders in the field of access to opioid analgesics in Georgia; 4) give recommendations for future (drug) policy and further research needed to inform such policy.

Mixed methods approach

To gain in-depth insights, a mixed methods approach with data triangulation was selected: information obtained from literature review and background documentary analysis fed into the focus-group discussion's (FGD) topic guide. A group of eleven stakeholders was brought together for an FGD lasting two hours (moderated by myself) and preceded by a mini-survey on barriers. The verbatim record of the FGD was first produced in Georgian and translated into English. Data analysis took place through categorizing/ indexing and subsequent coding/charting of data. Ethical approval for this qualitative research was obtained from both London School of Hygiene

ჯანმრთელობის და სოციალური

დაცვის სამინისტრო

არაგადამდები დაავადებები არასტეროიდული ანთების **NSAIDs** საწინააღმდეგო მედიკამენტები

ფონდი ღია საზოგადოება

საქართველო UHC

NCD

OSGF

ჯანმრთელობის უნივერსალური მოცვა: სისტემა, რომელშიც არის ჯანდაცვის სერვისების დაფინანსება, ჯანმრთელობის ხელშეწყობა, ჯანმრთელობის ხარჯების გამო მოქალაქეთა დასაცავად ფინანსური გაჭირვების თავიდან ასარიდებლად

and Tropical Medicine (LSHTM) and National Center for Disease Control and Public Health in Georgia.

Results

Literature review:

Thirty-six theoretical and research publications were identified for data extraction. Balance between control and access A general concern that the bulk of authors explicitly mention when discussing barriers is that despite advanced medical knowledge on pain, access to safe and rational use of opioid analgesics remains problematic. The undertone in the identified literature on opioid barriers is that the balance between control and access is a challenge to many countries and that it is not rare for the control arm of the equation to take the lead, steering towards a legislation which is often stricter than required by international conventions (Vrancken et al., 2014). Considering the 5 types of barriers, authors writing about demand-related barriers (type I, II, III) underline the fears, wrong beliefs, misconceptions, biased attitudes, stigma or ingrained prejudices that can impede the consumption of opioids for medical purpose (Abesadze, 2011, pers.comm. June 13, 2015); (Berterame et al., 2016); (HRW, 2015); (Lynch et al., 2009); (Sun et al., 2007); (Zerwekh et al., 2002). Brennan, Carr and Cousins (2007, p. 217) state: '[F]or too long, pain and its management have been prisoners of myth, irrationality, ignorance, and cultural bias'. Supply-related barriers (IV and V) are mostly discussed in correlation. Laws and regulations are generally considered unduly restrictive and different types of bureaucratic hindrance that opioids encounter on their pathway from the poppy field to the patient are analyzed (Cherny et al., 2010, Larjow et al., 2016, Vrancken et al., 2014).

Availability, accessibility, affordability

The literature distinguishes barriers to availability and accessibility (Cherny et al., 2006). Affordability (Lynch et al., 2009) is also a significant impediment for access to controlled medicines. Lynch underlines the existence of other systemic barriers like inappropriate locations for opioid dispensing (police stations) and lack of choice of opioid formularies. He notes further that much more than systemic barriers, impediments in the socio-cultural and educational sphere (opiophobia, stigmatization, lack of pain management education) are key in Georgia (Lynch, 2011).

Documentary analysis

The background documentary analysis pertained more to the theoretical framework's supply-related barriers (IV and V). The analysis served to provide an impression of the administrative frame in which opioid access in Georgia is regulated. Part of the identified pieces of legislation intends to control access and use of opioids (e.g. by limiting the validation of a prescription or the supply of opioids) whereas another part of the documents intends to enhance its access. An issue of great concern is the presence of certain ambiguities and inconsistencies in the Georgian legislation.

Focus-group discussion Diversity of insights

The FGD yielded very diverse insights for all five barrier types, summarized as follows: I) lack of knowledge: myths and misconceptions, e.g. morphine mostly administered at the final stage of life which establishes an apparent causal relationship between inception of morphine and death; morphine not seen as a pain medication but rather as an end-of-life cancer medicine; lack of education, lack of training to use assessment tools and insufficient knowledge about updated legislation; II) issue of side-effects: fear for side-effects leading to underdosage but also to the strengthening of a commercially inspired pharmaceutical lobby for NSAIDs; limited availability of globally recognized medication to treat side-effects of correctly prescribed opioids; III) fear of dependence and tolerance: phenomenon of opiophobia which seriously delays inception of opioid treatment; IV) healthcare system barriers (considering a health system's building blocks): concern about the role of police stations vs private pharmacies in dispensing opioids, narrow spectrum of available opioid formularies in Georgia (infrastructure and medical products); lack of palliative care and pain management specialists (human resources); governmental reluctance to promote medical use for -unjustified- fear of diversion, difference between urban and rural level (services); V) legislation (together with lack of knowledge, expressed by FGD as a major barrier to opioid access in Georgia): issue of prescribers, ambiguities and inconsistencies in legislation and regulatory frameworks as a result of which physicians or healthcare managers who are reluctant, biased or afraid to use controlled substances, avoid taking responsibility and persistently follow old habits.

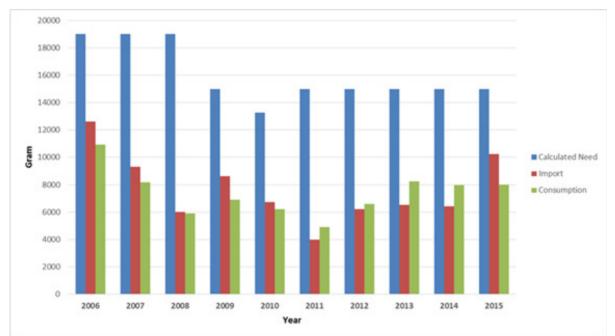


Figure 1: Calculated need, import and consumption in grams of morphine for Georgia (2006-2015), based on statistical information received from the Ministry of Labour, Health and Social Affairs.

Mixed methods' key findings

- Access to opioid pain relief, even if it is an essential medicine, is problematic in Georgia;
- Opioid access barriers are interrelated and occur often simultaneously. If barrier I (knowledge and information) is involved, then the other barrier(s) gets a synergistic effect;
- Even if reforms have taken place in opioid legislation over the last decennium, impeding factors hinder its implementation:
 - a) existence of legal ambiguities and inconsistencies in Georgia's policy and regulatory framework,
 - b) lack of knowledge leading to cautiousness and fear for control interventions by regulatory bodies leading to inaction and persistence of old habits.
- Existence of a strong pharmaceutical lobby for NSAID analgesics which cause more side-effects, and are less affordable, safe and effective;
- Lack of knowledge and persistence of the strong belief that opioids are a cancer medicine for terminal patients;
- Lack of time/arrangements for physicians to bridge their knowledge gaps and improve patient communication;
- Lack of opioid formulary availability and medicines to manage side-effects;
- Lack of governmental support to integrate palliative care in UHC schemes and promote strengthening of the discipline of pain management.

As long as above issues continue to play a role in Georgia, the widespread myths and misconceptions about opioid use causing dependence, side-effects and imminent death will only gain strength and opioid as an essential medicine will move further to the background.

Discussion

The cases raised and discussed by the FGD respondents show that impediments mostly occur concurrently, interact and maintain each other, as stated by Scholten (2013). I would even go a step further than Scholten by saying that misconceptions and myths (barrier I) can further synergize with other barriers. In this context I refer to a Georgian legislative document, Decree 32/O – N 102 (Government of Georgia, 2000) that mentions reconfirmation of a cancer diagnosis for opioid prescription. In the meantime, governmental resolution # 77 of a later date (Government of Georgia, 2011) has broadened the medical use of opioid analgesics from 'oncological' to 'incurable' patients, but without the older decree's specific passage being 'invalidated'. This legal ambiguity unfortunately gives physicians a 'way out' not to prescribe opioids if they feel uncomfortable doing so because of another type(s) of impediments. Opioid control is unduly strict in Georgia in comparison to the minor risk that diversion can bring to the illicit circuit. This issue was very well substantiated in the FGD and it was stated that far more harm can be done by avoiding opioids to reach suffering patients than to risk a part of it ending up with an 'unintended consumer'. To maintain on one hand distance and display sufficient moral detachment (Aveyard, 2014) while moderating and on the other hand apply

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interpretative and reflexive reading during data analysis was a challenge. I knew most of the FGD participants personally which helped me to establish rapport and improve communication through probing and prompting. The respondents knew me as someone who had been strongly involved in the Georgia's 2004-2013 government's opioid legislation reforms, a fact that could have resulted in the study's respondent bias. Nevertheless, I think I succeeded in creating an atmosphere of free, open and anonymous discussion and I did not have the impression that participants were hindered or reluctant to make supportive or criticizing statements about my former role. As an illustration: a decision-maker made a 'provocative' remark about the lack of progress over the past years in access to opioid analgesics. In fact, this comment was a turning point in the FGD discussion enlivening the debate and involving most of those attending.

Added value of the study

The study has clearly shown that barriers occur concurrently and often are even synergizing. New insights gained through the FGD point towards two challenging themes: the 'pharma-lobby' and the 'lack of time' issue felt by physicians without sufficient legal background and pain management knowledge.

Validity and representativeness

As an FGD can hardly be replicated by another researcher, its external validity seems limited. One of the respondents however noted that in a small country like Georgia, only a limited group of people is involved in and knowledgeable about pain management and palliative care –adding to the validity of the study results– and that the sample used can therefore be called representative. Admitting that there is no real consensus about the way to assess qualitative studies, Aveyard mentions that these are better judged by standards more appropriate than validity and reliability: i.e. by credibility (containing a 'truth value'), transferability, dependability and confirmability (2014, p. 122-123).

Limitation of the study

While analyzing the transcript, I needed advice from a pharmacologist to better understand the discussion on side-effects, I realized a pharmaceutical expert would have enriched the FGD discussion. Also, the FGD sample might have been complemented by patients, relatives and police officers (Mosoiu ,, pers.comm. November 13, 2015). The outputs of the FGD might have looked quite

different if the balance between decision-makers (three, two of whom came from the same institution) and stakeholders (eight) had been more equal.

In summary, the many strengths of data triangulation overshadow the setbacks, even if little literature was identified related to Georgia and if the documentary analysis linked only to two of the five barriers of the selected theoretical framework (i.e. 'healthcare system' and 'legislation'). Some focus-group respondents, depending on their governmental, non-governmental or academic affiliation, might have expressed opinions or described situations that did not objectively reflect reality and which can be classified as respondent bias, e.g. a representative of the governmental sector said that 'it cannot be that there is no recently updated List of Essential Medicines', whereas the latest version dates back to 2007.

Recommendations

Carefully considering the key findings from the study results and the topical discussions that followed, I would recommend a concrete list of health policy directions to guide future policy steps in Georgia:

- re-define governmental commitment: the role of the health authorities in avoidance of pain and suffering (UHC, subsidies, loan schemes), including analysis of the present opioid import-consumption gap and diversion risk ratio; establish pharmaceutical control including an update of the 2007 List of Essential Medicines, a wide opioid formulary choice, and different routes of opioid administration; enable import of internationally recognized medications to treat the most significant opioid side-effects (esp. constipation);
- remove legal inconsistencies and ambiguities from legal and policy framework through 'mapping' of the 'bottlenecks', an exercise that already has taken place according to the FGD participants (i.e. double-checking and updating will suffice);
- involve palliative care, pain management and patient communication in basic medical education curricula and introduce these topics in continuous medical education modules for existing staff;
- raise awareness among general public and patients/relatives about mild/medium and strong pain management, including non-opioid and non-medical interventions.

A point of great concern raised during the FGD is the pharmaceutical lobby: NSAIDs are less effective, cause more side-effects and are commercially marketed making pain relief less affordable. If the actions of the private sector will not be submitted to quality control and if state-financed opioids do not get promoted for their unique properties and favorable price-quality ratio, then the notion of essential medicine is seriously at stake in Georgia. A highly interesting topic for further research, and directly linked to the lack of knowledge finding, would be the psychosocial disentangling of prevailing myths and misconceptions. These tenacious prejudices and misunderstandings are the result of cultural beliefs, perceptions, use of terminology and attitudes in society. A KAP study (Knowledge-Attitude-Practices) could be a proper tool to this purpose. A similar research could inform following steps in awareness and education programs and initiatives.

Conclision

Reviewing EECA-related literature and listening to cases recounted by FGD participants, it became clear that the 'war on drugs' is still waging in many parts of Georgia, Armenia, Ukraine and Russian Federation, despite the fact that some legislative changes have been pursued and partly implemented and that Maurer et al. (2013) mention a gradual shift towards promotion of opioid availability.

The FGD yielded a few new insights on barriers, like the challenge of the NSAID pharmaceutical lobby and the lack of time that prevents physicians from being updated on legislative changes and on scientific progress in pain management.

Further on, the study has clearly shown that barriers to opioid access occur concurrently and are often synergizing.

As a final remark, the recommendations of this research are relevant and timely as Georgia has taken the road towards UHC. In 2014, the World Health Assembly adopted a resolution on 'Strengthening of palliative care as a component of comprehensive care throughout the life course'. This resolution refers to the ethical responsibility of health systems to provide palliative care, integrated in UHC packages (WHA, 2014).

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