PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Implementation of the Assistive Product List (APL) in Malawi through development of appropriate policy and systems: An Action Research Protocol
AUTHORS	Ebuenyi, Ikenna; Smith, Emma; Kafumba, Juba; Jamali, Monica; Munthali, Alister; MacLachlan, Malcolm

VERSION 1 – REVIEW

REVIEWER	Luc de Witte University of Sheffield United Kingdom
REVIEW RETURNED	31-May-2020

GENERAL COMMENTS	This paper describes the approach of a planned project aiming to develop and implement a national policy and related implementation system(s) for AT provision in Malawi. This is an important topic and it is relevant that the protocol of such research is published. There are, however, a few minor issues that, when resolved, would increase the relevance of the paper. In random order: 1. The title focuses on empowering users, but in the project approach this is not so obvious. The focus is more on developing and implementing a policy framework. It would be better if the aims of the study would be more clearly reflected in the title. 2. There is no mention of the planned study period. 3. There are quite a few minor typing errors (double words, words missing, etc.). It would be good to have the paper proofread to eliminate this (very minor) issues. 4. The description of the methodology is a bit confusing. In the section "methods and analysis" the approach is described in general terms, followed by a section "formative research" that give more detail and describes 5 phases. The general description is not entirely in line with the details under "formative research". I think it would be more clear to write one section with all the details. 5. The description of the methodology is very open ("The specific research methods described below are tactical and will be decided by....."). This is understandable given the chosen research paradigm, but I would prefer a more 'straight forward' description, something like: ..... The study will be conducted in five phases. The details of each phase will be decided during the project, but these phases will guide the work throughout the project......". Where it is impossible to give detail about the approach it is possible (and would be good) to describe how that detail will be decided. 6. In the methods section a whole range of tools, models and frameworks are introduced (EquiPP, SDG matrix, Smart Thinking

Matrix and others). Most readers will not be familiar with these, so I believe a bit more explanation/description would be good.

REVIEWER	Agnes Meershoek CAPHRI Care and Public Health Research Institute Maastricht University The Netherlands
REVIEW RETURNED	06-Jul-2020

| GENERAL COMMENTS | The paper describes a protocol for an project employing an Action Research approach to develop and implement policy with regard to Assistive Technology in Malawi. Given the number of people with disabilities in LIC in general and in Malawi in particular, and the problem of access to support this is a highly relevant project. The design is appropriate, especially as it provides the opportunity to not only investigate the situation, but to bring change in policy and practice and has the potential to empower recipients simultaneously. The approach is challenging as well, and at some points more explanation is needed on how the researchers envision to practical implementation.

In the introduction you introduce the 5Ps in the text, and mention an additional 5Ps that are covered in the figure that shows a 10 Ps model. These additional 5 Ps are not explained in the text however, and not for all it is clear what they mean.
The concept of collective leadership is not explained very well. Although I do understand that it is a shared responsibility of the main stakeholders, it is not clear who the main stakeholders are. Furthermore on page 9 you mention that decisions are taken in consultation with key stakeholders in ARG. Consultation is different from shared decision making. Also, the stakeholders are not equal in power and familiarity with decision making, meetings, negotiations etc. How do you guarantee that voices of less powerful are not overruled by more powerful, vocal stakeholders? Collective leadership can have advantages, but is also difficult to achieve. So, please clarify the distribution of responsibility between the research team, the stakeholders and the ARG and how you envision this collective leadership in practice and how you safeguard against pitfalls of collective leadership.

The paragraph on data analysis is not well developed. More precision on what type of analysis in each phase of the project will be used for what type of data is required.

In the introduction you mention that recipients should be in the center according to the 5Ps. But recipients are only a sub group in one of the 5 stakeholder groups. In action research I would expect a more prominent role for PwD in the ARG. Also, when you refer to main stakeholders you give the Ministries as example, not PwD or their representatives.
In Phase one, the preparatory work, you will conduct a literature review. Although you mention to include grey literature, I'm not sure whether that provides insides in the perspectives of PwD themselves. It might be necessary to use other methods, such as interview, to get insight in their perspectives. Now they are only mentioned explicitly in phase 4 Implementation and Evaluation. Given the fact that only 5% has access to AT, insight in their perspectives in why they do not make use of AT is crucial for the development phase as well. In a AR approach I would expect a more prominent role for PwD. |

You will make use of the EquiPP framework, but no explanation is given about this framework.

In the section on data collection and management you mention very briefly you will make use of the ethical principles for rather straightforward research with respondents (that anonymity is guaranteed and informed consent will be obtained). As you employ an action Research Approach, intend to involve stakeholders and ARG and opt for collective leadership this is not sufficient as study set up and interaction between study participants and researchers is far more complex. Who do you consider study participants? What different types can be distinguished and do the same procedures with regard to anonymity and informed consent apply to them? You employ an emergent design, in which methods will be decided upon during the research cycle; will informed consent be renewed in every phase? Deliberation between stakeholders is part of the research process, how can that be done anonymously? Or do you not consider the stakeholders as research participants? But if not, what procedures will be in place to deal with them in an appropriate way? How do you deal with power imbalances between stakeholders? More explanation should be provided on these ethical issues adjusted to this specific research design.

There is overlap between the discussion and conclusion and the previous sections of the protocol, especially in emphasizing the strengths of the study that are also mentioned in the study rationale. They can be written more concise to create space to address in more detail in the protocol how you will deal with the challenges of AR in the project.

REVIEWER	Olive Kobusingye Makerere University School of Public Health UGANDA
REVIEW RETURNED	11-Jul-2020

GENERAL COMMENTS	Minor edits Page 3, last sentence of the first paragraph, lines 13/14: the authors should decide if they want it to be 'that policy' or 'such policies'. Line 35: I think the authors are aiming to see that the policy is implemented – which would mean it is implementable. Page 5, line 29: reversed words. …'and systems' should be 'systems and' … Page 11, end of paragraph 1, lines 30 – 35: It is not clear what the country capacity assessment has to do with this project. Please clarify. Page 19, lines 15 and 23 have typos in them – wrong words. More serious concerns: The project is supposed to be hinged on the 10Ps of systems thinking for assistive technology, with people at the center. All the work that has been done, and it is all well referenced in the proposal, talks of the importance of involving the users of AT. The role of these users does not come out clearly in this proposal. They were not mentioned as a stakeholder group in the beginning (top of Page 10), and by implication they are not represented in the Action Research Group. It would seem that in this proposal, the role of the users is limited to their being beneficiaries of the policies and their implementation, but not part of the process. They

	are being identified in Phase 4 (Page 12, line 49), and being asked to make presentations of their experiences in a meeting of the Action Research Group. Timeframe: There is no timeframe. It is acknowledged that because of the method used, and the number of stakeholders and ministries involved, the process could be slow (Page 18, lines 42 – 47), but it would be helpful for the authors to give a sense of how long they anticipate for the various phases.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Luc de Witte
Institution and Country: University of Sheffield, United Kingdom Please state any competing interests or state 'None declared': None declared

This paper describes the approach of a planned project aiming to develop and implement a national policy and related implementation system(s) for AT provision in Malawi. This is an important topic and it is relevant that the protocol of such research is published. There are, however, a few minor issues that, when resolved, would increase the relevance of the paper. In random order:

Thank you for reviewing our manuscript ad confirming the importance of the topic and protocol. We have considered your suggestions and observations in the revised manuscript and our response to your specific comments are shown below:

1. The title focuses on empowering users, but in the project approach this is not so obvious. The focus is more on developing and implementing a policy framework. It would be better if the aims of the study would be more clearly reflected in the title.

Thank you for this observation. We believe that an implementable Assistive technology (AT) policy is pivotal to access to affordable assistive products. Access to AT would empower users of AT and increase participation (e.g in education). We have also modified the title to reflect this.

2. There is no mention of the planned study period.
Thank you for highlighting this omission. We have included the study period in the revised manuscript.

….. the 36 months (January 2019-December 2021) project. (Page 7, lines 13-14)

3. There are quite a few minor typing errors (double words, words missing, etc.). It would be good to have the paper proofread to eliminate this (very minor) issues.

Thank you for this observation, we have *reviewed the paper for typographical/ grammatical errors as recommended.*

4. The description of the methodology is a bit confusing. In the section "methods and analysis" the approach is described in general terms, followed by a section "formative research" that give more detail and describes 5 phases. The general description is not entirely in line with the details under "formative research". I think it would be more clear to write one section with all the details.

Thank you for the observations and suggestions. We have revised the method and analysis section to enhance understanding and flow.

The Approach section highlights a general overview of how the research is anticipated to be undertaken. The Formative research section is about events that happened prior to the project launch while the

research phases were developed during and after the project launch, as part of the action research decisions arrived at by the Action Research Group

We have rearranged the sections as shown in the revised manuscript.

Research Phases

The study will be conducted in five phases. The details of each phase will be collaboratively decided during the action research project, but these phases will guide the work throughout the project (Page 7, lines 30-32).

The five phases of the research are Preparatory Work, Policy Development, Systems Development, Implementation and Evaluation, and Knowledge Exchange (Figure 2). (Page 8, lines 1-2)

5. The description of the methodology is very open ("The specific research methods described below are tactical and will be decided by....."). This is understandable given the chosen research paradigm, but I would prefer a more 'straight forward' description, something like: ..... The study will be conducted in five phases. The details of each phase will be decided during the project, but these phases will guide the work throughout the project......". Where it is impossible to give detail about the approach it is possible (and would be good) to describe how that detail will be decided.

Thank you for the suggestion. We have included the suggestion under the approach and research phases section in the revised manuscript as shown below:

…..iterative process through a series of five phases,(Page 7, lines 1-2)

The study will be conducted in five phases. The details of each phase will be decided during the project, but these phases will guide the work throughout the project. (Page 7, lines 31-32)

5. In the methods section a whole range of tools, models and frameworks are introduced (EquiPP, SDG matrix, Smart Thinking Matrix and others). Most readers will not be familiar with these, so I believe a bit more explanation/description would be good.

Thank you for this observation and we agree that some readers may not be familiar with them. We have provided further explanations about them in the manuscript.

The EquiPP [32] tool was developed with the United Nations Partnership on the Rights of Persons with Disabilities (UNPRPD) and measures, evaluates and makes recommendations for improvement in regard to inclusive policy development and evaluation. It consists of 17 Key Actions that provide guidance on how to ensure an equitable and inclusive policy development process.(Page 8, line 32; Page 9, lines 1-3)

EquiFrame[36] which is a tool for Evaluating and Promoting the Inclusion of Vulnerable Groups and Core Concepts of Human Rights in Health Policy Documents. It consists of 21 Core Concepts that covers issues relating to universal, equitable and accessible healthcare. (Page 9, lines 16-18)

The SDG Matrix will be used to demonstrate the concept that that assistive products have a direct impact on the achievement of the SGDs. Tebbutt and colleagues suggest that assistive products can be both mediators and a moderators of SDG achievement.[5](Page 9, lines 26-28)

Force Field Analysis[34] *is a qualitative research method that conceptualises how forces for and against change are poised and thus helps in the systematic analysis of possible change processes. Bourdesian Analysis*[35] *applies the idea of the social space being composed of fields of identify and power relations which are likely to influence change process. (Page 9, lines 8-11)*

The SMART Thinking Matrix is a framework for conceptualizing intersections between systems levels and market shaping for assistive technology and was derived form a systematic review of the interface between these two literatures .[40]*(Page 10,lines 9-11)*

Reviewer: 2

Reviewer Name: Agnes Meershoek
Institution and Country: CAPHRI Care and Public Health Research Institute, Maastricht University, The Netherlands Please state any competing interests or state 'None declared': None declared

The paper describes a protocol for an project employing an Action Research approach to develop and implement policy with regard to Assistive Technology in Malawi. Given the number of people with disabilities in LIC in general and in Malawi in particular, and the problem of access to support this is a highly relevant project. The design is appropriate, especially as it provides the opportunity to not only investigate the situation, but to bring change in policy and practice and has the potential to empower recipients simultaneously. The approach is challenging as well, and at some points more explanation is needed on how the researchers envision to practical implementation.

We are grateful for the review our manuscript and for confirming the relevance of the topic and appropriateness of our study design. We have considered your suggestions and observations in the revised manuscript and our response to your specific comments are shown below:

In the introduction you introduce the 5Ps in the text, and mention an additional 5Ps that are covered in the figure that shows a 10 Ps model. These additional 5 Ps are not explained in the text however, and not for all it is clear what they mean.

Thanks for these observations and suggestions. We have listed the additional 5Ps and also explained them.

The additional 5Ps include Procurement, Place, Pace, Promotion and Partnership; and are key situational factors for systems in diverse context. These situate the previous 5 Ps in national and local contexts that determine access to AT. For instance, to ensure that Procurement or purchasing AT products occur at national level in line with national and contextual factors that take into account Place or differences in local settings; at a Pace that is feasible and can be absorbed within the systems' capacity, using context sensitive methods to promote positive images of AT users and with cross cutting partnerships.[15]*(Page 5,lines 2-8)*

The concept of collective leadership is not explained very well. Although I do understand that it is a shared responsibility of the main stakeholders, it is not clear who the main stakeholders are. Furthermore on page 9 you mention that decisions are taken in consultation with key stakeholders in ARG. Consultation is different from shared decision making. Also, the stakeholders are not equal in power and familiarity with decision making, meetings, negotiations etc. How do you guarantee that voices of less powerful are not overruled by more powerful, vocal stakeholders? Collective leadership can have advantages, but is also difficult to achieve. So, please clarify the distribution of responsibility between the research team, the stakeholders and the ARG and how you envision this collective leadership in practice and how you safeguard against pitfalls of collective leadership.

We are grateful for these observations. The proposed 'collective leadership' approach was borne out in discussions and information from stakeholders in Malawi including users of Assistive technology. Disability is a cross cutting issue involving different government actors (ministries) and non-government actors (e.g NGOs and INGOs); however, in Malawi (probably in some other setting too) they operate without optimal collaborations. It has led to duplication of activities that could have been undertaken together by these different actors.

We have deleted the word consultation and replaced it with working together to reflect what we have been doing since the project launch. The stakeholders and the ARG include persons with disabilities and users of AT. They dictate the pace and direction of the project while the research group provide research support.
We agree that collective leadership is difficult to achieve and we are experiencing and documenting those challenges. Managing and navigating the power relations has also been a learning curve and so far, all stakeholders have always voiced their support or reservations in the project in a constructive way. We are documenting all these events and intend to present it in future as part of lessons from our project.

We have defined collective leadership in the revised manuscript:

Collective leadership refers to a group of people working together to achieve a set goal.[28, 29] In this case, we envision co-construction of leadership and shared responsibility by different stakeholders involved in AT in Malawi.[30](Page 6, lines 24-26)

We have also highlighted how we intend to manage power imbalances and pitfalls of collective leadership:

We would strive to minimize power imbalances and the pitfalls of collective leadership by continuous learning and knowledge sharing to co-construct what works for everyone through reflective dialogues.[31](Page 6, lines 29-31)

The paragraph on data analysis is not well developed. More precision on what type of analysis in each phase of the project will be used for what type of data is required.

Thank you for the suggestion. We have revised the paragraph to provide further clarity:

The data analysis method adopted will be dependent on the data type from the different phases of the study. For instance, analytic review methods would be used for literature and document review in phases 1 and 5.[41] For qualitative data(From phases 1-5), content and framework analysis will be used while for quantitative data (Phase 1, 2 and 3), descriptive statistics and regression analysis will be undertaken to understand factors relevant for improved access to AT and creation of a nation AT policy in Malawi.[41]

The EquIPP and EquiFrame tools[32, 36] would also be used to analyze existing policy on disability and the proposed AT policy. (Page 12, lines 15-21)

In the introduction you mention that recipients should be in the center according to the 5Ps. But recipients are only a sub group in one of the 5 stakeholder groups. In action research I would expect a more prominent role for PwD in the ARG. Also, when you refer to main stakeholders you give the Ministries as example, not PwD or their representatives.

Thank you for this question and observation. The group categorization is for planning purposes and not a homogenous group. Persons with disabilities and users of AT are in all groups 1-4. There are persons with disabilities and users of AT among the government stakeholders, Non-governmental for-profit

stakeholders and academic institutions. Having a disability or being an AT user does not in any way affect those roles and some of stakeholders and ARG members wear different hats.

We have added further clarification to highlight the role of users of AT:

It is pertinent to state that persons with disabilities and users AT products are not restricted to only group four but are also in the other groups. They are involved in all the research processes and as part of the ARG. (Page 7, lines 25-26)

In Phase one, the preparatory work, you will conduct a literature review. Although you mention to include grey literature, I'm not sure whether that provides insides in the perspectives of PwD themselves. It might be necessary to use other methods, such as interview, to get insight in their perspectives. Now they are only mentioned explicitly in phase 4 Implementation and Evaluation. Given the fact that only 5% has access to AT, insight in their perspectives in why they do not make use of AT is crucial for the development phase as well. In a AR approach I would expect a more prominent role for PwD.

Thank you for this suggestion. We obtained secondary data from the country capacity assessment undertaken by CHAI. However, we also intend to conduct further interviews in this phase to understand the perspectives of the AT users.

We have included this in the revised manuscript.

In addition, we would conduct interviews with users and providers of AT guided by the data from a Country Capacity assessment by the Clinton Health Access Initiative (CHAI) in partnership with the Assistive Technology 2030 project. (Page 8, lines 28-30)

You will make use of the EquiPP framework, but no explanation is given about this framework.

Thank you for this suggestion. We have addressed this omission based on earlier comments from Reviewer 1:

The EquIPP [32] tool was developed with the United Nations Partnership on the Rights of Persons with Disabilities (UNPRPD) and measures, evaluates and makes recommendations for improvement in regard to inclusive policy development and evaluation. It consists of 17 Key Actions that provide guidance on how to ensure an equitable and inclusive policy development process. (Page 8, line 32; Page 9, lines 1-3)

In the section on data collection and management you mention very briefly you will make use of the ethical principles for rather straightforward research with respondents (that anonymity is guaranteed and informed consent will be obtained). As you employ an action Research Approach, intend to involve stakeholders and ARG and opt for collective leadership this is not sufficient as study set up and interaction between study participants and researchers is far more complex. Who do you consider study participants? What different types can be distinguished and do the same procedures with regard to anonymity and informed consent apply to them? You employ an emergent design, in which methods will be decided upon during the research cycle; will informed consent be renewed in every phase? Deliberation between stakeholders is part of the research process, how can that be done anonymously? Or do you not consider the stakeholders as research participants? But if not, what procedures will be in place to deal with them in an appropriate way? How do you deal with power imbalances between stakeholders? More explanation should be provided on these ethical issues adjusted to this specific research design.

Thank you for these insights and suggestions. Following the project launch, we had these discussions with the ARG and agreed on the data management plan with them. What we all agreed is that all data must be obtained with consent and anonymised. So far, we have observed this and thus refrained from naming organisations in the network analysis we just completed and submitted for publication.

Informed consent would be obtained from all study participants or stakeholders who provide information that would be used in the research. We have reiterated this in the updated manuscript:

All data will be anonymized, and informed consent will be obtained from all study participants and stakeholders at every stage of the research process. Study participants entail all who are recruited or invited to participate in the study and may include stakeholders who are users or providers of AT (Page 12, lines 6-8)

There is overlap between the discussion and conclusion and the previous sections of the protocol, especially in emphasizing the strengths of the study that are also mentioned in the study rationale. They can be written more concise to create space to address in more detail in the protocol how you will deal with the challenges of AR in the project.

Thank you for the suggestion. We have deleted the conclusion section and merged it with the discussion based on the editor's recommendation. We have also added a statement of how we intend to manage the challenges from our adopted research method.

We hope to address these through action learning and transdisciplinary approaches recommended for use in assistive technology projects.[26](Page 14, lines 8-9)

Reviewer: 3

Reviewer Name: Olive Kobusingye
Institution and Country: Makerere University School of Public Health UGANDA Please state any competing interests or state 'None declared': NONE declared

Thank you for the review of our manuscript and the suggestions. We have considered them in the updated manuscript as show below:

Minor edits
Page 3, last sentence of the first paragraph, lines 13/14: the authors should decide if they want it to be 'that policy' or 'such policies'.

Thank you for this correction, it has been addressed based on Reviewer 1's recommendation.

……specify a system capable of implementing such policies in low-income countries …(Page 2, line 10)

Line 35: I think the authors are aiming to see that the policy is implemented – which would mean it is implementable.

Thank you for the suggestion We have deleted implemented and left implementable (Page 2, line 18)

Page 5, line 29: reversed words. …'and systems' should be 'systems and' …

Thanks for the correcting, we have addressed it (Page 4, line 11)

Page 11, end of paragraph 1, lines 30 – 35: It is not clear what the country capacity assessment has to do with this project. Please clarify.

Thank you for the observation and question. The statement has been deleted from the revised manuscript as part of the recommended revisions.

Page 19, lines 15 and 23 have typos in them – wrong words.

Thank you for the identifying the errors. We have addressed these errors (Page 14, lines 8-16)

More serious concerns:
The project is supposed to be hinged on the 10Ps of systems thinking for assistive technology, with people at the center. All the work that has been done, and it is all well referenced in the proposal, talks of the importance of involving the users of AT. The role of these users does not come out clearly in this proposal. They were not mentioned as a stakeholder group in the beginning (top of Page 10), and by implication they are not represented in the Action Research Group. It would seem that in this proposal, the role of the users is limited to their being beneficiaries of the policies and their implementation, but not part of the process. They are being identified in Phase 4 (Page 12, line 49), and being asked to make presentations of their experiences in a meeting of the Action Research Group.

Thank you for these observations and suggestions. We have addressed this earlier thus:

The group categorization is for planning purposes and not a homogenous group. Persons with disabilities and users of AT are in all groups 1-4. There are persons with disabilities and users of AT among the government stakeholders, Non-governmental for-profit stakeholders, and academic institutions. Having a disability or being an AT user does not in any way affect those roles and some of the stakeholders and ARG members wear different hats.

We have added further clarification to highlight the role of users of AT:

It is pertinent to state that persons with disabilities and users AT products are not restricted to only group four but are also in the other groups. They are involved in all the research processes and part of the ARG. (Page 7, lines 25-26)

Timeframe: There is no timeframe. It is acknowledged that because of the method used, and the number of stakeholders and ministries involved, the process could be slow (Page 18, lines 42 – 47), but it would be helpful for the authors to give a sense of how long they anticipate for the various phases.

Thank you for highlighting this omission. We have included the study period in the revised manuscript.

….. the 36 months (January 2019-December 2021) project. (Page 7, lines 13-14)

VERSION 2 – REVIEW

REVIEWER	Agnes Meershoek Maastricht University The Netherlands
REVIEW RETURNED	07-Sep-2020

GENERAL COMMENTS	I think my concerns with the previous version are adequately addressed. I'm looking forward to publication of the results of this study.

REVIEWER	Olive Kobusingye Makerere University School of Public Health, Uganda
REVIEW RETURNED	20-Aug-2020

GENERAL COMMENTS	The manuscript is much improved by the clarifications and attention to suggested corrections.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2
Reviewer Name: Agnes Meershoek
Institution and Country: Maastricht University, The Netherlands
Please state any competing interests or state 'None declared': none declared

I think my concerns with the previous version are adequately addressed. I'm looking forward to publication of the results of this study.

Thank you for the review of our manuscript and the positive comments.

Reviewer: 3
Reviewer Name: Olive Kobusingye
Institution and Country: Makerere University School of Public Health, Uganda
Please state any competing interests or state 'None declared': None declared.

The manuscript is much improved by the clarifications and attention to suggested corrections.

Thank you for the review of our manuscript and the positive comments.