JABS FOR THE BOYS: HOW THE CAMPAIGN FOR GENDER-NEUTRAL HPV VACCINATION WAS WON IN THE UK

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ABSTRACT

The human papillomavirus (HPV) can cause a range of cancers as well as genital warts and recurrent respiratory papillomatosis in men and women. Most cases can be prevented by vaccination in adolescence. Many countries vaccinate girls and an increasing number, although still a minority, vaccinate both boys and girls. The case for vaccinating boys is based on arguments of public health, equity, ethics, and cost-effectiveness. The selective vaccination of females does not protect males sufficiently and provides no protection at all for men who have sex with men. In the United Kingdom (UK), the government’s vaccination advisory committee (Joint Committee on Vaccination and Immunisation [JCVI]) began to consider whether boys should be vaccinated as well as girls in 2013 and made clear in draft statements that it considered this not to be cost-effective. A campaign group, HPV Action, was established to advocate gender-neutral vaccination. This group became a coalition of over 50 organisations and used evidence-based arguments, political advocacy and media campaigning to make its case. One of its members initiated legal action against the government on the grounds of sex discrimination. In July 2018, the government agreed that boys in the UK should be vaccinated. The lessons for other campaigns in the men’s and public health fields include: be prepared for the long haul, focus on clear and specific goals, build alliances, align the objectives with existing policies, make a financial case for a change of policy, and use all legitimate means to exert pressure.
In July 2018, the United Kingdom (UK) government’s vaccination advisory committee (Joint Committee on Vaccination and Immunisation [JCVI]) recommended that the national human papillomavirus (HPV) vaccination programme should be extended to include adolescent boys. This decision was made after five years’ deliberation by JCVI. For most of that time, JCVI indicated that it was highly sceptical of the case for vaccinating boys. It is worth reflecting on how and why JCVI changed its position in the final few months and what the lessons might be for other men’s and public health campaigns in the UK and elsewhere.

**HUMAN PAPILLOMAVIRUS**

HPV is the name for a group of viruses that affect the skin and moist membranes lining the body. Vulnerable areas for HPV infection in males include the penis, anus, mouth and throat. In women, as well as the anus, mouth and throat, other susceptible areas are the cervix, vagina and vulva. There are around 200 types of HPV. Most are harmless, but persistent infection with some types can cause cancer or genital warts.

The main high-risk types of HPV are HPV 16 and 18. These, and a few other, types can cause cancer. Genital warts are caused by HPV 6 and 11. The cancer-causing and wart-causing types are different, meaning that genital warts are not a precursor of cancer. HPV infection is very common and is spread by sexual and skin-to-skin contact. Condoms reduce the risk of infection but do not eliminate it because HPV can infect areas not protected by a condom. Some studies suggest that deep kissing spreads HPV but this has not been definitely proven. High-risk HPV types cannot be caught from toilet seats, hugging, holding hands, swimming pools or hot tubs or sharing food or cutlery.

Nearly all sexually active people acquire HPV at some point in their lives: about 85% of women and 91% of men will be infected. Because the infection is so common, many people are infected shortly after becoming sexually active. Someone who has had only one sexual partner can get HPV although people who have many partners, or who have sex with someone who has had many partners, are more at risk. There is a 50–80% chance of HPV transmission following unprotected sexual intercourse with someone with a current HPV infection.

There are important differences in the epidemiology of HPV infection between men and women. For example, HPV transmission from females to males is higher (12.3%) than from males to females (7.3%). HPV infection rates also seem to stay constant in men, independent of age, whereas in women, who have a better immune response, HPV prevalence is highest during 18–24 years of age and then decreases until middle age, after which it generally remains steady.

Most people with HPV are unaware that they are infected and never develop a health problem as a result. HPV usually clears on its own: approximately 70% of men clear an HPV infection within 12 months. Having HPV does not therefore mean someone will automatically develop cancer or genital warts. But HPV infection can persist in some people, causing health problems sometimes years later. It is not possible to predict which people with HPV will go on to develop health problems but people with compromised immune systems are thought to be more at risk as are smokers. People with HIV/AIDS are among those at greatest risk.

**HPV-RELATED DISEASES**

HPV is believed to cause 5% of all cancers worldwide. A study of the impact of HPV on cancers in 32 European countries suggested that over 53,000 cancer cases a year are caused by high-risk HPV types. About 80% of these cases occur in women and 20% in men. Cervical cancer represents the highest burden (31,130 cases), followed by head and neck cancer (1,396 cases in women, 5,834 cases in men), anal cancer (3,834 in women and 2,303 cases in men), vulvar cancer (1,466 cases), vaginal cancer (1,360 cases), and penile cancer (1,113 cases).
as women. Mouth and throat cancers caused by HPV have become far more common over the past 30 years, a trend that is expected to continue over the next 20 years.\textsuperscript{15}

**Anal Cancer**

HPV causes the vast majority (90\%) of anal cancer cases.\textsuperscript{16} This cancer is relatively rare and is about twice as common in women. But the number of cases in men is expected to more than double in the period 1993 to 2035.\textsuperscript{17} In men, anal cancer is much more common in men who have sex with other men; in fact, rates of anal cancer are 17 times higher in men who have sex with men compared to heterosexual men.\textsuperscript{18}

**Penile Cancer**

HPV infection causes about two thirds (63\%) of penile cancer cases.\textsuperscript{19} This cancer is relatively rare in the UK, but is becoming more common with almost 25\% more cases now being diagnosed each year than in the early 1990s.\textsuperscript{20}

**Genital Warts**

Infection with HPV types 6 and 11 can cause genital warts, the second most common sexually transmitted infection. In men, warts can develop on the penis, scrotum, the upper thighs, and on or inside the anus. Both men and women are affected but the problem is much more common in men and particularly in men who have sex with men. A review of the international evidence found that, among males, prevalence of genital warts ranged from 0.16\% to 0.20\%; among females, prevalence ranged between 0.13\% and 0.16\%.\textsuperscript{21} Men experience high rates of recurrent genital warts: one study found that 44\% had one or more subsequent genital wart events detected, 22\% had two subsequent events, 11\% had three subsequent events, and 7\% had four or more subsequent events.\textsuperscript{22}

**Recurrent Respiratory Papillomatosis**

HPV types 6 and 11 can also cause recurrent respiratory papillomatosis (RRP).\textsuperscript{23} People with RRP have wart-like growths on their airways caused by HPV which can seriously affect breathing. RRP affects both children and adults. Children are infected while still in the womb or at birth. Males and females are about equally affected. RRP is rare but can be very distressing and is often difficult to treat.

**Other Diseases**

Some studies have suggested that HPV infection is associated with prostate cancer and some types of lung and breast cancers. A meta-analysis of 30 studies suggested that men who tested positive for HPV type 16 had a 37\% greater risk of developing prostate cancer.\textsuperscript{24} An international pooled analysis found that comparisons between tumour and normal lung tissue showed that HPV was almost four times more likely to be present in lung cancer rather than normal lung tissue.\textsuperscript{25} There has also been a recent suggestion of a link between HPV infection and cardiovascular disease.\textsuperscript{26} Most scientists consider these links to be unproven, however, and HPV vaccination is not considered to be a means of preventing prostate, lung or breast cancers or heart disease.

**HPV Vaccination**

HPV vaccination offers a very safe and very reliable protection against HPV infection but it is not a treatment for an existing infection. It is normally administered to adolescents before they become sexually active and at risk of exposure to the virus. There are three vaccine products available: Cervarix (which protects against HPV types 16 and 18), Gardasil (for HPV types 6, 11, 16 and 18) and Gardasil-9 (for HPV 6, 11, 16, 18 and five other oncogenic HPV types). Gardasil is currently the market leader globally; Cervarix accounts for about one-fifth of the market.\textsuperscript{27} When offered to adolescents, two vaccine doses are required for maximum protection. It is possible that current research will in the near future confirm that just one dose is sufficient.\textsuperscript{28}

HPV vaccination for girls was initially introduced in 2006 with the USA being the first country to do so. By March 2017, 71 countries (37\%) had introduced a female HPV vaccination programme.\textsuperscript{29} This has been on an inequitable basis however: only 1\% of vaccinated females have been from low-income or lower-middle-income countries. Many more women from high-income and upper-middle-income countries have been vaccinated against HPV while populations with the highest incidence and mortality of HPV-related disease have remained largely unprotected.\textsuperscript{30}

Males have not been included in HPV vaccination programmes in most countries. Data collected by
HPV Action suggests that, by early 2019, just over 30 countries have either decided to vaccinate boys or actively plan to do so. These countries are:

- Antigua and Barbuda
- Argentina
- Australia
- Austria
- Bahamas
- Barbados
- Bermuda
- Brazil
- Canada
- Croatia
- Czech Republic
- Denmark
- Germany
- Gibraltar
- Guam
- Guyana
- Ireland
- Israel
- Italy
- Liechtenstein
- New Zealand
- Norway
- Panama
- Portugal
- Puerto Rico
- Serbia
- Slovakia
- St Lucia
- Switzerland
- Trinidad and Tobago
- Turkmenistan
- United Kingdom
- United States of America

All the above countries are in the high- or upper-middle-income brackets, according to World Bank criteria.31

THE CASE FOR VACCINATING BOYS

Although the number of male cancer cases caused by HPV infection is lower than the number for females, the virus still causes significant levels of disease in males. Because optimal health is considered to be a fundamental human right, there is a very strong ethical argument for vaccinating both sexes.32 This is reinforced by arguments based in equity and equality which suggest that not vaccinating boys constitutes sex discrimination.

It has been suggested that in countries where vaccination rates in girls are sufficiently high (normally meaning ≥80%), boys are protected against HPV infection because, clearly, they cannot acquire it from vaccinated females.33 The protective (‘herd’) effect of the selective vaccination of adolescent girls against HPV implies a high probability that one of the two sexual partners is immunised, hence preventing the other from acquiring the virus.

This argument is highly problematic, however. The dynamic transmission models used to inform immunisation policy should include consideration of sexual behaviours and population mixing in order to demonstrate an ecological (‘real world’) validity, whereby the scenarios modelled remain faithful to the real-life social and cultural context.34 An assumption of herd protection by means of female vaccination first and foremost ignores the fact that men who have sex with men remain totally unprotected.35 There is also growing evidence that an increasing number of men who identify as heterosexual are sexually ‘fluid’ (i.e. have same-sex relationships)36 and embracing a significantly more inclusive, tactile and emotionally diverse approach to their relationships with other men37 which may well increase the risk of male-male HPV transmission.

A few countries, including the UK, have introduced vaccination programmes specifically for men who have sex with men. While these may benefit some individual men, the main drawback with such programmes is that men are likely to have acquired HPV before they are offered the vaccine and, in any event, many men who have sex with men will not be reached by these programmes.38 The most effective way to prevent HPV infection in men who have sex with men is to vaccinate all boys before they become sexually active.

Men also have sexual contact with women who have not been vaccinated. This may be in their own country – even if 80% of girls there are vaccinated, that means that, on average, one in five new sexual contacts will be with someone who has not been vaccinated (and that assumes that the contact is with a woman in an age-group for which vaccination was available). In Europe, just 4% of all women are estimated to have been vaccinated; in northern Europe, the best-performing region, the figure rises to 8%.

Vaccination uptake in girls varies significantly across European Union (EU) countries. Few meet the widely-accepted target of 80% coverage.39 In western and southern Europe, about one-third of girls in the targeted populations are estimated to have completed the full course of vaccinations. In eastern Europe, the proportion is one-fifth. In northern Europe, the best-performing region, about two-thirds of girls have been vaccinated. Vaccination rates can also vary widely within countries. The UK has a high overall vaccination rate (about 83%) but,
at the local level, uptake in girls varies from under 50% to 95%. Vaccinating boys helps to protect unvaccinated women.

Men may also have sex with women from other countries where there may be no HPV vaccination programme or where there is a programme with relatively low uptake. The growth of global tourism (including sex tourism), business travel and migration means that increasing numbers of men are at risk from unvaccinated women. Data from the UK shows that around 10% of men report forming a new sexual partnership while overseas in the past five years. The proportion among younger men is far higher: 13% of 16–24 year olds and 15% of 25–34 year olds.

There is evidence that vaccinating boys is cost-effective, although this is a highly-contested issue. Essentially, cost-effectiveness means that the outcomes of an intervention are worth the investment in terms of the savings in treatment and care that accrue when compared to investing in other health services. A study of the cost-benefits in Finland found that vaccinating girls eventually leads to annual savings of EUR 11.2 million in the treatment of HPV-related cancers and that vaccinating boys would produce additional annual savings amounting to EUR 4.1 million. Another study found that, in Canada, vaccinating boys could potentially save between CAD 8 and CAD 28 million in the treatment of oropharyngeal cancers alone.

It has been suggested that, rather than investing in vaccination for males, the focus should be on improving uptake in females. While higher levels of female uptake do protect some males, even 90% female uptake still leaves men at risk, not least men who have sex with men. It is also unrealistic to expect significant improvements in female uptake in many countries in the short-term; this has led to calls for gender-neutral vaccination in Africa and for Gavi, the Vaccine Alliance, which currently provides subsidised female-only HPV vaccines to eligible African countries, to extend the subsidy to gender-neutral vaccination.

ADVOCATING HPV VACCINATION FOR BOYS IN THE UK

The decision to vaccinate boys in the UK was not made, as it should have been, following an objective and independent assessment of the evidence of cost-effectiveness by an official advisory body. The JCVI’s decision that the HPV vaccination programme should be extended to boys came after a sustained advocacy campaign led by HPV Action, a partnership of (ultimately) 51 professional and patient organisations.

HPV vaccination for girls aged 12/13 years began in the UK in 2008. At the same time, a short-term catch-up programme for girls aged up to 18 years was introduced. The programme was delivered in schools and has achieved relatively high rates of uptake. The latest 2016/17 figure for the UK is 85% although this masks significant local variations.

JCVI began an assessment of whether boys should also be vaccinated in 2013 and, at that time, planned to announce a decision in 2015. In 2013, representatives of several organisations with a particular interest in HPV-related diseases (chiefly the Throat Cancer Foundation and the HPV and Anal Cancer Foundation charities) decided to establish an advocacy organisation, HPV Action, to make the case for the vaccination of boys. Peter Baker, an independent consultant in men’s health who had been Chief Executive at the Men’s Health Forum (Great Britain) and was now Director of Global Action on Men’s Health, was invited to become campaign director on a freelance basis.

The choice of a leading advocate from a background in gender and health inequalities who was already well-connected with a wide range of potential HPV Action members as well as key external stakeholders was undoubtedly helpful to the campaign. The appointment of a freelance contractor rather than using the more conventional option of a public affairs agency was also very cost-effective. The total cost of the campaign over five years was an estimated GBP 75,000.00, including in-kind contributions from members. This is a relatively small amount for campaigns of this kind.

HPV Action’s advocacy campaign was financed almost entirely by voluntary contributions from its own members with a small amount of extra income from individual donations and a commercial organisation without a direct financial interest in HPV vaccination. Not all members made a financial contribution and a few (the Oral Cancer Foundation, the Throat Cancer Foundation and the HPV and Anal Cancer Foundation) provided most of the support. Towards the end
of the campaign, Oral Health Foundation accepted an educational grant from a vaccine manufacturer (MSD) to enable HPV Action to produce online educational material on vaccination for boys and men. This grant was strictly ring-fenced and was not used to support the advocacy campaign. Some members also provided pro bono support such as meeting rooms, design and publication. A PR company working for the HPV and Anal Cancer Foundation, Street and Co, provided media support.

HPV Action began to recruit members and, by the end of 2013, had 22. A year later, it had 36, and this number continued to steadily increase. The members came from a range of backgrounds, including men’s health, gay men’s health, sexual health, cancer, oral health and public health. They ranged from the small to the large, from local to national, and from low- to high-profile. The level of participation by member organisations varied widely but all contributed to the overall visibility and influence of the campaign. HPV Action also benefitted from the active participation of Professor Giampiero Favato, a health economist based at Kingston University in the UK who had previously advised the Italian government on gender-neutral vaccination.

The campaign did not constitute itself as a formal organisation. It did not register as a charity or a company; it remained a network throughout. HPV Action’s finances were managed by one of its members, the Oral Health Foundation, which was also responsible for managing the work of the campaign director and for paying his fees. Strategic decisions were taken by regular meetings open to all members and a small number of members was responsible for executive decision-making. Members were kept informed through regular eBulletin updates. Terms of reference were agreed by members to ensure good governance and enable relatively fast decision-making and responses to external events.

The campaign was four-pronged in its approach. The first element was to influence professional opinion, including that of JCVI members. This was primarily achieved through evidence-based articles in professional journals for school nurses, dentists, public health specialists and others. There were also occasional papers in scientific and medical journals as well as presentations to conferences and seminars. HPV Action also had direct contact with JCVI by means of submissions to its consultations, direct correspondence and meetings with the officials who were supporting its work, chiefly based at Public Health England. It is difficult to assess objectively the impact of this activity but, by 2018, there seemed to be a professional consensus that gender-neutral vaccination would be beneficial to public health.

HPV Action consistently argued that JCVI’s approach to assessing cost-effectiveness was flawed. Public Health England, which undertook cost-effectiveness modelling for JCVI, admitted in a paper published after the decision was made that the outcome of any model is strongly dependent on the variance of the inputs chosen to inform its algorithm. Models based on deterministic inputs, such as the ones available to JCVI, might be affected by a different degree of ecological bias, which implies an inability to reflect the natural demographic and behavioural trends in their outcomes and, consequently, to accurately inform public healthcare policy. In particular, ecological bias has the effect of over-estimating the preference-based outcomes of selective immunisation. A relatively small (15–20%) over-estimation of the herd immunity gained with selective immunisation programmes could induce a significant error in the estimate of cost-effectiveness of universal immunisation by inflating its incremental cost-effectiveness ratio (ICER) beyond the acceptability threshold.

HPV Action successfully demonstrated that the model originally used by JCVI seriously underestimated the proportion of cancer cases in men caused by HPV. The campaign also cast doubt on the validity of using dated, pre-Tinder assumptions of sexual behaviour (there is evidence that dating apps constitute an emerging sexual risk factor and that high-risk sexual behaviours, notably anal sex, have become increasingly and rapidly prevalent) and highlighted the omission from the modelling of significant areas of cost, such as the cost of morbidity and mortality to employers.

Because the arguments about cost-effectiveness are complex and difficult to understand by people without a background in health economics, HPV Action produced a straightforward estimate of the
costs of introducing gender-neutral vaccination. Using publicly-available data about the cost of the vaccine in Italy combined with information about the cost of vaccine delivery in the UK, the campaign calculated that the annual cost of adding boys to the HPV vaccination program in the UK would be in the region of GBP 20-22 million. This was then compared to the significantly greater costs of treating HPV-related diseases.

Significant emphasis was also placed on the ethical and equity arguments as well as the potential public health outcomes. The risk of the potential impact of a fall in vaccine confidence on girls’ uptake was also highlighted; HPV Action cited the recent major downturns in vaccination in Denmark, Japan and Ireland which followed media coverage of some parents’ vaccine safety concerns. (There is no credible scientific evidence of any negative long-term impact of HPV vaccination.)

The contribution that gender-neutral vaccination could make to implementing other areas of policy were emphasised. The UK government had made a strong commitment to tackling health inequalities, for example, and HPV Action argued that vaccinating boys would help to reduce the gap in outcomes between men and women. It also suggested that it was unfair to expect girls to bear sole responsibility for tackling this sexually transmitted infection through the burden of vaccination.

The second element was political. Significant efforts were made to engage politicians from all political parties and to exert pressure on government ministers through correspondence and formal questioning and debates in parliament. Of particular importance was a parliamentary debate on gender-neutral vaccination held in May 2018, a few weeks before the meeting where JCVI decided to recommend gender-neutral vaccination. The debate was initiated by a senior MP from the governing Conservative Party and the case was supported by other Conservative MPs as well as MPs from the Labour, Scottish Nationalist and Democratic Unionist parties. During that debate, the public health minister, Steve Brine MP, conceded that equality issues needed to be considered alongside cost-effectiveness.

The third element involved the media. HPV Action succeeded in gaining sustained media coverage throughout its campaign. Stories were developed which created new angles, such as a report on the views of Nobel Prize winner Professor Harald zur Hausen (the scientist who discovered the link between HPV and cervical cancer and who strongly supports boys’ vaccination) and a national survey of dentists and doctors. Organised with the help of the British Dental Association, Faculty of General Dental Practice and BMA (the main trade union for doctors in the UK), the survey found that 95% of respondents thought boys should be vaccinated. Of most significance was the support of a major national newspaper, The Mail on Sunday (MoS), throughout the first six months of 2018. The MoS ran a series of hard-hitting articles, often based on the case-studies of people with HPV-related cancers, which made the case for gender-neutral vaccination. The MoS is the second best-selling Sunday newspaper in the UK and has a readership demographic that makes it influential with governments, especially Conservative governments.

The final element concerned the threat of legal action. One of HPV Action’s members, the Throat Cancer Foundation, initiated judicial review proceedings against the Department of Health and Social Care and the JCVI on the grounds that not vaccinating boys was direct sex discrimination. The Foundation raised sufficient funds through a crowdfunding site and a letter was sent in early 2018 to the potential defendants from a leading law firm, Leigh Day, with extensive experience in human rights and equality cases. This case did not proceed to court because the government decided to vaccinate boys before that step became necessary.

Many organisations and individuals not under the HPV Action umbrella also played an important role in the campaign. The BMA adopted a policy supporting HPV vaccination for boys in 2014. Professor Margaret Stanley of Cambridge University, now president of the International Papillomavirus Society, and Professor Chris Nutting, Consultant Clinical Oncologist at the Royal Marsden Hospital in London, were primus inter pares among the many individual and influential clinicians and academics who helped to make the case for gender-neutral vaccination.

The campaign was not without its downsides. HPV Action was unable to engage the general public,
especially parents who could have lobbied their MPs, primarily because of a lack of resources. At times, the campaign had very limited funds and the financial burden was borne by a relatively small number of member organisations, sometimes causing tension within the membership. The lack of funds also constrained HPV Action’s activities. An online petition, begun in 2013, was sidelined because HPV Action was unable to promote it sufficiently widely. Some significant organisations in the cancer and medical field, whose support would have been helpful, chose not to support the call to vaccinate boys until the decision was actually announced.

LESSONS FOR OTHER MEN’S AND PUBLIC HEALTH CAMPAIGNS

The ultimate success of HPV Action’s campaign suggests some useful lessons for other campaigns in the men’s and public health fields. These include:

1. Be prepared for the long haul. Significant change is unlikely to be achieved quickly.
2. Focus on clear and specific goals rather than a diverse set of demands.
3. Secure funding from sources that have no direct financial interest in the outcome of the campaign.
4. Base campaigns on credible evidence rather than assertion. But do not overlook the power of personal stories (e.g. of HPV-related cancer) and of appeals to people’s sense of fairness.
5. Make a financial case for a change of policy. Many politicians and policymakers are influenced by proposals that potentially reduce healthcare costs.
6. Build alliances. Support from other reputable organisations and individuals can be invaluable.
7. Engage politicians, ideally from more than one party, including the governing party. Politicians have a unique public platform and can also raise issues behind-the-scenes with government ministers.
8. Seek media coverage. This can be a way of recruiting further support, especially from the general public, and of exerting greater pressure on politicians and policymakers.
9. Align the campaign with existing policies to show how the desired objective would have wider benefits.
10. Use all legitimate means to exert pressure, including legal action if appropriate.
11. Appoint highly-motivated individuals to leadership positions within the campaign.
12. Conduct the campaign in a way that is respectful while also challenging manner and avoid divisiveness, for example by adopting the fallacious ‘men’s rights’ view that the health of men and boys is being ignored because of a feminist conspiracy to favour women and girls.

FINAL COMMENTS

When the JCVI’s recommendation to vaccinate boys was made in July 2018, it still came as a surprise to HPV Action and its members. It had looked as if JCVI would remain wedded to its earlier clearly-stated position that gender-neutral vaccination was not cost-effective. Its eventual support for universal vaccination against HPV was, without doubt, directly attributable to the campaign waged by HPV Action and its allies.

Because JCVI is regarded internationally as one of the most rigorous and reputable vaccination advisory bodies, its decision is likely to have a significant impact on other countries’ HPV vaccination policies. The UK’s decision should make it easier for advocates to make the case for gender-neutral HPV vaccination elsewhere.

A new organisation, HPV Action Europe, is likely to launch in 2019 with the primary aim of seeking gender-neutral vaccination throughout Europe, initially in the EU and then throughout the 53 countries in the WHO Europe region. Several of HPV Action’s members, and also the campaign director, would be actively involved in the new organisation and the advocacy work in Europe will be able to draw heavily on the experience gained during the UK campaign.

The vaccination of boys in the UK is due to begin in September 2019.

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