Ethics Committee Agenda

Wednesday 4th September 2019,

Venue: Swedish Exhibition & Congress Centre

Room: Meeting Room 2

Time: 07:15 - 08:15

Chair: Ruwan Fernando,

Members: Elise De, Antonella Giannantoni, Cristina Naranjo Ortiz, Heidi Moossdorff-Steinhauser, Anne M Suskind, Kimberly Leblanc,

Unconfirmed:

Apologies: Nina Davis, Tamara Dickinson, Martha Spencer, Alvaro Bedoya-Ronga,

Also in Attendance: David Castro-Diaz

1. Committee picture to be taken
2. Approval Philadelphia teleconference minutes (attached), June teleconference notes (attached),
3. Committee Terms of Office (attached)
4. Committee Terms of Reference (attached)
5. Reminder - SOP process
6. Review and discussion of results of Needs Assessment Survey as basis for consideration of changes in TOR and in abetting planning for 2020 Annual Meeting activities (attached report)
7. Frailty white paper discussion (Anne Suskind)
8. Ethics Award discussion (Alvaro Bedoya-Ronga)
9. Request from Antonella Giannantoni to review her presentation relating to pain as a potential basis for a future programme – discussion (See June teleconference minutes)
10. Actions- updates/outstanding
11. AOB

Ethics Committee Minutes

Tuesday 28th August,

Venue: Pennsylvania Convention CENTER (PCC)

Room: Meeting Room 3

Time: 15.30-17.00

Chair: Nina Davis

Members: Tamara Dickinson, Cristina Naranjo Ortiz, Heidi Moossdorff-Steinhauser

Apologies: Elise De, Martha Spencer, Ruwan Fernando, Alvaro Bedoya Ronga, Chris Chatterton, Ryuji Sakakibara,

Also in Attendance: Avicia Burchill

1. Committee picture was not taken because of limited number of members present. Instead, informal photos were taken for the microsite.

ACTION POINT: Informal photos from the meeting are to be added to the EC microsite.

2. Approval Florence minutes and minutes from teleconference 28 April

The minutes were reviewed and approved.

ACTION POINT: All committee members to check their membership record to ensure their contact details are correct.

3. **Committee Terms of Office**

- Cristina Naranjo Ortiz stepping down in 2019 – ND asked if she could stay on as Board representative but CN is already rep on two other committees. CNO said she would check into this.

- Chris Chatterton, Martha Spencer, Ryuji Sakakibara, Tamara Dickinson – 1st term completed, will need to confirm whether they would like to renew for a second term

TD confirmed would like to continue

Post script notes: Martha Spencer confirmed her renewal

A discussion was held concerning the in-activity of certain committee members and AB explained the procedure set out in the bylaws to start the removal of committee members.

ACTION POINT: Office to send procedure for removal of committee members

ND mentioned that ED asked if she should step down because of multiple conflicts with other ICS responsibilities but ND explained that she didn't want her to resign as she always contributes, especially in teleconferences, and is an invaluable resource.

ACTION POINT: ICS Office to send list of education committee scientists

4. **EC Terms of Reference** (attached)

The terms of reference were reviewed and ND noted that she would like to broaden the educational remit of the EC to include workshops etc

ACTION POINT: ND to amend TOR and circulate to the committee to review before sending to the board for approval.

5. Workshop update (Heidi). Everyone is encouraged to attend on Thursday, 30 August - Time: 1400-15:30

6. Other Ethics activities at ICS 2018: Ethics Eposter session Friday, 31 August 12.35-13.30.

No award will be given this year but we should still support.

7. **Awaiting action**
   a. Approval of SOP and publication on microsite and other relevant areas of the ICS website

ND wanted to create a document that would govern our activities and to help the next chair. ND has drafted this but it needs to be sent to the office for clarification on some points and any suggested additions/corrections.

ACTION POINT: ND to circulate her SOP for the Ethics Committee to the office to review.

   b. Needs assessment (with ICS Office) regarding ethics-related activities and educational materials for the Core Curriculum that would be of benefit to the membership. ND would like to find out what the membership thinks about what the Ethics Committee should do.

ACTION POINT: EC and ICS Office to construct and send out a survey with questions so that the EC can focus their activities and better align with the interests of the membership.

   c. ND has volunteered to do a video based on the workshop in Bristol 8th November. ND explained that she will await workshop in Philly and then produce content. Projects for 2018-2019 and specifically, ICS 2019

8. **Workshop topic** – ND requested that EC members think about "hot topics" in medical ethics or other subject matter that would be appropriate for next year's workshop.

9. EC members are also requested to propose other activities we might sponsor, e.g. a debate and/or a roundtable. AB reminded the group that these ideas need to be written up and submitted ASAP to the Program Committee and Scientific Committee.

10. **White paper topic/report**. Need topic and volunteer(s) to prepare a proposal for Trustees review.

    Post script notes: Later in the meeting, Alex Digesu brought up the topic for consideration by EC members.

ACTION POINT: Need to set up teleconference soon to determine project(s) for the upcoming year.

ACTION POINT: In preparation for the teleconference, letter needs to be obtained from Alex Digesu

11. Teleconferences

a. Weekends vs weekdays: It is clear that we have had the best attendance on the weekends primarily because everyone can control their schedules. Therefore, it is agreed that teleconferences will continue to be held on weekends.

b. Teleconferences vs WebXs – ND indicated that she prefers the former. There was no consensus one way or the other, so it was decided to proceed with teleconferences for now. The ICS Office has had discussions with the Trustees regarding the difficulties that we had over the past several months in joining the teleconferences,. Hopefully, these will be resolved going forward.

c. Proposed dates for teleconferences October 20/21 or 26/27, early-mid-December, mid-March and June 15 (advance planning)

Respectfully submitted,

Nina S. Davis, M.D., FACS

Ethics Committee Chair

ICS Ethics Committee Teleconference 6/28/19 - Minutes

Attendees: Nina Davis (Chair), Heidi Moossdorff, Martha Spencer, Tamara Dickinson, Anne Suskind (incoming member), Antonella Giannantoni (incoming member), Kimberley Leblanc (incoming member)

1. Welcome to new members:

Antonella, Giannantoni Urologist in Sienna, Italy; primary interest neurourology/functional urology

Kimberly LeBlanc , PhD (Allied Health) Ottawa, Canada; advance practice nurse specialist in wound, ostomy and continence

Anne Suskind, San Francisco (US), urologist and scientist with subspecialty in female pelvic medicine; research focus = frailty in older adults

2. ND is unable to attend the upcoming meeting in Sweden due to family commitments, so will need a surrogate to carry out her duties at the meeting. She will prepare all of the relevant materials. A volunteer was requested, but no offers were forthcoming. **This will be revisited via the EC Forum**

MS also mentions that she will be unable to attend.

3. The group reviewed the 2 abstracts submitted in the ethics category. Both were felt to have suitable subject matter for study, but the actual research question(s), rationale and outcomes to be assessed were unclear. In short, it was felt that these were poorly executed studies. As a result, it was unanimously agreed that neither merited an award. Therefore **no Ethics Award will be presented this year. ND to notify Dr. Stewart, Scientific Committee Chair.**

A decision will also need to be made at the EC meeting in Sweden as to whether or not the Ethics Award is to continue to be offered.

4. Needs Assessment was carried out earlier this year – "Five Questions in Five Minutes". 125 members responded. PDF summaries of the answers were prepared and reviewed in general terms. **The data will need to be placed on the forum** for further discussion and to be used as a guide to future programs.

The five questions were as follows (Most were 2-part questions. A yes or no question and an explanation of the answer including recommendations.)

1. *Do you believe the Ethics Committee is of value to the ICS? Briefly explain your answer.*
2. *Do you know of other organisations that have an Ethics Committee? If so, please name the organisation and the Ethics Committee's activities for that organisation.*
3. *Have you attended any programmes sponsored by the ICS Ethics Committee? If so, how many?*
4. *If you have attended any programmes conducted by the ICS Ethics Committee, did you benefit from the programmes? Please briefly explain why you did or did not benefit.*
5. *What type of programmes, activities or content should the Ethics Committee be providing to best serve the needs of the ICS membership?*

There was insufficient time before the meeting for dissemination and digestion of the results, so ND summarised some of the topics that were suggested for future programmes:

-the ethics of adopting medications or devices not adequately tested or proven to be effective or safe. [Thought for a programme, "From Snake Oil to Mesh-Ethical Discussion of Physician Adoption of New Medications and Technologies"]
-Transgender issues
-Research Ethics
-Basic course on biomedical ethics

The results have been converted to PDF form for ease of review and **will be posted on the forum** shortly. **A review by members is requested in preparation for in-depth discussion at the meeting in Goteborg.**

5. Regarding activities for this year, a video on frailty assessment prior to surgery was written and filmed by ND in Bristol in November. In conjunction with this, MS expressed a desire to proceed with a **white paper on frailty in the elderly** which was previously put forward. There was unanimous enthusiasm for this proposal. Given that oncoming member, AS, is both our scientific member and a geriatric urologist, she will help lead this effort. She proposed that there be further **teleconferences for planning, and ND suggested that these start soon (after the 4th of July holiday) so that a proposal can be put forth to the trustees, etc. for approval at or before the Annual Meeting. MS pointed out that the potential subject matter is broad, so she and AS will work on determining the areas upon which to focus the white paper. They will then solicit assistance from the EC members.**

6. New Business. Oncoming member, AG, asked if the EC would be interested in reviewing a recent programme she presented at her facility relating to pain as a potential basis for a future programme. **AG was encouraged to send the PowerPoint, etc. to ND for inclusion in the forum and for discussion at the Goteborg meeting.**

NOTE: Action items are bolded.

Respectfully submitted,

Heidi Moossdorff

Nina Davis

White paper not started. Martha will make an outline for a whitepaper. We will try to arrange a meeting before the end of July.

Nothing from the ethics committee in Sweden because nobody offered.

Antonella…**didn't hear it very well**. Antonella will present XX to the committee in Sweden. Send presentation or summary.

ICS Ethics Committee Terms of Reference

1.

PURPOSE: To establish and maintain proper conduct of the ICS in matters of ethical consideration

2. FUNCTIONS:

1. Develop policies to ensure that all research presented to the Society is carried out in compliance with international ethical standards for the conduct of human and animal research. These policies will then be presented to the Board of Trustees for approval and implementation. Establish, update, monitor and enforce disclosure policy regarding conflicts of interest as they apply to ICS members, officers and meeting participants
2. Organise an educational workshop and one or more other programmes dealing with ethical issues relevant to the interests of ICS members. These are to be presented at the annual scientific meeting.
3. Develop position papers on ethical matters on behalf of the ICS
4. Serve as a resource for resolution of ethical questions raised by the Board of Trustees or by the ICS membership
5. Serve as a liaison between the membership and the Board of Trustees to convey views and opinions regarding ethical issues that may arise.
6. Undertake such additional matters as may from time to time be **required** of the committee by the General Secretary and Board of Trustees.

3. RESPONSIBLE TO: ICS Board of Trustees and ICS General Secretary

4. COMPOSITION:

Total Members	**Method of Appointment**	**Name**	**Term of Office**
General Secretary/ Board Liaison rep	**Ex officio**	See Membership Page	**3 years**
Chair:	Elected. A member must sign his/her agreement to stand. This nomination is signed by nominator and seconder, all being current ICS members. The nominee for Chair would be a current or recent member (past 5 years) of the Ethics Committee. If no one is nominated the ICS Nominations committee may suggest a suitable candidate. Nominations received by 1st March for current members all other applications by 1st April.	See Membership Page	Term of office: 3 years, renewable once by formal election
Membership	All members of ICS committees must be active ICS members (paid for current membership year) (By-law 2.3.2) 9 members each with 3 year term of office, 3 retiring each year ensuring a regular rotation through the committee.	See Membership Page	3 years, renewable once by Chair/committee approval.

	The optimum representation is 10 Committee members formed preferably from the following: 2 gynaecologists 2 urologists 1 geriatrician 1 physiotherapists 1 Allied Health Professional 2 scientists 1 nurse		Further terms could be approved in exceptional circumstances and by referral to the ICS Trustees. The committee will have a maximum of 10 people.
Subcommittees (if any)	Ad hoc		
Updated December 2018			

5. **MEETINGS:** One face-to-face meeting during the Annual Scientific meeting. Other meetings throughout the year by teleconference, as required, and by email/online forum.

6. **QUORUM:** One third of committee membership plus one. For example, a committee of ten will have a quorum of four members.

7. **MINUTES:** Minutes are recorded at each meeting and posted on the ICS and CPC website in accordance to 2009 ICS Bylaw 6.1-6.4).

8. **REPORTING & ROLES:**
The Chair is responsible to the Board of Trustees, and to the members of the ICS at the AGM. The Chair must table a report at the AGM and be available to answer comments from members. The Report will be available to members 6 weeks ahead of the AGM so members can come prepared. The Chair should not read out the Report at the AGM but draw attention to important areas. If important issues should arise during the year, the Chair must advise the General Secretary, without delay.

For Terms of Office Information please see Membership Page

Ethics Committee Terms of Office

Member	Role	Term Start	Term End	Term Yrs	Elected	Term details	Additional Information
Nina Davis	**Chair**	23-Oct-14	28-Aug-20	**6**	**Y**	**6 year term will finish in 2020- CANNOT BE RE-ELECTED**	
Cristina Naranjo Ortiz	Committee member	29-Aug-13	05-Sep-19	6	N	**6 year term will finish in 2019 - CANNOT RENEW**	
Ruwan Fernando	Committee member	23-Oct-14	28-Aug-20	6	N	6 year term will finish in 2020- cannot renew	
Alvaro Bedoya Ronga	Committee member	23-Oct-14	28-Aug-20	6	N	6 year term will finish in 2020- cannot renew	
Elise De	Committee member	23-Oct-14	28-Aug-20	6	N	6 year term will finish in 2020- cannot renew	
Heidi Moossdorff-Steinhauser	Committee member	08-Oct-15	14-Oct-21	6	N	6 year term will finish in 2021- cannot renew	
Martha Spencer	Committee member	16-Sep-16	08-Sep-22	6	N	6 year term will finish 2022 - cannot renew	
Tamara Dickinson	Committee member	16-Sep-16	08-Sep-22	6	N	6 year term will finish 2022 - cannot renew	
Kimberly LeBlanc	Committee member	05-Sep-19	08-Sep-22	3	N	3 year term will finish in 2022- can renew	**Allied Health**
Anne Suskind	Committee member	05-Sep-19	08-Sep-22	3	N	3 year term will finish in 2022- can renew	**Scientific Rep**
Antonella Giannantoni	Committee member	05-Sep-19	08-Sep-22	3	N	3 year term will finish in 2022- can renew	**Scientific Rep**
David Castro-Diaz	Ex-officio	25-Feb-15	05-Sep-19	4	N	Ex-officio	

Quorate No=5
Committee number =10

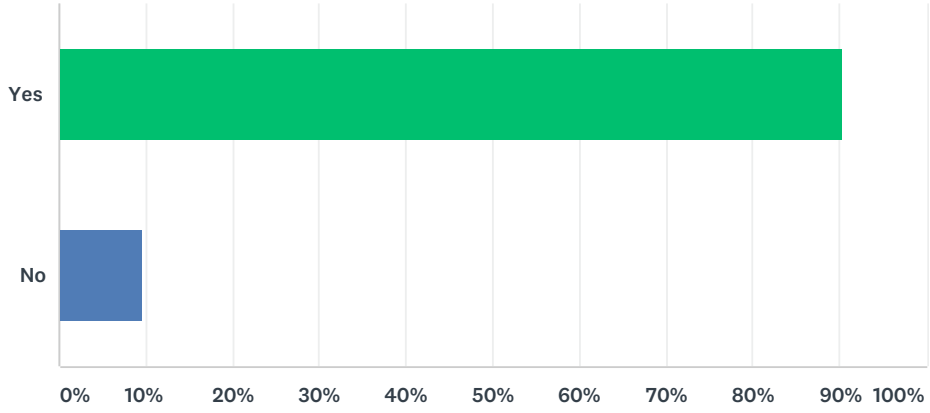
Nominations 2019

Stepping down in Gothenburg: Cristina Naranjo Ortiz
Elect: Will need to call for Chair position
Stepping down in Las Vegas: Ruwan Fernando, Alvaro Bedoya Ronga, Elise De
New members in Gothenburg: Kimberly LeBlanc, Anne Suskind, Antonella Giannantoni

Key	
Colour	**Meaning**
	Stepping down in Gothenburg
	Stepping down in Las Vegas
	Elect position- will need to re-apply
	Will need to confirm if renewing/ positions will need to be advertised after Gothenburg
	New member/position
	No action

Q1 1. Do you believe that the Ethics Committee is of value to the ICS?

Answered: 125 Skipped: 0



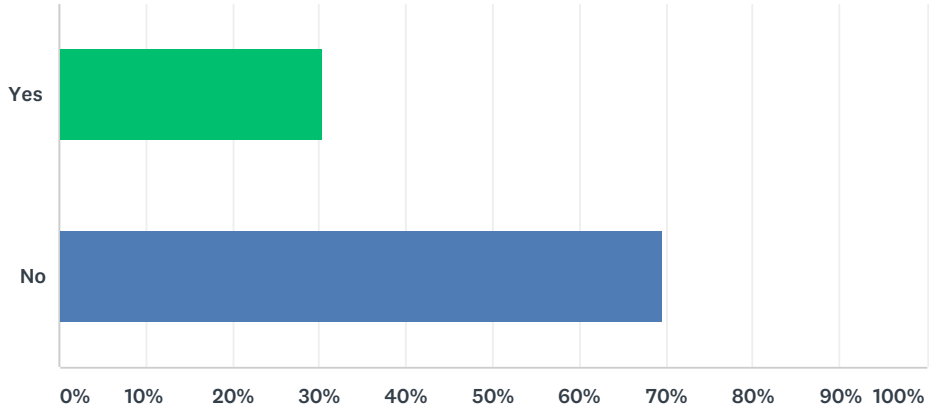
ANSWER CHOICES	RESPONSES	
Yes	90.40%	113
No	9.60%	12
TOTAL		125

Q2 Please briefly explain your answer

Answered: 65 Skipped: 60

Q3 2. Do you know of other organisations that have an Ethics Committee?

Answered: 125 Skipped: 0



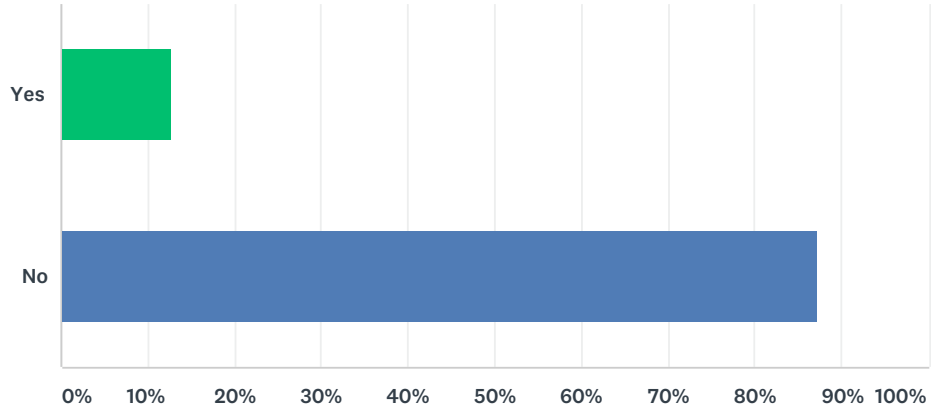
ANSWER CHOICES	RESPONSES	
Yes	30.40%	38
No	69.60%	87
TOTAL		125

Q4 If so, please name the organisation and the EC’s activities for that organisation.

Answered: 25 Skipped: 100

Q5 3. Have you attended any programmes sponsored by the ICS Ethics Committee?

Answered: 125 Skipped: 0



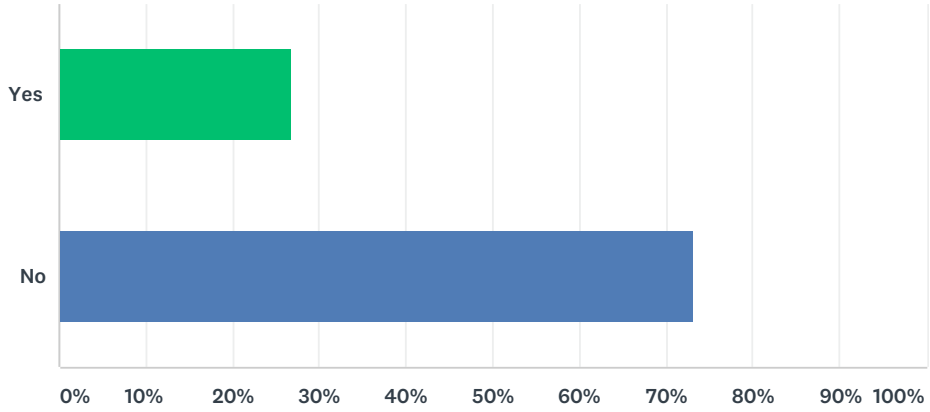
ANSWER CHOICES	RESPONSES	
Yes	12.80%	16
No	87.20%	109
TOTAL		125

Q6 If so, how many?

Answered: 14 Skipped: 111

Q7 4. If you have attended any programmes conducted by the ICS Ethics Committee, did you benefit from the programme(s)?

Answered: 56 Skipped: 69



ANSWER CHOICES	RESPONSES	
Yes	26.79%	15
No	73.21%	41
TOTAL		56

Q8 Please briefly explain why you did or did not benefit.

Answered: 25 Skipped: 100

Q9 5. What type of programmes, activities or content should the EC be providing to best serve the needs of the ICS membership?

Answered: 65 Skipped: 60

ETHICS COMMITTEE REPORT
ICS 2019

(Please note this document will be after the Ethics Committee (EC) meeting Wednesday, September 4, 2019.)

1. EC Committee Membership

The EC Membership normally includes 10 individuals including the Chair. This is felt to be the optimal number to support EC activities. However, this year, we lost our 2 scientific representatives – Chris Chatterton, Ph.D. who resigned due to health and professional reasons and Ryuji Sakakibara who was asked to leave the EC due to lack of participation.

Current EC Committee Membership

Nina S. Davis (US) Chair/Urologist
Alvaro Bedoya-Rongo (UK) Urogynaecologist
Elise De (US) Urologist
Ruwan Fernando (UK) Urogynaecologist
Cristina Naranjo-Ortiz (Spain) Physiotherapist
Heidi Moossdorff-Steinhauser (NL) Physiotherapist
Martha Spencer (CAN) Geriatrician
Tamara Dickinson (US) Advance Practice Nurse Practitioner

We are also grateful for the ongoing support of **David Castro-Diaz** as ex officio member from the Board of Trustees.
We will very much miss **Cristina Naranjo-Ortiz** who will be rotating off of the committee after this meeting.

After a very successful election this spring, the EC is welcoming 3 new members:
Anne Suskind (US) Urologist/geriatrician/scientist
Kimberly Leblanc (CAN) Advanced Practice Nurse Specialist in Wound/Ostomy/Incontinence
Antonella Giannantoni (IT) Neurourologist

Dr. Suskind was co-opted last year after joining the ICS to participate in our very successful workshop.

2. Activities/Achievements

- The ICS 2018 free workshop (Core Curriculum), **Ethical Dilemmas in the Care of the Aging Patient: A Case-Based Interactive Workshop** focused on medical decision-making

in the care of the frail elderly built on the success of the prior year and may have exceeded our prior attendance record, as it was, literally, standing room only. There was spirited interaction from all attendees. Once again, the workshop received high grades from the participants.

- Building on the success of the workshop, **Nina Davis** traveled to Bristol and filmed a video, "Frailty Assessment and Surgical Planning for the Geriatric Patient". Thanks to the ICS staff for their professionalism and expertise in filming and editing the piece and gratitude as well to Adrian Wagg for assistance with preparing the content.
- This year, no workshop is being offered, as it was felt by Chair, Nina Davis, that it was time to step back and re-evaluate the TOR of the EC via a needs assessment to help to better focus the activities of the committee and, by addressing the expressed needs of the membership, to be able to then integrate them as dictated by the Trustees' Strategic Plan.
- The EC continues to be committed to encouraging ethics submissions for the Annual Meeting. Sadly, only one award has been given out in the three years we have been offering the prize. This occurred at the Florence meeting. This year, in spite of a significant increase in PR efforts including reworking and reissuing of a video by **Alvaro Bedoya-Rongo**, an article and reminders in the eNews as well as inclusion of examples of appropriate submissions on the application website, there were no submissions worthy of consideration. That is, only 3 submissions were received. They were rejected by reviewers for inclusion in this year's Programme, and a further review by members of the EC found none to be deserving of consideration for the award. Therefore, it was decided not to give out a prize this year. The EC had hoped that, with time, the Ethics Award would become an inducement for trainee submissions in particular and a sought-after award, but this has not come to pass. At the EC's annual meeting here in Gothenburg, discussion was held as to whether or not to continue offering the award.

3. Future Projects and Activities

- A Needs Assessment was carried out earlier this year – "Five Questions in Five Minutes". **125 members** responded.
  The five questions were as follows (Most were 2-part questions. A yes or no question and an explanation of the answer including recommendations.)
- *Do you believe the Ethics Committee is of value to the ICS? Briefly explain your answer.*
- *Do you know of other organisations that have an Ethics Committee? If so, please name the organisation and the Ethics Committee's activities for that organisation.*
- *Have you attended any programmes sponsored by the ICS Ethics Committee? If so, how many?*
- *If you have attended any programmes conducted by the ICS Ethics Committee, did you benefit from the programmes? Please briefly explain why you did or did not benefit.*
- *What type of programmes, activities or content should the Ethics Committee be providing to best serve the needs of the ICS membership?*

Preliminary analysis of the survey was carried out this spring was discussed at our teleconference in June. **Elise De** was kind enough to summarise some of the key themes proposed by the respondents:

1) Research ethics
2) International differences
3) Public health ethics (e.g. FGM)
4) Clinical scenarios (e.g. neurogenic patient declining intervention)
5) Pharma/adoption of medications or devices not adequately tested

Additionally, a basic course in biomedical ethics has been requested off and on for many years and the survey reinforced this. **Elise De** proposed an early career session, but adding a video on the subject to the Core Curriculum seems essential. The EC will continue to mine and analyse the data for important subject matter to drive future activities.

- The EC will continue to expand its microsite with educational content so that it will also serve as an informational resource for membership.
- The EC will continue to develop materials with ethics-related content as its contribution to the ICS Core Curriculum. Our geriatric members, **Martha Spencer** and **Anne Suskind**, with the support of the EC member, are preparing a white paper on ethical care of the frail elderly. Preliminary planning has been carried out by teleconference, and, per the ICS SOP, a proposal is being prepared and will soon be submitted to the Trustees for review and approval.

4. Budget Request

The EC budget request for 2019-20 has been appended to this report.

5. Special thanks to the ICS Office for their forbearance, responsiveness and ongoing support of EC activities.

Respectfully submitted,

Nina S. Davis, M.D., FACS
Ethics Committee Chair

	2019-2020 BUDGET REQUEST - ICS ETHICS COMMITTEE			
Budget Item Request	Cost	Justification	Alignment to ICS strategy	Objectives (should be specific and measurable)
Conference calls, 3/year for up to 10 individuals including co-opted member(s), ICS Staff and Dr. Castro-Diaz, Trustee member	£500	*The conference calls are integral to conducting the business of the committee including communication of important information, sharing and expanding upon ideas regarding projects such as composing white papers or organising workshops/activities for the ICS Annual Meeting, as well as discussing issues of concern to the committee.*	*-Ongoing EC monitoring of COI compliance ensures that the integrity of the organization is maintained* *-Programmes deriving from a needs assessment survey distributed to the entire membership which, it is hoped, will guide the EC to ever more relevant educational programmes and materials that will significantly enhance the Core Curriculum.* *-Produce consensus and policy papers that will advance the academic objectives of the ICS and enhance its standing in establishing global policy.*	*-Maintain the highest level of academic integrity through monitoring of COI reporting and assessing commercial bias in the ICS-sponsored programmes* *-Publish 1-2 white papers or reviews/year on ethical topics of global concern* *-Provide an annual workshop to the scientific programme for the ICS Annual Meeting* *-Contribute a unique activity of interest to the general membership dealing with one or more "hot topics" in global ethics including debates that may be conducted as part of a workshop or as a stand-alone presentation at the Annual Meeting.*
Best Ethics Poster Award at the Annual Meeting	£500	*As approved by the Trustees. The cost would be applied to annual meeting budget.*	*Encourages submissions by trainees and early-career attendees*	*-Increased number of submissions under the Ethics category* *-Increased number of submissions by trainees and early-career professionals*
Total Cost	£1,000			

Chronic pain management: a right for patients, a challenge for physicians

Antonella Giannantoni

Department of Medical and Surgical Sciences and Neurosciences,
Functional and Surgical Urology Unit
University of Siena, Italy

1

Pain is a public health priority

The treatment of pain is a public health priority due to:

- the considerable, global burden of acute and chronic pain
- its continuous global increasing

Goldberg et al., BMC Public Health. 2011

2

Burden of chronic pain

A recent analysis of the burden of chronic pain without clear etiology in individuals living in low and middle income countries indicated that:

- prevalence of unspecified chronic pain is **34%** in the general population
- with **42%** suffering from a headache
- and **21%** from low back pain

Jackson et al., Anesth Analg. 2016

3

Global Burden of diseases and pain

Global Burden of Disease Study 2015 analysis on global, regional and national incidence, prevalence and years lived with disability for as many as 301 acute and chronic diseases, in 188 countries between 1990 and 2013:

- among the top ten diseases/conditions that caused disability, **pain** (low back pain) **was ranked at the first place**,
- anxiety and depression among the top ten

Global Burden of Disease Study 2013 Collaborators. Lancet 2015

4

Global Burden of diseases and pain

5

Data on Urologic chronic pelvic pain syndrome (UCPPS) from the MAPP Research Network-USA

Definition: it is a debilitating bladder disorder characterized by urinary urgency, frequency and pelvic pain

UCPPS is poorly understood, and treatment is mostly empyrical, with unsatisfactory patient outcomes

Prevalence exstimates in the past decade (USA):
> 10 million (3-7% in women; 2-4% in men)

Clemens et al., Nat rew Urol 2019

6

The right to pain relief

«Pain-relief treatment… is a fundamental human right»
Sommerville M.A. 2001

«Relief of severe, unrelenting pain would come at the top of a list of basic human rights»
Cousins, 1999

7

Pain management is a fundamental, human right

Brennan et al., 2004, 2007…2019
Lohman et al., 2010

8

A cry in the dark

These early statements linking pain management and human rights still are, in many ways, cries in the dark due to the enormous global burden of pain and its widespread under-treatment

9

Pain alleviation is a core ethical duty

To date pain management for physicians represents an ethical responsability and is a basic element of ethical codes

The *American Medical Association* states that:
"Physicians have an obligation to relieve pain and suffering"

JAMA 1992

The *World Health Assembly* states that:
"it is an ethical duty of health care professionals to alleviate pain and suffering"

Resolution 67, 19, 2014

10

Pain alleviation is a core ethical duty

Today at the dawn of the 21st century, the best available evidence indicates a major gap between an increasingly understanding of the pathophysiology of pain and widespread inadequacy of its treatment.

M. Daher. Pain relief is a human right - Asian Pac J Cancer Prev. 2010

11

The right to pain management lies in the rights to health

Although there may be a moral obligation to manage pain, is there a basis for a right to treatment of pain in human rights law?

Internationally, human rights are founded on recognition of the inherent dignity of the human person and expressed in international human rights conventions

The foundations for the assertion of pain management among human right lie in the **international rights to health**

12

Chronic non cancer pain (CNCP) and human rights

Much has been written about *the human rights dimensions* of pain management in acute cancer pain

Analyzing obligations about the right of health for CNCP is more complex, due to:

a. CNCP is a broad term including many different pain syndromes, with different etiologies

Treede et al., Pain 2015

b. Unlike cancer pain, who received clear guidelines on pharmacological treatment, **no WHO clinical guidelines exists for CNCP in adults**

Brennan et al., AJPH 2019

13

Problems in assessing and treating CNCP

For many types of CNCP the evidence for most effective treatment modalities is relatively weak

Efforts are still needed to determine whether pain treatment services meet the quality requirement under the right to health

Chronic pain requires a wide array of treatment modalities, but only some of the medicines used are included in the **WHO Model List of Essential Medicines**

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World Health Organization
Model List of Essential Medicines
21st List
2019

Core list: list of minimum medicine needs for a basic health-care system, with the most efficacious, safe and cost–effective medicines for priority conditions.

Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment…..

World Health Organization Model List of Essential Medicines, 21st List, 2019. Geneva: World Health Organization; 2019.

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World Health Organization

WHO Model List of Essential Medicines 21st edition

1.4 Medical gases	
oxygen*	**Inhalation** For use in the management of hypoxaemia. *No more than 30% oxygen should be used to initiate resuscitation of neonates less than or equal to 32 weeks of gestation.
2. MEDICINES FOR PAIN AND PALLIATIVE CARE	
2.1 Non-opioids and non-steroidal anti-inflammatory medicines (NSAIMs)	
acetylsalicylic acid	**Suppository:** 50 mg to 150 mg. **Tablet:** 100 mg to 500 mg.
ibuprofen [a]	**Oral liquid:** 200 mg/5 mL. **Tablet:** 200 mg; 400 mg; 600 mg. [a] Not in children less than 3 months.
paracetamol*	**Oral liquid:** 120 mg/5 mL; 125 mg/5 mL. **Suppository:** 100 mg. **Tablet:** 100 mg to 500 mg. * Not recommended for anti-inflammatory use due to lack of proven benefit to that effect.
2.2 Opioid analgesics	
codeine	**Tablet:** 30 mg (phosphate).
fentanyl*	**Transdermal patch:** 12 micrograms/hr; 25 micrograms/hr; 50 micrograms/hr; 75 micrograms/hr; 100 micrograms/hr *for the management of cancer pain
morphine*	**Granules (slow release, to mix with water):** 20 mg–200 mg (morphine sulfate). **Injection:** 10 mg (morphine hydrochloride **or** morphine sulfate) in 1- mL ampoule. **Oral liquid:** 10 mg (morphine hydrochloride **or** morphine sulfate)/5 mL. **Tablet (slow release):** 10 mg–200mg (morphine hydrochloride **or** morphine sulfate). **Tablet (immediate release):** 10 mg (morphine sulfate). *Alternatives limited to hydromorphone and oxycodone

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World Health Organization

methadone*	**Concentrate for oral liquid:** 5 mg/mL, 10 mg/mL (as hydrochloride) *For the management of cancer pain.
2.3 Medicines for other common symptoms in palliative care	
amitriptyline	**Tablet:** 10 mg, 25 mg, 75 mg.
cyclizine [a]	**Injection:** 50 mg/mL **Tablet:** 50 mg.
dexamethasone	**Injection:** 4 mg/mL in 1-mL ampoule (as disodium phosphate salt). **Oral liquid:** 2 mg/5 mL. **Tablet:** 2 mg [b]; 4 mg.
diazepam	**Injection:** 5 mg/mL **Oral liquid:** 2 mg/5 mL. **Rectal solution:** 2.5 mg; 5 mg; 10 mg. **Tablet:** 5 mg; 10 mg.
docusate sodium	**Capsule:** 100 mg. **Oral liquid:** 50 mg/5 mL.
fluoxetine [c]	**Solid oral dosage form:** 20 mg (as hydrochloride). [c] >8 years.
haloperidol	**Injection:** 5 mg in 1- mL ampoule. **Oral liquid:** 2 mg/mL **Solid oral dosage form:** 0.5 mg; 2mg; 5 mg.
hyoscine butylbromide	**Injection:** 20 mg/mL
hyoscine hydrobromide [c]	**Injection:** 400 micrograms/mL; 600 micrograms/mL **Transdermal patches:** 1 mg/72 hours.
lactulose [b]	**Oral liquid:** 3.1–3.7 g/5 mL.
loperamide	**Solid oral dosage form:** 2 mg.
metoclopramide	**Injection:** 5 mg (hydrochloride)/mL in 2 mL ampoule. **Oral liquid:** 5 mg/5 mL. **Solid oral form:** 10 mg (hydrochloride).
midazolam	**Injection:** 1 mg/mL; 5 mg/mL **Solid oral dosage form:** 7.5 mg; 15 mg. **Oral liquid:** 2mg/mL [c].
◻ ondansetron [c] [c]	**Injection:** 2 mg base/mL in 2 mL ampoule (as hydrochloride). **Oral liquid:** 4 mg base/5 mL.

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World Health Organization

Strengthening of palliative care as a component of integrated treatment within the continuum of care

The Executive Board… URGES Member States:

(1) to develop, strengthen and implement, where appropriate, palliative care policies…

(2) to ensure adequate domestic funding and allocation of human resources, as appropriate, for palliative care initiatives, …

(3) to provide basic support, including through multisectorial partnerships, to families, community volunteers and other individuals acting as caregivers,…

(4) to aim **to include palliative care as an integral component of the ongoing education** and training offered to care providers…

(5) to review, and, where appropriate, revise national and local legislation and policies for controlled medicines, with reference to WHO policy guidance1 to improve access and rational use of pain management medicines…

Agenda item 9.4 23 January 2014

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If it wasn't a dramatic situation it would be a someway ridiculous one…

While looking at many state legislations limiting or forbidding opioids, even for terminally ill patients, with the motivation that those drugs are "addictive", one can't help thinking of the old jokes about last cigarettes…

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…but isn't chronic non cancer pain a priority condition?

20

International Association for the Study of Pain (IASP)

"Chronic pain should receive greater attention as a global health priority because adequate pain treatment is a human right, and it is the duty of any health care system to provide it"

IASP 2019

Pain as a global public health priority. Goldberg DS, McGee SJ BMC Public Health. 2011

…patients have a **right to pain management**, and they give content to that right. Such content includes the patient's right to be believed in the expression of pain, the right to appropriate assessment and management of pain, the right to be cared for by health professionals with training and experience in assessment and management of pain

Brennan et al. 2007

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The more recent IASP contribution

The development of a new classification system for chronic pain diagnosis

IASP 2019 NANTES 24-27 SEPTEMBER FRANCE

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BACKGROUND

1. In the International Classification of Diseases of WHO, chronic pain diagnoses are not represented systematically
2. They lack of appropriate codes:
   a. this renders accurate epidemiological investigations difficult
   b. it impedes health policy decisions regarding chronic pain such as **adequate financing** of access to multimodal pain management

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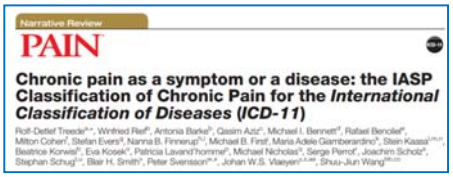
…WHO and IASP working Group on Chronic Pain

In cooperation with the WHO, the IASP Working Group has developed a classification system that is applicable in a wide range of contexts, including pain medicine, primary care, and low-resource environments


Narrative Review

PAIN

Chronic pain as a symptom or a disease: the IASP Classification of Chronic Pain for the *International Classification of Diseases* (*ICD-11*)

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On June, 3th 2019

WHO approved the International Classification of diseases (ICUD-11), with new codes for chronic pain

World Health Assembly of the WHO Approves 11th Version of the International Classification of Diseases (ICD-11), Including New Diagnostic Codes for Chronic Pain

IASP Task Force worked closely with World Health Organization to develop new classification system of chronic pain for improved patient care and research

WASHINGTON, DC – June 3, 2019 – The World Health Organization (WHO) has adopted ICD-11, the latest revision of its International Classification of Diseases, including a new classification system for chronic pain. The decision was made at the World Health Assembly on 25 May 2019.

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IASP definition of chronic pain

"Persistent or recurrent pain lasting longer than 3 months" This definition according to pain duration has the advantage to be clear and operationalized

Optional specifiers for each diagnosis record evidence of the **severity of the pain** and **psychosocial factors**

Pain severity can be graded based on pain intensity, pain-related distress, and functional impairment

Treede et al., Pain 2019

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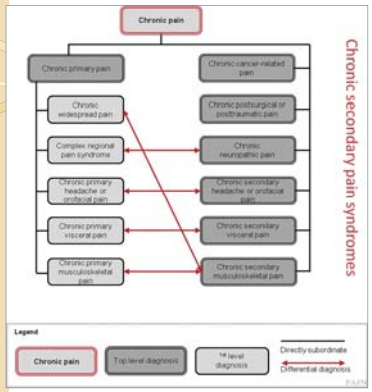
Figure 1



Chronic pain as a symptom or a disease: the IASP Classification of Chronic Pain for the International Classification of Diseases (ICD-11)

Treede, Rolf-Detlef; Rief, Winfried; Barke, Antonia; Aziz, Qasim; Bennett, Michael I.; Benoliel, Rafael; Cohen, Milton; Evers, Stefan; Finnerup, Nanna B.; First, Michael B.; Giamberardino, Maria Adele; Kaasa, Stein; Korwisi, Beatrice; Kosek, Eva; Lavand'Homme, Patricia; Nicholas, Michael; Perrot, Serge; Scholz, Joachim; Schug, Stephan; Smith, Blair H.; Svensson, Peter; Vlaeyen, Johan W.S.; Wang, Shuu-Jun

PAIN160(1):19-27, January 2019.

doi: 10.1097/j.pain.0000000000001384

Structure of the IASP Classification of Chronic Pain. In chronic primary pain syndromes (left), **pain can be conceived as a disease**, whereas in chronic secondary pain syndromes (right), pain initially manifests itself as a symptom of another disease such as breast cancer, a work accident, diabetic neuropathy, chronic caries, inflammatory bowel disease, or rheumatoid arthritis. Differential diagnosis between primary and secondary pain conditions may sometimes be challenging (arrows), but in either case, the patient's pain needs special care when it is moderate or severe. After spontaneous healing or successful management of the underlying disease, chronic pain may sometimes continue and hence the chronic secondary pain diagnoses may remain and continue to guide treatment as well as health care statistics.

Wolters Kluwer

27

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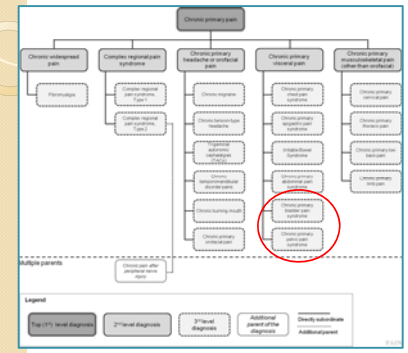
Figure 1



The IASP classification of chronic pain for ICD-11: chronic primary pain

Nicholas, Michael; Vlaeyen, Johan W.S.; Rief, Winfried; Barke, Antonia; Aziz, Qasim; Benoliel, Rafael; Cohen, Milton; Evers, Stefan; Giamberardino, Maria Adele; Goebel, Andreas; Korwisi, Beatrice; Perrot, Serge; Svensson, Peter; Wang, Shuu-Jun; Treede, Rolf-Detlef; The IASP Taskforce for the Classification of Chronic Pain

PAIN160(1):28-37, January 2019.

doi: 10.1097/j.pain.0000000000001390

The general structure of the classification of chronic primary pain. Level 1 and 2 are part of the 2018 frozen version of ICD-11; level 3 has been entered into the foundation layer. According to the new concept of multiple parenting in ICD-11, an entity may belong to more than one group of diagnoses.

Wolters Kluwer

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Extension codes: pain severity

Pain intensity: the strength of the subjective pain experience; **"how much does it hurt?"**

Assessment: verbally, or on a numerical (NRS) or VAS

Pain-related distress: psychological (cognitive, behavioral, and emotional), social, or spiritual distress;

"how distressed are you by the pain?"

Assessment: on a NRS or a VAS from "no pain-related distress" to "extreme pain-related distress"

Pain-related interference (last week): daily life activities & partecipation

"how much does the pain interfere with your life?"

Assessment: on a NRS or VAS

PAIN SEVERITY

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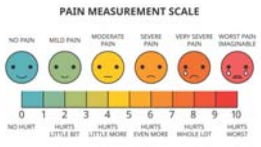
Extension codes: pain severity

Overall **severity** combines the ratings of **intensity**, **distress**, and **disability** using a 3-digit code:

Example: a patient with a moderate pain intensity, severe distress, and mild disability will receive the code "**231**."

The severity code is optional.



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Other extension codes

Temporal characteristics of the pain

a. continuous

b. episodic recurrent

c. continuous with exacerbations

Presence of psychosocial factors

This code permits coding problematic **cognitive** (eg, catastrophizing, excessive worry), **emotional** (eg, fear, anger), **behavioral** (eg, avoidance) and/or **social factor**s (eg, work, relationships) that accompany the chronic pain

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In 2013 EAU guidelines poned a question:

Is management of chronic pelvic pain a habit,

a philosophy, or a science?

10 years of development.

Engeler et al., Eur Urol 2013;64:431–9.

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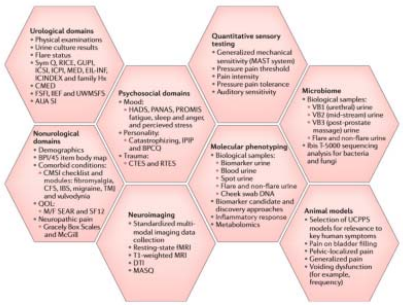
Urologic chronic pelvic pain syndrome: insights from the MAPP Research Network

Clemens et al., Nat Rew Urol 2019

MAPP I. First phase (10 yrs). Data domains and protocols



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Main observations from the MAPP Research Network

Clemens et al., Nat Rew Urol 2019

Key points

- In urologic chronic pelvic pain syndrome (UCPPS), urological pain and urinary symptoms co-vary, with only moderate correlation, and should be evaluated separately rather than as part of a composite score.
- Participants with UCPPS who report pain beyond the pelvis have more severe UCPPS symptoms and more symptom flares than those with pelvic pain only.
- Participants with UCPPS reported more psychosocial difficulties than pain-free healthy control individuals; poor psychosocial functioning in participants with UCPPS was associated with a low likelihood of symptom improvement over time.
- UCPPS involves disturbances in brain-level sensorimotor systems regulating urine storage; these disturbances are powerful enough to produce differences not only in brain function but also in brain structure.
- Different UCPPS symptom profiles are distinguishable by their biological correlates (for example, immune factors).
- Quantitative sensory testing has revealed markedly higher pressure pain sensitivity in participants with UCPPS than in healthy control individuals; high sensitivity was associated with a low likelihood of UCPPS symptom improvement.

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A need for physicians involved in pain management:

All the involved physicians require to know laws and ethics in management of pain

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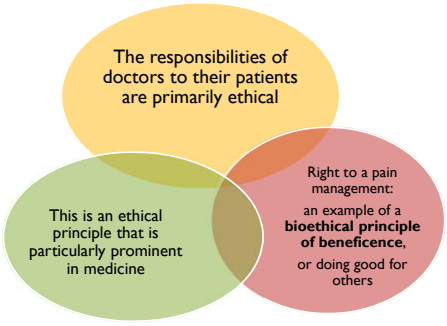
Law, ethics and management of pain: some of the concepts



Fishman SM. Anesth Analg 2007
Brennan et al., Anesth Analg 2007

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Law, ethics and management of pain: some of the concepts

An adequate pain management should be ensured to avoid the suggestion of **negligence**

The law of medical negligence emphasizes **to take reasonable care in all aspects of patient management**

Undermedication is considered as **a moral negligence**

Inadequate pain management of **an elderly person** may be considered **an elderly abuse**

Somerville M. CMAJ, 1987
Pandit et al., Indian J Urol 2009
Superior Court of California 1999

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Law, ethics and management of pain: some of the concepts

With respect to pain control, doctors may breach their standard of care

- By failing to take an adequate pain history from patients
- By treating pain inadequately
- And, by failing to consult an expert in pain management in cases of uncontrolled pain

Brennan et al., Pain: Clinical updates, 2004

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Law, ethics and management of pain: some of the concepts

Another message to physicians implicit in law verdicts is that

"there is a standard of care for pain management, a significant departure from which constitutes not merely malpractice but gross negligence.

Even if professional boards might not hold their licensees to that standard, juries will

Rich BA. West J Med 2001

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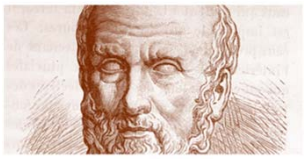
Law, ethics and management of pain: some of the concepts

Together with the bioethical principle of beneficence, the principle of **nonmaleficence** is also crucial, which prohibits the infliction of harm

"Primum non nocere"



Ippocrate (460-370 a.C.)

Gillon R. Br Med J 1985

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Precariousness of promoting pain management as a right

It is important to balance the message of right to pain relief, for both patients and physicians as: **not all types** of pain can be adequately treated

We should give the message: **«pain relief is not the right to a pain-free life»** as there is no guarantee of perfection in medicine

Physicians need to make clear that this right implies **«reasonable and proportionate»** response to the intensity and type of pain

Haddox et al., J Law Med Ethics 1998
Brennan et al., Clinical Updates 2004

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Need for improving education..

The Ethics' charter of The American Academy of Pain Medicine Requires to all physicians to improve in:

- assessment of pain
- treatment of pain with competence and compassion
- education in principles of pain medicine
- support to pain related research

AAPM, Pain Med 2005

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Challenges on chronic pain: what we dont' still know

Chronic pain commands particular attention: it is usually difficult to treat, particularly certain types such as neuropathic pain

Dosenovic et al., Anesth Analg. 2017

Currently, there is an ongoing debate whether chronic pain is a **disease** in its own right

Tracey et al., J Pain. 2009
Taylor et al., J Rheumatol. 2015
Cohen et al., Pain Med. 2013

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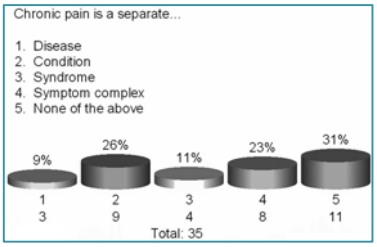
Debate on how to define chronic pain



Results of an informal poll conducted at the pre-OMERACT workshop on participants' opinions of how to define chronic pain

Taylor et al., J Rheumatol. 2015

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Synopsis of the debate for and against the concept of chronic pain as a disease

From: Discussions from a Pre-OMERACT 2014 Workshop on Chronic Pain

Factors	For Chronic Pain as a Disease	Against Chronic Pain as a Disease
Healthcare resources	Recognition may lead to increase in resources, education, and priority	CP seen as an LTC is gaining support in terms of increasing resources, education and priority; it does not require a disease definition to fulfill this support
The field of medical specialization	RTIC and individual pain medicine specialists and researchers propose CP as a disease	Other specialists and researchers, e.g., rheumatologists and neurologists may see pain more as a symptom of the presenting disease
Neuroimaging research	Structural and functional changes used to support pain as a disease; CP is a disease of the CNS	Structural and functional changes are proposed not to be purely due to pain but to the consequences of pain and its management
Signs and symptoms	CP is uniquely represented by physiological, psychological, and social signs and symptoms	Signs and symptoms of CP are not unique, they can accompany any LTC
Brain alterations	Results from a "real" disease-specific process	Results from an adaptive response to continuing nociceptive barrage
Management	CP treatment options are pharmacologically and behaviorally similar, suggesting similar mechanisms generating the pain	CP treatment options have only moderate success and there is a wide range of treatment options that can have some effect in one group and not in another (nociceptive pain vs neuropathic pain management, for instance)
CP as a symptom	If CP is a symptom, what is it a symptom of? It does not serve as a warning as in acute pain	CP is a symptom of a chronic disease such as OA, RA, etc.

Taylor et al., J Rheumatol. 2015

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IASP International Association for the Study of Pain

Ethical Guidelines for Pain Research in Humans

The goal of pain research is:

- to acquire new knowledge on the mechanisms, pathogenesis, diagnosis, and treatment of pain
- this requires research on humans and animals
- human research may be undertaken on both healthy persons and patients

This research may involve **painful stimuli** or **delaying pain relief** in patients

The primary intention is to advance knowledge so that patients in general may benefit; the individual patient may or may not benefit directly.

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IASP guidelines for pain research in humans crucial points to underline

Statement. The health, safety and dignity of human subjects have the highest priority in pain research. The investigator is personally responsible for the conduct of research and its effects on the experimental subject at all times, even though the patients have given their consent to participate

Point 6. In any pain research**, stimuli should never exceed a subject's tolerance limit** and subjects should be able to escape or terminate a painful stimulus at will. The minimal intensity of noxious stimulus necessary to achieve goals of the study should be established and not exceeded.

Point 7. In all circumstances, including studies that employ placebo and sham treatment methods, **an effective, accepted method of pain relief must be provided on request of the patient or subject**. The availability of alternative pain relief should be made clear in the consent form and the instruction before the study begins.

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Current Challenges in Pain Medicine

Current clinical practice is by and large devoid of outcome-based measures of efficacy

However, there are reports indicating that **multidisciplinary pain** management can significantly improve the health related quality of life of chronic pain patients compared with treatment at primary care

Heiskanen et al., Scand J of Pain 2012
Clemens et al., Nat Rew Urol 2019

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Questions to the audience

Have you never considered pain management as a human right?

Do your patients consider pain relief as a human right?

Do you clearly explain to your patients that «pain relief is not the right to a pain-free life», as there is no guarantee of perfection in medicine?

Do you know the new IASP-WHO classification of pain diseases?

How do you consider chronic pelvic pain: a syndrome, a disease, a disorder…

What istruments do you use in pain assessment? (i.e. pain severity.. urinary symptoms…objective assessments…)

When performing a research study about pain, do you follow the Ethical Guidelines proposed by IASP?

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