Report

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National Palliative Care Programm
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1. OBJECTIVES
1.1 To establish a National Palliative Care Programme reaching all in need of it through a
   WHO public Health Approach

1.2 To establish Georgia as a model and reference for effective Palliative Care in
   the Caucasus

2. SITUATION ANALYSIS
Palliative Care relieves suffering and improves the quality of life of the living and dying. Pain is one of the major symptoms (1). The existential, socio-economic and spiritual suffering of the dying and terminally ill and their families can be curbed by palliative care (2). There exists a scientifically valid and simple method for pain control that costs little and that is maintainable at community level so all can be covered (1,2,3). Palliative Care is a human
right. Not offering palliative care to those in need of it would be unethical, as effective affordable methods exists (4). Nothing would more quickly and dramatically improve the life for cancer sufferers, other patients dying of chronic diseases and the children and elderly terminally ill than being able to implement in a rational public health way the enormous knowledge accumulated in pain control and palliative care (4 and Annex 1,2,3,4). Dying is a natural part of life and the cultural, socio-economic and spiritual traditions and support in a society will be as important as the medical for our quality of life and death (4). What is needed is the political will to act, educate and train the health professionals and making the necessary affordable drugs easily available and to promote the cultural, spiritual and socio-economic support systems, so as to avoid dying becoming institutionalised and over-medicalised.

2.1 Georgia today and size of the problem
Georgia’s death rate of 9.09/1000 (5) with a population of 4.7 million gives over 42,000 deaths a year. It can be estimated that about 60% of the dying, 25,000 are in need of palliative care and pain relief in form of opioid analgesic like morphine. With at least two family members taking care of their terminally ill, there would be around 75,000 individuals yearly, at least, that would have their Quality of Life significantly improved if palliative care was introduced. Most people die at home, and would prefer to do so. Thus death has not yet become institutionalised in Georgia, something that ought to be avoided by strengthening the home care services in the future, cultural as well as medical. Based on the age structure in Georgia it is estimated (6) that there could be around 8,500 new cancers a year. There were over 5700 new patients registered at the National Cancer Centre since January 2004, of who over 4300 are dead and 2177 within the first year. A high number of the diagnosed cancer patients were late referrals and incurable (7). Thus for the majority of the cancer sufferers, pain relief and palliative care is the most humane realistic and relevant therapy to offer. At the end of 2005 there will have been around 250 cancer patients that got palliative care (7). The average life expectancy in Georgia is 74 years. The highest number in need of palliative care will be the elderly dying. The AIDS/HIV prevalence rate is 0.1% and deaths are below 200/year.
A Palliative Care Unit, with five 3 bed rooms, located at the NCC in a connected but separate building, was started in November 2004 covering both in-and outpatients. Staff consists of: a coordinator, an assistant, 6 Physicians, 4 nurses, 4 hospital attendants, the matron, an accountant and team of volunteer
students from Tbilisi State Medical University, IV-V courses. It is expected that around 250 patients will have been treated during year 2005.

A first mobile PC Team has been funded in 2004 by the “SOCO” foundation under the leadership of the First Lady of Georgia

2.2 Policies

Palliative care just included in the “State Policy on Oncology” The EC recommendations (2003) 24 on Palliative care to Ministers of Health, EU, have been translated into Georgian, but so far no commitments.

Cancer will be identified as a priority to be address in the upcoming National Health Plan. There is no NCCP (6) nor is Palliative care yet included. Pain relief and palliative care are not included in the undergraduate education of doctor, nurses, pharmacists or social workers. No policies on essential drugs for e.g. cancer chemotherapy or palliative care. Rational prescription of opioids is impeded by unrealistic, totally unpractical, outdated rules. Order 465/O of Minister of Health from November 29, 1999 and orders 32/O and 102 of Minister of Health and Minister of Internal Affairs, from March 13 and March 15, 2000 regulates opiate prescription.

2.3 Drug availability

For outpatients: opiates can only be prescribed for stage IV cancer patients with a proven diagnosis, preferably with histological proof. A committee (patient’s doctor, an oncologist and a chief medical officer) establishes the first dose after mandatory physical examination. Several different forms then filled out. Opiates can only be purchased on two strictly designated days/week, using a special form and from specially designated pharmacies only, located in a police station and monitored by the Ministry of Internal Affairs. If the patient should require a higher dose, the committee has to meet again and establish the new dose.

For hospitalised patients: treating doctor can prescribe. If the patient will return home, a committee has to meet, as outlined above.

Slow Release (SR) Morphine tablets are available. Immediate Release (IR) Morphine tablets are not available. The costs of drugs will be important and a policy of cost effective generic drug essential. Georgia has 54 % of it’s population below the poverty line and a 17 % unemployed rate. The official salary of a nurse is below 100USD/month.

Morphine consumption (all types) was last year 13 Kg, most as injectable and consumed for other reasons than palliative care/pain relief.
2.4 Education and training
Strong opioid phobia exists and doctors are afraid of being put in prison if prescribing morphine. A figure of 275,000 drug abuser existing was given by the Drug Abuse Authorities as a key reason for not allowing doctors to prescribe morphine rationally. This figure could not be substantiated in spite of repeated request for documentation but was often quoted by others too. It would mean that 5.85% of Georgia’s population, or 1/20 are substance users? Furthermore the Department of Internal Affairs has produced a list of restricted drugs, without consultation with the medical expertise. Establishment of facts and proper information and education of policy makers and the health profession is missing.

At present there is no doctor formally qualified in palliative care in Georgia. However the oncologist at the NCC, see above, have started to successfully deliver palliative care, integrating it into the routine cancer care. During the last two years several educational course, with international experts, sponsored by OSGF, OSI, HHF, MOHLHSA and SOCO have taken place. Guidelines and manuals have been translated into Georgian language, educational material been prepared and a 10 hours Course for Continuing Education in Palliative Care has been established, accredited by the State Council for Post-Diploma and CME, and done twice. Palliative Care/Pain Relief is not included in the undergraduate education of doctors, nurses, pharmacists or social workers. A Palliative Care Association “Humanist Union” (HU), has also been founded Tbilisi State Medical University = 500 x 7 years = 3,500 students. This year was the first for a new strategy for entrance to medical schools by scores. Private medical school = 50 / year; only 20-23 graduate. Medical Academy = 30 / year

First course in Palliative Care will start in January 2006. All students will have practical experiences at NCC Hospice and with Mobile Teams. Pain management and symptom control – will be presented by medical oncologists. Ethical issues and organizational topics – will be presented by Dimitri Kordzaya. Asking pharmacologists to help with training.

By the end of December 2005, 2 handbooks will be published in Georgian for Medical students (300 pages) and for nursing students (150 pages). These will be a compilation of already published materials, translated. Later in 2006, the Ministry of Health will issue a new list of specialties and subspecialties and will then try to include Palliative Care as a subspecialty. A 6-month course for specialty training is planned to start at the NCC in 2006.

To date there is no postgraduate training for nurses anywhere in Georgia. However this year, the MOH put out the first tender for postgraduate nursing education.
Palliative Care Guidelines have been published in Georgian and information pamphlets for family members and volunteers been distributed and Palliative Care has been included in the Continuing Medical Education system. Three international workshops have been held since 2000 (6).

3. MEETINGS WITH POLITICAL AUTHORITIES AND LEADERSHIPS

3.1 Meeting with First Lady of Georgia, the Minister and v. Minister of Health and the Member of Health Committee of Parliament of Georgia.
First Lady of Georgia, Sandra Roelofs, the Minister of Health, Dr. L. Chipashvili, the vice Minister Dr. L. Jugeli, the member of the Health Committee of the Parliament, Dr. O. Toidze, met with the International Faculty Dr. Jan Stjernsward, Dr. Frank Ferris and Dr. Maria Danilychev in the beginning of their mission, together with Dr. Dimitri Kordzaya and Dr. Rema Gvamichava.
At an informative and indeed constructive meeting the charges were given and expected outcome discussed. A National Palliative Care Program should be established that ultimately should cover all in need of palliative care, but starting with cancer sufferers as entry point. The Minister confirmed that Palliative care could be included in the upcoming National Health Strategy Plan and stressed that Cancer already was a priority and he hoped a NCCP also would be established in the near future. Palliative care inevitably is a major part of a comprehensive Cancer Control programm. It was agreed that a future NPCP would be under the Patronage of the First Lady of Georgia. Georgia’s NPCP should also become a demonstration project in PC for the Caucasus. Georgia already had received requests for help from Armenia.

3.2. Drug regulators and pharmacologists
Discussions with several distinguished national experts and colleagues occurred during the two Workshops as well as in follow up visits to individuals by J. Stjernsward and D. Kordzaya.
Professor Nick Gongadze, Responsible for the Drug Agency, Ministry of Health and Dean of School of Pharmacology, Dr. Nelly Antelava, Professor of Pharmacology, Dr. Tamara Kezeli, Consultant, Rational Prescribing WHO/EURO. Dr. Tamaz Kvirkvelia, Drug responsible Minister of Health, clarified the problems and gave suggestions for solutions, all incorporated in the recommendations. It was agreed that more rational rules for prescription should be addressed, that cost effective generic IR-and SR Morphine should be made available (Annex 5) and should constitute 90 % of the strong opioids.
(Annex 6) when tendering after a higher INCB quota (3 pp 46-58) had been approved for Georgia. Advocacy and information to policy makers (8), the health profession and the public was judged important (Annex 7). Pain relief and Palliative Care should be included in the undergraduate curricula of clinical pharmacologist. Clinical Pharmacists should also be included as participants in future hands on training courses.

Professor Gela Lezhava, Georgia Research Institute on Addiction quoted a figure of 275,000 drug abuser in Georgia as the main reason why he was strongly against a more rational prescribing of opioids for allowing effective palliative care.

3.3 Deans and Directors
Professor Ramaz Shengelia, Dean of Medical Faculty, Professor Mamuka Goletian Chairman, Scientific Educational Centre, (covers 3 State Nursing Schools, around 900 students/year) and Professor Nick Gongadze agreed to include pain relief and palliative care in the undergraduate curricula of doctors, nurses and clinical pharmacists, and that questions on the subject should be included in their exams. Hopefully it will be introduced already in the autumn 2006. However a critical mass of knowledgeable teachers must be available by then. Their education, the trainers of future educators, thus becoming a priority recommendation.

3.4 Georgian Young Lawyers Association
This association is highly respected for its efficient and factual advocacy and lobbying in National TV and Press as well as in the Parliament on important legal and human right issues. D. Kordzaya and J.Stjernsward visited them and met with Anna Dolidze, Chairperson and Lali Chkhetia, Programm Coordinator. They responded positively to our request and would present a plan, for advocacy of Palliative Care, supporting the implementation of our recommendations, as in this Report. It was agreed we would try to fund this activity from funds to be allocated to the NCCP.

3.5 The Committee of Health Care and Social Affairs, Parliament of Georgia
Under the Chairmanship of Dr. Gigi Tseritzeli and 7 other Members of this Committee and Member of the Staff, Doctors D.Kordzaya, T.Rukhadze, J.Stjernsward, F.Ferris, M.Danilychev met in the Parliament. The work of the committee and their visions for the future was described by Dr. Tseritzeli and Drs. D.Kordzaya and J.Stjernsward presented the need for Palliative Care and the NPCP being planned and commitments needed for its realisation.
Reassurance was given that within a 10 years period it had been shown that it would be possible to cover 80% of all (elderly terminally, cancer, other NCDs, HIV/AIDS). The Committee has identified cancer control as one of the top priorities and stressed the need for action. We suggested that a public health approach through establishing a comprehensive NCCP (6), covering primary prevention, earlier discovery, referral and diagnosis of certain common cancers, therapies and palliative care would be the most rational approach. Invitation to help with this was given. The Chairman pointed out that the new Health Strategy Plan was being finalised, but offered to include Palliative Care, if we before our Departure could submit 1) A short to the point Strategy plan and 2) Recommendations for It's implementation. This was submitted (see Annex 11 and 12) and thus Palliative Care, a NPCP, will be part of the next National Health Strategy and Plan.

3.6 Open Society Georgia Foundation (OSGF/OSI) and WHO
OSGF/OSI was the initiator and funder of the Workshops and our mission. Two visit for coordination and reporting took place, when Drs D.Kordzaya, R.Gvamichava, J.Stjernsward, F.Ferris, M.Danilychev met with David Darchiashvili, Director and Lasha Zaalishvili, Chief Administrator. The flexible, dynamic and generous support and advice from OSGF was critical for the success of our mission. OSGF pledged to continue to support the establishment of Georgia’s NPCP. J.Stjernsward proposed as a priority the funding of a full time 2 years position for a Champion, coordinator, implementing the recommendations necessary for establishing a NPCP. OSGF/OSI supported this idea and would explore possible funding.
WHO/Georgia: Dr. Rusudan Klimiaslislvili, head of WHO Country Office met with Drs D.Kordzaya and J.Stjernsward. Pain Relief and Palliative Care is not on WHO/EURO’s Country Programm for Georgia’s list of priorities for year 2006-2007. Thus she could not at present act or fund anything, but pointed out that the countries wishes for year 2008-2009 were being collected. We informed that most likely Palliative Care would be included in the upcoming National Health Strategy Plan for Georgia and thus hoped that Dr.Klimiaslislvili together with national colleagues would see to that palliative care and Pain Relief will also be included in the WHO Country plan for 2008-2009.
We were lucky to met Dr. Amiran Gamkrelidze, Country Coordinator STIsHIV/AIDS, and former Minister of Health. He has worked in Sweden and is well connected there. Dr. Gamkrelidze suggested that once Palliative Care was officially included in Georgia’s National Health Strategy Plan the Minister may consider writing the Swedish International Development Agency, SIDA, asking for support to the NPCP and perhaps also a future NCCP.
3.7 Grand Round at the National Cancer Centre
Professor Revaz Gagua, President of NCC chaired the Grand Round where Drs. J.Stjernsward and F.Ferris presented the importance of palliative care in cancer control and outlined the best ways for its integration, institutionalisation, in the NCC and the two other Cancer Centres in Georgia. Dr. R. Gvamichava is already pioneering its integration in the NCC (See Annexes 3 and 4) and it was agreed that this would be the future centre of excellence and focal point for education and training and for supporting the introduction of Palliative Care in the two other Cancer Centres.

3.8 Psychosocial support and research
On special request Professor Ramaz Sakvarelidze, Head of Department of Psychotherapy, Psychology and Psychosomatic Medicine, came to join the in the follow up Policy Workshop. It is very important to find out best ways of supporting present culture of dying at home besides building up Home Care teams, but by support to the families and society.

Dr. Irina Malinidze, Oncologist, informed that she had tested 40 cancer patients before and after they had got ecumenical support by a priest. The results showed that the majority of the patients were better after ecumenical support, as measured by a pain scale. Dr. Malinidze would need some minimal support for translating her write up into English and J.Stjersward would then help review her findings for possible publication.

4. POLICY WORKSHOP; NCCP
A National Workshop under the Patronage of the First Lady of Georgia and sponsored nationally by the Ministry of Health, SOCO, OSGF, and the “Humanists Union” was held with the objective to develop a national action plan and programme for Pain Relief and Palliative Care in Georgia. Details of the Agenda (Annex 8), list of Participants (Annex 9) and the recommendation to participants (Annex 10 A/B) are all given in the annexes.

5. RECOMMENDATIONS
Recommendations to the Policy NPCP Workshop are summarised in Annex 9, those to the Committee of Health Care and Social Affairs of the Parliament in Annex 11 and 12 and a summary of recommendations fundamental for establishing the G-NPCP in the Action Plan, point 7.4

5.1 Recommendations to the Participants. (Annex 9)
5.2 “Strategy Document to the Parliament” (Annex 11)
5.3 “First Recommendations to the Strategy Document” (Annex 12)
5.4 Recommendations prioritised (Annex 7, Action Plan, 7.4)

6. EDUCATIONAL COURSES
An intensive 6 days study course that also included bedside training for physicians, nurses, pharmacists and students was given by Dr. Frank Ferris and Dr. Maria Danilychev. Among the 20 doctors the oncologists dominated and the 5 Nurses were from the palliative or mobile care team. Lecture topics selected by the participants and addressed were e.g. pain management, depression, anxiety, psychological symptoms, cognitive issues, delirium, wound care, information sharing, breaking bad news, symptom management. The course was positively interactive and didactily empowering. Experience has shown that bedside training is critical for making colleagues confident using strong opioids. It is therefore recommended that another course is held when the planned generic IR-and SR Morphin will be available, and the prescription rules have been improved and when there is a critical mass of doctors and nurses committed to do Palliative Care.
A first educational course for the future teachers of palliative care at undergraduate levels when included in the curricula is recommended, and for the already committed teachers of palliative care. It would benefit significantly by having the same international faculty returning and then also specifically address how to teach and train interactively.

7. ACTION PLAN AND FOLLOW UPS
Three of the major impediments for implementing existing knowledge, namely weak human resources, lack of institutional infrastructure and lack of financing (14) have been addressed, now allowing meaningful action. Priorities and recommendations for what to do have been outlined and most important for reassuring success, several national champions (6) have been identified and a position been possible to create for a champion to coordinate and establish the NPCP.

7.1 Responsible focal persons
Georgia Pain and Palliative Care Program:
Patron:
First Lady of Georgia Sandra Elizabeth Roelofs (soco@soco.ge);
Chair:
L. Chipashvili – Minister of Health, Labor and Social Affairs
Members of the board:
L. Jugeli – vice Minister of Health, Labor and Social Affairs (l.jugeli@moh.ge);
G. Tsereteli – Chairman of the Committee of Health Care and Social Affairs, Parliament of Georgia;
O. Toidze – member of the Committee of Health Care and Social Affairs, Parliament of Georgia;

Responsible for Policy: { D. Kordzaya (pca_hu@telecom.ge)  
R. Gvamichava (rema@ip.osgf.ge)
}

Responsible for Drugs: { T. Turdzeladze (dodokezeli@tsmu.edu)  
N. Gongadze (dodokezeli@tsmu.edu)

R. Gvamichava (rema@ip.osgf.ge)  
M. Shavdia (mitsha_shavdo@yahoo.ca)  
J. Abesadze (rema_cpc@yahoo.com)  

D. Kordzaya (ctma@ctma.com.ge)  
T. Kezeli (dodokezeli@tsmu.edu)  
T. Rukhadze (trukhadze@tsmu.edu)  

N. Gongadze (dodokezeli@tsmu.edu)

Education of Doctors and Nurses

Education of Pharmacists

International Experts

Dr. Jan Stjernswärd (janstjernsward@hotmail.com)  
Dr. Frank Ferris (fferris@sdhospice.org)  
Mary Callaway (mcallaway@sorosny.org)

Katalin Muzbek (katalin.muszbek@hospicehaz.hu)

Georgia National Palliative Care Program G-NPCP suggested as working name, with the subtitle A Minister of Health/OSI Demonstration Project for the Caucasus.

In the spirit of the principle of “all for one and one for all” it is suggested that all focal persons identified are included in any future publication/abstracts from or on the G-NPCP, in the name of it’s collective authors, thus reassuring all upfront. All reports, abstracts, presentations or publications should be cleared by the Coordinator.

7.2. National coordinator position-NPCP

During present mission plans for a public health based National Palliative Care Program (NPCP) in Georgia is outlined in this Report and necessary commitments for it’s realization has successfully been established. Establishing the NPCP and implementing and coordinating all the recommendations would need a champion full time for the first two years. 

Doctor Dimitri Kordzaya was proposed and has accepted this position, to be funded by OSGF/OSI, starting January 2006, with responsibility to establish
and coordinate agreed upon foundation measures for the NPCP and all the recommendations. His office will be at the Parliament of Georgia, under the Patronage of the First Lady of Georgia, the Parliament, the Ministry of Health and the key NGOs.

7.3 Recommendations Prioritised (see also Participants Recommendations and to Parliament)

- Incorporation of “Palliative Care” in the upcoming National Health Plan of Georgia and integrating it into the healthcare system at all levels;
- Incorporation of Palliative Care into the Govermental Budget at all levels (federal, municipal and regional);
- Include definition and activities of “Pain Relief” and “Palliative Care” in the laws of Georgia covering “Medical Activity” and “Health Care”;
- Do necessary advocacy systematically to the policymaker, health professionals and the general public;
- Implementation of policy issued necessary for making opioids for pain relief available;
- Change the order of two Ministries (Health and Internal affairs) regulating the opioid prescription, dose definition, storage and distribution;
- Estimate increased future need of Morphine and initiate request to the International Board of Narcotic Control, INCB, Vienna, for increased quota for Georgia;
- Make generic Immediate-release and Slow-release Morphine available and develop a rational prescription policy;
- Change the Medical Doctors’ knowledge, attitude and practise about pain management, drug availability and opioid prescription via organizing of study courses over the country – using the modern video and multy-media teaching materials;
- Increase the Public (Society) awareness of importance of Palliative Care;
- Building up of Home Palliative Care to support of existing culture to die at home and related efforts necessary for this;
- Institutionalisation of Palliative Care into the 3 Cancer Centres in Georgia (Tbilisi, Batumi, Kutaisi);
- Support the establishment of a centre of excellence for education and training in Palliative Care at Palliative Care Unit, National Cancer
- Introduce Pain Relief and Palliative Care in the curricula of undergraduate education of doctors, nurses, pharmacists and social workers.

7.4 Time line

_A Time line with dates for implementation of all the recommendations should be elaborated_ and finalized by the Coordinator after the above mentioned focal persons have submitted their time plans.

7.5 Indicators for monitoring and evaluation

Policy changes
Number of patients covered
Morphine consumption
Number of persons trained
Number of full time positions in palliative care
Number of doctors and nurses having received undergraduate education in Palliative Care
Positions created
Advocacy done and evaluated

7.6 Financing and resource mobilisation

7.6.1 The first priority to finance, a _full time position_ for 1-2 years for a national champion that will lead, coordinate and implement the recommendations and establish the G-NPCP has already been reassured while writing this report. A small operational budget is built into the position.

7.6.2 _Funds for a larger two years operational budget should be mobilised_ for needed health care research, like establishing baselines for needs for dying at home, attitudes and wishes, implementation of different testing methods for monitoring effects of advocacy and education, production of advocacy and educational materials.

7.6.3 When Palliative Care will be included in the new National Health Strategy Plan, it should be _perused that it also will get allocated a budget_, important also symbolically for credibility.

7.6.4 WHO has a country budget; It has already been decided and allocated for 2006-2007. The next country plan for 2008-2009 will soon be negotiated. It will be important that Palliative Care, now being included in Georgia’s future Health Strategy Plan, NHSP, also will be _included in WHO next country plan_.

7.6.5 The same fact, inclusion of Palliative Care into the NHSP should
be used for negotiating funding to the NPCP when supporters and funders will be identified for another of Georgia’s priorities, namely establishing a comprehensive National Cancer Control Program (Palliative care is one of four main priorities in a NCCP).

7.6.6 Once the new NHSP is official, the international donor community to Georgia, like the Nordic countries DANIDA, NORAD, SIDA, USAID and perhaps the World Bank is combined with search for funding to a future NCCP.

8. REFERENCES

7. Gvamichava R “Georgia Cancer Prevention Center”, Report 1-6,Tbilisi , 2005

11. NNPC :”Work Book: International Workshop on Community Participation in Palliative Care” Manjeri, Malappuram District, Kerala 26-28 Nov.2004 by NNPC groups, Department of Community Medicine and Institute of Palliative Medicine, Medical College, Calicut, Kerala, 673008 India. nnpc_conference@yahoo.co.in


ANNEXES:
ANNEX 1: WHO FOUNDATION MEASURES

WHO Foundation Measures
Annex 2. WHO Recommendations to Governments

1- Governments should establish national policies and programmes for Palliative Care;
2- Governments of member states should ensure that Palliative Care programmes are incorporated into their existing health care systems; separate systems of care are neither necessary nor desirable;
3- Governments should ensure that health-care workers (physicians, nurses, pharmacists, or other categories appropriate to local needs) are adequately trained in Palliative Care;
4- Governments should review their national health policies to ensure that equitable support is provided for programmes of Palliative Care at home;
5- In the light of the financial, emotional, physical and social burdens carried by family members who are willing to care for cancer patients at home, governments, should consider establishing formal systems of recompense for the principal family caregivers;
6- Governments should recognize the singular importance of home care for patients with advanced cancer and should ensure that hospitals are able to offer appropriate back-up and support for home care;
7- Governments should ensure the availability of both non-opioid and opioid analgesics, particularly Morphine for oral administration. In future, they should make realistic determinations of their opioid requirements and ensure that annual estimates submitted to the INCB reflect actual needs;
8- Governments should ensure that their drug legislation makes full provision for the following:
   a. regular review, with the aim of permitting importation, manufacture, prescribing, stocking, dispensing, and administration of opioids for medical reasons;
   b. legally empowering physicians, nurses, pharmacists, and where necessary, other categories of health-care worker to prescribe, stock, dispense, and administer opioids;
   c. review of the controls governing opioid use, with a view to simplification, so that drugs are available in the necessary quantities for legitimate.

ANNEX 3: INTEGRATION OF PALLIATIVE CARE INTO ROUTINE CANCER CARE

Traditional approach: Palliative care first when “dropped” into hospice:

S, O + RT
P + PC

HC = Home Care

Recommended early Palliative Care involvement: at time of diagnosis and when deciding therapies to be given

S = Surgeon
O = Oncologist
RT = Radiation oncologist
P = Pathologist
PC = Palliative care physician

Modified from WHO: “Cancer pain Relief and Palliative Care” WHO TRS 804, 1995
ANNEX 4: Recommendations for NCCP:

WHO Recommendations for a Comprehensive NCCP

![Diagram of NCCP]

NC = Nat. Policy/Committee
PP = Primary Prevention
ED = Early Diagnosis
T = Treatment
PC = Palliative Care


ANNEX 5: Why generic morphine sulphate is best and how to estimate future needs

1. Optimal potential for benefit, with a minimum risk of adverse events and the most cost effective pain drug.

Morphine has been scientifically proven to be the single most effective opioid to achieve both immediate and long-term control of pain, and to manage breakthrough and procedural pain in either oral or parenteral formats. It has a very low incidence of adverse effects and less than 0.1% of patients who use Morphine to control pain ever go one to misuse it.

Oral Morphine has been shown to control more than 90% of patients’ chronic pain. Injections or infusions of parenteral Morphine are only needed to control 3-5% of patients with difficult to control chronic pain syndromes.

In contrast, more expensive preparations of other opioids, i.e. Transdermal Fentanyl:

do not add any increased potential for benefit, may have a much greater risk of misuse on the black market, may be more difficult to use effectively in a
hairy population in a hot climate where people are prone to perspire off the patches (and receive ineffective dosing).

While Pethidine has been used as though it was a step-3 opioid, it is only step-2 analgesic with weak efficacy. In addition, due to the accumulation of its toxic metabolite, it is associated with a high risk of serious adverse effects and is not appropriate for chronic pain management.

**Cost effective:**

Both immediate and slow-release Morphine preparations can be produced generically at a cost similar to Acetylsalicylic acid tablets (ASA / Aspirin).

In contrast, more elaborate preparations, i.e. Transdermal Fentanyl, may be much more expensive for the same Morphine-equivalent dose.

In our experience the relative cost of opioid preparations has been:

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<tr>
<th>Drug</th>
<th>Morphine</th>
<th>Fentanyl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>Oral IRM</td>
<td>Oral SRM</td>
</tr>
<tr>
<td>Relative costs</td>
<td>1x</td>
<td>3x</td>
</tr>
</tbody>
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**Strategy Drug Availability:**

<table>
<thead>
<tr>
<th>Oral IRM</th>
<th>Oral SRM</th>
<th>Parental</th>
<th>Other opioids</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>60%</td>
<td>5%</td>
<td>5%</td>
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<tr>
<th>Oral IRM (100mg)</th>
<th>Oral SRM (100mg)</th>
<th>Parental</th>
<th>Other opioids</th>
</tr>
</thead>
<tbody>
<tr>
<td>10mg</td>
<td>30mg</td>
<td>2 mg/ml</td>
<td>2 mg/ml</td>
</tr>
<tr>
<td>20mg</td>
<td>60mg</td>
<td>10mg/ml</td>
<td>10mg/ml</td>
</tr>
<tr>
<td></td>
<td>(100 mg)</td>
<td>50mg/ml</td>
<td>50mg/ml</td>
</tr>
</tbody>
</table>

**Important** that a National Policy specify the above, that will say that 90% of the increased INCB Quota of opioids for Georgia’s NPCP should be, when the Government tender, *generic IR- and SR Morphine*. If not this is clear, bitter experience has shown that the big multinational pharmaceutical companies introduces smartly unaffordable, expensive and not better drugs.

**Practical advice:**

- Incorporate principles in National Health Policy/Strategy and Essential Drug list;
- Contact directly manufactures of generic IR-and SR Morphine for tender;
- Improved rules for prescription and easier accessibility of drugs;
• Bedside training of future nucleus of Palliative Care professionals (doctors, nurses, pharmacists, social workers) when IR- and SR Morphine arrives;
• Monitoring and documentation of Morphine consumption and increase in number of patients treated.

Thus generic Morphine at costs similar to or less than Aspirin. In Kerala, India 10 mg IR Morphin tablet costs 2 cents US. In Uganda one months of oral Morphine solution corresponds to the cost of one loaf of bread for 2 weeks supply.

**ANNEX 6: ESTIMATION OF AMOUNT OF MORPHINE NEEDED**

Based on the average daily dose for control of cancer pain, being 100 mg/day/patient, and being given for an average time of 100 days. 10,000 mg or 0.01 kg per patient will be needed. Based on this 1 kg of Morphine would cover 100 patients.

However depending on types of cancers, stage of disease and treatment times the total amount needed may vary. The storage time of Morphine is 2 years, but biologically usually much longer. To start pain treatment and then run out of drugs is cruel towards the patients. Thus it is better to err on the higher side. Too high though may impede the ease of getting a higher INCB quota next year. If not enough it can always be increased.

When IR-and SR Morphine becomes available it is important that an Educational Course is held, preferably with one weeks interactive theory and a minimum of 2 weeks active bedside training, of doctors and nurses. A *new higher quota from INCB is therefore suggested* too be requested in good time ahead of the Course.

Again somewhere it should be specified, preferably in the National Policy or in an Order by the Ministry of Health and Ministry of Internal Affairs, that the new quota should be used for requiring generic immediate and slow release Morphine. Generic IR M- and SR M tablets should be listed in the EDL, and specified to be used in standard treatment protocols.
ANNEX 7: ADVOCACY

1) Public and health professional awareness of following point often needed:
Palliative Care will improve the patient’s quality of life, even if the disease is incurable.
Treatment exists that can relieve pain and many other symptoms.
The pain drugs ought to be inexpensive.
There is no need for patients to suffer prolonged and intolerable pain or other distressing symptoms.
Drugs for the relief of pain can be taken indefinitely without losing their “effectiveness”
“Addiction” (psychological dependence) does not occur when morphine is taken to relieve pain.
Family, volunteers and the community support systems can do much to improve the quality of life of the patients.

2) Politicians: Need to know the above too, and
That pain relief is a major problem.
That affordable effective method exist to control pain and other symptoms, thus a solvable problem
Thus unethically if not offered, lot of unessecentary suffering and should be a human right
One day everybody will die, concerns everybody.
“The same attention we give the newborn, those that enters life, we should give the elderly, terminally ill, those that leaves life” (JS 1986).

ANNEX 8: Agenda National Policy Workshop, NPCP
Georgia Pain Relief & Palliative Care Initiative

Pain Relief and Palliative Care
1) Public and health professional awareness of following point often needed:
Palliative Care will improve the patient’s quality of life, even if the disease is incurable.
Treatment exists that can relieve pain and many other symptoms.
The pain drugs ought to be inexpensive.
There is no need for patients to suffer prolonged and intolerable pain or other distressing symptoms.
Drugs for the relief of pain can be taken indefinitely without losing their “effectiveness”
“Addiction” (psychological dependence) does not occur when morphine is taken to relieve pain.
Family, volunteers and the community support systems can do much to improve the quality of life of the patients.

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That affordable effective method exist to control pain and other symptoms, thus a solvable problem
Thus unethically if not offered, lot of unessecentary suffering and should be a human right
One day everybody will die, concerns everybody.
“The same attention we give the newborn, those that enters life, we should give the elderly, terminally ill, those that leaves life” (JS 1986).
Objective: To develop a national action plan and programm for Pain Relief and Palliative Care in Georgia

Agenda
Welcome
Introduction of participants (Dr. Dimitri Kordzaya)
Background (Dr. Jan Stjernswärd)
What is good palliative care? (Dr. Frank D. Ferris)
Goals and strategies of the workshop (Dr. Jan Stjernswärd)
Lunch
Discussion of major problems in Working Groups
  • Policy
  • Opioid availability
  • Education
Workgroup Recommendations
Summary

ANNEX 9: Participants Policy Workshops and Educational Course

Parliament of Georgia
  1. GiGi Tsereteli – Chairman of the Committee of Health Care and Social Affairs
  2. Otar Toidze – Member of the Committee of Health Care and Social Affairs
  3. Nana Jebashvili - Member of the Committee of Health Care and Social Affairs
  4. Eka Khoreladze - Member of the Committee of Health Care and Social Affairs

Ministry of Health, Labor and Social Affairs
  5. Lado Chipashvili – Minister of Health, Labor and Social Affairs
  6. Levan Jugeli – vice Minister of Health, Labor and Social Affairs
  7. Nikoloz Pruidze - vice Minister of Health, Labor and Social Affairs
  8. Tinatin Turdzeladze – Chief of Drug Agency of Ministry of Health, Labor and Social Affairs
  10. Tamaz Kvirkvelia - Employee of Drug Agency of Ministry of
Health, Labor and Social Affairs
11. Irina Khavanskaia – Employee of Health Care Municipality Service

Palliative Care Association “Humanists Union”
12. Tamar Alibegashvili – President of the Association “Humanists Union”
13. Dimitri Kordzaya – Founder of the Association “Humanists Union”, Director of the project “Home Palliative Care” (HPC)
14. Ia Akhaladze – HPC doctor
15. Marine Turkhadze - HPC doctor
16. Tamar Rukhadze - HPC doctor
17. Khatuna Dolidze - HPC doctor
18. Tea Surmava - HPC doctor
19. Tea Kakabadze - HPC doctor
20. Shukhia Chincharauli – HPC nurse
21. Marina Zarnadze - HPC nurse
22. Tamar Gogoladze - HPC nurse
23. Irma Abuladze - HPC nurse

“Cancer Prevention” Centre
Hospice based on National Cancer centre (NCCH)
24. Rema Gvamichava - NCCH oncologist
25. Mikheil Shavdia - NCCH oncologist
26. Joseph Abesadze - NCCH oncologist
27. Tengiz Aroshidze - NCCH oncologist
28. Ludmila Iarkina - NCCH oncologist
29. Giorgi Metivishvili - NCCH oncologist
30. Natia Vekua - NCCH oncologist
31. Zurab Targamadze - NCCH oncologist
32. Tamar Djinjibukhashvili - NCCH psychologist
33. Marika Giorgadze – NCCH nurse
34. Maia Gigineishvili - NCCH nurse
35. Nana Jushoshvili - NCCH nurse

National Cancer Centre (NCC)
36. Revaz Gagua – President Of National Cancer Centre
37. Zaza Zarkua – NCC oncologist
38. Tamar Kapanadze - NCC oncologist
39. Paata Khorava - NCC oncologist
40. Ia Mchedlishvili - NCC oncologist
41. Miranda Gogishvili - NCC oncologist
42. Temur Kemoklidze - NCC oncologist
43. Maia Tatishvili - NCC oncologist
44. Giorgi Kachakhidze - NCC oncologist
45. Davit Kuchava - NCC oncologist
46. Tamaz Potskhveria - NCC oncologist
47. Lela Giorgobiani - NCC oncologist
48. Dina Kurdiani - NCC oncologist
49. Nana Ubilava - NCC oncologist
50. Vakhtang Shoshiashvili - NCC anaesthesiologist
51. Archil Kapanadze – NCC radiologist
52. Memed Djinchadze - NCC oncologist (Batumi)
53. Maia Agniashvili – NCC nurse

**Doctors of Primary Health Care Service**

54. Nunu Mandjgaladze – Oncologist
55. Manana Jangulashvili – Oncologist
56. Leila Gevorkiani - Oncologist
57. Ketevan Gigilashvili - Oncologist
58. Mila Belkania - Oncologist
59. Nana Kavtaradze – Oncologist
60. Natela Asabashvili – Oncologist
61. Inesa Giorgobiani – Oncologist
62. Manana Ramishvili – Oncologist
63. Daredjan Shavdia - Oncologist
64. Ketevan Eremeishvili – Oncologist
65. Marine Khavelashvili - Oncologist
66. Manana Giorgobiani – Oncologist
67. Irina Gubelidze – Oncologist
68. Nino Zenadze – Oncologist
69. Irina Malinidze - Oncologist
70. Inesa Giorgobiani – Oncologist
71. Tsitsino Gogvadze – Oncologist (Batumi)

**LTD “Medula”**

72. Nino Sharikadze – Oncologist
73. Lia Abshilava – Oncologist
WHO/GEORGIA
74. Rusudan Klimiashvili – Head of WHO country office

Georgian Association of Nurses
75. Marine Sakhvadze – President

Educational and Research Centres
76. Gela Lezhava – Director of Georgia Research Institute on Addiction
77. Tengiz Tsertsvadze – Head of the centre of AIDS and Immunology
78. Ramaz Sakvarelidze – Dean of Department of Psychotherapy, Psychology and psychosomatic Medicine
79. Ramaz Shengelia – Dean of Medical Faculty
80. Nikoloz Gongadze – Pharmacologist, Dean of School of Pharmacology
81. Nodar Bakradze – Director of Institute of Family Medicine
82. Gaioz Vasadze – Head of National Centre of Information
83. Mamuka Goletiani – Chairman of School of Nursing
84. Irina Kharosanidze – Head of Institute of Family Medicine
85. Revaz Morgoshia - Head of Institute of Family Medicine
86. Tamar Samkharadze – Psychologist of the centre of AIDS and Immunology
87. Tamar Kezeli – Pharmacologist
88. Neli Antelava – Pharmacologist

Physicians from different fields
89. Mariam Zhvania – Doctor
90. Tamar Kiknadze – Doctor
91. Tamar Gvardjaladze – Doctor
92. Irina Tsirkvadze – Doctor
93. Nana Tortladze – Doctor
94. Nino Turabelidze – Doctor
95. Alexsandre Gvazava – Doctor
96. Nukri Siradze – Doctor
97. Marine Abashidze – Doctor
98. Nona Odishelidze - Doctor
ANNEX 10 A and B: RECOMMENDATIONS OF PARTICIPANTS

Policy Workshop 25th October 2005, Tbilisi, Georgia

10 A: Policy / Drug Availability Workgroup Recommendations

- Establishing Institute of Palliative Care for Georgia;
- Training of Georgian faculty;
- Edit Georgian Essential Drugs list, to include MS oral, Tramadol, and generic MS;
- Confirm and increase number of MDs able to prescribe opioids;
- Step by step work out which community pharmacies can sell opioids, eg, category 1 pharmacies;
- Improve and increase hospice network in Georgia;
- Create and educate the group who will provide psychological support to patients (and families);
- Help families understand how to not over-care for their family members;
- Help MDs be more sensitive to patients' needs, and communicate what patients need and want to know;
- Introduce Palliative Care to public through media-goals: reduce Cancer phobia, increase knowledge of Palliative Care;
- Change national policy to include funding for other analgesics and medications for main symptoms, eg, NSAIDs, steroids, constipation, nausea, not just opioids (used to be 50-50 financing);
- Change the quantity of medication that can be delivered at one time, and the frequency of prescriptions;
- Change the need for supervising committees.

10 B: Education Workgroup Recommendations

- Patients Family Members, Volunteers, Society, Nurses, Doctors, Pharmacists Social Workers, Chaplains and Psychologists - All of these disciplines need to increase their skills in Palliative Care;
- In all medical, nursing and pharmacy schools and universities: Incorporate Palliative Care into a variety courses, including pharmacology, patient care;
- Medical students should start patient care in the first year of their studies;
- Teach all doctors how to care for patients at the end of life, including psychological and moral points;
- Increase physicians’ and trainees theoretical and practical knowledge about long-acting opioids and their pharmacology, and increase their practical clinical skills;
• Develop a separate course of Palliative Care in medical schools and postgraduate training;
• Establish postgraduate specialization in “Palliative Care”;
• Organize pain management courses for doctors, nurses, pharmacists (for everyone involved in pain management);
• Additional continuing education courses for doctors, nurses, pharmacists, psychologists, etc;
• Involve medical students as volunteers;
• Involve psychologists in regular visits with family members, to increase family member knowledge and skills;
• While some spiritual leaders have medical background, incorporate some aspects of Palliative Care in spiritual training;
• Each member of the Palliative Care team should learn how to increase family member knowledge;
• There is no social work in Georgia; families have unmet needs; is this an opportunity to introduce social work skills in Georgia;
• Volunteers can play a key role in Palliative Care. Students of medical schools may be ideal volunteers. This is an opportunity for members of the public;
• Improve the knowledge of the public through mass media, publications, etc.;
• Provide expert training for Palliative Care team members so they are both skilled at Palliative Care and know how to be effective teachers (trainer of trainers); And additionally:
• The addition of EPEC and ELNEC to the materials translated and disseminated in Georgia;
• There needs to be different advocacy materials for public and politicians;
• Include contact information for Palliative Care services where people can get information and care.

ANNEX 11: Strategy Document to Committee of Health and Social Affairs, Parliament of Georgia

Georgia National Pain Relief & Palliative Care Program

Strategy Document to the Parliament of Georgia, 30th October 2005

Palliative Care aims to relieve suffering and improve the quality of life of the living and dying. The World Health Organization (WHO) has advised all its member states on a rational public health approach to establish National Palliative Care programs. The European Council has advised Ministries of
Health on the importance of, and need for, Palliative Care.

Pain Relief and Palliative Care is one of the major unaddressed public health problems in Georgia. As there are over 43,000 deaths per year in Georgia, over 25,000 persons per year (60%) need palliative care. In cancer the need is higher. Of the 7,000-8,000 new cancers per year, two-thirds need palliative care.

Today, affordable, scientifically valid treatments exist to control pain and the multiple issues that cause suffering not only in cancer patients but also in terminally-ill elders and children regardless of their diagnosis, e.g. cardiovascular disease, stroke, accidents, AIDS. It is unethical not to implement Palliative Care to improve the quality of life for people living with advanced illnesses, and their family members.

Over the last three years significant steps have been taken to introduce Palliative Care in Georgia. Policy documents, handbooks and manuals for healthcare professionals, patients and families have been written as well as translated. More than 100 doctors, nurses and volunteers have successfully completed several continuing education courses conducted by both domestic and international faculty. Medical and nursing curricula for undergraduate training are ready to be implemented. Since late 2005, the new Palliative Care Unit at the National Cancer Centre has cared for about 200 patients and the mobile homecare team has cared for about 100 patients (more then 4 000 visits). National champions who are leading the implementation were also identified.

Even with these applaudable achievements, considering the size of the problem in Georgia, a National Palliative Care ProgramM is urgently needed.

It is recommended that Georgia:

- Establish Palliative Care as part of the national health plan and integrate it into the Georgia’s healthcare system at all levels;
- Make generic immediate-release and slow-release Morphine available and develop a rational prescription policy;
- Educate doctors, nurses, pharmacists, psychologists and social workers at all levels about Palliative Care.

As the majority of patients die at home in Georgia, in addition to establishing selected centres for excellence, this program should focus on a community approach so that the institutionalization and over medicalisation of death is avoided.

Following on our recent national policy workshop in Tbilisi, a national action plan with priorities and strategies, detailed steps to be taken and a first catalytic budget will be ready in December 2005.
Respectfully submitted, Tbilisi, Georgia, 30th October 2005

Dr. Dimitri Kordzaya
Ministry of Labor, Health and Social Affairs of Georgia
Founder of the Palliative Care Association “Humanists’ Union”

Dr. Rema Gvamichava
National Cancer Center
Director of Cancer Prevention Center
Founder of First Palliative Care Unit

Dr. Frank D. Ferris
Medical Director, Palliative Care Standards
San Diego Hospice & Palliative Care
International Advisor
Open Society Institute, New York

Dr. Jan Stjernswärd
Chief of Cancer, Emeritus
World Health Organization, Geneva
International Advisor
Open Society Institute, New York

WHO: Definition of palliative care, 1990, 2002


European Council: Recommendation Rec(2003)24 of the Committee of Ministers to member states on the organisation of palliative care

ANNEX 12: First Recommendations to Strategy Document

GEORGIA NATIONAL PAIN RELIEF AND PALLIATIVE CARE PROGRAM

The First Recommendations to the Strategy Document to the Parliament of Georgia
October 30, 2005

I. POLICY ISSUES:

1. Including Palliative Care in the priorities of upcoming National Health Plan for Georgia.
2. Development of comprehensive National Cancer Control Programm.
3. Establishment of a coordinating office at the Parliament of Georgia, in an
agreement between the Parliament, the Ministry of Labor, Health and Social Affairs of Georgia and NGO-s – for coordination and implementation of recommendations from the recent Policy workshop (upcoming Report December, 2005) together with international experts, during the coming two years. Dr. Dimitri Kordzaya (Officer of the Ministry of Labor, Health and Social Affairs, Founder of Palliative Care Association “Humanists’ Union”) is recommended as the head of the office.

4. Development of Palliative Care services throughout Georgia (at all the levels of the healthcare system) – Dr. Rema Gvamichava, - (“Cancer Prevention Centre”, National Cancer Centre, Ass. Professor of Tbilisi State Medical University) is recommended as the coordinator of the activities.

5. Making available generic immediate- release and slow- release Morphine combined with a change to rational prescription.

II. EDUCATION:

1. Introduction of “Palliative Care” into the curricula of medical and nursing students and clinical pharmacists;

2. Making Palliative Care (Palliative Medicine) sub-specialty and residency program;

3. Advocacy and continuous education system of policy-makers, drug regulators, the medical profession, social workers, volunteers, patients and their family members (trainings, workshops, TV programs and publications)

III. FINANCING

1. Continued and increased financing from the government:
   • Increase of budget for existing Palliative Care services (Palliative Care Unit and Mobile Home Care team)
   • Budget for new Regional Palliative Care services

2. Search for International donors support, in addition to already guaranteed OSI funded
   • For starting National Palliative Care Program
   • For future National Cancer Control Program (to be developed)
ANNEX 13: THE COMMUNITY APPROACH—NECESSARY TO ACHIEVE PALLIATIVE CARE FOR ALL

Stjernswärd Jan: Ind.J.PallCare, 2005, December 2005 ,11,2:52-58, and June 2005