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"GIU' LE MANI DAI BAMBINI®"

CAMPAGNA NAZIONALE PER LA DIFESA DEL DIRITTO ALLA SALUTE DEI BAMBINI

Al Ministro della Sanità On. Beatrice Lorenzin,
Lungotevere Ripa, 1
00153 - Roma

Al Direttore Generale dell'Istituto Superiore di Sanità
Dott.ssa Monica Bettoni
Viale regina Elena, 299 - 00161 Roma

Al Presidente del Consiglio di Amministrazione
dell'Agenzia Italiana del Farmaco,
Prof. Sergio Pecorelli
Via del Tritone, 181 - 00187 Roma

Al Presidente della Società Italiana
di Neuropsichiatria dell'Infanzia e dell'Adolescenza,
Prof. Bernardo Dalla Bernardina
Cattedra di NPI Università di Verona - Policlinico G.B. Rossi
Piazzale L. A. Scuro, 37134 - Verona

Torino, li 28/10/2013

Oggetto: richiesta di approfondimenti sul rapporto nazionale sulla sicurezza ed efficacia di Ritalin® (metilfenidato) e Strattera® (atomoxetina) sui minori iscritti nel Registro ADHD, e relativi costi economici a carico del Servizio Sanitario Nazionale[1], nonché approfondimento sulla diagnosi differenziale.

Illustrissimo Ministro,

Egregio Direttore Generale,

Egregio Presidente AIFA,

Egregio Presidente SINPIA,

Vi indirizzo questa lettera in qualità di portavoce di "Giù le Mani dai Bambini®"[2], il più rappresentativo comitato indipendente per la farmacovigilanza pediatrica in Italia, composto da duecentotrenta enti tra associazioni di

[1] Il Comitato "Giù le Mani dai Bambini®" ringrazia l'esperto Claudio Ajmone per l'indispensabile stimolo iniziale alla redazione di questo documento, e per i competenti contributi costruttivi garantiti nella fase di messa a punto dello stesso

[2] Comitato non a scopo di lucro, gestisce il portale informativo www.giulemanidaibambini.org, il più frequentato in Italia su questi temi; ha ricevuto nel 2007 la Targa d'Argento del Presidente della Repubblica Italiana e nel 2011 – nella Sala Capitolare del Senato della Repubblica - il Premio PAA per l'eccellenza nella comunicazione sanitaria; le attività del Comitato sono patrocinate da un terzo dei Capoluoghi di Provincia Italiani; il comitato scientifico dell'ente riunisce oltre trenta tra i massimi esperti in Italia – psichiatri, psicologi, pediatri, etc - di disturbi del comportamento infantile e di problematiche dell'età evolutiva ed ha distribuito gratuitamente fino ad oggi oltre 1 milione di opuscoli e fascicoli informativi alla cittadinanza.

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promozione sociale e di volontariato socio-sanitario, ASL, Università, Ordini dei Medici e degli Psicologi.

Abbiamo avuto modo di apprezzare l'utilità dello strumento del Registro per i minori ADHD (Sindrome da Iperattività e Deficit di Attenzione, ovvero bambini eccessivamente agitati e distratti), gestito dall'Istituto Superiore di Sanità (ISS) in collaborazione con l'Agenzia Italiana del Farmaco (AIFA), strumento che ha contribuito a permettere l'esercizio di un controllo sulle diagnosi e sui trattamenti farmacologici disinvolti o inappropriati, ma a distanza di circa sei anni dall'inizio del processo di medicalizzazione dei minori italiani diagnosticati ADHD i dati statistici forniti dall'ISS appaiono – malgrado tutto - ancora insufficienti, e tali da **non permettere ai cittadini una piena comprensione delle dinamiche sottese al processo di medicalizzazione, nonché tali da non consentire alla società civile una reale valutazione del rapporto costi/benefici di tale strategia.**

Le richieste contenute in questa nostra lettera mirano quindi a tentare di colmare tali carenze informative, anche al fine di permettere a tutti gli stakeholder coinvolti un'appropriata valorizzazione dell'azione del Ministero della Sanità a tutela del diritto alla salute dei minori. Inoltre vuol essere un stimolo rivolto alle Società scientifiche che si sono pronunciate con linee guida sull'argomento a voler ripensare il concetto di diagnosi differenziale, separandola dalla comorbilità e aggiornandone la casistica, obiettivamente lacunosa, e ciò al fine di garantire diagnosi e cure appropriate ai pazienti. A puro titolo di esempio, segnaliamo le linee guida SINPIA che a pagina 13 affermano "*Disturbi dermatologici, come ad esempio l'eczema, possono produrre comportamenti iperattivi*" ma poi non si inserisce le dermatiti nella "Tab. 2. Diagnosi differenziale e comorbidità" quando affronta la problematica dell'iperattività infantile.

DATI NAZIONALI SULLA SICUREZZA DEI FARMACI

Questi dati sono descritti in un report nazionale pubblicato a febbraio 2010 su "Adverse Drug Reaction Bulletin n° 260", intitolato "*Safety of psychotropic drug prescribed For attention-deficit/ hyperactivity disorder in Italy*" a cura di P. Panei, R. Arcieri, M. Bonati, M. Bugarini, A. Didoni & E. Germinario (1)

Il rapporto permette un confronto con analisi separata degli effetti collaterali dei due farmaci utilizzati, ma pare incompleto per quanto afferisce alle informazioni relative al profilo di sicurezza degli stessi, mancando tra l'altro i dati relativi alle somministrazioni contemporanee di altri diversi principi attivi, pratica a elevato rischio per i pazienti essendo ignoti i possibili effetti collaterali combinati. Tali dati furono da noi richiesti – senza alcun esito - già nel 2007 in un'audizione congiunta Commissione Sanità del Senato e Agenzia italiana del Farmaco (2)

A – Sarebbe quindi certamente utile conoscere:

1. il numero dei soggetti sottoposti a somministrazione combinata di più farmaci (polifarmacia);

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2. il nome di questi farmaci e il motivo per cui sono stati prescritti;
3. la tipologia di effetti collaterali riscontrati e ad essi imputabili, la loro gravità e durata, l'incidenza statistica di ognuno di loro e cumulativamente;
4. analisi statistica separata e comparata degli effetti avversi (ADR) tra i soggetti sottoposti solo a somministrazione di Ritalin® e Strattera® e quelli sottoposti a polifarmacia.

Nota 1: si chiede che i dati di cui ai punti da A1 e A4 siano illustrati sia per quanto riguarda il livello nazionale che quello regione, e articolati per fasce d'età.

DATI NAZIONALI SULLA EFFICACIA DEI FARMACI

Questi dati non sono mai stati pubblicati, e ciò parrebbe rappresentare una **grave omissione del diritto all'informazione della cittadinanza con riguardo a una tematica eticamente sensibile qual è la somministrazione di psicofarmaci ai minori.** E' del tutto anomalo che a distanza di anni non si conosca alcunché in merito a:

B – Durante il trattamento

1. percentuale di pazienti sottoposti a trattamento multimodale (indicando tutte le varie tipologie di intervento non farmacologico utilizzate, raggruppate per categorie);
2. percentuale di pazienti sottoposti al solo trattamento farmacologico;
3. percentuale di pazienti trattati solo con psicoterapia e/o counseling e/o intervento sociale;
4. percentuale di pazienti che hanno manifestato una completa remissione dei sintomi;
5. percentuale di pazienti che hanno manifestato un miglioramento del quadro clinico, inteso come riduzione del numero e/o intensità dei sintomi;
6. analisi statistica separata e comparata degli esiti terapeutici nel periodo di trattamento per le distinte categorie terapeutiche multimodale/farmacologico/psicosociale, separatamente per i due farmaci in oggetto e per quanto al punto B.1 in merito alle tipologie di intervento non farmacologiche;
7. Percentuale di pazienti che hanno dovuto interrompere la terapia farmacologica causa i gravi ADR indicando separatamente e cumulativamente l'incidenza statistica e il RR imputabile ai due farmaci utilizzati. Per questi pazienti è importante sapere quale tipo di terapia o supporto istituzionale hanno avuto dopo l'uscita dal Registro, oppure se è stato totalmente o in parte delegata alla famiglia e alla scuola la soluzione del problema ADHD.

Nota 2: Chiediamo che i dati di cui sopra siano illustrati a livello nazionale e regionale e per fasce di età.

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C - Dopo il trattamento:

Risulterebbe una durata media dell'intervento terapeutico pari a due anni, termine limite oltre al quale la terapia farmacologica dovrebbe essere stata interrotta senza eccezioni. Riteniamo importante conoscere:

1. la percentuale di soggetti che hanno manifestato nuovamente i sintomi di ADHD ai follow-up successivi all'interruzione della terapia (ricadute) e se la sintomatologia ADHD si sia aggravata rispetto alla diagnosi iniziale;
2. se le comorbilità inizialmente diagnosticate si sono aggravate/migliorate/evolute in una remissione sintomatica;
3. se sono comparse nuove psicopatologie;
4. se nuove problematiche di rilievo medico sono comparse;
5. l'analisi complessiva, separata e comparata, degli esiti terapeutici negativi post-trattamento per le distinte categorie terapeutiche multimodale/farmacologico/psicosociale e separatamente per i due farmaci in oggetto;
6. quali interventi terapeutici sono stati attivati per i soggetti in ricaduta o peggiorati, con particolare riguardo ad un eventuale nuovo ciclo di terapie farmacologiche.

D - Altri dati sensibili

Compliance della terapia farmacologica nel permettere il raggiungimento dei fini terapeutici globali indicati nella Conferenza Nazionale di Consenso *"Indicazioni e strategie terapeutiche per i bambini e gli adolescenti con disturbo da deficit attentivo e iperattività"* (3) *di Cagliare del 2003,* che al punto 4 testualmente recita:

1. migliorare le relazioni interpersonali con genitori, fratelli, insegnanti e coetanei;
2. diminuire i comportamenti dirompenti e inadeguati;
3. migliorare le capacità di apprendimento scolastico;
4. aumentare le autonomie e l'autostima;
5. migliorare l'accettabilità sociale del disturbo e la qualità della vita dei bambini affetti (dal disturbo, ndr).

Nota 3: è utile conoscere la percentuale di pazienti per i quali è stata attivata una programmazione didattica personalizzata a scuola. I dati di cui ai punti precedenti vanno profilati globalmente e separatamente per i due farmaci in oggetto, indicando gli strumenti utilizzati per rilevarli ed evidenziando anche le performance negative, con dati articolati a livello nazionale e regionale, e raggruppati per fasce di età.

E – Dati contestuali

Per una valutazione più ampia di quanto è avvenuto è utile avere i dati su:

1. rapporto diagnosi/trattamento farmacologico, articolati per regioni e nazionale;

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2. rapporto su tipologia e intensità delle patologie comorbili associate all'ADHD articolati per regioni e nazionale;
3. rapporto tra patologie psichiatriche diagnosticate e livello socioeconomico e culturale articolati per regioni e nazionale;
4. problematiche relative all'accesso agli interventi terapeutici non farmacologici con riguardo alla legislazione nazionale e locale (differenti dotazioni finanziarie per il LEA nelle diverse regioni) e alle possibilità economiche delle famiglie (NB: in una nota stampa del 15/04/09 è stata riportata a firma Panei e Bonati la frase *"Solo il 30% dei pazienti ha ricevuto una terapia psicofarmacologica associata a counseling e ad una terapia cognitivo-comportamentale come previsto dal protocollo del Registro e dalle linee guida nazionali e internazionali. L'applicazione dell'intero percorso diagnostico e terapeutico, riconosciuto come il più appropriato, è ancora ampiamente disattesa sull'intero territorio nazionale")*

COSTI ECONOMICI DEL TRATTAMENTO ADHD

Sarebbe assai utile permettere ai cittadini e alle associazioni rappresentative dei loro interessi di conoscere i dati relativi ai costi economici del trattamento dell'ADHD, globali e medio per singolo paziente. Potrebbero ad esempio essere utilizzati i parametri di valutazione della Dr. ssa Silvia Mazzotta et al. presso l'università degli Studi di Perugia, Scuola di Specializzazione in Neuropsichiatria Infantile (4). Il rapporto tra costi economici e benefici terapeutici è un buon indicatore della sostenibilità delle attuali linee guida ADHD, che sappiamo essere in corso di revisione. Il mero dato economico andrebbe a nostro avviso confrontato con le percentuali di guarigione, miglioramento e ricaduta, al fine di comprendere l'efficacia reale delle terapie proposte nonché valutare l'ipotesi di una maggiore attenzione verso una diagnosi differenziale più puntuale, al fine di prendere in carico e curare le vere patologie che "mimano" l'Adhd, come elencate nella relativa tabella (5). In merito – in allegato (A) - sottoponiamo alla Vostra attenzione un documento che ci auguriamo possa essere di adeguato stimolo per le autorità coinvolte e per la SINPIA ad aggiornare il listato – ad oggi assai carente - delle patologie oggetto di diagnosi differenziale, e dal momento che in più occasione da parte Vostra si è fatto riferimento alla medicina basata sulle evidenze (EMB), sostenendone giustamente l'importanza, abbiamo anche ritenuto opportuno segnalare in Appendice un'adeguata bibliografia scientifica, nella speranza che essa non venga un'ennesima volta ignorata.

il Portavoce Nazionale,
Luca Poma

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NOTE:

(1) di questo report parrebbe esistere solo una versione in lingua inglese (http://www.iss.it/binary/adhd/cont/Safety_of_psychotropic_drug_prescribed_for_1.pdf) , la cui correttezza è stata messa in discussione dal Prof. **David Cohen** (http://www.giulemanidaibambini.org/documentiscientifici/glm_documentiscientifici_60.pdf) in una sua analisi, per questa ragione chiediamo ne sia pubblicata e diffusa anche una versione in lingua italiana; http://www.giulemanidaibambini.org/documentiscientifici/glm_documentiscientifici_60.pdf

(2) http://www.giulemanidaibambini.org/documentiscientifici/glm_documentiscientifici_27.pdf

(3) http://www.sinpia.eu/atom/allegato/150.pdf

(4) http://adhd.altervista.org/it/doc/adhd_costi.pdf

(5) http://adhd.altervista.org/it/doc/lista_patologie.htm

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ALLEGATO (A)

La Diagnosi Differenziale che esclude la Diagnosi di ADHD[3]

La Diagnosi Differenziale in Psichiatria è stata da sempre assai difficile e complessa, in quanto di fronte a molteplici sintomi bisogna saper distinguere quelli del Disturbo principale da altri relativi al disturbo secondario; che a sua volta potrebbe essere conseguente al Disturbo principale o concomitante a questo o addirittura più precoce, ed entrambi possono avere la stessa causa o cause diverse.

E' quindi molto difficile stabilirne l'intima correlazione e comprenderne lo sviluppo psicopatologico, anche perché il parto e lo sviluppo successivo del bambino, il peso, l'altezza, le caratteristiche morfogenetiche e psicosociali, l'alimentazione e lo stile di vita, l'affettività e l'ambiente fisico, nonché altre malattie intercorrenti, risultano condizionanti circa l'insorgenza o meno delle diverse patologie, la loro riacutizzazione e/o cronicizzazione e le diverse recidive. Ed ancor più le terapie se riduttive o non appropriate possono ben condizionare il percorso dei Disturbi rendendoli poco riconoscibili alle comuni diagnosi.

In base a tali difficoltà sarà opportuno che il Medico che diagnostica una delle patologie elencate nella diagnosi differenziale in comorbidità all'ADHD ne faccia motivata segnalazione al registro ADHD, che provvederà alla elaborazione statistica di tale casistica, anche nell'intento di rendere più trasparente il concetto di "discrezionalità diagnostica" del DSM.

E sempre in ordine alle predette difficoltà diagnostiche sembra anche opportuno meglio indicizzare prevalentemente le nuove patologie più diffuse nella popolazione generale in aggiunta a quelle in elenco nella tabella 2. della SINPIA, che qui appresso si elencano con la relativa bibliografia: Disturbi del Sonno, Enuresi, Allergie ed Intolleranze alimentari, Disturbo dello sviluppo della coordinazione, Gestazione e Parto, Alimentazione scorretta o carente, Bioelementi quali manganese, ferro, zinco, magnesio, coloranti sintetici, mercurio, ftalati, marijuana, cocaina, alcool.

Inoltre la tabella 2 della SINPIA nelle "Linee-guida per la diagnosi e la terapia farmacologica del Disturbo da Deficit Attentivo con Iperattività (ADHD) in età evolutiva", inerente la Diagnosi differenziale e comorbidità, così come presentata, in linea con la filosofia del DSM, non separa le diagnosi differenziali da quelle di possibile comorbilità: ogni patologia è bivalente e discrezionalmente valutata, non tenendo in debito conto le complesse interrelazioni e la difficoltà proprie della Diagnosi differenziale.

[3] Documento scientifico originariamente elaborato a cura degli esperti Claudio Ajmone, Enrico Nonnis ed Emilia Costa, e successivamente fatto proprio dal Comitato "Giù le Mani dai Bambini"

Linee guida SINPIA ADHD: diagnosi & terapia farmacologiche

—— Approvazione CD il 24 giugno 2002 ——

Tab. 2. Diagnosi differenziale e comorbidità

Disturbi Psichiatrici

- Disturbo Oppositivo-provocatorio
- Disturbo di Condotta
- Disturbi dell'Umore
- Disturbo bipolare
- Disturbi d'ansia
- Disturbo ossessivo compulsivo
- Disturbi dell'Adattamento con sintomi di D. della condotta
- Sindrome di Gille de la Tourette /tic multipli
- Disturbi di personalità
- Disturbi specifici dell'apprendimento.
- Ritardo mentale
- Disturbo pervasivo dello sviluppo

Disturbi neurologici e Patologie Mediche

- Disturbi sensitivi (sordità deficit visivo)
- Effetti indesiderati di farmaci (antistaminici, betaagonisti, benzodiazepine, fenobarbital)
- Epilessia
- Patologie tiroidee
- Ascessi, neoplasie del Lobo frontale,
- Trauma cranico
- Abuso di sostanze
- Intossicazione da piombo

Disturbi di sviluppo

- Vivacità fisiologica
- Problemi situazionali, ambientali, familari.
- Inadeguato supporto scolastico (lieve ritardo o ,viceversa, particolare vivacità intellettiva con programmi scolastici "standard")
- Alterato supporto ambientale, sociale, familiare (ambiente caotico, divorzio, abbandono, abuso)

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Patologie e condizione che mimano l'ADHD

Integrazioni alla Tab. 2 della SINPIA

— gruppo di lavoro Comitato "Giù Le Mani Dai Bambini®" —

Per le ragioni sopra esposte, occorre - a nostro avviso - completare le flow-chart e le linee guida ISS, laddove intervengono sul concetto di Diagnosi differenziale, con particolare attenzione su:

1. Alimentazione scorretta o carente
2. Allergie e intolleranze alimentari
3. Asma
4. Dermatiti
5. Disordini del sonno
6. Disturbo di Sviluppo della Coordinazione
7. Enuresi
8. Encopresi
9. Ftalati
10. Mercurio
11. Organofosfati
12. PCB
13. Problemi legati alla gestazione e al parto
14. Riniti

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APPENDICE all'ALLEGATO (A):
bibliografia utile per eventuali integrazioni alla tab. 2 SINPIA e alle Linee Guida ISS

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