OVERVIEW

Re-organisation of the management of patients affected with chronic pathologies in Lombardy Region: critical points associated with the management of HIV positive patients

U. RESTELLI¹², D. CROCE¹², F. MILELLA³, G. RIZZARDINI⁴⁵

¹Center for Health Economics, Social and Health Care Management, LIUC - Università Cattaneo, Castellanza (VA), Italy; ² School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa; ³ LIUC - Università Cattaneo, Castellanza (VA), Italy; ⁴ Department of Infectious Diseases, ASST Fatebenefratelli Sacco University Hospital, Milan, Italy; ⁵ School of Clinical Medicine, Faculty of Health Sciences University of the Witwatersrand, Johannesburg, South Africa

Keywords

HIV • Chronic patients • Public health

Summary

The Regional Council of Lombardy Region published in 2017 two resolutions related to a re-organisation of the management pathway of patients affected with chronic pathologies, to meet the changing needs of the users. The objective of this document is to provide recommendations to the Regional Health Service of Lombardy Region to manage the implementation of the resolutions considering peculiar aspects related to the management of HIV positive patients.

These resolutions are a concrete answer to the changing needs of health care users within the regional context. The design of the new approach is coherent with the objectives stated, allowing a tighter integration between hospital services, primary care services and social services, however it should be adapted to each of the 62 chronic pathologies considered. In the case of HIV, not considering antiretroviral treatments within the tariff might limit the cost management capability of the case manager. The full implementation of the resolutions with the inclusion of social services will allow a complete management of chronic patients with positive consequences on their quality of life.

Introduction

The Regional Council of Lombardy Region published in 2017 two resolutions related to a re-organisation of the management pathway of patients affected with chronic pathologies [1, 2]. In details, the objectives of the Regional Health Service are to modify the organization of the health care services to meet the changing needs of the users within the Regional context.

In the last years, the number of chronic patients, in fact, is increasing due to better available health technologies, leading, as in the case of HIV infection, to an epidemiologic transition; and their clinical conditions are increasingly more complex, due to concomitant chronic pathologies.

Healthcare services related to chronic patients represents 70% of direct medical costs for the Regional Health Service, as reported in a Regional Bulletin of 2016, while chronic patients represents 30% of the total number of residents within Lombardy Region. Therefore, most of the regional healthcare resources are devoted to the management of a minority of the whole regional population [3].

The authors of this editorial, agree with the principles that lead the regional authorities to modify the approach to the management of chronic patients. The aforementioned resolutions, refer to the management of 62 chronic pathologies, with different health consequences in terms of clinical and humanistic burden for patients and different backgrounds in terms of available guidelines and clinical pathways implemented by pathology related scientific societies.

The objective of this document is to provide recommendations to the Regional Health Service of Lombardy Region to manage the implementation of the resolutions considering peculiar aspects related to the management of HIV positive patients.

The content of the two resolutions

With the resolutions of the Regional Council number x/6164 of the 30th of January 2017 and number x/6551 of the 4th of May 2017 [1, 2], Lombardy Region continued on the pathway of reforms of the Regional Health Service, started in 2015 with the Regional Law number 23 [4].

The focus of the two resolutions is the management of patients affected with chronic pathologies. In details, the principles of the documents are the shift of the actual curative pathway of patient to a pro-active approach in terms of programming on an annual basis the therapeutic and monitoring pathway of each patient, based on his/her needs; the identification of a single "managing provider" responsible for the management of the patient pathway (including co-morbidities); and the integration between health care and social services, and between different levels of care (i.e. hospitals and territorial services) at a regional level.

The objective is to increase the personalization of the curative pathway, overcoming the actual fragmentation of the health services, integrating the needs of the patient into a single pathway, defined and coordinated by the managing provider, that can be both identified at a hospital level or at a primary care level.

From a financial point of view, the resolutions indicate the overcoming of the actual remuneration system, based on the health services provided to patients (pay per service), to consider a single tariff per main chronic pathology and per level of complexity of the patient, that will cover all the health care needs of the patient associated with his/her chronic conditions. The tariffs will be based on the value of the health services provided in previous years to patients with homogeneous levels of complexity and main chronic pathology.

The three levels of complexity considered for each of the 62 chronic pathologies taken into consideration are based on the number of chronic co-morbidities: the third level consider patients affected by one chronic pathology, the second level consider patients affected by two or three chronic pathologies and the first level consider patients affected by four or more chronic pathologies.

The process of implementation of the new approach is based on four phases: the categorization of chronic patients; patients' enrollment; the organization of the curative pathway; and the monitoring of the activities and reimbursement of the managing provider.

HIV management peculiarity

Considering the level of complexity of the management of HIV positive patients and the specialization and experience needed to plan a medium-long term clinical pathway, we expect that the managing provider accredited for the management of HIV positive patients will be a hospital provider. HIV positive patients are nowadays already managed by hospital wards both for therapies dispensation and clinical pathway organization. From this point of view no differences are expected, beside the positive aspects related to the management of booking of examinations that will be performed by a service center, as indicated in the regional resolutions, to facilitate the access to health services for patients.

Furthermore, no differences in terms of patients' compliance to antiretroviral therapies and appropriateness of

prescriptions are expected, due to their estimated actual high level.

The implementation of pathways for each chronic condition of the patients, might lead to synergies among them, in case of concomitant pathologies, however, no significant differences in the cost of management of HIV positive patients are forecasted, due to the severity of the pathology.

Critical points and proposals

SOURCES FOR THE DETERMINATION OF THE INDIVIDUAL CARE PATHWAYS

Every year the clinical manager of each patient is responsible for the definition of an individual care pathway, indicating all the health care services expected for the monitoring and curative process of the patient.

The two referral documents should be the Italian national guidelines for the treatment of HIV positive patients and the Lombardy Region clinical pathway [5, 6]. These documents reports precise details related to the therapies to be provided to HIV positive patients, with limited indications related to diagnostic and monitoring activities.

The high variability of clinical decisions related to diagnostic activities grants the freedom of clinicians to identify the most appropriate diagnostic pathway but conflict with the objective to limit the variability of prescriptive choices.

According to the authors the Lombardy Region pathway for HIV patients should be revised, providing detailed information on the monitoring and diagnostic activities recommended for patients.

SERVICES CONSIDERED IN THE DEFINITION OF THE PATIENTS' MANAGING TARIFFS

The applicability of the model depends on the congruity of the tariffs related to the level of complexity of patients. The resolution of the 4th of May 2017 reports tariffs equal to 1,727.05 € for level 1, to 1,146.28 € for level 2 and to 999.55 € for level 3. The tariffs should cover outpatient activities and, for level 1, hospitalizations [2]. A recent study conducted within the former Local Health Authority of Brescia [7], reports a per capita annual cost for HIV positive patients for outpatient activities equal to 1,544 € between 2012 and 2014. This value is higher, than the tariffs of the levels of complexity 2 and 3, however it is not clear how the patients of the cohort considered were distributed among the three levels of complexity. Adding the cost for hospitalizations, the annual per capita cost would be of 2,727 €, higher than the tariff considered for the level of complexity 1.

An estimation of the per capita outpatient activities to be carried out on a yearly basis per type of monitoring (excluding specialist visits) can be derived from the Italian Guidelines on HIV/AIDS as follow: viral, between 221.70 € and 1,330.20 €; immunologic, between 17.95 € and 215.40 €; cardiovascular disease risk, 291.83 €; hy-

pertension / dyslipidemia / diabetes mellitus, between 7.40 € and 9.10 €; liver disease, between 77.35 € and 155.95 €; pulmonary disease risk, 144.08 €; kidney disease risk, 15.40 € and bone disease risk, between 78.08 € and 129.18 €.

The minimum and maximum per capita cost for the Regional Health Service related to the monitoring activities recommended (excluding specialist visits) are $853.79 \in$ and $2.291.14 \in$.

The analysis of the annex 1 of the resolution of the 4th of May, does not allow a calculation of the costs related to the health care services provided to HIV positive patients in Lombardy Region in the year 2016, due to the fact that some of the services are reported in aggregated form, i.e. "immune-hematology – transfusion", "clinical chemistry" and "laboratory in general". This information was partially clarified by the data presented in the resolution of the Directorate General for Health of Lombardy Region of the 3rd of August 2017 [8], which was, however, based on a lower number of patients compared with the previous resolution [2] and with the aggregated categories as "visit-clinical chemistry laboratory analysis, microbiology, etc...".

According to the authors, a higher degree of transparency should be provided by the Regional Health Service on the way the tariffs will be defined, i.e. considering historical data of reimbursements related to the services provided, or measuring the real cost of delivering the health care services within selected providers.

Furthermore, the level of each tariff should be revised on a yearly basis not only considering retrospective data, but also the most recent recommendations of Italian and international guidelines, the regional clinical pathway for HIV/AIDS and the availability of new health technologies.

THE ANTIRETROVIRAL THERAPY

The capacity of clinical managers to control the health expenditures related to HIV patients are significantly limited due to the exclusion of antiretroviral therapies from the tariff. Antiretroviral therapies, in fact, represent around 80% of the direct health costs for the management of HIV positive patients.

To allow a higher control of expenditures, the authors recommend to include the cost of antiretroviral therapies in the reimbursement tariff for the management of patients.

Definition of tariffs for complexity levels 1 and 2

The tariffs considered for the management of pluri-pathologic patients depend on the main pathology they are affected with. Within the regional resolutions it is not explained how the main pathology is determined. The determination of the main pathology, in fact, influences the tariff considered for the management of patients and varies from almost $33,000 \in$ for kidney failure to between $100 \in$ and $200 \in$. The congruity of the tariff, therefore, depends on the pathology that is considered as the main one to assign a patient to a specific category.

The aforementioned study conducted in the former Local Health Authority of Brescia reports additional direct health costs for comorbidities equal to +1,701.4 for diabetes, +2,087.7 for cardiovascular disease, +3,756.8 for gastroenterology pathologies, +4,103.3 for respiratory chronic pathologies, +4,388.8 for liver diseases, +7,557.6 for tumors, +13,665.3 for kidney failure.

These values would not be sustainable considering the tariffs for level 1 and level 2 for HIV positive patients. The authors recommend more transparency related to the algorithm used to define the prevalent chronic pathology that assign pluri-pathologic patients to a specific category.

INTEGRATION BETWEEN HOSPITAL AND TERRITORIAL SERVICES

To grant a real management of the health care needs of chronic patients, a further integration of the different care setting is necessary. The Regional law number 23 of 2015 [4], promoted the implementation of territorial services for the management of patients requiring low intensity of care, however, considering HIV positive patients, residential homes, as nursing homes, are often not able to offer services to these patients. A central role, in terms of integration between hospital and territorial services should be played by general practitioners.

CUSTOMER SATISFACTION

As reported in the resolution of May 2017 [2], the assessment of the customer satisfaction could identify critical aspects of the implementation of the new approach towards chronic patients.

It would be important to implement a regional document to be used within each managing provider, to provide homogeneous information within the regional context. Previous similar experiences at a primary care level (i.e. CReG) revealed high level of satisfaction among patients enrolled.

Conclusions

The resolutions on chronic patients management in Lombardy Region are a concrete answer to the changing needs of health care users within the regional context. The design of the new approach is coherent with the objectives stated in the regional documents, allowing a tighter integration between hospital services, primary care services and social services, however it should be adapted to each of the 62 chronic pathologies considered. In the case of HIV, for instance, not considering antiretroviral treatments within the tariff might limit the cost management capability of the case manager.

The full implementation of the resolutions with the inclusion of social services will allow a complete management of chronic patients with positive consequences on their quality of life. The overcoming of the critical aspects reported in this commentary might help the Regional Health Service to customize the approach pro-

.....

posed to fit the needs related to a relevant pathology as that of HIV infection.

Acknowledgements

The analysis was supported by an unconditional grant from Gilead Sciences.

Conflict of interest statement

None declared.

Authors' contributions

All authors contributed equally to this work.

References

- [1] Regional Council of Lombardy Region. Resolution X/6164 30/01/2017. Governo della domanda: avvio della presa in carico di pazienti cronici e fragili. Determinazioni in attuazione dell'art. 9 della legge n. 23/2015. Available at: http://www.consultazioniburl.servizirl.it/ConsultazioneBurl/temp/15132629666436039958749114080998.pdf#page=5 [Accessed on 10 January, 2018].
- [2] Regional Council of Lombardy Region. Resolution X/6551 04/05/2017. Riordino della rete d'offerta e modalità di presa in carico dei pazienti cronici e/o fragili in attuazione dell'art. 9 della legge regionale n.33/2009. Available at: http://www.consultazioniburl.servizirl.it/ConsultazioneBurl/te

- mp/15132629007817544192536948537911.pdf#page=2 [Accessed on 10 January, 2018].
- [3] Regional Council of Lombardy Region. Resolution X/4662 23/12/2015. Indirizzi regionali per la presa in carico della cronicità e della fragilità in Regione Lombardia 2016 2018. Available at: http://www.consultazioniburl.servizirl.it/ConsultazioneBurl/temp/15359018411547264450247025115002. pdf#page=3 [Accessed on 10 January, 2018].
- [4] Regional Council of Lombardy Region. Regional Law n. 23 11/08/2015. Evoluzione del sistema sociosanitario lombardo: modifiche al Titolo I e al Titolo II della legge regionale 30 dicembre 2009, n. 33 (Testo unico delle leggi regionali in materia di sanità). Available at: http://normelombardia.consiglio.regione.lombardia.it/NormeLombardia/Accessibile/main.aspx?view=showdoc&iddoc=lr002015081100023 [Accessed on 10 January, 2018].
- [5] HIV/AIDS Italian Expert Panel. Linee Guida Italiane sull'utilizzo della Terapia Antiretrovirale e sulla gestione diagnostico-clinica delle persone con infezione da HIV-1. (2017). Available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2696_allegato.pdf [Accessed on 10 January, 2018].
- [6] Directorate General for Health of Lombardy Region D.d.g. 31 May 2017 – n. 6442 – Approvazione del documento avente ad oggetto "Percorso diagnostico terapeutico (PDT) del paziente affetto da malattia HIV/AIDS – anno 2107".
- [7] Quiros-Roldan E, Magoni M, Raffetti E, Donato F, Scarcella C, Paraninfo G, Castelli F. The burden of chronic diseases and cost-of-care in subjects with HIV infection in Health District of Northern Italy over a 12-year period compared to that of the general population. BMC Public Health 2016;16(1):1146.
- [8] Directorate General for Health of Lombardy Region. Resolution X/7038 3 August 2017. Ulteriori determinazioni e indicazioni operative per la procedura di valutazione degli idonei di cui alla D.G.R. n. X/6551 del 4 maggio 2017: riordino della rete di offerta e modalità di presa in carico dei pazienti cronici e/o fragili in attuazione dell'art. 9 della legge n. 33/2009.

- Received on February 22, 2018. Accepted on October 8, 2018.
- Correspondence: Umberto Restelli, Center for Health Economics, Social and Health Care Management, LIUC Università Cattaneo, Castellanza (VA), Italy -Tel. +39 0331 572346 Fax +39 0331 572513 E-mail: urestelli@gmail.com