



ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF DISASTER RESPONSE

WORKSHOP ORGANISED BY THE CENTRE FOR SCIENCE SOCIETY AND CITIZENSHIP IN THE SCOPE OF THE PROJECT
NMFRODISASTER

Ethical Considerations in Research in the aftermath of Disaster

Dott. PIER LUIGI INGRASSIA



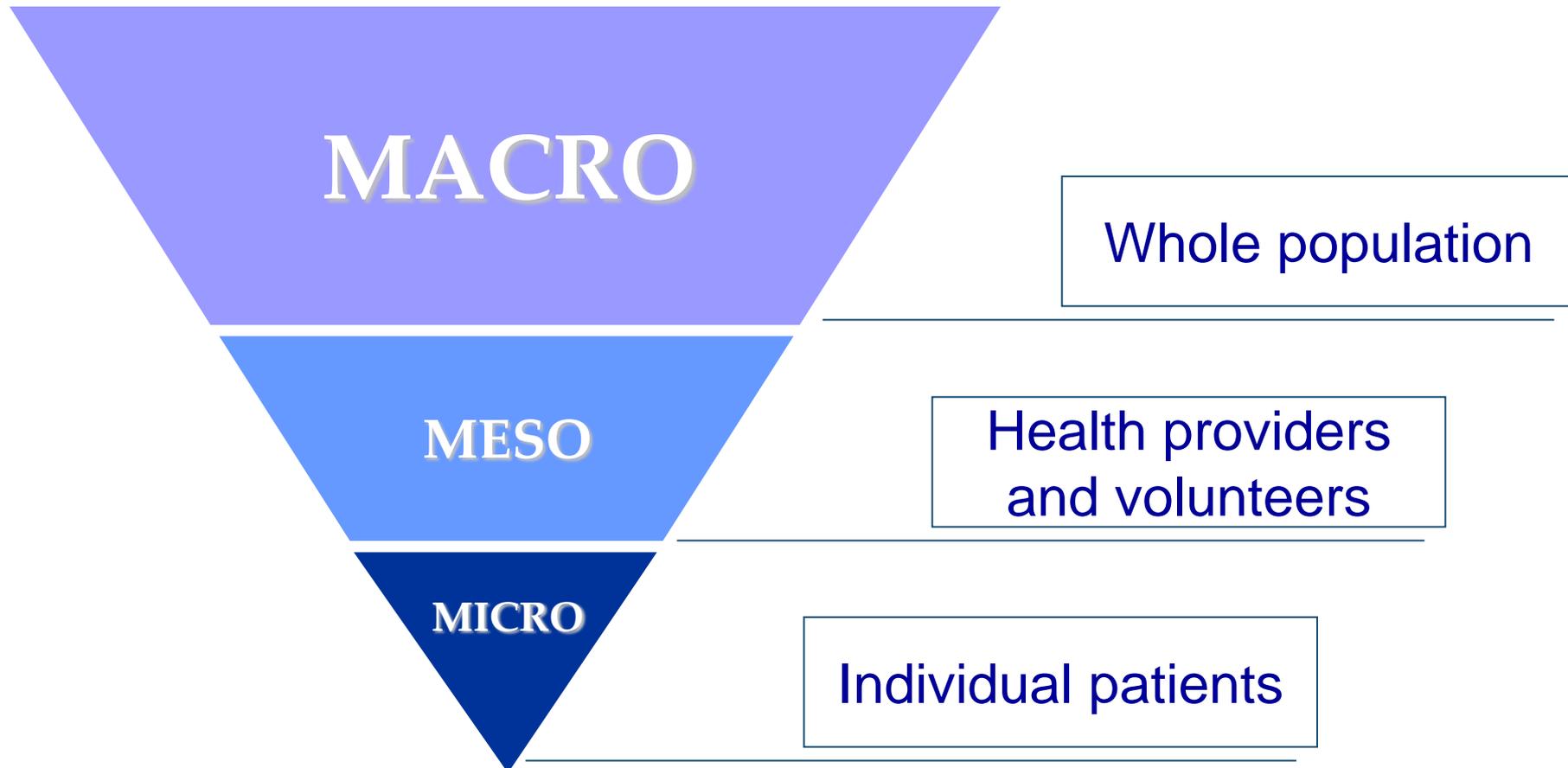
Centro di Ricerca Interdipartimentale in Medicina di Emergenza e dei
Disastri e Informatica applicata alla didattica ed alla pratica Medicina

A good ethical decision tends to **maximize** the various interests and **minimize** the negative side-effects in respecting the values of the victims, of the societies, of the institutions

P. Lesage-Jarjoura
Nouveaux défis professionnels pour le médecin des années
2000
Collège des médecins du Québec, 1998

INTRODUCTION

Ethical Challenges



INTRODUCTION

Disaster-related research

- ❖ **Psychological** difficulties
- ❖ **Medical** difficulties
- ❖ **Economic** difficulties
- ❖ **Social** difficulties



INTRODUCTION

four areas of critical importance to development and conduct of post-disaster research

1. decisional capacity of potential participants
2. vulnerability of research subjects
3. informed consent
4. risks and benefits of research participation

Newman E, Kaloupek DG. The Risks and Benefits of Participating in Trauma-Focused Research Studies. *Journal of traumatic stress* 2004;17(5):383-94

DECISIONAL CAPACITY

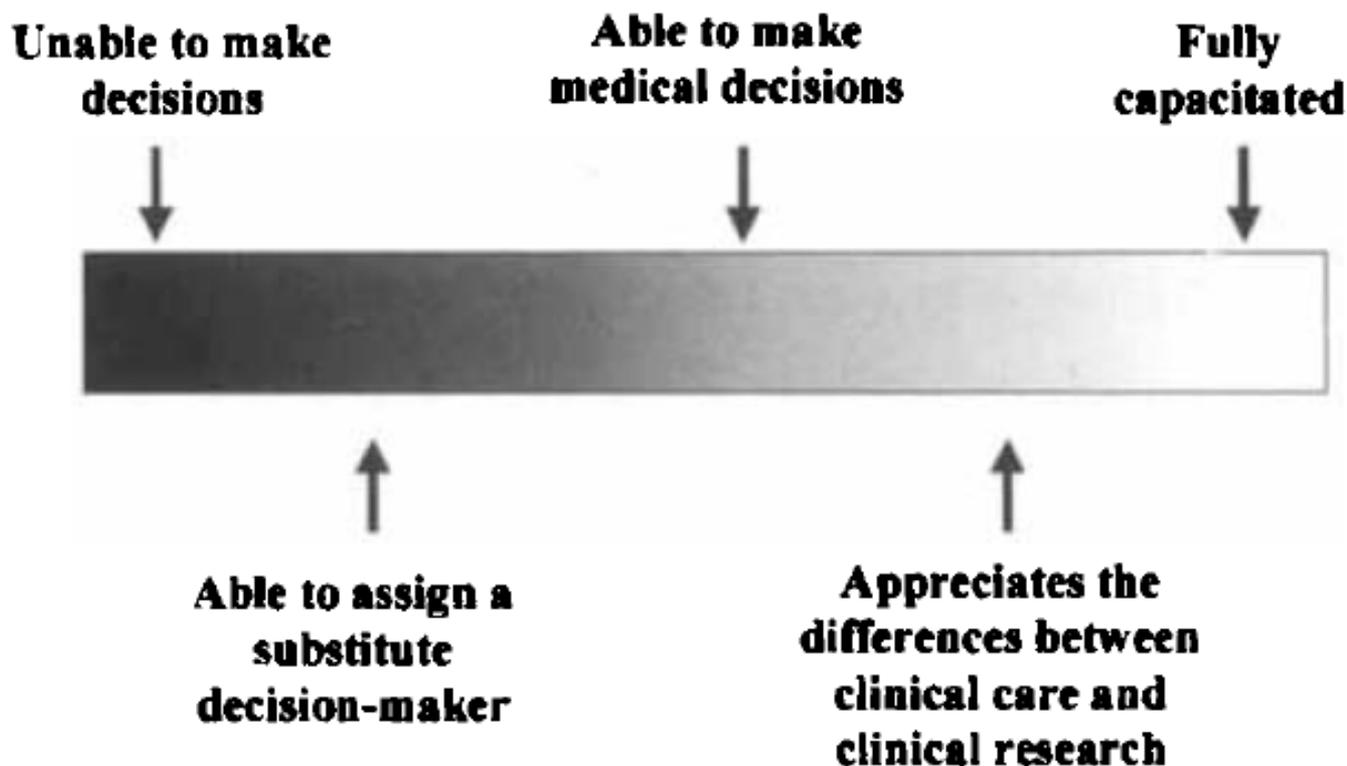
Ability to make capacitated, voluntary
and autonomous decisions

All the adults are legally competent to make
decisions for themselves

Rosenstein DL. Decision-Making Capacity and Disaster Research. Journal of traumatic stress
2004;17(5):373-81

DECISIONAL CAPACITY

Continuum of Decision-Making Capacity



Rosenstein DL. Decision-Making Capacity and Disaster Research. Journal of traumatic stress 2004;17(5):373-81

DECISIONAL CAPACITY

Who is at risk of impaired decisional capacity?

Little is known about the DMC of individuals who have experienced a disaster

- ✓ Minority of individuals exposed to “potentially traumatic experience (PTE)” will go on to develop various types of impaired DMC*
- ✓ Clinical experience and descriptive studies of ASD and PTSD suggest that depending on the nature and scope of the disaster, some individuals exposed to a PTE will have compromised DMC.

* Shalev AY. Acute stress reactions in adults. *Biological Psychiatry* 2002;51:532-543.

DECISIONAL CAPACITY

Who is at risk of impaired decisional capacity?

the characteristics of the disaster itself will suggest different strategies with respect to DMC

- ✓ Natural disaster vs act of terror or war
- ✓ Event with clear beginning and end vs event with multiple open-ended physical threats

Rosenstein DL. Decision-Making Capacity and Disaster Research. Journal of traumatic stress 2004;17(5):373-81

DECISIONAL CAPACITY

Capacity assessment tools exist

MacArthur Competence Assessment Tool for Clinical Research (McCAT-CR)*

- Used predominantly as research tool
- Pilot modified short version can be rapidly adapted for a new protocol

* Appelbaum, PS, & Grisso, T. MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR). Sarasota, FL 2001: Professional Resource Press.

DECISIONAL CAPACITY

Assessments of decision-making capacity performed by someone independent of the research team

Twostep strategy for recruiting research subjects in the aftermath of disaster

Description of how DMC determination might be included in published reports

Rosenstein DL. Decision-Making Capacity and Disaster Research. Journal of traumatic stress 2004;17(5):373-81

VULNERABILITY

Derived from the Latin word *vulnus* (wound)

Many interpretations and uses in ordinary language

In biomedical research:

“persons who are more likely than others to be misled, mistreated, or otherwise taken advantage of as participants in research studies.”

Levine C. The Concept of Vulnerability in Disaster Research. *Journal of traumatic stress* 2004;17(5):395-402

VULNERABILITY

No single approach to the definition of vulnerability.

In fact there is no definition or purposeful categorization at all.

Instead, we encounter a vast practice of identifying the particularly vulnerable for very limited purposes.”
(Morawa AHE, 2003)

VULNERABILITY

Those groups that might “bear unequal burdens in research” due to their “ready availability in settings where research is conducted”, such as prisons, hospitals, and institutions
It called for extra protections for these groups



National Commission for the Protection of Humans Subjects of Biomedical and Behavioral Research, 1978.

VULNERABILITY

Council for International Organizations of Medical Sciences' (CIOMS) 2002 guidelines for biomedical research defines, if not vulnerability, then at least vulnerable persons: “those who are relatively or (absolutely) incapable of protecting their own interests because they may have “insufficient power, intelligence, education, resources, strength, or other needed attributes”



VULNERABILITY

The World Health Association's latest version of the Declaration of Helsinki advises:

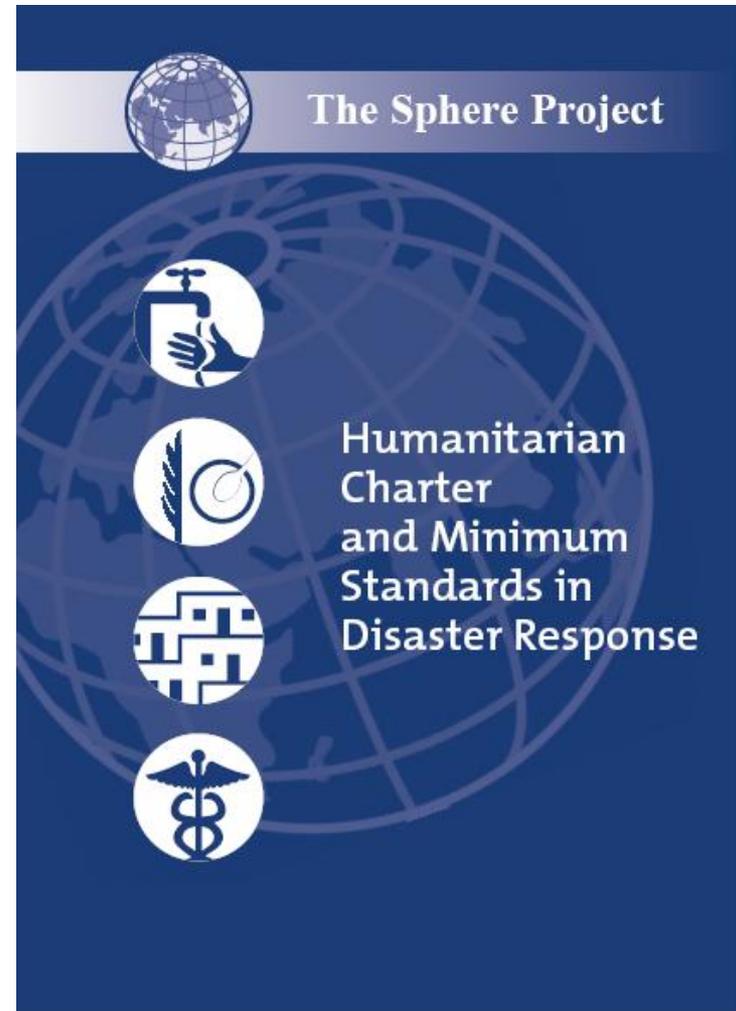
“The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.”

World Medical Association. (2000). Declaration of Helsinki. Available at: www.wma.net/e/policy17-c-e.html.

VULNERABILITY

Groups most frequently at risk in emergencies are”

- Women
- Children
- Older people
- Disabled people
- People living with HIV/AIDS



Sphere Project, 2004

VULNERABILITY

Victims of disasters are of course vulnerable in the sense of sometimes requiring additional care and attention, as they have often suffered trauma and loss.

However, available evidence does not indicate that as a class, they are unable to participate knowingly and voluntarily in decision making.

Collogan LK et al. Ethical issues pertaining to research in the aftermath of disaster. Journal of traumatic stress 2004;17(5):363-72

VULNERABILITY

Vulnerability vs Susceptibility

Susceptibility: being poor, undernourished, and lacking in medical care and therefore predisposed to additional harm

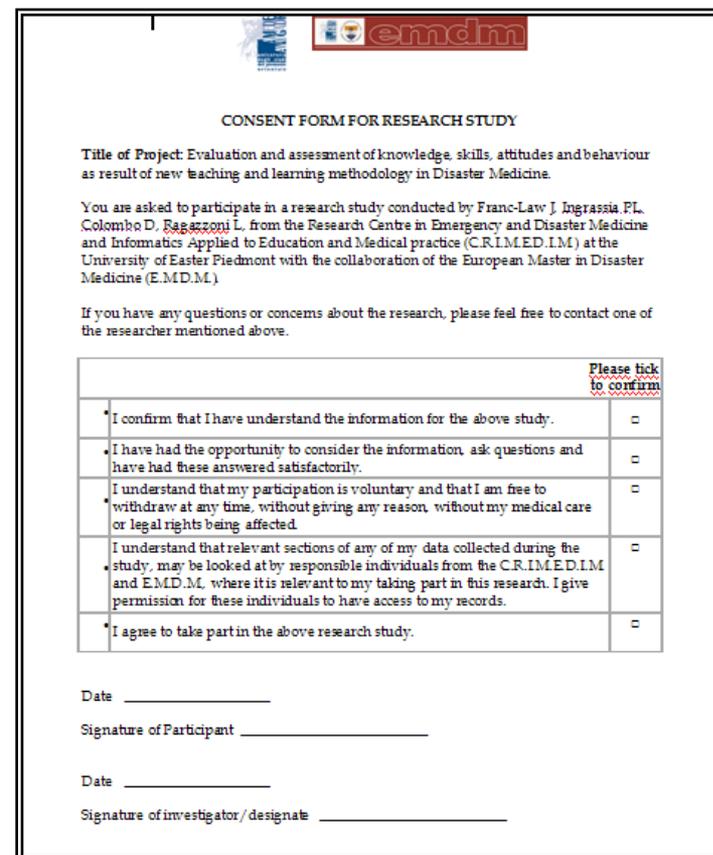


Kottow MH). The vulnerable and the susceptible. *Bioethics*, 2003; 17(5-6):460-471

INFORMED CONSENT

Not the mere document that is signed by the research participant

It is a much broader process which includes informing the potential subject of the procedures, potential risks, benefits, and alternatives to the research and then obtaining documentation of authorization to proceed.



emdm

CONSENT FORM FOR RESEARCH STUDY

Title of Project: Evaluation and assessment of knowledge, skills, attitudes and behaviour as result of new teaching and learning methodology in Disaster Medicine.

You are asked to participate in a research study conducted by Franc-Law J. Ingrassia, P.L. Colombo D. Ragazzoni L. from the Research Centre in Emergency and Disaster Medicine and Informatics Applied to Education and Medical practice (C.R.I.M.E.D.I.M.) at the University of Eastern Piedmont with the collaboration of the European Master in Disaster Medicine (E.M.D.M.)

If you have any questions or concerns about the research, please feel free to contact one of the researcher mentioned above.

	Please tick to confirm
<input type="checkbox"/> I confirm that I have understand the information for the above study.	<input type="checkbox"/>
<input type="checkbox"/> I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	<input type="checkbox"/>
<input type="checkbox"/> I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	<input type="checkbox"/>
<input type="checkbox"/> I understand that relevant sections of any of my data collected during the study, may be looked at by responsible individuals from the C.R.I.M.E.D.I.M. and E.M.D.M., where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>
<input type="checkbox"/> I agree to take part in the above research study.	<input type="checkbox"/>

Date _____

Signature of Participant _____

Date _____

Signature of investigator/ designate _____

Collogan LK et al. Ethical issues pertaining to research in the aftermath of disaster. Journal of traumatic stress 2004;17(5):363-72

INFORMED CONSENT

The therapeutic misconception

Much research postdisaster is not explicitly therapeutic in intent and the informed consent process must make the purposes of the research clear and not exaggerate the benefits of interacting with the investigators when treatment is not an intended part of the research and potential benefits may be less predictable

Appelbaum P, et al. False hopes and best data: Consent to research and the therapeutic misconception. *The Hastings Center Report*. 1987;17:20-24.

RISKS & BENEFITS

RISKS

- Enhanced awareness of material resources
- Medical and mental health services
- Empowerment
- Learning and insight
- Altruism
- Kinship with others
- Feeling of satisfaction or value after participating
- Favorable attention from investigators

BENEFITS

- Physical harm
- Inconvenience
- Legal action
- Economic hardship
- Psychological discomfort
- Loss of dignity
- Breach of confidentiality
- Unwanted media attention

Newman E, Kaloupek DG. The Risks and Benefits of Participating in Trauma-Focused Research Studies. *Journal of traumatic stress* 2004;17(5):383-94

RISKS & BENEFITS

characteristics of participants and protocols that may enhance potential for risks

- preexisting distress or mental illness,
- age (both young and old),
- history of multiple trauma exposures
- social vulnerability
- physical injury



Pakistan Earthquake, 2005

Newman E, Kaloupek DG. The Risks and Benefits of Participating in Trauma-Focused Research Studies. *Journal of traumatic stress* 2004;17(5):383-94

RISKS & BENEFITS

Emotional Distress

Sometimes referred as
“retraumatization”

Exacerbation of residual stress-
related symptoms may be an
**appropriate component of clinical
care** in a controlled and safe setting

Research participation **may upset**
subjects but it does not traumatize
them as a disastrous event would



Sri Lanka, 2004

Newman E, Kaloupek DG. The Risks and Benefits of Participating in Trauma-Focused Research Studies. *Journal of traumatic stress* 2004;17(5):383-94

RISKS & BENEFITS

Emotional Distress

subjects who experience strong emotional reactions **do not regret** or **negatively appraise** research participation



Indonesia, 2006

Newman E, et al. Assessing the ethical costs and benefits of trauma-focused research. *Annals of General Hospital Psychiatry*, 1999;21:187-196

RISKS & BENEFITS

Repetitive research involving the **same participants** carries a potential for risk



Enschede, Holland

Newman E, Kaloupek DG. The Risks and Benefits of Participating in Trauma-Focused Research Studies. *Journal of traumatic stress* 2004;17(5):383-94

RISKS & BENEFITS

Alfred P. Murray Federal Building in Oklahoma City, 1995

Research studies were centrally reviewed and approved through a special process put in place by the University of Oklahoma Health Sciences Center (UOHSC) with the imprimatur of the Governor.

The result was that the University's IRB became the single body approving research involving the population affected by the bombing as captured by a registry of victims.

The goals were to protect the survivors, maximize the knowledge obtained from the investigations, coordinate the numerous studies, minimize the burden on research subjects,

North, C., Pfefferbaum, B., & Tucker, P. Ethical and methodological issues in academic mental health research in populations affected by disasters: The Oklahoma City experience relevant to September 11, 2001. *CNS Spectrums*, 2002;7:580-584.

COMMUNITY ETHICS

There is broad agreement that post-disaster research is extremely important

Consider the ethics of **NOT** conducting research when research is needed to answer important questions as long as it is well designed and make every efforts to protect its research participants



Kilpatrick G. The Ethics of Disaster Research: a Special Section. Journal of traumatic stress 2004;17(5):361-62

CONCLUSIONS

- ✓ It should be assumed that, as a group, individuals affected by a disaster have the capacity to provide meaningful and voluntary informed consent to participation in research. When questions arise, individual assessments should be conducted. The decision to participate or not participate in research is entirely the purview of the competent prospective participant.
- ✓ Disaster-affected populations should not necessarily be considered "vulnerable" in the regulatory sense. However, research proposals should address the individual psychological state of potential participants and have explicit mechanisms available for timely referral of subjects in need of consultation, including training of investigators and research staff to recognize emotional problems in research participants.

CONCLUSIONS

- ✓ Specific research proposals should be scrutinized based on the level of risk, the novel nature of the research.
- ✓ Information for potential participants about a research project should make clear whether there is therapeutic intent. Informed consent procedures should reduce the likelihood of participants mistaking research for clinical services.
- ✓ Coordination and collaboration among researchers and IRBs may help minimize redundant research and participant burden

grazie

www.hdpnets.com
www.dismedmaster.com

pierluigi.ingrassia@med.unipmn.it