

Adults at 12? Trends in puberty and their public health consequences

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Adults at 12?

Over the past 150 years, the age of puberty onset has fallen substantially across many developed countries. Although trends are apparent in both sexes,¹ the evidence in females (where biological markers are clearer) suggests that, for instance, in northern Europe the age at menarche (first menstruation) fell during the 1800s, then further reduced by up to 3 years over the last century (fig 1). Factors contributing to this fall include a combination of public health successes and changes in social structures. Thus, successes such as improved childhood nutrition and health status through reduction in childhood infections have been major factors accelerating the onset of puberty.⁷

Socially, however, stress is also a puberty accelerator, with familial disruption, including father absenteeism, being one of the most effective stressors, and levels of divorce as well as single-parent families have rapidly escalated in many countries (eg, England, 2005).^{8,9} The sum effect of these changes has been relatively recent reductions in the age of puberty onset.⁷ However, these have not been matched by efforts to socially develop young people at an

equally accelerated rate, leaving an increasing gap between physical puberty and social puberty (the age at which people are mentally, educationally and legally equipped to function as adults in modern societies). Here, we propose that this disparity may underpin many of the major public health challenges associated with young people today.

Puberty is a physical preparation for adulthood that, along with bodily changes, promotes interest in sexual activity,¹⁰ increases aggression in adolescents,¹¹ encourages curiosity and can escalate risk-taking behaviours as people compete for social status and attempt to conform to perceived peer norms.¹² Increasingly, however, as social puberty lags behind physical puberty, the results can be ill-informed health-damaging behaviour. Thus, early sexual activity is associated with unprotected sex and, consequently, sexually transmitted infections and teenage pregnancies.¹³ Moreover, adolescent stresses resulting from mismatches in physical and social development may also promote substance use (including alcohol, tobacco and drug use) as ways of both self-medicating and trying to conform to peer pressures. Further, a lack of

knowledge of how to adapt to changes in physical, mental and social status may lead to self-harm, violence and bullying.¹⁴ Attributing all recent changes in sexual health, substance use and violence to earlier puberty (on a population basis) is oversimplistic, but disregarding the role of earlier physical maturation in these major health trends is equally inappropriate.

Dissociation of physical and social puberty is also likely to affect certain communities disproportionately (eg, the most deprived). For example, early menarche has been linked with a combination of poor prenatal nutrition and excess nutrition in childhood.⁷ Although studied mainly in immigrant populations, such combinations are also more likely to occur endemically in deprived areas. Equally, other factors capable of accelerating puberty, such as single-parent families, are also associated with deprived populations (eg, in the UK).⁹ Surprisingly, the contribution that such inequalities make to current variations in the onset of puberty, and how they then affect patterns of sexual health, substance use and violence, is largely unstudied.

The continued reduction in the age of onset of puberty should not be treated as a biological anomaly. It is likely that some 20 000 years ago, humans had already evolved to experience menarche at around 12 years and at present many countries are moving back to this position.^{7,15} However, for young people, although physical development has reverted to this earlier age, understanding their role in society is becoming substantially more complicated. Further, political, educational and even parental attitudes can often ignore earlier puberty, preferring to leave important lessons about sex, risk-taking and social behaviour until later in life. In the meantime, the earlier physical development of children has not been ignored by commercial sectors. Magazines, television and radio are increasingly using sexual imagery for marketing and storylines aimed at younger people¹⁰ while versions of adult make-up and fashion lines are now specifically developed for the pubescent. Sales of computer games that include fighting and risk-taking rely on people developing interests in these behaviours early in life. Such marketing is more likely to reinforce the confusion caused by separated physical and social puberty rather than providing the information necessary to deal with it.

In many countries, it is unlikely that population trends capable of affecting puberty have stabilised. Lone parent and divorce rates are still increasing. Further, in developed countries, changes

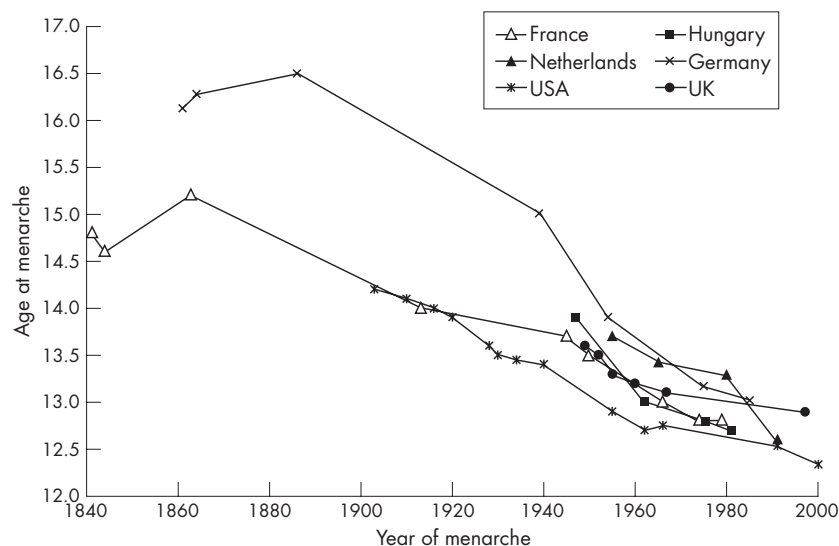


Figure 1 Secular trends in menarcheal age.²⁻⁶

in children’s diet mean that their body fat levels (a trigger for puberty) are rapidly increasing and, elsewhere, general improvements in child nutrition and child health are yet to plateau. In all cases, public health measures can affect the age at which children enter physical puberty. Where this considerably precedes social puberty, resultant pressures on children will contribute to public health problems through naive approaches to sex, risk-taking and aggression. Instead of tackling the consequences of such naive behaviour, a better understanding of puberty at the population level may offer new opportunities to address risk factors. In the long term, public health strategies may attempt to retain the benefits of improved childhood nutrition and reduced infection without necessarily increasing the gap between physical and social puberty. In the short term, however, responding to earlier puberty means moving away from societal attitudes that equate protecting children with regarding them as firmly ensconced in childhood long after their physical journey into adulthood has begun. Such pretence, however well intentioned, simply denies them the vital

information they require to complete this transition without damaging their health.

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Clinical trials

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European Medicines Agency policies for clinical trials leave women unprotected

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Relevance of equality of gender in clinical research

Specific strategies to implement guidelines for the study and evaluation of gender differences in the clinical evaluation of drugs have not been developed by the European Medicines Agency (EMA). This agency accepts “that some of the factors that influence the effect of a medicine in the population may be important when considering potential differences in response between men and women” and “gender-specific influences can also play a significant role in drug effect”. But besides these statements, in a document about gender considerations in the conduct of clinical trials, the EMA argues against the need for separate International Conference on

Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on women as a special population group, based on their internal review and experience, but without providing the sources.¹ The lack of sound fundamentals of these convictions is worrisome. This paper analyses the document of EMA,¹ and introduces some of the main reasons to reconsider the convenience to develop a policy on gender-related information for the clinical trials, an initiative already taken in the US.²

First of all, gender is not a demographic category of analysis as considered by the ICH guidelines. The

parameters disaggregated by sex are not always the same as those by gender sensitivity (in some instances both are used as the same, but they are not equal). The information disaggregated by sex tells us whether differences by sex exist in some specific dimension of health, but the information by gender sensitivity is constructed to help to know the reasons (and consequences) of the sex differences. So, the term “gender” should be removed and replaced by “sex” in not all but many instances of the ICH guidelines.

As early as 1986, the NIH policy recommended for the inclusion of women in clinical research. In 1993, the NIH Revitalization Act required adequate numbers of women for valid analyses of differences related to phase 3 trials, and the Food and Drug Administration (FDA) guidelines ended the restriction on women of child-bearing potential, emphasising sex representation in clinical trials to detect clinically significant differences.³

Clinical research in Europe was developed mostly in men until the 1990s. Afterwards, the ICH promoted the regulatory standards for clinical trials.⁴ The ICH guideline E8 requires that the study population should be representative of the target patient population, and also demands phase I pharmacokinetic