

Analysis of the costs of adverse events in the public healthcare system of the Lombardy Region over the five-year period 2016 – 2021.

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ABSTRACT

The monitoring of litigation (i.e., claims received by the public healthcare system of the Lombardy Region) is started following the implementation of the “Circolare 46/SAN/2004” by evaluating the risk management activities carried out over a five-year period (2016-2021) and following a systematic approach by the regional risk management coordination group. The paper presents a risks analyzed belong to the following 4 categories: Clinical Risk, Worker Risk Facility Accidental Damage.

The trend of the Average Settled (cash analysis) shows an increase of the amounts over the years. The average amount paid is from about €45k in 2017 to over €71k in 2021, with a 16% decrease in the average amount paid in 2021 compared to the previous year (2020).

The trend of the average amounts paid (analysis by accrual) shows a significant natural decrease over the years. The average amount settled is from about €74K in 2016 to almost 30K in 2021, recording a 30% decrease in the average amount liquidated in 2021 compared to the previous year (2020).

As presented in the paper, the analysis shows a decrease in the magnitude of claims over time, as a positive factor that could be explained by the centralization and continuous monitoring of financial statement data, and the presence of claims evaluation committees (CVS) that includes different skills, such as: broker, loss adjuster, risk manager, medical examiner, lawyers, company management, etc., and the insurance expertise that works in the revaluation of reserves linked to the budget reform.

BACKGROUND

Risk management in healthcare is a complex set of clinical and administrative systems, processes, procedures, and reporting structures designed to detect, monitor, assess, mitigate, and prevent risks to patients.

In this context, the monitoring of litigation (i.e., claims received by the public healthcare system of the Lombardy Region) is started following the

implementation of the “Circolare 46/SAN/2004” by evaluating the risk management activities carried out over a five-year period (2016-2021) and following a systematic approach by the regional risk management coordination group. The representative sample consists of the following public healthcare companies:

- 27 ASSTs (local health and social care companies of the Lombardy Region);
- 8 ATs (health protection companies of the Lombardy Region);
- 4 Foundations (Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Fondazione IRCCS Policlinico S. Matteo di Pavia, Fondazione IRCCS Istituto Nazionale dei Tumori, Fondazione IRCCS Istituto Neurologico Carlo Besta).

DATA AND METHODOLOGY

The risks analyzed belong to the following categories:

- Clinical Risk - events that have an impact on maintaining the patient's good health status and which are connected to clinical or healthcare activity;
- Worker Risk - events that affect the safety and health of the worker;
- Facility Risk - events that have an impact on maintaining the good state of health of the Assisted Patient, the Employee or Third Parties and which are not directly connected to the clinical activity (falls, personal injuries, etc.);
- Accidental Damage - accidental events such as theft, loss and damage to property belonging to the patient, employee or third party.

The data collected refers to:

- Claims received by the Company in the established years for events that also occurred in earlier years, and affected Patients, Workers, Third Parties (Visitors, etc.);
- Civil and criminal proceedings for adverse events that have led or may lead to a claim for damages;
- Conciliatory mediations requested by the Company or by the Counterparty to facilitate and accelerate disputes in civil matters.

Claims Analysis

The claims analysis was split into:

- Frequency Analysis -the analysis of claims trends over time
- Time Analysis -the analysis of the time intervals between the characteristic dates of the claim (event date, compensation request date, closure date, ...)
- Economic Analysis -analysis of the settled and reserved amounts

The Frequency Analysis analyzes the trends of claims over time, distinguished according to the two types of Damage: Claims (which have resulted/will result in financial loss, as a formal request for damages has been received) and Criminal Proceedings (these proceedings could coexist with civil proceedings). In addition, the analysis aimed at performing an initial investigation of the dynamics of the

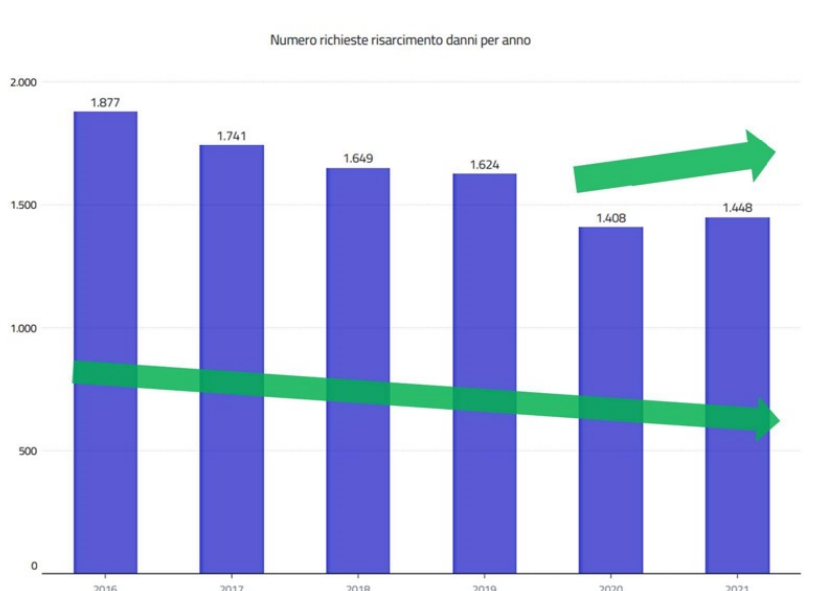
events, providing indications of the most frequent areas of origin, types of events that have occurred, consequences and those injured. This is to provide indications of possible intervention priorities for improving patient care processes and the safety of caregivers and third parties.

The Time Analysis aims to analyze the time interval between the occurrence of the event and the damage claim, and the time between the damage claim and the closure of the claim (for claims defined with an amount settled to the injured party or gone without follow-up). The first time interval allows an estimation of how many damage claims the Company can/should expect for events that occurred in the past but will generate claims in the future. The second one outlines that faster claims handling should lead to smaller economic outlays.

The Economic Analysis aims to analyze claims from an economic point of view. The analysis interests both claims closed with an amount paid to the injured party (DEFINED claims) and those that are still under management with reserves allocated (OPEN claims). The Economic Analysis (which follows the same criteria as the Frequency Analysis) allows to identify the major economic outlays that could increase the insurance premium paid by the Companies, distributed by events and areas, and therefore require priority interventions.

RESULTS

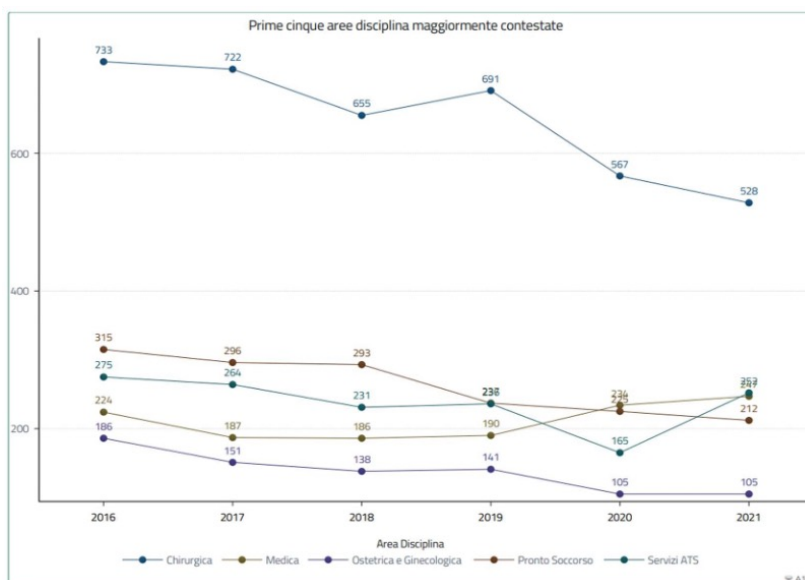
Trends in damage claims



The trend of the damage claims decreased from 2016 to 2021, as shown in the above chart. In particular, data show a decrease of 22.9% in 2021 compared to 2016, even though about +3% claims were filed in the last year under analysis

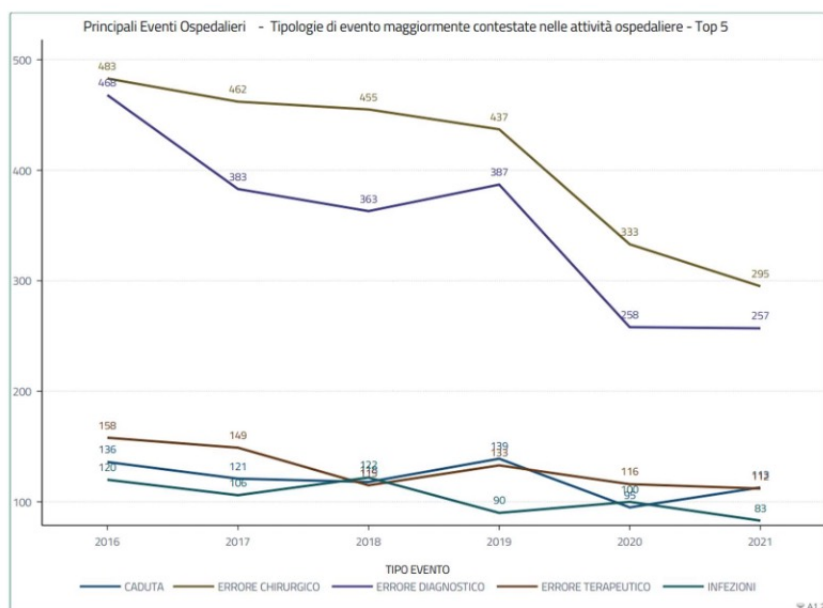
(2021) than in the previous year (2020). The decrease in the number of claims over time is a positive factor that could be explained by a whole series of activities done by the Region since 2004 in terms of Prevention and Risk Management on Medmal risk.

Frequency analysis - Main Hospital areas



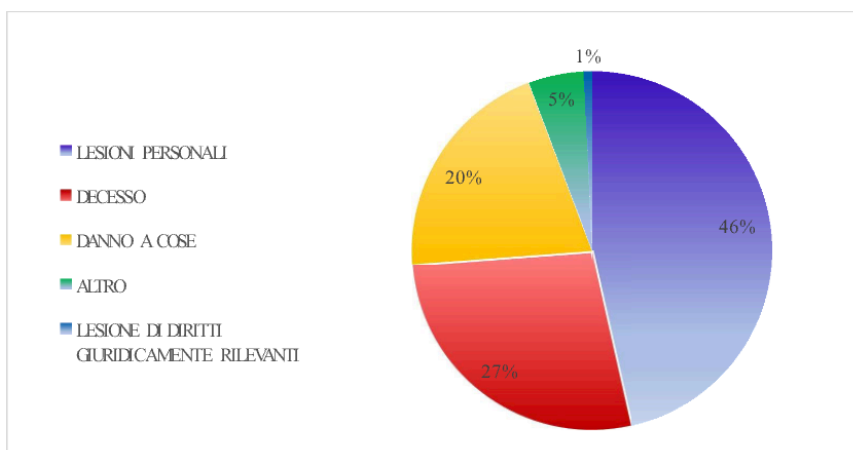
The graph shows a reduction in claims mainly in the Obstetric and Gynecological area (-44%), in the Emergency Department area (-33%), followed by the Surgical area (-28%). An increase in damage claim numbers is recorded for the Medical area(+10%).

Frequency Analysis – Main Hospital events



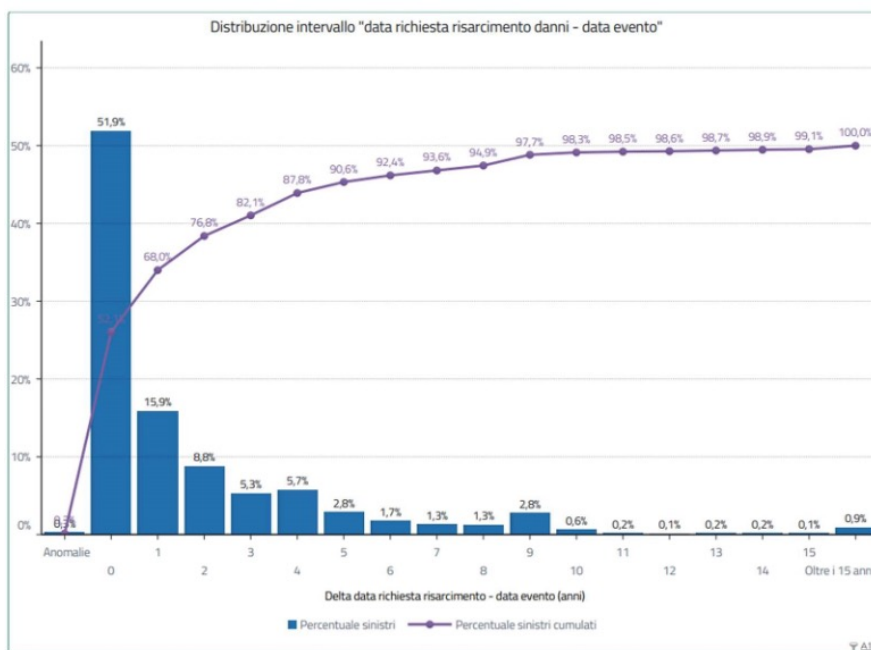
The most commonly types of events in hospital activities show a decreasing trend: Diagnostic Errors (-45%), Surgical Errors (-39%), Infections (-31%), Therapeutic Errors (-29%) and Falls (-17 %).

Frequency analysis - Type of damage



The most reported types of damage are personal injuries (46%), deaths (27%) and property damages (20%), followed by legally relevant injuries (1%). The 5% of requests are allocated to other types of damage.

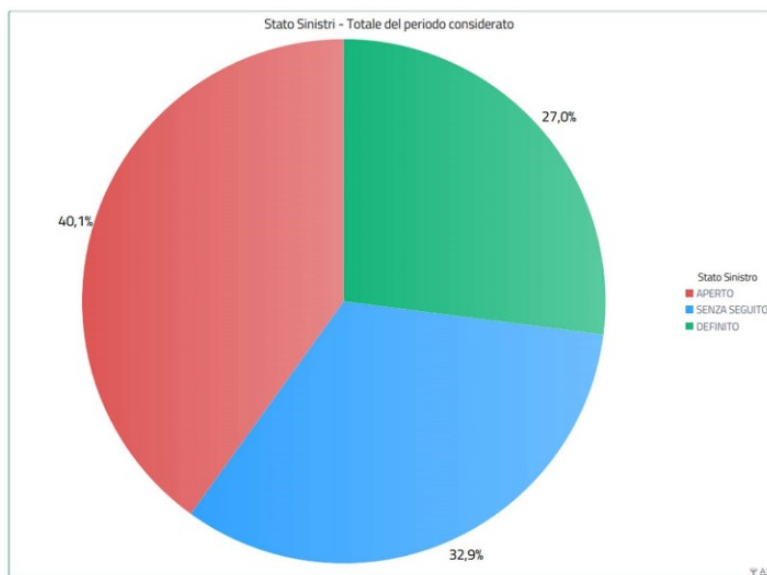
Analysis of reporting times - Total SSR



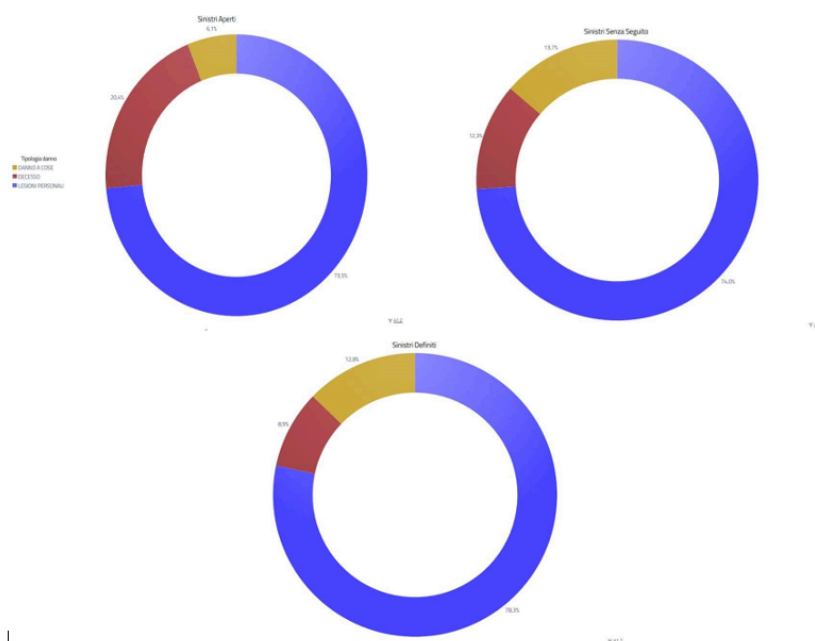
The 51.9% of claims are reported in the year of occurrence, reaching 92% within

the next 5 years. Approximately 1% of damage claims are received more than 15 years after the event that originated them. These data are useful for making an estimate of how many damage claims Companies could/should expect for events that occurred in the past but will generate complaints in the future. It is worth to note that anomalies are records in which the event date is after the date requested for compensation or when accidents have a missing event date.

Claims Status - Analysis by event type

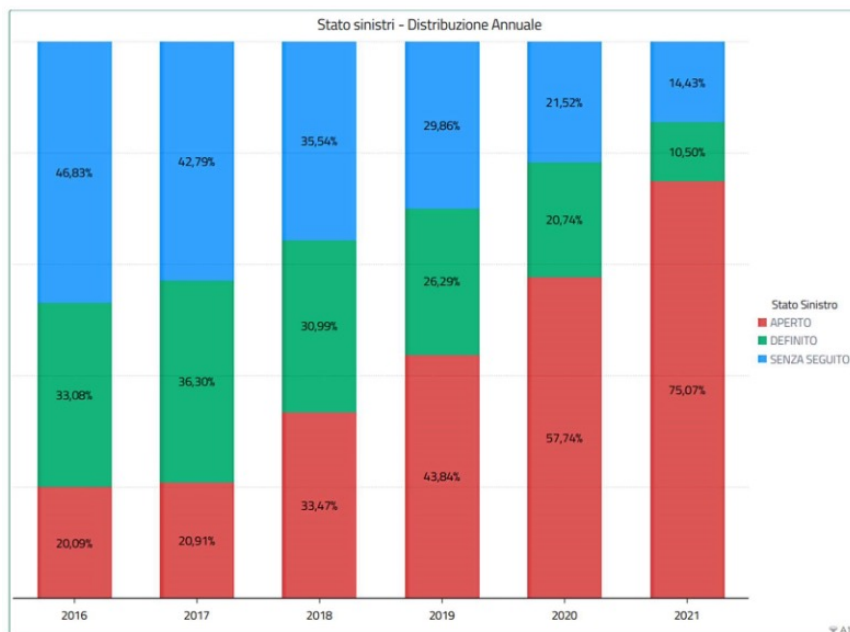


The 60% of claims are closed (27% of claims have an amount paid to the injured party - PAID claims - and approximately 33% of requests are WITHOUT FOLLOW-UP), while the remaining 40% of claims are currently still under management (OPEN claims).



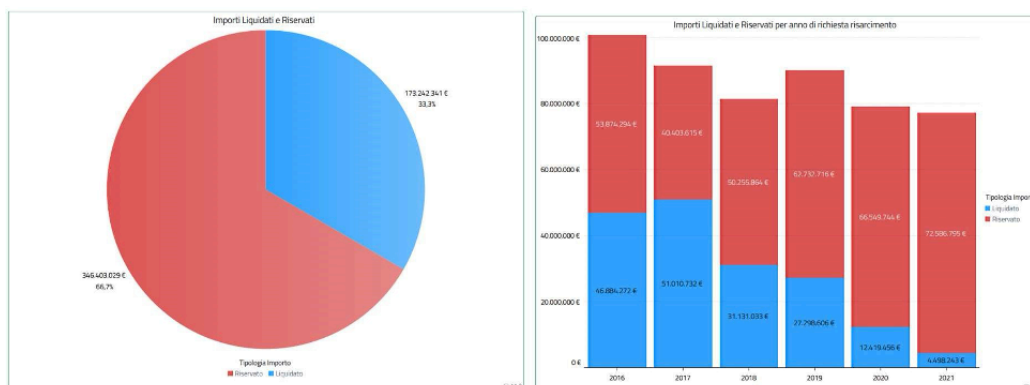
Almost 21% of claims for death are still open. Almost 14% of Unfollowed Claims are related to Property Damages. Over 78% of claims for Personal Injury have already been paid.

Claims Status - Percentage distribution



About the claims status, data show an increasing trend over the years, compared to a reduction in the percentage of Settled and Unattended claims.

Economic Analysis - Amounts liquidated and reserved



The total amount settled (defined claims) is over €173M (33%), compared to a total of reserves (open claims) of over €346M euros (67%) and a total amount of almost €520M relating to the period 2016-2021. It is worth to note that the total reserved amount is twice the total settled amount.

The economic amounts (Settled + Reserved) show a decreasing trend over the years (from €100M in 2016 to €77M in 2021).

Economic Analysis - Amounts liquidated and reserved

Reserved					
Area Disciplina ▲	Conteggio Sinistri ▼	Tot. Importi	Media Importi	Max Importi	Dev. std. Importi
Chirurgica	1.514	120.124.831 €	85.316 €	1.500.000 €	135.992,0511
Pronto Soccorso	589	44.159.374 €	79.281 €	1.000.000 €	136.903,1290
Medica	571	51.864.945 €	99.932 €	2.000.000 €	152.979,3894
Servizi ATS	504	21.124.317 €	52.288 €	1.250.000 €	130.991,2680
Ostetrica e Ginecologica	379	49.568.371 €	138.073 €	1.270.000 €	228.133,4809
Servizi	167	10.393.591 €	67.491 €	850.000 €	118.665,2037
Pediatria	58	7.567.346 €	140.136 €	1.270.000 €	212.985,1169
Psichiatrica	55	4.771.559 €	97.379 €	520.000 €	140.957,4923
Servizi Intensivi	38	5.032.999 €	139.806 €	400.000 €	130.394,2829
DATO MANCANTE	30	806.000 €	89.556 €	500.000 €	163.108,9445
Totale	3.905	315.413.334 €	88.874 €	2.000.000 €	152.287,2901

The average reserve over the entire 2016-2021 time horizon is equal to over €88K while the maximum reserved amount is €2M.

Liquidati					
Area Disciplina ▲	Conteggio Sinistri ▼	Tot. Importi	Media Importi	Max Importi	Dev. std. Importi
Chirurgica	1.305	88.418.796 €	67.806 €	1.950.000 €	143.826,5044
Pronto Soccorso	385	25.245.974 €	65.067 €	1.000.000 €	143.790,9212
Servizi ATS	297	2.688.012 €	9.020 €	452.752 €	33.765,5442
Medica	268	17.760.518 €	66.271 €	1.070.000 €	151.176,6289
Ostetrica e Ginecologica	215	29.549.631 €	136.173 €	2.517.375 €	345.560,4773
Servizi	83	4.821.649 €	58.092 €	1.055.000 €	151.445,5768
Psichiatrica	43	637.439 €	14.165 €	430.660 €	64.587,6968
Pediatria	21	2.932.993 €	139.666 €	1.372.400 €	315.846,6529
Servizi Intensivi	13	1.115.387 €	85.799 €	850.000 €	232.468,2685
DATO MANCANTE	5	71.942 €	14.388 €	54.500 €	22.701,4542
Totale	2.635	173.242.341 €	65.572 €	2.517.375 €	167.614,5465

The average amount settled over the 2016-2021-time horizon is equal to over €65K while the maximum amount settled is equal to over €2.5M.

Although the maximum settled amount is greater than the maximum reserved amount, the average settled amount still remains lower than the average reserved amount.

Economic Analysis - Amounts liquidated and reserved

Focus Top Claims settled and reserved

Anno evento	Anno richiesta risarcimen...	Disciplina	Tipologia Evento	Causa sinistro	Importo
2017	2019	ONCOLOGIA	ERRORE TERAPEUTICO	INESATTEZZA	2.000.000 €
2019	2020	NEUROCHIRURGIA	NON IDENTIFICATO	INESATTEZZA	1.500.000 €
2017	2019	NEUROCHIRURGIA	ERRORE PROCEDURE INVASIVE	INESATTEZZA	1.500.000 €

The maximum amount reserved is €2M for a claim generated by a Therapeutic Error in Oncology in 2019. Following are two claims with a reserved amount of

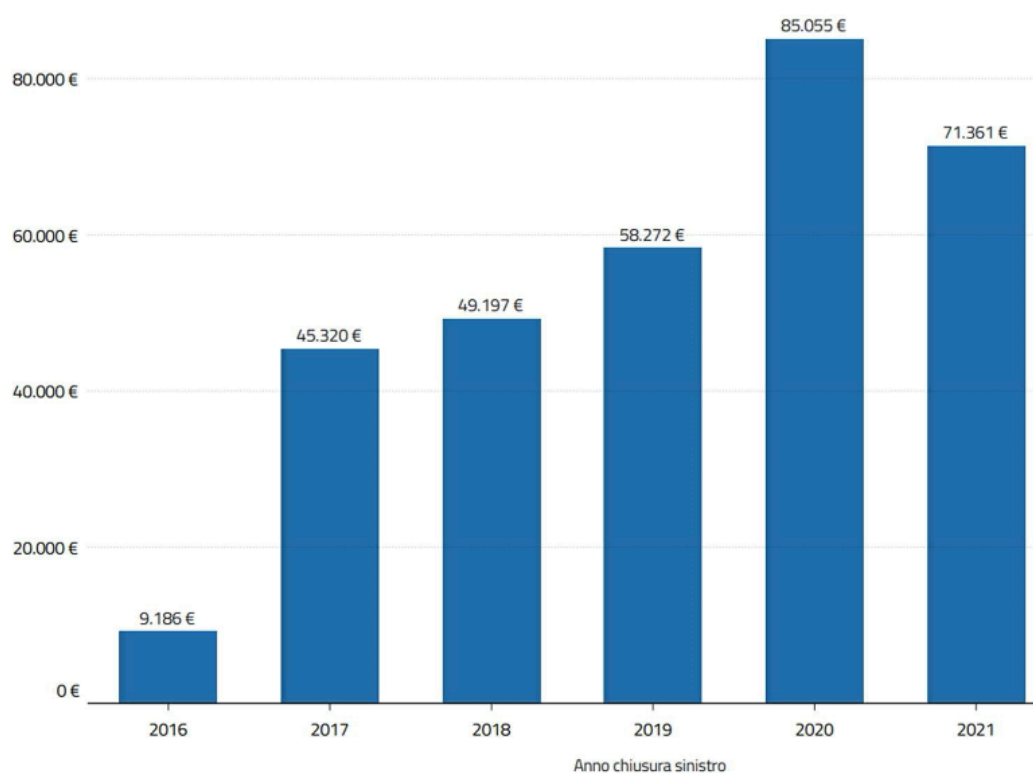
€1.5M each, both generated in Neurosurgery, one occurred in 2017 and the other in 2019.

Anno evento	Anno chiusura sinistro	Disciplina	Liquidati	Tipologia Evento	Causa sinistro	Importo
2003	2017	OSTETRICIA E GINECOLOGIA		ERRORE DIAGNOSTICO	ALTRO	2.517.375 €
2016	2022	OSTETRICIA E GINECOLOGIA		ERRORE DIAGNOSTICO	OMISSIONE	2.000.000 €
2015	2021	CHIRURGIA GENERALE		ERRORE ANESTESIOLOGICO	ALTRO	1.950.000 €

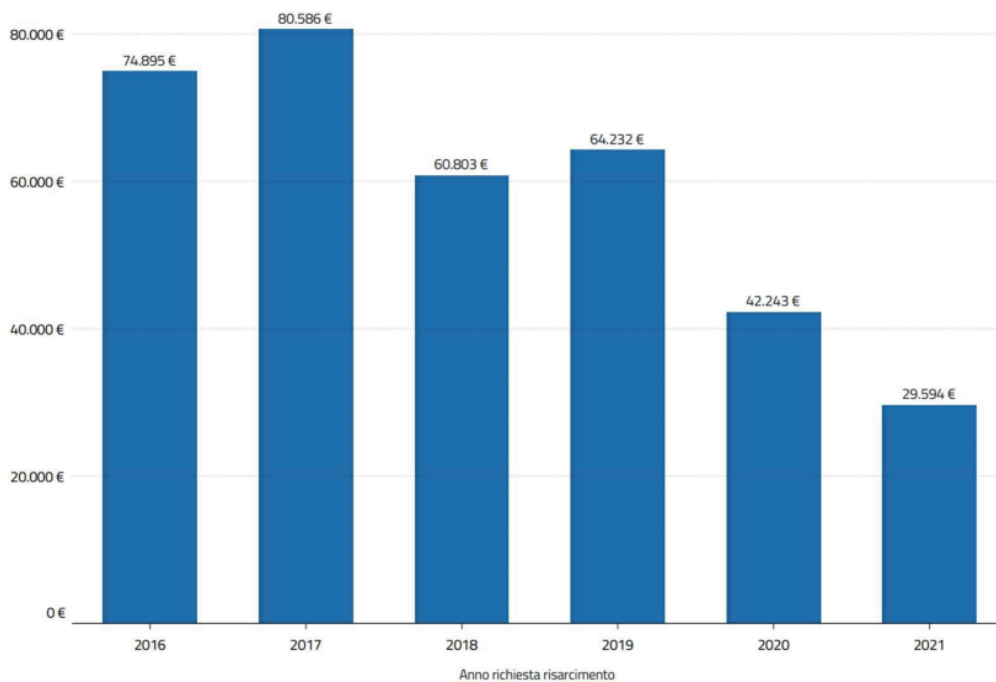
The two maximum settled amounts are allocated to Diagnostic Errors generated in Obstetrics and Gynecology, one amounting to more than €2.5M for an event that occurred in 2003 and paid in 2017 and another amounting to €2M for an event in 2016 which was defined in 2022. The third maximum amount refers to more than €1.9M for an Anesthetic Error in General Surgery that occurred in 2015 and paid in 2021.

Economic Analysis - Average amounts settled

Cash analysis

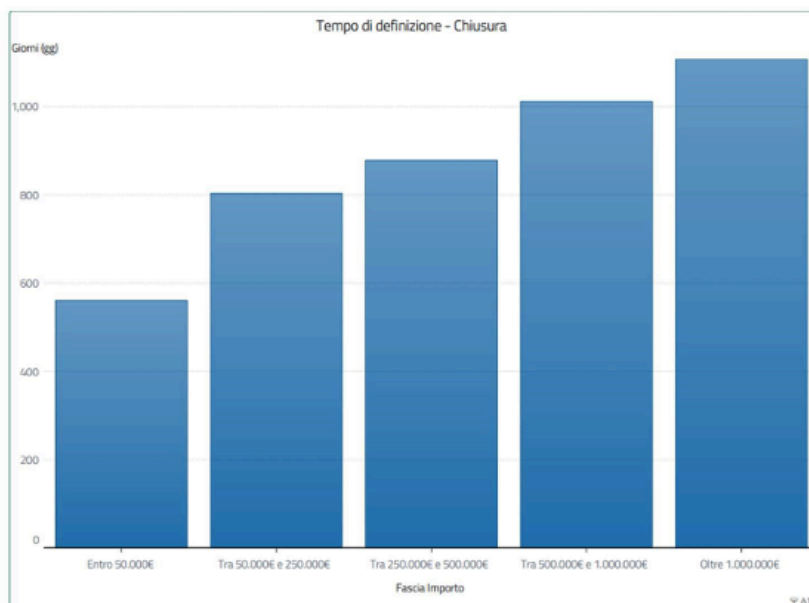


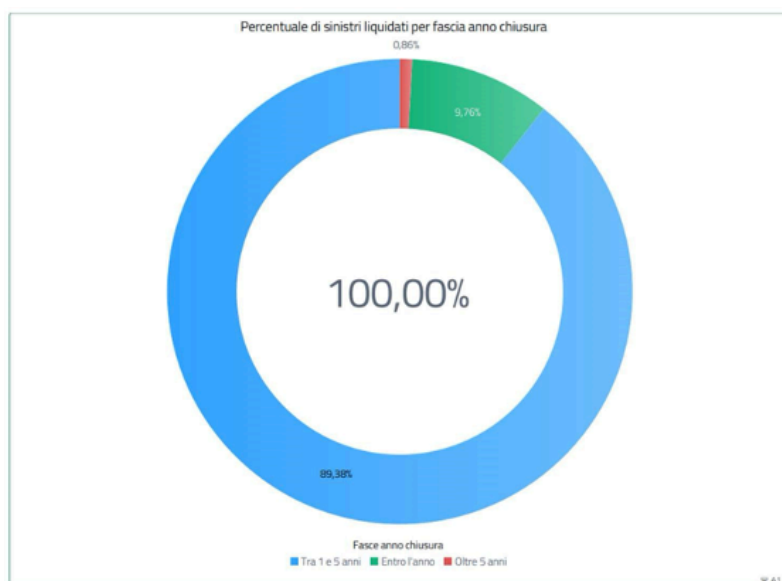
Economic Analysis – Average amounts settled Analysis by competence



Analysis of CLOSURE Times - SEVERITY - FREQUENCY Defined Claims (Hospitals only)

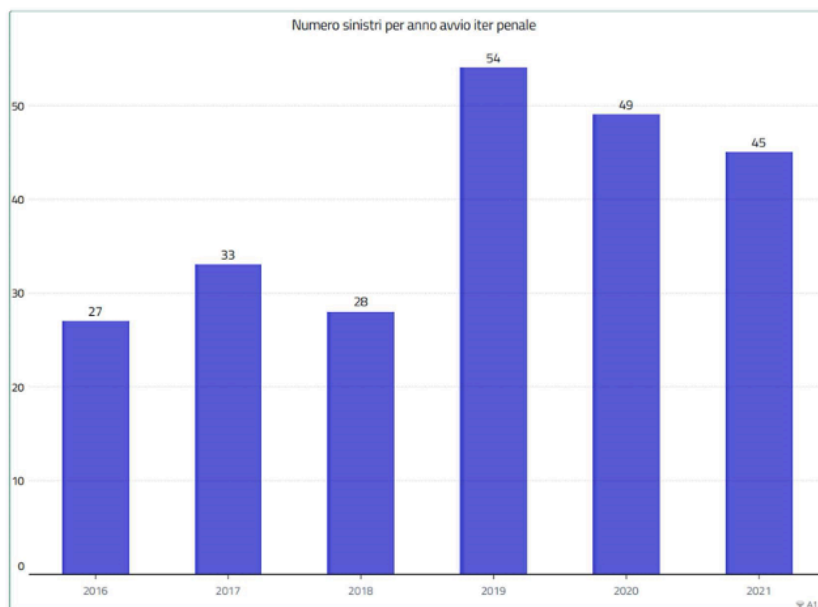
Fasce anno chiusura ▲	Entro l'anno	Tra 1 e 5 anni	Oltre 5 anni
Fascia Importo ▲	N. Sinistri	N. Sinistri	N. Sinistri
Entro 50.000€	755	1.209	6
Tra 50.000€ e 250.000€	59	429	2
Tra 250.000€ e 500.000€	9	100	2
Tra 500.000€ e 1.000.000€	3	45	1
Oltre 1.000.000€	1	14	.
Totale	827	1.797	11





Almost 90% of claims are closed in the range between 1 to 5 years from the request, almost 10% in the same year the request is received and less than 1% after 5 years¹. This data is very interesting as it allows to understand which claims management to intervene on, as faster claims should lead to more limited financial outlays.

Criminal Process Analysis



236 criminal proceedings were initiated from 2016 to 2021. The above graph shows an increasing trend until 2019, followed by a decreasing trend. In 2021 there was -16.7% of criminal proceedings compared to the peak year of the phenomenon (2019).

¹The average cash settlement amounts are affected by the fact that only the complaints received from 2016 to 2021 were analysed.

Results

In the six years analyzed (2016-2021), almost 10,000 damage claims were entered from/on behalf of the injured party (judicial and extrajudicial actions) for damages suffered in the context of clinical or healthcare activities.

The main hospital areas where the largest number of events leading to civil claims for damages occurred are: the surgical area (44%), the emergency room (18%), the ATS services area (16%), the Medical (14%) and the Obstetrics – Gynecology area (9%). Surgical, diagnostic, and therapeutic errors represented the main types of events that led to damage claims, followed by falls and infections.

As shown, there is a delay in reporting the damage downstream of its occurrence, so an event that occurred many years ago may not yet have resulted in a formal claim for compensation. The analysis of the time between the occurrence of the event and the request for compensation for damages shows that 51.9% of requests for damages are formally made in the same year as the event, reaching 92% within the following 5 years.

The claims received within the six years of analysis are still being managed (open) in 40% of cases, while in 27% of cases settlement has been achieved. The remaining 33% of claims have already been closed without follow-up.

The damage claims that resulted in a settlement within 2016-2021 costed almost 173 million euros. The average amount liquidated reaches over 65,000 euros. The total reserved amount is equal to over 346 million euros with an average value of over 88,000 euros.

The distribution of criminal proceedings against Lombardy public SSR companies reported on RCT/O policies shows a greater concentration on hospital activities. In the six years of analysis, 236 criminal proceedings were initiated which show a fluctuating trend over the years with a peak in 2019.

This information is necessary for a strategic management to improve the overall risk management and insurance of the healthcare structures as well as the implementation of quality and safety of care improvement actions.

In fact, the centralized monitoring of claims related to adverse events has ensured the credibility of SSRB companies for the insurance market resulting in the relative reduction of policy premiums and SIRs (Self Insurance Retentions).

Discussion

The trend of the Average Settled (cash analysis) shows an increase of the amounts over the years. The average amount paid is from about €45k in 2017 to over €71k in 2021, with a 16% decrease in the average amount paid in 2021 compared to the previous year (2020).

The trend of the average amounts paid (analysis by accrual) shows a significant natural decrease over the years. The average amount settled is from about €74K in 2016 to almost 30K in 2021, recording a 30% decrease in the average amount liquidated in 2021 compared to the previous year (2020).

Lastly, the 24% of criminal proceedings originate from events that occurred in the

Emergency Room, another 21% in the Medical Area and a further 19% in the Surgical Area.

Conclusion

As presented in the paper, the analysis shows a decrease in the magnitude of claims over time, as a positive factor that could be explained by the centralization and continuous monitoring of financial statement data, and the presence of claims evaluation committees (CVS) that includes different skills, such as: broker, loss adjuster, risk manager, medical examiner, lawyers, company management, etc., and the insurance expertise that works in the revaluation of reserves linked to the budget reform.

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Development of a prescriptive appropriateness project in RSAs affiliated with Local health authority of Vercelli: repercussions on the correct use of the drug and on the economic sustainability of the SSN.

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Keywords: prescriptive appropriateness, residential and semi-residential care, economic sustainability

INTRODUCTION

Law 405/2001, DGR of 30 July 2012, n. 45-4248 and the DGR of 2 August 2013, n. 85-6287 provide that ASLs guarantee the direct distribution of drugs from the Company's Therapeutic Handbook (PTA) necessary for the treatment of patients in residential and semi-residential care. In this context, some critical issues have emerged such as: long dispensing times with repercussions of "extemporaneous" prescriptions in the area by GPs and consequent disbursements under contract (CONV) and distribution on behalf (DPC), poorly controlled stocks of medicines within the structures, lack of appropriateness of therapies, significant increase in costs. The final objective is to describe the process of supplying and managing medicines for guests hospitalized in facilities for the elderly and disabled (here in after RSA) and identify strategies to optimize appropriateness pathways. **METHODS** In 2022, there were 46 RSAs present in ASL VC, of which 31 were enrolled in the project and for which a retrospective descriptive study was conducted. Each RSA sends an Excel and a PDF (stamped and signed by the GP) of the drug request to the SC Farmaceutica Territoriale (SFT). The request indicates: date of completion, GP, tax code/patient name, surname, drug, quantity, dosage, AIFA note, any notes. The SFT checks the requests for quantity (packages requested/indicated dosage) and quality (prescriptive appropriateness) and forwards them to the Hospital Pharmacy for processing. **RESULTS** From 2019 to 2022, enrollment grew from 18 to 31 RSAs and guests from 1,387 to 1,678 with an average age of 83.84 (\pm 11.64); at the same time, there was a reduction in the average number of drugs given to patients from 62.5 to 47.3 and in prescriptions per patient from 32.8 to 31.7. Over the years the percentage of checks carried out by the SFT has increased from 2% to 5%. The most frequent inappropriatenesses were: lack of known AIFA (22.5%), missing PT (12.3%), drugs outside PTA (11.2%), expired PT (9.3%), absence of diagnosis (6.5%). The gross per capita affiliated pharmaceutical expenditure of €163.83 in 2019 fell to €136.97 in 2022

(-19%). The DPC increased from €27.83 to €38.80 in relation to the expansion of the drugs included in the PHT. **DISCUSSION** The project guarantees, through prescriptive appropriateness paths, a more controlled and punctual supply of the drug with a consequent reduction in the expenditure paid by the NHS. It also highlights the importance of the figure of the pharmacist, as a drug specialist, for the correct management and organization of procedures aimed at obtaining favorable results such as the deprescribing of drugs. **CONCLUSION** The project will continue with the enlistment of other RSAs and the proposal to include the pharmacist in the Supervisory Commission which inspects the structures to evaluate the management of the drug on site to guarantee the protection of patient health.

INTRODUCTION

Local health authority of Vercelli (here in after ASL VC): territory and population

The ASL VC, located in North Eastern Piedmont, operates on an area of 2,038 km² largely coinciding with the borders of the province of Vercelli, with a population density of 80.3 inhabitants per km², lower than the regional average (168 inhabitants/Km²) and includes 87 Municipalities (Figure 1).

It is structured in a single Health District, although it is made up of two territorial areas which are very different in terms of geographical characteristics: to the south the Vercelli area, flat, characterized by rice cultivation, with 44 municipalities including the capital Vercelli (the largest urban centre), and to the north the Valsesia, mountainous and green, which includes 43 municipalities.

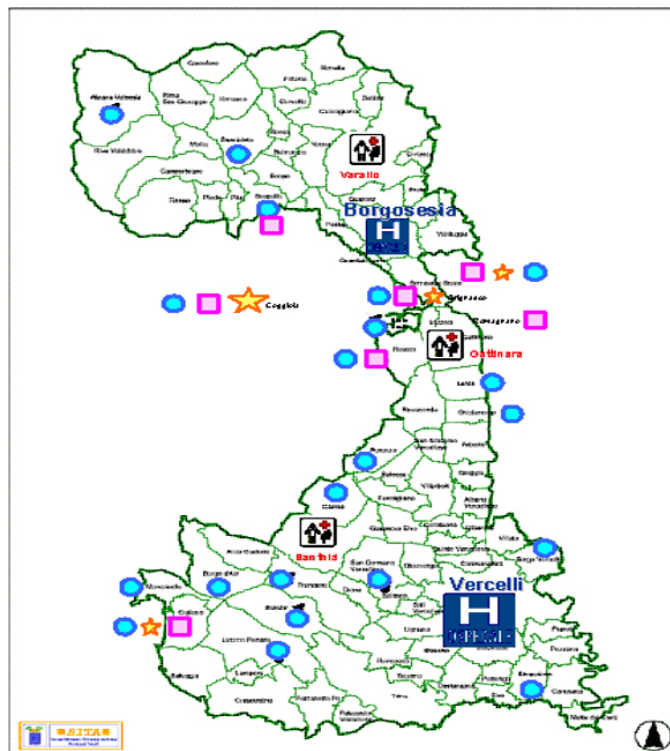


Figure 1. Map of the ASL VC.

As of 31/12/2021, 163,140 inhabitants live in the territory of the ASL VC, equal to 3.8% of the Piedmontese population, whose main characteristics are described in Table 1.

Table 1. Territory and population assisted in summary.

Surface area (km ²)	2,038
Density (inhabitants/km ²)	80.0
Municipalities (n°)	87
Resident population as of 31/12/2021	163,140
Males	79,341 (48,6%)
Females	83,799 (51,4%)
Natural balance	-1,527
Net migration	1,007
Total balance	-520
Birth rate	5.97 ‰
Mortality rate	15.33 ‰
Old age index [1]	252.83%
Aging index [2]	27.97%

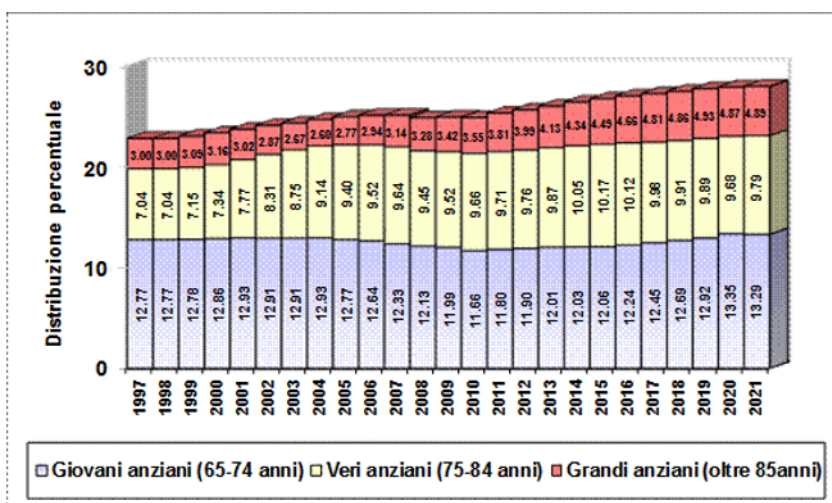
[1] The old age index represents a synthetic but very dynamic indicator which estimates the degree of aging of the population. It is obtained by comparing the population aged 65 years or more to the youth population (0 to 14 years), per 100 inhabitants.

[2] The aging index is the ratio between the population aged 65 or over and the total population per 100 inhabitants.

The demographic dynamics of the ASL VC highlights a negative natural balance (-1,527) and a positive migratory balance (1,007) which, however, determines a total negative balance of -520 (table 1).

In particular, those over sixty-five are 45,625 and represent 27.9% of the company population (in the Piedmont Region they are 1,116,681 equal to 26.2% of the Piedmontese population), with a percentage of true elderly people (75-84 years old) and very old people (over 85 years old) equal to 14.7% of the total population compared to the regional 13.8% (Figure 2).

Figure 2. Population of the ASL VC aged 65 and over by age group (1997-2021).



Considering the structural demographic indices of the population relating to old age and aging which appear in Table 1, which outlines the territory and population assisted in the ASL VC, the old age index in 2021 was equal to 252.83% compared to 219.86 % of the Piedmont Region and the aging index, again in 2021, was equal to 27.97% compared to 26.24 of the Piedmont Region. With Figure 2, which analyzes the distribution of the population, over 65 years of age and over by age group, with percentage reference, of the ASL, and the data well represented in detail in Figures 3 and 4, it clearly emerges that the population of the ASL VC is strongly characterized by progressive aging.

Figure 3. Population old age index (Region and ASL VC Years 2012 -2021).

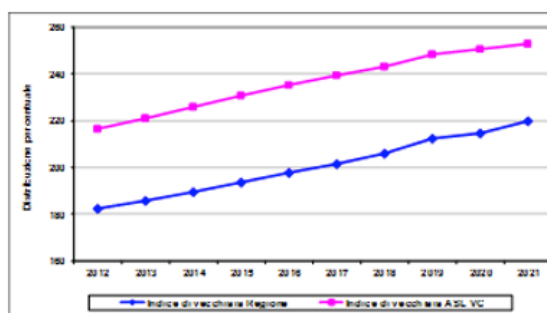
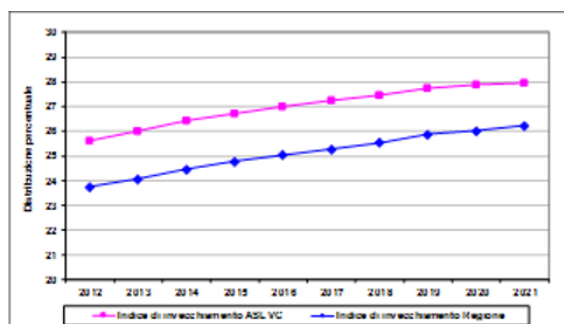


Figure 4. Population aging index (Region and ASL VC Years 2012-2021).



Regulatory context

The network of residential socio-health facilities for non-self-sufficient elderly and disabled people (for whom, however, the management standards of the RSA have not yet been identified) has experienced a reorganization of the management model in recent decades based on the gradual increase in the flexibility of the offer and performance.

With the "mother" resolution of the Piedmont Region (here in after Region), from which all subsequent measures derive, both general and relating to specific typologies (elderly, disabled, minors), adopted with DGR n. 38-16335 of 29 June 19921, the typologies and structural and management standards of residential and semi-residential social assistance facilities have been defined.

Furthermore, in compliance with the guidelines contained in law 405/20012, the local health authorities are required to guarantee the distribution of the medicines necessary for the treatment of patients in home, residential and semi-residential care.

The following necessary attention can be deduced from the afore mentioned legislation in order to have efficient and at the same time economically sustainable pharmaceutical assistance based on compliance with the planned spending limits imposed by the financial regulation on the Regions:

- monitor and rationalize consumption;
- guarantee the appropriateness of pharmaceutical prescriptions and cost containment;
- identify, evaluate and prevent adverse effects related to the use of medicines, to ensure that they are used in such a way that the benefits outweigh the risks;
- inform health professionals on the correct use of the drug in accordance with independent information criteria and make them aware of health education regarding the correct methods of storage and administration of drugs;
- evaluate the cost-effectiveness ratio of pharmacological therapies, which are often expensive and in fact do not always respond to objective advantages on the patient's health, in order to distribute the available resources in the most rational and convenient way.

In particular, the Region (with DGR n. 29-29519 of 1 March 2000)³ introduced the concept of individualized assistance plan and, subsequently, with DGR n. 17-15226 of 30 March 20054, confirmed the principles of flexibility and dynamism of the organizational models, also setting itself the objective of achieving a standard of offer, in terms of performance, which is homogeneous across the regional territory.

Subsequently, with DGR n. 25-12129 of 14 September 20095, defined the requirements and timing of implementation of the accreditation of hospitalization facilities, offering a further improvement in the quality of the services offered under the agreement with the Regional Health Service (SSR).

With DGR n. 45-4248 of 30 July 2012⁶, while maintaining the essential structure of the previous model approved with DGR n. 17-15226 of 30 March 2005⁴, then introduced elements of organizational flexibility, which allow hospitalized elderly people to be guaranteed personalized services tailored to their actual health and care needs, and identified the management and structural requirements necessary for issuing the authorization to operate of facilities for non-self-sufficient elderly people.

The DGR n. 45-4248 of 30 July 2012⁶ redefined the organizational model of residential and semi-residential facilities for non-self-sufficient elderly people into 2 residential typologies RSA (the RAFs authorized under definitive regime were automatically reclassified as RSA) and NAT (Temporary Alzheimer's Unit) and 4 typologies CDI (Integrated Day Center inserted in a facility), CDIA (Independent Integrated Day Center), CDAI (Alzheimer's Day Center inserted in a facility) and CDAA (Independent Alzheimer's Day Center).

In this regulatory context, the DGR n. 85-6287 of 2 August 2013⁷, "Approval of the tariff plan for residential care services for non-self-sufficient elderly people as provided for by DGR 45-4248 of 30 July 2012"⁶. The legislation describes, in Annex A, the prosthetic, integrative and pharmaceutical assistance for guests hospitalized in a nursing home (RSA): "for all guests hospitalized in the facility, resident in the Piedmont Region, specialist, prosthetic assistance, integrative, pharmaceutical and diagnostic-therapeutic services are guaranteed by the A.S.L. where the facility is located, where possible directly at the host facility, according to the needs of the guests".

The DGR n. 85-6287 of 2 August 2013⁷ underlines, in particular, that the ASL in which the facility is located guarantees assistance for both guests in the agreement and in the private regime and that it directly supplies the medicines for the guests on the basis than what is provided for in the Company Therapeutic Handbook (PTA), which must be adapted to the specific needs and requirements of pharmaceutical assistance in residential facilities. The supply of drugs not present in the PTA (drugs ad personam or drugs in class C) to guests of the facilities is evaluated by the Company Therapeutic Commission. Finally, as regards guests undergoing oxygen therapy, the supply can take place directly from the local health authority where the facility is located or through the use of a specific system with which the facility may be equipped.

In light of the above, according to the afore mentioned DGR n. 45-4248 of 30 July 2012⁶, the general practitioner (GP) remains primarily responsible for the diagnosis, treatment and medical follow-up, and therefore for the pharmaceutical prescription.

The ASL VC, in compliance with the widely described national and regional legislation, initially (as is), guaranteed the direct supply of drugs through the processing, by the complex Hospital Pharmacy (SCFO) structure, of a cumulative request for the drugs present in the PTA.

In this context, some critical issues have emerged such as: long dispensing times with repercussions of "extemporaneous" prescriptions in the area by GPs and consequent disbursements under contract (CONV) and distribution on behalf (DPC), poorly controlled stocks of medicines within the structures, lack of appropriateness of therapies, significant increase in costs.

In order to resolve these critical issues, the complex structure Territorial Pharmaceutical (SCFT) has revised the DD path, with particular regard to the prescriptive appropriateness of drugs distributed to guests of residential facilities, through the activation of a dedicated project (to be).

The final objective is to describe the process of supplying and managing medicines for guests hospitalized in facilities for the elderly and disabled (here in after RSA) and identify strategies to optimize appropriateness pathways.

In particular, we want to pursue it through the following intermediate objectives:

- monitor the prescriptions made in order to guarantee the safety of the drugs, the quality of care and the reduction of inappropriate prescriptions;
- reduce the costs of pharmaceutical spending by promoting economic sustainability and limiting the GP's prescription in CONV/DPC exclusively to impromptu requests and/or emergencies only;
- underline that the pharmacist guarantees prescriptive appropriateness and improves the allocation of the few resources available (rational choice theory), through synergistic collaboration with other professional figures.

MATERIALS AND METHODS

Study setting

In the observation period examined (2019 - 2022), 46 RSAs were detected (15 located in the Northern Area and 31 in the Southern Area), of which 41 accredited for a total of 2,238 residential beds (1,399 accredited), 9 disabled units with 189 accredited residential beds and 140 in day centers (semi-residential).

Study design

A retrospective descriptive study was conducted in the period 2019 - 2022 on 31 RSAs located in the ASL VC territory, considering both the affiliated beds (paid by the National Health Service) and private beds.

Prescription drugs tool

An excel file was created, containing a sheet in which all the drugs present in the PTA are shown and another called "drug prescription" in which the GP must report the requested information, i.e.: date of preparation, GP, tax code of the guest together with the name and surname, drug, quantity in packs, dosage expressed as dosage units/day (UP/day), AIFA note, date of preparation of the therapeutic plan (PT) and any notes (Figure 5).

Figure 5. Prescription drugs tool.

Date	General practitioner	Tax ID code of the guest	Name and surname	Drug	Quantity in packs	Dosage UP/day	AIFA note	Date of PT	Any notes
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Furthermore, for each individual RSA, an Access database (DB) was created which allowed automatic control of prescriptions, as well as the generation of the cumulative file to be sent to the SCFO for preparation and subsequent delivery.

The database made it possible to cumulatively collect data on what was prescribed to guests and allowed further checks to be carried out, such as, for example, cross-referencing with the CONV/DPC flow or verifying therapies over a defined period of time. This is a dynamic tool by means of which it is possible to systematise further controls that can arise from the constant monitoring of the pharmaceutical expenditure incurred by the ASL VC.

Phases of the study

Enlistment

During the enrollment phase, each RSA was sent the "drug prescription" excel file together with the operational compilation instruction.

Compiling and sending requests

The nursing coordinator of each RSA filled out the "drug prescription" on a nominative basis and, after having it checked, stamped and signed by the GP in charge of the patients of the facility, sent it in electronic (xls) and paper format (pdf), to the SCFT.

The SCFT pharmacists, to guarantee an efficient service in the supply of drugs, have organized a monthly calendar based on which from the moment they received the "drug prescription", after the necessary checks of prescriptive appropriateness, within 3 working days, they forwarded it to SCFO, which took care of the preparation and delivery within the following 5 working days.

Prescriptive appropriateness checks such as - quantitative

SCFT pharmacists checked the requests both in terms of quantity and quality.

The checks with respect to the prescribed quantities were carried out by comparing the number of packs of each medicine prescribed to the guest with the data indicated in the "dosage (UP/day)" field of the Access DB which was also compared with what was reported in the summary of product characteristics (RCP), to check whether the prescription was on label or off label.

The qualitative analyzes were carried out considering whether the drugs were prescribed according to the therapeutic and use indications (dose, posology, duration of therapy, route of administration) reported in the RCP and whether they respected the limits established by the AIFA notes or whether it was present and the PT foreseen for those medicines used to treat pathologies requiring recurrent monitoring is currently valid.

Furthermore, documentation or diagnosis to support therapies such as low molecular weight heparins (LMWH) or antibiotics was requested.

In accordance with the regional notes, particular attention was paid to the prescription of proton pump inhibitors (PPIs), evaluating whether the therapy conformed to the provisions of the therapeutic/use indications reported in the RCP and AIFA notes 1 and 48.

The system of appropriateness checks was also implemented, requiring diagnosis to support therapies with drugs based on rifaximin (often prescribed off label for diverticular disease) and the PTA was remodulated on the basis of ministerial recommendation no. 19 (divisibility and crushability notes on each medicinal specialty according to RCP and SIFO guidelines)^{8,9}. In particular, a sheet has been inserted in the "drug request" file with the following information in the columns: ATC (level 5), active ingredient, trade name, divisible, crushable, bibliographic source.

Furthermore, control on non-PTA drugs has also been included and further controls have been set up by implementing the list of AIFA notes (AIFA notes 96, 97 and 99) to be monitored.

In 2020 it was decided to analyze the off-label prescriptions of mesalazine in oral formulation, indicated both for the treatment of ulcerative colitis/Crohn's disease and for the prevention of relapses but often prescribed for pathologies for which it is not authorized.

In 2021, the formalities necessary for the prescription of clozapine were also verified (mandatory presence of certification of the leukocyte formula) and the mismatch between the prescription inserted in the xls file and the paper one (pdf).

Further checks were also carried out on the prescribing appropriateness of bisoprolol bis in the day (off-label) since a higher consumption had been found in the ASL VC compared to regional levels (over-prescription).

Progressive and final indicators dashboard

Before listing the indicators identified to evaluate the level of achievement of the expected objectives, it should be remembered that they are measurable variables with high information content, which allow complex phenomena (processes, care paths) to be synthetically evaluated, with the aim of reducing the costs of non quality, both in terms of health and economics.

The indicators identified in the study in question, measured for each year of observation, are:

1. number of RSAs enrolled;
2. number of guests hospitalized in the RSAs referred to in point 1;
3. gender and average age of the guests referred to in point 1;
4. number of requirements for guests referred to in point 2;
5. top ten active ingredients prescribed to guests referred to in point 2;
6. prescriptive appropriateness checks such as - quantities carried out on the requirements referred to in point;
7. costs of pharmaceutical expenditure stratified by delivery method: direct distribution (DD), affiliated (CONV) and distribution on behalf (DPC). It is specified that the CONV was considered the gross expense and the DPC was the sum of the purchase price together with the charge paid to the pharmacy for the service provided.

In particular, the Access DB was used to measure the indicators indicated in points 1 to 5, indicated in the section dedicated to "Prescription drugs tool".

For the calculation of the indicator referred to in point 6, in order to valorise the pharmaceutical expenditure generated by the DD, the OLIAMM management system was used, in which each RSA is inserted with a cost centre.

For CONV and DPC pharmaceutical expenditure, the databases were used (for the period 1 January 2019 - 31 March 2022), provided by the companies that (following the award of the regional tender) carried out the prescription processing and registration service. For the period 1 April 2022 - 31 December 2022, due to the bankruptcy of the supplier responsible for the aforementioned service, the flows extracted from Sistema TS were used.

The per capita pharmaceutical expenditure of guests hospitalized in the enrolled RSAs was calculated by dividing the sum of the three expenditure items (DD, CONV, DPC) by the number of guests referred to in point 1.

Statistic analysis

The data collected were entered into a computerized database through which, as a first level of study, a descriptive analysis of the results was carried out, calculating the absolute and/or relative frequencies of each indicator.

RESULTS

Analysis of the usefulness of the project and the cost-benefits of carrying out the project

Indicators (1 - 5)

From 2019 to 2022, the care facilities enrolled in the project increased from 18 to 31, with an increase in the number of guests from 1,387 to 1,678 (Figure 6), with an average age of 83.84 (\pm 11.64), the whose distribution by sex is shown in figure 7.

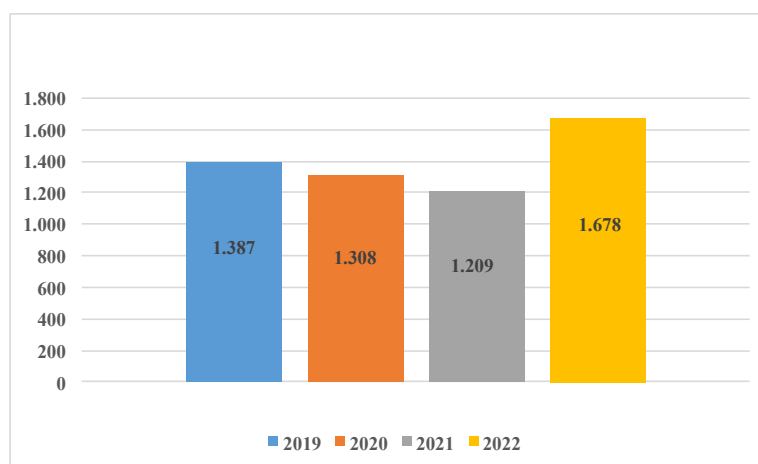


Figure 6. Number of guests of the enrolled RSAs (2019 – 2022).

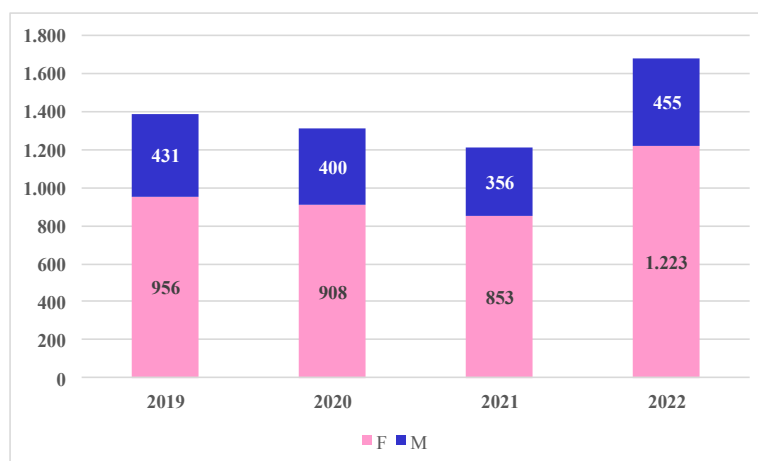


Figure 7. Distribution by sex of residents of the enrolled RSAs (2019 – 2022).

An increase in the number of prescriptions was also observed from 45,509 to 53,449 (Figure 8), with a reduction in the total number of prescriptions prescribed from 86,784 to 79,403 (Figure 9) followed by a decrease in the average number of guest prescriptions (31.7 vs 32.8) and packs/guest (47.3 vs 62.5).

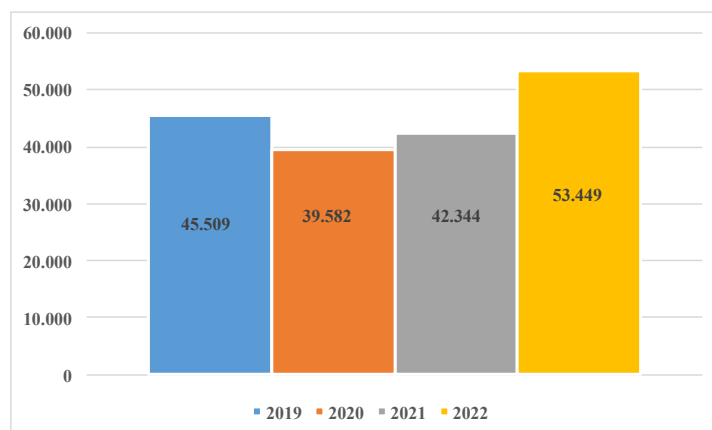


Figure 8. Prescription number (2019 – 2022).

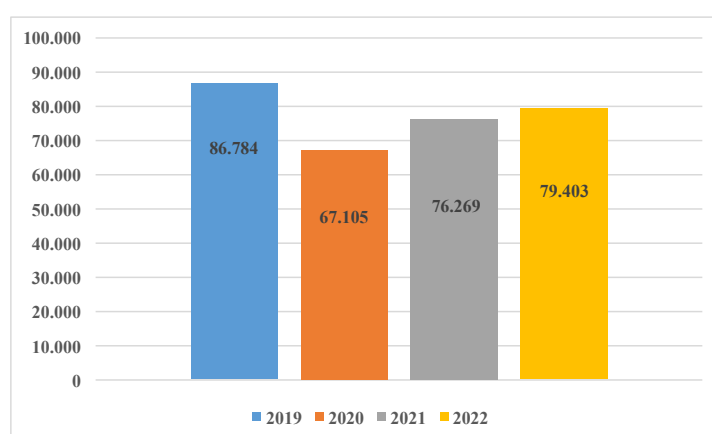


Figure 9. Number of packages prescribed (2019 – 2022).

Consumption monitoring highlighted the top 10 most prescribed active ingredients (in terms of packaging) which, as can be seen from Tables 2, 3, 4 and 5, are always the same, whose consumption has remained constant despite having increased the structures enrolled in the appropriateness project.

2019			
RANKING	DRUG	TOTAL PACKAGES	PERCENTAGE OF TOTAL PACKAGES
1	PANTOPRAZOLE 14 CP 20 MG	10,693	12.32%
2	SODIUM CHLORIDE PHYSIOLOGICAL SOLUTION 500 ML	8,744	10.08%
3	FUROSEMIDE 25MG 30CPR	4,946	5.70%
4	ACETYLSALICYLIC ACID 100*30CPR100MG	2,592	2.99%
5	QUETIAPINA 25MG 30 CPR	2,327	2.68%
6	CARBOHYDRATES GLUCOSE SOLUTION 5% 500 ML	2,061	2.37%
7	CEFTRIAZONE 1G/3,5ML IM FL+F	1,859	2.14%
8	BISOPROLOL 1,25MG 28 CPR	1,567	1.81%
9	SERTRALINA 30 CPR DIV. 50 MG	1,538	1.77%
10	RAMIPRIL 14 CPR DIV. 5 MG	1,400	1.61%

Table 2. Top ten most prescribed active ingredients in enrolled RSAs (2019).

2020			
RANKING	DRUG	TOTAL PACKAGES	PERCENTAGE OF TOTAL PACKAGES
1	PANTOPRAZOLE 14 CP 20 MG	10,321	15.38%
2	SODIUM CHLORIDE PHYSIOLOGICAL SOLUTION 500 ML	7,889	11.76%
3	FUROSEMIDE 25MG 30CPR	3,905	5.82%
4	ACETYLSALICYLIC ACID 100*30CPR100MG	2,050	3.05%
5	CARBOHYDRATES GLUCOSE SOLUTION 5% 500 ML	1,940	2.89%
6	BISOPROLOL 1,25MG 28 CPR	1,531	2.28%
7	QUETIAPINA 25MG 30 CPR	1,486	2.21%
8	SERTRALINA 30 CPR DIV. 50 MG	1,165	1.74%
9	AMLODIPINE 14 CPR 10 MG	1,064	1.59%
10	RAMIPRIL 14 CPR DIV. 5 MG	1,049	1.56%

Table 3. Top ten most prescribed active ingredients in enrolled RSAs (2020).

2021			
RANKING	DRUG	TOTAL PACKAGES	PERCENTAGE OF TOTAL PACKAGES
1	PANTOPRAZOLE 14 CP 20 MG	10,654	13.97%
2	SODIUM CHLORIDE PHYSIOLOGICAL SOLUTION 500 ML	8,749	11.47%
3	FUROSEMIDE 25MG 30CPR	4,181	5.48%
4	QUETIAPINA 25MG 30 CPR	2,621	3.44%
5	ACETYLSALICYLIC ACID 100*30CPR100MG	2,503	3.28%
6	BISOPROLOL 1,25MG 28 CPR	1,675	2.20%
7	SERTRALINA 30 CPR DIV. 50 MG	1,596	2.09%
8	AMLODIPINE 14 CPR 10 MG	1,473	1.93%
9	METFORMIN 500MG 30 CPR	1,386	1.82%
10	LANSOPRAZOLE 14 CPR OROD 30 MG	1,259	1.65%

Table 4. Top ten most prescribed active ingredients in enrolled RSAs (2021).

2022			
RANKING	DRUG	TOTAL PACKAGES	PERCENTAGE OF TOTAL PACKAGES
1	PANTOPRAZOLE 14 CP 20 MG	9,295	11.7%
2	SODIUM CHLORIDE PHYSIOLOGICAL SOLUTION 500 ML	7,131	9.0%
3	FUROSEMIDE 25MG 30CPR	4,709	5.9%
4	QUETIAPINA 25MG 30 CPR	2,654	3.3%
5	ACETYLSALICYLIC ACID 100*30CPR100MG	2,471	3.1%
6	CARBOHYDRATES GLUCOSE SOLUTION 5% 500 ML	1,995	2.5%
7	SERTRALINA 30 CPR DIV. 50 MG	1,479	1.9%
8	BISOPROLOL 1,25MG 28 CPR	1,354	1.7%
9	CLONAZEPAM OS GTT 10 ML50,25%	1,302	1.6%
10	RAMIPRIL 14 CPR DIV. 5 MG	1,246	1.6%

Table 5. Top ten most prescribed active ingredients in enrolled RSAs (2022).

Prescriptive appropriateness checks such as - quantitative (indicator 6)

For each verified drug prescription, the document “prescriptive appropriateness checks_requests of dd.mm.yyyy)” containing the items for which counter-deductions were requested was sent to the RSA.

Over the years, the percentage of checks sent has increased, going from 2% to 5% (Figure 10) with the consequent increase in counter-deductions requested (Table 6) and a percentage decrease in compliant requests (Figure 11).

DESCRIPTION	2019	2020	2021	2022
RSA 1	33	118	96	90
RSA 2	121	257	100	73
RSA 3	40	14	14	47
RSA 4	43	78	98	104
RSA 5	98	117	101	71
RSA 6	25	45	48	33
RSA 7	53	237	104	65
RSA 8	36	155	295	289
RSA 9	257	240	207	202
RSA 10	23	75	104	33
RSA 11	24	74	48	55
RSA 12	55	26	71	52
RSA 13	13	34	80	92
RSA 14	33	33	11	46
RSA 15	157	265	128	16
RSA 16	26	49	128	48
RSA 17	8	24	23	49
RSA 18	77	102	206	119
RSA 19	NE	35	22	5
RSA 20	NE	36	63	85
RSA 21	NE	NE	170	176
RSA 22	NE	NE	168	279
RSA 23	NE	NE	120	167
RSA 24	NE	NE	47	28
RSA 25	NE	NE	14	33
RSA 26	NE	NE	32	111
RSA 27	NE	NE	77	38
RSA 28	NE	NE	NE	190
RSA 29	NE	NE	NE	80
RSA 30	NE	NE	NE	32
RSA 31	NE	NE	NE	0
TOTALE	1.122	2.014	2.575	2.708
NE: Not enrolled				

Table 6. Number of requests for counter-arguments requested (2019-2022).

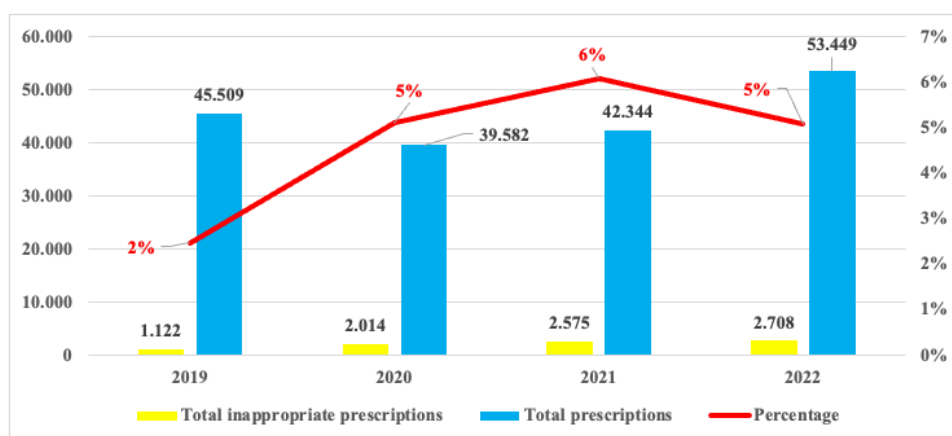


Figure 10. Prescriptive appropriateness checks (2019 – 2022).

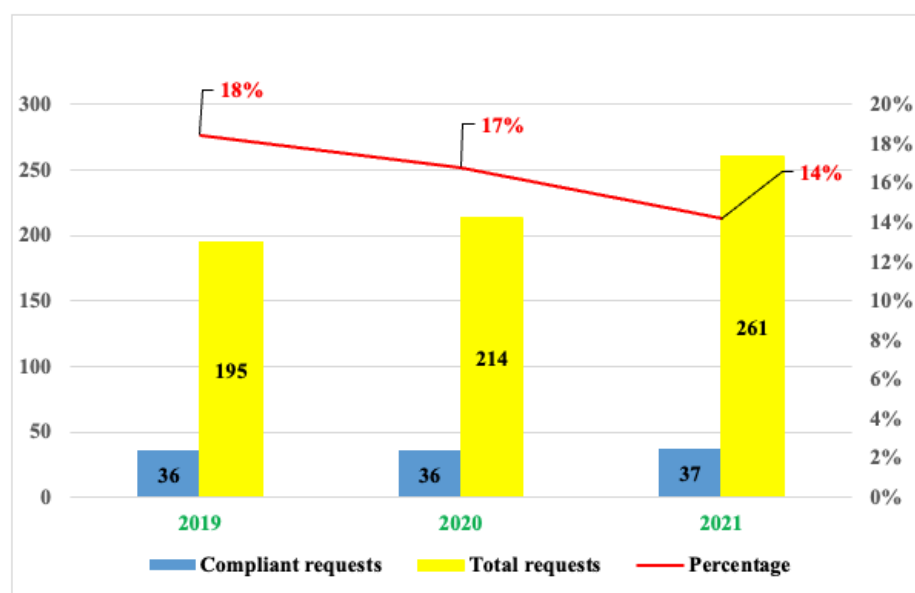


Figure 11. Compliant requests (2019 – 2021).

The data proves that the most frequent inappropriateness was surely the lack of the AIFA note (22.5%), especially referring to AIFA notes 1 (14.4%) and 48 (5.9%) to which PPIs are subject, the missing PT (12.3%), the request for drugs outside the PTA (11.2%), the expired PT (9.3%), the absence of diagnosis where requested (6.5%), the absence of supporting documentation for the prescription of antibiotics (3.3%), the indication of the incorrect AIFA note (2.9%), the quantity requested not consistent with the dosage (2.8%), the prescription of the drug off label (2.5%) and LMWH without indication (2.5%), the prescription of rifaximin (1.3%) or bisoprolol (0.8%) off label, the dosage different from that indicated in the PT (0.6%), the lack of formalities required for the prescription of clozapine (0.5%), the prescription of mesalazine off label (0.4%), double therapy prescribed to the same guest (0.1%), the absence of necessary documentation for drugs in band H (0.1%).

Indicator (7)

Figures 12 and 13 show, respectively, the amounts relating to the three distribution channels (DD, CONV, DPC) determined by the guests hospitalized in the enrolled facilities and the related per capita values.

Figures 12 and 13 highlight that, over the four-year period, there was a reduction in total per capita spending for guests of care facilities, with a maximum peak of CONV in the year 2021.

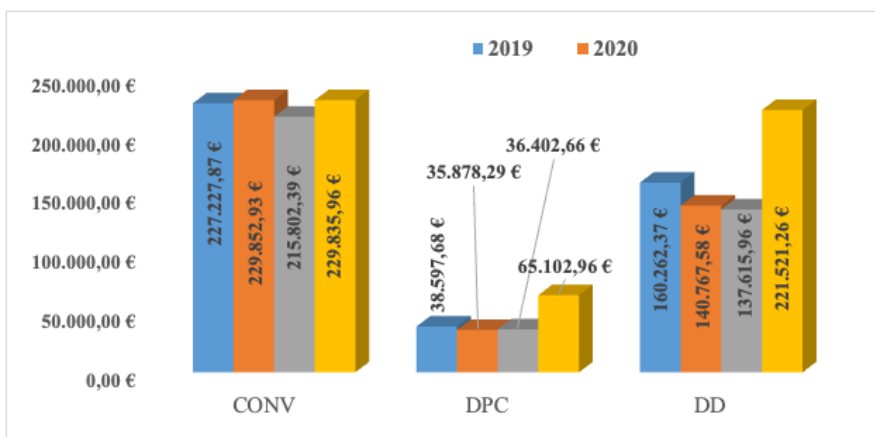


Figure 12. Total pharmaceutical expenditure (DD, CONV, DPC) (2019 – 2022).

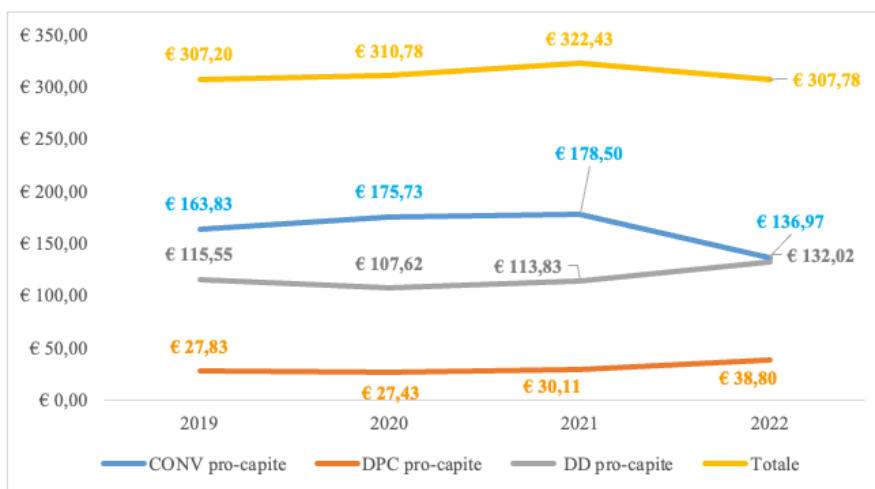


Figure 13. Pro-capite pharmaceutical expenditure (CONV, DPC, DD) and total (2019 – 2022).

DISCUSSION

The increase in the number of guests, with an average age over 65, is in line with the national trend, characterized by progressive aging and the high increase in elderly people with related individual and social fragilities, for which always more often it is necessary to resort to residential social and healthcare facilities for non-self-sufficient elderly and disabled people¹¹.

Studies, in fact, have shown that, in the next twenty years, the population over the age of

60 will double²⁷ and that the elderly, due to the presence of more morbidity, will be prescribed more drugs, with consequent polypharmacy^{12,13}.

This is a growing concern especially in those residing in nursing homes, as they are generally more frail, very elderly (≥ 80 years) and consequently subject to higher health risks and complications, such as an increase in adverse events from drugs, disability, hospitalization and death¹⁴⁻¹⁹. Therefore, managing drug use among older adults in nursing homes is critical to preventing unnecessary harm and improving drug use.

In fact, the literature shows that the intervention of pharmacists in the review of therapies has a positive impact on the reduction of inappropriate prescriptions but these studies have mainly concentrated in other healthcare settings²⁰⁻²³ and there are still few systematic reviews that have examined the impact of pharmacists' interventions in nursing homes²⁴⁻²⁶.

The study described above, carried out in the ASL VC, underlined that the management of drugs even in nursing homes is a complex process because it is necessary to take into account the healthcare professionals who intervene in the different phases (prescription, dispensing, preparation, administration, monitoring, suspension of the drug) and that the systematic intervention of the pharmacist is fundamental in order to pursue favorable results, highlighted by the data obtained.

First of all, although the number of guests and prescriptions increased, a significant reduction was observed in the average number of drugs/patients from 62.5 to 47.3 and prescriptions/patient (from 32.8 to 31.7). This indicator is noteworthy because it demonstrates how important the pharmacist's control is to ensure a change in the quality of the prescription with a constant reduction in the number of drugs taken¹⁴⁻¹⁶. Observed deprescribing is a systematic process of identifying and "discontinuing" drugs or drug regimens in circumstances in which evident or potential adverse effects outweigh their current and/or potential benefits, taking into account goals of care, level of functioning, life expectancy, values and preferences of the individual patient. It is often aimed at patients with multiple chronic conditions, who are often elderly or have a limited life expectancy, because, in these situations, drugs may contribute to an increased risk of adverse events and people may benefit from a reduction in load of drug²⁷⁻²⁸.

Surely, the pharmacist, guaranteeing a more controlled and punctual direct supply of the drug, has also limited the prescription of drugs in CONV by the GP exclusively to impromptu requests and/or emergencies only. The gross agreed expenditure was thus reduced by 19% from € 163.87 in 2019 to € 136.97 in 2022, while the DD increased which represents an important service provided to patients to guarantee hospital-territory therapeutic continuity, as well as source of savings, considering the lower purchase cost of drugs supplied directly by healthcare companies compared to the territorial costs of CONV pharmaceuticals.

The increase in the DPC from € 27.83 to € 38.80 is to be related to:

- the expansion of medicines supplied in pharmacies in health emergencies, with a view to reducing travel, promoting access to medicines thanks to the widespread network of pharmacies;
- the inclusion of new drugs in the PHT (622 in 2021) as well as the extension of the distribution method of low molecular weight heparins in DPC (regardless of the therapeutic indications);

- the price of drugs established at regional level through a tender procedure, most of which have a high cost;
- the fee paid to affiliated pharmacies for each package dispensed is higher than the purchase price of the drug (e.g. the direct purchase price of the clopidogrel package is € 6.44 to which an average fee of € 7.564 must be added).

The project has had very positive feedback, so much so that the SCFT has received requests from other RSAs to be included in the process, despite the difficulties linked to the lack of staff. This highlights that the direct contact and collaboration between doctors, pharmacists and nurses leads to an integration of mutual skills and the SCFT pharmacist, operating transversally between the hospital and the territory, is seen not only as a drug specialist but also as a reference figure for the definition of correct procedures for daily management of therapy.

Given some limitations that could be observed in the study, such as the enrollment of 31 RSAs out of a total of 46 (so without a sufficiently large sample size, the analyzes could lack the statistical power necessary to identify significant differences in the results) and from a selection of the same, which was not targeted, however voluntarily, but still followed the criteria described above, and of the GPs, strengths emerged which represent a concrete and interesting possibility, which allows correct and efficient management of the dispensing of drugs.

CONCLUSIONS

The intervention of the pharmacist, whose role is fundamental in the procedural process, has made it possible to obtain favorable results, such as the deprescribing of drugs, the reduction of extemporaneous requests and the consequent reduction in the expenditure amounts generated by the affiliate but which a multidisciplinary team, made up of a doctor, nurse and pharmacist, is essential to provide elderly patients with appropriate/safe pharmacotherapy and at the same time allow the economic sustainability of the system.

The project, given the significant results, will continue with the enlistment of other RSAs and the proposal, already favorably accepted by the General Management of the ASL VC, to include the pharmacist in the Supervisory Commission which inspects the structures in order to evaluate on site the complex drug management process. The control is intended to guarantee the patient, whose health must also be protected against any event that constitutes a threat to his integrity.

ACKNOWLEDGEMENT

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