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Experience in Italy in the development and application of clinical guidelines for low back pain

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Clinical Guidelines (CG) reflect the up to date scientific knowledge in the treatment of Low Back Pain (LBP). The diffusion of CG and their everyday application by health care professionals is a significant problem. As most CG are developed in English, the concerns are obviously greater in non English-speaking countries. The first CG on LBP by the Quebec Task Force (1987) was introduced in 1990 by the Gruppo di Studio della Scoliosi (GSS). Some studies where planned to verify their everyday application. The first one was carried on in Mantua, and evaluated the assessment of patients by General Practitioners (GPs): there is a clear tendency to over-prescribe examinations in acute cases, while in chronic cases under-prescription is sometimes seen. An educational approach was then proposed through a number of meetings, with fable results. A third experience verified the help GPs could receive through two different educative interventions such as a booklet and a direct access to a classical Back School. In acute patients a Booklet is useful, while Back School is not; at long term follow-up, chronic cases were significantly reduced only by the Back School approach. Finally, the Abruzzo Study's results on GPs management through computerassisted evaluation is reported.

The second part of the paper deals on the new experiences that are underway on the application of Diagnostic-Therapeutic Pathways (DTP) to Low Back Disorders.

Key words: Low back pain, diagnosis - Low back pain, therapy - Treatment, outcome.

The low back pain (LBP) epidemic, as it has been called, seems not to be different in Italy from that in other western countries. In 1997 1.9% of all inpatient

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treatment within the National Health Service (NHS) was classified in the Diagnosis Related Group 243 (Back-related medical disorders);² this group absorbed 5.8% of the economic resources of the NHS; the corresponding data for rehabilitation were 7.9% and 6.9% respectively.² No in-depth evaluations of all the other costs of LBP have been carried out, although those relating to other western countries and proposed in the literature ^{1, 3} can, without substantial variations, presumably be considered applicable to Italy, too. The Italian National Health Programme for the years 1998-2000 ⁴ proposed LBP as one of the 11 priorities for research and clinical practice, mainly due to its costs and high social impact and prevalence.

Since the first publication of the "Scientific approach to the assessment and management of activity-related spinal disorders, a monograph for clinicians" by the Quebec Task Force on Spinal Disorders in 1987,³ many commissions throughout the world have proposed clinical guidelines (CG) on the management of LBP.^{1, 3} A significant problem is the diffusion of

Table I.—Percentage of GPs who answered that they routinely perform the following tests at first examination of a patient with acute LBP. MBPS: Mantua Back Pain Study: our results; Little: results obtained by Little et al.6

| Test | MBPS % | Little % |
|------------------------|--------|----------|
| Palpation of the spine | 89.6 | 95.5 |
| Straight leg raise | 82.9 | 90.2 |
| Reflexes | 55.5 | 72.7 |
| Muscle weakness | 50.2 | 41.0 |
| Sensation | 43.6 | 44.3 |

Table II.—Percentage of GPs who think that the following signs and symptoms justify immediate hospital referral of a patient with acute LBP. MBPS: Mantua Back Pain Study: our results; Little: results obtained by Little et al. 6 NE: not evaluated.

| | MBPS % | Little % |
|---------------------------------------|--------|----------|
| Probable red flag | | |
| Neurological signs at multiple levels | 64.6 | 84.9 |
| Extensor plantar response | 61.3 | 55.3 |
| Saddle anesthesia | 58.0 | 93.9 |
| Possible red flag | | |
| Bilateral leg signs | 33.9 | 53.5 |
| Constant night pain | 22.2 | 31.3 |
| Probably not red flag | | |
| Loss of reflex at one level | 66.9 | 10.5 |
| Unilateral sciatica below the knee | 21.2 | 2.6 |
| Straight leg raise | 20.8 | NE |
| Severe localized back pain | 14.6 | 7.7 |
| | | |

these CG and their everyday application by health care professionals,⁵ both general practitioners (GPs)⁶ and specialists.⁷ As most CG are developed in and/or translated into English, the concerns over their dissemination are obviously greater in non English-speaking countries, such as Italy, where no CG have as yet been developed.

The aim of this paper is to discuss some of the experience already accumulated in Italy on the introduction of CG, and to present the new projects under way in this field.

Translation

The first step for the introduction of CG in Italy was the process of translation and dissemination through publication. Since 1978 in Italy there has been a study group, the Gruppo di Studio della

Table III.—Percentage values of correct prescriptions by GPs for each examination and diagnosis and average values according to the examination and the diagnosis. CT: computed tomography; MRI: magnetic resonance imaging.

| | I | LBP | Sci | A | |
|------------------|-------|---------|-------|---------|---------|
| | Acute | Chronic | Acute | Chronic | Average |
| Radiographs | 14.6 | 70.7 | 36.1 | 50.2 | 42.9 |
| CT scan | 54.3 | 80.3 | 65.1 | 61.3 | 65.3 |
| MRI | 75.5 | 89.4 | 70.5 | 80.9 | 79.1 |
| Laboratory tests | 62.4 | 70.0 | 66.6 | 61.3 | 65.1 |
| Consultation | 71.5 | 83.6 | 60.6 | 84.1 | 75.0 |
| Average | 55.7 | 78.8 | 59.8 | 67.6 | |

Table IV.—Percentage values of correct prescriptions by GPs for each therapy and diagnosis and relative average values. NSAIDs: non steroidal anti-inflammatory drugs.

| | I | .BP | Sci | Arramana | |
|---------------------------------|--------|---------|-------|----------|---------|
| | Acute | Chronic | Acute | Chronic | Average |
| Therapies usually prescribed by | GP | | | | |
| Bed rest for less than 2 days | 53.4 | 61.4 | 47.7 | 54.7 | 54.3 |
| Bed rest for more than 2 days | 58.4 | 73.2 | 53.0 | 54.7 | 59.8 |
| NSAIDs | 95.8 | 63.4 | 93.2 | 64.4 | 79.2 |
| Oral steroids | 50.7 | 49.5 | 25.3 | 41.3 | 41.7 |
| Muscle relaxants | 67.8 | 49.2 | 53.9 | 40.1 | 52.8 |
| Physical therapy | 35.0 | 6.9 | 38.3 | 10.0 | 22.6 |
| Inpatient treatment | 90.1 | 54.4 | 42.2 | 54.8 | 60.4 |
| Average | 64.5 | 51.1 | 50.5 | 45.7 | |
| Therapies not usually prescribe | d by G | P | | | |
| Injections | 88.2 | 81.6 | 47.0 | 54.5 | 67.8 |
| Spinal manipulation | 51.3 | 30.0 | 92.5 | 40.0 | 53.5 |
| Traction | 68.3 | 32.8 | 72.8 | 36.3 | 52.6 |
| Exercises | 49.2 | 63.8 | 59.2 | 52.6 | 56.2 |
| Corsets | 77.0 | 48.8 | 76.8 | 66.9 | 67.4 |
| Average | 66.8 | 51.4 | 69.7 | 50.1 | |

Scoliosi e delle patologie vertebrali (GSS), whose aim is to publicize the latest scientific knowledge in the field originally of scoliosis, but currently mainly of back pain, in Italy.

The first clinical guideline in this field was published in a monographic number of Spine by Spitzer *et al.* (the Quebec Task Force).³ In September 1988 "The Pain Clinic" meeting was held in Florence, in which Nachemson presented the main results of the Quebec Task Force, provoking a generalized debate, not to say a dispute, with most participants, while a synthesis of this first Guideline was proposed by GSS in 1990 to his members.⁸

Between 1991 and 1994 there was a breakthrough

Table V.—Relative frequencies of prescription of a treatment by GPs: the range reported in our results corresponded to the answers from (always+frequently) to (always+frequently+sometimes). MBPS: Mantua Back Pain Study: our results; USA: results reported by Cherkin et al. 7 NE: not evaluated. NSAIDs: non steroidal anti-inflammatory drugs.

| | LBP | | | | | Scia | atica | |
|---------------------|-----------|-----|-----------|-----|-----------|------|-----------|-----|
| | Acute | | Chroni | с | Acute | | Chronic | |
| | MBPS | USA | MBPS | USA | MBPS | USA | MBPS | USA |
| Bed rest (>2 days) | 14.4-41.6 | 70 | 7.9-26.9 | 31 | 24.6-53.6 | 87 | 18.5-45.3 | NE |
| Muscle relaxants | 67.3-88.4 | 77 | 37.5-75.5 | 50 | 56.5-75.9 | 69 | 41.7-67.0 | NE |
| NSAIDs | 95.8-99.5 | 81 | 80.2-94.7 | 87 | 93.2-97.6 | 78 | 82.9-96.6 | NE |
| Injections | 0.5-11.8 | 12 | 2.3-18.5 | 12 | 4.4-19.9 | 3 | 4.9-24.0 | NE |
| Physical therapy | 27.8-64.9 | 41 | 65.5-95.1 | 54 | 25.4-61.7 | 29 | 52.6-90.0 | NE |
| Spinal Manipulation | 14.3-38.6 | 2 | 25.1-69.9 | 0 | 7.4-24.0 | 1 | 21.2-60.0 | NE |
| Traction | 6.6-31.7 | 3 | 26.5-67.2 | 4 | 5.6-27.1 | 12 | 21.2-63.7 | NE |
| Exercises | 26.9-50.7 | 26 | 63.8-93.3 | 51 | 18.0-40.8 | 13 | 52.6-87.0 | NE |
| Corsets | 8.8-32.9 | 9 | 21.8-51.1 | 16 | 9.1-23.2 | 4 | 16.8-33.1 | NE |
| Inpatient treatment | 2.1-9.9 | 4 | 8.4-32.8 | 1 | 2.1-16.5 | 7 | 11.2-39.4 | NE |
| Bed rest (≤2 days) | 38.6-66.3 | NE | 13.7-38.6 | NE | 43.1-73.9 | NE | 18.5-45.3 | NE |
| Oral steroids | 12.4-49.2 | NE | 12.2-50.5 | NE | 31.4-74.5 | NE | 21.4-58.6 | NE |

of CG for LBP, with 3 of the most important contributions, coming from the American AHCPR,⁹ the British CSAG ¹ and the Swedish USB.¹⁰ All existing CG, together with those presented by the Quebec Task Force3 and the Australian Workover,¹¹ *i.e.* all the CG published till that time in the world, were presented and compared in 2 volumes published in 1996 ¹² and 1997 ¹³ for the members of the GSS.

Application by general practitioners

However translating and publishing does not mean reading and applying. The main field of application of CG is at GP level,⁶ and researches were focused there. In Italy GPs constitute the first level of everyday clinical practice and it is they who, through the prescription of examinations, therapies and consultation, distribute the resources of the NHS. This level is skipped only in cases where there is direct hospital intervention *via* the emergency services, but this is not a frequent occurrence, particularly in the case of LBP. Moreover, GPs issue NHS prescriptions on the basis of specialists' recommendations: they are not obliged to do this, but refusals are rare. Furthermore, the behavior of GPs is often conditioned by what they learn from such recommendations. In order to influence the costs and everyday clinical management of LBP it is thus necessary to concentrate on GPs; at the same time their behavior is also a reflection of that of the specialists.

The only publication in 1998 was that already cited of the GSS, ^{12, 13} and was directed to its members, who are mainly rehabilitation specialists, physiotherapists and trainers, but not GPs. The only information GPs received at that time, was the one that they obtained via their own reference to documents written in English. Now things have changed, mainly through the Società Italiana di Medicina Generale — SIMG — and Dr. S. Giovannoni, head of SIMG in this field, but that was the situation in 1998.

The Mantua Back Pain Study

A 1st cross-sectional study with the ASL of Mantua (Head of the Project [HP]: E. Politano) to evaluate the assessment ¹⁴ and therapy ¹⁵ of patients with LBP by GPs in Italy and to compare it with AHCPR and CSAG suggestions has been carried out. A validated questionnaire was sent to all GPs in the province of Mantua. Three-hundred and eighteen GPs were involved, with a response rate of 68.2%.

As a first step, it was evaluated what examinations are routinely performed, and what danger symptoms and signs prompt referral of patients. GPs indicated the frequency of prescription of radiographs, CT Scans,

MRI, laboratory tests and consultations. A comparison was made with a gold standard: the AHCPR and CSAG suggestions. Twenty-eight percent of GPs performed all the tests considered important by the CG (Table I),6 and 33% were aware of all the red flags (Table II).6 A gold standard was identified in the CG. The choice of the gold standard and the ordinal scale proposed in the questionnaire allowed the researchers to determine percentages of over- or under-evaluation of the problem. The correspondence with the recommendations of the CG ranged between 14.6% and 89.4% (Table III). There was a clear tendency to over--prescribe examinations in acute cases, while in chronic cases, under-prescription was sometimes seen, too. These results were worse than those in English-speaking countries.⁶ On the contrary, best prescriptions were found in chronic cases for CT scans, MRI and consultations.

In a second paper, 15 the advice that GPs give regarding daily activities, and the frequency with which they prescribe bed rest, NSAIDs, oral steroids, muscle relaxants, physical therapy, exercises, spinal manipulation, traction, corsets, and inpatient treatment was evaluated. Again, their answers were compared with the same gold standard. Correspondence with the recommendations of the CG ranged from 6.9% to 95.8%: physical therapy and oral steroids gave rise to problems, while the best results were obtained with NSAIDs in acute cases and inpatient treatment for acute LBP (Table IV). There was a clear tendency to over-prescribe therapies, mainly in chronic cases. Differences emerged between USA and Mantua data, presumably due more to medical habits than to knowledge of the literature (Table V).7 It was concluded that the bio-psycho-social model does not seem to be applied and a waste of economic resources is probable; the gap between research and everyday practice by GPs should be reduced.

According to these studies, the concerns over the application of CG must be considered greater in non English-speaking countries, where thorough presentation to GPs of the existing evidence based CG is to be recommended.

Spreading the knowledge

Once the low application rate of CG by GPs had been verified, the following step was to try to increase this rate, and different projects were developed with this aim.

The Mantua Back Pain Study

An educational approach to GPs in the Mantua ASL (HP: E. Politano) was proposed through a number of meetings focused on different points of the CG with the participation of experts and direct experience by GPs. First of all a quantitative analysis was carried out: results were poor, with no changes according to prescriptions and costs directly derived from the register of the ASL. Moreover, the qualitative analysis carried on made it possible to verify some critical points: the main difficulties expressed by GPs referred to the great number of exams and treatments not considered useful by CG even if generally widely proposed, and the not applicability of CG without an agreement with local specialists, that many times deny GP indications even if coherent with current CG. By the same token, the main concern expressed by GPs included the time-consuming requirements of a true psychosocial approach.

The Vittorio Veneto study

A completely different study was also carried out with the ASL of Vittorio Veneto (HP: F. Gattinoni). 16 Here the focus was on the critical aspect of the psychosocial approach to improve the general management of LBP by GPs and tried to verify the help they could receive through 2 different educative interventions such as a booklet (mainly based on the English Back Book) and direct access to a classical back school to be given to their patients: our aim with this new study was then to compare their use by specifically trained GPs to usual GP care. One-hundred and forty voluntary patients (78 males) were consecutively recruited in 1 month in 15 GP practices. Inclusion criteria were: acute LBP or sciatica (<2 weeks), no radicular signs, no more than one episode of pain in the previous 6 months. GPs were randomized into 3 groups: 10 were educated according to the CG approach; 5 received only a booklet, developed according to the English back book, while the others were prescribed a 10-session back school too, provided by a well trained physiotherapist; 5 served as controls. The evaluations included standardized and validated questionnaire. The study groups were evaluated at 0, 1 and 48 months, the control group at 0 and 48 months. The results are reported in Table VI. At baseline in both study groups NSAIDS were prescribed and examinations in a sig-

Table VI.—Main results of the Vittorio Veneto Study.

| PATIENT'S CLINICAL CONDITIONS AT 1 MONTH | | | | | | | | |
|--|------|----------|-----------|-----------------------------|--|--|--|--|
| | | Total | | | | | | |
| Group | Same | Improved | Recovered | answering the questionnaire | | | | |
| Back book | 50% | 32% | 18% | 28 (74%) | | | | |
| Back school | 8% | 43% | 49% | 53 (73%) | | | | |

COSTS ANALYSIS 1 MONTH AFTER RECRUITMENT

| Group | Variation | Same | Improved | Recovered | Absenteism |
|-----------------------------------|-----------|------------------|------------------|-----------------|------------------|
| Back school v. | s p | 0.14 (-15.5%) | 0.01 (-56.1%) | 0.09 (44.9%) | 0.05 (37.4%) |
| Back school <i>v</i> . Control | s р | 0.00 (-34.8%) | 0.00 (-61.5%9 | 0.14 (38.4%) | 0.23 (-18.1%) |

CLINICAL CONDITIONS AT 2 YEARS

| | Variation % | Number of relapses | Chronicization | Relapses |
|----------------|-------------|--------------------|------------------|---------------------|
| Back school vs | p | 0.56 (-16%) | 0.07 (-79.8%) | 0.237 (112.6%) |
| Back school | p | 43% (-23.4%) | 49% (-54.6%) | 53 (73%) (71.8%) |

COSTS ANALYSIS AT 2 YEARS

| Group | Variation | Drug use | Exams | Consultations | Absenteism |
|-----------------------|-----------|----------|----------|---------------|------------|
| Back school <i>vs</i> | p | 0.97 | 0.93 | 0.5345 | 0.0001 |
| Control | | (-1.9%) | (-57.0%) | (-10.8%) | (+78.2%) |
| Back school <i>vs</i> | р | 0.09 | 0.30 | 0.0004 | 0.0011 |
| Control | | (-46.3%) | (-46.3%9 | (-51.6%) | (-32.3%) |

nificantly inferior quantity than in the control group. At 1 month the booklet group had significantly better subjective results and lower absenteeism, use of NSAIDs, examinations and consultations than the back school group. At 48 months there were significantly fewer chronic cases in the back school group than in the control one, and less absenteeism, use of NSAIDs and consultations in the booklet group than in the controls; finally, there was more absenteeism in the back school group than in the controls. The authors concluded that in acute patients a booklet is useful, while in the back school it is not: the direct assump-

tion of responsibility by GPs in the booklet group and not in the back school group could be a possible explanation. Interestingly, at long term follow-up chronic cases (a critical outcome) were significantly reduced only by the back school approach (-78%). The type of back school proposed (exercises, more than a cognitive approach) could be an explanation for these conflicting results. The results of these studies show that GPs have many doubts in CG applicability to everyday clinics, and confirm that there are great difficulties with the bio-psycho-social model.

The Abruzzo study and the "Health Search" data base

Health Search is a research institute of the Italian GP Society (Società Italiana di Medicina Generale - SIMG), whose main aim is to create a complete database of all patients treated by GPs involved. Health Search also created a database on LBP, recording more than 700 000 patients: a project has been proposed and included in the National Health Research Program (1999) involving GPs mainly from Abruzzo (HP: L. Fabiani). GP enrolment began in 1998 and ended in April 2002, while the finalized research project was finally completed in June 2003.

The aim of this project was to describe LBP management and the impact that shared diagnostic therapeutic pathways (DTP) may have on epidemiology and quality of life of patients. The project is based upon the consideration that informatized database creations constitute a valid research methodology, already recognized in some other Countries (for instance, UK General Practice Research Database). Database advantages are to be found in the constant and easy data retrieval depending on assistance necessity, to the rich clinic detail, useful for controlling disease evolution in time.¹⁷

The researchers involved have participated in project development and in the experimental constitution of DTP, upon evidence based medicine findings, creating an informatized schedule.

The database collected considers 28 937 patients followed by researchers and 23 863 patients involved as controls; 5 266 cases of LBP were analyzed in the selected periods, 2729 patients in the population of GP researchers and 2537 patients in the control group. For each of these patients was possible to clearly and easily define several clinical, historical LBP characteristics, obtaining the complete profile

Table VII.—Year percentages concerning the study groups.

| | Abruzzo | | | | Control | | | |
|-------------------------|---------|------|------|------|---------|------|------|------|
| | 2000 | 2001 | 2002 | 2003 | 2000 | 2001 | 2002 | 2003 |
| Year percentage (rough) | 38.0 | 42.7 | 39.5 | 31.1 | 58.2 | 59.4 | 65.8 | 54.2 |
| IC lower limit | 33.2 | 36.7 | 34.4 | 26.4 | 54.0 | 55.0 | 61.0 | 49.4 |
| IC higher limit | 43.0 | 48.0 | 44.6 | 35.8 | 62.6 | 63.8 | 70.6 | 58.6 |

of the population involved. The researchers used educational material (booklets) with their patients, giving clinical recommendations about LBP, holding residential and formative courses, and also local consensus process with direct teaching of correct LBP management 18. LBP incidence was 53.2 cases/year/ 1000 patients in the research group and 59.4 cases/year/1 000 in the control group. The incidence of LBP in Abruzzo did not appear high, and the diminution during the study period was more evident than in the other groups (Table VII). Sex distribution showed a major incidence in women - except for the region of Abruzzo, while the age class most involved was between 45 and 64, this also due to work related activity that can represent a greater risk in muscleskeletal disease development.

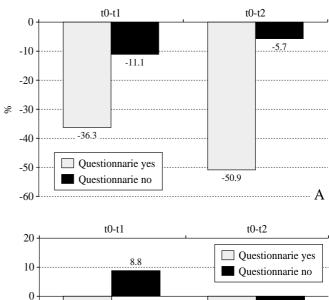
The study also showed that the LBP classification used in published CG or in clinical practice ¹⁹ does not correspond to the ICD IX CM international classification, determining some difficulties in the case definitions.

The booklet efficacy was proved through 4 different measurement instruments: SF-36 Questionnaire, Roland Morris and fear avoidance beliefs questionnaire, and VAS scale.²⁰⁻²³ LBP improvement was reached in the booklet group in a better way (Figure 1).

Moreover, the high incidence of LBP and the relative health service demand shows (Table VIII) how GPs become a fundamental reference for this kind of patient, ranging from the preventive, to diagnostic, to therapeutic and prognostic aspects. In line with the results of this study we can see the importance in developing shared guidelines for GPs.²⁴⁻²⁶

Other experiences in Italy

Other experiences have been carried out in Italy, at an institutional level: the Emilia Romagna Region proposed new CG ²⁷ while Tuscany and Lazio are still working in this field. Moreover, for some 7-8 years



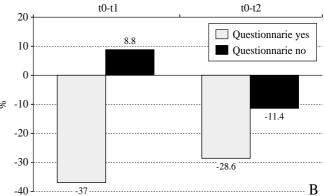


Figure 1.—Increases of RMQ and VAS scores. A) Increases of the Roland Morris Questionnaire scores. B) Increases of VAS scores for pain.

Table VIII.—Distribution of LBP cases (percentage values) according to presence/absence of check-up and therapy (years 2000-2003).

| | | Abruzzo | | | | Co | ntrol | |
|----------|----------|-------------|-------------|----------|----------|-------------|-------------|-------------|
| | 2000 (%) | 2001 (%) | 2002 (%) | 2003 (%) | 2000 (%) | 2001 (%) | 2002 (%) | 2003 (%) |
| Check-up |) | | | | | | | |
| No | 61.4 | 63.4 | 60.7 | 62.3 | 61.3 | 55.8 | 56.0 | 55.6 |
| Yes | 38.6 | 36.6 | 39.3 | 37.7 | 38.7 | 44.2 | 44.0 | 44.4 |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| Therapy | | | | | | | | |
| No | 48.2 | 42.7 | 38.8 | 35;5 | 35.5 | 34.3 | 37.3 | 38.4 |
| Yes | 51.8 | 57.3 | 61.2 | 64.5 | 64.5 | 65.7 | 62.7 | 61.6 |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

Table IX.—The 7 sub-projects included in the finalized project approved and financed by the Italian Health Ministry on DTP to low back disorders.

Finalized project by IRCCS Fondazione Don Gnocchi evidence based DTP for low back disorders (Head of the Project: S. Negrini)

- 1. Development of the Italian evidence based DTP for low back disorders (HP: S. Giovannoni)
- 2. Evaluation of inpatient treatment costs of non-surgical low back disorders (DRG 243) in Italy (HP: G. Baraldi),
- 3. Development, application and evaluation of evidence based DTP for low back disorders in Milan (HP: S. Chirchiglia)
- 4. Evaluation of software developed to standardize GP approach to low back disorders (HP: L. Fabiani)
- 5. Evaluation of a new inpatient treatment of workers with low back disorders (HP: P. Capodaglio)
- 6. Quality of life measurements applied to inpatient treatment for low back disorders (HP: L. Padua)
- 7. Comparison between back school and everyday treatments by physiotherapists (HP: A. Corigliano)

there has also been a wonderful project of the HNS, the National Plan on Guidelines (PNLG), to collect all CG and disseminate them, mainly through an internet website (*www.pnlg.it*). A great section of the site is devoted to LBP, but the main problem continues to be there: the local implementation of CG.

The future in Italy: from clinical guidelines to diagnostic-therapeutic pathways

Recently, the HNS proposed the new concept of DTP, that are developed following CG but are something a little bit different. Like CG, DTP are instruments developed according to scientific evidence and, in the gray areas where there is no evidence, according to the clinical experience of experts: the main difference is that they have to be developed locally, according to what local clinicians offer, so as to be applicable in everyday practice. In view of the experience that had already been accumulated on CG and described in this paper, a project has been presented by IRCCS Fondazione Don Gnocchi (HP: S. Negrini) to the HNS, that approved and financed it, to develop new experience in the application of DTP to low back disorders. This project included 7 sub-projects (Table IX): the 2 most important are presented below, while one is the continuation of the Abruzzo Study already discussed.

Table X.—Scientific societies participating in the development of the Italian evidence based DTP for low back disorders.

- SIMG Società Italiana di Medicina Generale (coordinazione)
- AIFI Associazione Italiana Fisioterapisti
- SIMEU Società Italiana Medicina d'Urgenza
- SIMFER Società Italiana Medicina Fisica e Riabilitazione
- SIMLII Società Italiana Medicina del Lavoro
- SIN Società Italiana Neurologia
- SINCH Società Italiana Neurochirurgia
- SIOT Società Italiana Ortopedia e Traumatologia
- SIPCM Società Italiana Psicologi Clinici Medici
- SIR Società Italiana Reumatologia
- SIRM Società Italiana Radiologia Medica

The Italian evidence based diagnostic-therapeutic pathways for low back disorders

This is a national project (HP: S. Giovannoni), involving all scientific societies engaged in the field of LBP, to develop a unique, national, evidence based model to be proposed to local organizations. As already stated, DTP should be developed locally, but the idea in this sub-project is to create a national tool, some kind of a common background, to avoid all bias and problems that arise locally according to different not scientifically oriented pressures on the local commissions created to develop the local DTP or CG. Instead of having a list of recommendations as in classic CG, the DTP will be flow charts, according to the model of the USA Institute for Clinical System Improvement (ICSI). The algorithms will be detailed, specific to clinical presentations, commented and fully developed according to actual evidence (references included). Together with an epidemiologist, the group of experts has been chosen directly by all scientific societies engaged in the field of LBP (Table X). Some secondary tools will be developed to help in the final consensus conference, that include:

- research on what patients ask their physicians when they seek help for LBP: it will be performed collecting 2 000 validated questionnaires in 40 GP practices around Italy;
- research on what physicians usually do in their everyday practices: it will be performed through validated questionnaires proposed to 100 members randomly chosen in each scientific society participating in the project.

This will provide a picture of everyday practice

(obviously different from what is represented by the experts of the scientific society) and the real ideas and problems of patients. In the final consensus conference patients will also be represented by consumer associations and administrative personnel of the NHS will be invited.

The Italian evidence based DTP will relate to these clinical presentations:

- acute LBP, first episode;
- acute recurrent LBP;
- sub-acute LBP;
- chronic LBP;
- acute sciatica, first episode;
- acute, recurrent sciatica;
- sub-acute sciatica;
- chronic sciatica.

A clinical presentation will be considered acute when it lasts less than 6 weeks, sub-acute between 6 and 12 weeks, chronic more than 6 weeks. An episode is considered recurrent when it appears more than once in a year. Sciatica means pain appearing below the knee. Developing flow-charts on sub-acute and recurrent LBP and sciatica is almost new, because there are only a few paper on these topics, and usual CG do not evaluate these topics. Anyway, everyday clinical practice is full of these problems that, in our view, could not be avoided by good DTP.

Development, application and evaluation of evidence based diagnostic-therapeutic pathways for low back pain in Milan

In the District 5 of the ASL of Milan, where teams of GPs have long existed, a project for the development, application and evaluation of evidence based DTP for LBP is under way (HP: S. Chirchiglia).

The goal of this project is expected to be achieved through meetings involving GPs, specialists and ASL physicians to produce shared evidence based DTP, relative flow-charts, and a common instrument for the recording of epidemiological data.

The first aim is represented by the possibility to develop evidence based DTP for LBP and related disabilities which can become shared among GPs, specialists and ASL physicians. The second aim consists of setting up a local network among GPs, specialists and ASL physicians to improve LBP management, pathology at high social impact. The third aim is the active spread of evidence based DTP among GPs and ASL physicians of the other ASL districts .

The project work methodology provides for several meetings among GPs, specialists and District 5 of Milan ASL physicians to share evidence based CG, to work out the relative flow-charts, and evidence based DTP, and to identify the correct instrument for finding significant epidemiological data.

Later, the research methodology provides for epidemiological data gathering and the experimentation of DTP by GPs involved in the study.

Once the collection phase is concluded, we will proceed with data analysis and with final data evaluation; this will be followed by the active dissemination of DTP to all GPs of the District and of the Milan ASL.

Conclusions

The translations of CG began in Italy in 1990. It was verified that GP behavior had to be improved, but the means applied to increase this knowledge were not enough to change GP behavior. According to GPs, the main problems were the need for some positive assumptions from the literature, even if they showed resistance to the use of a true bio-psycho-social model.

These considerations and experience led to new insights on the problem of filling the gap currently existing between literature results and everyday clinical practice.

The new duty is the development of the Italian evidence based DTP.

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