

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 novel health systems service design checklist to improve healthcare access for marginalized, underserved communities in Europe"
AUTHORS	Lazarus, Jeffrey; Baker, Lee; Cascio, Mario; Onyango, Denis; Schatz, Eberhard; Smith, Alyna; Spinnewijn, Freek

VERSION 1 – REVIEW

REVIEWER	Andrew Hayward UCL Collaborative Centre for Inclusion Health UCL Institute of Epidemiology and Health Care UK
REVIEW RETURNED	22-Nov-2019

GENERAL COMMENTS	<p>This is a very helpful description of a checklist produced by consensus methodology led by advocacy groups for marginalized populations. The checklist has been structured along the lines of WHO guidelines for integrated care which is very helpful. The checklist makes a valuable contribution to the emerging field of Inclusion Health and it may be worthwhile explicitly aligning it to this notion - as defined by Luchenski et al Inclusion Health is a service, research, and policy agenda that aims to prevent and redress health and social inequities among the most vulnerable and excluded populations.</p> <p>"https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31959-1/fulltext". The checklist will be of value to those designing, and auditing and improving, and commissioning services for socially excluded groups.</p> <p>Minor comments</p> <p>Page 9 - line 8 - it would be more accurate to say "in high income countries most chronic non communicable diseases are substantially more common and have worse outcomes in marginalised groups"</p> <p>Page 13 line 1 - I am not sure I agree with the comment about prisoners not being hard to reach - prisoners can be hard for health services to reach due to prioritisation of security measures over health measures - it can be very challenging for prisoners to access outpatient secondary care and prison health services are often not provided to be of the same quality as in the community. I do agree that prisons provide a good opportunity for multifaceted public health interventions though.</p> <p>Page 10 line 21 This section could be strengthened by mentioning the high cost of care that is characterised by high levels of unplanned emergency care - the most expensive types of hospital admission that may be reduced by better access to routine care.</p>
-------------------------	---

	<p>p12 line 12 - It might be helpful to reference this as an extreme example of Tudor Hart's Inverse Care Law https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(71)92410-X/fulltext</p> <p>p13 line 12 - It might be relevant to talk about the concept of audit of existing provision using the checklist</p> <p>Page 27 line 54 - I realise this table is reporting agreed statements so it may be difficult to change - however the wording about collection of data for research and advocacy implies that consent for such data collection is always needed - however in many instances analysis of appropriately anonymised service data for research and advocacy can be conducted without consent. Seeking consent may bias the findings by excluding those who are unable to engage in the consent process who may be most at need.</p>
--	---

REVIEWER	Elizabeth Such SchHARR, University of Sheffield, UK
REVIEW RETURNED	27-Jan-2020

GENERAL COMMENTS	<p>This communication paper is a useful addition to the applied literature on how to improve access to healthcare for marginalised populations. It describes the 'Nobody Left Outside (NLO)' Service Design Checklist which has been co-developed with NLO participants, representing marginalised service users. It is encouraging to see some helpful actionable tools in this field.</p> <p>General comments:</p> <ul style="list-style-type: none"> • I would like to know more about who the NLO participants were so that it is easy to scrutinise who is being represented in the process. This should go beyond the acknowledgements. Looks like 14 people involved. A clearer explanation of the process would help. I am left wondering about the internal and external validity of the tool; how it has been iteratively designed and how it will be tested. • It seems a little odd to me that there is Community involvement at the centre of Figure 1 but not any community involvement in the development of the tool or some apparent plans for testing it with communities. • A clearer definition of which communities are 'marginalised' would be helpful. There is reference to many but these are not consistently referred to. • These sorts of actionable tools require mobilising. I would like to know what plans there are in place to mobilise the tool <p>Specific comments:</p> <ul style="list-style-type: none"> • P.12 S line 15. Say in what way target communities can play a key role in services – development? Shaping? Defining? • Define PWUD – p.12 line 16 • P.12 line 22. Replace 'the homeless' with 'homeless people' or 'people who are homeless' • P.13 line 16 reference(s) needed • P.13 lines 9-11 the point about digital health tools is interesting but there is a very poor evidence base on the extent to which they help marginalised people access services. Digital access and literacy may actually be stratified and may contribute to widening health inequalities. • P.14 line 16 – definition of equity is inaccurate here. Equity about providing support proportionate to need, not providing all service users with the same access (equality) • P.15 lines 21-22. Some grammar issues with this sentence • Empowerment – a tricky concept. Please define/discuss
-------------------------	--

	<ul style="list-style-type: none"> • Table 1 section A1 – the notion of ‘community representatives’ is controversial; who judges this process? Risky. Should the item read ‘were people from the community involved in ...?’ • Table 1 A18. Item seems incomplete. What about age, sexuality, generation, ethnicity, migration background ...? • A23. What do you mean by incentives? Financial? Other? Clarify • A24 – digital tools. Is this an evidence led recommendation? Please identify evidence base, if so. • Define what is ‘peer’ in the main text – referenced in table 1. A25
--	---

VERSION 1 – AUTHOR RESPONSE

Response to peer review comments

Reviewer: 1. Andrew Hayward

UCL Collaborative Centre for Inclusion Health, UCL Institute of Epidemiology and Health Care, UK
 This is a very helpful description of a checklist produced by consensus methodology led by advocacy groups for marginalized populations. The checklist has been structured along the lines of WHO guidelines for integrated care which is very helpful.

The checklist makes a valuable contribution to the emerging field of Inclusion Health and it may be worthwhile explicitly aligning it to this notion - as defined by Luchenski et al Inclusion Health is a service, research, and policy agenda that aims to prevent and redress health and social inequities among the most vulnerable and excluded populations.

"[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)31959-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31959-1/fulltext)".

• RESPONSE: p.4. We agree and have added a sentence in the Introduction

P4: "An emergent approach termed "inclusion health" aims to address such extreme health and social inequities [Luchenski et al. 2018]"

• We have also cited this paper among the recommendations toward which our Checklist is aligned on P6.

The checklist will be of value to those designing, and auditing and improving, and commissioning services for socially excluded groups.

• RESPONSE: We agree and appreciate this acknowledgement.

Minor comments

Page 9 - line 8 - it would be more accurate to say "in high-income countries most chronic non-communicable diseases are substantially more common and have worse outcomes in marginalised groups"

• RESPONSE: Thank you, we have amended using your suggestion verbatim (current P4).

Page 13 line 1 - I am not sure I agree with the comment about prisoners not being hard to reach - prisoners can be hard for health services to reach due to prioritisation of security measures over health measures - it can be very challenging for prisoners to access outpatient secondary care and prison health services are often not provided to be of the same quality as in the community. I do agree that prisons provide a good opportunity for multifaceted public health interventions though.

• RESPONSE: We accept this point and suggest the following revised sentence to highlight the specific challenges faced by prisoners, based on this feedback.

P6: "Prisoners are another group facing specific challenges in accessing healthcare. In particular, access to secondary care may be limited by the prioritisation of security measures over healthcare services, while primary care services in prisons are often not provided to the same quality as in the community."

Page 10 line 21 This section could be strengthened by mentioning the high cost of care that is characterised by high levels of unplanned emergency care - the most expensive types of hospital admission that may be reduced by better access to routine care.

• RESPONSE: We accept this point. The fact that provision of timely routine care is cost saving versus hospital care was made in the previous version, with respect to migrants. But we agree that

this is a broader benefit across the marginalised underserved groups discussed and hence we have added the following sentence in the paragraph above

Page 11: “In particular, providing access to routine primary care services has potential to reduce the need for more expensive, unplanned emergency hospital care.”

p12 line 12 - It might be helpful to reference this as an extreme example of Tudor Hart's Inverse Care Law [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(71\)92410-X/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(71)92410-X/fulltext)

- Thank you – we agree and have added a clause (in italics) as follows.

p. 13 “Some of the people in Europe most in need of healthcare are amongst the least likely to receive it – this may be considered an extreme example of Tudor Hart's Inverse Care Law” (citation to Tudor Hart 1971].

p13 line 12 - It might be relevant to talk about the concept of audit of existing provision using the checklist

- RESPONSE: We agree, and we have added reference to this aspect as follows (in italics)

P15. “We believe the Checklist will be of use to health service policymakers, public health bodies, healthcare practitioner bodies and NGOs at all levels to use the Checklist when developing, updating, monitoring or auditing national or regional service provision and action plans for target groups.”

Page 27 line 54 - I realise this table is reporting agreed statements so it may be difficult to change - however the wording about collection of data for research and advocacy implies that consent for such data collection is always needed - however in many instances analysis of appropriately anonymised service data for research and advocacy can be conducted without consent. Seeking consent may bias the findings by excluding those who are unable to engage in the consent process who may be most at need.

- RESPONSE: We accept this point and have amended this item in the Checklist, with agreement from our collaborating groups, as follows (bold italics). Since the items are not discussed in detail, a specific explanation is out of the scope of the text, though we will consider addressing this point in the Guidance document provided online to support use of the Checklist.

P. 30: “C6. Are data gathered (with informed consent where appropriate and in a data protection-compliant manner) for research and advocacy purposes?”

Reviewer: 2. Elizabeth Such

SchHARR, University of Sheffield, UK

This communication paper is a useful addition to the applied literature on how to improve access to healthcare for marginalised populations. It describes the ‘Nobody Left Outside (NLO)’ Service Design Checklist which has been co-developed with NLO participants, representing marginalised service users. It is encouraging to see some helpful actionable tools in this field.

- RESPONSE: We welcome this acknowledgement.

General comments:

I would like to know more about who the NLO participants were so that it is easy to scrutinise who is being represented in the process. This should go beyond the acknowledgements. Looks like 14 people involved. A clearer explanation of the process would help. I am left wondering about the internal and external validity of the tool; how it has been iteratively designed and how it will be tested.

- RESPONSE – COMMUNITY PARTICIPATION: The Checklist has indeed been developed collaboratively by a unique collective of community advocacy organisations working together at the European level as the Nobody Left Outside initiative. These organisations were already listed in the Acknowledgements, and representatives of five of these organisations are co-authors of this paper. Further feedback was obtained from community organisations via the 2019 NLO Thematic Network, convened under the Health Policy Platform of the European Commission. We have made changes to ensure that these aspects are made fully clear – as detailed further below.

P2. “The Checklist was a collaborative project involving nine community advocacy organizations, with a focus on homeless people, PWUD, LGBTI people, prisoners, sex workers, and undocumented migrants.”

P5. "The Checklist was a collaborative project involving representatives of the following advocacy organizations working together as the NLO initiative: Africa Advocacy Foundation (AAF), Correlation European Harm Reduction Network, European AIDS Treatment Group (EATG), European Federation of National Organisations Working with the Homeless (FEANTSA), European Association for the Study of the Liver (EASL), Hepatitis C Trust, International Committee on the Rights of Sex Workers in Europe (ICRSE), International Lesbian, Gay, Bisexual, Trans and Intersex Association Europe (ILGA Europe), and the Platform for International Cooperation on Undocumented Migrants (PICUM), together with the Barcelona Institute for Global Health. Representatives of each organization were involved during the conception, development, revision and final approval of the Checklist."

P5. "The Checklist was developed with particular reference to the following communities: homeless people, people who use drugs (PWUD), lesbian, gay, bisexual, transgender and intersex (LGBTI) people, prisoners, sex workers and undocumented migrants – although its utility is not intended to be limited to these groups."

- **RESPONSE – TESTING:** We ensured internal validity during the collaborative development and consultation regarding external validation: as the paper acknowledged, the Checklist is not designed to be applicable in its entirety in any single situation – rather it provides a range of considerations for flexible use by stakeholders to improve service accessibility by marginalised groups. That said, pilot implementation studies are necessary and we have amended the paper to explain this and the NLO plans to this end.

P14: "As such, the Checklist is not intended to be universally applicable, wholesale. Rather, it provides a range of considerations that may be used flexibly for diverse purposes and adapted (with translation when needed) to particular settings. By the same token, given its breadth and the commonality of many access barriers, we expect the Checklist to have applications beyond the specific aforementioned communities."

P14. "We encourage researchers and other stakeholders to triangulate the Checklist versus existing available documentation and best practices relevant to service design for target communities. Pilot studies are also necessary to evaluate the functionality of the Checklist in practice. NLO participant organizations have recently called on the European Commission to support a Pilot Programme to coordinate and evaluate implementations of the Checklist in the context of delivering UHC in Europe.¹² Lazarus et al. 2019 NLO members are considering applications with their own communities while drawing attention to the Checklist to promote its use more broadly [Lazarus et al. 2019], with the support now of the NLO Goodwill Ambassador, former EU Commission for Health and Food Safety, Vytenis Andriukaitis. Users are invited to report their experience and to provide feedback via the NLO website (www.nobodyleftoutside.eu)."

It seems a little odd to me that there is Community involvement at the centre of Figure 1 but not any community involvement in the development of the tool or some apparent plans for testing it with communities.

- **RESPONSE:** As addressed in the Responses and changes above, the Checklist was indeed developed by community advocacy organisations and the NLO coalition is in the process of planning pilot evaluations.

A clearer definition of which communities are 'marginalised' would be helpful. There is reference to many but these are not consistently referred to.

- **RESPONSE:** The Checklist was developed with a focus on certain communities, given the expertise of NLO participating organisations. These were listed in the previous version but to make this clearer we have reiterated these as follows:

Abstract P2: "The Checklist was a collaborative project involving nine community advocacy organizations, with a focus on homeless people, PWUD, LGBTI people, prisoners, sex workers, and undocumented migrants."

Methods: p. 5: "The Checklist was developed with particular reference to the following communities: homeless people, PWUD, LGBTI people, prisoners, sex workers and undocumented migrants – although its utility is not intended to be limited to these groups."

Discussion:

P14. “The NLO Checklist was developed with particular attention to homeless people, PWUD, LGBTI people, prisoners, sex workers and undocumented migrants, based on the expertise of participating community organizations.”

P.14: “By the same token, given its breadth and the commonality of many access barriers, we expect the Checklist to have applications beyond the specific aforementioned communities.”

These sorts of actionable tools require mobilising. I would like to know what plans there are in place to mobilise the tool.

- RESPONSE: We agree and we have amended the Discussion to explain our actions to this end – as detailed in the above Responses.

Specific comments:

P.12 S line 15. Say in what was target communities can play a key role in services – development? Shaping? Defining?

- RESPONSE: We have amended this sentence as follows:

P8: “Target communities can play a key role in designing, delivering and assessing these services.”

Define PWUD – p.12 line 16

- RESPONSE: PWUD was/is already defined on page 4.

P.12 line 22. Replace ‘the homeless’ with ‘homeless people’ or ‘people who are homeless’

- RESPONSE: We agree – this has been changed here and elsewhere.

P.13 line 16 reference(s) needed

- RESPONSE: We believe the reviewer is referring to the sentence: “Negative attitudes among health professionals towards marginalized groups can also be an important barrier to access and can compromise care”. We have amended this sentence and added a reference of the Joint United Nations on ending discrimination in healthcare settings, as follows:

P9. “Discrimination within healthcare settings towards marginalized groups can also be an important barrier to access and can compromise care [Joint UN Statement]”

P.13 lines 9-11 the point about digital health tools is interesting but there is a very poor evidence base on the extent to which they help marginalised people access services. Digital access and literacy may actually be stratified and may contribute to widening health inequalities.

- RESPONSE: We maintain that digital health tools show promise and hence have cited additional examples together with the 2019 WHO guidance on this aspect. However, we do accept that the evidence base is limited, and that a potential unintended consequence of digital health interventions could be to widen inequalities. Accordingly, we have amended this sentence as follows to acknowledge these points.

P9: “Digital health tools, especially mobile phone apps, also show promise for this purpose [Fernández-Gutiérrez et al. 2019; Strestha et al. 2020; WHO 2019]. For example, the Refaid app (<https://refaid.com>) shows migrants and refugees the location of nearby services. However, the evidence base supporting these interventions is limited at present, and care must be taken to ensure their use does not contribute to widening health inequalities.

P.14 line 16 – definition of equity is inaccurate here. Equity about providing support proportionate to need, not providing all service users with the same access (equality)

- RESPONSE: We accept that some caveat with respect to need is appropriate here and so have amended the sentence as follows:

P. 10: Service design should be based on the fundamental principle of equity, whereby all protocols, guidelines and policies should provide all service users with the same access to medical products and technologies as everyone else, subject to need and according to the best standard of care that is locally available (C1; Table 3).

P.15 lines 21-22. Some grammar issues with this sentence

- RESPONSE: Apologies, we have corrected this sentence as follows:

P12. “Evidence also clearly indicates that housing assistance for homeless people benefits health service utilization...”

Empowerment – a tricky concept. Please define/discuss

- RESPONSE: This term is used with reference to the alignment of the Checklist with the WHO framework for action on integrated health services. Accordingly, we have added a definition of empowerment based on the WHO text.

P14: "... empowerment of target communities (i.e. providing people with the necessary education, skills and resources they need to take control of their own health and to play an active role in defining problems, decision-making and actions to manage their health), ..."

Table 1 section A1 – the notion of 'community representatives' is controversial; who judges this process? Risky. Should the item read 'were people from the community involved in ...?'

- RESPONSE: We accept this point and have changed the item to read:

P27. "Were people from the target community involved in the design of the service?"

Further, we have made the following additional changes

p. 10 as follows: "... and that people from target communities (including but not limited to community advocacy organizations) are involved in this process."

P 12: "The NLO Checklist (Table 4) is intended to promote the involvement of people from target communities and/or community advocacy organisations in the planning..."

We have also changed the text on p. 2, p. 3, p.15 to refer to "community advocacy organizations" rather than organizations representing communities.

Table 1 A18. Item seems incomplete. What about age, sexuality, generation, ethnicity, migration background ...?

- RESPONSE: We accept this point and the value of adding these additional items (except 'generation'). We have amended the sentence as follows:

P28: "A18. Being suitably tailored to be sensitive to users' sexuality, ethnicity, migration status, culture, faith, gender, housing status and lifestyle?"

A23. What do you mean by incentives? Financial? Other? Clarify

- RESPONSE: We have amended this sentence as follows: "A23. Providing incentives (e.g. financial) for users to use the service?"

A discussion of the types of incentives (which may differ between target groups) is beyond the scope of this article.

A24 – digital tools. Is this an evidence led recommendation? Please identify evidence base, if so.

- RESPONSE: In response to the reviewers comment above, we have added two extra references to support the usefulness of certain digital tools in the corresponding part of the body text, together with an acknowledgement that the evidence based is limited at present.

- Further, to take this point into account we have amended this item as follows:

A24. Using digital tools with evidence of benefit to help link people to care?

Define what is 'peer' in the main text – referenced in table 1. A25

- RESPONSE: We have now defined "peer" on page 8 as "... (people with lived experience of challenges similar to those faced by the service user)", based on and citing the 2019 WHO guidance module on this topic.