PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

| TITLE (PROVISIONAL)   | A POLICY IMPLEMENTATION ANALYSIS ON ACCESS TO HEALTHCARE AMONG UNDOCUMENTED IMMIGRANTS IN 7 AUTONOMOUS COMMUNITIES OF SPAIN, 2012 – 2018 |
|-----------------------|-------------------------------------------------------------------------------------------------------------------|
| AUTHORS               | Gogishvili, Megi; Costa, Sergio; Flórez, Karen; Huang, Terry                                                        |

VERSION 1 – REVIEW

| REVIEWER                  | Urtaran-Laresgoiti, Maider                                                                                         |
|---------------------------|-------------------------------------------------------------------------------------------------------------------|
| University of Deusto, Deusto Business School Health |                                                                                                                   |
| REVIEW RETURNED           | 14-Nov-2020                                                                                                       |

GENERAL COMMENTS

The topic presented in this paper is of relevance as it contributes to highlight the restrictions in access to healthcare services of undocumented immigrants and to describe the heterogeneity in the responses to overcome legal barriers. The manuscript contributes with update data to reinforce previous research results and conclusions, which I consider relevant to drive changes at policy level to guarantee equity and healthcare quality for all population groups.

Having said this, I think one of the main aspects to be considered when reviewing is the issue concerning interviewee sample selection criteria, which might a priori bias the results and conclusions of the “policy implementation and monitoring practices” section. Although it is acknowledged in the manuscript, I believe the section presents a lack of methodological strength and therefore I suggest removing from the final version. Unlike the first analysis of legal measures that were adopted in each AC, which is support by the review of rich primary data, this second analysis does not seem to have enough solidity to be published as for the bias it might present.

Furthermore, I would recommend authors eliminating all repeated information in the discussion section that has been previously detailed in the results. In this sense, I propose reducing (or eliminating) paragraphs 2 and 3 of discussion section.

I also suggest using one same term to refer to Autonomous Communities. Along the manuscript “Autonomous Community” and “region” and use indistinctively, which might lead to confusion the reader. I would choose the term Autonomous Communities, as this is the legal name that is adopted in Spain. Consider also the possibility to include a brief reference or explanation of AC, as readers from other countries may not be familiarized with this term.

Finally, I would advise authors to consider the incorporation of some reflection in the manuscript about the appropriateness for conducting future research on the impact in terms of health outcomes derived of
the policy changes, beyond the comparative analysis of legal and other policy measures adopted by AC.

In order to improve the whole manuscript, please, consider the points listed down below before its publication.

▲ Introduction:
- Page 5. Line 2: “...and excluded undocumented immigrants from publicly funded,...”.
I would suggest noting that not only undocumented immigrants were affected, even if the measure particularly affected them. There are many references to this statement: 1) Real Decreto-ley 16/2012, de 20 de abril, de medidas urgentes para garantizar la sostenibilidad del Sistema Nacional de Salud y mejorar la calidad y seguridad de sus prestaciones. BOE 2012 Abr 24; or 2) Urtaran-Laresgoiti M, Fonseca Peso J, Nuño-Solínis R. Solidarity against healthcare access restrictions on undocumented immigrants in Spain: the REDER case study. International Journal for Equity in Health. 2019;18(1).
- Page 5. Line 13: “… a total of 3,366 newly...”. Correct thousands separator, please.

▲ Methods:
- Page 6. Line 12: “Aragón, Basque Country...”. I would suggest homogenizing all AC names into Spanish. All AC names are written in Spanish except Basque Country. The most correct way to resolve this issue without hampering the understanding might be referring to its as “Euskadi” and clarifying its meaning for English speakers, when first mentioned in the manuscript.
- Page 8. Line 29: “...also based on the number of months...”. Is there any reason to choose this variable for the analysis? Please explain.
- Table 1: Which are the reasons behind the selection of the two access level indicators? Are there any previous researches that use same methodology? Please explain.
- Page 10. Line 7: “...assumed that a patient needed to show...”. Is this correct, or does it need to be correct to the opposite meaning? If the type of identification was not specifically indicated by governmental instructions, it was assumed that patients needed to show or not? Please check.

▲ Results:
- Table 3: (page 29. Line 8 and 3): reference numbers should appear as superscripts. Please correct.
- Page 32. Line 59: “... (the) Basque Country issued...”. Please consider this correction.
- Page 34. Line 41: “Madrid issued 1 official (...) and one internal...”. Please homogenize either to numerical or written form to keep consistency. Consider the way that is chosen in other parts of the manuscript.
- Table 4: (Page 39, Line 24): I think that with EOSICS it is refer to what is called EOXI in Galician. Please check and correct if needed. EOXI stands for “Estructura Organizativa de Xestión Integrada”.
- Page 40. Line 55. Please correct Castilla- La Mancha. Please, check and correct same mistake in all the manuscript.

▲ Discussion:
- Page 41. 1st paragraph: Noted that this is not the first study to document healthcare access in Spain since enactment of RDL 16/2012. I suggest considering this research as an update of
previous ones, such as Cimas et al 2016.

Pages 43 and 44: I propose including some quotations to support interviewees opinions and ideas.

- References: I recommend including DOIs that are missing, and checking for misspelling and format errors in the references.

Good luck with the paper and thanks you for the consideration of the suggestions.

REVIEWER
Doshi, Monika
University of Michigan
REVIEW RETURNED
20-Nov-2020

GENERAL COMMENTS

General Comments:
1. The authors tackle an important and timely issue focusing on a highly understudied and underserved population. Moreover, implications of variability in public policies on healthcare access and utilization cannot be more relevant today given the global pandemic (COVID-19) that nation states are attempting to navigate, address, and curtail. Furthermore, it will be important to characterize those most directly impacted. That is, who are these undocumented immigrants, from where do they emigrate, etc.

2. Presentation of the information can be made more digestible for consumption through the use of additional tables, figures, illustrations, charts, etc. There is quite a bit of detailed information shared in this manuscript which is very dense and difficult to engage with as written.

3. The relevance of the analysis and its relation to health and wellbeing of undocumented immigrants is skirted but not explored in any depth. A deeper dive is critically necessary to more fully illuminate why this work is important focusing on the aforementioned connections between health and public policy.

4. The impact of the regulatory policy on healthcare access is not measured in this study. The study seems to be focused largely on interpretation, implementation, monitoring and evaluation of the 2012 RDL and RD. Suggest structuring and presaging the paper, including the title, to reflect this.

5. Key words listed on the cover page do not match key words listed in the actual manuscript.

6. General flow and connections between paragraphs need to be strengthened further. Suggest linking paragraphs more tightly throughout the manuscript.

7. Add an acronym/abbreviation section.

8. Acronyms should probably be spelled out when used for the first time in the main body of the manuscript.

Specific Comments:
Introduction
Page 5
1. Line 8-10: Clarify what is meant by "carrying the force of the law" and "carrying the force of the regulation".
2. Line 10: Authors suggest that changes have been made to previously practiced universal healthcare but do not go into too many specifics to outline these changes.

3. Line 14-19: The downstream effects of economic crises on public health needs to be unpacked in greater detail.

4. Line 49-50: The connection between the "bridge population" and the general population needs to be more clearly stated.

Page 6

1. Line 26-33: Wasn't the intention of RDL 16/2012 to exclude undocumented immigrants from publicly funded, free healthcare services? If so, is the aim to study the impact of these restrictions at the regional level? This paragraph does not seem to imply this as it states the study's aim to "provide a comparative policy implementation analysis on access to free general healthcare services and HIV care". What is missing here is the signal that this is a study of the adoption of the national policy at the regional level and the impact of the latter on healthcare access among undocumented immigrants.

Methods

Page 6

1. Line 41: Why were representatives from nongovernmental NGOs included? Consider providing some background for readers who may not be familiar with the Spanish healthcare infrastructure and the associated relationships between NGOs and government entities and the importance of including both perspectives.

2. Line 43: What was the sampling framework used to recruit interviewees? What was the sampling framework used to choose the ACs? Were the interviewees consented before participation?

3. Line 46: What is meant by "active participation"?

4. Line 46: The authors state that the IRB approval was not required. However, was this decision vetted through an institutional IRB? Authors need to elaborate further on how this decision was reached.

5. Line 57: Unclear what is meant by the sentence "consequent development of laws and government instructions…"

Page 7

1. Line 17-18: Unclear what is meant by the sentence "an open-ended exploration of the regional policy changes…"

2. Line 21-29: It seems that interviews were not conducted with all interviewees. Some simply responded by completing the qualitative guide. This hybrid use of qualitative methods needs to be explained further. The interview guide also seems to be more of a survey – more quantitative than qualitative. The authors should also address this.

3. Line 31-43: The numbers do not add up.

4. Line 36: What type of experts?

5. Line 38: Unclear what is meant by the sentence "In 4 ACs, more than 1 person…" How were those interviews different compared to the others?

6. Line 42-43: Either the last sentence here belongs in the Results section or more descriptive statistics are needed here to describe the participants/interviewees in greater detail.

7. Line 46: Patient and public partnerships: The necessity for this section is unclear.

8. Line 57: Which published policies did the authors review? National? AC related? Both?
1. Line 30-33: It is unclear whether indicators related to access (i.e., categorization of individual, residency requirement, and ID requirement) were newly incorporated as a result of the RDL and RD? Were these requirements not in play prior to the 2012 changes?
2. Line 35-36: The two terms described here (free general health care and free healthcare access) probably should be explained earlier on in the manuscript.
3. Line 46: When was the first instruction issued in each AC? Did it differ for each AC? This should be made clear here.
4. Line 48: A clear definition of what is being measured (i.e., restrictions or permissions) is getting lost here.
5. Line 60: How was the preceding method (as described in this paragraph) decided upon? Is there precede in the literature for employing this method?

Page 9
1. Table 1: What are these exceptions and how were they considered in the categorization of ID requirements?
2. Coding assumptions: Consider clarifying and specifically delineating to what these assumptions apply since there are a few things for which coding was required (e.g., ID, residency requirement). This is unclear in the paragraph that follows.

Page 10
1. Line 5: So, does this mean that an ID was required but the instruction did not state exactly the type of ID required? This can be made clearer here.
2. Line 5 (again): In this writing, it will be important to distinguish between regional and national when speaking about “government instructions”.
3. Line 8: What specific requirement? Consider providing examples.
4. Line 15: For when the possibility of exemption is stated, what do these exemptions entail and how were they considered in your calculations/assessments?
5. Line 20: If otherwise stated, then how was this information considered in your calculations and assessments?
6. Line 31: Were there instances where the governmental documents did not provide sufficient information to discern/calculate access? If so, how was this addressed and/or reconciled?

Results
Page 10
1. Line 55-58: This implies that actual access was measured in this study, which it was not. Thus, is the measure really “effects on access” or “regional governmental barriers to access”? Access to healthcare for undocumented immigrants can potentially be affected by many factors and this study’s specific attention seems to be on just one of those factors.
2. Line 60: This entire paragraph is a bit unclear.

Page 12
1. Table 2: This table is extremely difficult to follow and unpack as laid out here. For example, how does one reconcile the “Issued Governmental Instructions and Required Documents” with “Access Level Indicators”. Same question as before, is the governmental instruction related to the national policy or the interpretation of the national policy at the regional level. If the latter, then for Andalucia, the reconciliation between the aforementioned columns becomes difficult. Consider revising and presenting this table more clearly.
2. Table 3: Recommend including the level of access for each AC region highlighted here.

Page 32
1. Sections that follow here
   - There is quite a lot of detailed information in this section and it is easy to get lost as a reader. Consider revising this section, teasing out pertinent information that is relevant to the study aim(s).
   - There seem to be some requirements for this region (i.e., Andalucia) despite their categorization as "high access". It will be important to speak to those requirements and how, if at all, they served as barriers to access.

Discussion
Section as a whole
1. Much of this discussion section seems to repeat the results section without really unpacking the implications of the findings. A greater and more in-depth dive would be beneficial here.

Page 42
1. Line 35-36: How was the regional commitment to human rights measured? This should be noted here.

Page 43
1. Line 44-45: What other ways might this work assess regional commitments to human rights. The current proxy measures and their presentation can be strengthened.

Conclusion
Page 45
1. Line 24: Consider providing examples for the structural barriers mentioned here

REVIEWER
De Vito, Elisabetta
University of Cassino and Southern Lazio, Human, Social and Health Sciences

REVIEW RETURNED 26-Nov-2020

GENERAL COMMENTS
Policy Implementation Analysis is a difficult issue. Considering the few interviews, the title “A tentative of analysis……” would be more correct. The few responders also affect the tentative to compare the point of view of the official service responders and the NGO responders. The discussion of this article missed to analyse the social, political and economic framework which lead the Nation to step back in 5 years on this crucial problem. I suppose that such a decision should be based on a wide political debate not clearly analysed. In my opinion, even if this is a Country decision, Spain is in the EU so would be important to offer a comparison with other EU Country debate on this issue and considering also the EU recommendation in the framework analysis. The legal framework and entitlement regarding UM access to health care services is a crucial point in each EU countries.
In my opinion the article needs a better framework analysis otherwise, in this form, is fairly difficult to understand its value.
Finally, I would like to suggest to find a style more concise and a to adopt a logic of exposition which can easily lead the reader to the conclusion.
Reviewer: 1  
Dr. Maider Urtaran-LAresgoiti, University of Deusto

Thank you very much for your feedback. Your insightful comments were reviewed and changes were made to the manuscript. For your convenience, the changes made to the manuscript are also copied in this document and, where appropriate, the relevant page number is indicated.

Comments to the Author:

The topic presented in this paper is of relevance as it contributes to highlight the restrictions in access to healthcare services of undocumented immigrants and to describe the heterogeneity in the responses to overcome legal barriers. The manuscript contributes with update data to reinforce previous research results and conclusions, which I consider relevant to drive changes at policy level to guarantee equity and healthcare quality for all population groups.

Having said this, I think one of the main aspects to be considered when reviewing is the issue concerning interviewee sample selection criteria, which might a priori bias the results and conclusions of the “policy implementation and monitoring practices” section. Although it is acknowledged in the manuscript, I believe the section presents a lack of methodological strength and therefore I suggest removing from the final version. Unlike the first analysis of legal measures that were adopted in each AC, which is support by the review of rich primary data, this second analysis does not seem to have enough solidity to be published as for the bias it might present.

We have removed the interviews from the paper, including the section on “policy implementation and monitoring practices.”

Furthermore, I would recommend authors eliminating all repeated information in the discussion section that has been previously detailed in the results. In this sense, I propose reducing (or eliminating) paragraphs 2 and 3 of discussion section.

Both paragraphs have been eliminated.

I also suggest using one same term to refer to Autonomous Communities. Along the manuscript “Autonomous Community” and “region” and use indistinctively, which might lead to confusion the reader. I would choose the term Autonomous Communities, as this is the legal name that is adopted in Spain. Consider also the possibility to include a brief reference or explanation of AC, as readers from other countries may not be familiarized with this term.

Thank you for this suggestion. Term region/regional has been changed to AC throughout the paper. Also, in Strengths and Limitations of this Study section (page 2) and discussion section (page 8) we now indicate that Spain is formed by 17 Autonomous Communities. 

Finally, I would advise authors to consider the incorporation of some reflection in the manuscript about the appropriateness for conducting future research on the impact in terms of health outcomes derived of the policy changes, beyond the comparative analysis of legal and other policy measures adopted by AC.

This is a very important point. Thank you. We have now highlighted the need for research on health outcomes as a result of the policy changes, especially among immigrants (Discussion section, page 38 and 39).
In order to improve the whole manuscript, please, consider the points listed down below before its publication.

§ Introduction:
- Page 5. Line 2: “...and excluded undocumented immigrants from publicly funded,…“.
I would suggest noting that not only undocumented immigrants were affected, even if the measure particularly affected them.
There are many references to this statement: 1) Real Decreto-ley 16/2012, de 20 de abril, de medidas urgentes para garantizar la sostenibilidad del Sistema Nacional de Salud y mejorar la calidad y seguridad de sus prestaciones. BOE 2012 Abr 24; or 2) Urtaran-Laresgoiti M, Fonseca Peso J, Nuño-Solinís R. Solidarity against healthcare access restrictions on undocumented immigrants in Spain: the REDER case study. International Journal for Equity in Health. 2019;18(1).

In the introduction section, we expanded on the impact of the law per the reviewer’s suggestion. For example, the 2012 health reform not only excluded undocumented immigrants but also anyone age 27 and above who has never been employed (page 4). We included the references suggested (page 41, reference 5 and 6).

- Page 5. Line 13: “… a total of 3,366 newly...”. Correct thousands separator, please.
Corrected.

§ Methods:
- Page 6. Line 12: “Aragón, Basque Country…”. I would suggest homogenizing all AC names into Spanish. All AC names are written in Spanish except Basque Country. The most correct way to resolve this issue without hampering the understanding might be referring to its as “Euskadi” and clarifying its meaning for English speakers, when first mentioned in the manuscript.
Thank you. Basque Country has been changed to Euskadi throughout the paper. Basque Country was put in parentheses after mentioning Euskadi for the first time in the abstract section (page 2), methods section (page 5), and result section (page 30).

- Page 8. Line 29: “…also based on the number of months...”. Is there any reason to choose this variable for the analysis? Explain if so, please.
This was selected as a proxy for the severity of the restriction.

- Table 1: Which are the reasons behind the selection of the two access level indicators? Are there any previous researches that use same methodology? Explain, please.
We added to the start of the paragraph access indicators and its measures (Methods section, page 6) the source for selection of the two access level indicators. Specifically we indicate that “According to the main systemic barriers presented across official documents, we identified two access level indicators: proof of identification and proof of residency in an AC. We developed a model (see Figure 1) using these two indicators to assess the severity of the limitation on free general healthcare access among undocumented immigrants”

- Page 10. Line 7: “…assumed that a patient needed to show...”. Is this correct, or does it need to be correct to the opposite meaning? If the type of identification was not specifically indicated by governmental instructions, it was assumed that patients needed to show or not? Please check.
The sentence is correct. If there was no indication that a patient needed to show an identification, it was assumed that they needed to present such identification. This assumption is based on the fact that the national law required this and that most services in Spain require identification unless a waiver is explicitly indicated.

§ Results:
- Table 3: (page 29, Line 8 and 3): reference numbers should appear as superscripts. Please correct.
  Corrected.
- Page 32. Line 59: “… (the) Basque Country issued…”. Please consider this correction.
  Corrected.
- Page 34. Line 41: "Madrid issued 1 official (…) and one internal…". Please homogenize either to numerical or written form to keep consistency. Consider the way that is chosen in other parts of the manuscript.
  Corrected. Everywhere in the paper we use spelled out numbers except for where we discussed percentages, amounts, age, months, and years.
- Table 4: (Page 39, Line 24): I think that with EOSICS it is refer to what is called EOXI in Galician. Please check and correct if needed. EOXI stands for “Estructura Organizativa de Xestión Integrada”.
  Table 4 was removed from the paper following the reviewer’s comment on the validity of the “policy implementation and monitoring practices” section.
- Page 40. Line 55. Please correct Castilla- La Mancha. Please, check and correct same mistake in all the manuscript.
  Corrected. ‘L’ in ‘La’ has been capitalized throughout the paper where needed.

§ Discussion:
- Page 41. 1st paragraph: Noted that this is not the first study to document healthcare access in Spain since enactment of RDL 16/2012. I suggest considering this research as an update of previous ones, such as Cimas et al 2016.
  It is correct that a similar study was published by Cimas et al (now indicated in discussion section, page 35). However, Cimas et al. focused on the implementation of 2012 Royal Decree Law and Royal Decree and on general access to care. Our study has extended the scope to access to HIV treatment and most importantly on all policies and instructions implemented until Royal Decree law 7/2018. This paper extends the work published previously to cover further the contemporary issues stemming from the onset of the 2012 laws.
- Pages 43 and 44: I propose including some quotations to support interviewees opinions and ideas.
  The interviews have been removed from the article per the reviewer’s concern.

§ References: I recommend including DOIs that are missing, and checking for misspelling and format errors in the references.
  DOIs have been added where it was available and other corrections made to the references where
applicable.

Good luck with the paper and thanks you for the consideration of the suggestions.

Thank you.

Reviewer: 2
Dr. Monika Doshi, University of Michigan

Thank you very much for your feedback. Your insightful comments were reviewed and adequate changes were made to the manuscript. For your convenience, the changes made to the manuscript are also copied in this document or relevant page number is indicated.

Comments to the Author:
General Comments:
1. The authors tackle an important and timely issue focusing on a highly understudied and underserved population. Moreover, implications of variability in public policies on healthcare access and utilization cannot be more relevant today given the global pandemic (COVID-19) that nation states are attempting to navigate, address, and curtail. Furthermore, it will be important to characterize those most directly impacted. That is, who are these undocumented immigrants, from where do they emigrate, etc.

We agree with that this would be of enormous interest and value. Unfortunately, information on undocumented immigrants ethnicity or origins (or general statistics) is not officially documented due to the sensitivity of the topic. While we would like to add this information it is currently not possible.

2. Presentation of the information can be made more digestible for consumption through the use of additional tables, figures, illustrations, charts, etc. There is quite a bit of detailed information shared in this manuscript which is very dense and difficult to engage with as written.

The paper has been cut significantly by removing the interviews per Reviewer 1’s suggestion. In addition, we have improved the description of the results. For example, a new Table 2 (Results section, page 11) has been created to summarize the findings (the previous Table 2 is now Table 3(supplemental)).

3. The relevance of the analysis and its relation to health and wellbeing of undocumented immigrants is skirted but not explored in any depth. A deeper dive is critically necessary to more fully illuminate why this work is important focusing on the aforementioned connections between health and public policy.

We have reflected on this important point further in the discussion section (page 35 and 38). Specifically, we highlighted a previously demonstrated connection between legal restrictions and health outcomes among immigrants as well as the need for further research on the impact of the 2012 health reform (and laws/instructions that came after) on actual health outcomes among immigrants residing in Spain.

4. The impact of the regulatory policy on healthcare access is not measured in this study. The study seems to be focused largely on interpretation, implementation, monitoring and evaluation of the 2012 RDL and RD. Suggest structuring and presaging the paper, including the title, to reflect this.
We have changed the title to “A policy implementation analysis of the 2012 Spanish health reform restricting undocumented immigrants’ access to healthcare.” We stress particularly that this paper is an analysis of the implementation of the said policy.

5. Key words listed on the cover page do not match key words listed in the actual manuscript.

We have ensured the key words are aligned.

6. General flow and connections between paragraphs need to be strengthened further. Suggest linking paragraphs more tightly throughout the manuscript.

The paper was reviewed for general flow and connections between the paragraphs. Beside sections in methods and results were clear title is indicated for each part, changes have been made to introduction section to strengthen the flow of the information and amendments have been made through-out the discussion section. The removal of the interview-related materials should also help with the readability of the paper, centering the focus on the document reviews.

7. Add an acronym/abbreviation section.

Abbreviation section has been added on page 3.

8. Acronyms should probably be spelled out when used for the first time in the main body of the manuscript.

The main body of the article was checked to make sure that all acronyms were spelled out when used for the first time.

Specific Comments:
Introduction
Page 5
1. Line 8-10: Clarify what is meant by “carrying the force of the law” and “carrying the force of the regulation”.

More information has been added to the meaning of RDL and RD (Introduction, page 4). Specifically, “Royal Decree Law (RDL, carrying the force of law issued by the government in exceptional cases without need of preliminary approval by the parliament) 16/2012 and Royal Decree (RD, carrying the force of regulation indicating certain norms on a matter requiring specific guidance and requiring parliamentary approval)”.

2. Line 10: Authors suggest that changes have been made to previously practiced universal healthcare but do not go into too many specifics to outline these changes.

More information has been added (Introduction section, page 4). The changes that revoked previously universal health coverage are: exclusion of undocumented immigrants from public healthcare system and anyone age 27 and above who has never been employed (exception: disabled individuals). How the exclusion has been realized is central to the thesis of our paper.

3. Line 14-19: The downstream effects of economic crises on public health needs to be unpacked in greater detail.

As suggested by the reviewer we explored effect of economic crises on public health needs, however
we felt this fit better in the discussion (page, 36 and 38).

4. Line 49-50: The connection between the “bridge population” and the general population needs to be more clearly stated.

It is unclear what the reviewer meant by “bridge population.” However, we rephrased and simplified the sentence to make the meaning clearer (Introduction section, page 5):
“Given the highly decentralized health system in Spain, the aim of this study was to provide a comparative policy implementation analysis on access to free general healthcare services and HIV care among undocumented immigrants in different ACs, from the implementation of RDL 16/2012 until the enactment of RDL 7/2018, which was intended to reinstate universal health coverage.”

Page 6
1. Line 26-33: Wasn't the intention of RDL 16/2012 to exclude undocumented immigrants from publicly funded, free healthcare services? If so, is the aim to study the impact of these restrictions at the regional level? This paragraph does not seem to imply this as it states the study's aim to "provide a comparative policy implementation analysis on access to free general healthcare services and HIV care". What is missing here is the signal that this is a study of the adoption of the national policy at the regional level and the impact of the latter on healthcare access among undocumented immigrants.

It has been stated more clearly that the comparative policy implementation refers to implementation of RDL and RD across the ACs. Specifically, “Given the highly decentralized health system in Spain, the aim of this study was to provide a comparative policy implementation analysis on access to free general healthcare services and HIV care among undocumented immigrants in different ACs, from the implementation of RDL 16/2012 until the enactment of RDL 7/2018, which was intended to reinstate universal health coverage.” The start of the sentence also indicates that the study will investigate the difference across the country – “Given the highly decentralized health system in Spain.”

Methods
Page 6
1. Line 41: Why were representatives from nongovernmental NGOs included? Consider providing some background for readers who may not be familiar with the Spanish healthcare infrastructure and the associated relationships between NGOs and government entities and the importance of including both perspectives.

The interview section has been removed from the article per comments from Reviewer 1.

2. Line 43: What was the sampling framework used to recruit interviewees? What was the sampling framework used to choose the ACs? Were the interviewees consented before participation?

The interview section has been removed from the article.

3. Line 46: What is meant by “active participation”?

The interview section has been removed from the article.

4. Line 46: The authors state that the IRB approval was not required. However, was this decision vetted through an institutional IRB? Authors need to elaborate further on how this decision was reached.

The interview section has been removed from the article, but yes, the CUNY IRB deemed interviews with public officials about the implementation of public law to be non-human subjects research.
5. Line 57: Unclear what is meant by the sentence “consequent development of laws and government instructions…”

The interview section has been removed completely from the article thus this explanation is no longer needed.

Page 7
1. Line 17-18: Unclear what is meant by the sentence “an open-ended exploration of the regional policy changes…”

The interview section has been removed completely from the article.

2. Line 21-29: It seems that interviews were not conducted with all interviewees. Some simply responded by completing the qualitative guide. This hybrid use of qualitative methods needs to be explained further. The interview guide also seems to be more of a survey – more quantitative than qualitative. The authors should also address this.

The interview section has been removed completely from the article.

3. Line 31-43: The numbers do not add up.

The interview section has been removed completely from the article.

4. Line 36: What type of experts?

The interview section has been removed completely from the article.

5. Line 38: Unclear what is meant by the sentence “In 4 ACs, more than 1 person…” How were those interviews different compared to the others?

The interview section has been removed completely from the article.

6. Line 42-43: Either the last sentence here belongs in the Results section or more descriptive statistics are needed here to describe the participants/interviewees in greater detail.

The interview section has been removed completely from the article.

7. Line 46: Patient and public partnerships: The necessity for this section is unclear.

This section was requested by BMJ Open.

8. Line 57: Which published policies did the authors review? National? AC related? Both?

Documents reviewed were published “after April 2012 that related to entitlements granted to undocumented immigrants for free general healthcare services and/or HIV care in the seven ACs of Spain.” Since Spain has a decentralized health system, each AC can develop its own instruction on the topic. Thus, documents reviewed are ones published by the ACs, as the purpose of the paper is to take a closer look at how the national decrees were implemented at the regional level in different ACs. We clarified this detail (Methods section, page 8) by stating specifically, “Reviewed governmental documents issued by the seven ACs were published between April 20, 2012 and July 30, 2018 in both Spanish and Galician.”
Page 8

1. Line 30-33: It is unclear whether indicators related to access (i.e., categorization of individual, residency requirement, and ID requirement) were newly incorporated as a result of the RDL and RD? Were these requirements not in play prior to the 2012 changes?

Before the health reform, Spain had universal health care coverage which meant providing everyone free healthcare coverage. After 2012 RDL and RD, requirements of residency and identification have been established to exclude many undocumented immigrants already with a public health insurance card and ones who would need care in the future. We verified that this was articulated in the paper (Introduction, page 4).

2. Line 35-36: The two terms described here (free general health care and free healthcare access) probably should be explained earlier on in the manuscript.

The term ‘free general health care’ and ‘free healthcare access’ are described specifically here so that a reader can understand the explanation of the indicators that follow (free general healthcare access versus access to HIV care, and ‘free healthcare access’ when referring to access to both) and afterwards for the results. We presented this information here to avoid reader confusion in later sections.

3. Line 46: When was the first instruction issued in each AC? Did it differ for each AC? This should be made clear here.

Each AC published initial instructions during different times since the Spanish system is decentralized. All information in detail and with date of publishing are presented in the results section and more concisely in Table 2. To make it even clearer, we indicated the following "Months were calculated from the first instruction of an AC (date differed for each AC) granting free general healthcare coverage" (Methods section, page 6).

4. Line 48: A clear definition of what is being measured (i.e., restrictions or permissions) is getting lost here.

The following clarification has been included in the result section (page 9) "We assessed level of access to free healthcare granted to undocumented immigrants by each AC according to the restrictions that instructions entailed."

5. Line 60: How was the preceding method (as described in this paragraph) decided upon? Is there precedence in the literature for employing this method?

Due to the unique structure of Spain, there exist few cases where we can take a Royal-Decree law that applies to all parts of a country and examine implementation differences by region. The only study that provides a similar model for comparison is Cimas et al (2016) which studied the implementation of 2012 Royal Decree Law and Royal Decree (without consideration of subsequent regulations/instructions). Their decision on ranking the level of access was based on weights assigned to various indicators and a final vote among participating investigators. Extending from Cimas et al (2016), we aimed in our paper to investigate a longer time frame and include 21 more instructions issued by the ACs. We also sought to develop a more rigorous method to assess the level of access by estimating the time instructions granted access to free care to undocumented immigrants. To our knowledge, this represents a novel approach that is aligned with the unique healthcare structure in Spain.
Page 9

1. Table 1: What are these exceptions and how were they considered in the categorization of ID requirements?

As noted, the word ‘exception’ is indicated under some indicators. Some ACs would still provide services if a person did not have an ID as an exception. Depending on the AC, an exception could be made for different reasons (e.g., public health insurance card was issued but 3 months was given to present valid ID card; acceptance of non-official IDs such as a gym membership card, etc.).

Exceptions were subjective among those providing services, so we did not account for these in the methodology of assessing level of access. To avoid reader confusion, we removed exceptions from the descriptions of indicators in Table 1 and Table 2.

2. Coding assumptions: Consider clarifying and specifically delineating to what these assumptions apply since there are a few things for which coding was required (e.g., ID, residency requirement). This is unclear in the paragraph that follows.

This refers to information we extracted from the documents reviewed. The two indicators measured are requirement of ID and proof of residence for general healthcare services and HIV care. We added (Methods section, page 8): “For the purpose of this study, the following assumptions were made while coding selected indicators to determine level of access granted to free healthcare services to undocumented immigrants:"

Page 10

1. Line 5: So, does this mean that an ID was required but the instruction did not state exactly the type of ID required? This can be made clearer here.

We have made it clearer now (Methods section, page 8 and 9), indicating that if an ID was not specifically mentioned as a requirement in an instruction, it was assumed that a patient still needed to present it in accordance with the national decree in order to receive healthcare coverage. Specifically, “If requirement to present an identification was not specifically indicated by regional governmental instructions, it was assumed that a patient needed to show proof of identity during registration for healthcare coverage;” We assumed this because when an instruction does not specifically discuss the ID requirement, this decision is left to a local administrator. Considering that ID is required for any type of services in Spain, it seemed more plausible that a patient would be asked for such proof of identity.

2. Line 5 (again): In this writing, it will be important to distinguish between regional and national when speaking about “government instructions”.

Throughout the text, it was specified that documents reviewed were issued by the ACs. In the 1st paragraph of the Methods section (page 6), we stated “Reviewed governmental documents issued by the seven ACs were published between April 20, 2012 and July 30, 2018 in both Spanish and Galician.”

3. Line 8: What specific requirement? Consider providing examples.

Examples were included – legal identification, proof of residence (Methods section, page 8).

4. Line 15: For when the possibility of exemption is stated, what do these exemptions entail and how were they considered in your calculations/assessments?

This part was taken out of the sentence since it was not relevant to our methodology for assessing
level of access. However, the idea of exemptions was left in the description of the instructions (Table 3(supplemental file)) just to accurately present requirements detailed in each document.

5. Line 20: If otherwise stated, then how was this information considered in your calculations and assessments?

Exemptions were not considered per comment above.

6. Line 31: Were there instances where the governmental documents did not provide sufficient information to discern/calculate access? If so, how was this addressed and/or reconciled?

All documents reviewed addressed access to free care for populations no longer granted such access if specific requirements were not met. Since two requirements set by the RDL and RD were ID and proof of residence, all documents reviewed specified information on selected indicators used to calculate the level of access.

Results
Page 10
1. Line 55-58: This implies that actual access was measured in this study, which it was not. Thus, is the measure really “effects on access” or “regional governmental barriers to access”? Access to healthcare for undocumented immigrants can potentially be affected by many factors and this study’s specific attention seems to be on just one of those factors.

We are assessing/evaluating barriers that were put in place. Recall this is a policy implementation analysis, not an epidemiological study. Thus, the title of the results section is “Level of administrative barriers to accessing free general and HIV healthcare services among undocumented immigrants.” The sentence has been adapted to make this point clearer (Results section, page 9), specifically “Table 2 provides a summary of the policy actions taken in each AC during the study time frame (total of 75 months), as well as level of access granted to free general health care among undocumented immigrants calculated according to the model in Figure 1.”

2. Line 60: This entire paragraph is a bit unclear.

Yes, we agree. First paragraph of the result section has been edited for clarity and one more paragraph has been added.

Page 12
1. Table 2: This table is extremely difficult to follow and unpack as laid out here. For example, how does one reconcile the "Issued Governmental Instructions and Required Documents" with "Access Level Indicators". Same question as before, is the governmental instruction related to the national policy or the interpretation of the national policy at the regional level. If the latter, then for Andalucía, the reconciliation between the aforementioned columns becomes difficult. Consider revising and presenting this table more clearly.

A revised Table 2 has been created with just the summary of findings (streamlined version of the prior Table 2) so that a reader can easily follow and understand the results. The part about ‘governmental instructions’ has been cleared up in the text by highlighting that all documents reviewed were instructions issued by each AC. The prior Table 2 has been renamed to Table 3 (included as a supplemental table) so that any reader who wishes to see more details on why each AC was categorized with a certain level of access can reference the specific instructions issued by a given AC.

We clarified information on the instruction developed by Andalucía (Result section, page 12). While
the instruction was developed to provide ‘temporary free assistance’ to undocumented immigrants, it was not replaced with any other official document. Andalucía continued providing free general healthcare assistance to undocumented immigrants under the instruction of 2013 document throughout the study period.

2. Table 3: Recommend including the level of access for each AC region highlighted here.

Table 3 has been taken out as it was based on the data extracted from the interviews. The interview section has been removed completely from the article.

Page 32
1. Sections that follow here
   • There is quite a lot of detailed information in this section and it is easy to get lost as a reader. Consider revising this section, teasing out pertinent information that is relevant to the study aim(s).

   All extra information that took away focus from the main barriers/selected indicators was taken out from the paragraphs describing actions taken in each AC. In some cases, there were a lot of different developments took place, such as in Euskadi (Basque country). We decided to keep information that showed the relevant policy history, including some rationale for why certain regional implementations deviated from the more restrictive national policy.

   • There seem to be some requirements for this region (i.e., Andalucia) despite their categorization as “high access”. It will be important to speak to those requirements and how, if at all, they served as barriers to access.

   These requirements have been removed from the description of all ACs in the result section since it did not serve as a barrier and was just a administrative paperwork.

Discussion
Section as a whole
1. Much of this discussion section seems to repeat the results section without really unpacking the implications of the findings. A greater and more in-depth dive would be beneficial here.

   Paragraph 2 and 3 of this section have been removed. Three new discussion paragraphs (page 36) have been added to shed light on motivations behind this health reform from social, economic and political perspectives. More discussion has been added on the need for research on actual health outcomes as a result of these policy changes (page 38).

Page 42
1. Line 35-36: How was the regional commitment to human rights measured? This should be noted here.

   We removed the stakeholder interviews from this paper. However, we modified and left some language on the notion of human rights (page 37 and 38) given this articulation in specific regional government instructions. “Specifically, governmental instructions published in four of seven ACs (Andalucía, Aragón, Euskadi, Valencia) indicated the notion that “everyone has the right to health protection” (which is also guaranteed by the Constitution of Spain) as one of the main rationales of the guidelines.”

Page 43
1. Line 44-45: What other ways might this work assess regional commitments to human rights. The current proxy measures and their presentation can be strengthened.
Please see comment above. Assessment of regional stances on human rights was not the focus of this paper. We bring it up in the discussion in an attempt to explain why some ACs chose to implement a less draconian version of the national law. However, we do hope to motivate future research on the topic. “More research is warranted on the general attitudes of the ACs on the acceptability of denying the right to access free healthcare services to undocumented immigrants.”

Conclusion
Page 45
1. Line 24: Consider providing examples for the structural barriers mentioned here

We rephrased the sentence and removed the term to avoid any ambiguity (Conclusion section, page 39).

Reviewer: 3
Dr. Elisabetta De Vito, University of Cassino and Southern Lazio

Thank you very much for your feedback. Your insightful comments were reviewed and changes were made to the manuscript. For your convenience, the changes made to the manuscript are also copied in these document or relevant page number is indicated.

Comments to the Author:
1. Policy Implementation Analysis is a difficult issue. Considering the few interviews, the title “A tentative of analysis……” would be more correct. The few responders also affect the tentative to compare the point of view of the official service responders and the NGO responders.

We appreciate the point. The focus of our analysis is centered solely on a detailed review of the relevant documents issued by each AC. The interview section and all other sections related to it have been completely removed from the article.

2. The discussion of this article missed to analyze the social, political and economic framework which lead the Nation to step back in 5 years on this crucial problem. I suppose that such a decision should be based on a wide political debate not clearly analyzed. In my opinion, even if this is a Country decision, Spain is in the EU so would be important to offer a comparison with other EU Country debate on this issue and considering also the EU recommendation in the framework analysis. The legal framework and entitlement regarding UM access to health care services is a crucial point in each EU countries.
In my opinion the article needs a better framework analysis otherwise, in this form, is fairly difficult to understand its value.

Social, political, and economic perspectives have been added to the discussion section (page 36 and 38).

3. Finally, I would like to suggest to find a style more concise and to adopt a logic of exposition which can easily lead the reader to the conclusion.

We appreciate the reviewer’s suggestion. By shortening the paper via the removal of interviews, we believe the paper is now more digestible and focused. In addition, we have created a new Table 2 to summarize the findings. The original Table 2 is now supplemental Table 3 for readers who wish to learn more details about the contents and interpretation of relevant documents in
VERSION 2 – REVIEW

| REVIEWER | Urtaran-Laresgoiti, Maider |
|----------|---------------------------|
|          | University of Deusto, Deusto Business School Health |
| REVIEW RETURNED | 10-Apr-2021 |

| GENERAL COMMENTS | I appreciate the work done and your effort to consider all points raised by reviewers. |
|------------------| I believe that changes made have contributed to improve the quality of the paper before its publication. However, I think some minor changes are still necessary before the final version of the manuscript is published. |
|                  | Find below my responses to authors to each of the points raised. |
|                  | Once more, I congratulate authors for their idea to do this research and contribute to such a necessary area of knowledge in the path to guarantee equity and quality in healthcare access. |
|                  | Responses to authors: |
|                  | The topic presented in this paper is of relevance as it contributes to highlight the restrictions in access to healthcare services of undocumented immigrants and to describe the heterogeneity in the responses to overcome legal barriers. The manuscript contributes with update data to reinforce previous research results and conclusions, which I consider relevant to drive changes at policy level to guarantee equity and healthcare quality for all population groups. |
|                  | Having said this, I think one of the main aspects to be considered when reviewing is the issue concerning interviewee sample selection criteria, which might a priori bias the results and conclusions of the “policy implementation and monitoring practices” section. Although it is acknowledged in the manuscript, I believe the section presents a lack of methodological strength and therefore I suggest removing from the final version. Unlike the first analysis of legal measures that were adopted in each AC, which is support by the review of rich primary data, this second analysis does not seem to have enough solidity to be published as for the bias it might present. |
|                  | We have removed the interviews from the paper, including the section on “policy implementation and monitoring practices.” |
|                  | Thank you for considering this point in your revision. I believe this change has resulted in making the manuscript more concise and targeted to answer paper objectives. |
|                  | Furthermore, I would recommend authors eliminating all repeated information in the discussion section that has been previously detailed in the results. In this sense, I propose reducing (or eliminating) paragraphs 2 and 3 of discussion section. |
|                  | Both paragraphs have been eliminated. |
|                  | All changes in this section have helped to improve clarity and add |


relevant information in order to discuss and compare results with previous documented knowledge.

I also suggest using one same term to refer to Autonomous Communities. Along the manuscript “Autonomous Community” and “region” and use indistinctively, which might lead to confusion the reader. I would choose the term Autonomous Communities, as this is the legal name that is adopted in Spain. Consider also the possibility to include a brief reference or explanation of AC, as readers from other countries may not be familiarized with this term.

Thank you for this suggestion. Term region/regional has been changed to AC throughout the paper. Also, in Strengths and Limitations of this Study section (page 2) and discussion section (page 8) we now indicate that Spain is formed by 17 Autonomous Communities.

I appreciate your consideration.

Finally, I would advise authors to consider the incorporation of some reflection in the manuscript about the appropriateness for conducting future research on the impact in terms of health outcomes derived of the policy changes, beyond the comparative analysis of legal and other policy measures adopted by AC.

This is a very important point. Thank you. We have now highlighted the need for research on health outcomes as a result of the policy changes, especially among immigrants (Discussion section, page 38 and 39).

Thank you, I think the idea is well taken up.

In order to improve the whole manuscript, please, consider the points listed down below before its publication.

§ Introduction:
- Page 5, Line 2: “...and excluded undocumented immigrants from publicly funded,...”. I would suggest noting that not only undocumented immigrants were affected, even if the measure particularly affected them.

There are many references to this statement: 1) Real Decreto-ley 16/2012, de 20 de abril, de medidas urgentes para garantizar la sostenibilidad del Sistema Nacional de Salud y mejorar la calidad y seguridad de sus prestaciones. BOE 2012 Abr 24; or 2) Urtaran-Laresgoiti M, Fonseca Peso J, Nuño-Solinís R. Solidarity against healthcare access restrictions on undocumented immigrants in Spain: the REDER case study. International Journal for Equity in Health. 2019;18(1).

In the introduction section, we expanded on the impact of the law per the reviewer’s suggestion. For example, the 2012 health reform not only excluded undocumented immigrants but also anyone age 27 and above who has never been employed (page 4). We included the references suggested (page 41, reference 5 and 6).

Please, correct this statement. It is not totally true. I would suggest considering what it is said in ref. 6 (in English), which explicitly mentioned that entitlement rights were linked to the working status of individuals, and thus the RD predominantly affected undocumented immigrants.
- Page 5. Line 13: “… a total of 3,366 newly…”. Correct thousands separator, please.
Corrected.
Ok.

Methods:
- Page 6. Line 12: “Aragón, Basque Country…”. I would suggest homogenizing all AC names into Spanish. All AC names are written in Spanish except Basque Country. The most correct way to resolve this issue without hampering the understanding might be referring to its as “Euskadi” and clarifying its meaning for English speakers, when first mentioned in the manuscript.

Thank you. Basque Country has been changed to Euskadi throughout the paper. Basque Country was put in parentheses after mentioning Euskadi for the first time in the abstract section (page 2), methods section (page 5), and result section (page 30).

Please, consider correcting in page 30, line 210 “the Euskadi” (without “the”).

- Page 8. Line 29: “…also based on the number of months…”. Is there any reason to choose this variable for the analysis? Explain if so, please.
This was selected as a proxy for the severity of the restriction.
I believe it has been clearly explained in the manuscript.

- Table 1: Which are the reasons behind the selection of the two access level indicators? Are there any previous researches that use same methodology? Explain, please.

We added to the start of the paragraph access indicators and its measures (Methods section, page 6) the source for selection of the two access level indicators. Specifically we indicate that “According to the main systemic barriers presented across official documents, we identified two access level indicators: proof of identification and proof of residency in an AC. We developed a model (see Figure 1) using these two indicators to assess the severity of the limitation on free general healthcare access among undocumented immigrants”

Well clarified, thank you.

- Page 10. Line 7: “…assumed that a patient needed to show…”. Is this correct, or does it need to be correct to the opposite meaning? If the type of identification was not specifically indicated by governmental instructions, it was assumed that patients needed to show or not? Please check.

The sentence is correct. If there was no indication that a patient needed to show an identification, it was assumed that they needed to present such identification. This assumption is based on the fact that the national law required this and that most services in Spain require identification unless a waiver is explicitly indicated.

My apologize. Understood; I think this new version makes easier to understand the idea.
Results:
- Table 3: (page 29. Line 8 and 3): reference numbers should appear as superscripts. Please correct.
Corrected.
Ok.

- Page 32. Line 59: “… (the) Basque Country issued…” Please consider this correction.
Corrected.
Ok.

- Page 34. Line 41: “Madrid issued 1 official (…) and one internal…”. Please homogenize either to numerical or written form to keep consistency. Consider the way that is chosen in other parts of the manuscript.
Corrected. Everywhere in the paper we use spelled out numbers except for where we discussed percentages, amounts, age, months, and years.
Ok.

- Table 4: (Page 39, Line 24): I think that with EOSICS it is refer to what is called EOXI in Galician. Please check and correct if needed. EOXI stands for “Estructura Organizativa de Xestión Integrada”.
Table 4 was removed from the paper following the reviewer’s comment on the validity of the “policy implementation and monitoring practices” section.
Ok.

- Page 40. Line 55. Please correct Castilla- La Mancha. Please, check and correct same mistake in all the manuscript.
Corrected. ‘L’ in ‘La’ has been capitalized throughout the paper where needed.
Ok.

Discussion:
- Page 41. 1st paragraph: Noted that this is not the first study to document healthcare access in Spain since enactment of RDL 16/2012. I suggest considering this research as an update of previous ones, such as Cimas et al 2016.

It is correct that a similar study was published by Cimas et al (now indicated in discussion section, page 35). However, Cimas et al. focused on the implementation of 2012 Royal Decree Law and Royal Decree and on general access to care. Our study has extended the scope to access to HIV treatment and most importantly on all policies and instructions implemented until Royal Decree law 7/2018. This paper extends the work published previously to cover further the contemporary issues stemming from the onset of the 2012 laws.

Pages 43 and 44: I propose including some quotations to support interviewees opinions and ideas.
The interviews have been removed from the article per the reviewer’s concern. Ok.

-References: I recommend including DOIs that are missing, and checking for misspelling and format errors in the references.

DOIs have been added where it was available and other corrections made to the references where applicable.

Please, DOIs to include, if possible:
Ref. 6: https://doi.org/10.1186/s12939-019-0971-9
Ref. 15: https://doi.org/10.1016/S0025-7753(01)72211-7

| REVIEWER          | De Vito, Elisabetta                |
|-------------------|-----------------------------------|
|                   | University of Cassino and Southern Lazio, Human, Social and Health Sciences |
| REVIEW RETURNED   | 25-Apr-2021                        |

| GENERAL COMMENTS  | The authors carried out an extensive revision, following the suggestions of peer reviewers. |