



JCVI INTERIM ADVICE ON A ONE-DOSE SCHEDULE FOR THE ROUTINE HPV IMMUNISATION PROGRAMME

RESPONSE FROM THE EUROPEAN CANCER ORGANISATION'S HPV ACTION NETWORK

Summary of key points

- The introduction of a one-dose HPV vaccination schedule in the UK is highly likely to impact on vaccination policy elsewhere in Europe and beyond.
- The European Cancer Organisation (ECO) is concerned that the currently-available evidence is not sufficient to justify a change from a two-dose to a one-dose HPV vaccination schedule.
- We note that some of the trials referred to in the consultation contained relatively small one-dose population samples in a range of low- or medium-income countries and have not been reported as peer-reviewed published papers.
- Only one of the trials cited contains males and none relates to the non-cervical cancers caused by HPV. We are concerned about the possible impact of a one-dose schedule on both males and on the prevention of all the cancers caused by HPV.
- It is possible that a change to a one-dose schedule could negatively impact vaccination uptake by suggesting that HPV is now a low-risk infection. It may also further fuel anti-vaccination campaign groups who will take the opportunity to claim that the change 'proves' that the vaccine is inherently unsafe at any dosage.
- We agree with the concern expressed in the consultation that the change has the potential to widen further inequalities already present in uptake.
- There is some evidence that supports a change to a one-dose HPV vaccination schedule; however, we are concerned that the decision could be made before sufficiently robust evidence is available. In these circumstances, we recommend that the JCVI proceeds with caution and postpones its final decision in order to prevent the introduction of unwarranted and unnecessary risk.

Introduction

1. The European Cancer Organisation (ECO) welcomes this opportunity to respond to the consultation by the JCVI on its interim advice on a one-dose schedule for the routine HPV immunisation programme.
2. ECO is a Brussels-based not-for-profit federation of member organisations working in cancer at a European level. We convene oncology professionals and patients to agree policy, advocate for positive change and be the united voice of the European cancer community. Our mission is to reduce the burden of cancer, improve outcomes and the quality of care for cancer patients, through multi-disciplinarity and multi-professionalism. More information about ECO is available here: www.europeancancer.org.
3. ECO's HPV Action Network comprises some 45 organisations with a wide range of perspectives on HPV issues. Several of these organisations are based in the UK. The Network played a leading role in influencing the content of Europe's Beating Cancer Plan which includes a 'flagship' commitment to gender-neutral HPV vaccination throughout the European Union. The Network aims to promote policies that eliminate all the cancers caused by HPV across the WHO European Region, which includes the UK.
4. We are responding to this consultation not only because this is an important issue for public health in the UK but also because decisions made by the JCVI will impact on HPV vaccination policy elsewhere in Europe and beyond.

Concerns about a one-dose schedule

5. First, we welcome research that is emerging about the potential of a one-dose schedule. Clearly, a one-dose schedule, if it is supported by robust research evidence, could have a significant and positive impact on HPV vaccination policy and practice, especially in low- and medium-income countries.
6. However, we are concerned that the available research evidence is not sufficiently robust to justify a change from two doses.
7. We note that in the Costa Rica Vaccine Trial, just 112 women (out of a total sample of 1783) received one dose of the HPV vaccine, and that the IARC Indian Trial will not report on the follow-up of participants until at least 2026. In the DoRIS study, there were 115 one-dose recipients and the findings have, as far as we can ascertain, not yet been peer-reviewed. We understand that the KEN SHE trial has also not been peer-reviewed. The delayed booster study (DEBS) has not been completed and initial findings have not been published. The DEBS study also has a relatively small number of one-dose participants.

8. None of the trials referred to by JCVI in its consultation paper, with the exception of the uncompleted and small-scale DEBS study, contains males or their associated HPV cancer risks. This is a major limitation as there may be unforeseen differences in immunity response between males and females receiving one dose which leave males with a lower level of protection and therefore at a higher risk of cancers.
9. All of the trials cited in the consultation paper focus on cervical cancer alone. HPV vaccination can protect against a wide range of other cancers and, before moving to a one-dose schedule, the JCVI should make an assessment of any impact on the vulval, vaginal, penile, anal, head and neck cancers also caused by HPV exposure. There should also be an assessment of any impact on levels of protection against anogenital warts and recurrent respiratory papillomatosis (RRP).
10. We note that all but one of the studies referred to in the consultation were based in low- or medium-income countries, not high-income countries comparable to the UK.
11. It is recommended that, before any decision is taken to change to a one-dose schedule, further two-dose trials should be commissioned in the UK and/or comparable populations with variable time-periods between the first and second doses to enable analysis of the impact of vaccination on those who have (so far) received one dose.
12. The consultation paper suggests that a one-dose schedule is 'likely to be more acceptable to the population'. While this at first may seem to be an intuitive truth, and may well turn out to be the case if a one-dose schedule is introduced, it is not inconceivable that the change could signal to some young people and their parents/carers that their risk of HPV cancers is actually low and that vaccination is therefore less important and may be safely missed. We would recommend that this issue should be investigated thoroughly before any change in policy.
13. It is entirely possible that anti-vaccination campaign groups will seek to exploit a change to a one-dose schedule by claiming that this 'proves' that the vaccine is inherently unsafe. We have seen the impact of HPV vaccine safety scares in several countries, including Ireland and Denmark; these have seriously threatened the resilience of national vaccination programmes. If the change to a one-dose schedule goes ahead, a significant communications campaign will be needed to prevent, or at least mitigate, safety concerns.
14. It should be noted that an HPV Action Network stakeholder, a physician based in Romania, has expressed concern that a decision to introduce a one-dose schedule in the UK could have a particularly negative impact on countries, like Romania, where there are already high levels of vaccine hesitancy caused by a belief that the HPV vaccine is unsafe.

15. The consultation paper states that a one-dose schedule would ‘free up funding and resources’. Such a comment could create the impression that the change in policy is, at least in part, a cost-cutting exercise. Such a perception could undermine public confidence in the programme. It is also possible that any significant fall in uptake could actually make a one-dose programme less cost-effective than the current two-dose programme.
16. The JCVI acknowledges that a move to a one-dose schedule and a single vaccination visit to schools could reduce opportunities to catch-up those who miss their first HPV dose and that this has the potential to widen inequalities in uptake. We consider this to be a very real concern that carries significant detrimental risks.
17. If the JCVI decides, following this consultation, to recommend a one-dose schedule, we strongly believe that there must be very close monitoring of HPV infection and immunity levels and associated cancer incidence rates. If there is any indication that the risk of any of the cancers caused by HPV is increasing, then immediate steps must be taken to reintroduce a two-dose schedule and to provide booster vaccinations to those who have received one dose under the revised policy.
18. Finally, we are concerned to note that a change to a two-dose schedule for people aged over 15 has been implemented without consultation. We believe that this change in policy should have been included in the current consultation.

Conclusion

19. While we acknowledge that there is some evidence that supports a possible change to a one-dose HPV vaccination schedule, we are concerned that the decision may be made prematurely, before sufficiently robust scientific evidence is available. In these circumstances, we urge caution on the JCVI and recommend that it postpones a final decision. It is surely better to be safe than sorry when so much remains at stake.

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