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THIRTY-SIXTH INTERNATIONAL CONFERENCE ON: “SOCIAL
AND NATURAL SCIENCES – GLOBAL CHALLENGE 2024”
(ICSNS XXXVI-2024)

Stockholm - 23 September 2024

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TABLE OF CONTENTS

Effective rain maps for Albania	5
<i>Andrin Kërpaçi</i>	
Liability for Extracontractual Damage Caused by Third Parties: A Legal and Practical Analysis	16
<i>Anjeza Liçenji</i>	
Implementation of bone marrow biopsy as a new practice at Mother Theresa University Hospital Center in Tirana, Albania - Diagnostic challenges	26
<i>Ejona Çeliku</i> <i>Majlinda Ikonomi</i>	
The elimination of non-tariff barriers to the free movement of goods based on ECJ Jurisprudence	39
<i>Ersila Abazaj</i>	
Indicators of supply chain responsibility in relation to corporate social responsibility and sustainable development	45
<i>Ina Balukja</i>	
Early warning climate system and agronomy advisories services in Albania: A case study of medicinal plant in “Malesi e Madhe”	56
<i>Irida Gjermani</i>	
Business perceptions for a transition towards circular economy in Albania	80
<i>Evisi Kopliku</i>	
Impact of radiotherapy on Her2 expression in breast cancer: A comparative analysis before and after therapy	88
<i>Siltana Zeneli</i>	
Healthcare in the Albanian penitentiary system	92
<i>Skerdian Kurti</i> <i>Emiliano Likaj</i>	

Effective rain maps for Albania

Andrin Kërpaçi

UPT Polytechnic University of Tirana, Albania

Abstract

Rainwater is one of the main sources for the development of agriculture. Its absence during the development of the plant creates a moisture deficit in the soil, and therefore we must fill this deficit with frequent irrigations.

The number of these irrigations and their quantity is a function of the area where the plant grows, the type of plant and the amount of rain that falls in this area.

Albania is a country where about 70% of the amount of rain falls in the rainy period from November to March, and the rest falls in the dry period of April - October, when it is also the season of plant development.

In this study we will use the U.S.D.A, SCS method. This is a procedure for estimating effective rainfall by processing long climatic and soil moisture data.

Effective rain is proportional to the Evapotranspiration, the holding capacity of the active layer related to the characteristics of the soils of this layer and the amount of rain that falls in the area of plant cultivation.

Keywords: Effective rainfall, Agriculture, Hydrology, Albania.

Introduction

Rainwater is one of the main sources for the development of agriculture. Its absence during the development of the plant creates a moisture deficit in the soil, and therefore we must fill this deficit with frequent irrigations. The number of these irrigations and their quantity is a function of the area where the plant grows, the type of plant and the amount of rain that falls in this area.

Albania is a country where about 70% of the amount of rain falls in the rainy period from November to March, and the rest falls in the dry period of April - October, when it is also the season of plant development. With the climate changes, this amount of precipitation is concentrated in a shorter time and the precipitation falls in the form of storm rains, and if the same amount of precipitation fall, a much larger part flows will be Runoff and a small part will be absorbed by the soil and therefore by the plant. Considering this great variability, it is very important to determine the Effective Rain, which is the amount of rain that the soil holds and is usable by the plant.

The exact determination of this amount helps in the planning and design of irrigation systems as well as the best management of natural or artificial water sources such as dams.

In the conditions of Albania, where a large part of the population deals with agriculture, these resources must be used in the most optimal way.

In the publication of FAO-25 (Dastane), it is assumed that the daily rain with a layer of less than 5 mm will not be considered effective during the dray period period, since this amount of precipitation can evaporate from the ground before it to infiltrate the layers of the roots. This assumption is accepted to be correct for plants with

deep roots such as fruit plants, while for plants with shallow roots such as cereals or vegetables this amount of precipitation can complete the deficit that comes from Evapotranspiration.

Materials and methods

The purpose of this work is to prepare the maps of Albania for: Effective rain with 75 and 90 return period for the dry period (March – September) and for the annual period.

The process of evapotranspiration

The combination of the two separate processes whereby water is lost from the soil surface due to evaporation and from plants due to transpiration is defined as Evapotranspiration (ET).

Evapotranspiration

Evaporation and transpiration occur simultaneously and there is no easy way to distinguish between the two processes. When the plant is small, water is mostly lost by evaporation from the soil, but when the plant is well developed and manages to cover the soil completely, transpiration becomes the main process. In the first stage of planting, almost 100% of evapotranspiration comes from evaporation, while with the full growth of the plant, more than 90% of ET comes from transpiration.

Factors affecting evapotranspiration

Weather parameters, crop characteristics, management and environmental aspects are factors that affect evaporation and transpiration.

Meteorological data

The meteorological data used for this paper were obtained from the NASA Langley Research Center (POWER) project established by the NASA Earth Science Directorate Applied Science Program.

POWER supports three user communities with solar and/or meteorological data:

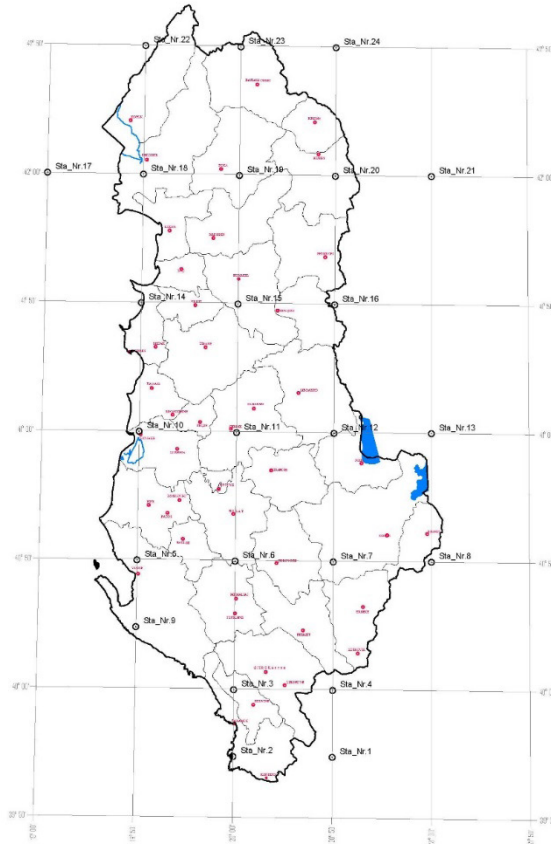
- Renewable Energy (RE),
- Sustainable Buildings (SB)
- Agroclimatology (AG).

Bearing this in mind, to download the data for this work, 24 stations (data points) were taken. For each of these points (stations), daily data were obtained for:

- Maximum temperature at 2 m height (T2M_MAX)
- Minimum temperature at 2 m height (T2M_MIN)
- Dew point temperature at 2 m height (T2MDEW)
- Daily precipitation layer (PRECTOTCORR)
- Wind speed at 2 m height (WS2M)

- Atmospheric pressure (PS)

For the above 6 parameters, daily data were obtained from 03 - January - 1981 and until 31 - December 2020.



Map of data stations

U.S.D.A, SCS method

The U.S. Department of Agriculture’s Soil Conservation Service has developed a procedure for estimating effective rainfall by processing long climatic and soil moisture data. To avoid high degree of complexity, neither the soil intake rate nor rainfall intensities are considered in this method. From total rainfall and monthly consumptive use, effective rainfall values were computed. The values were based on 3 inches or 75mm net irrigation application which is equal to the available storage capacity in the root zone at the time of irrigation application. To convert this data to other net depts, factors were worked out which are shown in the table below. The monthly effective rainfall cannot exceed the rate of consumptive use or Evapotranspiration. If it does, the lower value of the two is taken.

Monthly mean rainfall mm	Mean monthly consumptive use mm													
	25.00	50.00	75.00	100.00	125.00	150.00	175.00	200.00	225.00	250.00	275.00	300.00	325.00	350.00
	Mean monthly effective rainfall mm													
12.50	7.50	8.00	8.70	9.00	9.20	10.00	10.50	11.20	11.70	12.50	12.50	12.50	12.50	12.50
25.00	15.00	16.20	17.50	18.00	18.50	19.70	20.50	22.00	24.50	25.00	25.00	25.00	25.00	25.00
37.50	22.50	24.00	26.20	27.50	28.20	29.20	30.50	33.00	36.20	37.50	37.50	37.50	37.50	37.50
50.00	25.00	32.20	34.50	35.70	36.70	39.00	40.50	43.70	47.00	50.00	50.00	50.00	50.00	50.00
62.50	41.70	39.70	42.50	44.50	46.00	48.50	50.50	53.70	57.50	62.50	62.50	62.50	62.50	62.50
75.00		46.20	49.70	52.70	55.00	57.50	60.20	63.70	67.50	73.70	75.00	75.00	75.00	75.00
87.50		50.00	56.70	60.20	63.70	66.00	69.70	73.70	77.70	84.50	87.50	87.50	87.50	87.50
100.00		80.70	63.70	67.70	72.00	74.20	78.70	83.00	87.70	95.00	100.00	100.00	100.00	100.00
112.50			70.50	75.00	80.20	82.50	87.20	92.70	98.00	105.00	111.00	112.00	112.00	112.00
125.00			75.00	81.50	87.70	90.50	95.70	102.00	108.00	115.00	121.00	125.00	125.00	125.00
137.50			122.00	88.70	95.20	98.70	104.00	111.00	118.00	126.00	132.00	137.00	137.00	137.00
150.00				95.20	102.00	106.00	112.00	120.00	127.00	136.00	143.00	150.00	150.00	150.00
162.50				100.00	109.00	113.00	120.00	128.00	135.00	145.00	153.00	160.00	162.00	162.00
175.00				160.00	115.00	120.00	127.00	135.00	143.00	154.00	164.00	170.00	175.00	175.00
187.50					121.00	126.00	134.00	142.00	151.00	161.00	170.00	179.00	185.00	187.00
200.00					125.00	133.00	140.00	148.00	158.00	168.00	178.00	188.00	196.00	200.00
225.00					197.00	144.00	151.00	160.00	171.00	182.00				
250.00						150.00	161.00	170.00	183.00	194.00				
275.00						240.00	171.00	181.00	194.00	205.00				
300.00							175.00	190.00	203.00	215.00				
325.00							287.00	198.00	213.00	224.00				
350.00								200.00	220.00	232.00				
375.00								331.00	225.00	240.00				
400.00									372.00	247.00				
425.00										250.00				
450.00	25.00	50.00	75.00	100.00	125.00	150.00	175.00	200.00	225.00	250.00				

The effective rain is calculated for the reference evapotranspiration calculated based on the Penman-Monteith calculation model

$$ET_0 = \frac{0.408\Delta (R_n - G) + \gamma \frac{900}{T + 273} u_2 (e_s - e_a)}{\Delta + \gamma(1 + 0.34u_2)}$$

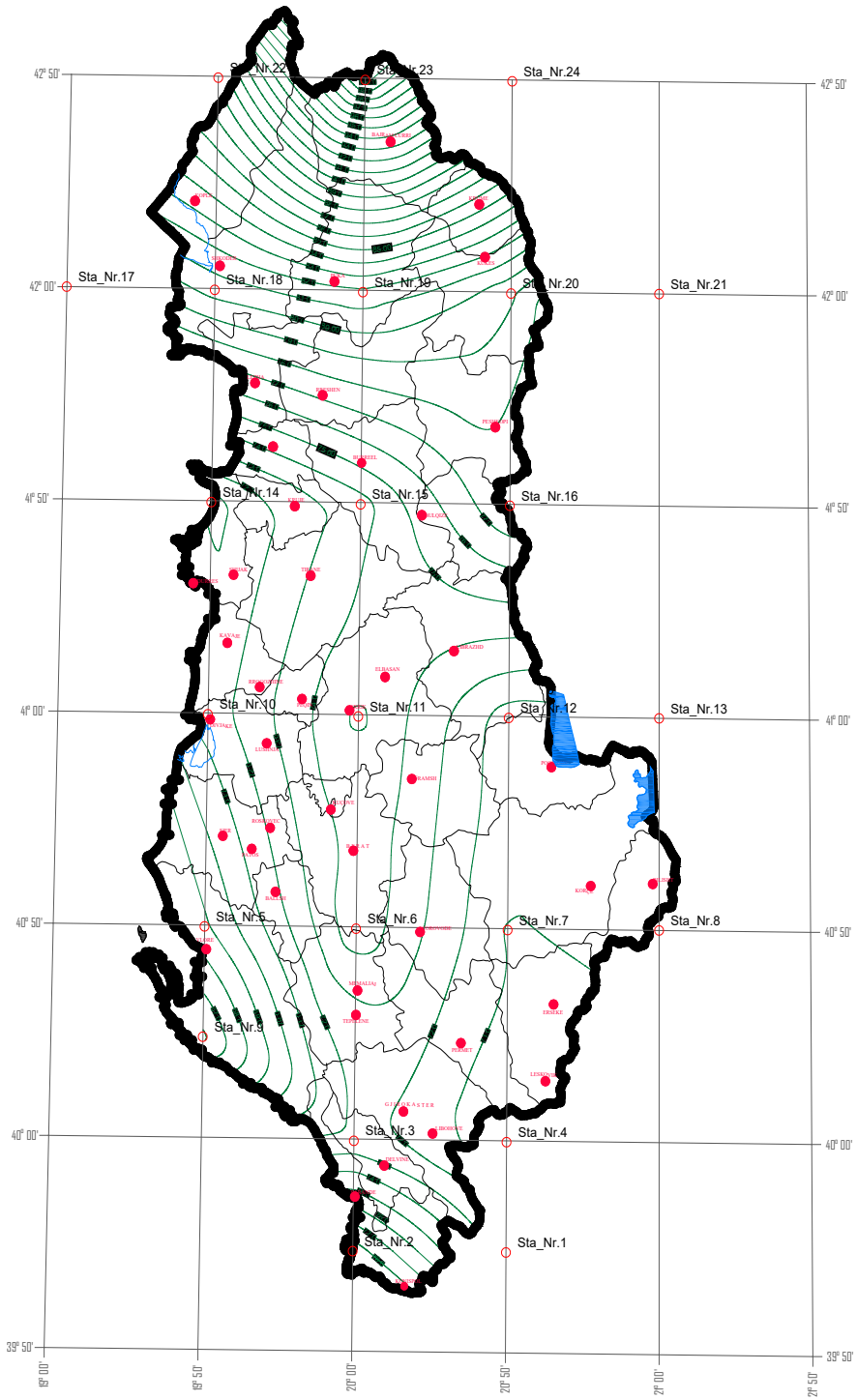


Results and Discussions

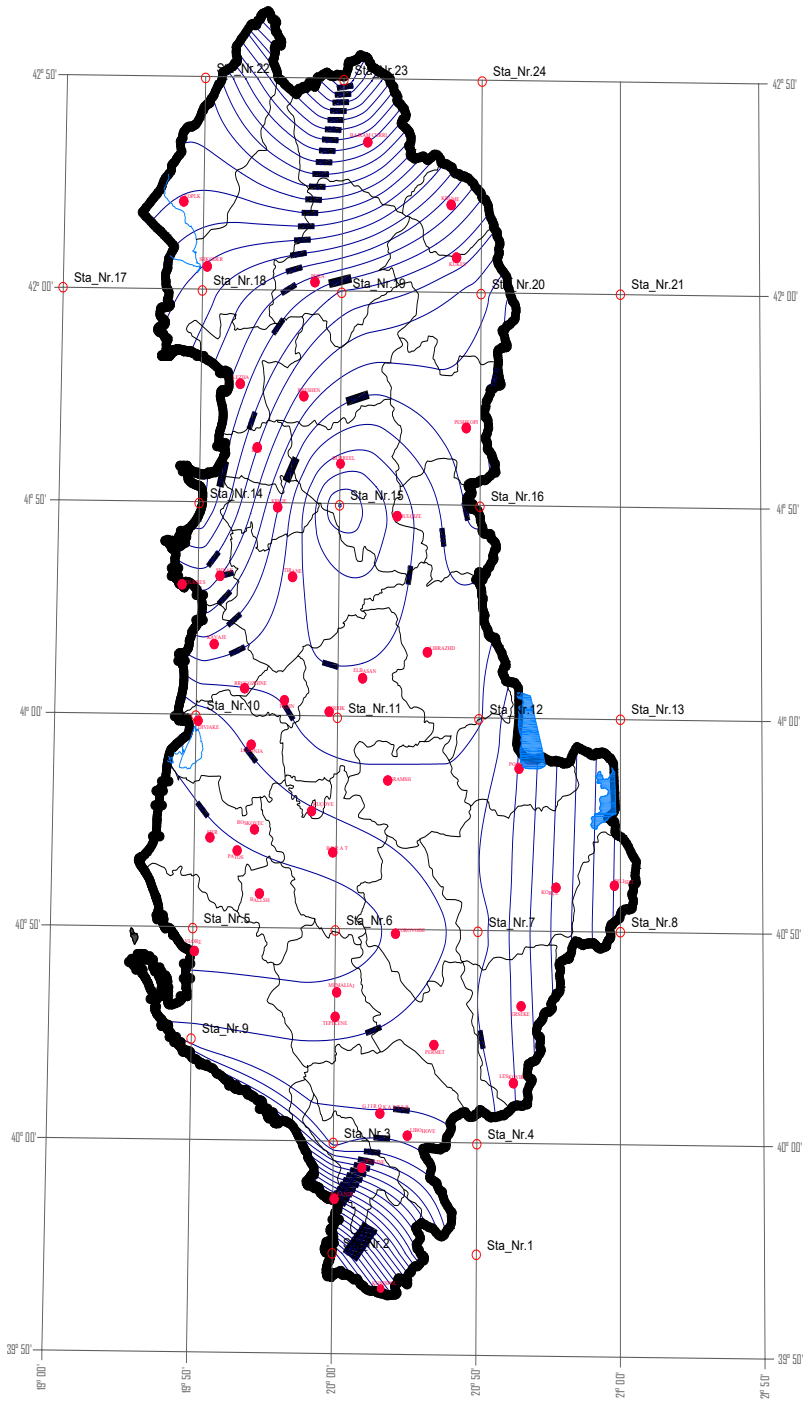
According to the procedure from U.S.D.A, SCS method, the calculation was done based on monthly data.

Nr.	Station	Koo. UTM			Effective Rainfall (mm) 75 year return period												
		North	East	March - September	Annual	January	February	March	April	May	June	July	August	September	October	November	December
1	Stac. Nr.1	4,399,019.92	457,158.62	72.48	143.87	14.84	15.13	11.06	9.61	9.20	10.50	11.70	11.20	9.20	10.12	19.76	11.55
2	Stac. Nr.2	4,399,378.46	414,316.64	78.63	189.15	19.31	19.15	18.62	10.35	9.48	9.20	10.50	10.00	10.48	18.74	27.22	26.11
3	Stac. Nr.3	4,428,236.06	414,639.54	72.28	147.22	14.27	15.62	10.88	9.93	9.20	10.50	11.20	10.50	10.07	10.37	21.28	13.40
4	Stac. Nr.4	4,427,876.92	457,320.05	70.03	145.88	14.09	14.40	10.80	9.98	9.49	10.00	10.50	10.00	9.27	10.60	11.14	25.61
5	Stac. Nr.5	4,484,335.40	372,896.91	68.80	140.42	11.01	10.96	10.20	10.35	9.52	9.20	10.00	10.00	9.54	10.45	19.82	19.38
6	Stac. Nr.6	4,483,734.99	415,265.46	74.75	140.10	14.83	14.88	10.77	10.30	10.14	10.50	11.70	11.20	10.13	10.35	16.82	8.47
7	Stac. Nr.7	4,483,374.79	457,632.99	70.93	144.96	12.67	12.99	10.47	10.22	9.93	10.00	10.50	10.50	9.31	10.42	12.64	25.31
8	Stac. Nr.8	4,483,254.73	500,000.00	71.36	131.27	10.53	10.73	10.13	9.88	10.45	10.00	11.20	10.50	9.20	9.55	14.83	14.27
9	Stac. Nr.9	4,455,474.48	372,407.40	65.80	144.58	17.88	11.46	10.36	9.97	8.98	9.00	9.00	9.00	9.50	10.32	19.74	19.37
10	Stac. Nr.10	4,539,840.58	373,845.67	71.42	143.00	11.04	11.19	10.27	10.61	9.73	10.00	10.50	10.00	10.30	10.57	19.63	19.15
11	Stac. Nr.11	4,539,238.59	415,897.87	75.23	147.64	13.71	14.43	10.59	10.57	10.47	10.50	11.70	11.20	10.20	10.19	21.47	12.62
12	Stac. Nr.12	4,538,877.44	457,949.16	71.44	146.26	12.62	13.33	10.32	10.54	10.06	10.00	10.50	10.50	9.52	10.44	13.61	24.82
13	Stac. Nr.13	4,538,757.06	500,000.00	71.65	131.59	10.42	11.13	10.12	10.19	10.71	10.63	10.50	10.50	9.00	9.48	15.01	13.89
14	Stac. Nr.14	4,595,350.26	374,804.07	70.63	162.94	17.13	17.66	10.48	10.75	9.79	9.20	10.00	10.00	10.41	18.42	19.23	19.86
15	Stac. Nr.15	4,594,746.87	416,536.70	73.54	139.82	13.42	14.91	10.46	10.72	10.45	10.00	11.20	10.50	10.21	10.20	18.33	9.43
16	Stac. Nr.16	4,594,384.88	458,268.55	78.07	151.23	12.32	13.30	10.27	17.83	10.24	10.22	10.00	10.00	9.52	10.17	10.46	26.91
17	Stac. Nr.17	4,651,711.06	334,361.18	77.50	173.09	17.66	18.27	10.65	18.06	9.81	9.00	10.00	10.00	9.98	18.41	20.73	20.52
18	Stac. Nr.18	4,650,864.46	375,772.06	80.42	167.03	17.60	21.18	11.12	18.04	9.93	10.00	10.50	10.50	10.33	10.71	19.10	18.01
19	Stac. Nr.19	4,650,259.85	417,181.93	81.74	157.67	14.81	12.32	10.96	18.11	10.16	10.54	11.20	10.50	10.27	10.53	15.38	22.89
20	Stac. Nr.20	4,649,897.12	458,591.13	79.19	152.88	12.82	13.42	10.35	18.03	10.37	10.37	10.51	10.00	9.55	10.10	9.60	27.74
21	Stac. Nr.21	4,649,776.22	500,000.00	72.58	137.12	11.92	12.62	10.24	10.75	10.35	10.80	10.50	10.50	9.44	9.91	15.37	14.71
22	Stac. Nr.22	4,706,383.17	376,749.55	88.21	175.48	24.66	9.20	11.05	18.53	18.45	10.33	10.00	10.00	9.84	17.18	10.77	25.46
23	Stac. Nr.23	4,705,777.53	417,833.50	100.35	197.96	27.14	23.14	20.60	19.00	18.91	10.64	10.69	10.49	10.00	11.13	8.39	27.80
24	Stac. Nr.24	4,705,414.19	458,916.89	91.48	168.83	13.83	14.70	10.91	18.43	18.78	11.06	11.40	11.20	9.70	10.54	12.53	25.74

Distribution map of dray period effective rain with 75 year return period (mm)

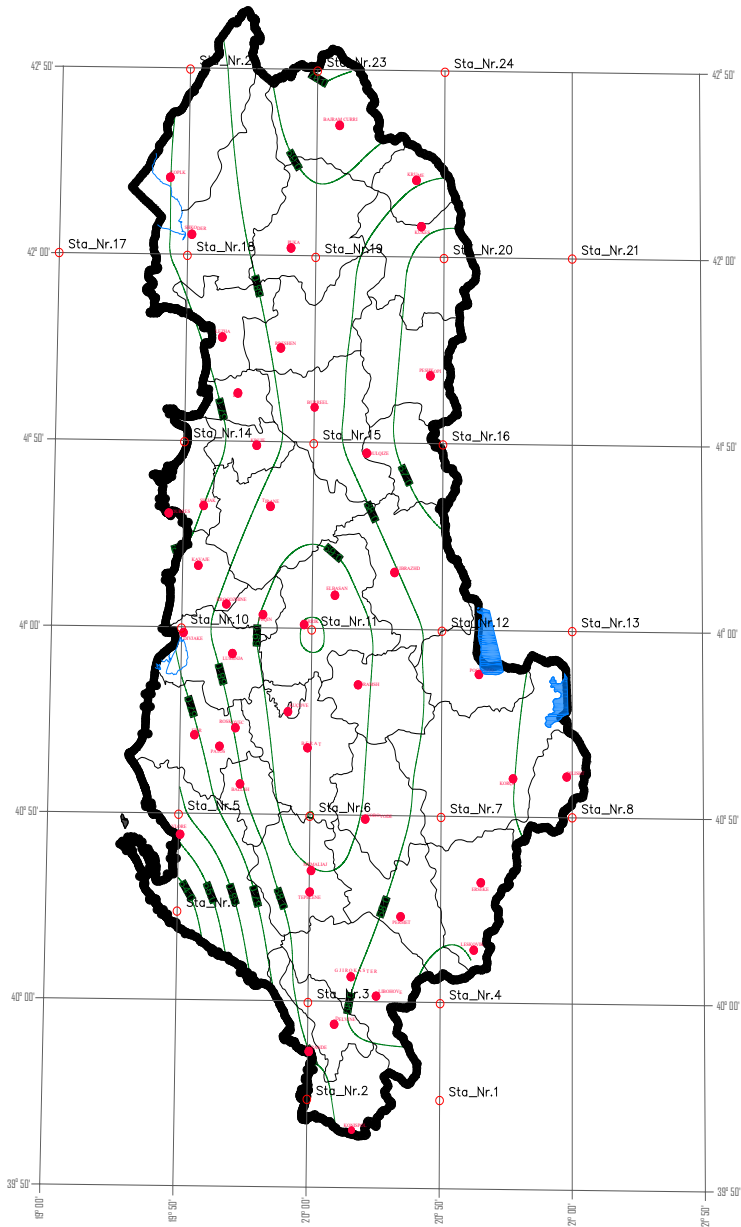


Distribution map of annual effective rain with 75 year return period (mm/year)



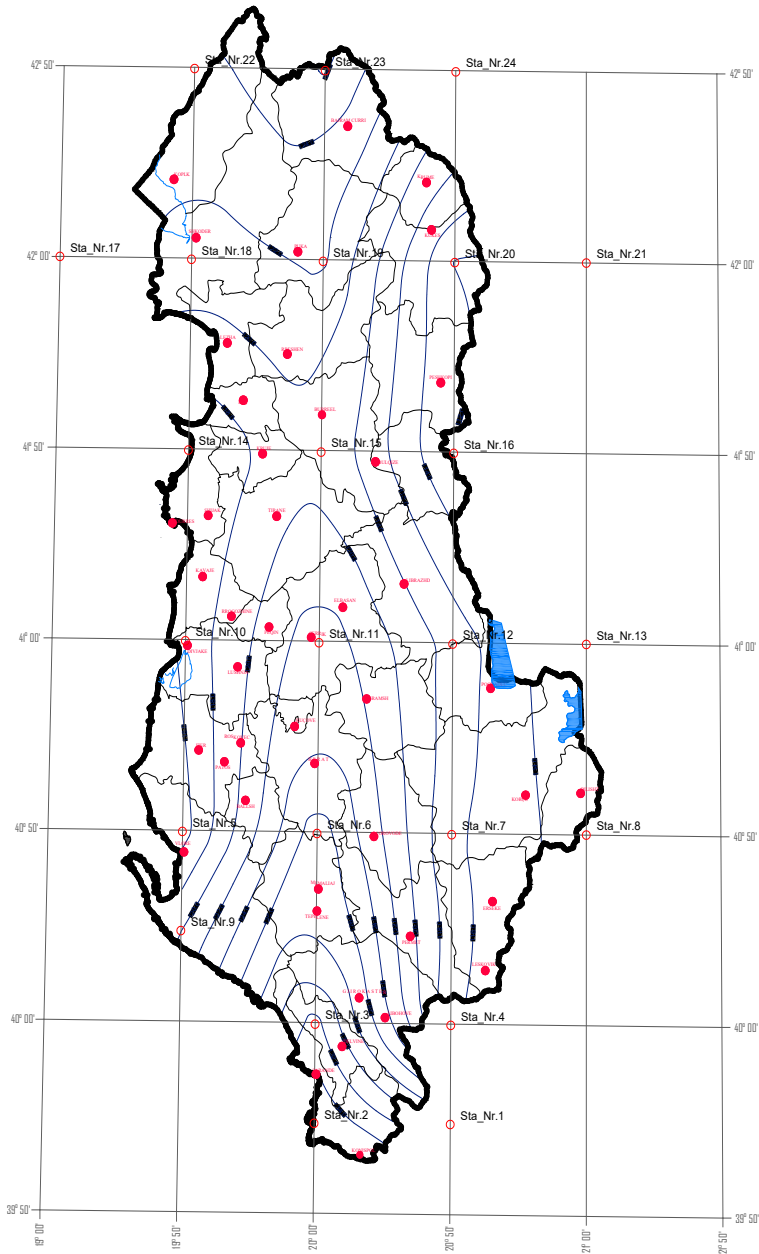
Distribution map of dry period effective rain with 90 year return period (mm)

Nr.	station	Koo. UTM			Effective Rainfall (mm) 90 year return period												
		North	East	March - September	Annual	January	February	March	April	May	June	July	August	September	October	November	December
1	Stac. Nr.1	4,399,019.92	457,158.62	69.68	129.58	8.24	8.64	9.18	8.70	9.20	10.50	11.70	11.20	9.20	9.07	19.76	14.19
2	Stac. Nr.2	4,399,378.46	414,316.64	67.62	135.89	10.74	10.69	10.17	9.54	9.00	9.20	10.50	10.00	9.20	9.96	18.70	18.18
3	Stac. Nr.3	4,428,236.06	414,639.54	68.56	132.79	9.76	9.34	8.82	9.14	9.20	10.50	11.20	10.50	9.20	9.29	21.28	14.56
4	Stac. Nr.4	4,427,876.92	457,320.05	66.54	116.39	8.14	8.40	8.92	9.12	9.00	10.00	10.50	10.00	9.00	8.93	11.14	13.25
5	Stac. Nr.5	4,484,335.40	372,896.91	65.73	115.15	8.90	8.79	8.97	9.56	9.00	9.20	10.00	10.00	9.00	9.36	11.41	10.97
6	Stac. Nr.6	4,483,734.99	415,265.46	70.06	127.19	9.16	8.86	8.76	9.50	9.20	10.50	11.70	11.20	9.20	9.27	16.82	13.02
7	Stac. Nr.7	4,483,374.79	457,632.99	67.38	116.42	7.50	7.50	8.71	9.37	9.29	10.00	10.50	10.50	9.00	8.76	13.68	11.60
8	Stac. Nr.8	4,483,254.73	500,000.00	68.52	112.80	7.50	7.50	8.64	9.02	9.96	10.00	11.20	10.50	9.20	8.70	11.27	9.31
9	Stac. Nr.9	4,455,474.48	372,407.40	63.05	119.95	9.44	9.23	9.11	9.24	8.70	9.00	9.00	9.00	9.00	9.53	18.25	10.45
10	Stac. Nr.10	4,539,840.58	373,845.67	67.42	116.71	8.88	9.07	9.02	9.71	9.00	10.00	10.50	10.00	9.20	9.43	11.14	10.76
11	Stac. Nr.11	4,539,238.59	415,897.87	70.26	123.41	8.04	8.87	8.00	9.68	9.98	10.50	11.70	11.20	9.20	9.09	14.11	13.04
12	Stac. Nr.12	4,538,877.44	457,949.16	67.64	117.25	7.50	8.13	8.54	9.65	9.45	10.00	10.50	10.50	9.00	8.68	12.99	12.30
13	Stac. Nr.13	4,538,757.06	500,000.00	68.14	111.53	7.50	7.50	8.62	9.31	10.21	10.00	10.50	10.50	9.00	8.70	10.68	9.01
14	Stac. Nr.14	4,595,350.26	374,804.07	66.19	116.01	9.04	9.64	9.07	9.72	9.00	9.20	10.00	10.00	9.20	9.64	10.51	10.98
15	Stac. Nr.15	4,594,746.87	416,536.70	68.53	119.89	7.50	9.66	8.00	9.71	9.92	10.00	11.20	10.50	9.20	9.02	12.85	12.34
16	Stac. Nr.16	4,594,384.88	458,268.55	66.00	111.93	7.50	8.48	8.46	9.76	9.58	9.20	10.00	10.00	9.00	8.00	11.56	10.39
17	Stac. Nr.17	4,651,711.06	334,361.18	65.86	123.50	9.28	9.92	9.09	9.77	9.00	9.00	10.00	10.00	9.00	9.87	17.43	11.15
18	Stac. Nr.18	4,650,864.46	375,772.06	67.19	121.02	8.98	10.99	8.00	9.76	9.23	10.00	10.50	10.50	9.20	9.49	10.73	13.64
19	Stac. Nr.19	4,650,259.85	417,181.93	68.84	122.30	8.39	10.45	8.64	9.84	9.46	10.00	11.20	10.50	9.20	9.32	13.88	11.42
20	Stac. Nr.20	4,649,897.12	458,591.13	66.27	111.89	7.50	8.60	8.42	9.96	9.69	9.20	10.00	10.00	9.00	8.00	11.28	10.24
21	Stac. Nr.21	4,649,776.22	500,000.00	67.53	110.77	7.50	7.77	8.00	9.86	9.66	10.00	10.50	10.50	9.00	8.00	10.56	9.40
22	Stac. Nr.22	4,706,383.17	376,749.55	67.11	123.12	9.40	11.15	8.55	10.52	9.84	9.20	10.00	10.00	9.00	9.48	14.21	11.77
23	Stac. Nr.23	4,705,777.53	417,833.50	70.11	126.16	9.40	11.57	10.16	11.01	10.25	9.99	10.00	10.00	8.70	9.20	13.58	12.30
24	Stac. Nr.24	4,705,414.19	458,916.89	69.70	119.05	8.02	9.90	8.88	10.25	10.07	10.49	10.50	10.50	9.00	8.68	11.79	10.96



Distribution map of annual effective rain with 90 year return period (mm/year)

Based on the U.S.D.A, SCS method, the effective rain varies according to the active layer of the soil as well as according to the type of plant. The deeper the active layer, the higher the evapotranspiration and the higher the effective rain. From the studies carried out before, the accuracy of this method is high and it is very suitable for planning or designing irrigation systems.



Conclusions

As a conclusion, we can say that the effective rain is proportional to the Evapotranspiration, the holding capacity of the active layer related to the characteristics of the soils of this layer and the amount of rain that falls in the area of plant cultivation. According to the U.S.D.A, SCS method, the larger the active layer, the greater the value of the effective rain will be and therefore the amount of water needed for plant irrigation will be reduced.

These developed maps can be used for planning and designing irrigation systems in Albania.

They can be improved with new climatic data for the following years.

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Liability for Extracontractual Damage Caused by Third Parties: A Legal and Practical Analysis

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Abstract

This paper aims to examine the legal liability for damage caused by third parties, a significant category of extracontractual damage. Liability for damage arising from the actions of another, which is identified as fault-based and conditional liability, represents a scenario where an individual is held responsible not for their own actions but for the actions of others. This principle serves as an exception to the general rule of liability, which typically holds that the individual who causes the damage is responsible for it.

Through a thorough analysis of legislation, jurisprudence, and practical cases, this paper seeks to uncover and describe in detail the legal liability for damage caused by the actions of third parties, such as minors, employees, or individuals learning a trade or craft, as well as damage caused by animals. As an important issue in civil jurisprudence, the law often seeks to determine liability based on standards of care and in relation to the activity that caused the damage.

The characteristics of extracontractual damage, resulting from the unlawfulness of behavior in society, toward third parties, are treated not only from a general perspective on the form and content of this damage but with due attention to the general conditions related to the presence of the constitutive elements of liability arising from causing extracontractual damage.

The conclusions of this paper provide a deeper understanding of the legal rules and practices governing liability for damage caused by third parties. These insights can be particularly useful for legal professionals, researchers, and practitioners involved in the field of civil justice.

Keywords: liability, damage, unlawfulness, third parties, compensation.

1. Introduction

Obligations may not only arise from contractual agreements but can also result from the actions or omissions of individuals where the manifestation of will is not a defining factor. (Semini, 2008). This is particularly relevant in the context of tort law, where a person may be held liable for harm caused to another due to negligence or wrongful actions. In other terms, this is referred to as non-contractual obligations.

Article 420 of the Civil Code recognizes both contracts and statutory provisions as sources of obligations. One notable instance where the law establishes obligations is in cases involving unlawful actions or omissions, which give rise to non-contractual liability.

In civil law, it is a well-established principle that an individual who, through unlawful conduct, causes harm to another, is personally liable for the resulting damages. The act of causing harm constitutes a fundamental element in the determination of civil liability. Consequently, it is essential to demonstrate that damage has occurred as a direct result of an illegal or wrongful act. The occurrence of damage serves as the

primary condition for the establishment of a legal obligation, and it is the critical legal fact that triggers the formation of such an obligation.

Damage may be inflicted on an individual's property interests, leading to a loss or diminution of value, or impeding its potential future growth. At the same time, damages may also extend to the individual personally, affecting their life, health, honor, and dignity. (Article 608 Civil Code). Consequently, there arises a responsibility to provide compensation for the losses incurred, with the objective of restoring the violated rights. Furthermore, there is an obligation to compensate for the loss of prospective gains resulting from the harm caused.

In certain circumstances, an individual may be held liable for the actions of third parties due to a presumption of culpability. This presumption arises from the existence of a recognized legal relationship between the parties that imposes responsibility on the individual. In such cases, a specific legal relationship exists between the liable party and the perpetrator. Examples include a company's liability for the actions of its employees, as well as relationships such as parent-child, guardian-ward, teacher-student, and employer-employee. (Galgano, 2006)

One of the most fundamental legal principles is the legal security of the parties involved. Therefore, whenever damage occurs, the injured party cannot be left without compensation. In such cases, there is both a factual cause of the damage—the third party who directly committed the act—and a legal cause, which is the person held responsible according to the law, even though they did not directly cause the damage themselves. (Alishani, 1962)

2. Liability for Damage Caused by Minors

According to the Civil Code, specifically Article 613, minors under the age of 14, as well as individuals lacking legal capacity, are not held personally responsible for damages they cause. Since minors under 14 are deemed incapable of understanding the consequences of their actions, their parents or legal guardians are held responsible for compensating damages. In general, parents bear liability for damages caused by their minor children. However, parents may be exempted from this liability if they can demonstrate that they took all necessary precautions to supervise the minor and prevent harm. (Nuni, Vokshi, Hasneziri, 2008)

It is important to note that minors over the age of 14 are personally liable for any damage they cause. The law recognizes that individuals of this age possess the capacity to understand their actions and the consequences that follow. Therefore, they can be held civilly liable for the harm they inflict.

In cases of damage caused by minors, the resulting liability is considered fault-based but is presumed or imputed to the parents. Parents are presumed to bear responsibility for the upbringing and supervision of their children, and insufficient education or supervision may lead to unlawful actions by minors. This liability arises from an objective presumption of fault, as it reflects the parents' failure to adequately educate and supervise their children. Consequently, the blame is attributed to the parents for the damages caused by their minor children, stemming from their failure to fulfill fundamental parental duties.

To establish parental liability for damages caused by their children, several conditions must be met. First, there must be demonstrable harm. Second, the harm must have

been caused by the minor. Third, at the time of the incident, the minor must have been residing with the parents. Finally, the minor must not have been under the supervision of another individual at the time the damage occurred. (Wilson, 1980) Our legal doctrine has established that parental liability is fundamentally based on the parents' fault. This presumption is based on the attribution of responsibility to the parent (and other individuals specified by law) for:

- Failing to adequately supervise the minor's behavior (known as *culpa in vigilando*),
- Failing to properly fulfill their educational duties (known as *culpa in educando*).

However, this presumption can be overturned if it can be demonstrated that the parent could not have prevented the act. (Di Luigi, 2023)

The same principle applies to individuals who have been deprived of legal capacity to act. In such cases, the legal guardian or the person appointed as the supervisor will be held responsible for any damage caused by the individual lacking legal capacity. The very condition of being deemed incapable of acting necessitates ongoing supervision, which constitutes an obligation imposed on the guardian. (Geis, Binder, 2012)

Article 613 of the Civil Code specifically addresses damage caused by minors and individuals lacking legal capacity to act. According to this article: "A minor under the age of fourteen and individuals who are entirely incapable of acting are not liable for the damage they cause. Parents, guardians, or those entrusted with the care or supervision of individuals lacking legal capacity are responsible for the damage caused by the unlawful actions of children under the age of fourteen, individuals under their guardianship, and those under their supervision with whom they reside, but who lack the capacity to act, except when they can prove that they could not have prevented the occurrence of the damage."

It is essential to acknowledge that the Civil Code stipulates that parents may be exempt from liability for compensation only if they can demonstrate that they took all reasonable measures to prevent the damage, yet it remained unavoidable. In other words, they must establish that it was impossible to avert the occurrence of the damage. (Gjata, 2010)¹

Regarding damages caused by children under the age of 14, both parents are jointly liable. If the parents are separated, liability falls upon the parent with whom the minor resided at the time of the incident. This liability is terminated once parental responsibility is revoked.

The law equates individuals lacking legal capacity with minors under the age of fourteen concerning legal responsibility. Similarly, individuals whose legal capacity has been restricted are treated similarly to minors over the age of fourteen who are recognized by law as having limited legal capacity. However, minors over the age of fourteen can be held civilly liable for damages. This legal provision is in place because, at this age, the law grants minors certain property rights, such as managing and disposing of their earnings, opening bank accounts, and saving from their own earned income.

Therefore, minors in this age group are personally responsible for compensating any damage they cause through unlawful actions. If they do not have personal income from their work, their parents will be held liable for damages caused to third parties, but only if the parents fail to prove that they have properly educated and supervised

¹ This solution is also accepted in the Swiss Civil Code (Article 333), the French Civil Code (Article 1384), as well as in the Italian Civil Code (Articles 2047 and 2048/3).

their children.(Alishani, 2002)

Individuals deprived of legal capacity or capacity to act cannot be held personally liable for damages they cause. In such instances, responsibility is transferred to their legal guardian, appointed either by a court decision or as prescribed by law. This shift in responsibility arises because a person lacking legal capacity is incapable of assuming rights or obligations, and, as a result, cannot be held accountable for damages.²

For liability to be imposed, it is required that the injured party is unable to obtain compensation from those entrusted with the care of the individual in question. However, even in cases where care was inadequate, the guardian may either lack the financial resources necessary to compensate the injured party or successfully demonstrate that they could not have prevented the harmful act.³

3. Liability for Damage Caused by Persons Under Supervision

Article 615 of the Civil Code stipulates: “Teachers and other individuals responsible for the supervision of minors or for instructing others in a trade or profession are liable for any unlawful damage caused by their students or those under their supervision, or by individuals learning a trade or profession from them, during the period they were under direct supervision, unless they can prove that they could not have prevented the damage.”

To establish liability under Article 615, a specific supervisory relationship must exist between the responsible party and the individual who caused the damage. For instance, a teacher—such as a kindergarten teacher, dormitory supervisor, or healthcare worker—may be held liable for harm caused by minors in their care. Similarly, a master craftsman would bear responsibility for damages inflicted by an apprentice under their instruction. However, this liability is confined to the time during which the individuals were under the direct supervision of the responsible party. The duty to supervise is thus limited to the period of direct oversight, ensuring that damage is not caused during this time. Consider the case in which a student, while on a school trip with their class, causes harm to third parties while under the supervision of their teacher. In such a scenario, the liability for the damages would rest upon the teacher. (Di Luigi, 2023)

In such cases, the teacher is responsible for the student, considering this responsibility as culpable responsibility because if the teacher had taken proper care the student would not have committed the illegal act. (Légier, 2009).

Failure to fulfill the obligation of supervision results in the teacher or master being held liable for any damages incurred. If damages occurs while the individual is under their temporary supervision, this liability activates the duty to compensate for the resulting damages. However, this presumption of liability is not absolute and may be rebutted if the responsible party can provide evidence that they were unable to prevent the occurrence of the damage. In such cases, demonstrating the impossibility of preventing the damage serves as a valid defense against the imposed liability.

² Civil Court of Cassation, Section III, sentence no. 1148, 20 January 2005.

³ Civil Court of Cassation, Section III, sentence no. 3242, 2 March 2012.

4. Employer Liability: Conditions for Employer Liability

As a general rule, for an employer to be held liable for damages caused by an employee, certain conditions explicitly stipulated by the legislation must be met. Article 618 of the Civil Code of the Republic of Albania states: "The employer is liable for damages caused to third parties due to the fault of employees in his service, while performing the duties entrusted to them." Additionally, "A legal entity is liable for damages caused by its organs in the performance of their duties." (Article 618, Civil Code)

Thus, for employer liability to arise, it is essential that:

1. The damage must be caused by an employee who is performing their duties within the scope of their employment.
2. The employee's actions or omissions must be the result of their fault or negligence while executing their assigned tasks.
3. The legal entity, or the employer, is responsible for the actions of its organs or representatives in the course of fulfilling their duties.

These conditions ensure that liability is appropriately attributed to the employer for actions conducted within the framework of their professional obligations.

The conditions under which an employer may be held liable for damages caused by their employees are specified in the relevant legal provisions. Article 618 of the Civil Code outlines several key elements of employer liability. First, the employee must be performing their duties during the time and at the place designated by the employer. In other words, the employee must be in an employment relationship and carrying out tasks assigned by the employer (Bardhi, 2015). Therefore, the foundation of this liability is the existence of a legally regulated employment relationship between the employee and the employer.

Secondly, there must be a concrete damage caused by the employee's fault, which may take the form of either intent or negligence. The employee must be employed by the employer under a valid employment contract in accordance with the applicable legislation. Furthermore, it is required that, at the time the damage occurred, the employee was performing the services and duties assigned by the employer, thus being present at the designated time and place of work.⁴

In summary, employer liability arises when there is a valid employment relationship, the employee is performing their assigned duties, and the damage is caused by the employee's fault, whether intentional or negligent.

Employer liability for damages caused by employees is presumed by law to be unconditional. In such cases, the burden of proof shifts to the employer, who must demonstrate that the employee acted in accordance with the required standards and did not deviate from professional rules. The employer must prove that the employee's actions were aligned with their assigned duties and that there were no deviations from established procedures or work protocols.⁵

This liability is based on the principle of legal fault, whereby the employer is held responsible if they fail to implement the necessary measures to prevent harm or if they inadequately supervise their employees while they perform their duties. The employer's liability arises from their failure to ensure proper oversight and adherence

⁴ Civil Court of Cassation, Section III, sentence no. 22717, 20 July 2022.

⁵ Civil Court of Cassation, Section III, sentence no. 1786, 20 January 2022.

to workplace regulations, highlighting the importance of effective supervision and enforcement of procedural norms in the workplace.

Additionally, the Civil Code establishes the liability of legal entities (juridical persons) for damages caused by their governing bodies in the course of performing their duties. For instance, if an administrator of a limited liability company causes damage to a third party while carrying out their official responsibilities, the liability rests with the company, not the administrator personally. This means that any claims for compensation must be directed towards the legal entity—the company—rather than the individual acting on its behalf. In such cases, the company assumes the legal and financial responsibility for the actions of its organs, reinforcing the principle that legal persons, rather than individuals, bear the burden of liability when official duties are involved.

5. Liability of the Representative

As a general rule, a representative act within the scope of authority granted by the principal and performs actions in the name and on behalf of the principal. When a representative causes damage to a third party while carrying out these activities, they will be held liable for the harm caused. However, liability also extends to the principal, even if the principal did not personally commit the harmful act and is not directly at fault for the damage caused. (Semini, 2008)

Pursuant to Article 66 of the Civil Code, actions taken by a representative produce direct legal consequences for the principal. Consequently, even though the principal did not personally execute the act, they are required to compensate for the damage caused, alongside the representative. This legal attribution arises because the representative's actions are considered to be the actions of the principal.

Since a principal can appoint a representative to act on their behalf with full authority, it is reasonable to conclude that liability for damages extends to both the representative and the principal, rendering them jointly and severally liable to the injured third party. This joint and several liability ensures that the injured party can seek full compensation from either the representative or the principal, reflecting the principle of shared responsibility for actions taken within the scope of representation.

6. Liability for Damage Caused by Animals

According to the Civil Code, specifically Article 621, the owner or current possessor of an animal is liable for any damages caused by the animal to third parties. This liability is presumed whenever the animal's actions result in harm, obligating the owner or possessor at the time of the incident to compensate for the damage.

However, an exception exists within this rule. The owner or possessor may avoid liability if they can demonstrate that they took all necessary and reasonable measures to control the animal's behavior and prevent any potential damage, yet the harm occurred despite these precautions. This defence shifts the focus to the adequacy of the preventive actions taken, allowing the owner to escape liability if they can prove that the damage was unavoidable despite their efforts to manage the animal's conduct effectively. (Semini, 2008)

Thus, two parties can be held responsible for damages caused by an animal:

- **The Owner:** The owner is liable due to their legal obligation to care for, raise, and supervise the animal.
- **The Person in Possession:** If the damage occurs while the animal is under the care and control of someone other than the owner—such as a person who has temporarily taken responsibility for a stray animal—they are equally liable for any harm caused during that period of possession.⁶

In summary, responsibility for damages caused by animals extends not only to the owner but also to anyone who, though not the owner, is in possession and control of the animal at the time the damage occurs. This dual liability ensures that whoever has effective control over the animal when harm is caused can be held accountable.

When discussing this type of liability, we include damages caused by all types of animals that have an owner or are in the possession of a person fulfilling legitimate purposes. In practice, numerous cases have resulted in substantial compensation for individuals who have suffered injuries—such as bites or other forms of harm—caused by animals like snakes, dogs, and others. Such cases often arise from the failure of owners or custodians to control their animals' dangerous behaviors.

In modern legal frameworks, liability for harm caused by animals is increasingly recognized as a form of liability for damages arising from hazardous activities and dangerous objects. This approach reflects the heightened risk associated with handling certain animals, thereby imposing strict responsibility on those who own or control them to prevent harm to others. (Gjata, 2010)

The issue that arises in the context of this type of liability pertains to damages caused by wild animals or animals without an owner. While the Civil Code does not explicitly address this scenario, referring to Italian jurisprudence provides some guidance. In cases where compensation is sought for damages caused by wild animals, liability rests exclusively with the municipality. The municipality, as the regulatory authority responsible for matters concerning the management of wild animals, as well as for the planning, coordination, and control of wildlife protection and management, bears responsibility for such damages.⁷

Moreover, the municipality has the right to seek reimbursement through a recourse action against other authorities that, in the scope of their specific functions or delegated duties, should have taken appropriate measures to prevent the damage. This legal framework places the responsibility for controlling and managing wild animal populations on the municipality while allowing it to pursue further legal action against those who have failed to fulfill their respective obligations.⁸

It is also crucial to recognize that an animal owner remains liable for damages even when not physically present with the animal at the time the harm occurs. This means that if the animal is temporarily separated from the owner, the owner still retains responsibility for any damage caused. Additionally, liability extends to cases where the injured party has made efforts to calm or subdue the animal, and the animal responds with aggressive behavior that results in injury.

Liability for damages caused by animals is sometimes classified as either objective

⁶ The Court of Cassation ordered the manager of a riding school to pay compensation for damages resulting from a fall from a horse (Cass. civ., n. 7903/2015).

⁷ The Basic Court of Peja has considered the Municipality responsible for the injury caused to a student by the bite of a stray dog in the school yard. The court has forced the Municipality to compensate both material and non-material damage caused. Basic Court of Pej, decision no. 2019:137359, date 30.06.2021

⁸ Civil Court of Cassation, Section III, sentence no. 7969, 20 April 2020.

or subjective, with subjective liability involving a presumption of fault. In academic discussions, there are varying perspectives on this issue. However, when addressing subjective liability, the presumption of fault on the part of the owner or handler is based on their duty to supervise and control the animal's behavior. This responsibility includes taking all necessary precautions to prevent any potential harm that the animal might cause.

In this framework, subjective liability is understood as a form of fault-based liability, where the owner's failure to fulfill their obligation to properly manage and restrain the animal creates a presumption of negligence.⁹

7. Liability Arising from the Exercise of Dangerous Activities or Use of Dangerous Objects

There are numerous activities and objects in daily life that can be classified as dangerous or that pose an increased risk to human life and the surrounding environment. While the doctrine does not provide a specific definition of what constitutes a dangerous activity, a dangerous object can be characterized by its inherent risk due to its properties, composition, impact on the environment, or even its mere existence.

To establish liability related to dangerous activities or objects, two essential conditions must be met:

- **Intrinsically Dangerous Activity:** The activity must be inherently dangerous, meaning that due to its nature or the nature of the tools or materials used, it has the potential to cause harm. This encompasses activities that, by their very nature, carry risks that cannot be fully mitigated.
- **Preventive Measures:** It is necessary that all appropriate measures are taken to prevent such harm. This includes implementing safety protocols, using protective equipment, and adhering to relevant regulations to minimize the risk associated with the activity or object.¹⁰

In summary, liability for dangerous activities or objects hinges on the inherent risk they present and the proactive steps taken to mitigate potential harm.

A person who uses a dangerous object due to its inherent nature or engages in an activity classified as dangerous and subsequently causes damage is obligated to compensate the injured party, unless they can demonstrate that they have taken all necessary and appropriate measures to prevent such damage. (Article 622, Civil Code)

The question of who should be held liable for damages arising from these dangerous activities and objects is subject to varying scholarly opinions. Some authors classify this liability as objective, while others consider it subjective, presuming fault on the part of the individual.

In this context, liability for compensation will typically rest with the individual whose actions, through their fault, have caused harm as a result of engaging in a dangerous activity or using a dangerous object. However, if the individual cannot prove that the damage was caused by the fault of a third party, the owner of the object or structure will be held liable for the incurred damages. This framework underscores the importance of accountability in the context of dangerous activities, emphasizing

⁹ <https://heinonline.org/HOL/LandingPage?handle=hein.journals/jolpa1&div=6&id=&page=>

¹⁰ Civil Court of Cassation, Section VI-3 sentence no., 16170, 19 May 2022.

the need for individuals to exercise due diligence in their actions.

For the owner of a dangerous object to be relieved of liability for compensating damages, and for that responsibility to be assigned to a third party who used the object or engaged in a dangerous activity, there must be no legal relationship or connection between the third party and the owner. In other words, the third party who caused the damage through their activities or use of the dangerous object must not have been authorized by the owner to engage in such actions; they must have acted beyond the scope of the owner's permission.¹¹

As a result, the third party will be held liable for compensating the damage caused by their own actions. This framework emphasizes the principle that liability for damages can shift to the individual who misuses the dangerous object or engages in hazardous activities without proper authorization, thereby protecting the owner from responsibility when their property is misappropriated.

When discussing what constitutes a dangerous object, vehicles serve as a pertinent example. Vehicles are considered dangerous not only because of their inherent characteristics but also due to the potential for hazardous actions taken by drivers or users, which can lead to significant damage for which they are required to compensate. To address these risks, compulsory motor vehicle insurance has been established, regulated by specific legislation. This insurance aims to protect and ensure compensation for third parties who may suffer property damage or moral harm as a result of road accidents. By mandating insurance coverage, the legal framework seeks to provide a safety net for victims, facilitating compensation and mitigating the financial consequences of accidents involving dangerous vehicles. (Semini, 2008)

Conclusions

Civil liability for damages caused by third parties is indeed an area that has not been sufficiently explored by legal scholars and academics. Moreover, Albanian legislation encompasses numerous concepts that remain underdeveloped, creating significant space for debate and differing interpretations. This lack of comprehensive scholarly analysis and legal clarity underscores the need for further research and detailed examination in this area, particularly to address ambiguities and enhance the legislative framework.

In the law of obligations, the general principle holds that each individual is liable for their harmful actions and must compensate for any damage caused to another party. To be exempt from liability for compensation, the individual must demonstrate that the harm was caused by the fault of a third party, whose actions were unforeseeable, and that they were unable to prevent the resulting consequences despite reasonable efforts.

Damage arises exclusively from unlawful actions that infringe upon rights and property interests protected and guaranteed by the laws of the country. Such actions inevitably lead to harmful consequences for the individual's person or property, prompting the injured party to seek compensation and the restoration of their violated rights. This legal framework emphasizes the principle that unlawful conduct which disrupts legally protected interests entitles the victim to pursue remedies for both the damage incurred and the re-establishment of their legal standing.

¹¹ <https://www.jstor.org/stable/761732>

And finally, we can say that many provisions of our legislation have been closely aligned with the provisions of the Italian Civil Code and the French Civil Code. Many stipulations, principles, and concepts are similar, and the types of liability and their foundations are regulated in both Albanian legislation and the legal systems of many developed European countries.

It can be stated that in our legislation, liability for damage caused by third parties is fault-based and conditional. This conclusion is clearly derived from a direct interpretation of the provisions of the Civil Code in force, particularly from Article 613 onwards, where it is specified that individuals who are legally responsible for the damages caused to third parties are exempt from liability “except when they can prove that they could not have prevented the damage, despite their efforts.” However, the standard of proof, as well as the actions or omissions that must be taken, are not explicitly defined in this Code, although these preventive measures are provided for in secondary legislation.

I would suggest that the necessary actions to be taken by the responsible party to avoid damage should be specified in the Civil Code, and that clear limits should be set to determine when a person can be exempt from liability for compensating damages.

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Implementation of bone marrow biopsy as a new practice at Mother Theresa University Hospital Center in Tirana, Albania - Diagnostic challenges

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Abstract

Background: This study is a retrospective, descriptive study, where all the parameters, after being entered into an Excel database, were statistically processed to calculate frequencies and statistical significance (P). Bone marrow biopsies, taken mainly from the superior posterior iliac spine, are fixed with 10% buffered formalin and decalcified with EDTA 6% process and stained with H-E, reticulin and trichrome. Whenever necessary, immunochemistry stains were used.

Objectives: The distribution of diagnostic categories in different years and their correlation with the literature. Creation of an epidemiologic database in relation to age, gender and different time periods. Evaluation of the diagnostic difficulties by determining the factors that influence them. Evaluation of histopathological diagnostic tools and future perspectives.

Materials and methods: We included in our study 372 bone marrow biopsies accepted and screened at our laboratory in a period of three years, from January 2019 to December 2021. The biopsies came from patients admitted to the haematologic department with various hematologic disorders. The data collected from the biopsy reports were analysed and compared with each other in relation to the clinical diagnosis, age, gender, their distribution in time and the histopathologic data such as cellularity, clonal maturation, fibrosis and the addition of immunochemistry panels.

Conclusions and Results: The most frequent diagnosis is that of myeloproliferative disorders with 193 cases or 52% ($p < 0.01$) followed by lymphoproliferative disorders with 78 cases or 21% (non-Hodgkin lymphoma 69.2 %). The distribution of myeloproliferative disorders according to years shows a significant difference between polycythemia vera ($p < 0.01$) and essential thrombocytopenia ($p < 0.01$). The average age of patients with hematologic disorders is 58.9 years. There is a predominance of cases in the sixth decade (33.2% of cases), followed by the fifth decade (25.1%) and the seventh decade with 19.4%. In the gender ratio, a slight predominance of men is observed over women in the ratio M:F 1.2:1. Significant change in the ratio M:F ($p < 0.01$) in the ratio 1.8:1. In 2021, a new category of biopsy reports (1%) is observed with data consisting of reactive changes with trilinear hyperplasia, predominance of histiocytes and plasma cells. These histologic alterations, according to the literature, were observed in patients with severe COVID infection.

Introduction

Bone marrow biopsy BMB is a valuable diagnostic procedure commonly performed for evaluation of a wide spectrum of diseases including hematologic abnormalities, nonhematologic malignancies, metabolic abnormalities, and tumor treatment response such as chemotherapy and bone marrow transplantation, hematologic tumor staging, suspected infection in patients with fever of unknown origin

and when the routine examination of a blood smear has failed^{1,2}. As we know, bone marrow trephine biopsy offers a comprehensive view of the bone marrow architecture and although conventional morphology remains the gold standard for paraffin-embedded BM trephines, with the addition of immunohistochemical (IHC) staining we can have a firm diagnosis. The bone marrow is one of the most common sites involved by metastatic tumor; nonhematologic and hematologic origin. The diagnosis of metastatic involvement of the bone marrow may have a profound effect on prognosis and treatment^{3,4}. Furthermore, manual evaluation of BMB can be challenging and time-consuming and are highly dependent on examiner skill and experience, especially in unclear cases⁵. Hence, the number of high-quality histological examinations is limited by the availability and experience of trained experts, whereas examiner classifications have been found to be subject to substantial inter-variability⁶. Having a good knowledge of microscopic cellular morphology and bone marrow overall architecture implies the correct diagnosis and it requires also a good specimen preparation.

Bone marrow consists of functional units, composed of many cell-types arranged in an organized framework surrounding haemopoietic stem cells (HSCs) that constitute its microenvironment or niche^{7,8}. The alterations between stroma and parenchyma of the bone marrow interferes with its normal functions activating mesenchymal stem cell to produce marrow fibrosis, a condition correlated especially with myeloproliferative neoplasms, myelodysplastic syndromes and lymphomas⁷.

BMB is often taken at the pelvic bone and is a painful procedure owing to the bigger bore of the needle and the collection of the material, and its processing takes at least 48-72 hours. Thus, performing trephine biopsies on all patients may not be cost-effective in terms of clinician and laboratory personnel's time, efforts, and patient discomfort⁹⁻¹⁰.

This study aims to assess the distribution of different diagnostic categories acquired from screening bone marrow biopsies received at our Pathology Department at the University Hospital Center of Tirana between 2019-2021, to correlate it with the literature and to create and epidemiologic data in relation to age, gender and different time periods. Furthermore, evaluate our diagnostic difficulties by determining the factors that influence them.

Materials and methods

A hospital-based retrospective/descriptive study was conducted on 372 biopsies over a period of two years from 2019 to 2021 at the Department of Pathology, Mother Theresa University Hospital. The patients were admitted at the Hematology Department at the same hospital diagnosed with hematologic disorders. We analyzed the biopsies reports and compared with each other according to different diagnosis, age, sex and distribution in time. Furthermore, the histopathologic characteristics present in bone marrow biopsies such as cellularity, clonal maturation and fibrosis were compared in relation to different hematologic diseases. Most of the BM biopsies were performed on the anterior/superior (ASIS) or posterior iliac spine (PSIS). The tissue samples were fixed in 10% neutral buffered formaldehyde and were decalcified according to the

ETDA method, the first two years for 24 hours and during 2021 only 4 hours¹¹. Paraffin blocks were stained with H-E and with Silver Stain for reticular fibres and Masson's Trichrome Stain for collagen fibres, simultaneously. Whenever necessary, IHC stains were used. IHC methodology is performed automatically with the Benchmark XT device from Ventana as well as with different IHC clone antibodies from Ventana. The results were statistically analyzed using Excel and were statistically processed to calculate frequencies and statistical significance (P).

Results

Diagnosis distribution

Out of 372 biopsies were identified 193 cases (52%) with myeloproliferative disorders, 78(21%) lymphoproliferative disorders LPD, 13(3.5%) myelodysplasia MDS, 13(3.5%) hypoplasia/aplasia, 2(0.5%) metastases, 4(1.1%) infectious/metabolic diseases, 5(1.3%) reactive changes, 1(0.2%), macrophage activation syndrome and 62(16.7%) were inconclusive ;Table1. The most frequent diagnosis was the myeloproliferative disorders MPD with a significant difference in frequency from other diagnoses (p <0.01), followed by lymphoproliferative disorders with 78 cases (21%).

Diagnosis	Nr. Cases	Percentage %
MPD	193	52%
LPD	78	21%
MDS	13	3.50%
Hypoplasia/Aplasia	13	3.50%
Metastasis	2	0.50%
Infectious/Metabolic D	4	1.10%
Reactive changes	6	1.60%
MAS	1	0.20%
*Unconclusive	62	16.70%
Total	372	100%

Table 1: Distribution of microscopic diagnosis

LPD, lymphoproliferative disorders; MPD, myeloproliferative disorders; MDS, myelodysplastic disorders; MAS, macrophage activation syndrome; *Unconclusive BOM: Inadequate tissue/incompatible with clinical diagnosis

The years-wise distribution of myeloproliferative disorders (MPD) diagnoses, had a significant difference from polycythemia vera (PV) (p<0.01) and essential thrombocythemia (ET) (p<0.01). In a three-year period, we observed, in relation to the other diagnoses, included in the MPD, that essential thrombocythemia (ET) predominates with 41% of cases, followed by PV with 29%, primary myelofibrosis (PMF) 24% and chronic myeloid leukemia (CML) and (NOS) only 3%; Table 2.

According to a large population-based study in Singapore that collected 2557 individuals from 1968 to 2017, diagnosed with MPN, identified 1031 diagnosed with chronic myeloid leukemia (CML), 424 with polycythemia vera (PV), 389 with essential thrombocythemia (ET) and 134 primary myelofibrosis (PMF)¹² which is compatible with the data from our study¹³. In another study the incidences of CML, PV, and ET were relatively similar at 1.0-2.0 per 100,000 person-years, while PMF is rarer with an incidence of 0.3 per 100,000 person-years¹⁴ but in our study even if PMF was present in just 24% of the cases, CML was only described in 3% of our biopsies.

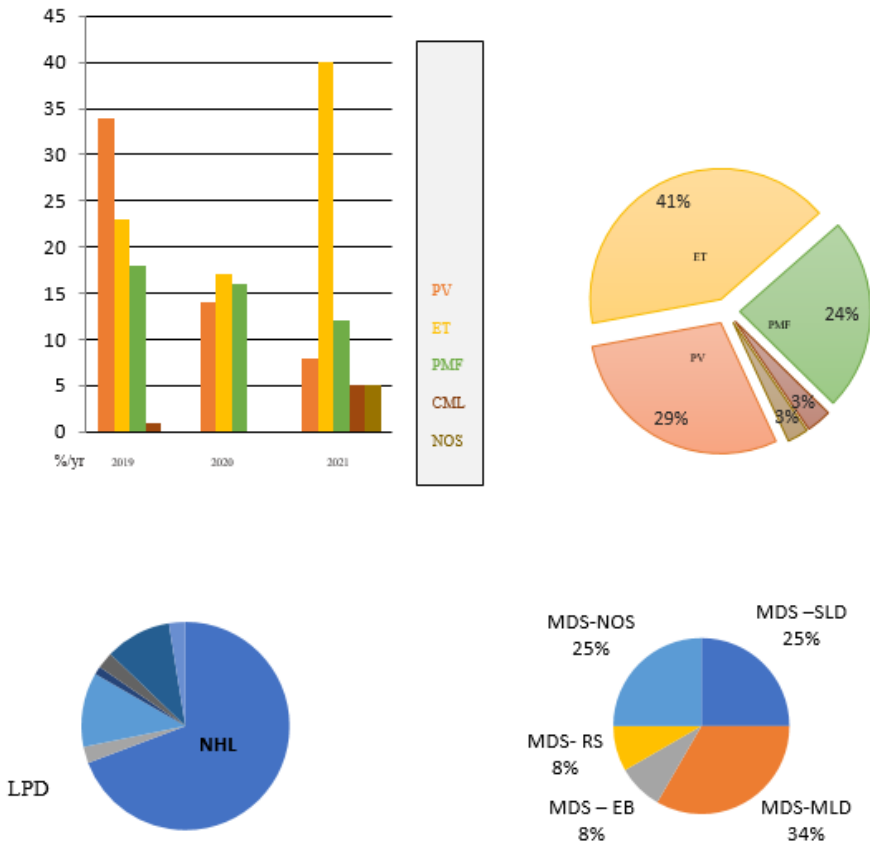


Table 2: Distribution in time of MPD, LPD and MDS 2019-2021

No significant change in years was found in the distribution of LPD category diagnoses. During the three years, NHL prevails (69.2 %) ^{15,16}.

In the subcategories of myelodysplasias, we see that multilineage myelodysplasia disease MDS-MLD is the most frequent with 34% of cases, followed by single lineage myelodysplasia disease MDS-SLD and unspecified MDS with 25% each. According to literature was also found that MDS-MLD was the most frequently encountered subtype, 19/50 (38%) followed by MDS-SLD; 11/50 (22%)¹⁷.

Age and gender variation

Among all the patients with bone marrow biopsies analyzed, 168 were men and 142 were women. A slight predominance of men is observed over women with ratio M:F 1.2:1.

A significant difference in the distribution of diagnoses by gender was found only for lymphoproliferative disorders (LPD) ($p=0.01$), where the M:F ratio is 1.8:1 (50 males, 28 females). The average age of patients with hematological disorders was 58.9 years (interval 50yr-69yr). There is a predominance of cases in the 6-th decade of life (33.2%), followed by the 5-th decade (25.1%) and the 7-th decade (19.4%). No significant difference was found in the age distribution group between MPD and LPD ($p=0.3$). They both prevail in the 6th decade of life (average age 62 years). In our study MDS appeared to be present at a younger age, mean age 46.3 years, while in literature the average age of patients with MDS is 53 years¹⁸. Aul et al. found a strong correlation between the proportion of elderly patients and the relative frequency of MDS diagnoses¹⁹. Furthermore, Zeidan et al., an epidemiologic study, confirmed a high incidence of MDS between 60-90 years of age²⁰; Figure 1. The reasons for this age discrepancy in MDS was not investigated further.

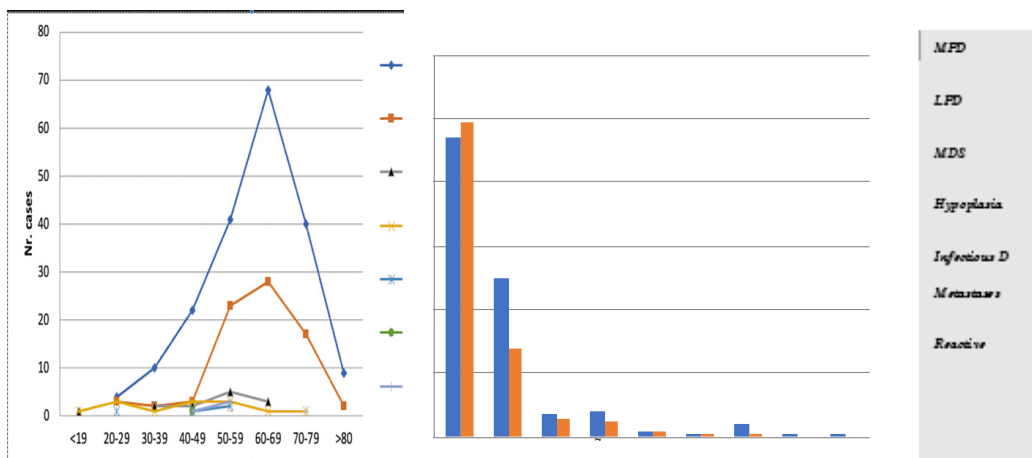


Figure 1: Gender and Age-wise distribution of final diagnosis

LPD lymphoproliferative disorders; MPD myeloproliferative disorders; MDS myelodysplastic disorders; MAS macrophage activation syndrome

Cellularity, maturation and fibrosis distribution

In our study, 73% of biopsies diagnosed with myeloproliferative disorders MPD were hypercellular, 22% normocellular and only 5% hypocellular. According to literature myeloproliferative disorders are characterized by mutations in hematopoietic stem cells that results in clonal expansion in myeloid cells; polycythemia vera PV and primary myelofibrosis PMF show significant hypercellularity in contrast with

essential thrombocythemia ET with mild hypercellularity²¹. Cellular maturity was not reported.

In lymphoproliferative disorders LPD was found a significant difference in the distribution according to cellularization ($p < 0.01$). The presence of hypercellularization prevails in 75% of cases. Hypo-cellularization was not observed in any case. Cellularization was normal in MM (66.7%). According to the literature²³, LPD have more frequent hypercellular marrow, with cells that are difficult to differentiate. Immunochemistry is required²². Hodgkin lymphoma HL, multiple myeloma MM and hairy-cell leukemia HCL presented 100% tissue maturation; Figure 2.

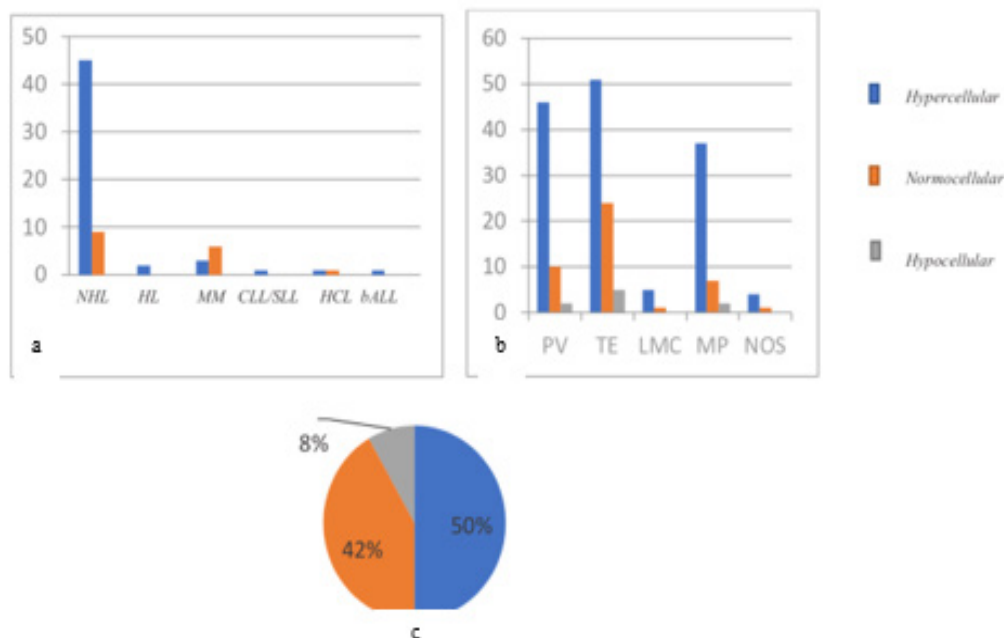


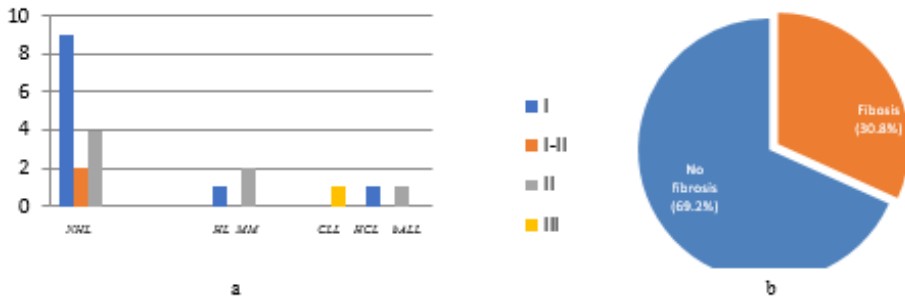
Figure 2: Distribution of cellularity in BOM 2019-2021: a. LPD; b. MPD; c. MDS

NHL non-Hodgkin lymphoma; HL Hodgkin lymphoma; MM multiple myeloma; HCL hairy cell leukemia; CLL chronic lymphocytic leukemia; bALL Acute lymphoblastic leukemia.

In myelodysplastic syndromes MDS, the majority of the BOM, 42% were hypercellular and 8% (1) hypocellular. MDS biopsies were characterized by ineffective hematopoiesis of one or more major myeloid cell lineages, with the potential to evolve into acute myeloid leukemia. In the study by Kini J et al (2001), 84% of patients had hypercellular marrow, 68% of patients had trilinear dysplasia²⁴. We identified 13 biopsies diagnosed with aplastic anemia AA, 72.7% of them presented severe low cellularity.

A significant difference was found in the distribution of fibrosis in LPD according to diagnose and the fibrosis grade ($p < 0.01$). Most cases of LPD, (47) 69.2% did not present fibrosis while 30.8% of them presented fibrosis ($p < 0.01$). In total, stage I fibrosis predominates with (11)17.5% of the total, followed by stage II with (7) 11.1%

of the total and only (1) 1.6% stage I-II and stage III. The most frequent diagnosis of LPD associated with fibrosis was NHL (in 27.8% of cases). In two cases of hairy cell leukemia HCL only one of them had developed secondary fibrosis; Figure 3.



Secondary myelofibrosis occurred in 33.3% of chronic myeloid leukemia CML, 26.8% of PV, 11.25% of ET and zero cases of MPD-NOS. According to the literature, myeloproliferative lesions that are most often associated with secondary myelofibrosis are PV and chronic myeloid leukemia CML. ET is not usually associated with MF even if according to Tefferi et al²⁵ study, 2021 approximately 15% of patients with ET or PV might progress into a PMF-like phenotype (post-ET/PV MF) during their clinical course. According to the literature in secondary MF the most frequent causes are metastatic tumor and malignant lymphoma. It also occurs relatively often in the course of chronic myeloproliferative disorders, such as chronic myeloid leukemia and polycythemia vera. We studied also the different grades of fibrosis in primary myelofibrosis PMF and our results are 22% stage pre-fibrotic, 15% grade I, 6% grade II and 9% grade III.

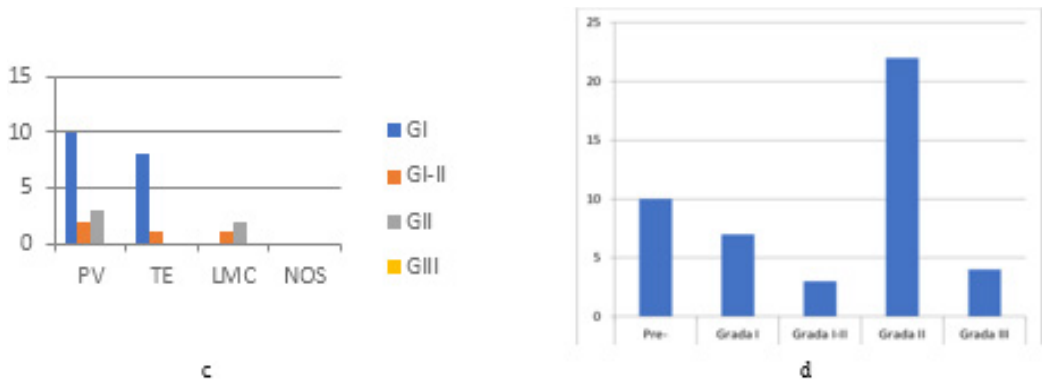


Figure 3: Distribution of bone marrow fibrosis; a/b. LPD; c. MPD; d. PMF grade fibrosis

NHL non-Hodgkin lymphoma; HL Hodgkin lymphoma; MM multiple myeloma; HCL hairy cell leukemia; CLL/SLL chronic lymphocytic leukemia; bALL Acute lymphoblastic leukemia.

Discussion

Evaluation of bone marrow trephine biopsy specimens is critical to the diagnosis of benign and malignant hematologic conditions. Most of hematologic patients that underwent bone marrow needle biopsy and were screened in our laboratory were diagnosed myeloproliferative neoplasms (MPNs) that are clonal diseases originating from a single hematopoietic stem cell that cause excessive production of mature blood cells. The 7 seven subcategories are: chronic myeloid leukemia, chronic neutrophilic leukemia, polycythemia vera (PV), primary myelofibrosis (PMF), essential thrombocythemia (ET), chronic eosinophilic leukemia-not otherwise specified and MPN, unclassifiable (MPN-U) according to the World Health Organization (WHO) and international consensus classification (ICC) criteria²⁶. In our study, we screened 372 bone marrow biopsies, from which 52% with myeloproliferative disorders (MPD), 41% with essential thrombocythemia (ET), 29% with polycythaemia vera (PV) and 24% with primary myelofibrosis (PMF). Morphological features of bone marrow of patients with myeloproliferative neoplasms may initially be difficult for pathologists to recognize, especially in cases where the experience lacks, as in our case, as we started examining BOM in 2018 for the first time. Another problem in our facility that is confirmed in other studies, was the fact that most of the bone marrow biopsies were viewed in isolation, without clinical and laboratory information²⁷. According to the literature, the discovery of the Janus Kinase 2 mutation (*JAK2*V617F) has changed the diagnostic approach for myeloproliferative disorders, unfortunately in our university hospital center molecular examination are not performed. Molecular testing has become a critical diagnostic tool in the evaluation of patients with suspected PV. *JAK2*-p. V617F is present in >95% of PV patients, and also in about half of the patients with ET or PMF^{28,29}. Also, in MPN with nonmutated *JAK2* and *MPL*, somatic mutations in the gene for calreticulin (*CALR*) was identified according to Nangalia et al.³⁰ that sequenced exomes from 151 patients with MNP and concluded that *CALR* mutations were found in 70 to 84% of samples of myeloproliferative neoplasms with nonmutated *JAK2*³¹. Thus, when BCR-ABL1-negative myeloproliferative neoplasia is suspected, in addition to markers of hematopoietic cells of the three lineages; erythroid lineage (CD71); granulocyte lineage (myeloperoxidase) megakaryocytic lineage (CD42b) and hematopoietic stem cells (CD34), CAL2 monoclonal antibody immunostaining should be performed³¹. The discovery of recently identified molecular features has yielded new perspectives regarding diagnostic and prognostic markers that provide novel insights for the understanding of the pathobiology of these disorders^{30,31}. Current diagnostic challenges of chronic myeloproliferative disorders (MPD) include the differentiation of essential thrombocythemia (TE) from its mimics: early polycythemia vera (PV) and/or “pre-fibrotic”/early primary myelofibrosis (pre-PMF) which was recognized as a separate entity in the 2016 revised WHO classification of myeloproliferative neoplasms³². This distinction is important, because the frequency of complications such as progression to “overtly fibrotic” myelofibrosis, blast crisis and overall prognosis are markedly different in the two conditions. The progression to the fibrotic phase is 0-1% in TE vs 10-12% in PMF, and leukemic transformation is 1-2% in TE vs 2-6% in PMF.

Furthermore, about 15% of patients with ET or PV develop a PMF-like phenotype over time, referred to as post-ET or post-PV myelofibrosis and according to the same study over a total of 125 patients with secondary myelofibrosis, after a 3-year follow-up were documented 86(69%) deaths and 10(8%) leukemic transformations³³. According to another study the median survival in these cases were 9.3 years (95% CI: 8-not reached-NR-)³³. Furthermore, bone marrow screening is important for lymphoma staging. Haematological disorders are complex and require additional techniques such as hemogram, immunophenotyping and molecular examinations for the diagnostic needs and the clinical scenario^{35,26}. Technical preparation of BOM specimen for histologic samples is specific and important for the correct interpretation of histopathologic samples. Bone marrow trephine biopsy can appear altered and show a variety of changes that do not match the clinical diagnosis for a variety of technical problems. In our cases, a study was made on the technical problems of the period October - December 2021, were requested new slides preparations in 13% of the BOM, due to problems of biopsies preparation. According to the literature, other problems related to technical issues in the interpretation of the BOM are also the fact that occasionally, in patients who undergo frequent repeat biopsies, a specimen can be obtained from a recently biopsied site. In these cases, the presence of granulation tissue in the biopsy may result in misinterpretation of the sample³⁶. Furthermore, the bone marrow biopsy taken bilaterally at the posterior iliac bone offers the advantage of doubling the sample size and allows examination of specimens from separate sites, thus increasing the number of cases diagnosed as positive for NHL by biopsy³⁴. From this data we can say that the material, despite being optimal and technically suitable, may not be representative to evaluate it as compatible with NHL infiltration. On the other hand, involvement of the bone marrow by Hodgkin's lymphoma is rare with an average incidence of 10%. However, the incidence of bone marrow involvement has been shown to be less than 1% in patients with clinical stage IA or IIA disease³⁴. Usually marrow involvement in a patient with Hodgkin's lymphoma represents stage IV disease.

We identified 62 BOM (16.7%) that were classified as inconclusive due to inappropriate material (suboptimal, hemorrhagic, subcortical, damaged material), incompatible with the clinical diagnosis and require further examinations to conclude. The most frequent reason for material inadequacy in three-year period was subcortical material (with 40%), followed by suboptimal material reason (27%). According to the literature an adequate biopsy specimen should contain at least five to six intertrabecular spaces. It should be at least 1.5 - 2cm in length after processing³⁷. Since bone marrow involvement in NHL is focal, the volume of biopsy material may account for their underdiagnosis. In the difficulties encountered in the histopathologic diagnosis was simultaneous coexistence of lymphoproliferative and myeloproliferative lesions presented clinically as a myeloproliferative lesion, in our study we identified two cases. Myeloid and lymphoid malignancies are assumed to have different pathogenetic mechanisms. The recent observation that patients with a myeloproliferative neoplasia have an increased risk of developing lymphoproliferative malignancies has challenged this assumption³⁸. Another issue that we encountered was the evaluation of bone marrow biopsy in patients after treatment for lymphoproliferative disorders.

The difficulties were due to the fact that the pathologist had to consider a vast number of heterogeneous diseases, for which different treatments may have been applied. Furthermore, different clinical issues usually need to be addressed for which the diagnostic strategies performed are also different and are usually performed in different laboratories by different investigators. To minimize difficulties, a systematic, an integrative and interdisciplinary approach is suggested, which includes prior knowledge of the primary diagnosis and previous therapy.

Conclusions

In conclusion in our laboratory, between 2019 to 2021 we screened in total 193 BOM, most of them were myeloproliferative disorders, the most frequent was essential thrombocythemia followed by lymphoproliferative disorders, among them non-Hodgkin lymphoma leaded. In a three-year period, we observed that, in relation to the other diagnoses, included in the MPD, essential thrombocythemia (ET) predominates with 41% of cases, followed by PV with 29%, primary myelofibrosis (PMF) 24% and chronic myeloid leukemia (CML) and (NOS) only 3%. In 2021, a new category of biopsy reports (small category 1%) is observed with data consisting of reactive changes with trilinear hyperplasia, predominance of histiocytes and plasma cells. Based on literature data, these alterations could be found in patients after a severe infection of COVID 2019, and we could say that this new category is probably a consequence of the COVID 19 pandemic³⁹. The average age of patients with bone marrow biopsies was 58.9 years old. There is a predominance of cases in the sixth decade of life (33.2% of cases), followed by the fifth decade (25.1%) and the seventh decade with 19.4%. In our study MDS appeared to be present at a younger age, mean age 46.3 years, while in literature the average age of patients with MDS is 53 years¹⁸. A slight predominance of men is observed over women in the ratio M:F 1.2:1. Significant change in the ratio M:F ($p < 0.01$) in the ratio 1.8:1.

The technical challenges and diagnostic complexity of bone marrow biopsy specimens usually arise as a result of scarce information accompanying the specimen, poor specimen quality, inadequate sections and stains, lack of experience in the histological interpretation of BOM, furthermore, from being in the first steps of bone marrow histopathologic interpretation that we started only in 2018, as well as the lack of access to more advanced studies such as genetic and molecular biology examinations. Overcoming these challenges requires a high degree of collaboration between histopathologists, hematologists, samplers, laboratory technicians and other scientific personnel. Relying on more advanced techniques such as those of genetics and molecular biology are a hope for easing our diagnostic challenges in the evaluation of BOM.

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The elimination of non-tariff barriers to the free movement of goods based on ECJ Jurisprudence

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Abstract

The internal market is one of the EU's greatest achievements. It is at the heart of the European project, has fueled economic growth in the past decades, and brought concrete benefits to European consumers and businesses. From a legal perspective, the principle of the free movement of goods has been a key element in creating and developing the internal market. Articles 34 to 36 TFEU define the scope and content of the principle by prohibiting unjustified restrictions on intra-EU trade. However, they are only applicable in non-harmonized areas.

Beginning with an examination of the legal framework provided by Articles 34 to 36 of the TFEU, this paper delves into the core principles governing the elimination of non-tariff barriers (NTBs), emphasizing the mandate to ensure the unhindered movement of goods among EU member states. Through an analysis of relevant case law, including landmark decisions by the European Court of Justice (ECJ), such as *Cassis de Dijon* and *Keck*, this abstract elucidates the evolving jurisprudence surrounding NTBs.

Through a systematic examination of select cases, this paper scrutinizes the diverse manifestations of NTBs, ranging from regulatory requirements to product standards, and evaluates the compatibility of such barriers with EU law. By dissecting the reasoning behind ECJ decisions, it identifies key principles and criteria employed in assessing the justifiability of NTBs and delineates the boundaries within which member states may enact regulatory measures without impeding intra-EU trade.

In conclusion, this research underscores the paramount importance of addressing NTBs effectively to uphold the principles of the internal market while accommodating legitimate regulatory objectives of member states. By synthesizing insights from case law analysis, it offers valuable guidance for policymakers, practitioners, and stakeholders seeking to navigate the complexities of eliminating non-tariff barriers in the pursuit of a more integrated and prosperous European Union.

Keywords: Internal market, European Union, Restriction, Mutual Recognition.

1. Introduction

The elimination of non-tariff barriers to the free movement of goods represents a significant goal within the realm of international trade and regional economic integration. While tariffs, or customs duties, have long been recognized as obstacles to trade, non-tariff barriers (NTBs) have emerged as increasingly important barriers in recent years. NTBs refer to a wide range of measures, policies, and regulations that impede or restrict the flow of goods across borders, without necessarily involving the imposition of customs duties. These barriers can take various forms, including technical regulations, product standards, licensing requirements, sanitary and phytosanitary measures, and administrative procedures. Addressing and eliminating these non-tariff barriers is essential for creating an environment that promotes seamless trade, fosters economic growth, and enhances the efficiency of global supply chains.

2. Elimination of Non-Tariff Barriers according to the TFEU

The elimination of non-tariff barriers to the free movement of goods, based on Articles 34 to 36 of the Treaty on the Functioning of the European Union (TFEU), implies the establishment of a single market characterized by the free movement of goods among the member states of the European Union (EU). These articles form the legal basis for addressing barriers that hinder the trade of goods within the EU and aim to create a unified and competitive market without any unjustified obstacles.¹

Article 34 TFEU prohibits quantitative restrictions on imports and exports between member states. It states that “quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states.” This provision prohibits direct or indirect restrictions on the import or export of goods, such as quotas, import bans, or any other measures that limit the flow of goods across borders. The goal is to ensure that goods can move freely within the EU, allowing businesses to access larger markets and consumers to have a wider range of choices. Article 35 TFEU complements Article 34 by prohibiting discriminatory internal taxation that hampers the free movement of goods. It states that “quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between member states.” This provision ensures that goods produced in one member state can be exported to other member states without facing discriminatory taxes or charges that impede their access to these markets. It ensures equal treatment and a level playing field for businesses operating within the EU.

Article 36 TFEU allows for certain exceptions to the principles outlined in Articles 34 and 35. It lists specific grounds on which member states may justify the adoption of measures that restrict the free movement of goods. These grounds include public morality, public policy, public security, protection of human, animal, or plant health, protection of national treasures, and the preservation of cultural heritage. Member states must demonstrate that the measures they adopt are necessary and proportionate to achieve the stated objective. The article ensures that legitimate public interests can be safeguarded while also maintaining the free movement of goods.

The elimination of non-tariff barriers based on these articles implies that member states must refrain from adopting measures that directly or indirectly restrict the import, export, or movement of goods. They must align their regulations and standards to ensure the smooth functioning of the single market, promote fair competition, and enhance consumer choice. Additionally, member states must avoid discriminatory taxation practices that impede the access of goods from other member states to their markets. The European Court of Justice (ECJ) has played a crucial role in interpreting and applying these articles in cases related to non-tariff barriers. The ECJ’s rulings have provided guidance on the interpretation of the provisions and have contributed to the development of a comprehensive body of EU case law that addresses the elimination of non-tariff barriers and ensures the free movement of goods.

3. Types of Non-Tariff Barriers

Non-tariff barriers encompass a broad range of measures that hinder trade, and they have gained prominence in international trade discussions. While tariffs involve the imposition of customs duties on imported goods, non-tariff barriers take on diverse forms and often result from domestic regulations or policies. These barriers can be classified into several categories, including technical barriers to trade (TBT), sanitary and phytosanitary (SPS) measures, quotas and import restrictions, intellectual property rights (IPR) regulations, subsidies, and discriminatory government procurement practices.

Technical barriers to trade encompass regulations and standards set by governments or standardization bodies that aim to protect consumers, the environment, and public health. However, these regulations can sometimes create unnecessary obstacles for trade, especially when they differ significantly between countries. Sanitary and phytosanitary measures relate to regulations concerning food safety, animal and plant health, and the prevention of diseases. While important for protecting public health and ensuring the quality of agricultural products, SPS measures can become non-tariff barriers when they are applied inconsistently or excessively.

Import quotas and restrictions limit the quantity or value of certain goods that can be imported into a country. These measures aim to protect domestic industries from competition, but they restrict market access and hinder the free flow of goods. Intellectual property rights regulations, such as patents and trademarks, can also serve as non-tariff barriers by imposing additional requirements on imported goods or limiting market access for certain products. Subsidies, in the form of financial support or tax incentives provided by governments to domestic industries, can distort competition and create unfair advantages, thereby acting as non-tariff barriers. Discriminatory government procurement practices involve preferential treatment or restrictions on foreign companies in public procurement contracts, hindering their access to government contracts.

4. The impact of Non-Tariff Barriers

a. Increased Trade Costs and Reduced Competitiveness

Non-tariff trade obstacles greatly raise importers' and exporters' costs. Additional investments in technology, R&D, quality control, and certification procedures are needed to comply with many and frequently conflicting norms and standards. Small and medium-sized businesses (SMEs), who frequently lack the resources and knowledge necessary to negotiate complicated regulatory frameworks, are disproportionately affected by this onerous compliance process. Small and medium-sized businesses (SMEs) have a harder time competing in global marketplaces as a result of the higher expenses, which restricts their ability to grow and reduces overall competitiveness.

b. Market Access Limitations

Non-tariff barriers limit market access by posing challenges for international companies looking to expand into new areas. Technical trade barriers, such as product standards and laws, can differ greatly between nations, making it difficult for exporters to satisfy the unique needs of each market. Because of the market fragmentation caused by this lack of harmonization, products that are deemed compliant in one area might not be in another. As a result, exporters must pay more to modify their products to meet various criteria or risk having their products completely rejected from some countries. Such restrictions impede market integration, reduce economies of scale, and prevent global trade from reaching its full potential.

c. Impact on Developing countries

For emerging nations, non-tariff barriers provide special difficulties. These countries frequently lack the infrastructure and capacity needed to adhere to strict laws, which hinders their incorporation into global value chains. They may be unable to export to developed countries due to the high expenses of complying with strict regulatory requirements. As a result, emerging nations may find themselves in a disadvantaged trade position that impedes their efforts to grow their economies, create jobs, and reduce poverty. For emerging economies to more easily integrate into the global trading system and to ensure a more fair distribution of benefits, non-tariff trade barriers must be addressed.

d. Diffusion of technology

Non-tariff obstacles may hinder innovation and the spread of technologies. Strict laws governing intellectual property rights may hamper the movement of knowledge across nations and restrict access to cutting-edge technologies. Furthermore, strict product standards and technical requirements may favor existing organizations with more financial resources, effectively preventing creative and possibly disruptive companies from entering the market. This lack of competition decreases consumer options and innovation incentives, which ultimately slows down overall economic growth and wellbeing.

e. Environmental and social considerations

Trade's effects on the environment and society can also be influenced by non-tariff barriers. While certain laws are intended to safeguard the environment and promote sustainability, they may unintentionally obstruct trade. Businesses may be required to adopt particular production procedures or adhere to strict ecological requirements under environmental norms and regulations, which can be difficult for overseas corporations. Similar to this, social factors like labor laws or obligations for protecting human rights might make it more difficult for corporations to comply. While ensuring these restrictions are implemented effectively without creating trade obstacles is a delicate balance that policymakers must strike, they are essential for encouraging moral and responsible behavior.

5. Case Studies

One notable legal European case that addressed non-tariff barriers is the “Cassis de Dijon” case.² The case originated from a dispute between the German liquor retailer Rewe-Zentral and the German federal monopoly authority for spirits, Bundesmonopolverwaltung für Branntwein. The German authority refused to allow the importation and sale of a French liquor called “Cassis de Dijon” by Rewe-Zentral, arguing that the product did not meet the minimum alcohol content required by German law. Rewe-Zentral challenged this decision, claiming that it constituted a non-tariff barrier to trade within the EU.

The ECJ established a principle in its decision that is now known as the “Cassis de Dijon principle” or “mutual recognition principle.” The court ruled that a product should be permitted to be sold in other EU member states even if it does not adhere to their specific standards provided it is lawfully manufactured and marketed in one of those states and satisfies all key health and safety requirements. The court ruled that unless such regulations are justified on genuine reasons, such as defending public health or consumer safety, member states cannot impose additional criteria on imported goods that restrict the free movement of commodities within the EU.

The removal of non-tariff trade restrictions within the EU was significantly impacted by the “Cassis de Dijon” decision. It introduced the mutual recognition principle, which made it easier for commodities to flow freely by forbidding member states from placing disproportionately onerous restrictions on imported goods. By highlighting the harmonization and liberalization of trade inside the EU single market, the case established a significant precedent.

Through later legal proceedings and EU legislation, the idea of mutual recognition has been improved upon since the “Cassis de Dijon” decision. The decision has shaped how the EU views non-tariff trade restrictions, encouraged the elimination of unjustified trade barriers and built a more integrated and dynamic European market.

Conclusion

In conclusion, the elimination of non-tariff barriers to the free movement of goods is a crucial aspect of international trade and economic integration. Non-tariff barriers encompass a wide range of measures, policies, and regulations that impede or restrict the flow of goods across borders, without necessarily involving customs duties. These barriers can significantly impact trade costs, limit market access, and hinder the competitiveness of businesses. Efforts to eliminate non-tariff barriers are driven by the desire to create an environment that fosters seamless trade, promotes economic growth, and enhances the efficiency of global supply chains. By addressing and removing these barriers, countries can enhance market access for businesses, encourage fair competition, and stimulate innovation. Moreover, the elimination of non-tariff barriers plays a crucial role in facilitating the integration of developing economies into the global trading system, contributing to their overall economic development.

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Indicators of supply chain responsibility in relation to corporate social responsibility and sustainable development

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Abstract

The growing emphasis on Corporate Social Responsibility (CSR) and sustainable development highlights the necessity of responsible supply chain management. This paper investigates the indicators of supply chain responsibility, examining their connection to CSR and sustainable development goals. Through a comprehensive literature review, this paper outline the evolution of CSR and sustainable development principles and their relevance to supply chain management, emphasizing frameworks such as ISO 26000 and the Global Reporting Initiative. This study categorizes supply chain responsibility indicators into four key dimensions: environmental, social, economic, and governance. Environmental indicators include resource efficiency, waste management, and carbon footprint reduction. Social indicators cover labor practices, human rights, community engagement, and fair trade practices. Economic indicators assess ethical sourcing, financial performance, and anti-corruption measures. Governance indicators focus on transparency, stakeholder engagement, and regulatory compliance. The methodological approach combines an extensive literature review with case studies of companies renowned for their responsible supply chain practices. These case studies provide practical insights and showcase diverse strategies for aligning supply chains with CSR and sustainability objectives. A comparative analysis reveals common practices and innovative approaches that enhance supply chain responsibility. Key findings indicate that robust supply chain responsibility frameworks not only improve CSR performance but also significantly contribute to sustainable development. Integrating ethical, social, and environmental considerations into supply chain management enhances brand reputation, fosters stakeholder trust, and drives long-term business success. However, challenges such as the complexity of global supply chains, varying regulatory environments, and the need for continuous improvement persist. In conclusion, this paper underscores the importance of supply chain responsibility as a crucial component of CSR and sustainable development. It offers actionable recommendations for businesses seeking to enhance their supply chain practices, emphasizing transparency, stakeholder engagement, and comprehensive sustainability frameworks. This paper aims to contribute to the discourse on ethical and sustainable business practices, serving as a resource for academics, practitioners, and policymakers dedicated to fostering responsible supply chains and sustainable development.

Keywords: supply chain responsibility, corporate social responsibility, sustainable development, sustainability indicators, ethical sourcing.

1. Introduction

The integration of corporate social responsibility (CSR) and sustainable development principles into business practices has become increasingly imperative in today's globalized economy. Companies are no longer judged solely by their financial performance but also by their contributions to society and the environment. CSR, which encompasses ethical practices, social equity, and environmental stewardship,

urges companies to operate in a manner that enhances society and the environment, rather than contributing to their detriment. Sustainable development, defined by the Brundtland Commission¹ as meeting the needs of the present without compromising the ability of future generations to meet their own needs, complements CSR by emphasizing long-term environmental, social, and economic sustainability.

Supply chains, which involve the production and delivery of goods and services, are a critical area where CSR and sustainable development principles must be applied. The complexity and global nature of supply chains present both challenges and opportunities for implementing responsible practices. Ethical sourcing, environmental impact, labor rights, and community engagement are key aspects that businesses must consider to ensure their supply chains contribute positively to society and the environment.

The objective of this paper is to explore the indicators of supply chain responsibility and their alignment with CSR and sustainable development goals. By identifying key metrics and frameworks, we aim to provide insights into effective supply chain management practices that support ethical, social, and environmental objectives. The importance of responsible supply chain management is underscored by increasing consumer awareness and demand for transparency, as well as regulatory pressures and the potential for significant reputational and financial risks associated with unethical practices.

This paper begins with a comprehensive literature review that details the evolution of CSR and sustainable development principles, highlighting their relevance to supply chain management. We then categorize supply chain responsibility indicators into environmental, social, economic, and governance dimensions. Environmental indicators focus on resource efficiency, waste management, and carbon footprint reduction. Social indicators address labor practices, human rights, community impact, and fair trade practices. Economic indicators include ethical sourcing, financial performance, and anti-corruption measures, while governance indicators emphasize transparency, stakeholder engagement, and compliance with laws and regulations.

The methodological approach involves an extensive literature review coupled with detailed case studies of companies that exemplify responsible supply chain practices. These case studies provide practical insights and highlight diverse strategies for aligning supply chains with CSR and sustainability goals. The discussion section synthesizes the findings, outlining the key implications for businesses and identifying common challenges and opportunities for improvement.

In conclusion, this paper underscores the importance of supply chain responsibility as a pivotal element of CSR and sustainable development. It provides actionable

¹ The Brundtland Commission, originally known as the World Commission on Environment and Development, was established by the United Nations (UN) to foster global collaboration for sustainable development. Founded in 1983, it was initiated by then-UN Secretary-General Javier Pérez de Cuéllar, who appointed Gro Harlem Brundtland, the former Prime Minister of Norway, as its chair. Brundtland was selected due to her extensive expertise in science and public health. The commission concluded its work in 1987 with the publication of "Our Common Future," widely referred to as the Brundtland Report, which introduced and popularized the concept of "sustainable development." This seminal report earned the Grawemeyer Award in 1991. Following the dissolution of the Brundtland Commission, the Center for Our Common Future was established in 1988 to continue advancing its objectives. For more see: United Nations. (1987). Report of the World Commission on Environment and Development: Our Common Future. *Oxford University Press*.

recommendations for companies seeking to enhance their supply chain practices, emphasizing the need for transparency, stakeholder engagement, and comprehensive sustainability frameworks. This paper aims to contribute to the ongoing discourse on ethical and sustainable business practices, serving as a valuable resource for academics, practitioners, and policymakers dedicated to fostering responsible supply chains and sustainable development

2. Literature Review

The integration of Corporate Social Responsibility (CSR) and sustainable development into business operations has become a critical focus in contemporary corporate governance. This literature review examines the evolution of these concepts, their relevance to supply chain management, and the frameworks guiding responsible business practices.

2.1. Corporate Social Responsibility (CSR)

CSR has evolved significantly since its inception, with early definitions centering around philanthropy and voluntary business practices that benefit society. Over time, the concept has expanded to include a broader range of responsibilities, encompassing ethical behavior, economic performance, social equity, and environmental stewardship.² Key frameworks guiding CSR practices include the ISO 26000 standard³, which provides guidelines on social responsibility, and the Global Reporting Initiative (GRI)⁴, which offers a comprehensive framework for sustainability reporting. These frameworks emphasize the importance of transparency, stakeholder engagement, and continuous improvement in CSR efforts.

ISO 26000 defines CSR as the responsibility of an organization for the impacts of its decisions and activities on society and the environment, through transparent and ethical behavior that contributes to sustainable development. This standard outlines seven core subjects: organizational governance, human rights, labor practices, the environment, fair operating practices, consumer issues, and community involvement and development.

The GRI framework complements ISO 26000 by providing detailed guidelines for reporting on economic, environmental, and social impacts. It encourages organizations to disclose their performance in a standardized manner, facilitating comparability and accountability.

² Carroll, A. B. (1999). Corporate Social Responsibility: Evolution of a Definitional Construct. *Business & Society*, 38(3), 268-295. Balukja, I. (2023). Corporate Social Responsibility and Diversity Management: A Literature Review, Proceedings Book of 11th International Conference Recent Challenges in Entrepreneurship Innovation and Legal Framework", Faculty of Economy, University of Elbasan "Aleksandër Xhuvani", 18 November 2023.

³ Herciu, M. & Blaga, L. (2016). ISO 26000 – An Integrative Approach of Corporate Social Responsibility. *Studies in Business and Economics* 11(1).

⁴ E-Vahdati, S., Airipin, N. (2023). A Review of Global Reporting Initiative (GRI) Research with Sustainability Reporting: 1999-2020 dataset: Una revisión de la investigación de Global Reporting Initiative (GRI) con informes de sostenibilidad: conjunto de datos 1999-2020. *Revista de Contabilidad*, 26(2): 274-290.

2.2. Sustainable Development

Sustainable development, as articulated in the Brundtland Report, is defined as development that meets the needs of the present without compromising the ability of future generations to meet their own needs. This concept encompasses three pillars: economic sustainability, social sustainability, and environmental sustainability⁵.

Economic sustainability involves practices that support long-term economic growth without negatively impacting social, environmental, and cultural aspects of the community. Social sustainability focuses on maintaining and improving social quality, including aspects such as equity, health, education, and community development. Environmental sustainability involves actions that protect and preserve natural resources and ecosystems, ensuring their availability for future generations.

The United Nations' Sustainable Development Goals (SDGs) provide a global blueprint for achieving sustainable development by 2030. The 17 SDGs address a wide range of issues, including poverty, inequality, climate change, environmental degradation, peace, and justice. Businesses are increasingly aligning their strategies with the SDGs, recognizing that sustainable development is essential for long-term success and resilience.

2.3. Supply Chain Responsibility

Supply chain responsibility⁶ is an integral component of CSR and sustainable development. It involves managing the social, environmental, and economic impacts of a company's supply chain in a responsible manner. Responsible supply chain management encompasses a range of practices, including ethical sourcing, labor rights protection, environmental impact reduction, and community engagement. The complexity of global supply chains presents significant challenges, as companies must ensure that their suppliers adhere to high standards of conduct across diverse regulatory and cultural contexts.

Environmental indicators in supply chain responsibility focus on minimizing resource usage, reducing waste, and lowering carbon emissions. Key practices include sustainable sourcing of raw materials, efficient use of energy and water, and waste reduction initiatives. Social indicators address labor practices, human rights, and community impacts. Companies are expected to ensure fair labor practices, respect for human rights, and positive contributions to local communities. Economic indicators include ethical sourcing, financial performance, and anti-corruption measures, emphasizing the need for integrity and transparency in business operations. Governance indicators highlight the importance of robust management systems, stakeholder engagement, and compliance with laws and regulations⁷.

⁵ Fischer. M., Ford. D., Frecè. J., Hillebrand, K., Kissling-Näf. I., Meili. R., Peskova. M., Risi. D., Schindpeter. R. & Stucki. T. (2023). The Concept of Sustainable Development. *Sustainable Business*, 17-27.

⁶ L-Vaaland. T. & Owusu. R. (2012). What is a Responsible Supply Chain? *International Journal of Business and Management*, 7(4).

⁷ Suhi. A., Enayet. R., Haque. T., Ali. S.M., Moktadir. A. & Paul. K.S. (2019). Environmental sustainability assessment in supply chain: An emerging economy context. *Environmental Impact Assessment Review*, Volume 79.

2.4. Frameworks and Standards

Several frameworks and standards guide responsible supply chain management⁸. The UN Global Compact, for example, is a voluntary initiative that encourages businesses to adopt sustainable and socially responsible policies. It outlines ten principles in the areas of human rights, labor, environment, and anti-corruption. The Ethical Trading Initiative (ETI) is another framework that promotes ethical trade practices, focusing on improving the working conditions of people in global supply chains. The ETI Base Code provides a set of standards for labor practices, including fair wages, safe working conditions, and freedom of association.

The literature review on CSR, sustainable development, and supply chain responsibility underscores the importance of integrating ethical, social, and environmental considerations into business operations. By adopting comprehensive frameworks and adhering to established standards, companies can enhance their CSR performance and contribute to sustainable development. This literature review sets the stage for a detailed examination of supply chain responsibility indicators and their alignment with CSR and sustainability goals, as discussed in the subsequent sections of this paper.

3. Indicators of Supply Chain Responsibility

Effective supply chain management is essential for ensuring that companies uphold their commitments to Corporate Social Responsibility (CSR) and sustainable development. Indicators of supply chain responsibility can be broadly categorized into four dimensions: environmental, social, economic, and governance. These indicators provide a comprehensive framework for evaluating and improving supply chain practices, ensuring alignment with CSR and sustainability objectives.⁹

3.1. Environmental Indicators

Environmental indicators focus on minimizing the ecological footprint of supply chain activities. These indicators include metrics related to resource efficiency, waste management, carbon footprint, and biodiversity conservation¹⁰.

- *Resource efficiency*: Efficient use of resources, such as raw materials, energy, and water, is critical for reducing the environmental impact of supply chains. Metrics include energy consumption per unit of output, water usage, and the percentage of recycled or sustainably sourced materials.
- *Waste management*: Effective waste management practices reduce the volume of waste sent to landfills and promote recycling and reuse. Indicators include the amount of waste generated, the percentage of waste recycled, and the implementation of zero-waste initiatives.
- *Carbon footprint*: Reducing greenhouse gas emissions is a key component of

⁸ Carter. G. & Rogers. D. (2008). A Framework of Sustainable Supply Chain Management: Moving Toward New Theory. *International Journal of Physical Distribution & Logistics Management* 38(5): 360-387.

⁹ Santiteerakul. S., Sekhari. A., Ouzrout. Y. & Sopadang. A. (2011). Indicators for Sustainable Supply Chain Performance Measurement. *International Conference on Software, Information Management and Applications (SKIMA)*, Benevento, Italy.

¹⁰ Epstein, M. J., & Buhovac, A. R. (2014). *Making Sustainability Work: Best Practices in Managing and Measuring Corporate Social, Environmental and Economic Impacts*. Berrett-Koehler Publishers.

environmental sustainability. Carbon footprint indicators measure the total emissions produced by supply chain activities, including transportation, manufacturing, and distribution. Companies often set targets for reducing their carbon footprint and track progress over time.

- *Biodiversity conservation*: Protecting biodiversity involves ensuring that supply chain activities do not harm ecosystems and wildlife. Indicators include the impact of raw material sourcing on biodiversity, efforts to restore degraded habitats, and partnerships with conservation organizations.

3.2. Social Indicators

Social indicators assess the impact of supply chain activities on workers, communities, and society at large. These indicators focus on labor practices, human rights, community engagement, and fair trade.¹¹

- *Labor practices*: Ensuring fair and safe working conditions is a fundamental aspect of responsible supply chain management. Labor practice indicators include compliance with labor laws, the implementation of health and safety standards, fair wages, and the prevention of child and forced labor.
- *Human rights*: Respecting human rights is essential for maintaining ethical supply chains. Human rights indicators include the presence of policies and practices that protect workers' rights, grievance mechanisms for addressing violations, and training programs on human rights issues.
- *Community engagement*: Engaging with local communities and contributing to their development is a key aspect of social responsibility. Community engagement indicators include the impact of supply chain activities on local communities, investments in community development projects, and partnerships with local organizations.
- *Fair trade*: Promoting fair trade practices ensures that producers in developing countries receive fair compensation for their goods. Fair trade indicators include the percentage of products sourced from fair trade-certified suppliers and adherence to fair trade principles.

3.3. Economic Indicators

Economic indicators evaluate the financial performance and ethical conduct of supply chain operations.¹² These indicators focus on ethical sourcing, financial performance, and anti-corruption measures.

- *Ethical sourcing*: Ethical sourcing involves procuring goods and services in a manner that respects ethical standards and promotes sustainability. Indicators include the percentage of suppliers that comply with ethical sourcing standards, audits of supplier practices, and initiatives to improve supplier sustainability.
- *Financial performance*: Ensuring the financial viability of supply chain operations is essential for long-term sustainability. Financial performance indicators include cost savings from sustainable practices, return on investment (ROI) for sustainability initiatives, and overall financial health of the supply chain.

¹¹ Benoit-Norris. Ch., Cavan. D.A. & Norris. G. (2012). Identifying Social Impacts in Product Supply Chains: Overview and Application of the Social Hotspot Database. *Sustainability*, 4(9).

¹² Chen. J. Y. & Slotnick. S.A. (2015). Supply chains disclosure and ethical sourcing. *International Journal of Production Economics*, Volume 161, 17-30.

- *Anti-Corruption measures:* Implementing measures to prevent corruption and promote transparency is crucial for maintaining ethical supply chains. Anti-corruption indicators include the presence of anti-corruption policies, training programs for employees, and mechanisms for reporting and addressing corrupt practices.

3.4 Governance Indicators

Governance indicators focus on the management systems, policies, and practices that ensure the integrity and accountability of supply chain operations¹³. These indicators include transparency, stakeholder engagement, and compliance with laws and regulations.

- *Transparency:* Transparency in supply chain operations involves disclosing relevant information to stakeholders, including customers, investors, and regulators. Transparency indicators include the publication of sustainability reports, disclosure of supply chain practices, and adherence to reporting standards such as the Global Reporting Initiative (GRI).
- *Stakeholder engagement:* Engaging with stakeholders, including suppliers, employees, customers, and communities, is essential for understanding their needs and addressing their concerns. Stakeholder engagement indicators include the frequency and quality of stakeholder consultations, feedback mechanisms, and collaboration with stakeholders on sustainability initiatives.
- *Compliance with laws and regulations:* Ensuring compliance with legal and regulatory requirements is a fundamental aspect of responsible supply chain management. Compliance indicators include adherence to environmental and labor laws, certification to relevant standards (e.g., ISO 14001 for environmental management), and regular audits to verify compliance.

4. Case Studies

To illustrate the practical application of supply chain responsibility indicators in alignment with Corporate Social Responsibility (CSR) and sustainable development, we examine the practices of three companies renowned for their responsible supply chain management: Unilever, Patagonia, and IKEA. These case studies highlight diverse strategies and innovative approaches that have enhanced their CSR performance and contributed to sustainable development.

4.1. Case Study 1: Unilever

Unilever, a global consumer goods company, is recognized for its commitment to sustainability and ethical business practices. The company has integrated CSR into its business strategy through the Unilever Sustainable Living Plan (USLP), which aims to decouple growth from environmental impact while increasing positive social impact¹⁴.

- *Environmental indicators:* Unilever has set ambitious goals to improve resource

¹³ Ryciuk. U. (2020). Supply Chain Governance Mechanisms: A Review and Typology. Eurasian Business Perspectives, 145-159.

¹⁴ Nicholls. L. (2015). Unilever's Sustainable Living Plan drives business growth. Edie Newsroom, <https://www.edie.net/unilevers-sustainable-living-plan-drives-business-growth/>

efficiency and reduce its carbon footprint. The company aims to achieve zero net deforestation associated with its raw materials by 2023 and has committed to sourcing 100% of its agricultural raw materials sustainably. Unilever's efforts to reduce waste include redesigning packaging to minimize plastic use and increase recyclability.

- *Social indicators:* Unilever focuses on improving labor practices and promoting human rights across its supply chain. The company has implemented the Responsible Sourcing Policy (RSP), which ensures fair wages, safe working conditions, and respect for workers' rights. Unilever also engages with local communities through initiatives such as enhancing livelihoods of smallholder farmers and improving health and hygiene practices.
- *Economic indicators:* Ethical sourcing is a key component of Unilever's supply chain strategy. The company collaborates with suppliers to ensure adherence to ethical standards and conducts regular audits to verify compliance. Unilever's commitment to financial performance is reflected in its sustainable business practices, which have contributed to cost savings and long-term profitability.
- *Governance indicators:* Unilever emphasizes transparency and stakeholder engagement in its supply chain operations. The company publishes detailed sustainability reports in accordance with the Global Reporting Initiative (GRI) standards and actively engages stakeholders through regular consultations and partnerships with NGOs and industry groups.

4.2. Case Study 2: Patagonia

Patagonia, an outdoor clothing and gear company, is renowned for its environmental activism and commitment to sustainability. The company integrates CSR into its core business operations, focusing on environmental stewardship and ethical practices¹⁵.

- *Environmental indicators:* Patagonia is committed to reducing its environmental footprint through initiatives such as using recycled materials, minimizing water use, and implementing energy-efficient manufacturing processes. The company aims to be carbon neutral by 2025 and has invested in renewable energy projects to offset its carbon emissions.
- *Social indicators:* Labor practices and human rights are central to Patagonia's supply chain strategy. The company ensures fair labor practices through its Fair Trade Certified™ program, which guarantees fair wages and safe working conditions for workers. Patagonia also promotes community engagement by supporting environmental organizations and grassroots activism.
- *Economic indicators:* Ethical sourcing is a priority for Patagonia. The company sources materials from suppliers that adhere to strict environmental and social standards. Patagonia conducts regular audits and collaborates with suppliers to improve sustainability practices, ensuring the integrity and ethical conduct of its supply chain.
- *Governance indicators:* Transparency and stakeholder engagement are integral to Patagonia's operations. The company publishes an annual Environmental and Social Responsibility report, detailing its sustainability initiatives and progress.

¹⁵ Miller, S. G. (2023). Sustainable Trailblazing: A Comprehensive Analysis of Patagonia's Corporate Social Responsibility Initiatives and their Ethical Implications.

Patagonia actively engages stakeholders through its “Worn Wear” program, encouraging customers to repair and reuse products, and its advocacy for environmental policies.

4.3. Case Study 3: IKEA

IKEA, a global home furnishings retailer, is committed to sustainability and responsible business practices. The company integrates CSR into its business model through the People & Planet Positive strategy, aiming to have a positive impact on people and the environment¹⁶.

- *Environmental indicators:* IKEA focuses on resource efficiency, waste reduction, and renewable energy. The company aims to use only renewable or recycled materials in its products by 2030 and has invested in renewable energy projects to achieve climate-positive operations by 2030. IKEA’s waste reduction initiatives include circular economy practices, such as recycling and repurposing products.
- *Social indicators:* IKEA is dedicated to improving labor practices and promoting human rights in its supply chain. The company implements the IWAY Standard, which ensures fair working conditions, respect for human rights, and environmental stewardship. IKEA also engages in community development projects, supporting local communities through various social initiatives.
- *Economic indicators:* Ethical sourcing is a cornerstone of IKEA’s supply chain management. The company collaborates with suppliers to ensure compliance with ethical standards and conducts regular audits to verify adherence. IKEA’s commitment to financial sustainability is reflected in its cost-effective and innovative business practices.
- *Governance indicators:* Transparency and stakeholder engagement are fundamental to IKEA’s operations. The company publishes annual sustainability reports, providing detailed information on its CSR initiatives and progress. IKEA engages stakeholders through various channels, including customer feedback, partnerships with NGOs, and participation in industry forums.

Conclusions

This paper has explored the crucial role of supply chain responsibility in advancing corporate social responsibility (CSR) and sustainable development. By examining the key indicators of environmental, social, economic, and governance dimensions, we have highlighted how comprehensive and responsible supply chain management can significantly enhance a company’s overall CSR performance and contribute to sustainable development goals.

The analysis underscores that integrating responsible practices into supply chain operations is not merely a regulatory or ethical obligation but a strategic imperative that drives long-term business success. Environmental indicators, such as resource efficiency and carbon footprint reduction, demonstrate how companies can mitigate their ecological impact, reduce costs, and comply with environmental regulations. Social indicators, including labor practices and community engagement, reveal the importance of fostering fair working conditions, respecting human rights, and

¹⁶ IKEA (2020). People & Planet Positive Strategy, https://www.ikea.com/global/en/images/people_and_planet_positive_ikea_sustainability_strategy_august_2020_6b95a7e8f5.pdf.

positively impacting local communities. These practices not only build trust and loyalty among stakeholders but also enhance the company's reputation.

Economic indicators, such as ethical sourcing and anti-corruption measures, emphasize the significance of maintaining integrity and transparency in supply chain operations. By ensuring that suppliers adhere to high ethical standards, companies can avoid risks associated with unethical practices and improve their overall financial performance. Governance indicators, including transparency and stakeholder engagement, highlight the necessity of robust management systems and active participation of all stakeholders in the supply chain process. Transparent practices and regular stakeholder consultations foster an environment of trust and accountability, which is essential for sustainable business operations.

The case studies of Unilever, Patagonia, and IKEA demonstrate that integrating supply chain responsibility indicators into business operations can significantly enhance CSR performance and contribute to sustainable development. These companies exemplify how focusing on environmental, social, economic, and governance dimensions can drive positive change and long-term business success. Their innovative practices and commitment to transparency, stakeholder engagement, and continuous improvement serve as valuable models for other businesses seeking to foster responsible and sustainable supply chains.

Despite the evident benefits, challenges such as the complexity of global supply chains, varying regulatory environments, and the need for continuous improvement persist. Addressing these challenges requires a proactive approach, including regular audits, stakeholder collaboration, and investment in sustainable technologies and practices. Companies must remain committed to continuous improvement, leveraging new technologies and methodologies to advance their supply chain responsibility.

In conclusion, the integration of responsible supply chain practices is a pivotal element of CSR and sustainable development. By focusing on comprehensive indicators and adopting best practices, companies can ensure that their supply chains not only meet ethical and sustainability standards but also contribute to their long-term success. This paper provides a foundation for further research and practical application, aiming to inspire businesses, academics, and policymakers to foster responsible and sustainable supply chain management. As the global business environment continues to evolve, the commitment to responsible supply chain practices will be essential for achieving a sustainable and equitable future.

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Early warning climate system and agronomy advisories services in Albania: A case study of medicinal plant in “Malesi e Madhe”

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Abstract

The purpose of this research is to evaluate farmers' risk perception, awareness towards climate change and the impact on production caused by climate changes events in farming areas of the “Malesia e Madhe” region of Albania. The main objective of the paper was to identify willingness to pay for early warning climate system and explore the potential factors that contribute to the understanding of climate change. The main material of this research comes from a sample of 201 farmers among 5 administrative units in “Malesia e Madhe” who were chosen via a simple random sampling method. Sampling was conducted in end 2023 and start of 2024 and participants were interviewed face to face by questionnaires and local interviewers were used in order to maximize the reliability of the results. The binary logistic regression and marginal effect were used for analysis. The results indicate that 64.7% of farmers have a risk perception about climate change but only 3.5% (n = 7) of farmers accept paying for Early warning climate system to reduce its potential effects. The results from the chi-square test analysis suggest that willingness to pay is influenced by source of access to climate information, farmer's access climate information's from internet (60.7%), but even though the perceived risk is at high levels, farmers are not willing to pay for early warning climate system. The logit regression and marginal effects was performed on socio-demographic, farm topology and impact on plant production. Our findings suggest that the majority of smallholder farmers were not willing to pay for the cost of receiving climate information. The marginal effects logistic regression shows statistically significant effect in household predictors such as farmer's age, experience in Medicinal plant cultivation, and access to internet as a source of climate information, in farm topology such as, Average Medicinal plant yield and in impact on cultivated MAPs related to increase of farm losses. Findings highlight that the delivery of climate information should be designed and fitted to meet the needs of smallholder farmers with different socioeconomic backgrounds, farm characteristics and level of impact on plant production to enable farmers manage climate risks and build adaptive capacity.

Keywords: farmer's risk perceptions, early warning weather system, willingness to pay, climate impact in plant production.

1. Introduction

Agriculture contributes significantly to Albania's Gross Domestic Product and provides employment to great percent of low-income families across the country. Evaluating greater effects of climate change on agriculture in Albania, smallholder farmers will need to be supported through the provision of accurate and timely early warning Climate Information Services to provide useable information on climate change risks affecting their livelihoods. According to Elsayed et al., 2022 farmers should adopt Early Warning Services in their strategies for monitoring and managing their farms, which helps them make the right decision to protect their crops from climate change that affects crop production.

In many developing countries, local weather stations are very expensive for the use of small farmers and their systems are isolated, and unable to connect to the internet to visualize real-time data under a web page or mobile application.

Climate information services can be effective to direct and guide adaptation strategies towards climate change impact (Nkiaka et al., 2019; Vaughan et al., 2019; Singh et al., 2018). This is particularly useful in developing countries whose economies depend on rain fed agricultural systems. Recent studies have identified that farmers use climate information in a many ways including their important cropping decisions such as time to plant, apply fertilizers and the heterogeneity of crops to grow (Nyadzi et al., 2018; Ouedraogo et al., 2018). Identifying type of climate information farmers are accessing, using and are willing to pay for will provide efficient delivery of effective climate information services (Vincent et al., 2020). Understanding the type of climate information consumers are willing to pay for, can be a useful guide for policymakers to arrange policy decisions, which is critical for the sustainability of climate services as private sector is the main player in providing climate information to users. Smallholder farmers' decision and willingness to pay for climate information is determined by the supposed benefits to be obtained from the use of such information. Based on the utility maximization theory, a smallholder farmer judges how to achieve the upper level of utility from the payment and application of climate information (Adzawla et al., 2019; McConnell and Leibold, 2009).

According to Hansen, Challinor, Ines, Wheeler and Moron (2006) who emphasize that predictions can

provide advance information so that farmers can tailor critical agricultural decisions, with purpose improving efficiency and enabling them to adopt the most appropriate coping strategies for the situation. The Early Warning System (EWS) includes providing timely and effective information, through identified institutions, which enables individuals exposed to a risk to take action on it avoid or reduce their risk and prepare for effective responses (Shakespeare & Godwell, 2014). Consequently, for farmers to prepare, they must have early warning systems in place to disseminate information so that farmers can take the necessary actions forward. However, (Vermeulen & Aggarwal & Ainslie & Angelone et al. 2010) posited that many of the promising opportunities offered by early warning and climate information is lacking is fully utilized. Contrary to the above, Dinku, et al., (2014) pointed out that availability and access to such information and the ability to use it is a serious challenge in most rural areas.

The main objectives of this study are:

- I. To identify the socio-economic characteristics of the respondents in the study area
- II. To analyze how farmers approach weather forecasting and early warning information.
- III. Review the main sources of climate forecasting information
- IV. To assess how access to climate forecast information influenced farmers' decision making
- V. To assess barriers to the use of information from early forecasts
- VI. To evaluate their willingness to pay (WTP) according to the type and attribute of agricultural information (reliability of market partners, price information, quality of information)

Although Albania is one of the country's most at risk from climatic conditions, there is no early warning system in any of its sectors.

In recent years there have been studies dealing with farmers' perceptions of ICT tools, including mobile phones, but it does not extend to examining farmers' willingness to pay for weather forecasting. Thus, the determinants of farmers' WTP for weather information can be determined to be location, time and crop specific.

This study brings some facts to assess how the human, social, technical, and financial capitals may affect awareness, access, use, value, or uptake of CIS by smallholder farmers.

2. Literature review

Rowling et al 1987 identify an agricultural information system as the effective development and transfer of technology through an interactive, holistic system.

An information system of Agriculture consists of 3 subsystems: research; of distribution; of the user.

For the System to ensure the start and continuation of the information flow process, it must fulfill 6 basic functionalities. (Nagel et al 1979): (a) identification of producer problems; (b) generation of innovations; (c) validity according to farmers' conditions; (d) distribution; (e) exploitation; and (f) evaluation.

The basic model that combines the subsystems, the six functions, and responsibilities for each subsystem are given in figure 1.

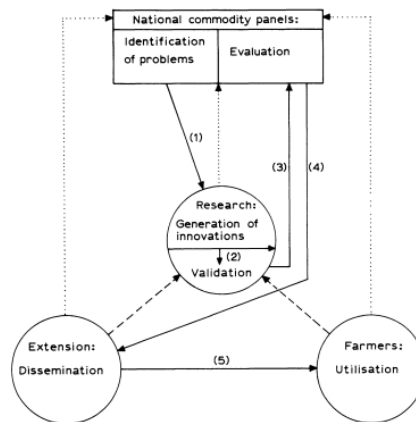


Fig 1. Agriculture information system, subsystems, functionality and actors. (Arnon et al 1989)

The search subsystem which is responsible for generation of innovations and for which the extension service should be responsible the distribution process is also called the Agricultural Technology Management System (ATMS) or the Agricultural Knowledge and Information System (AKIS) (Kaimowitz, 1987).

Agricultural Information Systems (AIS) help farmers meet their information needs, including agricultural inputs, education on extension programs, agricultural technology knowledge, credit programs, and marketing information (Lu & Pan & Lu & Qin & Wang et al, 2015). During the nineties, the concept of precision agriculture or wire farming appeared in agriculture. Several technologies were grouped into this concept, including Global Positioning Systems (GPS), Geographic Information Systems (GIS) and other modern technologies (Husemann & Novković et al. 2014). The use of precision agriculture led to an increase in the amount of data being generated leading to the development of several Decision Support Systems (DSS), helping farmers make informed decisions. An example of a DSS can be mentioned DSSAT - a tool for soil cultivation, etc. (Husemann & Novković et al. 2014). The use of AIS help reduce the cost of agricultural production, minimize the pre-cultivation time, and increase the agricultural productivity (Santoso & Delima, 2017).

To manage crops and decisions making a new method called “Smart farming” has been emerged. This method is part of modern agriculture (Kamilaris & Kartakoullis & Prenafeta-Boldú et al. 2017; Tyagi et al.2016), which includes the use of advanced information and communication technologies in agricultural practices (Kamilaris & Kartakoullis & Prenafeta-Boldú et al. 2017; Lokers & Knappen & Janssen & Randen & Jansen et al. 2016). Climate monitoring and EWS are necessary for crop management since there is a strong relationship between climate variables and the nature of spread, incidence and severity of diseases on plant.

Farmers need to adopt EWS in their farm management strategies, as this system helps them make the right decisions to protect their crops from climate change that affects crop production. According to Grasso et al 2011 who emphasize that “Early Warning is the provision of timely and effective information, through identified institutions, that enables individuals exposed to risk to take action to avoid or reduce their risk and to prepared for effective response”.

Traditional weather stations cannot be used for wide use in favor of small farmers as they have a high cost. On the other hand, these stations do not have access to the Internet and it is impossible to connect to web pages or Internet applications. According to Glantz et al. 2003 EWS is an effective system consisting of monitoring and forecasting linked to communication systems and response plans.

Due to non-operation between research and advisory services, the adoption to new agricultural technologies by farmers is often very slow, as research is not focused on current needs of farmers. In many countries, the low agricultural production has been attributed, among others other factors, including the weak link between Research-Extension-Farmers. Technology delivery systems can often be considered ineffective, including poor information packaging, inadequate communication weak systems and methodologies. This is one of the reasons why information systems that integrate farmers, for agriculture, they should include agricultural researchers, researchers, extensionists and farmers. researchers and extensionists act as facilitators and communicators who help farmers in their decision making and ensure the application of appropriate knowledge to obtain the desired results in conditions of sustainable production and general rural development. (FAO, 2005).

Around the 1970s the concept of Global Information and EWS (GIEWS) was introduced. This system was the property of FAO and the first major source of global information on food production and food quality assurance. At its inception, the system provided information on crop production and markets on a comprehensive scale. In 2011 GIEWS introduced the Agricultural Stress Index (ASI) to early label agricultural areas that may be affected by droughts or dry spells (Dekad et al. 2022). Andersson et al. 2020 study the possibility of a local EWS to improve the drought preparedness of smallholder farmers. To suit farmers' needs, EWS focused on forecasting hydrological variables such as rainfall to represent meteorological drought, soil moisture to represent agricultural drought and streamflow to represent hydrological drought.

Actual and potential benefits to society from climate services are substantial, when provided without any monetary value, these benefits are under-exposed and under-utilized (Gunasekera et al. 2004). Identifying the value of services can motivate users to be willing to pay for climate services. It can also help justify funding and guide priorities for investing in managing weather and climate impacts across economic sectors (Zillman et al. 2005).

Using the contingent valuation method, this study aims to estimate the willingness of farmers to have and use an early warning forecasting system to be informed about climatic conditions, as well as to investigate the value that they are willing to pay for these services. Identifying the type of climate information that farmers are accessing, using and would be willing to pay for would help in the effective provision of climate information services (Vincent et al., 2020).

Smallholder farmers' decision and willingness to pay for climate information is influenced by the expected benefits they will derive from using such information. Based on utility maximization theory, a smallholder farmer considers how to achieve the highest level of utility from paying for and using climate information (Adzawla et al., 2019; McConnell & Leibold et al. 2009).

3. Materials and Methods

3.1 Study Area

"Malesia e Madhe" has a land area of 15,255 ha, of which agricultural land for planting: 12,227 ha. Its surface is spread over about 37% in the plain and about 67% in the hills and mountains. Malësia e Madhe is watered by Shkodra Lake in a 30 km linear line and by the Cem River in a 31 km linear line. The agricultural potentials in "Malesi e Madhe" are:



- medicinal plants planted on an area of about 4000 ha.
- Orchard planted on an area of 476 ha
- Vineyard planted on an area of 356 ha
- Tobacco planted on an area of 510 ha
- The rest of the surface is planted with vegetables, potatoes, fodder, wheat, corn, etc.

"Malesi e Madhe" belong to Warm-summer humid continental climate, which means the coldest month averaging below 0 °C (32 °F), all months with average temperatures

below 22 °C (71.6 °F), and at least four months averaging above 10 °C (50 °F).

“Malesia e Madhe”, as mentioned above, is an area that cultivates medicinal plants that are affected by the following climatic conditions:

- Climate change affects the life cycle and distribution of medicinal and aromatic plants (MAP)
- Droughts and temperature fluctuations affect the photosynthesis of these plants, and may even lead to their disappearance.
- Changes in the amount of precipitation cause changes in the length of the life cycle of medicinal plants.

3.2 Data Collection

The data were collected using a structured questionnaire that refers to the socio-economic characteristics of farmers, production factors/Typology of the farm, perceptions towards climate change, adaptations toward climate changes, and sources of information.

The questionnaire was built based on the Contingent Valuation (CVM). Contingent valuation involves the creation of a hypothetical market within which respondents are asked to state bids for various goods based on the information they have (Hanemann, et al 1995; Mitchell & Carson et al. 1989). The first concept of CVM was proposed by Ciriacy-Wantrup (1947). In other cases, the “direct access method” was used to estimate the value of public goods. Davis (1963) used CMV to measure the economic benefits of outdoor recreation (Johnston et al., 2017). By the mid-1970s, the contingent valuation method was widely used to estimate the values of non-market goods.

“BIDS” refer to the random values used for the dichotomous choice (DC) question. Respondents answered whether they favor or oppose such an offer value as a payment in return for the provision of a public good, for example, meteorological information obtained from an early warning weather system.

Researchers have found a closed frame by setting a bid value and asking the interviewee if they are willing to accept it. In the closed question, the researcher offers the research participant options on which the respondent is expected to answer (Arrow et al., 1993; Haab & McConnell et al. 2002; Johnston et al., 2017). Research closed bidding was mainly based on two methods, which are DC selection with a single limit or DC selection with two limits. The DC method with two limits is considered statistically more efficient than the DC method with a single limit (Hanemann et al., 1991). The method with a single limit it is easier to implement than the double bound method, especially in data collection and evaluation. Furthermore, the single-boundary DC extraction format is theoretically stimulating compatible (Vossler & Holladay et al., 2018). DC format requires extra assumptions about the distribution of WTP and is also statistically less efficient than the open format (Bengochea-Morancho et al., 2005). Nonparametric approaches are simple to calculate and robust to distributions, but have limited capabilities for deal with covariates (Haab & McConnell et al., 2002; Kriström et al., 1990). Calia and Strazzera (2010) explained that there are no relevant differences in the evaluations performed for both models, even for small sample sizes, so that neither the rater can be said to be less biased than the other. Based on previous studies, the results obtained using probit or logit models to estimate the parameters are often similar.

CMV is a stated preference method (survey). Stated preference methods are applied to hypothetical questions about future behavior on hypothetical markets. CVM is a stated preference assessment method that requires willingness to pay, willingness to accept that directly assess non-market benefits. The contingent assessment method is called a “contingent” assessment because it uses information about how the interviewees think they would behave in certain hypothetical situations, depending on being in the real situation. The usual role of CVM in cost-benefit analysis is to assess the monetary impact of the non-market impacts of a project or policy, decisions made in other parts of the cost-benefit analysis will influence the decisions made in the CVM study. Within the Applicability Limits of CMV is any quasi-public good for which implicit markets exist by comparison and public goods for which there are no implicit markets.

The study used a survey to determine farmers’ perceptions of climate change and their willingness to pay for early weather forecasting systems. In this study, the quantitative method with a five-point Likert scale was used to allow respondents to indicate their level of perception towards changes in climatic conditions and strategies of adoptions to adapt to these changes (Halstead et al., 1993) and the single-boundary DC questions to evaluate the farmer’s willingness to pay amount for early warning weather system. (Whitehead & Haabet al., 2013). The questionnaire consisted of four parts. Part I contains questions about the demographic background of each respondent, part II contains questions about the typology of the farm, Part III contains questions about the level of perceptions and adaptations to climate change, and Part IIII contains questions about how much extra he would be willing to pay respondent for a climate early warning system.

For this study, the targeted sample size was 201 farmers through a face-to-face interview located in 28 villages surveyed from November 2023 to January 2024 in the areas of “Malesi e Madhe”. In each village, farmers were randomly selected for the survey.

3.3 Data Analysis

To investigate the socio-economic, farm’s properties, impact on cultivation predictors that influence willingness to pay for receiving climate information services, the logit regression technique was applied (Deressa et al., 2009).

The logit estimation technique was employed to examine the factors influencing a farmer’s probability of willingness to pay for the cost of receiving CIS.

To describe the logit model, we focused on a case where the response y_i (denoting WTP for CIS) is a binary variable such that:

$$y_i = \begin{cases} 1 & \text{if the } i\text{th farmer is willing to pay for CIS} \\ 0 & \text{otherwise} \end{cases} \quad (1)$$

The y_i follows a Bernoulli distribution with parameter r_i , which can be expressed as:

$$P(Y_i = y_i) = r_i^{y_i} (1 - r_i)^{1-y_i} \quad (2)$$

for $y_i = 0, 1$. Note that if $y_i = 1$ then we can obtain r_i , which is the probability of making a decision to pay for early warning climate information. By denoting “v” as the set

of independent variables illustrating the individual and environmental attributes which may determine pay for climate information; then the probability that a farmer is willing to pay for CIS conditioned on the “v” is given by where exp is exponent and b represents the unknown parameter to be estimated.

$$P(y = 1|v) = ri = \frac{\exp\{vib\}}{1 + \exp\{vib\}} \quad (3)$$

Equation (3) yields parameter estimates that do not reflect the probabilities nor the magnitude of change, they are only appropriately interpreted in relation to the direction of effect of the independent variables on the dependent variables of willingness to pay. Our focus is on finding out the factors that determine WTP for climate information; we consider the marginal effects of the explanatory variables based on the logit model. According to Green et al., 2000, this requires differentiating equation (3) with respect to the independent variables such that:

$$\partial P(y = 1|v)/\partial v_{ij} = b_j r i (1 - r i) \quad (4)$$

The list of explanatory variables used is shown in Table 1. The explanatory variables include household characteristics (such as age, gender, number of household members working on farm, employment of household, highest education level) farming characteristics (such as farming experience, irrigation facilities). Extension services, procedure of land acquisition, and access to labor), asset ownership (such as land size, channel of information’s) as well as institutional or environmental factors (such as drought experience, training, seeds for sowing, access to ready market). We observed marginal differences in awareness toward climate changes in farmers sampled; which provides support for group invariance and engenders adequate support for group comparison of access to, use of, and willingness to pay for climate information.

Explanatory Variables	Awareness about climate change				All Sample (N=201)		Description	Hypothesized relationship with willingness to pay
	Yes (N=75)		No (N=126)		Mean	SD		
Age of the respondent	52.262	50.254	56.276	50.474	53.129	10.560	Continuous	Younger people will be more willing to pay than older ones
Gender of the respondent	1.205	0.907	1.143	0.956	1.120	0.284	Categorical: 1 = Male; 2 = Female	More experienced farming are less willing to pay
Years in farming	12.331	4.371	20.600	4.378	12.093	4.401	Continuous	More experienced farming are less willing to pay
Number of household members working on farm	2.180	0.984	1.929	0.604	2.145	0.943	Continuous	Higher number of household residents will lead to higher willingness to pay
Main employment of household (HH) head	3.262	1.190	3.741	0.754	3.328	1.151	Categorical: 1. Wage employment in public sector; 2. Wage employment in private sector; 3. Self-employed in non-agricultural sector; 4. Self-employed in farming sector	People who are employed will be more willing to pay
Highest education level (HH) head	4.012	1.293	3.429	0.690	3.930	1.153	Categorical: 1. No education; 2. Elementary school (4 years); 3. Mandatory education (up to 9 years); 4. Agricultural high school; 5. General and other technical high school; 6. Non-agricultural University education; 7. Agriculture university education degree	The greater the level of education attained the greater the willingness to pay will be
MAPs skills / training	1.779	0.676	1.286	0.465	1.711	0.671	Categorical: 1. Never trained for MAPs production; 2. Rarely trained; 3. Regularly trained	More trained farming are less willing to pay
Cultivated Area	79.122	93.856	48.680	31.530	74.623	88.201	Continuous	The greater the cultivated area attained the greater the willingness to pay will be
Owned area	54.129	51.258	38.407	21.264	51.797	48.289	Continuous	
Rented	69.839	101.240	34.500	33.941	65.422	95.994	Continuous	
Costs	3.975	0.252	4.037	0.192	3.984	0.245	Likert scale: 1. Decreased much; 2. Decreased; 3. Same; 4. Increased; 5. Increased much	Accurate weather information can help farmers take prudent decisions to reduce the wasteful use of agricultural inputs
Profitability	2.503	0.539	2.519	0.509	2.505	0.533	Likert scale: 1. Decreased much; 2. Decreased; 3. Same; 4. Increased; 5. Increased much	
Quality of MAPs	2.903	0.319	2.963	0.338	2.912	0.321	Likert scale: 1. Decreased much; 2. Decreased; 3. Same; 4. Increased; 5. Increased much	
% of total income from MAPs	75.544	18.031	77.931	21.444	77.600	18.505	Continuous	People who earn more will be more willing to pay
Sage Area	62.798	60.315	41.815	26.601	59.591	57.020	Continuous	
Sage production	192.740	195.173	92.407	54.427	195.022	116.940	Continuous	
Sage price	1414.379	115.091	1407.407	103.500	1413.333	113.182	Continuous	
Thymus Area	10.000	2.828	12.000	0.000	10.571	2.567	Continuous	
Thymus production	25.400	10.164	63.000	38.184	36.164	25.465	Continuous	
Thymus price	1880.000	238.747	1930.000	70.711	1872.429	197.605	Continuous	Type of production implies the willingness to pay decision
Lavandula area	16.464	16.556	11.000	2.236	16.016	15.934	Continuous	
Lavandula production	14.973	18.066	8.200	1.246	14.410	17.404	Continuous	
Lavandula Price	3798.214	5130.071	8400.000	12079.942	4175.410	5955.912	Continuous	
Helichysum Area	23.583	51.538	12.000	7.583	22.171	48.440	Continuous	
Helichysum Production	31.222	188.130	41.000	10.247	35.317	176.865	Continuous	
Helichysum price	1241.667	60.356	1250.000	50.000	1242.683	58.695	Continuous	
Concerned about impacts of climate change	4.130	0.535	3.034	0.823	3.955	0.695	Likert scale: Strongly disagree 1 to 5 Strongly Agree	Climate services enhance farmers' resilience and adaptation to climate variability and risks.
Extreme weather events	4.093	0.554	3.069	0.799	3.945	0.694	Likert scale: Strongly disagree 1 to 5 Strongly Agree	
source of information to receive climate information	2.221	0.964	1.791	1.011	2.167	0.981	Categorical: 1. Radio/TV; 2. Internet; 3. Other farmers; 4. Government extension agent; 5. Agricultural pharmacies; 6. Other, specify	cc

Source: Own elaboration

The Chi-squared test as denoted by Ugoni et al. 1997 is used to determine whether there is a statistically significant difference between the actual outcomes and the results that were perceived in one or more areas of a probability chart. Groups of measures that are typically mutually exclusive are created Chi-square analysis was conducted to examine the influence of independent variables on the willingness to pay for an early warning climate system. Chi square of association was used to find out whether gender, education, age, income, type of product cultivated have no association on intention to for an early warning climate system combined with agronomy advisors at significance level $p = 5\%$. The test statistic calculated from the measurements confirms chi-square frequency correlations, which is consistent with the null hypothesis that there are no differences between the groups in the population. Assessing how appropriate the perceived rates would be if the null hypothesis were true is the main objective of the investigation. The formula of square is as below:

$$\chi^2 = \frac{(O_i - E_i)^2}{E_i}$$

Here, χ^2 is the Chi-Square, O_i and E_i denote the observed and expected values respectively. The calculated X^2 value is then compared to the critical value from the X^2 distribution table with degrees of freedom $df = (R - 1)(C - 1)$ and chosen confidence level. If the calculated X^2 value $>$ critical X^2 value, then we reject the null hypothesis.

4. Results and Discussion

4.1 Farmers' Current Access to climate informations and risk perceived now and in the future. (done)

A large majority (3% able to pay and 82.6% not able to pay) of farmers expressed awareness of climate changes in last 10 years (Table 6). Linda et al., 2008 had discovered a link among environmental change awareness, attitudes toward climate risk and the willingness to implement potential solution. At the same time Howden et al., 2008 reveals, farmers would not adapt to climate change if they are not aware of it existence or do not perceive it as a hazard. For better understanding farmer's awareness toward climate change and the way in which they perceive climate phenomena, adaptations measures used by farmers are crucial to promote successful adaptations in the agriculture sector (Mertz et al., 2009; Nicholas et al., 2012). The results of the Fisher's exact test ($p = 1 > 0.05$) do not indicate a significant association between WTP for early warning system/ Consulting services and farmers awareness.

Nearly 60.7% of the farmers in the sample received the forecast information by Internet. The results of the Fisher's exact test ($p < 0.001$) indicate a significant association between source of information and WTP.

Variables	WTP for early warning climate system			WTP for advisories services		
	yes	No	p-value	yes	No	p-value
Source of Information			<0.001			0.49
Radio/TV (%)	0	20.7		0	20.7	
Agricultural pharmacies (%)	0.5	0.5		0	1	
Internet (%)	0.5	60.7		0	61.1	
Government extension agent (%)	2.5	14.6		0	17.2	
Awareness			1			1
yes (%)	3	82.6		1	84.6	
No (%)	0.5	13.9		0	14.4	

Table 7. Chi-square test result, Fisher exact test.

Source: Author own' creation

As can be seen from figures 4 and 5, farmers are aware of the high risk that climate change causes, but in both cases (Early warning Climate system and consulting services) they are not willingness to pay. From the results of the Chi-square analysis Fisher exact test, the association is statistically not significant ($\chi^2(3) = 1,572, p=1 > 0.05$) that the null hypothesis, that is, "there is no relationship between high perceived risk and willingness to pay", is not rejected.

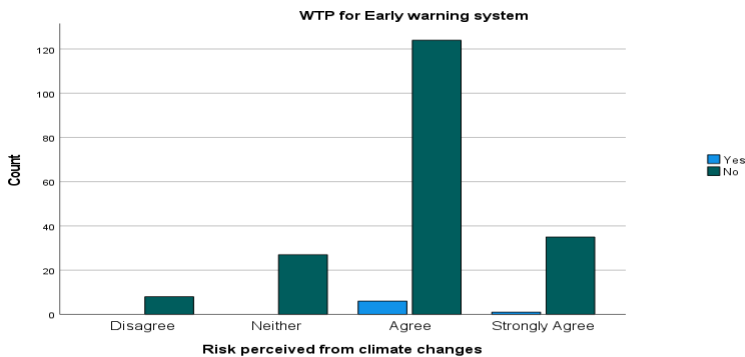


Figure 4. Risk perceived by farmers toward climate changes and WTP for EWCS

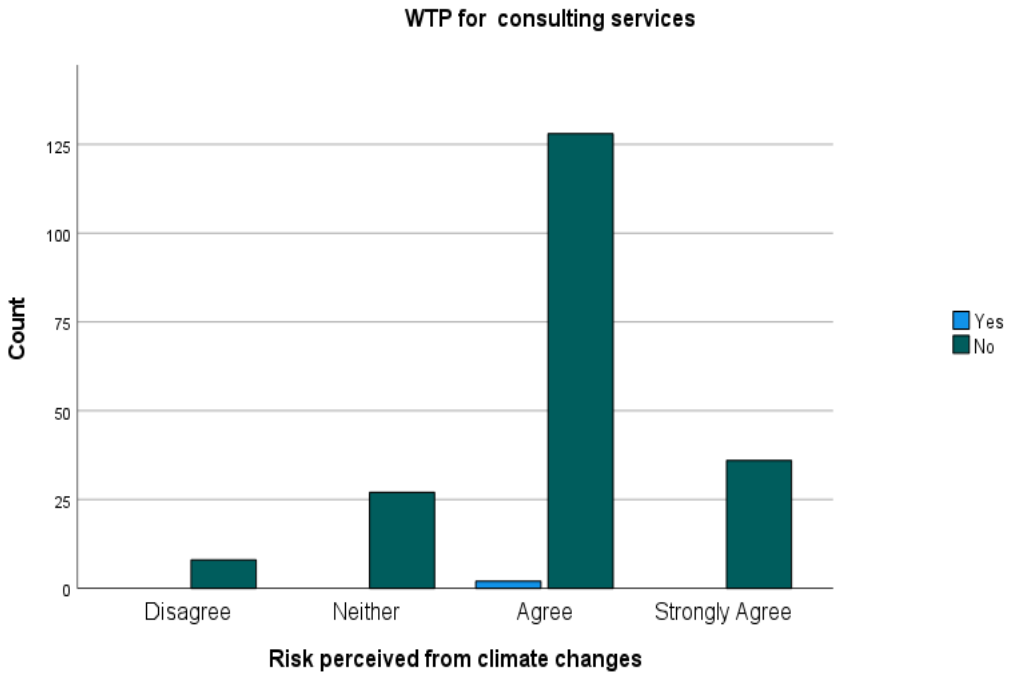


Figure 5. Risk perceived by farmers toward climate changes and WTP for consulting services
Source: Author own' creation

Risk is an subjective concept that may potentially result in individuals' loss of values, and risk perception differs based on many factors, which contribute to an understanding of the overall risk perception (Sjöberg et al., 2002). Human risk perception changes across individuals, households, and societies (Smith & Barrett & Box et al., 2000). Preferences toward risk, time, and the environment shape the decision-making processes of individuals and can be used as an important source of information (Cárdenas et al., 2009). When risk perception increases, it results in increasing the attitudes of individuals due to livelihood considerations.

4.2 *Impact on cultivated MAPs and willingness to pay for early warning climate system caused by climate changes (done)*

The binary logistic regressions in this section were used to analyze the impact of cultivation processes determinants of farmers' WTP. The results reveal a difference between the determinants of demand for early warning climate system and WTP (Table 11a and Table 11b). The variables significantly affecting farmers' demand for early warning climate system are increased of farmers' size and increase in farm losses due to climate changes event.

Table 11a. Logistic regression on willingness to pay for early warning climate

information system and impact in cultivation processes, by smallholder farmers in study communities

Variables	Odds Ratio	Std. Err.	z	P>z	[95% Conf.Interval]
Increase in Yields level	3.32	4.06	0.98	0.33	0.30 36.42
Increase in harvests time	7.86	11.14	1.45	0.15	0.49 126.47
Increase in Etero Oli Content	0.25	0.34	(1.02)	0.31	0.02 3.70
Increase in planting time	0.34	0.55	(0.67)	0.50	0.01 8.09
Increase in quality of the product plant	1.07	1.07	0.07	0.94	0.15 7.55
Increase in Farm losses	0.15**	0.16	(1.85)	0.07	0.02 1.12
Constant	0.03	0.03	(3.37)	0.00	0.00 0
Observations	200.00				
2 Log likelihood	(26.11)				
P-value > Chi Square	0.2064				
Pseudo R-square	0.14				

, **, * denotes parameter estimates are significant at 10%, 5% and 1% respectively.*

Source: Author's survey (November 2023 – January 2024).

Farmer Loses has a significant ($p=0.07 \leq 10\%$) effect on farmers' WTP for early warning climate services. Based on the marginal effect from Table 11b, can be shown that, even Farmer losses seemed to have an impact on WTP, marginal effect doesn't report this impact. Ouedraogo et al. 2022 reported that Climate information services provide crop specific and advisory services that target agro-climatic regions and specific crops grown in the communities to enhance the uptake of Climate information services. Farmers benefit more from climate information which assists them to make decisions on their specific farming enterprise. Crop specific information decreases the probability of losses and increases reliability of the information.

Table 11b. Marginal effects on willingness to pay for early warning climate information system and impact in cultivation processes, by smallholder farmers in study communities

Variables	dy/dx	Std. Err.	z	P>z	[95% Conf.Interval]	
Increase in Yields level	0.031	0.026	1.180	0.238	-0.020	0.081
Increase in harvests time	0.123	0.135	0.910	0.363	-0.142	0.388
Increase in Etero Oli Content	-0.034	0.027	-1.260	0.208	-0.087	0.019
Increase in planting time	-0.027	0.034	-0.810	0.416	-0.093	0.038
Increase in quality of the product plant	-0.068	0.046	-1.490	0.136	-0.158	0.022
Increase in Farm losses	-0.090	0.055	-1.640	0.100	-0.197	0.017

*, **, *** denotes parameter estimates are significant at 10%, 5% and 1% respectively.

Source: Author's survey (November 2023 – January 2024).

4.3 Socio-economic predictors of willingness to pay for early warning climate system (done)

The binary logistic regressions were used to analyze the Socio-economic determinants of farmers' WTP. The results reveal a difference between the determinants of demand for early warning climate system and WTP (Table 9a and Table 9b). The variables significantly affecting farmers' demand for early warning climate system are farmers' age, access on internet and experience in farming sectors.

Table 9a. Logistic regression on willingness to pay for early warning climate information system, by smallholder farmers in study communities

Variables	Odds Ratio	Std. Err.	z	P>z	[95% Conf. Interval]	
Age	0.93*	0.04	(1.67)	0.10	0.85	1.01
Access to Internet	0.03**	0.05	(2.44)	0.02	0.00	0.52
Experience in the MAPs sector	0.81**	0.07	(2.35)	0.02	0.68	0.96
Awareness about climate change	1.12	1.68	0.08	0.94	0.06	21.09
Members working on farm	1.48	0.72	0.80	0.43	0.57	3.84
Training	0.86	0.72	(0.15)	0.88	0.11	6.54
Education level						
Up to 9 years	8.19	0.72	1.62	0.10	0.65	103.81
High school	7.87	0.72	1.26	0.21	0.32	194.86
Employment in non-farming sector	1.09	1.27	0.08	0.94	0.11	10.74
Constant	3.05	9.47	0.36	0.72	0.01	1,332

Observations	201.00
-2 Log likelihood	(17.70)
P-value > Chi Square	0.00
Pseudo R-square	0.42

*, **, *** denotes parameter estimates are significant at 10%, 5% and 1% respectively.

Source: Author's survey (November 2023 – January 2024).

The analysis shows, that the access to internet negatively affects the WTP for early warning climate system at a threshold of 2%. Internet access significantly associated with an increase in people's environmental sustainability awareness (Zhang & Gong et al., 2023). Internet use impact the individual pro-environmental behavior (Gong et al., 2020; Awan et al., 2022), satisfaction toward government environmental protection (Zhang et al., 2019), environmental risk perception or environmental quality perception (Shi et al., 2023; Zhang et al., 2023). However, there are limited studies to examine how Internet use affects people's environmental sustainability awareness. According to the marginal effect estimates, a unit increase in farmers' access of internet is detected to lead to a decrease of 9.8% reduction in the probability to pay for climate information.

Farming experience has a significant ($p=0.02<5%$) effect on farmers' WTP decision. Farming experience obtained over a period of time in the same location causes the farmer to rely more on their own knowledge as they perceive that the scientific forecast sources are inaccurate and unreliable (Antwi-Agyei et al., 2021, Antwi-Agyei & Stringer et al., 2021, Chisadza et al., 2020, Kabobah et al., 2018). A low level in reliability, accuracy, timeliness and inequitable distribution of climate information can be translated to reduced confidence in the information (Antwi-Agyei et al., 2021; Antwi-Agyei & Stringer et al., 2021; Jiri et al., 2016; Ziervogel et al., 2005). An increase in the number of years an individual has engaged in farming activities induces 0.5% decrease in the probability of the farmer paying for early warning climate information system ($p = 0.009$).

According to Ouédraogo et al., 2018 factors such as gender, age, education, awareness of climate information, use of SWC techniques and organic manure significantly influenced farmers' WTP for climate information system. Younger or non-educated farmers are more willing to pay for all climate information and services. Such results are proved here in our findings ($p=0.10=10%$), which contradicts the results of other authors (Zongo & Diarra & Barbier & Zorom & Yacouba & Dogot et al., 2016; Debaeke & Pellerin & Scopel et al., 2017; Ouédraogo & Zougmore & Barry & Somé & Baki et al., 2015; Sanou & Bationo & Barry & Nabie & Bayala & Zougmore et al., 2016; Mabe & Nketiah & Darko et al., 2014) who showed that age has a positive impact on the WTP for climate information demand. Our results indicate that younger farmers are more likely to pay for climate system than old or matured one. According to the marginal effect estimates, a unit increase in farmers' age is detected to lead to a decrease of 0.2% reduction in the probability to pay for climate information.

Table 9b. Marginal effects on willingness to pay for early warning climate information system, by smallholder farmers in study communities

Variables	dy/dx	Std. Err.	z	P>z	[95% Conf.Interval]	
Age	(0.002)*	0.00	(1.67)	0.10	(0.00)	0.00
Access to Internet	(0.098)**	0.04	(2.36)	0.02	(0.18)	(0.02)
Experience in the MAPs sector	(0.005)**	0.00	(2.32)	0.02	(0.01)	(0.00)
Awareness about climate change	0.003	0.04	0.07	0.94	(0.07)	0.07
Members working on farm	0.009	0.01	0.79	0.43	(0.01)	0.03
Training	0.860	0.72	(0.15)	0.88	0.11	6.54
Education level						
Up to 9 years	(0.004)	0.02	(0.14)	0.89	(0.05)	0.05
Hight school	0.046	0.03	1.69	0.09	(0.01)	0.10
Employment in farming sector	0.002	0.03	0.08	0.94	(0.05)	0.05

*, **, *** denotes parameter estimates are significant at 10%, 5% and 1% respectively.

Source: Author's survey (November 2023 – January 2024).

The results indicate that awareness about climate changes, number of householders working on farm, training skills in Medicinal plants, Education level, type of employments, does not have a statistically significant impact on farmers' WTP for early warning climate system. (Tables 9a and 9b).

4.4 Farm typology predictors of willingness to pay for early warning climate system

The binary logistic regressions were used to analyze the farm property determinants of farmers' WTP. The result reported in Table 10a and Table 10b reveals the variables significantly affecting farmers' demand for early warning climate system are productivity. Medicinal plant yield has a significant ($p=0.000<1\%$) effect on farmers' WTP decision. An increase in the yield of medicinal plants with 1 Kv induces 0.03% increase in the probability of the farmer paying for early warning climate information system ($p = 0.004$). Farmers should to take into account information provided from Early Warning System in their strategies for monitoring and managing their farms. This information helps farmers make accurate decision to protect their crops from climate change variances that affects crop production (Elsayed & Moawad et al., 2022).

Table 10a. Logistic regression on willingness to pay for early warning climate information system, by farm property

Variables	Odds Ratio	Std. Err.	z	P>z	[95% Conf.Interval]	
Average Medicinal plant yield	1.01***	0.00	3.49	0.00	1.01	1.02
Average selling price	1.00	0.00	0.43	0.67	1.00	1.00
% of income from medicinal plants	0.97	0.04	(0.72)	0.47	0.90	1.05
Constant	0.02	0.06	(1.44)	0.15	0.00	4
Observations	200.00					
2 Log likelihood	(18.12)					
P-value > Chi Square	-					
Pseudo R-square	0.40					

, **, * denotes parameter estimates are significant at 10%, 5% and 1% respectively.*

Source: Author's survey (November 2023 – January 2024).

Table 10b. Marginal Effect on willingness to pay for early warning climate information system, by farm property

Variables	dy/dx	Std. Err.	z	P>z	[95% Conf.Interval]	
Average Medicinal plant yield	0.0003***	0.0001	2.8600	0.0040	0.0001	0.0005
Average selling price	0.0000	0.0000	0.4200	0.6720	0.0000	0.0000
% of income from medicinal plants	-0.0006	0.0008	-0.7200	0.4740	-0.0022	0.0010

, **, * denotes parameter estimates are significant at 10%, 5% and 1% respectively.*

Source: Author's survey (November 2023 – January 2024).

4.5 Amount Farmers' WTP for early warning climate system

The results reveal that the majority of the smallholder farmers are not ready to pay for receiving climate information (Table 11). Only 3.5% (n=7) of the farmers are willing to pay for receiving climate information (Table 11a). However, 85.6% of the farmers are awareness about climate changes but are not willing to pay for it (Table 11b).. The average of WTP is estimated as LEK 32,142.86/year per farmer. The median WTP shows that are willing to pay LEK 30,000/year to benefit from the climate information.

According to Calia and Strazzera et al 1998, that despite the sample size, both single and double bound CVM perform well in giving point estimates for the parameters and of the mean WTP.

Table 11a. WTP for early warning climate system.

<i>WTP for early warning climate system</i>	
<i>Yes(%)</i>	3.5
<i>No(%)</i>	96.5
<i>Average WTP</i>	32142.86
<i>Median WTP</i>	30000

Source: Own elaboration

Table 11b. Risk perceived by farmer's from extreme climate weather occurrence in the future.

<i>Variables</i>	<i>Farmers awareness about climate changes</i>
	<i>%</i>
<i>yes(%)</i>	85.6
<i>No(%)</i>	14.4

Conclusions and Recommendations

Results suggests that the provision of climate information should be defined and adopted to meet the needs of smallholder farmers with different socioeconomic backgrounds to enable farmers manage climate risks and build reasonable adaptive capacity.

The adoption of climate information services as an adaptation strategy to climate changes by smallholder farmers in Albania is key in securing sustainable farming systems. It is important to know the risk perception regarding climate change and the WTP of farmers for early warning system in the formation of these policies.

The statistically significant results were obtained based on the variables and the reference groups found in this research. Despite the farmers' high awareness (85.6%) and perceptions (64.7%) towards climatic conditions, again the 3.5% of them who are willingness to pay for early warning climate system was low. The average of WTP for access to climate information and use of early warning climate system is estimated as LEK 32,142.86/year per farmer. Farmer's age, experience in Medicinal plant cultivation, access to internet as a source of climate information, Medicinal plant yield and impact on cultivated MAPs related to increase of farm losses employees have

been identified as important factors in the formation of this WTP for early warning climate system.

When the age, access to internet and farmers experience in MAP sector decrease, the WTP amount decreases as well, and vice versa.

Early warning systems are needed to reduce the harmful effects of climate change in vulnerable regions of

Albania. Application of ICT-based technologies, EWS, AWS, and decision support systems for decision-making, accuracy water and nutrient management technologies, and crop insurance may be helpful for sustainable production under climate change.

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Business perceptions for a transition towards circular economy in Albania

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Abstract

The concept of a circular economy has gained significant attention in recent years, following global commitments to climate neutrality and sustainability. At European Union (EU) level, the objective of climate and carbon neutrality lies at the heart of the European Green Deal and many emerging strategies and regulations that aim towards not only a green transition, but a twin one (green and digital). Such are the Circular Economy Action Plan, as one of the main building blocks of the European Green Deal, and the Green Agenda for the Western Balkans (GAWB), stemming from the European Green Deal and adjusting to the Western Balkans region.

Putting Circular Economy (CE) into effect requires the essential role of business management (Ahmad et. al. 2023)¹. However, the perceptions of small and medium enterprises (SMEs) towards a circular economy vary, often showing uncertainty and persisting challenges. For example, according to Balkan Barometer (2023)², a large number of surveyed SMEs in the Western Balkans still did not take any steps towards CE, some took action by minimizing waste, whereas few turned to recycling, renewable energies, greener supplies of materials, etc. Based on a qualitative analysis of secondary data, the study analyzes perceptions of SMEs on the transition towards circular business models, identifies challenges and opportunities and how perceptions have changed over time. The results show that while there is more awareness on the need for circular business models and on the obligations stemming from the European Green Deal, the GAWB and other relevant regulatory frameworks, SMEs still share similar views on the challenges and barriers, mainly related to added costs, access to finance, lack of incentives, regulatory environment and skills.

Keywords: Circular Economy, Circular Business Models, EU, Western Balkans.

Introduction

The EU Circular Economy Package, also known as “*Closing the loop - An EU action plan for the Circular Economy*” was adopted by the European Union in December 2015. This represented a step closer to taking concrete action to change the economy from linear to circular, and incorporated various measures that aimed to support the business sector to benefit from business opportunities that this shift towards a circular economy can bring.

Despite this, the EU economy was rather linear (with only 12% of materials used in EU industry being recycled ones³) by the time the European Green Deal (EGD) was adopted. The EGD resulted also in a new Action Plan for Circular Economy, which unlike the initial Action Plan, expanded the range of sectors covered and incorporated new concepts, such as the “right-to-repair”. And as a significant victory for circular economy, it is worth mentioning that quite recently, on 30 July 2024, the Right-to-Repair (R2R) Directive entered into force.

Narrowing down geographically, given the article focuses on Albania, the Green Agenda for the Western Balkans (GAWB) is an important strategic document for this

region that mirrors the European Green Deal and explains five pillars: 1) decarbonization, climate, energy; 2) circular economy; 3) biodiversity; 4) depollution; and 5) sustainable food systems and rural areas (SWD, 2020).

In the Country Climate and Development Report, the World Bank (2024) identifies the private sector as the one that should make the majority of investments required to achieve net zero by 2050, with the government acting in a complementary role. However, the question as to what the private sector should expect and how ready it is, still prevails. For example, as per Balkan Barometer (2023), only 42% of businesses surveyed in the Western Balkans think that going green will benefit their company. Hence, the study analyses barriers and opportunities for the private sector to embrace circular business models in Albania, based on a review of secondary data and comparative analysis with private sector in the EU, that show the perceptions of the business sector regarding a shift towards circular economy.

Literature review and methodology

The Circular Economy (CE) business model offers an alternative to the traditional linear business models, with the aim to reduce the negative effect on environment in the final product or service. Yet, the world is only 8.6% circular (Circle Economy, 2021) and the EU circularity rate in 2021 was 11.7% (European Court of Auditors, 2023), showing that a lot more effort needs to be put into transforming business models.

Circular economy is *“a system where materials never become waste and nature is regenerated”*, as defined by Ellen McArthur Foundation⁴; it is *“a system which maintains the value of products, materials and resources in the economy for as long as possible, and minimises the generation of waste”*, according to the EU⁵.

Fifty-four measures were put forward in the Circular Economy Action Plan adopted by the European Commission in 2015; followed by a new Circular Economy Action Plan in 2020, encompassing also one of the main building blocks of the European Green Deal. The new CE Action Plan (2020) highlights that adopting circular economy principals can add up to 700,000 new jobs and support companies that spend on average 40% on materials, especially in sectors like manufacturing.

But while the business case is clearly set in the CE Action Plans; and as mentioned above, the private sector is expected to engage heavily in supporting efforts to achieve net zero objective by 2050 (Ahmad et. al., 2023; World Bank, 2024); the private sector is not prepared to do so, not well informed on the benefits or lacks capacities to do so. The latter are the results from this report, based on analysis of secondary data, surveys with business sector representatives and comparative analysis with business perceptions in the EU.

Recognizing the importance of the circular economy transition, Western Balkan countries have adopted Circular Economy Roadmaps. Hence, the CE Roadmap in Albania puts the private sector at the forefront, based on the fact that SMEs constitute 99.8% of the private sector; and therefore, supporting SMEs to adopt circular business models is considered to contribute significantly to environmental sustainability and efficient use of resources (OECD, 2024).

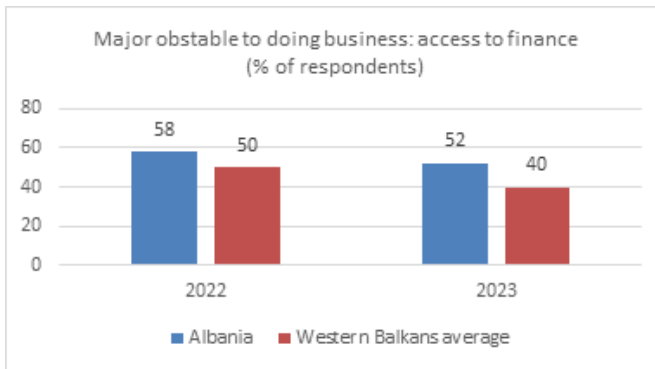
Despite policy frameworks, action plans or roadmaps in place, the EU example shows that SMEs are not ready for the CE transition due to restricted capacities, time, resources and knowledge (EREK, 2019). In particular, access to finance seems to be

imperative in securing the financial capacity to transform one’s business model into a circular business model. In fact, access to finance remains in general a significant obstacle for companies in the Western Balkans to grow their businesses, with 69% of the businesses using their own funds and retained earnings to finance business operations (Balkan Barometer, 2023). The same survey shows that additional expenses represent also a major obstacle to shifting towards circular economy; looking specifically at Albania, additional costs for shifting towards circular business models are a significant concern for 74% of businesses (Balkan Barometer, 2023).

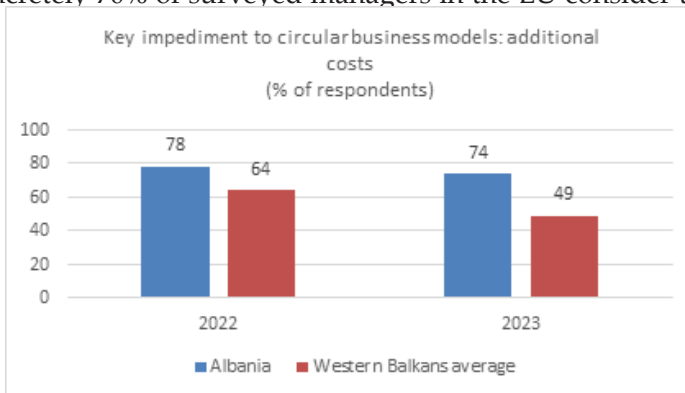
The trend is similar year-on-year even though there is some improvement at Western Balkans average in 2023 with slightly less than 50% of businesses surveyed considering additional costs as the major obstacle; however, at country-level, Albania is one of the countries in the region whose business sector representatives consider the additional costs as an obstacle and these perceptions stand well above regional average.

Source: Balkan Barometer (2022, 2023)

Source: Balkan Barometer (2022, 2023)



Access to finance is a barrier for a large majority of business representatives in the EU as well, concretely 70% of surveyed managers in the EU consider this as an obstacle



(EREK, 2019); it is the second biggest obstacle for businesses in Albania (in 2022) and the third biggest in 2024 (Albania Investment Council/AIC, 2024), impeding among

others, integration into international value chains (AIC, 2024). Ability to internationalize or lack of incentives to do so might impede the private sector from engaging in innovative and circular practices, in line with global or EU standards and recent developments, and cause the private sector as well to miss out on benefits that come from innovation and circularity.

Furthermore, one needs to look at the reasons explaining these considerations and opinions of the business sector. Factors such as subsidies by the government (or lack of), access to bank loans, grants, EU funds, and other alternative access to finance instruments, technical support and proper regulatory environments differ from country to country and might influence also the perceptions of business sector for shifting their business models into circular ones.

In addition to establishing a comprehensive framework and putting CE at the forefront of the European Green Deal, the EU's CE Action Plan has focused on key sectors, such as batteries, electronics, packaging, textiles, construction, food, etc. In the case of Albania, a breakdown of value added by economic sectors shows that industry represents almost 22% of GDP, including construction, energy, manufacturing and mining (OECD, 2024); and these include resource-intensive and waste-producing sectors, highlighting the potentials that could result from sector-specific interventions. This is also important for the development of markets, as experience in Saudi Arabia has shown where despite efforts to transform business models to circular economy, activities are limited due to small markets and low business opportunities for recycling of paper, plastics and metal (Fujiwara et.al., 2021).

Despite sectorial focus, EREK (2019) shows that circular economy impacts all industries and clusters. Hence, it is worth noting that also moving towards circular economy should engage many stakeholders. Some of the key stakeholders are industry clusters and regional policymakers (EREK, 2019). Research shows that in the case of Albania there is limited to no clustering; however, efforts are demonstrated for example, by joining regional networks, such as the Western Balkans Green and Circular Economy Stakeholders Platform⁶ or at country-level, by creating circular economy platforms (such as Qarkonomia⁷, Qarkon⁸, etc.)

This study is based on an exploratory research, analyzing literature and available secondary data to understand and recommends solutions to the object of the study. The research uses desk research and a qualitative approach, it looks at business perceptions for implementing circular business models in Albania, together with a comparative analysis of business perceptions in the EU, in order to identify potentials and barriers in the implementation of circular economy. This specific topic is still facing limited data and is rather new, so secondary data are found mainly in surveys of various sources at EU and Albania level.

Results

The Circular Economy Roadmap (2024), the OECD Competitiveness Outlook 2024, the SME Policy Index 2022 and Regional Cooperation Council's Balkan Barometer surveys demonstrate that circular economy is still in its early phases in Albania and

⁶ <https://www.rcc.int/news/864/bregu-circular-economy-strategies-can-reduce-greenhouse-gas-emissions-create-hundred-thousands-of-jobs-and-unlock-trillion-dollars-worth-economic-opportunity>

⁷ Qarkonomia – Circular Economy Platform – Center For Competitive Skills

⁸ Kreu | PLATFORMA QARKON

further progress is needed. Only 20 – 30 % of businesses in Albania think that their business models allows for a shift towards circular economy (Balkan Barometer, 2022); only half of business representatives in Albania are familiar with or have information on circular economy (Qarkonomia, 2020).

However, the concept of CE is gaining momentum (OECD, 2023) and despite the noted difficulties and obstacles, Albania might benefit greatly from the development of circular business models. With resource-intensive and waste-producing sectors representing one-fifth of the GDP, transforming business models by focusing on these specific sectors, as well as on SMEs which represent 99% of the private sector in Albania (even if, one might argue, SME’s footprint might be small) can help greatly to tap into unused potential and achieve sustainability.

The Circular Economy Roadmap for Albania has identified priority areas for circular economy in Albania (OECD, 2024). It is too early to assess the implementation of this Roadmap and measure the impact on the private sector and the shift towards circular economy, but it will be important at this point to engage in awareness campaigns and provide proper incentives for implementation.

A comparative analysis between Albania and the EU show the following key results:

Key barriers for CE shift for SMEs	Key drivers for CE shift for SMEs
Increased costs for the business	New technologies / innovation
Access to finance opportunities	Certification programmes
Lack of government incentives	Availability of government incentives
Lack of funds dedicated to R&D	Regional integration and cooperation -> larger markets and consumer demand for CE products
Lack of knowledge / skills	Internationalization
(Lack of) consumer awareness and demand	Changing consumer preferences, focused on product/service sustainability, environmental protection, reuse, recycling etc.
Lack of understanding or low awareness of policy & regulatory frameworks	Sector-specific interventions for businesses operating in resource-intensive sectors

The reviewed secondary sources and data provided an understanding of key barriers and key drivers of CE for SMEs, barriers and drivers that seem to be similar most of the times, where it’s an SME in the EU or in Albania. The findings are summarized in (a non-exhaustive) table below:

Key barriers and key drivers for circular economy identified are as following:

Key barriers for CE shift for SMEs	Key drivers for CE shift for SMEs
Additional costs	Operation in resource-intensive sectors
Access to finance	Digitalisation / new technologies / innovation
Lack of funds dedicated to R&D	Responding to consumer behaviors and preferences (<i>changing preferences towards sustainable products, services, etc.</i>)
Lack of knowledge / skills	Financial incentives (financing, subsidies, etc.)
Lack of incentives from governments	Other incentives (labelling regulations, certification programmes, etc.)
Consumer awareness and demand	Facilitation of partnerships and networking
Lack of understanding or awareness of policy & regulatory frameworks	Awareness raising campaigns

The incentives practice is highly recommended and it was put forward as recommendations to G20 governments in Ghose and Kapur (2019) highlighting the G20 governments that aim to support circular business models should provide instruments that facilitate access to finance, provide subsidies, encourage CE models through labelling regulations or by integrating green criteria in public procurement and offering not only awareness programmes but also creating feedback systems. OECD (2024) highlights better infrastructure, economic instruments and awareness raising as important elements to ensure a circular transition.

Conclusions and recommendations

The transition towards circular economy in Albania can bring great potential if the right drivers identified in this report are in place, and at the same time if the existing barriers are tackled. Despite limited data, there is a lot of secondary data, surveys and research establishing a good understanding of business perceptions regarding the shift towards a circular economy, be that at EU level or in Albania.

Policymakers have an important role to play in addressing barriers to circular economy for the private sector, but also it is clear from this research that transitioning to a circular economy requires multi-stakeholders efforts. The private sector should invest, the policymakers should provide the proper legal and regulatory frameworks, incentives, subsidies, etc., cities should facilitate with the proper incentives, regional networks and cluster should be established to facilitate partnerships.

In addition, specific strategies and roadmaps should be in place to determine a way of action. For example, the transition to CE could be tackled on a sectorial-basis, with the government incentivizing businesses in the most resource-intensive industries. Albania has taken an important step forward by adopting a Circular Economy

Roadmap in 2024, which identifies key sectors as well as support to SMEs in the CE transition. Additionally, development of circular economy in Albania can drive sustainability not only in resource-intensive industries such as manufacturing, but also in emerging sectors like tourism which has seen a significant growth over the past couple of years but at the same time such growth could have a negative impact on environment.

Access to finance results as a key barrier for private sector's transition to circular economy, so the government of Albania should increase and offer different types of financial support for the private sector. For example, supporting producers that make additional efforts to bring to the market "circular products" (recycled, reused, etc.) in specific sectors such as packaging, batteries, electronics, would not only encourage these producers to go fully circular, but also stimulate circular innovations and incentivize other sectors and producers.

Adopting circular economy principles, which are in line with important EU and regional agendas, such as the European Green Deal and the Green Agenda for the Western Balkans, would in addition facilitate integration of Albanian businesses into regional and European value chains, but it would also enhance traceability (regarding compliance with regulations and standards) of companies across value chains.

Finally, literature shows that regional alliances and platforms are beneficial for knowledge sharing and progress, so it could be beneficial to establish regional alliances on circular economy for Albania, or join existing international alliances, as per global good practices, for example the Global Alliance on Circular Economy and Resource Efficiency (GACERE), where not only EU and countries have joined, but also regional networks and strategic partners that are committed to fostering circular economy initiatives, such as Ellen Macarthur Foundation or the Platform for Accelerating the Circular Economy.

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Impact of radiotherapy on Her2 expression in breast cancer: A comparative analysis before and after therapy

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Abstract

HER2 (Human Epidermal Growth Factor Receptor 2) testing is a crucial biomarker evaluation in breast cancer for determining treatment strategies, particularly in cases of HER2-positive breast cancers. This study investigates the changes in HER2 expression before and after radiotherapy, a standard treatment for localized breast cancer. Radiotherapy's impact on tumor biology may influence HER2 expression, potentially altering treatment outcomes or resistance mechanisms. By analyzing pre- and post-radiotherapy tissue samples, this research aims to evaluate whether radiotherapy induces significant changes in HER2 status. HER2 expression was evaluated in breast cancer tissue samples before and after radiotherapy using immunohistochemistry and silver in situ hybridization (SISH) methods. A total of 180 patients with confirmed HER2-positive status diagnosed in the University Hospital "Mother Theresa" in Tirana were included. Pre-radiotherapy, all patients exhibited HER2 overexpression or gene amplification. Post-radiotherapy analysis revealed that 75.6% (n=136) of patients maintained stable HER2 expression, while 24.4% (n=44) showed altered HER2 status. Among the cases with altered HER2 expression, 16% (n=7) experienced a reduction in HER2 positivity, with some cases converting to HER2-negative. These results suggest that radiotherapy may induce alterations in HER2 expression in a subset of patients, potentially affecting the efficacy of HER2-targeted therapies post-radiotherapy. Further studies are recommended to explore the underlying mechanisms and to assess whether HER2 reevaluation should be routinely considered after radiotherapy.

Keywords: Breast cancer; immunohistochemistry; Her2; therapy.

Introduction

Breast cancer remains a significant global health issue, with complex biological underpinnings that vary among individuals. The HER2 gene plays a pivotal role in this landscape, particularly for HER2-positive breast cancers characterized by aggressive tumor behavior (Giordano & Cohen, 2021). Targeted therapies, such as trastuzumab, have dramatically improved outcomes for these patients, yet variations in treatment responses can arise (Rugo & Aft, 2021). Notably, radiotherapy is a standard intervention that can modify tumor biology, including HER2 expression (Hwang & Lee, 2022). This study aims to explore the nuanced impact of radiotherapy on HER2 expression in breast cancer patients, emphasizing the need for personalized treatment approaches.

Background

- **HER2 in Breast Cancer**

HER2 is a member of the human epidermal growth factor receptor family, crucial for

cell proliferation and survival. Its overexpression or gene amplification is observed in approximately 20-30% of breast cancer cases (Olopade & Eshleman, 2020). Testing for HER2 is typically performed through immunohistochemistry or in situ hybridization, critical for identifying patients eligible for targeted therapies (Barroso-Sousa & D'Amico, 2020). Importantly, understanding the mechanisms behind HER2 expression may provide insights into potential resistance pathways, influencing therapeutic decisions.

- **Radiotherapy in Breast Cancer Treatment**

Radiotherapy is commonly employed after breast-conserving surgery to minimize the risk of local recurrence (Tzeng & Chiu, 2023). It applies high-energy radiation to eliminate residual cancer cells. However, the biological effects of radiation can lead to various cellular changes, including potential modifications in receptor expression (Li & Liu, 2021). Given the dynamic nature of tumor biology, it is essential to consider how treatments like radiotherapy might alter HER2 expression and, by extension, treatment efficacy.

Methodology

This retrospective study was conducted at the University Hospital "Mother Theresa" in Tirana, involving 180 patients diagnosed with HER2-positive breast cancer. Inclusion criteria encompassed patients who underwent radiotherapy following surgical intervention. Tissue samples were collected from each patient before and after radiotherapy. HER2 expression was evaluated using immunohistochemistry for protein detection and silver in situ hybridization (SISH) for gene amplification assessment. This dual approach ensures a comprehensive understanding of HER2 status changes.

Immunohistochemistry was performed on the automated Ventana Benchmark XT with ultraView Universal DAB Detection Kit (Ventana Medical Systems, Tucson, AZ, USA) and PATHWAY anti-HER-2/neu (clone 4B5) Rabbit Monoclonal Primary Antibody. Samples with equivocal result (Her2 2+) were stained with HER2/SISH utilizing INFORM HER2 DNA Probe for insitu hybridization.

Protocols and antibody were validated to ensure consistent and accurate detection. The stained sections were examined under light microscope according to the detection method used. In all these patients' parameters were evaluated before and after radiation therapy was applied. All results were reported. Data were analyzed using descriptive statistics to determine the proportion of patients with stable versus altered HER2 expression post-radiotherapy.

Results

In this study, HER2 expression was evaluated in breast cancer tissue samples before and after radiotherapy using immunohistochemistry and silver in situ hybridization (SISH) methods. A total of 180 patients with confirmed HER2-positive status were included.

Pre-radiotherapy, this group of patients displayed HER2 overexpression or gene

amplification. Post-radiotherapy analysis revealed that 75.6% (n=136) of patients maintained stable HER2 expression, while 24.4% (n=44) exhibited altered HER2 status. Among the cases with altered HER2 expression, 16% (n=7) experienced a reduction in HER2 positivity, with some cases converting to HER2-negative 6.8% (n=3).

Comparison with other studies

The findings of this study align with recent literature indicating that a notable percentage of HER2-positive breast cancer patients may experience changes in HER2 status after radiotherapy. For example, a study by Hwang and Lee (2022) reported that approximately 20-30% of patients can lose HER2 positivity following radiotherapy, which is consistent with the 24.4% observed in our cohort. This highlights the necessity for careful monitoring of HER2 expression in this population.

Additionally, research has shown that radiation can induce cellular stress, leading to changes in receptor expression (Li & Liu, 2021). The mechanisms underlying these alterations emphasize the importance of reevaluating HER2 status after radiotherapy to adapt treatment plans accordingly.

Overall, the results of this study underscore the significance of post-treatment HER2 assessment to optimize therapeutic strategies for patients with HER2-positive breast cancer.

Conclusion

The observed changes in HER2 expression following radiotherapy raise critical considerations for treatment planning. The 24.4% of patients who experienced alterations may represent a subset that could benefit from reevaluation of HER2 status post-therapy. Continuous monitoring may identify those who lose HER2 positivity, potentially guiding subsequent treatment choices. These results emphasize the importance of personalized treatment strategies, particularly in adapting to the evolving nature of the tumor. Future studies should focus on the biological underpinnings of HER2 expression changes, exploring whether specific patient characteristics influence these alterations.

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Healthcare in the Albanian penitentiary system

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Abstract

The right to healthcare in the penitentiary system constitutes an essential aspect of respecting the prisoners' rights, which is particularly reflected in the realization of the primary function of the prison sentencing, rehabilitation with the aim of reintegrating prisoners into society as quickly as possible. Respecting the prisoners' rights and guaranteeing their right to healthcare within the Albanian penitentiary system constitute important challenges in ensuring the effective functioning of the criminal justice system.

The purpose of the thesis is to provide a general analysis of the right to healthcare in the Albanian penitentiary system within the framework of respect for international standards and principles. The focus will be on the application of this right at the time of admission to the institution and then during the execution of the criminal decision, but special aspects of the health treatment of prisoners in certain situations, among which we mention, will not be left unaddressed, cases of the application of disciplinary measures, cases of the application of force or coercive means, the application of the special regime in high security institutions or the application of this right for special categories of prisoners such as prisoners with mental health problems, juvenile prisoners or incarcerated women.

This thesis aims to evaluate the implementation of the right to healthcare in the Albanian penitentiary system and for certain situations to offer recommendations to improve current practices by highlighting the importance of enforcing healthcare standards and improving infrastructure and monitoring mechanisms to ensure effective healthcare for prisoners.

Keywords: penitentiary system, rights of prisoners, right to healthcare, rehabilitation of convicts, respecting human rights.

1. Healthcare in the penitentiary system and international standards

The treatment of prisoners is based on several fundamental principles and standards, and failure to adhere to these makes it impossible to achieve the primary goal, which is the rehabilitation of prisoners for their swift reintegration into society. Generally, it is essential to ensure that all categories of prisoners are treated with dignity and that their basic rights are respected. In any case, the torture or inhumane, degrading, or humiliating treatment of prisoners is strictly prohibited. They should be treated equally, without bias or discrimination (Kurti, 2022).

Under the European Prison Rules, prison authorities are obligated to safeguard the health of all prisoners under their care. Healthcare services within the institution should be organized in close cooperation with the public health administration that serves the general population. The health policy within the penitentiary system is integrated into, and aligned with, national health policies. Prisoners are entitled to

access healthcare services available to the general community, without discrimination based on their legal status. Healthcare services within the institution aim to detect and treat various physical, mental, or other conditions that prisoners may suffer from. Ensuring the right to healthcare has been, and continues to be, a subject of consideration in the jurisprudence of the European Court of Human Rights. In numerous cases, the jurisprudence of the Strasbourg Court has addressed issues concerning the obligation to provide healthcare, including instances of violations of Article 2 of the European Convention on Human Rights, which guarantees the right to life, and Article 3, which protects against torture and inhuman or degrading treatment. The European Convention on Human Rights and the jurisprudence of the European Court of Human Rights impose a range of positive and negative obligations on member states with the aim of protecting the right to life. As a negative obligation, the state must refrain from interfering with an individual's health unless justified by the Convention. As a positive obligation, the state is required to take proactive measures to protect the health of individuals deprived of their liberty.

According to the jurisprudence of the ECtHR, when assessing the health condition of a prisoner, it has been established that failure to provide appropriate conditions for their health, the absence of adequate medical treatment, and prolonged or severe suffering amount to inhuman and degrading treatment (*Ebedin Abi v. Turkey*, 2018; *V.D. v. Romania*, 2010; *Slyusarev v. Russia*, 2010; *Price v. United Kingdom*, 2001). The jurisprudence of the ECtHR acknowledges that, although medical care provided in prison hospitals may not always match the same standards as that available in the best institutions for the general public, the state must ensure that the health and well-being of detainees are safeguarded in the most appropriate manner. (*Bigovic v. Montenegro*, 2019; *Akimenkov v. Russia*, 2018; *Kalashnikov v. Russia*, 2002; *Kudla v. Poland*, 2000). The adequacy of medical care remains the most challenging element to determine. For medical care to be considered adequate, several criteria must be met: the doctor must maintain comprehensive medical records for each prisoner or detainee, including detailed notes on their health condition; diagnoses and care must be prompt and accurate; medical oversight must be regular and systematic, and include a comprehensive therapeutic strategy aimed at the appropriate treatment of the health of detainees and prisoners (*Blokhini v. Russia*, 2016). To determine whether detainees or prisoners have received the necessary medical care during their detention or imprisonment, it is crucial to assess whether state authorities have provided sufficient medical supervision for timely diagnosis and treatment of illnesses (*Khani Kabbara vs Cyprus*, 2018; *Mechenkov vs Russia*, 2008; *Popov vs Russia*, 2006). Overall, the court exercises sufficient flexibility in determining the required standard of healthcare, assessing it on a case-by-case basis. However, it emphasizes that this standard must be compatible with the human dignity of detainees or prisoners, taking into account the practical constraints of imprisonment (*Kavkazskiy v. Russia*, 2017; *Aleksanyan v. Russia*, 2008).

2. Admission of prisoners to the institution

According to the European Prison Rules, at the time of admission, several important

pieces of information about each prisoner must be recorded immediately, including details regarding any health information related to their physical and mental well-being and that of others, while ensuring compliance with medical confidentiality requirements. Immediately after being admitted to the institution, the prisoner should undergo a medical examination to assess their health condition, and subsequently, a treatment plan should be developed for the entire duration of their stay in the institution. Reports and information regarding prisoners should be maintained with individual confidentiality, updated regularly, and accessible only to authorized personnel. In application of these rules, our legislator has taken all necessary measures to ensure adherence to recommendations for the most humane treatment of prisoners. Regarding our legislation, it can be stated that based on the court's decision and the prosecutor's execution order, the prisoner will be placed in the appropriate institution and will be subject to the admission rules stipulated in the current legislation (Kurti, 2022).

The reception of newly arrived prisoners is managed by the Reception Committee, which includes representatives from the legal sector, the social affairs sector, the healthcare service, and the security service. This committee is required to convene no later than 24 hours after the prisoner's admission, or immediately if the circumstances, such as the prisoner's health condition, necessitate expediting the admission procedures.

Immediately after admission to the institution, the prisoner undergoes a medical examination and interview by the institution's doctor to assess their physical and psychological health. This is done to prevent the spread of infectious diseases within the institution, to prevent suicides, and to record any signs of physical injuries sustained outside the institution at the time of the examination. Signs of physical injuries identified during the admission examination must be recorded in a separate register, along with explanations regarding the circumstances in which they were sustained. If there is data and evidence that create a reasonable belief that a criminal offence may have been committed against the prisoner, the criminal prosecution authorities are notified in accordance with the provisions of the Criminal Procedure Code. The doctor, if requested, must provide the newly arrived prisoner with a medical report explaining his/her health condition. A copy of this report becomes part of the newly admitted prisoner's medical record and is made available to them. After the medical examination, the prisoner is usually placed in the reception section for a period not exceeding 10 days from the date of their admission. During this time, the Reception Committee carries out several tasks, including checking personal hygiene, reviewing personal and family information, education, profession, the criminal offence, the reason for committing the offence, and assessing the risk. Members of the Reception Committee are tasked with assessing each prisoner's personality based on the provided documentation, the prisoner's statements, the details in the risk assessment form, and the medical report. Based on this information, the Reception Committee registers its findings and prepares an individual treatment plan for the prisoner. After completing the risk assessment and preparing the individual treatment plan, the prisoner is assigned to their cell, thereby commencing the application of the plan for their rehabilitation and reintegration into society.

3. The right to healthcare for prisoners

In the Albanian legislation, the right to healthcare is provided for in Article 55 of the Constitution, and it ensures that all citizens have an equal right to healthcare provided by the state. *Everyone has the right to health insurance according to the procedures established by law.*

According to Law No. 81/2020 “*On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees*”¹ healthcare services are guaranteed to all prisoners within the criminal execution institution, without discrimination based on any grounds specified by anti-discrimination legislation. Healthcare services during the stay in the institution are provided by the General Directorate of Prisons and are covered by mandatory health insurance, regardless of any possible refusal of healthcare services by the prisoner. Prisoners fall into the category of economically inactive individuals under the current legislation and receive all the services provided by the health insurance scheme free of charge. The General Directorate of Prisons is obligated to provide the conditions, tools, and personnel necessary for the protection of the health of prisoners. The organization and delivery of healthcare are carried out by the institution’s administration in cooperation with the prison hospital and the relevant state health authorities.

The prisoner is entitled to the same treatment and healthcare that is provided to the general population. They have the right to undergo medical visits by a doctor and/or at a healthcare institution within the country, provided that they cover their own medical expenses and any other expenses arising as a result of their choice of doctor. Exceptionally, prisoners in institutions for the execution of high security criminal decisions may benefit from medical visits by a doctor and/or at a healthcare institution of their choice only after assessing the dangerousness of the convict. The right to undergo medical visits with a doctor and/or at a hospital of the prisoners’ choice does not apply to prisoners placed in special regime in high-security prisons, according to Article 17 of Law No. 81/2020 “*On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees*”, except in cases where the requested service is not provided by the healthcare service within the correctional facility or prison hospital centres.

Healthcare services provide a) prevention, diagnosis, and treatment of diseases; b) supply of medications and medical equipment in cases of health emergencies when not covered by mandatory health insurance; c) prophylaxis for diseases, with special attention to infectious and communicable diseases; and d) maintenance of environmental hygiene and sanitary education for detainees and convicts. Each institution has a healthcare and pharmaceutical service which responds to the needs for the prevention and maintenance of the health of prisoners.

A prisoner who is suspected or has a contagious disease is immediately isolated in special environments and treated according to the same standards as persons of the same category outside the institution. The medical personnel have the obligation to visit every day the sick prisoner, who makes a written or verbal request to the health staff or security personnel in the regime, and periodically check all other prisoners according to a schedule drawn up by the directorate of the institution. Medical personnel promptly identify and report any diseases that require specialized

treatment. For cases of contagious diseases or other conditions whose diagnosis and treatment cannot be provided within the institution, the prisoner is transferred to the prison hospital centre and, if necessary, to the Tirana University Hospital Centre or regional hospital institutions under its jurisdiction. Diagnosis and treatment at the University Hospital Centre and regional hospitals are conducted according to the guidelines established by a joint directive from the Minister of Justice and the Minister of Health. In emergency situations where the prisoner's life is at risk, they are transferred for treatment to the prison hospital centre or to regional healthcare institutions.

The state structure responsible for the health inspection, as well as each of its dependent institutions, have the obligation to inspect, at least twice a year, the institutions for the execution of criminal decisions, the hygienic-sanitary condition of the environment and the measures taken by the institution's health service for prevention of infectious diseases. Health experiments involving prisoners that may cause physical harm, mental disorders, or other injuries are prohibited.

The healthcare of prisoners includes a thorough screening to determine primary healthcare needs including, but not limited to, screening for: a) sexually transmitted diseases; b) congenital blood diseases; c) mental healthcare; c) post-traumatic disorders; d) risk of suicide or self-harm; dh) history of reproductive health; e) the presence of drug addiction; e) sexual abuse and other forms of violence, which may have occurred before entering the institution.

Prisoners showing signs of drug use, psychotropic substances, alcohol, or stress are subject to the same health and social programs that are applied outside the institution. Persons carrying infectious diseases, including the HIV virus, are treated in accordance with the standards that apply to these categories in hospital institutions. Prisoners with chronic illnesses or those who are elderly receive healthcare services in accordance with the standards applied to these categories at specialized institutions outside the prison system.

The right to healthcare is more comprehensive and is also applied in other provisions of the law on the rights and treatment of convicts and detainees.

Regarding the application of disciplinary measures, Articles 64 and 65 of Law No. 81/2020 *"On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees"* stipulate that disciplinary measures involving exclusion from common activities cannot be enforced without a prior report issued by a doctor, which confirms the physical and mental condition of the prisoner. The application of the disciplinary measure of exclusion from joint activities is subject to daily medical control. The doctor participates in the meetings of the disciplinary committee without the right to vote and may provide clarifications if requested by the disciplinary committee.

According to Article 69 of Law No. 81/2020 *"On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees"*, the Special Supervision Regime may restrict certain rights outlined in the law, but only to the extent necessary to achieve a legal purpose. Such restrictions are permitted solely for maintaining order and security within the institution and for safeguarding the rights of other prisoners. The restrictions that apply during the regime of special supervision cannot violate, among other things, the provisions of this law regarding the health service.

According to Article 70 of Law No. 81/2020 *“On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees”*, which regulates the use of physical force and coercive means, it is provided that, during physical coercion, the prisoner must be under the constant control of the health service.

According to Article 78 of Law No. 81/2020 *“On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees”*, the transfer of prisoners is also done for health reasons. Upon receiving the request for the transfer of a detainee or convict, the institution’s director immediately registers the request in a special log and instructs the healthcare sector to prepare a detailed and reasoned report within 5 days from the date of registration. This report should include necessary information about the prisoner’s health condition, medical reports and tests that confirm the prisoner’s condition, as well as the healthcare needs that justify the transfer. In this case, the risk assessment is carried out by the police sector, according to the necessary security measures to be implemented.

4. The treatment of prisoners with mental health issues

Individuals with mental disorders who commit a criminal offence are classified into several categories: Persons with mental health disorders that have been mentally incapable at the time of committing the criminal offence. Pursuant to the first paragraph of Article 17 of the Criminal Code: *“No one shall be held criminally liable who at the time of committing the offence suffered from psychic or neuropsychiatric disorders ruining his mental balance entirely and, consequently, was unable either to control his actions or omissions, or to be aware of committing a criminal offence”*. Interpreting this provision, it is clear that these persons are not punished, in other words, they do not bear criminal responsibility. Although these individuals are not in a penitentiary institution, they require healthcare not only to treat any existing conditions but also to prevent future criminal behaviour. It’s important to note that individuals with mental health disorders are considered responsible for their actions at the time the criminal offence was committed. Pursuant to the second paragraph of Article 17 of the Criminal Code: *“A person, at the time of committing the criminal offence, suffering from psychic or neuropsychiatric disorders, having lowered his mental capacity to be aware and fully control his actions or omissions, shall be liable, however, this circumstance shall be considered by the court in determining the extent and the kind of punishment”*. In this case, we are dealing with prisoners who, at the time of committing the offence, had mental health disorders that impaired their ability to understand their actions. These people also need healthcare within the framework of serving the sentence for the criminal offence committed; Persons who are serving a sentence and while serving a sentence are affected by mental health disorders. Such persons need medical treatment within the framework of the right to healthcare (Kurti, 2024).

Prisoners with mental health disorders primarily receive the rights and treatment outlined for prisoners in Law No. 81/2020 *“On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees”*: on the other hand, according to Article 29 of Law No. 44/2012 *“On mental health”*, convicts and detainees who are in institutions for the execution of criminal decisions and who suffer from mental health disorders,

enjoy the right to special health treatment at these institutions or at the Prison Hospital Centre. Prisoners with mental health disorders are entitled to equal treatment, free from discrimination, while ensuring their physical integrity and human dignity are respected. Their treatment is carried out according to the health standards, which apply to the categories of persons with mental health disorders, outside the institutions of execution of criminal decisions. The Ministry of Health, through mental health services, provides all necessary assistance for the diagnosis, treatment, and rehabilitation of individuals with mental health disorders, based on their needs. In this context, it is crucial to provide specialized, efficient, and effective healthcare. Failure to do so could result in inhumane or degrading treatment, which would conflict with Article 3 of the European Convention on Human Rights. If such mistreatment continues and leads to severe adverse outcomes, it could also violate the right to life under Article 2 of the European Convention on Human Rights.

There is a higher incidence of psychiatric symptoms among prisoners compared to the general population. Therefore, a doctor qualified in psychiatry should be assigned to the healthcare service in each institution for the execution of criminal decisions, and some of the nurses employed there should be trained in this field. Prisons should be adequately staffed with medical and nursing personnel, and their facilities should support the regular implementation of professional therapy, psychotherapeutic, and pharmacological programs.

Prisoners with mental health disorders are classified as economically inactive under current law and receive all health insurance services free of charge. The institution's administration is responsible for providing the necessary conditions, tools, and personnel to protect the prisoners' health. The organization and delivery of healthcare services are managed by the institution's administration, in collaboration with the prison hospital and the relevant state health authorities. Healthcare services provide prevention, diagnosis, and treatment of diseases; supply of medications and medical equipment in cases of health emergencies when not covered by mandatory health insurance; prophylaxis for diseases, with special attention to infectious and communicable diseases and maintenance of environmental hygiene and sanitary education for detainees and convicts. In simpler words, the State has the obligation to guarantee the right to healthcare and therefore must take all the necessary measures in order not to be held responsible in case of complicated situations. If there is harm to the health of convicts or detainees, or, worse, if their death results from health complications, the State has a positive obligation to demonstrate that it took all necessary measures to address their health issues. The State must prove that the death occurred due to causes unrelated to its efforts to provide care.

In this context, the emergence of mental health disorders should be recognized as a need for appropriate healthcare. Therefore, individuals in need should initially receive appropriate care within the institution. If the necessary help cannot be provided there, detainees and convicts should be transferred to the Prison Hospital Centre. If further specialized care is required, they may be referred to the Tirana University Hospital Centre or other county or district-level hospitals, as needed. Individuals with mental health disorders may be transferred to an institution other than their current penitentiary facility if that institution offers better healthcare services tailored to their mental health needs.

5. Healthcare for incarcerated minors

According to the Havana Rules, minors in detention must receive adequate healthcare, which includes both preventive and curative services. This encompasses dental care, ophthalmological care, mental health services, as well as access to pharmaceutical products and special diets as prescribed by a doctor. Whenever possible, healthcare for minors should be provided through suitable health facilities and community services near the institution where they are held. This approach aims to prevent the stigmatization of minors, foster self-respect, and support their integration into the community. Every minor has the right to be examined by a doctor immediately upon his admission to the premises where he is detained, in order to record any data on previous maltreatment and to identify any physical or mental condition that requires medical attention. Medical services provided to minors must identify and address any physical or mental illness, substance abuse or any other condition that may hinder the minor's integration into society. Facilities where incarcerated minors are held must have immediate access to adequate medical facilities and equipment commensurate with the number and requirements of the occupants as well as personnel trained in preventive healthcare and the treatment of medical emergencies. A minor who is ill, complains of illness, or exhibits symptoms of physical or mental difficulties must be promptly examined by a doctor. Any physician who believes that a minor's physical or mental health is or will be negatively affected by continued deprivation of liberty, a hunger strike, or any other condition of confinement must immediately report this to both the institution's director and the independent authority responsible for the safety and welfare of minors. A minor suffering from a mental illness must be treated in a specialized institution under independent medical direction. In coordination with relevant agencies, measures should be taken to ensure the continuity of mental healthcare following discharge.

Institutions for the execution of criminal decisions, where minor prisoners are held, must have specialized programs of prevention and rehabilitation for drug abuse, administered by qualified personnel. These programs must be tailored to the age, sex, and other needs of the minors in question. Additionally, detoxification facilities and services with qualified personnel must be available for minors with drug or alcohol addiction. Medications should be administered solely for medically necessary treatments and, whenever possible, with the consent of the minor involved. They should not be administered for the purpose of eliciting information or confession as punishment or as a means of coercion. Minors shall, under no circumstances, be subject to testing in experimental uses or treatments of medications. Administration of any medication should always be authorized and administered by qualified medical personnel.

In our domestic legislation, this right is regulated by the Code of Criminal Justice for Children and pursuant to Article 115 CCJC, the detained minor is provided with medical care and treatment, including but not limited to: psychiatric and psychological services, drug and alcohol rehabilitation, dental and ophthalmological care, sexual and reproductive health services, HIV/AIDS treatment, prenatal care for

pregnant minors, regular medical check-ups, including gynecological examinations if applicable, and care to identify any other conditions that may hinder the minor's integration into society. Every prison or minor detention facility must have immediate access to adequate medical facilities and equipment proportionate to the number and needs of its inmates, as well as trained staff for preventive healthcare and the treatment of medical emergencies. If the required healthcare cannot be provided within the institution, the minor has the right to obtain permission and, in case of emergency, to be offered permission to perform a medical check-up and receive the necessary health treatment.

A minor who is ill, complains of illness, or exhibits symptoms of physical or mental difficulties must be promptly examined by a doctor. For any medical treatment, the minor's consent must be obtained after being informed about it. When a minor's life is at risk or when there is a potential for permanent health impairment, and the minor refuses to consent to medical treatment, consent must be obtained from the minor's parents or legal representative. If they are unavailable, consent must be sought from the court. When the doctor determines that immediate treatment is needed to protect the health or life of the minor and/or the health of others, treatment is initiated without the consent of the minor's parent or legal representative. The minor is examined and treated by a doctor of the same gender or of the gender selected by them. Any period of medical treatment shall be counted as part of the period of the minor's sentence.

When it is established from the medical examination that the minor has suffered physical or sexual abuse before placement or during his stay in the Institution for the Execution of Criminal Decisions for minors, the doctor immediately notifies the competent prosecution. After this announcement, the prosecutor's office takes immediate measures to provide the minor with free legal advice to support them in any claim. The medical report and treatment data are recorded and kept in the minor's personal folder. Such data will be transferred to any other Institution of Execution of Criminal Decisions where the minor may be placed.

6. Healthcare for incarcerated women

According to the Bangkok Rules, *the specific needs of incarcerated women must be taken into account throughout the implementation of these rules. The measures taken to meet these needs should not be considered discriminatory.* One of the key aspects emphasized by the Bangkok Rules is the issue of sexual abuse and violence, including domestic violence, faced by incarcerated women. There is a strong emphasis on preventing the recurrence of such trauma, which includes implementing appropriate protocols for interactions between incarcerated women and staff—particularly male staff. Additionally, careful attention must be given during interviews to identify any violence that may be of a domestic nature. The Bangkok Rules devote significant attention to the specific needs of women in areas such as gynaecological health (PAP tests, breast examinations, etc.), psychological and psychiatric care, and recommend providing access to treatments equivalent to those available to free women outside the penitentiary system. The Bangkok Rules represent the first international legal document that addresses the rights of children held in a penitentiary institution together with their mothers,

recognizing their right to adequate healthcare. Ample attention is given to prenatal care for the mother, breastfeeding the child who is with her, the challenging decision of how long to keep the baby with the mother in the institution, and how to prepare for their separation in the least traumatic way possible for both, always prioritizing the best interests of the child.

The Bangkok Rules also include an important chapter on prison staff, who play a crucial role in supporting the reintegration of incarcerated women into society. It is essential for staff at women's institutions to receive specific professional training that effectively addresses gender-specific needs and eliminates discriminatory practices against women.

The European Prison Rules also outline measures for cases where incarcerated women give birth while serving sentences, ensuring that prisoners are permitted to give birth outside the penitentiary institution. However, if a child is born within the institution, the authorities must provide all necessary support and facilities. The institution is obligated to ensure that all hygienic and sanitary needs of incarcerated women are met comprehensively. At the very least, prisoners should be provided with water, as it is essential not only for meeting basic hygienic needs but also for addressing the health requirements of pregnant and breastfeeding women.

According to Article 230 of the Code of Criminal Procedure, pre-trial detention cannot be ordered against a woman who is pregnant or has a child under the age of 3 years living with her. In such cases, pre-trial detention can only be imposed if there are exceptional reasons related to crimes that carry a minimum sentence of ten years. Based on Article 476 of the Criminal Procedure Code, the court that issued the sentencing decision, at the request of the convict, the defender, or the prosecutor, can decide to postpone the execution of the decision in the case when the convict is pregnant or with children under 1 (one) year old. The execution shall be postponed until the child reaches the age of 1 (one) year.

According to Article 42 of Law No. 81/2020 "*On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees*", institutions for the execution of criminal decisions for women are required to provide the necessary and special conditions for the care and treatment of pregnant women, both before and after childbirth. The birth of the child occurs in a healthcare facility outside the prison system. If a child was born while the mother was serving the sentence, this fact is not recorded on the birth certificate.

According to Article 70 of the General Prison Regulations, pregnant women who give birth while detained or imprisoned receive assistance and care in specialized obstetric-gynecology centers outside the penitentiary system throughout their pregnancy, during delivery, and postpartum. Pediatric specialists are responsible for providing medical care for the children of detained and convicted mothers.

According to Article 41 of Law No. 81/2020 "*On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees*", institutions housing women and girls must provide specialized services for pregnant women and those with nursing children. Additionally, Article 42 of the same law mandates that women and minors in prison receive specific programs and services tailored to their age and gender. They are informed in an understandable language about healthcare, about the prevention of various diseases, about personal hygiene, about forms of violence and about any kind of abuse.

Women and minors who have experienced physical, psychological, and sexual violence are subject to healthcare programs for their treatment and rehabilitation. In the case of incarcerated women, the institution provides periodic check-ups by a gynecologist, a psychiatrist and periodic check-ups for the prevention and diagnosis of breast cancer and other diseases for women.

According to the General Prison Regulations, the healthcare of incarcerated women is provided based on gender-specific needs and includes full screening to determine primary healthcare needs. The medical check-up of incarcerated women should include a comprehensive check-up to determine primary healthcare needs, and should also determine: the presence of sexually transmitted diseases or blood-borne diseases and, depending on the risk factors, women of female convicts can be offered HIV tests, with counselling before and after the test; mental healthcare needs, including post-traumatic stress disorder and risk of self-harm and/or suicide; the reproductive health history of the convicted woman, including existing or recent pregnancies, as well as childbirth and other reproductive health-related problems; the existence of drug addiction; sexual abuse and other forms of violence suffered before admission. Juvenile convicts or detainees are guaranteed specific programs and services with access according to age and gender. They are informed in an understandable language about healthcare, about the prevention of various diseases, about personal hygiene, about forms of violence and about any kind of abuse.

Conclusion

The right to healthcare, in the Albanian penitentiary system, is an important right that is guaranteed to prisoners in accordance with international standards. All prisoners, regardless of age, gender, or nationality, are recognized by law to have this right from the moment of admission. Upon entry, they undergo a medical examination and interview with the institution's doctor to assess their physical and psychological health. This process aims to prevent the spread of infectious diseases within the institution, mitigate the risk of suicides, and document any signs of physical injuries sustained outside prior to their admission.

During their stay in the institution, the prisoner is entitled to the same treatment and healthcare that is provided to the general population. They have the right to undergo medical visits by a doctor and/or at a healthcare institution within the country, provided that they cover their own medical expenses and any other expenses arising as a result of their choice of doctor. Exceptionally, prisoners in institutions for the execution of high security criminal decisions may benefit from medical visits by a doctor and/or at a healthcare institution of their choice only after assessing the dangerousness of the convict. The right to undergo medical visits with a doctor and/or at a hospital of the prisoners' choice does not apply to prisoners placed in special regime in high-security prisons, according to Article 17 of Law No. 81/2020 "*On the Rights and Treatment of Convicted Prisoners and Pretrial Detainees*", except in cases where the requested service is not provided by the healthcare service within the correctional facility or prison hospital centres.

The right to healthcare for prisoners is not violated even in specific circumstances,

such as the implementation of disciplinary measures, the use of coercive means and force, special surveillance regimes, or during potential transfers. However, despite these legal advances, a significant challenge in practice is the shortage of specialized medical staff within penitentiary institutions.

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