Meeting Report: Ethical Issues Surrounding Preconception Care

Hafez Ismaili M'hamdi, Meertien K Sijpkens, Inez de Beaufort, Medard Hilhorst, Brian Jack, Guido Pennings, Wim Pinxten, Jill Shawe, Regine P. M. Steegers-Theunissen, Elsbeth van Vliet Lachotzki, Eric A. P. Steegers.

Meeting Report: Ethical Issues Surrounding Preconception Care submitted

Abstract

Background: Embryonic and fetal development are key determinants for pregnancy outcomes and life-long health. Preconception care aims to identify, manage and counteract risk factors to prevent or limit the impediment of this development. Moreover, it provides an excellent opportunity to improve couples informed decision-making by providing information on reproductive choices. Unfortunately, in most countries the uptake of PCC remains low. Moreover, it is usually provided infrequently and on an opportunistic basis.

Objective: In response to the high prevalence of adverse pregnancy outcomes, especially among vulnerable women, and the poor uptake of PCC, an international and interdisciplinary expert meeting was organized in October 2016. The objective was to (i) discuss the key barriers in the provision, uptake and implementation of preconception care, (ii) to explore the gaps in current research and (iii) to explore the potential of new scientific insights to further improve pregnancy outcomes.

Results: This report presents the most important outcomes of this meeting. These include the provision of tailor-made care; the definition and distribution of roles and responsibilities of caregivers; the inclusion of fertility counseling in preconception care and the development of pathways that cut across the medical and non-medical domains.

Keywords: preconception care, ethics, expert meeting, responsibility, inequity, epigenetics, fertility counseling, nudging

Introduction

Embryonic and fetal development are key determinants for pregnancy outcomes and life-long health.(1-3) Preconception care (PCC) aims to identify, manage and counteract risk factors to prevent the impediment of this development and it aims to improve couples informed decision-making by providing information on reproductive choices.(4) Especially vulnerable women living in deprived circumstances face higher risks to have adverse pregnancy outcomes due to an accumulation of risk factors.(5) There is compelling evidence for the effectiveness of a list of PCC interventions such as folic acid supplementation, smoking cessation and dietary improvement.(6) Given that the risks of adverse pregnancy outcomes can be reduced, the empowerment of mothers-to-be to adequately prepare for pregnancy by offering them PCC is a medical and a moral imperative.

Unfortunately, in most countries the uptake of PCC remains low and it is usually provided infrequently and on an opportunistic basis.(7) In response to the unnecessary high prevalence of adverse pregnancy outcomes especially among vulnerable women, and the poor uptake of PCC, an international and interdisciplinary expert meeting was organized in October 2016. The aim was to (i) discuss the key barriers in the provision, uptake and implementation of PCC, (ii) to explore the gaps in current research and (iii) to explore the potential of new scientific insights to improve pregnancy outcomes. This report presents the most important outcomes of this meeting.

Method

The expert panel of 11 members consisted of clinicians, clinical researchers, medical ethicists, and a representative of a patient- federation (an alliance of 70 patient organizations). The discussion was structured around the following topics: (1) 'The concept of PCC and the role of caregivers' (2) 'reaching those who need care the most' (3) 'societal valorization of new knowledge' and (4) 'translating behavioral insights into PCC'. Each topic was introduced by a member of the expert panel. The subsequent discussions were guided by a list of questions and statements (Table 1). The results of this meeting are presented in the form of four recommendations. All panel members participated in reviewing and providing suggestions related to the content of the manuscript.

Recommendations

1. Reach consensus about the organization of PCC

a. Appoint a PCC-provider responsible for the uptake

Although there is consensus about the content of PCC (4, 8), a uniform strategy about the best ways to maximize the uptake of PCC is largely lacking.(7) This is mainly due to the poor organization of PCC, in which it is unclear who should develop, offer, provide, and fund PCC interventions. According to the expert panel, the poor uptake of PCC can in part be improved by appointing an easily identifiable PCC-provider, who acts as a case manager, responsible for the first contact for entry into PCC. Preferably, this contact should be someone who is easily approachable for parents-to-be, which in many cases is the general practitioner or public health nurse.

b. Provide tailor-made care

A major problem in improving the uptake in PCC, is that those who could benefit most from entering PCC are often unaware of PCC or do not consider themselves as the target public.(9, 10). Barrett et al. reported that different PCC approaches are needed for different groups of women with differing investments in pre-pregnancy health and care.(11) Building on these findings, clinical experts mentioned that it is necessary to consider that parents-to-be are mainly interested in their own personal risks and possible benefits rather than the entire package of PCC aims. For example, patients who were interested in identifying their personal genetic risk, were generally not interested in a general preconception consultation. The need for tailor-made care including personal risk identification and a clear presentation of possible health benefits is thus not only necessary for adequate PCC delivery but also for an improved uptake of PCC. Digital assessment tools such as 'Gabby' (12, 13), the mHealth coaching tool Smarter Pregnancy, (14) and the preconception risk assessment tool 'Preparing for Pregnancy' (15) may prove to benefit the uptake of PCC as they are easily accessible, generate personal risk assessments and provide tailor-made information and advice explaining why the identified risks are a potential problem and how the user can minimize these risks.

c. Define and distribute the roles and responsibilities of caregivers

In accordance with existing research, the panel was in agreement on the fact that PCC encompasses medical and non-medical domains such as gynecology and obstetrics, general medicine, reproductive health, pharmacy, public health, social services and personal lifestyle.(16) Whereas the preconception consultation and the delivery of health care clearly belong to the medical domain, the duty to provide preconception

information and the improvement the socioeconomic determinants of adverse pregnancy outcomes cuts across the medical and non-medical domains. In accordance with existing literature, a shared care model, an approach to care that includes the skills and knowledge of a range of professionals such as pregnancy related healthcare professionals, policy makers, social peer group networks and community social workers, has been proposed to secure the involvement of all relevant stakeholders and ameliorate the fair distribution of the responsibility to improve pregnancy outcomes.(17)

Members of the panel mentioned that the lack of a shared care model sometimes results in the untimely referral of patients to specialist care. For example and in line with existing research(10) they experience that some caregivers tend to treat patients too long and consequently misestimate the appropriate moment of referral. Members mentioned that caregivers tend to only deliver the care relevant to their domain, thereby overlooking other possible risks to pregnancy. For example, not all oncologists mention the possibility of egg freezing to women who will likely lose their fertility after treatment. Likewise, teratogenic medication is too often prescribed to women who might become pregnant without informing them about the reproductive risks. These examples reinforce the need for a shared care model.

2. Reach those who need care the most

a. Include fertility counseling in PCC

Most members mentioned that parents-to-be are highly motivated to explore issues related to fertility during the period before pregnancy. One clinical expert mentioned that discussing fertility as part of PCC, would offer an opportunity to engage men as well. Van der Zee et al. and Tuomainen et al. also report that fertility is an important subject for women with a desire to become pregnant.(18, 19) The gains of fertility care –achieving pregnancy or not– are moreover clear and visible, whereas the gains of PCC that deals with prevention are less clear to parents-to-be and perhaps also less clear to caregivers. Therefore, including fertility counseling in PCC may improve the uptake as couples are arguable most motivated to hear about PCC when fertility issues will also be discussed.

b. Develop pathways that cut across the medical and non-medical domain to address health inequalities

The observed inequalities in perinatal morbidity and mortality and the socioeconomic gradient which describes these inequalities raised questions of social justice and health equity.(20) One clinical expert mentioned that some women have such an accumulation of social and economic problems that they have lost self-governance and

autonomy which makes them powerless; unable to overcome their problems without help from social workers and caregivers. The member mentioned the 'Mothers of Rotterdam initiative' as an example of care that cuts across the medical and non-medical domain, not only guiding women towards the appropriate healthcare providers but also guiding women towards debt management plans, housing services, educational plans and employment agencies.(21) In short, tailor-made help is offered to vulnerable women with the aim of helping them to regain control over their lives. Although all members supported such initiatives, the question was raised about what the exact role of the health care professional should be. There was however consensus on the suggestion that PCC-providers should at least identify non-medical problems and refer women to the appropriate institutions. 'Care pathways' should be in place to facilitate these referrals to non-medical institutions.

c. Emphasize the importance of PCC and care pathways as a medical imperative and as a demand of social justice

Members also mentioned that inequalities in perinatal health outcomes deserve special attention as these are often the result of existing injustices such as poverty, racism and lack of access to high quality care for a vulnerable group of parents-to-be.(22-25) Moreover, if these inequalities remain unaddressed they perpetuate and exacerbate poor pregnancy outcomes, possibly over generations, as one's ability to escape deprivation and poor health is curbed by the very inequality one is trying to escape. Inequality begets greater inequality if left unaddressed. This makes the provision of PCC not only a medical imperative but a demand of social justice, as although PCC cannot address inequalities directly, it can mitigate the detrimental effects on pregnancy.

3. Societal valorization of new knowledge

a. Use new scientific insights to promote PCC and public health policy in general

The panel agreed on the fact that PCC could gain from new scientific insights such as those from the field of epigenetics. One clinical expert mentioned that epigenetics offered an interesting and appealing 'frame' to raise awareness about the importance of the preconception period for adequate pregnancy preparation. In addition, the effects of adverse changes to the epigenome that may result from generations of social, economic and cultural insults can insufficiently be addressed through only the delivery of PCC as a clinical form of care and require a concerted effort from other domains such as public health, education and social welfare as well.(26, 27) Therefore, it is quite possible that "the future of PCC will require an innovative multigenerational approach to health promotion for women and men to achieve optimal reproductive health outcomes." (28)

b. Include the discussion on epigenetics and social inequities in the overall strategy to counteract adverse pregnancy outcomes

Epigenetics is a new and burgeoning field that attracts a lot of attention. Careless and oversimplified interpretations of epigenetics however, suggesting that mothers are the sole responsible for the health of their children, are unwarranted. Moreover, epigenetics has the potential to open up the discussion on the social determinants of adverse pregnancy outcomes. Epigenetic insights suggest that social inequities can become biologically impinged to the detriment of the health and wellbeing of newborns. Therefore, the improvement of maternal (and paternal) and child health involves not only the provision of adequate pregnancy related care. Discussing how social injustices affect maternal and child health should become part of a comprehensive strategy to counteract adverse pregnancy outcomes.

c. Valorize new insights in the form of pregnancy-related policy and interventions

The experts mentioned that scientific researchers have a duty to valorize new scientific insights which should lead to interventions that benefit parents- and children-to-be.(29) Although caution is well advised regarding the translation of new scientific insights into policy, passivity from policy makers based on incomplete evidence is not always warranted. The dire situation of vulnerable parents-to-be in combination with reasonable scientific predictions should temper the requirement of conclusive scientific evidence before introducing pregnancy related policy.

4. Translating behavioral insights into PCC interventions

a. Explore the potential of incentives and nudges such as E-health and m-Health tools to promote PCC

Members discussed the potential of behavioral insights to increase the uptake of PCC. In addition to information and education about the benefits of an adequate pregnancy preparation, parents-to-be could also be incentivized or 'nudged' to seek PCC.(30) Nudges use people's propensity to apply heuristics and biases, which are 'mental rules of thumb', when making decisions, such as decisions about lifestyle or decisions about seeking care. Behavioral interventions such as an opt-out rather than an opt-in system for organ donation and financial rewards to quit smoking were mentioned as successful interventions, in the sense that the aim of the intervention was achieved.(31, 32)

Possibilities for PCC were discussed. For example, people tend to favor immediate small gains over future bigger gains (hyperbolic discounting). Therefore, a future gain, for example child benefits (in the Netherlands) could be paid in advance, for example when visiting a PCC consult, to increase the uptake of PCC. As people tend to make

decisions based on availability (availability bias) and people use the internet 'en masse', the possibility of incentivizing parents-to-be through E-Health and m-Health tools was also discussed. "Gabby", "Preparing For Pregnancy" and "smarter pregnancy" which are digital E-health and m-Health tools, were mentioned as successful digital tools that provide tailor-made risk assessments, health advice and can incentivize parents-to-be to seek PCC on the basis of a personal risk assessment.(12, 14, 33)

b. Ethical justification of these interventions is needed to avoid charges of paternalism, infantilization and reliance on incentives

Behavioral insights which can be used to 'nudge' parents-to-be towards PCC need to be ethically justified to prevent charges of paternalism and infantilization.(30) In addition, the problem with relying on incentives is that when the incentive disappears the effect, in this case an expected increase of uptake, may also disappear as the use of incentives does not increase the intrinsic motivation to adequately prepare for pregnancy.

Conclusion

The main recommendations of the expert panel are: the provision of tailor-made care; the definition and distribution of roles and responsibilities of caregivers; the inclusion of fertility counseling in PCC, and the development of pathways that cut across the medical and non-medical domains. Moreover, the discussion on how to promote maternal and child health should include the detrimental effects of social inequities and the potential use of incentives such as E- and mHealth tools.

References

1. van Uitert EM, Exalto N, Burton GJ, Willemsen SP, Koning AH, Eilers PH, et al. Human embryonic growth trajectories and associations with fetal growth and birthweight. Human Reproduction. 2013:det115.
2. Barker DJ, Eriksson JG, Forsén T, Osmond C. Fetal origins of adult disease: strength of effects and biological basis. International journal of epidemiology. 2002;31(6):1235-9.
3. Gluckman PD, Cutfield W, Hofman P, Hanson MA. The fetal, neonatal, and infant environments—the long-term consequences for disease risk. Early human development. 2005;81(1):51-9.
4. Temel S, van Voorst SF, de Jong-Potjer LC, Waelput AJ, Cornel MC, de Weerd SR, et al. The Dutch national summit on preconception care: a summary of definitions, evidence and recommendations. Journal of community genetics. 2015;6(1):107-15.
5. de Graaf JP, Steegers EA, Bonsel GJ. Inequalities in perinatal and maternal health. Current Opinion in Obstetrics and Gynecology. 2013;25(2):98-108.
6. Temel S, van Voorst SF, Jack BW, Denktaş S, Steegers EAP. Evidence-based preconceptional lifestyle interventions. Epidemiologic reviews. 2014;36(1):19-30.
7. Shannon GD, Alberg C, Nacul L, Pashayan N. Preconception Healthcare Delivery at a Population Level: Construction of Public Health Models of Preconception Care. Matern Child Health J. 2013.
8. Organization WH. Meeting to develop a global consensus on preconception care to reduce maternal and childhood mortality and morbidity: World Health Organization Headquarters, Geneva, 6–7 February 2012: meeting report. 2013.
9. Poels M, Koster MP, Boeije HR, Franx A, van Stel HF. Why do women not use preconception care? A systematic review on barriers and Facilitators. Obstetrical & Gynecological Survey. 2016;71(10):603-12.
10. M'hamdi HI, van Voorst SF, Pinxten W, Hilhorst MT, Steegers EA. Barriers in the Uptake and Delivery of Preconception Care: Exploring the Views of Care Providers. Maternal and Child Health Journal. 2016:1-8.
11. Barrett G, Shawe J, Howden B, Patel D, Ojukwu O, Pandya P, et al. Why do women invest in pre-pregnancy health and care? A qualitative investigation with women attending maternity services. BMC pregnancy and childbirth. 2015;15(1):236.
12. Jack B, Bickmore T, Hempstead M, Yinusa-Nyahkoon L, Sadikova E, Mitchell S, et al. Reducing preconception risks among African American women with conversational agent technology. The Journal of the American Board of Family Medicine. 2015;28(4):441-51.
13. Boston University Medical Campus Family Medicine. Meet Gabby 2015 [
14. Van Dijk MR, Huijgen NA, Willemsen SP, Laven JS, Steegers EA, Steegers-Theunissen RP. Impact of an mHealth Platform for Pregnancy on Nutrition and Lifestyle of the Reproductive Population: A Survey. JMIR mHealth and uHealth. 2016;4(2):e53.
15. Landkroon A, De Weerd S, van Vliet-Lachotzki E, Steegers E. Validation of an internet questionnaire for risk assessment in preconception care. Public Health Genomics. 2010;13(2):89-94.
16. Jack BW, Atrash H, Coonrod DV, Moos M-K, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. American journal of obstetrics and gynecology. 2008;199(6):S266-S79.

17. Denktaş S, Bonsel G, Van der Weg E, Voorham A, Torij H, De Graaf J, et al. An urban perinatal health programme of strategies to improve perinatal health. Maternal and child health journal. 2012;16(8):1553-8.

18. van der Zee B, de Beaufort ID, Steegers EA, Denktas S. Perceptions of preconception counselling among women planning a pregnancy: a qualitative study. Fam Pract. 2013;30(3):341-6.

19. Tuomainen H, Cross-Bardell L, Bhoday M, Qureshi N, Kai J. Opportunities and challenges for enhancing preconception health in primary care: qualitative study with women from ethnically diverse communities. BMJ open. 2013;3(7):e002977.

20. Braveman P. What is health equity: and how does a life-course approach take us further toward it? Maternal and child health journal. 2014;18(2):366-72.

21. Mothers of Rotterdam Program & Research Fact Sheet, [Available from: https://www.moedersvanrotterdam.nl/wp-content/uploads/Factsheet-Moeders-van-Rotterdam-ENG-nummering-def2.pdf.

22. Zhang S, Cardarelli K, Shim R, Ye J, Booker KL, Rust G. Racial disparities in economic and clinical outcomes of pregnancy among Medicaid recipients. Maternal and child health journal. 2013;17(8):1518-25.

23. Dominguez TP, Dunkel-Schetter C, Glynn LM, Hobel C, Sandman CA. Racial differences in birth outcomes: the role of general, pregnancy, and racism stress. Health psychology. 2008;27(2):194.

24. Poeran J, Denktas S, Birnie E, Bonsel GJ, Steegers EA. Urban perinatal health inequalities. The Journal of Maternal-Fetal & Neonatal Medicine. 2011;24(4):643-6.

25. de Graaf JP, Ravelli AC, de Haan MA, Steegers EA, Bonsel GJ. Living in deprived urban districts increases perinatal health inequalities. The Journal of Maternal-Fetal & Neonatal Medicine. 2013;26(5):473-81.

26. Wallack L, Thornburg K. Developmental origins, epigenetics, and equity: moving upstream. Maternal and child health journal. 2016;20(5):935-40.

27. Barouki R, Gluckman PD, Grandjean P, Hanson M, Heindel JJ. Developmental origins of non-communicable disease: implications for research and public health. Environmental Health. 2012;11(1):1.

28. St. Fleur M, Damus K, Jack B. The future of preconception care in the United States: multigenerational impact on reproductive outcomes. Upsala Journal of Medical Sciences. 2016;121(4):211-5.

29. Steegers EAP, Barker ME, Steegers-Theunissen RPM, Williams MA. Societal Valorisation of New Knowledge to Improve Perinatal Health: Time to Act. Paediatric and perinatal epidemiology. 2016;30(2):201-4.

30. M'hamdi HI, Hilhorst M, Steegers EA, de Beaufort I. Nudge me, help my baby: on other-regarding nudges. Journal of Medical Ethics. 2017:medethics-2016-103656.

31. Blumenthal-Barby JS, Burroughs H. Seeking better health care outcomes: the ethics of using the "nudge". Am J Bioeth. 2012;12(2):1-10.

32. Quigley M. Nudging for health: on public policy and designing choice architecture. Medical Law Review. 2013;21(4):588-621.

33. Vink-van Os LC, Birnie E, van Vliet-Lachotzki EH, Bonsel GJ, Steegers EA. Determining Pre-Conception Risk Profiles Using a National Online Self-Reported Risk Assessment: A Cross-Sectional Study. Public health genomics. 2015;18(4):204-15.

Table 1

Description sessions

Session 1 'The concept of PCC and the role of caregivers'

Introduction: Prof Eric Steegers and Prof Inez de Beaufort on the concept of preconception care, is there consensus about what it entails and why it is an important form of care (10 min)

Perspective: The role of caregivers and their reported barriers : Hafez Ismaili M'hamdi (10 min)

Discussion: Chair Prof Inez de Beaufort, discussion on the basis of cases. **Case 1.** PCC, one concept, one form of care (Is there consensus about PCC and what are the barriers to achieve consensus? What are the barriers that result from a lack of consensus? Who is primarily responsible for reaching consensus? How does reaching consensus about PCC promote the goals of PCC?)

Case 2. The proactive role of the caregiver (How to promote proactivity of caregivers? what can we reasonably expect from caregivers? How to overcome the barriers they experience, perceived lack of evidence-based interventions/ competition with other practices of preventive care? Which caregiver is the gatekeeper of PCC?) **Case 3.** Late referral to adequate caregiver (Why are parents-to-be who need specialist care referred (too) late to the specialist? Are there examples of well-organized referral to adequate caregiver in general and to the specialist in particular? What can be done to advance timely referral?) **Case 4.** What to do with non-medical risks? (Poor socio- economic circumstances are recognized as risk factors. Are caregivers sufficiently able to identify non-medical risks? What can/should a caregiver do when a non-medical risk factor is identified? Can, as it is now organized, PCC adequately address non-medical risks?) **Case 5.** No directivity, no care? (How to offer PCC to women/couples who would be well-advised to postpone their desire to become pregnant? How to offer PCC to high-risk women/couples who do not perceive any urgency? How far can a caregiver go on behalf of the unborn/ future child? Is non-directive counseling/advising of couples effective/adequate/sufficient?)

Session 2 'Reaching those who need care the most'

Introduction: Meertien Sijpkens, presentation results qualitative research on perceptions of vulnerable women with a desire to become pregnant (10 min)

Perspective: Prof Eric Steegers, why are we, despite all efforts, not succeeding at increasing the uptake of PCC? (10 min)

Discussion: Chair Medard Hilhorst, discussion on the basis of questions. **Question 1** Should pregnancy and birth be perceived as medical events by future parents and what are the advantages and disadvantages of such a perception?

Question 2 Which measures have already been taken to increase the uptake? **Question 3** Which of these measures are successful or unsuccessful? **Question 4** What is the adequate measure of PCC uptake, consultation visits/delivery of care/ maternal-parental-fetal-newborn health? **Question 5** How to deal with the discrepancy between perceived subjective health of parents-to-be and their actual objective health with respect to adequate pregnancy preparation? how do we overcome this discrepancy in a responsible and ethically justified way? **Question 6** How should we counteract pregnancy outcome inequalities? Is it justified to target higher risk groups (especially when they do not perceive themselves as high risk groups) for extra care. **Question 7** The most vulnerable future parents tend to have an accumulation of non-medical/socio- economic risk factors. How well equipped is PCC/ are caregivers to counteract these risk factors? ""*Why treat people and send them back to the conditions that made them sick?"* (M. Marmot chair of WHO social determinants of health)

Session 3 'Societal valorization of new knowledge'

Introduction: Prof Eric Steegers, presentation of new scientific knowledge (DOHaD and epigenetics) and the ways in which this can be translated into policy (10 min)

Perspective: Hafez Ismaili M'hamdi, how does new scientific knowledge influence ethical and philosophical ideas about perinatal health inequalities, parental responsibility and social justice? (10 min)

Discussion: Chair Prof Wim Pinxten, discussion on the basis of statements.

Statement 1 As long as knowledge is not translated in sound evidence based interventions, it has no use for PCC. **Statement 2** Insights from DOHaD and epigenetics show that pregnancy outcome inequalities are the result of socio economic inequalities rather than a lack of individual responsibility of parents-to-be. **Statement 3** There is a real danger that insights from DOHaD and epigenetics will be used to shift too much responsibility for a healthy pregnancy on to the mother. **Statement 4** The potential of PCC to play an important role in reducing chronic diseases which manifest in adult life is currently underused.

Session 4 'Translating behavioral insights into PCC'

Introduction: Hafez Ismaili M'hamdi, bounded rationality and other-regarding nudges (10 min)

Perspective: Professor Regine Steegers-Theunissen, presentation on the potential of E-health/m-Health (10 min)

Discussion: Chair Prof Inez de Beaufort, discussion on **Issue 1** is there reason to believe that future parents make decisions based on bounded rationality to their and their future children's detriment? **Issue 2** What types of interventions are ethically justified to counteract bounded rationality? Nudges? Directive counseling? Paternalistic policy? **Issue 3** How can e-Health/ m-Health tools promote healthy pregnancies? **Issue 4** What are the pitfalls when poor pregnancy outcomes are framed as results of bounded rationality/ is it adequate to perceive the problem of poor pregnancy outcomes as one of poor choice behavior on the part of mothers-to-be?