INTRODUCTION
According to the definition of the National Institutes of Health, a consensus conference is: “...a technique developed with the aim of providing a help to clinical decision making and health planning through a clear definition of the indications by which a given process can be considered appropriate, inappropriate or deserving of a further close examination”. In other words, it is a useful initiative to find valid, timely and comprehensible responses on a health technology of topical interest whose definition, use, effectiveness, and methods of application are debated in scientific literature or among those people who use it.

In conformity with the associative mission that states “To improve the quality of assistance to the citizens with chronic cutaneous wounds” through the promotion and the implementation of appropriate services, targeted to this pathology, and the reduction of the complications, this project is placed in one of the intervention areas defined by the Association as “proper”, and precisely in the “Operative proposals of optimal management addressed to the Health Administrations.”

It will contribute to satisfying the increasing demands for appropriate services required by an elderly population suffering from those chronic, degenerative multi-pathologies, not infrequently associated (as epiphenomenon or adverse event) with chronic cutaneous wounds.

This problem, studied and monitored by AISLeC over one decade, has been identified several times, in ministerial context, as deserving of attention (see the last two PSNs) because of its high prevalence in the population: the studies conducted by our Association show that the incidence of this pathology is greater than 13% in the clinical setting and than 34% in the home care setting.

THE PROBLEM
In view of the above, there is an absence of an unequivocal classification of devices available in the market that addresses the prevention and treatment of chronic cutaneous wounds.

This is because of;
1. the difficulty in drawing up competitive tenders and relative specifications,
2. the varied and differing information and training messages,
3. the lack of a standardised quality of health services and products across the various regions,
4. the need to update the Nomenclature to include the actual and most valid products on the market, on the basis of the criteria of effectiveness and appropriateness imposed by the L.E.As.

To these specific elements, it is necessary to add general ones that, as mentioned, increase the problem considerably. These are:
a. the confirmation that the high ageing rate will lead to a doubling of the population over 65 years in 2050, with a heavy problem of self-sufficiency in the elderly that will lead to the problem being seen as a “demographic time bomb” (Dr. Pier Ugo Carbonin. CNR, Rome 2002);
b. the rapidly ageing population and the less rapid adjustment speeds of the social and economic structures (and the necessary resources for this adjustment) (Dr. Antonio Golini);
c. controlling the phenomenon of “pressure ulcers”. In addition to being ethically right, controlling the problem would also promote the reduction of waste and the recovery of economic and technological resources in a preventive setting, including other sectors such as the therapeutic and rehabilitative ones, where the impact on finances and resources is increasing due to the high prevalence of cutaneous wounds.

OBJECTIVE
The objective of the project is to contribute to increasing the appropriateness of the health interventions, targeting them to prevent and to treat the chronic ulcers, through the production of a document providing recommendations for interventions with proven effectiveness in the field of the pressure-relief surfaces (in light of the current literature and the opinion of international experts – EBM) and that have the best cost to treatment effectiveness performance.
It must be emphasized that the correct management of pressure relief surfaces, in conjunction with the prompt and intelligent identification of patients at risk, are recognized as the cornerstone of pressure ulcer prevention in the scientific world.

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Scientific Committee
A.I.S.Le.C. Executive Board

MATERIALS AND METHODS
The selected method has been to identify and compare the best quality results produced by international clinical research, supplemented by the experience of healthcare professionals in the principal Italian groups involved in care and research in this sector.

The strategic phases of the project are:
1. research and critical evaluation of the results coming from the international clinical research, with particular attention to the integrative studies (guidelines and systematic reviews), produced by the most important institutions and international professional and scientific associations;
2. comparison with the indications and the references of the PNGL (I.S.S. – Italy) and the Health Technology Assessment of the NHS R&D HTA Programme (GB);
3. multi-professional and multi-disciplinary involvement;
4. involvement of the Italian Health Ministry;
5. comparison of the users/patients with the associations;
6. transparent comparison with the manufacturers of pressure-relief devices and products for the treatment of the pressure ulcers (dressings above all) available on the market;
7. direct involvement of recognized international experts in the field.

The principal steps in the development of the Consensus Conference (C.d.C.) have been the following:
1. definition of the objectives and sharing of the operative definitions related to the pathology and care settings of interest;
2. bibliographical review.

In particular:
a. integrative documents produced by institutions, associations and internationally accredited scientific societies have been searched (guidelines, systematic reviews, report of technology assessment). The search has been conducted in the data-banks available online and it has been completed with direct contact with the main worldwide experts in the sector,
b. clinical trials conducted in the area of interest have been searched and evaluated critically, through the use of electronic data-banks (Medline, Cinhal), manual search, and contact with the experts,
c. the collected information has been the object of discussion and comparison in repeated study sessions with recognized international experts between 2002 and 2004,
d. the information produced by the clinical research will constitute the base on which the C.d.C., organized in April 2004, will be founded.

As shown in the National Plan of the Guidelines, the Association, constituting the ‘Promoting Committee’, will present a first ‘draft’ version of the scientific documentation in which the material deduced from the literature will be synthesized.

The evaluation of the problem starts from the definition of Settings; for each setting a number of Indications/Questions will be defined; for every question the relative Cues – the factors that need to be kept in mind to appraise the questions – will be emphasized.

There will be three principal participants involved in this process: jury, public, and chairman.
The jury will be formed from ten/twelve experts, drawn from varied geographi-
The phases of the C.d.C.:
1. the evidence supporting the single indications are presented by the different groups (it is desirable to have a multiple presentation that reflects various points of view); in this phase the subject presenting the assertions\ recommendations may also be recognized international experts,
2. the jury and the public can ask questions; the discussion is moderated by the chair,
3. the jury compares and decides,
4. the discordances are formally defined and explicitly declared. The minority opinions are included in the document.

The project is being formulated and communicated in the following meetings/actions:

Europe. September 2002/February 2003
Preliminary meetings with international opinion leaders and national experts for the definition of the planning basis

Milan – April 1st 2003
Preliminary meeting with technical, company advisors, international opinion leaders

Pisa. May 22/24th 2003
Presentation of the project to the EWMA (European Wound Management Association) Congress

Livigno. July 7/12th 2003
Analysis and drafting of a summary of the scientific literature preparatory to the C.d.C.

Meeting of the promoting committee and the teamwork delegates.

Cavaion Veronese (VR). April 28/29th 2004

Analysis by the C.d.C. Jury of the final document and presentation of the findings in the presence of the Health Ministry representatives, the Administrations and the patients’ representatives.

Pavia. May 2004/December 2004
Monitoring and outcome analysis of the indications from the Consensus

Pavia. January/May 2005
Evaluation of the results

Results awaited in the short term:
• ‘re-orientation’ of the regulations (laws: D.M. n° 332), with cutting of the costs for obsolete devices and improper hospitalizations caused by inappropriate management of patients with pressure ulcers;
• better opportunities for the health public corporations and hospitals to produce detailed specifications for the supplies of the pressure-relief surfaces and consequently to optimize the performances of the health staff.
• the adoption of effective and appropriate surfaces will entail, among other things, a reduction in complications involving the nursing staff because of the excessive manual handling of the patients and a consequent reduction in the days of absence from work.

Results awaited in the medium-long term:
With a wide acceptance and the reception of the first results to national level, the achievement of the following results can be reasonably hypothesized:
• reduction of the severe bedridden complications in the hospital setting;
• reduction of the workload in the home care setting as a consequence of the reduction of 3°/4° stage (NPUPAP 1989) pressure ulcers as well as an optimal management of the remaining ones;
• best management, with only social resources, of patients with motor disability;
• smaller impact of the costs on the families, with an appreciable social advantage;
• improvement of the quality-of-life for the patients at risk of and already suffering from pressure ulcers.

MONITORING AND EVALUATION
AISLeC proposes assessing the results through the monitoring and analysis of two indicators:
1. degree of diffusion,
2. real use of the guidelines/recommendations produced by the C.d.C.

This will be achieved through the production of a questionnaire that will be sent to a representative sample of health and hospital companies in the national territory and the results will be published. On the basis of the results, possible lines of actions will be decided upon, in accordance with the competent partners.

Note: the realization times of the project may be subject to some modifications on the basis of the dynamics of teamwork and the time required to make sure of the real collaboration of other scientific societies, exponents and patients, as well as the representatives of the interested Ministries.

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References
• Murphy MK et al. Consensus development methods, and their use in clinical guideline development. Health Technology Assessment (systematic review). 1999; Vol 2 n.3
• ISS. PNLG da www.pnlg.it/LG
• ISS. “Manuale metodologico – come prodire, differenziare e aggiornare raccomandazioni per la pratica clinica”. 05/02
• AAIV. “Gestione intraospedaliera del personale HBsAg o anti-HCV positivo. Consensus Conference”. www.pnlg.it/LG/003/cons/b-metodo.htm
• Paola Di Giusto, Giovanni Renga, Lucia Saiani “Modelli e metodologie o anche clinica nella Laurea Specialistica in scienze infermieristiche” – Smith-Kline Consensus Conference” da Assiistenza Infermieristica e Ricerca 2003, 32, 1