

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The Children and Young People's Health Partnership Evelina London Model of Care: Process Evaluation Protocol
AUTHORS	Satherley, Rose-Marie; Green, Judith; Sevdalis, Nick; Newham, James Joseph; Elsherbiny, Mohamed; Forman, Julia; Wolfe, Ingrid; Lingam, Raghu

VERSION 1 - REVIEW

REVIEWER	David Keller University of Colorado, School of Medicine Aurora, Colorado, USA
REVIEW RETURNED	06-Jan-2019

GENERAL COMMENTS	<p>I applaud the authors and the journal for taking the initiative to prepare and publish for peer review a plan for the process evaluation of novel population-based child health initiative. Unfortunately, this paper does not adequately describe the rationale for the evaluation methods chosen or the actual details of the mixed methods to be used to allow one to determine whether or not the proposed evaluation will adequately describe the processes implemented in the course of this initiative. It would be useful for the authors to clarify their thinking with special attention to the details of the evaluation process and the limitations of the methods proposed, so that we can judge, in the final analysis, whether they were able to achieve their goals.</p> <p>I apologize in advance if some of my comments reflect the American usages of the English language, as that may account for some of the difficulty that I experienced in understanding this manuscript. My specific comments follow.</p> <p>Abstract: This was actually the clearest part of the paper, defining the purpose of this study as "understanding the barriers and facilitators to implementing the model of care". The mixed methods proposed in the abstract include qualitative (interviews) and quantitative (administrative/clinical data, trial outcomes and questionnaires). In the body of the paper, other qualitative data sources were identified (focus groups, policy review)- that should be reflected in the abstract. I am not certain how "trial outcomes" help to understand the process of implementation. It seems to me that that should be part of the outcome evaluation discussed in the separate paper. The discussion of limitations seems to focus on the inevitable "desirability bias" associated with an unblinded qualitative evaluation. There are many other pitfalls in this type of evaluation, since the project is so large that it is impossible for the evaluator to look at all of the pieces and parts that go into it.</p>
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	<p>Introduction: The opening paragraph is grammatically unclear. I do not understand what the phrase “and in multi-morbidity” means in this context. In the second paragraph, the authors assert that current caregivers do not provide “planned, multidisciplinary” care, even though inpatient and subspecialty care are often provided by multidisciplinary teams. I would hesitate to characterize these systems weak, as suggested by your call for “stronger” health systems Please clarify. While I don’t practice in Britain, I believe that your system has had a focus on primary prevention similar to ours in the United States, including nutritional and developmental screening and immunizations through your general practitioners. The current practice may not be adequate (neither is ours, frankly), but it is not non-existent.</p> <p>The Intervention: The intervention is described at a high level, but it would be helpful in judging the appropriateness of the evaluation have more detail- what are the universal services that you intend to implement throughout Lambeth and Southwark and what are the targets services that you intend to implement regarding the three tracer conditions? It would also be helpful to understand the rationale for selecting those conditions. While they are common, they are not the conditions I would have selected to best improve health outcomes, given how common behavioral and developmental problems are within the child health population. Finally, the intervention seems to be focused on enhancing the care provided by GPs, who will be randomized to provide either universal services or universal services plus targeted services. Since you briefly describe a 4 part evaluation of the of that randomized trial, it would be helpful to clarify how the process evaluation described in the this paper with mesh with the larger evaluation proposed there. You also mention an economic evaluation, but it is not clear whether that is part of the outcome evaluation or the process evaluation.</p> <p>Theoretical construct for the process evaluation: I applaud the authors for using the RE-AIM model for this evaluation. The “E” of RE-AIM could be seen to overlap somewhat with the outcomes trial being described in the second paper. For purposed of this paper, I would try to look at the impact of the intervention on the entire population (the 90,000 children mentioned as living in the two boroughs) rather than on the more focused groups targets by the RCT. Adoption should look at not only the number of settings in which the new protocols are adopted, but also the degree to which they are adopted by providers/staff within those settings. Maintenance should not focus on the maintenance of outcomes in this context, but in maintenance of the “change package” that you have instituted.</p> <p>I am not certain that adding a second model (Normalisation Process Theory) adds anything to this analysis. I would suggest for clarity that you stay focused on RE-AIM.</p> <p>Aim: The two numbered overarching aims are clearly stated.</p> <p>Methods: The Stakeholders were intimately involved in the design of the intervention. Where they as engaged in the development of the evaluation? If so, state clearly. In defining the target groups for the intervention, the authors mention school nurses. Are they part of the change package? This presents further evidence of the need for more information about the intervention to help us assess</p>
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	<p>the appropriateness of the evaluation. The use of a “purposeful” sampling invite bias- how will the authors assure that their biases will not drive the selection of subjects for surveys or focus groups. Will there be incentives or offsets offered for participation? Finally, the limitation of the “tracer” conditions should be discussed. Extrapolating from one set of conditions to the broad array of development, physical and behavioral problems of children and youth may result in misestimating the impact of the intervention.</p> <p>Thank you for the opportunity to review this manuscript. I look forward to the results of the evaluation when it is published.</p>
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REVIEWER	Jeanne W. McAlister, BSN, MS, MHA Indiana University School of Medicine, Department of Pediatrics USA
REVIEW RETURNED	08-Jan-2019

GENERAL COMMENTS	<p>This paper is so interesting. It describes a broad reaching model of care capable of improving child, family, provider and health system outcomes. I very much value the qualitative and quantitative mixed method approach to the evaluation which I believe is spot on. I also value the “evolve” nature, that there will be learning and the model may change, improve, etc., over time. The interview and focus group depiction was very good and the capacity to use art expression for small children wonderful.</p> <p>I asked for but did not receive from the publishers the article describing the intervention itself. I studied the figure and table which helps somewhat.</p> <p>Having worked on pediatric care and system improvement efforts extensively what I have learned is very important to the work is a deep description of the “how” of the intervention. This helps understanding of those expected to change and also guides spread to scale for future learners. Therefore I would like to see a tighter hypothesis with more detailed outcomes. I find the language VERY broad (integrated model leads to better care). My experience is that the devil is in the details. Many will be learned from the evaluation but what exactly are the implementation steps of the intervention? Understanding these more explicitly helps with statement of the problem and clearly defined outcomes.</p> <p>With more clarification statements of the intervention and more specifics of the outcomes expected, I would recommend this paper (and its future results) for publication.</p> <p>Thank you.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Comments	Authors Response	Location in Manuscript
1 I applaud the authors and the journal for taking the initiative to prepare and publish for peer review a plan for the process evaluation of novel	Thank you for your positive comments. We feel the detail in this document provides additional information beyond the overview provided by the accompanying over-arching protocol	N/A

	population-based child health initiative.		
2	I would like to see a tighter hypothesis with more detailed outcomes. I find the language VERY broad (integrated model leads to better care). My experience is that the devil is in the details. Many will be learned from the evaluation but what exactly are the implementation steps of the intervention?	<p>This is a very good point, thank you. To try and clarify this we have included a brief description of the intervention of the CYPHP model of care. This is further detailed in our accompanying paper, which has been referenced. We have also amended the logic model (Figure 1) to provide more detail on the hypothesised mechanisms of change and related this to the TDF. We hope this details how we anticipate the interventions to have an effect. We have also briefly described how the CYPHP Model of Care was implemented.</p> <p>“To facilitate the design and operationalisation of the programme, the measurement and analysis of the implementation and outcomes of the CYPHP Evelina London model of care, the components of the programme have been conceptualised as a theoretical framework (or logic model; see Figure 1). The theoretical framework has been guided by the WHO health systems building blocks concept¹³ and was developed using workshop methods with the CYPHP programme team and wider stakeholders. The framework in Figure 1 shows how the CYPHP guiding principles (e.g. early intervention and prevention) and health system building blocks (e.g. technology) are in turn reflected in outputs (e.g. interventions and targeted/universal services), that are in turn reflected in outcomes (e.g. improved child health).</p> <p>The interventions within this framework were guided by the Theoretical Domains Framework (TDF¹⁰, which describes 12 behavioural domains which interventions may target to influence</p>	<p>Page 5</p> <p>Figure 1</p>

		<p>behaviour change. In brief, the targeted and universal interventions within the CYPHP Model have been designed to targeted barriers to effective management of physical, mental and social determinants of health at both the service-provider and patient-level to maximise behaviour change. In our accompanying paper, the hypothesised active components of each individual intervention have been mapped onto the TDF to evidence the proposed mechanisms of action through which the intervention may become effective.⁸In addition, the mechanism of action across the whole programme, at the service provider, family and system level are detailed in Figure 1.”</p> <p>“To aid implementation of the CYPHP Evelina London Model of Care, regular meetings with primary and secondary care providers, local Clinical Commissioning Groups, GP Federations, and materials to aid implementation using established behaviour change techniques were used.”</p>	
5	<p>Unfortunately, this paper does not adequately describe the rationale for the evaluation methods chosen or the actual details of the mixed methods to be used to allow one to determine whether or not the proposed evaluation will adequately describe the processes implemented in the course of this initiative</p>	<p>We appreciate these comments, and hope the further details we have now provided throughout the papers help to clarify our rationale for the evaluation methods and further details of methods. In particular, please refer to responses to reviewers comments 2 and 13 for review 1, and comments 2 and 3 for review 2.</p>	<p>Throughout manuscript, following reviewers comments</p>
6	<p>The mixed methods proposed in the abstract</p> <p>include qualitative (interviews) and quantitative (administrative/clinical data, trial outcomes and questionnaires). In the body of the paper, other qualitative data sources were identified (focus groups, policy review)- that should be reflected in the abstract.</p>	<p>Thank you, these have now been reflected in the abstract</p> <p>“Data collection and analysis include qualitative interviews and focus groups with stakeholders, a policy review and a quantitative analysis of routine clinical and administrative data and questionnaire data.”</p>	<p>Page 2 - Abstract</p>

7	<p>It would be useful for the authors to clarify their thinking with special attention to the details of the evaluation process and the limitations of the methods proposed, so that we can judge, in the final analysis, whether they were able to achieve their goals</p> <p>The discussion of limitations seems to focus on the inevitable “desirability bias” associated with an unblinded qualitative evaluation. There are many other pitfalls in this type of evaluation, since the project is so large that it is impossible for the evaluator to look at all of the pieces and parts that go into it</p>	<p>The limitations have been expanded on to include not only social desirability biases, but also the difficulties of studying the nuances of implementation processes in a complex intervention with a variety of stakeholders.</p> <p>“Given the complexity of the proposed interventions and the variability in both the target population and service providers, it is challenging to understand the nuances of implementing the CYPHP Evelina London Model of Care. However, by ensuring the inclusion of all stakeholders within the model, we hope to achieve a greater insight into how integrated care can be implemented for children and young people. We anticipate that this process evaluation will allow us to provide a comprehensive understanding of how outcomes were achieved by the program and how to implement programmes and integrated care models of this nature in alternative settings. ”</p>	Page 14
8	<p>Abstract: I am not certain how “trial outcomes” help to understand the process of implementation. It seems to me that that should be part of the outcome evaluation discussed in the separate paper.</p>	<p>Reference to “trial outcomes” has been removed from the abstract but the trial outcomes are briefly described in the paper (and separate paper referred to), to provide both context to the process evaluation and described in context of the E for Effectiveness. The trial outcomes have been described in a separate paper (please see response 9 for more information).</p>	Page 2 - Abstract
9	<p>The “E” of RE-AIM could be seen to overlap somewhat with the outcomes trial being described in the second paper. For purpose of this paper, I would try to look at the impact of the intervention on the entire population (the 90,000 children mentioned as living in the two boroughs) rather</p>	<p>Interesting point, thank you. This sister paper describes a population-level evaluation that will look at the effect of the intervention on the population of children in Lambeth and Southwark. However, the components of the process evaluation, particularly interviews and surveys with service providers, will help to understand the</p>	Table 1 Pages 9-10

	<p>than on the more focused groups targets by the RCT.</p>	<p>impact of universal services on the population as well as the targeted services.</p> <p>“All primary care service providers participating in the intervention arms of the CYPHP Evelina Model of Care will be invited to complete the Normalisation Process Theory tool (NoMAD), to understand the implementation of both the universal and targeted services.¹⁴”</p> <p>In this paper, we have discussed how the trial outcomes, form part of the E, but through the process evaluation we can gain deeper understanding into the E. Supplemented by outcome evaluation, the process evaluation can further explore these dimensions of the effectiveness of the CYPHP Evelina London Model of Care, and understand the conditions and mechanisms that contributed to this effectiveness (e.g. are there other programmes initiatives that may account for the trial outcomes).</p> <p>Table 1 has been amended to remove the details of the trial outcomes and elaborate on the assessment of conditions and mechanisms that may lead to these trial outcomes.</p> <ul style="list-style-type: none"> • What are the conditions and mechanisms that lead to trial outcomes? What explains variation in trial outcomes across sites? • What are stakeholder's perceptions of factors contributing to effectiveness (or ineffectiveness) of CYPHP outcomes? • Are there any unintended consequences? 	
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9	I do not understand what the phrase “and in multi-morbidity” means in this context.	<p>Apologies for this typo, it has been corrected:</p> <p>“In the context of increases in the numbers of children and young people (CYP) living with long-term conditions (physical and psychosocial) and multi-morbidity, current fractures within the system and healthcare delivery allow individuals to “fall through the gaps” in care.”</p>	Page 4
10	<p>In the second paragraph, the authors assert that current caregivers do not provide “planned, multidisciplinary” care, even though inpatient and subspecialty care are often provided by multidisciplinary teams. I would hesitate to characterize these systems weak, as suggested by your call for “stronger” health systems. Please clarify. While I don’t practice in Britain, I believe that your system has had a focus on primary prevention similar to ours in the United States, including nutritional and developmental screening and immunizations through your general practitioners. The current practice may not be adequate (neither is ours, frankly), but it is not non-existent.</p>	<p>Thank you for this point. We agree that the practices in Britain are weak and not ‘non existent’, and have modified the introduction to reflect this.</p> <p>“In the United Kingdom, paediatric healthcare models were originally developed to deliver acute, inpatient, and high intensity specialist services rather than to prevent illness and disease complications to maximise well-being and developmental potential.⁵ Despite improvements, current services are not as responsive to families’ needs as they should be, and are often inefficient with a reliance on high-cost emergency department attendance and acute admissions.^{5-7x} To improve CYP’s health, more effective, evidence-based care models are needed, together with public health, social and economic policies to promote and protect health.”</p>	Page 4
11	<p>The intervention is described at a high level, but it would be helpful in judging the appropriateness of the evaluation have more detail- what are the universal services that you intend to implement throughout Lambeth and Southwark and what are the targets services that you intend to implement regarding the three tracer conditions?</p> <p>It would also be helpful to understand the rationale for selecting those conditions While they are common,</p>	<p>Further details on the intervention have been included in the introduction of the paper and in Figure 1.. To try and clarify this we have included a description of the intervention components the CYPHP model of care, mapped to the Theoretical Domains Framework. This is further detailed in our accompanying paper, which has been referenced. We hope this details sufficiently how we anticipate the interventions to have an effect. Please see also response 2 for a more detailed response to this point.</p>	Pages 5-6

	<p>they are not the conditions I would have selected to best improve health outcomes, given how common behavioral and developmental problems are within the child health population.</p>	<p>We have tried now to make more explicit the rationale for selecting these conditions, described in the paper.</p> <p>“Tracer conditions were chosen as they are examples of long term and common conditions, which will provide generalisable lessons about improving outcomes through healthcare for CYP with ongoing conditions with the intention of designing a generalizable model of care for CYP with common and chronic conditions as part of a health system response to the epidemiological transition to chronic disease. ”</p>	
12	<p>Since you briefly describe a 4 part evaluation of the of that randomized trial, it would be helpful to clarify how the process evaluation described in the this paper with mesh with the larger evaluation proposed there. You also mention an economic evaluation, but it is not clear whether that is part of the outcome evaluation or the process evaluation.</p>	<p>The economic evaluation is part of the outcome evaluation and we have amended the wording to make this clear in this paper. In addition, we have further clarified how the process evaluation meshes with the larger randomised controlled trial.</p> <p>“In summary, the evaluation has four component parts: the outcome evaluation consists of a pseudo-anonymised population-based evaluation for all CYP in participating GP practices to explore changes in health service use across control and intervention arms, an evaluation of CYP with selected tracer conditions to understand changes in health and healthcare across control and intervention arms, and an economic evaluation to assess the costs of delivery and cost effectiveness of the CYPHP Evelina London Model of Care across tracer conditions. Alongside the outcome evaluation, a nested process evaluation, detailed in this paper, aims to understand how and why the CYPHP Evelina London model is effective or ineffective in achieving health, healthcare and health service use outcomes, and to identify</p>	Page 7

		contextually relevant strategies for successful implementation as well as practical difficulties in adoption, delivery, and maintenance to inform wider implementation.”	
13	Adoption should look at not only the number of settings in which the new protocols are adopted, but also the degree to which they are adopted by providers/staff within those settings. Maintenance should not focus on the maintenance of outcomes in this context, but in maintenance of the “change package” that you have instituted.	<p>The CYPHP programme is unusual, in that as a partnership the CYPHP Model of Care as a whole was agreed and adopted. Roll out was phased and iterative, allowing an opportunistic trial. However, some components of the CYPHP programme (e.g. referral to CYPHP Nursing Services, CYPHP Clinics) do require adoption from GP practice staff. We anticipate that these interventions will show variation in adoption. As a result, the paper describes the methods used to assess adoption in service providers (interviews, questionnaires, routinely collected data). No changes to content have been made, but we have changed the wording and structure of Table 1 to make this clearer to the reader.</p> <ul style="list-style-type: none"> • What proportion of targeted GP practices adopted CYPHP? Are there differences between GP practices and service providers that do or do not adopt CYPHP? • What affects stakeholder participation? • To what extent are intended stakeholders adopting and complying with the CYPHP program? <p>Data will not systematically be collected during the post-intervention period; however stakeholder will explore intentions to continue the principles of the CYPHP Evelina London Model of Care. This was described in Table 1, however, the wording has been changed to ensure this is clear that we are referring to the integrated care principles of the</p>	Table 1

		<p>programme and not the CYPHP programme itself.</p> <ul style="list-style-type: none"> • What are service managers and commissioner intentions to continue integrated care services for CYP, and what are the barriers to maintaining this way of working? • How have aspects of the model been incorporated into usual care; and/or incorporation of integrated care for CYP into future business planning? 	
14	<p>I am not certain that adding a second model (Normalisation Process Theory) adds anything to this analysis. I would suggest for clarity that you stay focused on RE-AIM.</p>	<p>The NoMAD tool (which was developed using NPT) will be used to assess the level of implementation of CYPHP services across primary care service providers. This can provide insight into the adoption/acceptability from the service provider perspective. Unfortunately, there is no other developed tool based on the RE-AIM framework to assess implementation. However, we agree that a detailed description of the NPT is not necessary and have instead included a brief description of NPT when describing the NoMAD tool.</p> <p>“All primary care service providers participating in the intervention arms of the CYPHP Evelina Model of Care will be invited to complete the Normalisation Process Theory tool (NoMAD).¹⁴ Normalisation Process Theory (NPT)¹² focuses on the implementation of new practices and how these new practices become embedded and sustained in their social contexts and the NoMAD is the NPT’s accompanying tool. The NoMAD tool consists of 23 items that measure the process of implementation from the perspectives of professionals directly involved in implementing complex interventions.</p>	Page 10

		The NoMAD tool was selected as it is the first validated measure to assess implementation processes and can be used across multiple stakeholders and settings, providing insight into the adoption of new services at the service provider level. In addition, routinely collected service satisfaction data from CYP and family surveys will be audited to assess satisfaction with the CYPHP services.”	
15	The Stakeholders were intimately involved in the design of the intervention. Where they as engaged in the development of the evaluation? If so, state clearly.	<p>We have improved the wording here, thank you.</p> <p>“Stakeholders were involved in the development of the theoretical framework for CYPHP, identification of research questions and refining the research methodology, including the development of questions for qualitative interviews and focus groups.”</p>	Page 9
16	In defining the target groups for the intervention, the authors mention school nurses. Are they part of the change package?	<p>As part of the health system strengthening initiative, there will be higher integration with schools and school nurses, however, school nurses are not directly targeted by the model of care. As a result, we have removed reference to school nurses when describing the target groups.</p> <p>“These interventions target service providers (GP receptionists, practice nurses, primary care providers), CYP and families.”</p>	Page 9
17	The use of a “purposeful” sampling invite bias- how will the authors assure that their biases will not drive the selection of subjects for surveys or focus groups. Will there be incentives or offsets offered for participation?	<p>No incentives will be offered for completion of the process evaluation, other than reimbursement of travel expenses.</p> <p>“Families will be reimbursed for any travel expenses, but no other form of incentive will be offered.”</p>	Pages 9 and 11

	<p>In purposeful sampling commonly, participants are directly selected by researchers; this situation can be perceived as increasing the risk of having a bias based on recruiters' decisions of who meets criteria for eligibility. However, in the context of this trial, the CYPHP research team are blinded to the amount or type of intervention a family has received, reducing recruiter decision bias. In addition, the use of purposive sampling ensures families who are invited to interview, have not been interviewed before.</p> <p>"Sampling will be purposive rather than statistical, to include CYP and families from diverse settings with a wide range of circumstances that may influence responsiveness and accessibility to healthcare. Families will be contacted via the researcher, who is blinded time, intensity or outcome of treatment."</p> <p>For recruitment of primary care providers to interviews, recruitment is guided by completion of the NoMAD tool and implementation strength, in order to target those from high and low engaging practices. All Primary Care providers will be invited to complete the NoMAD tool. Further details have been added to the protocol to make this more clear to the reader.</p> <p>"All primary care service providers participating in the intervention arms of the CYPHP Evelina Model of Care will be invited to complete the Normalisation Process Theory tool (NoMAD)."</p> <p>"Completion of NoMAD surveys and administrative data (previously described) will be used as an indicator of engagement and implementation</p>	
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		<p>strength to inform recruitment of service providers and these interviews. This will result in sufficient heterogeneity to provide examples of relatively poor and good adoption, delivery and maintenance, and will allow us to identify barriers and facilitators to implementation and to generate hypotheses about factors that may be associated with differing outcomes.”</p>	
18	<p>Finally, the limitation of the “tracer” conditions should be discussed. Extrapolating from one set of conditions to the broad array of development, physical and behavioral problems of children and youth may result in misestimating the impact of the intervention.</p>	<p>We understand the limitations of selecting a series of “tracer” conditions, but these conditions were chosen carefully to illustrate particular issues and challenges of care, and there is a literature supporting the use of tracer conditions for these purposes. We feel this approach will help us to identify lessons that can be applied for the integrated management of other ongoing conditions. We do not expect the same impact across the tracer conditions and will be looking for both parallels and divergences across tracer conditions. Although this limitation has been reflected on, we also highlight the advantages that we anticipate from examining these tracer conditions.</p> <p>We would also like to stress that the process evaluation is not specific to the tracer condition evaluation but aims to better understand the whole CYPHP model of care. For example, to better understand the barriers to embedding the CYPHP clinics which are available to all children, we will be examining service provider perspectives and examining, how representative of the population of children receiving services are, and principles of embedding and understanding aspects of the model of care.</p>	Page 14

		<p>“A large part of this process evaluation focuses on four tracer conditions to understand the implementation of integrated care models for CYP. These conditions were selected with the intention of designing a generalizable model of care for CYP with common and chronic conditions as part of a health system response to the epidemiological transition to chronic disease. In addition, by selecting four tracer conditions we will be able to examine the parallels and divergences across a range of conditions, to support us in understanding how integrated care may be applied to a variety of conditions. However, these findings should be treated with caution and applying these findings to other conditions to another should be done cautiously.”</p>	
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Reviewer 2 comments		Author's response	Location in manuscript
1	<p>This paper is so interesting. It describes a broad reaching model of care capable of improving child, family, provider and health system outcomes. I very much value the qualitative and quantitative mixed method approach to the evaluation which I believe is spot on. I also value the “evolve” nature, that there will be learning and the model may change, improve, etc., over time. The interview and focus group depiction was very good and the capacity to use art expression for small children wonderful.</p>	<p>Thank you for your very positive comments as it is a delight to hear such enthusiasm for the work we are doing</p>	N/A
2	<p>I asked for but did not receive from the publishers the article describing the intervention itself. I studied the figure and table which helps somewhat.</p>	<p>This is a very good point. To try and clarify this we have included a brief description of the intervention of the CYPHP model of care. This is further detailed in our accompanying paper, which has been referenced. We have also amended the logic model (Figure 1) to provide more detail on the hypothesised mechanisms of change and related this to the TDF. We</p>	<p>Pages 4-5 Figure 1</p>

		<p>hope this details how we anticipate the interventions to have an effect.</p> <p>“To facilitate the design and operationalisation of the programme, the measurement and analysis of the implementation and outcomes of the CYPHP Evelina London model of care, the components of the programme have been conceptualised as a theoretical framework (or logic model; see Figure 1). The theoretical framework has been guided by the WHO health systems building blocks concept¹³ and was developed using workshop methods with the CYPHP programme team and wider stakeholders. The framework in Figure 1 shows how the CYPHP guiding principles (e.g. early intervention and prevention) and health system building blocks (e.g. technology) are in turn reflected in outputs (e.g. interventions and targeted/universal services), that are in turn reflected in outcomes (e.g. improved child health).</p> <p>The interventions within this framework were guided by the Theoretical Domains Framework (TDF¹⁰, which describes 12 behavioural domains which interventions may target to influence behaviour change. In brief, the targeted and universal interventions within the CYPHP Model have been designed to targeted barriers to effective management of physical, mental and social determinants of health at both the service-provider and patient-level to maximise behaviour change. In our accompanying paper, the hypothesised active components of each individual intervention have been mapped onto the TDF to evidence the proposed mechanisms of action through which the intervention may become effective.⁸In addition, the mechanism of action across the whole programme, at the service provider, family and system level are detailed in Figure 1.”</p>	
3	Having worked on pediatric care and system improvement efforts extensively what I have learned is very important to the work is a deep description of the “how” of the	This is a very good point. To try and clarify this we have included a brief description of the intervention of the CYPHP model of care. This is further detailed in our accompanying paper, which has been	Figure 1 Pages 5-6

intervention. This helps understanding of those expected to change and also guides spread to scale for future learners. Therefore I would like to see a tighter hypothesis with more detailed outcomes. I find the language VERY broad (integrated model leads to better care). My experience is that the devil is in the details. Many will be learned from the evaluation but what exactly are the implementation steps of the intervention? Understanding these more explicitly helps with statement of the problem and clearly defined outcomes.	referenced. We have also amended the logic model (Figure 1) to provide more detail on the hypothesised mechanisms of change and related this to the TDF. We hope this details how we anticipate the interventions to have an effect. We have also briefly described how the CYPHP Model of Care was implemented. A detailed response to this comment can be found in response to reviewers comment 2.	
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VERSION 2 – REVIEW

REVIEWER	David M Keller University of Colorado School of Medicine, Aurora CO USA
REVIEW RETURNED	11-Apr-2019

GENERAL COMMENTS	The revised paper addresses quite nicely all of the concerns raised in my initial review. Look forward to seeing it in print.
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