Health policy 129 (2023) 104703

Contents lists available at ScienceDirect

Health policy

journal homepage: www.elsevier.com/locate/healthpol

Effectiveness of measures to preserve labour and childbirth companionship at the times of COVID-19 outbreak

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ARTICLE INFO

Keywords:
Maternal care
Childbirth
Labour companionship
Childbirth companionship
Interrupted time series analysis
COVID-19

ABSTRACT

Introduction: Although childbirth services were accessible after COVID-19 outbreak, the measures taken by the Italian Government for contagion containment required some restrictions on the presence of trusted persons for mothers, forcing them to isolation during hospitalization. To preserve companionship, the Regional Health Authority of Tuscany issued a resolution providing partners with the possibility to be present during labour and childbirth for non-asymptomatic women.

Objectives: In this study, we: 1) analyse the impact of pandemic on companionship in terms of significant reduction of the possibility for women to be accompanied by a trusted person during labour and childbirth; and 2) ascertain if the regional resolution issued was effective in containing the reduction of companionship.

Methods: We performed an interrupted time series analysis to measure the variation of the possibility for women to be accompanied by a trusted person during labour and childbirth, in response to formalization of lock-down due to COVID-19 outbreak and the introduction of the regional resolution aimed at contrasting negative effects on companionship.

Results and conclusions: The ITS analysis showed that there was a significant decrease in the women-reported experience of companionship in the month of the formalization of lock-down, namely March 2020, followed by a slight increase in the upcoming months. A trend reversal was observed after May 2020, when the regional resolution was fully operational.

1. Introduction

In the first months following the COVID-19 outbreak, social distancing measures resulted as effective enough in containing the massive spread of the infection by COVID-19 and such evidence was provided by several Countries all over the world [1–5]. However, if on the one hand social distancing proved to be an ally in the fight against COVID-19, on the other one it was not a method without collateral effects. Indeed, as some scholars argued, it produced concrete difficulties in the provision of care, as well as "existential suffering" [6], and it somehow "eroded human rights" [7]. Unfortunately, in the worst cases, forced isolation throughout social restrictions and physical distancing unavoidably caused feeling of loneliness and related mental health problems such as stress, anxiety and depression [8–10], especially amongst the most vulnerable groups like children, adolescents and elders [11–13], as well as pregnant, labouring and postpartum women [14–16]. Therefore, several strategies were implemented by different Countries to contrast isolation, in order to contain the negative effects of loneliness, in particular amongst the elderly [17]. Nevertheless, the literature offers dearth of evidence regarding measures aimed at constraining the detrimental effects of isolation for mothers in pre- and post-natal periods; hence piloting interventions for immediate use was deemed as necessary [18].

Looking at numbers of the European Centre for Disease Prevention and Control (ECDPC), throughout 2020 the total cases of infection by COVID-19 in the European Union were 15.857.298, while the total number of deaths were 376.891 [19]. Particularly, that year one of the Countries that reported most cases of infection and, overall, the highest number of deaths was Italy [20]. Based on the recommendations, actually confirmed, of the World Health Organisation (WHO) regarding the COVID-19 containment [21], the President of the Italian Republic enacted the first legislative decree including urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, which came into force on 23rd February 2020 [22]. Due to the general increasing of the pandemic crisis, in the beginning of March such legislative decree was converted into law, as promulgated

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https://doi.org/10.1016/j.healthpol.2022.12.011
Received 11 February 2022; Received in revised form 17 December 2022; Accepted 20 December 2022
Available online 21 December 2022

by the President of the Italian Republic with the measure come into force on 10th March 2020 [23]. Based on this law, the Italian Prime Minister formalized the first phase of lock-down in Italy by signing the Prime Minister Decree on 11th March 2020 [24]. The lock-down and social distancing measures were prolonged without interruptions all over spring, until the second half of May.

In the Tuscany Region, the first case of COVID-19 was diagnosed on 24th February 2020 and, since then, the situation worsened on a regular and constant basis throughout spring 2020, with a great burden for the health care system to manage the unbridled diffusion of the emergency. All areas of the health sector were under pressure because of the pandemic and most of available resources were massively redirected towards the management of the COVID-19 emergency, thus leaving other categories in need without the necessary social and health services at disposal [25]. One area of care that did not stop because of the pandemic is that related to maternal and childcare, as pregnant women always continued seeking healthcare services related to pregnancy, delivery, and post-partum [26–28]. In fact, this also became a great area of interest, to keep pregnant women, new-borns, and mothers safe from COVID-19, with several information campaigns on prevention that were undertaken also at the international level [29–31]. On the other hand, even though the maternal care services, especially regarding the phase of childbirth, were accessible at the hospital level, the measures taken by the Italian Government required some restrictions on the presence of caregivers for mothers and new-borns, forcing them to isolation during the hospitalization.

Nevertheless, since the assistance of a caregiver during labour, childbirth and postpartum is fundamental for mother's health, this kind of measures and policies should be avoided unless strictly necessary to guarantee a high quality of care to women also in times of pandemic [32–34]. Indeed, the inconsistent application of such restrictions may deteriorate women's childbirth experience [35]. For this reason, the Regional Health System (RHS) of Tuscany issued a regional resolution on 14th April 2020 [36] providing partners with the possibility to access the ward during labour and childbirth for non-asymptomatic women. Therefore, in this paper, we aim to answer the following research questions applied to the Tuscany Region context. First, we seek to understand if the formalization of lock-down in Italy had an impact on companionship in terms of reduction of the possibility for women to be accompanied by a beloved or trusted person during labour and childbirth. Secondly, they aim at eviscerating whether the resolution issued by the Tuscany Region was effective in containing the reduction of companionship, as possibly determined by the safety provisions undertaken in response to the COVID-19 emergency.

2. Methods

The present study has a quasi-experimental design [37] based on Interrupted Times Series (ITS) analysis to examine whether the data pattern concerning the companionship experience in the Tuscany Region observed post-intervention is different from that observed pre-intervention. The interventions considered are, on the one hand, the first phase of lock-down aimed at the containment of the COVID-19 pandemic in Italy, and on the other one the regional resolution issued by Tuscany to limit the detrimental effects of the formalization of lock-down on companionship. In terms of methodology, the reason beyond the choice of ITS analysis as the method of the present study is that, as a quasi-experimental design, ITS analysis is recommended to estimate causal effects using observational approaches when randomisation is not possible, especially for evaluation of health policy interventions [38–41].

2.1. Study setting

The Italian National Health Service (NHS) provides universal coverage, and it is mainly funded by general taxation, with essential health care services that are largely free of charge at the time of delivery [42]. Particularly, according to Garattini et al. 2021, 2017 [43,44], the Italian NHS has undergone massive decentralization from 1992, with the institutionalization of Regional Healthcare Systems (RHS) substantially autonomous and entitled to develop health strategies without necessary national endorsement. All RHSs are mandated to provide, amongst other essential levels of care to be publicly guaranteed, also maternal and childcare services aimed at protecting and promoting women's and children's health [45,46]. In Tuscany, childbirth assistance is almost ensured to all pregnant women through the continuous activity of 23 public birth centres. The number of deliveries in 2020 amounted to 22.583, with a 4,7% reduction with respect to 2019 and a 30,9% reduction with respect to 2010 [47].

2.2. Data source

Tuscany is one out of 10 Italian Regions belonging to a Network sharing the health care performance evaluation system (IRPES) designed, developed, and implemented since 2004 by the Management and Health Laboratory (MeS) of the Sant'Anna School of Advanced Studies in Pisa [48]. Amongst the characteristics of the above-mentioned IRPES, there is the inclusion of the multidimensional nature of the performance attained by the healthcare systems [49,50]. More particularly, the experience reported directly by the patients and, more in general, by the users of the healthcare services is one of the crucial dimensions of healthcare performance evaluation [51]. Several examples of patient-reported experience collection and use are found in the literature [52,53,54]. Maternal and childcare is a fundamental area within the multidimensional IRPES [55]. As for maternity services, there is a specific survey ongoing at the regional level. Such survey investigates the various phases that characterise the pathway of women from pregnancy until one-year post-partum, by collecting women-reported experience and outcome measures. The continuous and systematic survey on the maternal and childcare pathway started in March 2019, thanks to the launch at the regional level of the hAPPy-Mamma system [56], which allows continuous and systematic recruitment of women from the moment of delivery of the pregnancy booklets. The implementation of this survey helped establish a permanent regional observatory of the experience and outcomes perceived by women during the maternal and childcare pathway. The process is digital and automatic. Women, who decide to participate in the survey at the time of delivery of the pregnancy booklet, and accept to communicate their contact data, receive an invitation to access the survey by e-mail and can complete the questionnaire online. Additionally, the results from the survey are returned in aggregate and anonymous form to policymakers, health care managers and health professionals by means of a data return web platform updated in real time. Regarding the sections composing the survey, it includes longitudinally 8 questionnaires delivered in different moments along the maternal care pathway. Particularly, the longitudinal survey includes three questionnaires administered during pregnancy: at the time of delivery of the pregnancy booklet, and approximately around the 22nd and the 32nd weeks, respectively. Then, there is one questionnaire that is administered at the time of childbirth, approximately around the 39th week. Plus, four more questionnaires are administered to new mothers in the post-partum phase, specifically one month, three and six months, and one year after childbirth. The present study is based on the data concerning the fourth questionnaire of the survey related to the childbirth experience (T0p).

2.3. Data analysis

We performed a single-group multiple interventions ITS analysis [57] over a sample of 9548 women who had childbirth and responded to the related questionnaire in between August 2019 and October 2020. In accordance with the research questions presented in the introduction,

we considered a specific set of questions from the childbirth questionnaire to perform the ITS analysis, namely two questions asking directly to the women if, during labour and childbirth, they had the opportunity to have a relative or trusted person near them. Based on the selected dichotomous questions, we performed ITS analysis to assess how the COVID-19 outbreak and the regional resolution issued by the Tuscany Region impacted women's mean response trend to the childbirth questionnaire. More particularly, to avoid biases related to other factors that may have possibly affected companionship during the pandemic, such as fears and anxiety, the variables for the statistical analysis were determined so that only women, who could not have a caregiver during labour and childbirth because of the restrictions adopted by hospitals for pandemic containment, were considered. In other words, women declaring no interest in companionship or having no companionship for any other reason, different from hospital restrictions and regulatory access, were excluded from the analysis. After loading the data and declaring the dataset as panel, we specified a single-group multiple interventions ITS analysis with responders to the T0p questionnaire as the treatment group. Additionally, they identified two intervention times, considering 1) March 2020 as the start of the first intervention (corresponding to the formalization of lock-down in Italy), and 2) May 2020 as the start of the second intervention (corresponding to the first month after the issue of the regional resolution). Instead, as previously mentioned, the whole period included in the analysis was from August 2019 until October 2020, and we conducted the analysis month-by-month. We estimated the model, using *itsa* command, with single treatment, double intervention and one lag. Therefore, we sought to assess whether the formalization of lock-down and the regional resolution introduction resulted in a shift in the mean level and trend of women's responses on companionship, as compared with those of the pre- and post-intervention periods.

3. Results

We present, in turn, the results of the analysis with respect to the labour and childbirth phases. As far as it concerns the labour phase, as shown in the regression table below (Table 1), the mean response level of companionship was estimated at 0.933, and it appeared to decrease slightly every month prior to March 2020 by 0.007, although this result is not statistically significant. In the month of the formalization of lock-down in Italy (March 2020), there appeared to be a significant decrease in the mean response level of 0.124 ($P < 0.01$, CI=[-0.1924, -0.0567]), which continued decreasing slightly by 0.263 (P=0.00, CI=[-0.2842, -0.2423]). This effect, however, after the regional resolution issued by Tuscany (May 2020), was followed by an increase in the mean response level of 0.384 (P=0.00, CI=[0.3037, 0.4642]), with a positive subsequent monthly trend of mean response of 0.283 (P=0.00, CI=[0.2613, 0.3060]).

As it regards the data presented in Table 1, *_cons* indicates the mean response level regarding labour companionship, *_t* indicates the change in the mean response level regarding labour companionship prior to interventions, *_x0* indicates the change in the mean response level regarding labour companionship in correspondence of the first intervention, *_x_t0* indicates the change in the mean response level regarding labour companionship in between the first and second intervention, *_x2* indicates the change in the mean response level regarding labour companionship in correspondence of the second intervention and *_x_t2* indicates the change in the mean response level regarding labour companionship after the second intervention. The above-mentioned results, and more particularly the effects of the two interventions on the mean and trend response level on companionship, are presented even more clearly in the graph below (Fig. 1). The values on the y-axis indicate, respectively, the mean values of women responses to the T0p questionnaire, by confirming that they could be accompanied by a beloved or trusted person during labour at the moments in time provided along the x-axis, namely month and year.

Regarding the childbirth phase, the regression table below (Table 2) shows that the mean response level was estimated at 0.810, and it appeared to decrease slightly every month prior to March 2020 by 0.001, although this result is not statistically significant. In the month of the formalization of lock-down in Italy (March 2020), there appeared to be a significant decrease in the mean response level of 0.061 ($P < 0.05$, CI=[-0.1096, -0.0124]), which continued decreasing slightly by 0.046 (P=0.00, CI=[-0.0635, -0.0300]). This effect, however, after the regional resolution issued by Tuscany (May 2020), was followed by an increase in the mean response level of 0.064 ($P < 0.01$, CI=[0.0343, 0.0953]), with a positive subsequent monthly trend of mean response of 0.061 (P=0.00, CI=[0.0506, 0.0706]).

With respect to the data presented in Table 2, *_cons* indicates the mean response level regarding childbirth companionship, *_t* indicates the change in the mean response level regarding childbirth companionship prior to interventions, *_x0* indicates the change in the mean response level regarding childbirth companionship in correspondence of the first intervention, *_x_t0* indicates the change in the mean response level regarding childbirth companionship in between the first and second intervention, *_x2* indicates the change in the mean response level regarding childbirth companionship in correspondence of the second intervention and *_x_t2* indicates the change in the mean response level regarding childbirth companionship after the second intervention. Also in this case, the results are better shown using a graph (Fig. 2), with the mean values of women responses to the T0p questionnaire on the y-axis, indicating whether they could be accompanied by a beloved or trusted person during childbirth at the moments in time provided along the x-axis, again expressed in terms of month and year.

4. Discussion

In this ITS analysis we demonstrated the negative impact of the first intervention, namely the formalization of first phase of lock-down in Italy due to COVID-19 outbreak, on the possibility for women to be accompanied by a beloved or trusted person in hospital, during both labour and childbirth phases. Additionally, the results of the ITS analysis showed that the second intervention, that is the introduction of the regional resolution issued by the Tuscany Region to allow partners of non-asymptomatic women to access the ward during labour and childbirth, was effective enough in counterbalancing and offsetting the negative trend in the experience reported by women through the questionnaire on the chance not to be left alone in the ward during labour and childbirth. These findings are aligned with previous literature results on this theme. Particularly, the National Institute of Health

Table 1
Single-group multiple interventions ITS analysis on the companionship during labour.

Labour companionship	Coef.	Newey-West Std. Err.	t	P>|t|	[95% Conf.	Interval]
Change in mean response level prior to interventions	-0.0079	.0092	-0.86	0.411	-0.0289	.0129
Change in mean response level along with the first intervention	-0.1245	.0300	-4.15	0.002	-0.1924	-0.0567
Change in mean response level in between first and second intervention	-0.2633	.0092	-28.43	0.000	-0.2842	-0.2423
Change in mean response level along with the second intervention	.3840	.0354	10.82	0.000	.3037	.4642
Change in mean response level after the second intervention	.2837	.0098	28.71	0.000	.2613	.3060
Mean response level regarding labour companionship	.9338	.0403	23.12	0.000	.8424	1.0252

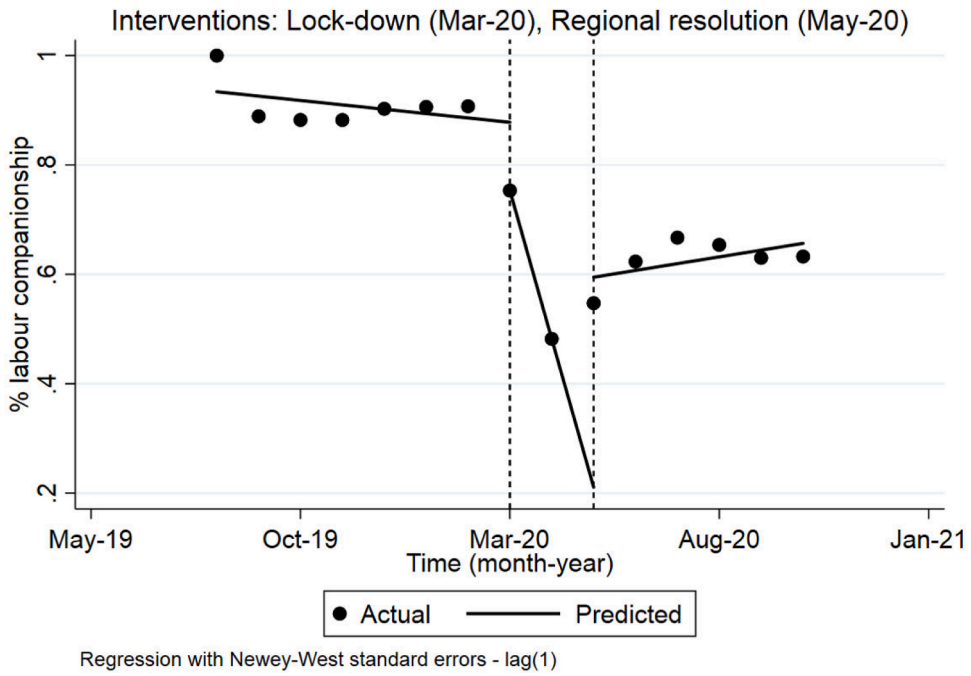

Fig. 1. Effects of formalization of lock-down and regional resolution introduction on companionship, regarding the labour phase.

Table 2
Single-group multiple interventions ITS analysis on the companionship during childbirth.

Childbirth companionship	Coef.	Newey-West Std. Err.	t	P>|t|	[95% Conf. Interval]	
Change in mean response level prior to interventions	-0.0001	.0074	-0.02	0.988	-0.0168	.0166
Change in mean response level along with the first intervention	-0.0610	.0214	-2.84	0.019	-0.1096	-0.0124
Change in mean response level in between first and second intervention	-0.0468	.0074	-6.33	0.000	-0.0635	-0.0300
Change in mean response level along with the second intervention	.0648	.0134	4.81	0.001	.0343	.0953
Change in mean response level after the second intervention	.0606	.0044	13.74	0.000	.0506	.0706
Mean response level regarding childbirth companionship	.8103	.0355	22.79	0.000	.7299	.8908

reported that, during the first COVID-19 wave, just 52% of pregnant women could be accompanied by a beloved or trusted person during labour and childbirth, in accordance with our findings referring to the period between the first and second intervention [58]. However, the results of this study showed that, after the second intervention, this percentage reached values above 60%. This study contributes to the health policy literature related to the effectiveness of measures undertaken to contrast forced isolation induced by the pandemic. Isolation of people, especially amongst youth and the elderly, with consequent increase of loneliness and related problems of mental health, were widely documented in the months following the COVID-19 outbreak [11,12]. As such, several strategies were implemented by different Countries to fight against isolation and, thus, contain the negative effects of loneliness, in particular amongst the elderly [17]. Nevertheless, to the best of our knowledge, this is the first research attempt of this kind relating to maternal and childcare.

Some possible limitations of the present study may be that the results of the analyses performed do not take into consideration specific socio-demographic characteristics of women, such as age, education, social and employment status, origins and, particularly, parity, which could be explored in further research. Also, it could be interesting to observe if and how such socio-demographic characteristics relate remarkably with other aspects and dimensions that characterise the quality of care provided to pregnant women and new mothers, and check if these vary from the pre- to the post-intervention periods. However, such aspect should not be conflicting with the results presented in this article since, as explained in the methods section, the possibility of women to have their partner close was exclusively conditioned by the organizational policies of the birth centres for the containment of the COVID-19 pandemic, rather than by their socio-demographic characteristics. Another related aspect that is worth mentioning is that there may be a bias given by the fact that analysed data are reported by women, who voluntarily accepted to participate in the survey. Therefore, there may be an auto-selection bias in terms of the socio-demographic characteristics of participants. Nevertheless, it is noteworthy that the study cohort included in the analysis represents more than one third (9548 women) of eligible population, that is all women who gave birth in the Tuscany Region in the reference period of the study, therefore the quite high response rate should somehow offset this possibly detrimental effect. No matter these limitations, this is the first study demonstrating that this kind of policies, issued to contain the negative effects on population well-being of the preventive measures undertaken in response to COVID-19 outbreak, were effective enough in limiting conditions that could negatively affect the quality of care provided to pregnant women.

In terms of implications for policy and practice, we argue that greater effort should be provided by the central and local governments to guarantee companionship of choice to women during labour and

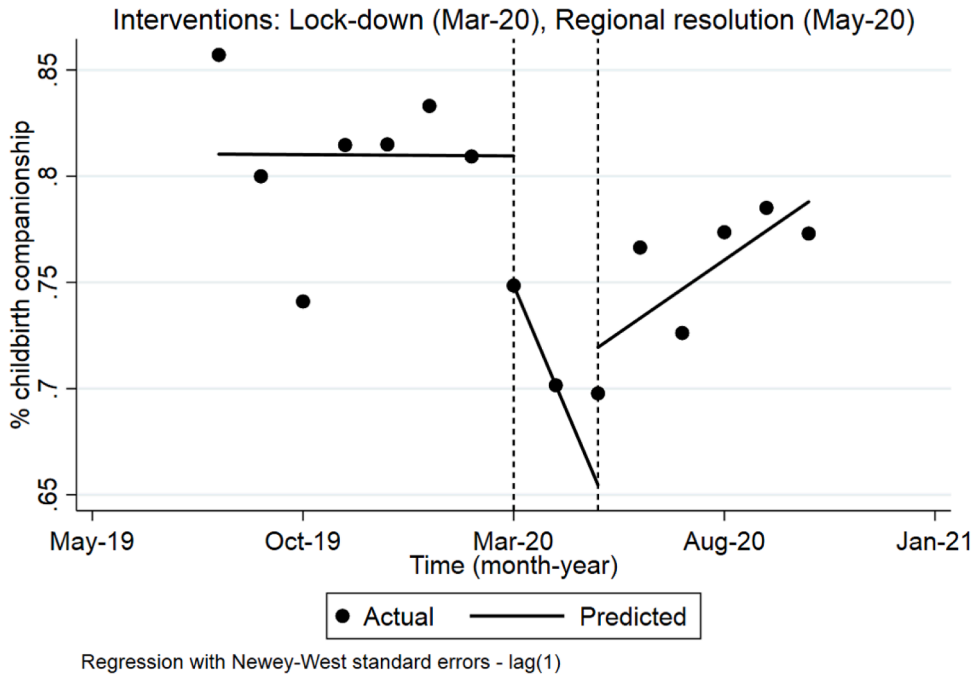

Fig. 2. Effects of formalization of lock-down and regional resolution introduction on companionship, regarding the childbirth phase.

childbirth also in critical times since, as defended by the WHO, companionship is a "low-cost and effective intervention to improve the quality of maternity care, including women's experience of childbirth" [59]. For the sake of this purpose, it is of primary importance to create an environment that effectively enables companionship of choice [34]. To create an enabling environment in this respect, the strategies that can be possibly implemented are: either to issue targeted policies or change adequately the existing ones [60,61], or to ascertain those policies are aligned with actual practice [62,63], with the aim to cull structural and cultural barriers or raise awareness. All Italian Regions and, especially, Tuscany used to guarantee to women companionship of choice in the ward during labour and childbirth. However, the COVID-19 outbreak raised the necessity to issue strict large-scale social restrictions and physical distancing that also concerned provision of care, unheeding the needs and preferences of healthcare users. Given widespread evidence in the literature regarding the importance to ensure companionship of choice to optimize women's experience of childbirth and protect their health, based on the present findings, we state that the restrictions issued by the government and implemented by the hospitals and healthcare facilities should be conceived reasonably. Indeed, the trend of results shows clearly that the opportunity for women to be accompanied by the partner or another trusted person was impacted by the restrictions implemented by healthcare providers and not for any other reasons related to the pandemic, such as fear of contagion. The spread of infection may have eventually been kept under control by means of other methods, such as the use of tampon tests. The introduction of the regional resolution in Tuscany showed that the phenomenon of decrease in the companionship of choice was associated with an external factor, namely a structural barrier, and not with reluctance by women's relatives or beloved ones. The policy issued was effective enough in counterbalancing the effect of governmental large-scale social restrictions and physical distancing measures, therefore we believe that another important implication of this study is that, if necessary, this kind of measure be adopted and implemented if necessary to guarantee social relationships of healthcare users also by other Italian Regions, although further enquiry is necessary on how the resolution may have affected access to care of companions across diverse areas within the same Region.

Furthermore, we identified several opportunities for further research. First, as anticipated, the analysis presented here focused on the regional level, in Tuscany, without digging deeper into sub-regional levels. Thus, it could be interesting to assess if the resolution issued by the regional government had an equal impact across the three different Local Health Authorities (LHAs) of Tuscany. Along this, we have no information about if and how similar policies were issued and implemented in other Italian regions, according to the national recommendations produced by the Italian National Institute of Health [58]. Also, this study provides specifically an overview relative to the childbirth phase in hospital, but it could be investigated further if women suffered from isolation and loneliness during the other salient phases of the maternity experience, namely pregnancy and post-partum; although this analysis could not be replicated easily, as we are not aware of the existence of other policies targeted to contrast isolation during pregnancy and post-partum. Additionally, as above mentioned, the survey administered to women consists of quali-quantitative questionnaires, namely including both closed- and open-ended questions. Therefore, it could be possible also to enrich the quantitative evidence collected so far with qualitative results, by conducting a content analysis over the free comments left by women who filled in the different questionnaires, thus providing further feedback on the dimensions of care investigated by the structured questionnaires. Finally, other stimulus for further research may be run quantitative analysis over a broader timeframe, thus including other COVID-19 outbreaks and restrictions imposed by the Government and, besides that, include a wider selection of questionnaire items to investigate also other dimensions of interest regarding maternal and childcare, such as for example psychological support that turned into an extremely urgent issue during the pandemic.

5. Conclusions

There are two main findings of this study. First, according to the results of the analysis it seems that the pandemic strongly impacted labour and childbirth companionship, especially as it regards the opportunity for women to be accompanied by a beloved or trusted person during labour, which may possibly lead to negative consequences for childbirth experience. On the other hand, the results of the analysis showed that the regional resolution issued by the Tuscany Region on 14th April 2020 was effective enough in containing the reduction of

companionship, although it was more impactful on the time of labour rather than childbirth. In the perspective of the policymakers, these results should encourage the introduction of this kind of measures, which are addressed to guarantee a positive experience of different aspects and phases of childbirth for pregnant women.

Source of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CRediT authorship contribution statement

Ilaria Corazza: Conceptualization, Data curation, Project administration, Formal analysis, Methodology, Visualization, Writing – original draft, Writing – review & editing. **Amerigo Ferrari:** Writing – review & editing. **Manila Bonciani:** Conceptualization, Data curation, Project administration, Writing – review & editing.

Declaration of Competing Interest

The authors whose names are listed immediately above certify that no conflict of interest holds with regards to the subject matter or materials discussed in the present manuscript.

Acknowledgments

The authors would like to thank, on the one hand, all professionals involved along the maternal and childbirth pathway, who contribute to the participation of women in the survey on their experience and outcomes of care, and on the other hand all women taking part in the survey throughout the different phases of the maternal and childcare pathway.

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