

## CORSO NAZIONALE

# RACCOMANDAZIONI CLINICO-TERAPEUTICHE SULL'OSTEONECROSI DELLE OSSA MASCELLARI (ONJ) ASSOCIATA A FARMACI E SUA PREVENZIONE

**CD REALIZZATO  
A OPERA DI**  
Argo Antonina  
Bedogni Alberto  
Campisi Giuseppina  
Di Fede Olga  
D'Alessandro Natale  
Fusco Vittorio  
Lo Casto Antonio  
Lo Muzio Lorenzo  
Lo Russo Lucio  
Panzarella Vera

**EDITING A CURA DI**  
Campisi Giuseppina  
Di Fede Olga  
Bedogni Alberto

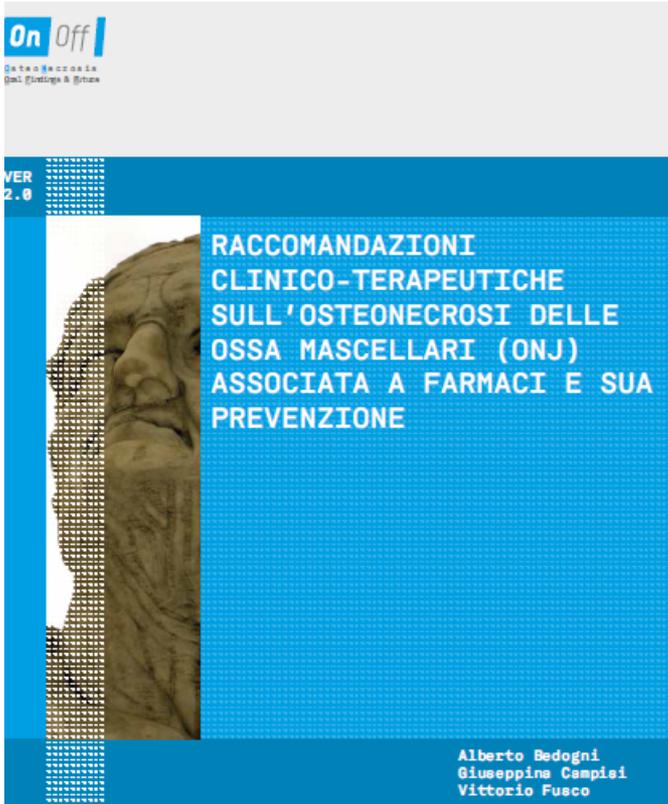


# INDICE CD



1. BACKGROUND e OBIETTIVI del CD
2. DEFINIZIONE di ONJ
3. EPIDEMIOLOGIA di ONJ e FARMACI ASSOCIATI
4. DIAGNOSI di ONJ
  - Diagnosi clinica
  - Diagnosi radiologica
5. STAGING di ONJ
6. PREVENZIONE PRIMARIA e DIAGNOSI PRECOCE di ONJ
7. TERAPIA di ONJ
8. MEDICINA LEGALE e ONJ
9. MANAGEMENT ODONTOIATRICO

CENTRI di RIFERIMENTO



# 1. *BACKGROUND e OBIETTIVI del CD*

Versione 2.0/2015



SICMF  
SOCIETÀ ITALIANA  
DI CHIRURGIA  
MAXILLO-FACCIALE



SPMO  
SOCIETÀ ITALIANA  
DI PATOLOGIA  
E MEDICINA ORALE

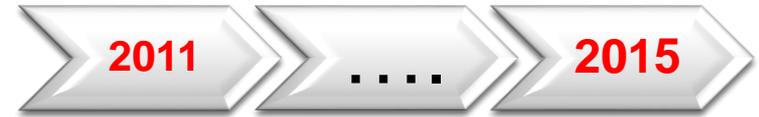


# ONJ

## è un problema?

2

**Un problema è "un problema" quando viene avvertito come tale e  
quando non si hanno le giuste risposte alle domande.**



# PROGETTO “BIS”



FEDERAZIONE NAZIONALE ORDINE DEI MEDICI CHIRURGI ED  
ODONTOIATRI

CAO- COMMISSIONE ALBO ODONTOIATRI NAZIONALE

OSTEONECROSI DEI MASCELLARI DA **BIS**FOSFONATI (BRONJ)  
PROGETTO DI PREVENZIONE PRIMARIA SECONDARIA E TERZIARIA

*PER OPERATORI SANITARI ODONTOIATRICI E MEDICI*

IN COLLABORAZIONE CON



# Razionale originario

2011

## IL VALORE DEL PROGETTO

- migliorare la consapevolezza dei professionisti della salute orale e generale sui fattori di rischio noti per BRONJ
- migliorare la loro capacità di informare
- allenare gli operatori sanitari odontoiatrici alla diagnosi precoce di BRONJ
- fornire una **Rete di Riferimento** di strutture accreditate specializzate nelle strategie di diagnosi e terapia di BRONJ

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# Difetto di conoscenza e di comunicazione

# IMPATTO SOCIALE

## Protagonisti

PAZIENTE/FAMILIARI

ODONTOIATRA

MEDICO PRESCRITTORE

Tutta l'informazione in un CLICK?

COUNSELLING

INFORMAZIONE  
"INFORMATA"

BISFOSFONATI

≠

ONJ

### ATTIVA COLLABORAZIONE

1. ODONTOIATRA
2. MEDICO PRESCRITTORE
3. PAZIENTE

# IMPATTO SOCIALE



**Tutta l'informazione in un CLICK?**

La cattiva informazione o l'errata interpretazione dei dati può creare PANICO tra la popolazione non medica che cerca su Internet le risposte ai propri dubbi



File Modifica Visualizza Preferenze

Google osteonecrosi da bifosfonati

Effettua la ricerca

Condividi

Controlla

Google osteonecrosi da bifosfonati

Web Immagini Shopping Notizie Maps Altro Strumenti di ricerca

Circa 10.200 risultati (0,22 secondi)

Web Immagini Video Pagine Gialle Shopping altro

osteonecrosi da bifosfonati

Cerca Opzioni

1 2 3 4 5 Successiva

YAHOO! ITALIA

31,600 risultati

VIRGILIO RICERCA

osteonecrosi da bifosfonati

CERCA

Web

nel Web nelle pagine in italiano

2.350 di risultati per osteonecrosi da bifosfonati - tempo di risposta: 0.099 secondi

Cerca: osteonecrosi da bifosfonati

LIBERO

nel Web Pagine in italiano Ricerca avanzata

2.350 di risultati per osteonecrosi da bifosfonati - tempo di risposta: 0.092 secondi

Risultati 1 - 10 su circa 777 per osteonecrosi da bifosfonati (0.08 secondi)

# Conoscenza del problema da parte di studenti di odontoiatria e dentisti libero-professionisti – Spagna

## Risultati dell'indagine

- 50% degli studenti ed il 41% dei laureati erano aggiornati relativamente ad aspetti clinici e presunti fattori di rischio
- Solo il 13,33% degli studenti ed il 33,33% dei dentisti avevano nozioni corrette circa la prevenzione e il trattamento delle osteonecrosi.

**López-Jornet P, Camacho-Alonso F, Molina-Miñano F, Gomez-Garcia.**

*Bisphosphonate-associated osteonecrosis of the jaw. Knowledge and attitudes of dentists and dental students: a preliminary study.*

*J Eval Clin Pract. 2010 Oct;16(5):878-82.*

# Conoscenza del problema osteonecrosi in un gruppo di pazienti in terapia orale con bisfosfonati - USA

## Risultati dell'indagine

- 84% degli intervistati sapeva quali farmaci stava assumendo
- 80% non ricordava il periodo di assunzione
- 82% non risultava informato del rischio di osteonecrosi

**Migliorati CA, Mattos K, Palazzolo MJ.**

*How patients' lack of knowledge about oral bisphosphonates can interfere with medical and dental care.*

*J Am Dent Assoc. 2010 May;141(5):562-6.*

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## Conoscenza della ONJ e delle problematiche connesse:

- ✓ **60% of Ontario general dentists and specialists have a good knowledge about ONJ**
  - Alhussain A et al. Knowledge, Practices, and Opinions of Ontario Dentists When Treating Patients Receiving Bisphosphonates. *Journal of Oral and Maxillofacial Surgery*. 2015 Jan.
- ✓ **59.6 % of dentists 58 % of dental students did not recognize ONJ as an oral side effect of BP**
  - de Lima PB et al. Knowledge and attitudes of Brazilian dental students and dentists regarding bisphosphonate-related osteonecrosis of the jaw. *Support Care Cancer*. 2015 Mar 11.

# Conoscenza della ONJ e delle problematiche connesse:

- ✓ **37.5 % of participants (prescribing physicians) were unaware of bisphosphonate-related ONJ**
  - Osta El L et al. Bisphosphonate-related osteonecrosis of the jaw: awareness and level of knowledge of Lebanese physicians. *Support Care Cancer*. 2015 Feb 13.

# IL VALORE DEL PROGETTO

E' la **seconda volta** che in Italia  
**CAO** (Commissione Albo Odontoiatri Nazionale)  
e  
le società scientifiche nazionali di riferimento  
in tema di salute orale (**SIPMO e SICMF**)

pianificano un **intervento congiunto di motivazione ed educazione, in questo caso** alla prevenzione primaria e secondaria per ONJ con presentazione di una Rete di Riferimento

# IL VALORE DEL PROGETTO

- migliorare la **consapevolezza** dei professionisti della salute orale e generale sui fattori di rischio noti per ONJ
- migliorare la loro **capacità** di informare
- **allenare** gli operatori sanitari odontoiatrici alla diagnosi precoce di ONJ
- fornire una **Rete di Riferimento** di strutture accreditate specializzate nelle strategie di prevenzione, diagnosi e terapia di ONJ

# Obiettivo specifico

Il progetto prevede di raggiungere l'obiettivo specifico di migliorare la performance degli odontoiatri in termini di prevenzione primaria e secondaria di

**ONJ (Osteonecrosis of Jaws) da farmaci**

# Azione #1: Costituzione della commissione per la opinione condivisa e la stesura del manuale di riferimento (fine 2011)

composta da Chirurghi Maxillo-Facciali, da Odontoiatri e Medici con competenze di Medicina e Patologia Orale, Chirurgia Orale e Oncologia\*

**Alessandro Agrillo, Alberto Bedogni, Giuseppina Campisi, Vittorio Fusco**

e con la collaborazione scientifica di\*

**Olga Di Fede, Antonio Lo Casto, Lucio Lo Russo, Claudio Marchetti, Giorgia Saia, Stefano Valsecchi, Paolo Vescovi**

\*(in ordine alfabetico)

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# Prodotto #1: *Position paper* su protocolli odontoiatrici-2011

## REVIEWS

IT J MAXILLOFAC SURG 2011;22:103-24

### *BRONJ expert panel recommendation of the Italian Societies for Maxillofacial Surgery (SICMF) and Oral Pathology and Medicine (SIPMO) on Bisphosphonate-Related Osteonecrosis of the Jaws: risk assessment, preventive strategies and dental management*

G. CAMPISI <sup>1</sup>, L. LO RUSSO <sup>2</sup>, A. AGRILLO <sup>3</sup>, P. VESCOVI <sup>4</sup>, V. FUSCO <sup>5</sup>, A. BEDOGNI <sup>6</sup>

Bisphosphonate-related osteonecrosis of the jaw (BRONJ) is an adverse drug reaction that negatively impacts on the quality of life of afflicted patients. To date, the pathogenesis of this disease is still controversial and the most effective treatment protocols are still not established. In this scenario, the construction of a preventive strategy for BRONJ and, above all, the identification of efficient dental strategies to manage patients taking aminobisphosphonates (NBP) have become a clear need for physicians and dentists. The Board of the Italian Societies for Maxillofacial Surgery (SICMF) and Oral Pathology and Medicine (SIPMO) appointed a Panel of experts for the study of bisphosphonate-related osteonecrosis of the jaws with the following aims: 1) to provide updated perspectives on categories of patients at risk for BRONJ and give a thorough description of the most recognized risk factors; 2) to supply clinicians with updated strategies for prevention of BRONJ; 3) to provide clinicians with a schematic approach to the routine dental management of patients at risk for BRONJ. The BRONJ pertinent literature was collected and studied. On the basis of available evidence and after discussion among panelists, the main local and systemic risk factors as well as prevention strategies have been reviewed, discussed and presented; in addition, flow charts with clinical recommendations for the dental

*Acknowledgements.*—The authors acknowledge dr. Valeria Mercadante (DMD), currently PhD student at the UCL Eastman Dental Institute of London, UK for her important contribution to the final editing of the paper.

*Conflicts of interest.*—The authors state that they do not currently hold or have held any full-time or part-time employment or service as officers or board members, any consultant or advisory arrangements, any ownership interest in any company (publicly traded or privately held) having an investment, licensing, or other commercial interest in the subject matter under consideration in the present manuscript.

Received on November 15, 2011.

Accepted for publication on November 16, 2011.

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management in patients affected by malignancies or osteometabolic disorders, who are about to start or have already started NBP intake, are provided.

**KEY WORDS:** Osteonecrosis, prevention and control - Jaw - Practice management, dental.

Bisphosphonate-related osteonecrosis of the jaw (BRONJ) is an adverse drug reaction that negatively impacts on the quality of life of afflicted patients. Since the first report of BRONJ in 2003, hundreds studies have focused on this topic; nonetheless, the pathogenesis of this disease is still controversial and effective treatment protocols are away from being recognized. In this view, the construction of a preventive strategy for BRONJ and, above all, the

## Autori:

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Vittorio Fusco, Alberto Bedogni

# Prodotto #2: Letter to Editor su Definizione ONJ- 2012



## LETTER TO THE EDITOR

### Learning from experience. Proposal of a refined definition and staging system for bisphosphonate-related osteonecrosis of the jaw (BRONJ)

Dear Editor,

It is the authors' belief that the internationally accepted definition of bisphosphonate-related osteonecrosis of the jaws (BRONJ) (Ruggiero *et al.*, 2009) has several limitations that prevent clinicians from being confident with the diagnosis of the disease. Following recognition of the non-exposed BRONJ clinical variant (Lazarovici *et al.*, 2009), we all became aware that the presence of 'exposed necrotic bone in the oral cavity', as outlined in the American Association of Oral and Maxillofacial Surgery (AAOMS) case definition, is just one of the possible clinical manifestations of BRONJ and is not found in all BRONJ patients. As 'bone exposure' is certainly not the initial sign of BRONJ in most patients and a minimum of 6-8 weeks' persistence is required to confirm the clinical suspicion, the final diagnosis is usually delayed for several weeks or months. Therefore, to date, it has been almost impossible to study the early phases of BRONJ. This delayed diagnosis can also explain, at least in part, why the disease is often refractory to the medical and surgical treatments commonly used.

We believe that clinicians will benefit from a definition of BRONJ that contains only robust information, without considering any definite clinical picture or a binding timeframe (i.e. 6-8 weeks). As qualified members of the Expert Panel of the Italian Society for Maxillofacial Surgery (SICMF) and the Italian Society of Oral Pathology and Medicine (SIPMO) on Bisphosphonate-Related Osteonecrosis of the Jaws, we are submitting to the attention of the scientific community the following definition of BRONJ: *bisphosphonate related osteonecrosis of the jaw (BRONJ) is an adverse drug reaction described as the progressive destruction and death of bone that affects the mandible or maxilla of patients exposed to the treatment with nitrogen-containing bisphosphonates, in the absence of a previous radiation treatment.*

Along with this new definition of BRONJ, we set up and propose a diagnostic work-up to be used to reach the final diagnosis.

Although exposed necrotic bone in the oral cavity still remains the best indicator of BRONJ (Ruggiero *et al.*, 2009), other non-specific signs and symptoms (Table 1) should raise the suspicion of BRONJ, even in a patient with a well-recognized dental or periodontal disease (Fedele *et al.*, 2010). In short, BRONJ should be always

investigated in a patient taking nitrogen-containing bisphosphonates (NBP), when one or more clinical signs are present. Because BRONJ is primarily a disease that affects the jawbone, we strongly believe that radiological examination is an important step of the diagnosis. However, as the radiological findings may be characteristic not only of BRONJ (Khan *et al.*, 2008), these findings should always match the clinical picture, in order to progress from the clinical suspicion to the final diagnosis. This is of utmost importance as bone biopsies for histology are still not routinely advised for the risk of worsening the disease process. A schematic approach to the work-up for a diagnosis of BRONJ is proposed (Scheme 1), where computed tomography (CT) currently represents the most useful diagnostic tool because of its widespread use and accessibility for patients (Bianchi *et al.*, 2007). Structural alteration of trabecular bone is a consistent finding of CT scans performed in patients with BRONJ (Table 2) (Arce *et al.*, 2009). CT scans can clearly depict the degree of osteosclerosis of the affected site, visible as the loss of contrast definition between the endosteal cortex and the subjacent medullary bone (i.e. trabecular thickening and/or regional or diffuse osteosclerosis), with respect to the uninvolved bone tissue (Hutchinson *et al.*, 2010). Osteosclerosis seems to characterize the early stages of disease and also precedes the occurrence of frank bone exposure in the oral cavity (Saia *et al.*, 2010), and thus it should be searched for to provide an early diagnosis.

Even though magnetic resonance imaging (MRI) provides more detailed information than CT on focal bone marrow alterations (Bislan *et al.*, 2008), the former could provide non-diagnostic results owing to magnetic artifacts caused by the presence of dental casting alloys (Shafiq *et al.*, 2003) as well as to motion artifacts caused by the prolonged time necessary to scan the head and neck region (Lenz *et al.*, 2000). The majority of BRONJ cases could be diagnosed and staged correctly by the combined use of clinical methods and CT, the latter method currently being more cost-effective and easily accessible than MRI. On the other hand, we believe that MRI should be used to evaluate cases difficult to identify with CT and to establish the real extent of jawbone and soft-tissue involvement in BRONJ patients who are candidates for surgical resection.

The staging system of a bone disease that relies on the use of radiologic imaging for its diagnosis should also be based on the common radiologic features of the disease. The current AAOMS staging system (Ruggiero *et al.*,

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## Autori:

Alberto Bedogni, Vittorio Fusco,  
Alessandro Agrillo, Giuseppina Campisi



## Manuale di riferimento

Raccomandazioni clinico-terapeutiche nella osteonecrosi delle ossa mascellari associata a bisfosfonati e sua prevenzione

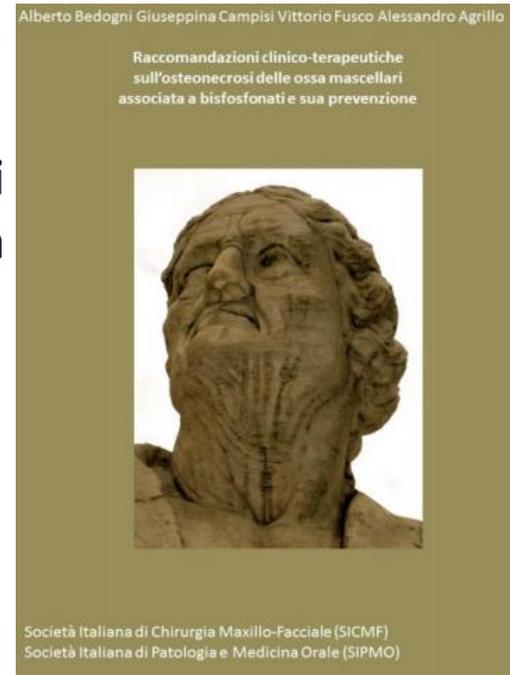
Bedogni A, Campisi G, Fusco V, Agrillo A. **Marzo 2013**

[http://www.sipmo.it/webook/ebook/book1/index\\_max.html](http://www.sipmo.it/webook/ebook/book1/index_max.html)

### A chi si rivolge?

- **Odontoiatri e Chirurghi oro-maxillo-facciali**
- **Specialisti delle discipline odontostomatologiche**

*e altri Professionisti della salute operanti sul territorio nazionale*



# Prodotto #4: Raccomandazioni Ministero della Salute



## MINISTERO DELLA SALUTE

*Dipartimento della sanità pubblica e dell'innovazione*

Logo Ministero della Salute

02/apr/2014 | News Italy

0 Comments

Raccomandazioni per la promozione della salute orale, la prevenzione delle patologie orali e la terapia odontostomatologica nei pazienti adulti con malattia neoplastica

...

### 9. APPENDICE

PREVENZIONE ODONTOIATRICA E SICUREZZA DEI TRATTAMENTI ODONTOIATRICI NEI PAZIENTI CON MALATTIA NEOPLASTICA TRATTATI CON BISFOSFONATI, DENOSUMAB E/O ANTI-ANGIOGENETICI.

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# ... a causa della osservazione di nuovi farmaci associati a osteonecrosi delle ossa mascellari

Br Dent J. 2015 Sep 11;219(5):203-7.

## **New cancer therapies and jaw necrosis.**

Patel V, Kelleher M, Sproat C, Kwok J, McGurk M.

Guys Dental Hospital, London Bridge, London, SE1 9RT.

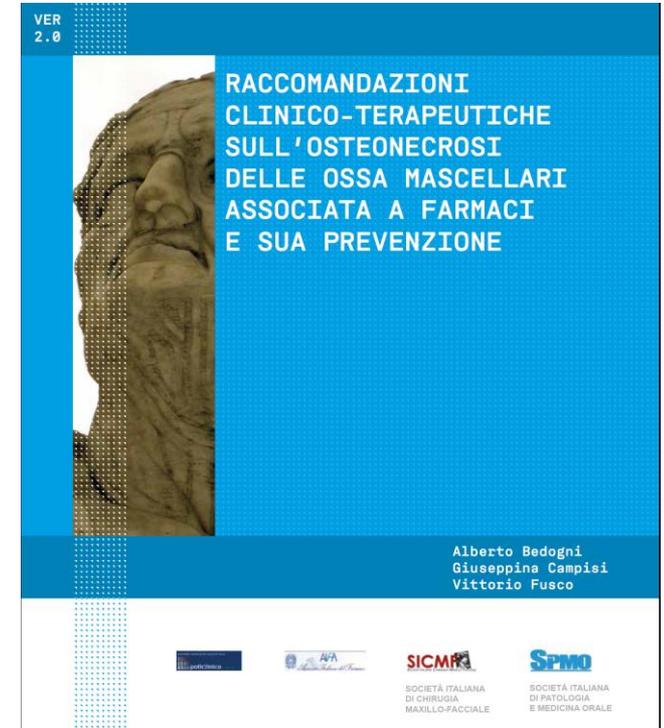
### **Abstract**

Osteonecrosis of the jaw (ONJ) has a number of causes, the most familiar being radiation or bisphosphonate induced. Various other novel anti-neoplastic and bone-targeting therapies that can also cause jaw necrosis have recently become available. This has led to the suggested acronym MRONJ for medication-related osteonecrosis of the jaw. This article summarises the available information on these drugs and their implications for the dental surgeon.

# Prodotto #5: Manuale di riferimento - REVISIONE

Vers 2.0

Revisione motivata dalla necessità di divulgare raccomandazioni non solo per la prevenzione di ONJ da BP, ma anche altri antiriassorbitivi (denosumab) e antiangiogenetici (e.g. bevacizumab)  
*INCOMING*



# Razionale **aggiornato** del progetto originario (SIPMO-SICMF-CAO)

Diffondere gli alert relativi agli altri farmaci coinvolti nell' ONJ, oltre a BP

- ✓ BP
- ✓ altri antiriassorbitivi (denosumab)
- ✓ antiangiogenetici (e.g. bevacizumab)

# Obiettivo specifico **aggiornato**

**Diffondere gli alert relativi agli altri farmaci coinvolti nell' ONJ**

Divulgare nuove conoscenze in tema di ONJ

Implementare la Farmacovigilanza  
SEGNALAZIONE DI ONJ DA BP E ALTRI FARMACI

Motivare alla prevenzione primaria e rinforzare la prevenzione secondaria

Ampliare il network dei centri di riferimento e uniformare i percorsi di prevenzione, diagnosi e cura della ONJ

# Letteratura consigliata

- ✓ **Osteonecrosis of the Jaw in Patients With Metastatic Renal Cell Cancer Treated With Bisphosphonates and Targeted Agents: Results of an Italian Multicenter Study and Review of the Literature.**

Fusco V, Porta C, Saia G, Paglino C, Bettini G, Scoletta M, Bonacina R, Vescovi P, Merigo E, Lo Re G, Guglielmini P, Di Fede O, Campisi G, Bedogni A.

*Clin Genitourin Cancer.* 2015 Aug;13(4):287-94.

- ✓ **Up to a quarter of patients with osteonecrosis of the jaw associated with antiresorptive agents remain undiagnosed.**

Fedele S, Bedogni G, Scoletta M, Favia G, Colella G, Agrillo A, Bettini G, Di Fede O, Oteri G, Fusco V, Gabriele M, Ottolenghi L, Valsecchi S, Porter S, Fung PP, Saia G, Campisi G, Bedogni A.

*Br J Oral Maxillofac Surg.* 2015 Jan;53(1):13-7.

- ✓ **Staging of osteonecrosis of the jaw requires computed tomography for accurate definition of the extent of bony disease.**

Bedogni A, Fedele S, Bedogni G, Scoletta M, Favia G, Colella G, Agrillo A, Bettini G, Di Fede O, Oteri G, Fusco V, Gabriele M, Ottolenghi L, Valsecchi S, Porter S, Petrucci M, Arduino P, D'Amato S, Ungari C, Fung Polly PL, Saia G, Campisi G.

*Br J Oral Maxillofac Surg.* 2014 Sep;52(7):603-8.

# Letteratura consigliata

- ✓ **Osteonecrosis of the jaw (ONJ) in renal cell cancer patients after treatment including zoledronic acid or denosumab.**  
Fusco V, Bedogni A, Campisi G.  
*Support Care Cancer*. 2014 Jul;22(7):1737-8. Erratum in: *Support Care Cancer*. 2014 Jul;22(7);1739.
- ✓ **Epidemiology, clinical manifestations, risk reduction and treatment strategies of jaw osteonecrosis in cancer patients exposed to antiresorptive agents.**  
Campisi G, Fedele S, Fusco V, Pizzo G, Di Fede O, Bedogni A.  
*Future Oncol*. 2014 Feb;10(2):257-75.
- ✓ **Learning from experience. Proposal of a refined definition and staging system for bisphosphonate-related osteonecrosis of the jaw (BRONJ).**  
Bedogni A, Fusco V, Agrillo A, Campisi G.  
*Oral Dis*. 2012 Sep;18(6):621-3.

# Azione #2: Rete di riferimento (e sua divulgazione)



<http://www.sipmo.it/wp-content/uploads/2014/12/STRUTTURE-SANITARIE-PUBBLICHE-ITALIANE-PER-ONJ.pdf>

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# Azione #3: Corso SIPMO- SICMF- CAO aa 2015-16

*Referente CAO Nazionale*  
Dott. Giuseppe Renzo

*Referente Nazionale del Progetto*  
Prof. Lorenzo Lo Muzio

## *Comitato organizzatore*

Dott. Alessandro Zovi (CAO)  
Prof.ssa Giuseppina Campisi (Vice-Presidente SIPMO)  
Prof. Pierfrancesco Nocini (Presidente SICMF)

## *Comitato Scientifico*

Prof.ssa Giuseppina Campisi (Vice-Presidente SIPMO)-*Coordinatore*  
Dr. Alberto Bedogni (SICMF)  
Dr. Vittorio Fusco (Rete Oncologica Piemonte e Val d'Aosta)  
Prof. Claudio Marchetti (SICMF)

# Azione #3: Corso SIPMO-SICMF-CAO aa 2015-16

## CORSO NAZIONALE

### RACCOMANDAZIONI CLINICO-TERAPEUTICHE SULL'OSTEONECROSI DELLE OSSA MASCELLARI (ONJ) ASSOCIATA A FARMACI E SUA PREVENZIONE

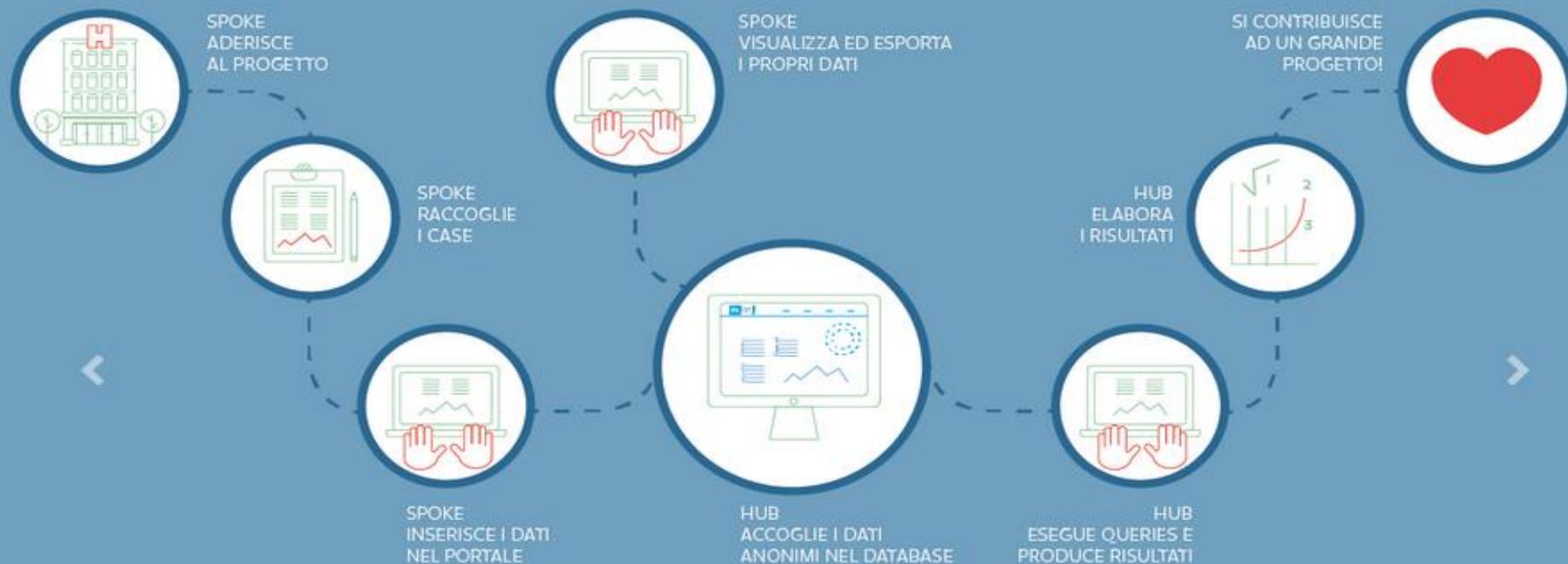


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EDITING A CURA DI  
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Di Fede Olga  
Bedogni Alberto

# Prodotto #7: database per gestione casi ONJ di singolo centro

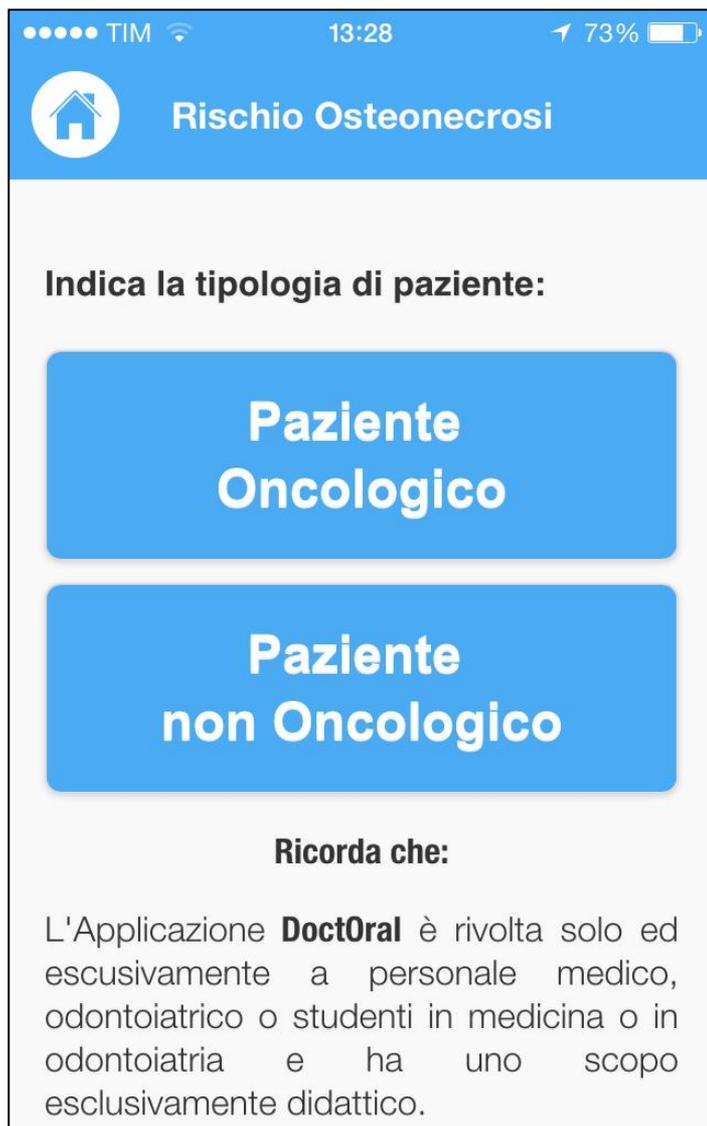
[http://onoff.sipmo.it/on\\_off/login](http://onoff.sipmo.it/on_off/login)



ACCEDI



## Prodotto #8: App con sezione dedicata alla gestione odontoiatrica del paziente a rischio di ONJ



per iOS

<https://itunes.apple.com/us/app/doctoral/id1071070334?l=it&ls=1&mt=8>

per Android

<https://play.google.com/store/apps/details?id=com.olgadifede.olgapp&hl=it>



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● fax: +39 091 23860861