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| The ethics of State-sponsored and clinical promotion of long-acting reversible contraception        |
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## **REVIEW FORMAT**

#### **Contributors**

SR conceived the idea for the paper. SR did an initial literature search; JW checked and added to this. Both authors were equally involved in the analysis. SR produced an outline written concept and JW produced the first full draft. Both authors reviewed/edited subsequent drafts and approved the final manuscript.

#### **ABSTRACT**

#### **Objectives**

To review ethical aspects of the promotion and provision of long-acting reversible contraception (LARC). Specifically, to examine (1) the tension between informational exchange and the active promotion of LARC methods to new and existing contraceptive users by healthcare professionals; (2) the distinct ethical issues arising from the promotion of LARC methods by State-sponsored actors and healthcare professionals.

#### Methods

Narrative review and ethical analysis.

#### **Findings**

There is an ethical difference between raising awareness/ informational provision and actively promoting or prioritising specific contraceptive methods. It matters whether the policy choice is made, or the promotional activity about contraception is undertaken, by individual healthcare professionals at a local level or by more remote State-sponsored actors, because the relationship between the promoter and the (potential) contraceptive user is of a different kind. Imposing a dual responsibility upon healthcare professionals for raising awareness/ informational exchange and the active promotion of LARC, creates an unnecessary tension and barrier for the delivery of patient-centred care.

#### **Conclusions**

This review has highlighted the need for ethical reflection on: the central role of the promoting agent and the distinction between facilitating informational awareness and active promotion of LARC. LARC methods should not be prioritised in isolation and without regard to the wider implications of public promotion. A balanced narrative and information sharing programme that respects the individual interests of each contraceptive user is called for, especially in direct professional/ service user relationships. No assumption should be made that user decision-making will necessarily be determined and influenced solely by the relative effectiveness of the contraceptive method.

## **Key messages**

- LARC offers many advantages but should not be promoted as an unqualified good to all.
- Raising awareness, informational exchange and the active promotion of LARC methods give rise to distinct ethical and professional considerations.
- The identity/role of the agent promoting the fertility control option is important.
   Clinical relationships generate specific professional obligations in the context of fertility control.

## Keywords

Long-acting reversible contraception; Ethics; Promotion; State sponsorship.

#### **INTRODUCTION**

Long-acting reversible contraception (LARC) methods offer highly effective fertility control options for many contraceptive users and have been actively promoted to the public and to individual patients. Probably as a result, LARC use has increased over the last decade in Britain, especially among the under-25 age group. Whilst the clinical, safety and economic benefits of LARC have been investigated at length, less attention has been devoted to the ethical issues arising from the promotion and provision of these contraceptive methods.

Widespread coercive practices using reversible contraception and sterilisation<sup>2-4</sup> have arguably produced a legacy of suspicion in some communities about the intentions of promoters and providers of contraceptive services. This review examines two ethical aspects of LARC provision and promotion. Firstly, the tension between informational exchange and the active promotion of LARC methods to new and existing contraceptive users by healthcare professionals (HCPs). Secondly, the distinct ethical issues arising from the promotion of LARC methods by State-sponsored actors (SSAs) and HCPs. For our purposes, SSAs include policymakers, regulatory bodies, clinical commissioning groups and publicly-funded service providers. In contrast, HCPs are individuals directly engaged in providing information, offering advice and making recommendations to contraceptive users. We distinguish the activities and behaviours of individual HCPs from the organisations that they work for. Although there is scope for overlap, we maintain that there is credible distinction between the creation and setting of organisational policies, strategies and targets by senior HCPs/ leadership staff, and the activities of most individual HCPs working within those organisations. This distinction will be most apparent in those operating in and working for large public healthcare organisations.

Terminological inconsistency has slightly distorted the discourse on LARC with different jurisdictions and bodies using variable inclusionary rules based on the duration of action or effectiveness. We have adopted the NICE definition: namely reversible "contraceptive methods that require administration less than once per cycle or month".<sup>5</sup> NICE therefore includes subdermal implants, intrauterine contraception and injectable contraceptives, but excludes the transdermal patch and vaginal ring from their LARC definition.<sup>5</sup> 6

#### **METHODS**

Our research strategy looked for material freely available on the subject or otherwise available through academic repositories and published in the English language. These sources included peer-

reviewed journals concerned with the medical, sociological, ethical and legal aspects of contraception, books, theses, documentary films, government publications, publications by non-governmental organisations, articles in the lay press and information from reliable internet sources. We did not limit our search to particular years, although most sources date from 2014 onwards. We selected and filtered sources using abstracts (where available), before evaluating complete papers and other sources where relevant. The evaluation process included sources falling within our broader definition of LARC. We did not restrict our literature search to any single jurisdiction, although our primary focus was on sources published in and concerning high-resource countries, including the USA, United Kingdom and Europe. We looked for material that was relevant to and informed our discussion on the issue of promotion and informational exchange. Our research strategy facilitated the review of different ethical perspectives, although contextual variations across jurisdictions present a limitation.

#### **FINDINGS**

#### **Contemporary practices**

Many counselling aids rank contraceptives by effectiveness: implants and intrauterine devices belong in the first or higher tier (on a par with sterilisation) and injectables in the second or middle tier. Uptake of LARC has increased progressively as confidence in the methods increased – higher-tier methods offer women the equivalent peace of mind to sterilisation but with the benefit of reversibility. The 'fit and forget' nature of higher-tier methods, has offered some users more freedom in their lives. From this initial understanding and experience - combined with evidence of cost effectiveness - has grown an emphasis on ensuring that all LARC methods are readily available and accessible to those who wish to use them. There can be no criticism of this, as it is a human right that citizens should be able to enjoy the benefits of scientific progress. In order to achieve this, it is frequently identified that some HCPs need further training.

However, what has emerged in the last 15 years is a tendency to progress from higher-tier effectiveness to the primary promotion of LARC when contraceptive methods are explained to women and men attending services. A number of organisations have issued guidance on contraception encouraging counselling in the order from most effective to least effective method.<sup>10</sup> This provides a platform for citing LARC as the 'first-line' methods of contraception,<sup>10</sup> making the highly-significant leap from raising awareness to the active promotion and prioritisation of LARC. Where counselling prioritises LARC above other contraceptive methods, without first taking into

account individual circumstances and priorities, this can steer the user in a direction determined by the HCP.<sup>10</sup> This has also been referred to as 'optimising contraceptive decision-making through selection of the most effective methods'; <sup>11</sup> suggesting that the final choice is one that the HCP approves of and positioning LARC as the *only* responsible choice.<sup>12</sup>

These behaviours and positions are often initiated or encouraged by local public health departments and national Health Ministries and facilitated by HCPs because of beneficent concern for patients. This pattern of promotion has been described as a 'push' for LARC with a 'widespread consensus that access to LARC methods is an important public health goal'. <sup>13</sup> This promotion can be in the form of a general statement<sup>14</sup> or in the form of specific performance indicators to be measured. <sup>15</sup> There have been examples of promotion being directed at specific demographic groups including young people<sup>16</sup>, those at risk of child removal<sup>17</sup> and those undergoing induced abortion. <sup>18</sup> The concern is that some promoters are mixing up what is good for the public health with what is good for an individual patient. <sup>19</sup>

There is some evidence that HCPs have started to 'pull back' from a potentially coercive position to an individual rights-based approach. For example, in its original 2012 guidance on young people, the ACOG recommended:

'Increasing adolescent access to LARC is a clinical and public health opportunity for obstetricians-gynecologists. With top-tier effectiveness, high rates of satisfaction and continuation, and no need for daily adherence, LARC methods should be first-line recommendations for all women and adolescents'.<sup>20</sup>

This phrasing was radically changed in favour of patient autonomy in 2018 to:

'Coercive provision of LARC has been used as a means of fertility control in marginalized women. Patient choice should be the principal factor driving the use of one method of contraception over another, and respect for the adolescent's right to choose or decline any method of reversible contraception is critical. Obstetrician-gynecologists should recognize that potential sources of coercion could include parents, partners, clinicians, and peers. In addition, obstetrician-gynecologists should be cautious that their own enthusiasm for LARC may be an additional source of coercion '.21

#### Jurisdictional variation

In some countries, a range of contraceptive methods is available free of charge to the user (e.g. UK-save for condoms from general practitioners outside a condom scheme). In others, there are social security arrangements which heavily subsidise contraception (e.g. Belgium and France<sup>22</sup>); or insurance schemes (e.g. USA which has State Medicaid reimbursement schemes for immediate postpartum LARC placement<sup>23</sup>). In some, an item-of-service payment is made to general practitioners who insert LARC (e.g. Ireland and Finland). These funding differentials can produce variations in the uptake of LARC and other contraceptive methods. For example, in one region of Finland, a zero-cost public LARC scheme resulted in a doubling of LARC uptake.<sup>24</sup>

Variations in the degree of State-sponsored interference in the decisions and practices of HCPs is likely. Some clinicians have complained about undue influence on their clinical freedom by policymakers and service managers.<sup>25</sup> Awareness of these contextual factors is needed when judging the behaviours of HCPs at a practice level.

#### **CRITICAL ANALYSIS**

LARC methods have benefitted millions of users around the world; a substantial number have been satisfied with their LARC and many have stayed with their method, having repeated reinsertions/injections over time. However, others have had difficulties, seeking help with side-effects or uneasiness with the device or circulating hormone within their bodies, with many requesting discontinuation of the method before the end of its lifespan.

#### **Preliminary considerations**

A central consideration and a *prima facie* advantage is the so called 'fit and forget' nature of the higher-tier LARC methods – where the user can be freed from the continuous burden of regular thought and action otherwise prevalent and necessary with other forms of reversible contraception. Whilst this may not be the lived experience of some LARC users, the legitimacy of this default position is reinforced by the overarching effectiveness and reversibility of LARC options. However, the fact that users might not need to actively think or manifest daily action about their contraceptive method, provides a platform or opportunity for coercive abuse. Any default position requires active choice to change the pre-existing state of affairs, and the incidence of burdens or risks make path-altering outcomes less likely. Whilst SSAs may have good reasons to nudge citizens towards certain contraceptive methods (influencing outcomes using default rules, practices or priorities), this

should not be confused with the legitimacy of nudges or incentives used by HCPs in the clinical encounter.<sup>27</sup> In the former, we have an impersonal, anonymous relationship; in the latter we have an identifiable relationship that is supposed to be founded on trust.<sup>27</sup>

There are several distinctive features that require careful consideration in the context of the promotion and provision of LARC. Firstly, LARC methods are not an unqualified good or a risk-free option for users. Not all options are equivalent, either in terms of effectiveness, delivery or effect. Hormonal side-effects are relatively common with LARC (with the exception of copper IUDs).<sup>5</sup> Injectables are associated with a decrease in bone mineral density during use.<sup>28</sup> Uterine perforation is a rare complication of intrauterine devices.<sup>29</sup> Intravascular device embolism is a very rare but serious complication of subdermal implants.<sup>30</sup> Not all options are suitable for every user; there are contraindications for specific groups.<sup>56</sup> LARC methods do not provide general protection against sexually transmitted infections (STIs).

Secondly, SSAs and HCPs may lack objectivity because not all forms of contraception are cost or resource neutral. As such, it would be unfair to suggest that reproductive decisions are being made in a neutral choice environment.<sup>27 31</sup> The relatively high unit cost of LARC is offset by intended long-term use. This has implications for the allocation of resources in respect of fertility control and the types of choices encouraged by SSAs. LARC use generally requires relatively stable and lengthy use periods to justify the additional upfront unit cost and may not be suitable where instability is a prevalent feature.

Thirdly, the controversies surrounding LARC in some settings should not be ignored – these methods have not always been an unqualified success<sup>32</sup> and uptake is likely to be influenced by historical, cultural and local context. The fact that contemporary methods are safe, flexible and highly effective does not obviate the distortionary effects of history upon the user or professional practice. In particular, promoters should be alert to the fact that, in some cases, they are promoting hormone-based products with sustained effects on the human body. Promoters ought to be sensitive to these wider contextual factors.

Fourthly, promoters should acknowledge that default use has long-term economic benefits for device and drug suppliers/ manufacturers, together with ongoing burdens for the LARC user.

Certain options may tie users into a specific manufacturer or supplier, even if they have a theoretical

entitlement to switch method. Similarly, promoters should be transparent about the availability of choice for each option offered.

Fifthly, even if singular nudging (LARC offered as a default choice) is ethically acceptable (doubtful), combined nudging – for example, where default use of LARC is combined with the offer of incentives for use - gives rise to differing considerations and should not be evaluated in isolation. The more the overall nudging approach undermines individual autonomy - including the freedom to choose any available option - the greater the objection, especially as it relates to such a highly personal and sensitive area of human life. This is why schemes that combine conditional contraceptive use with access to other support services are so controversial. To be clear, we do not regard LARC information provision by HCPs which accounts for a full range of contraceptive options and the values of users as being equivalent to nudging.

Sixthly, promoters need to be aware and acknowledge that LARC options remove immediate control from the woman – users will often require medical intervention to switch or remove the device or implant. Even where medical intervention is not required, the contraceptive effects may not be reversed immediately – for example, it can take up to a year for fertility to return after injectable methods have been stopped.<sup>28</sup> These factors can create invisible barriers for users, especially if there are cost or access considerations at play. Some may prefer short term contraceptive methods that allow greater user control.<sup>18 33</sup>

It is this combination of features that warrants a more reflective and evaluative ethical approach to the promotion of LARC. We need to be alert to the type of LARC involved – the practical and ethical issues for each method are not necessarily identical. For example, access to removal services for different types of LARC may be variable (due to lack of training or other reasons), impacting on the level of control that women have in any given community. Finally, it remains important that HCPs do not confuse or conflate their professional obligations to individual patients with the wider policymaking objectives of SSAs. Although states ultimately work through individuals, creating tension for HCPs operating within policy/target driven frameworks, we argue that any conflict ought to be resolved in favour of the contraceptive user.<sup>19 34</sup>

#### Targeting, discrimination and inequality

As already indicated, some policymakers may be more concerned with lowering birth rates in certain population groups than with improving users' lives.<sup>35</sup> There is a range of literature discussing the

specific promotion and use of LARC in vulnerable and marginalised groups, including those in poverty, <sup>36</sup> with drug/alcohol issues (e.g. <a href="www.projectprevention.org">www.projectprevention.org</a>) and within racial and ethnic communities. <sup>26 37</sup> There is evidence from the USA that HCPs recommend LARC more to women of colour than to white women and preferentially to socioeconomically disadvantaged women. <sup>38 39</sup> Even comparatively recent papers refer judgementally to the 'right candidates' for LARC. <sup>40</sup> Interviews with homeless women found perceptions of biased counselling from HCPs, who played down potential side effects. <sup>41</sup> Also of concern is the setting of preconditions about LARC or other contraceptive use for access to support for certain demographic groups. <sup>17</sup> Targeted approaches should be alert to the potential discriminatory effects of promotion, the specific intersections between gender, race and class, and historical/ existing inequalities in society. <sup>4 42</sup>

One of the central dilemmas for HCPs is to decide how best to inform, advise and counsel individual contraceptive users living in an unequal world, where decisions are shaped by wider social, political and historical context. Some commentators have argued for a reproductive justice approach where the primary responsibility of HCPs:

'is not necessarily to reduce public expenditures, nor to ensure that all socially disadvantaged women use the most effective contraception possible. Rather, our ultimate reproductive justice endgame is to enhance the health, social well-being and bodily integrity of all our contraceptive clients.' 35

However, HCPs also need to avoid the conflation of wider societal good with the promotion or protection of individual interests. The possibility of harm should not be used as a basis for inflicting actual harm on that same individual.<sup>4</sup> HCPs should focus on and prioritise the protection and promotion of current patient interests - including respect for self-determination and governance - rather than speculative concern about future possible risk(s). These wider concerns might be valid considerations for SSAs, but HCPs have to be careful not to prioritise consequential benefits, jeopardising their professional obligations and the trust placed in them by individual service users. <sup>36</sup>

We should also acknowledge that there are currently no reliable LARC methods for men. Industry backing for the development of male contraceptive methods has been virtually abandoned. The promotion of LARC as a higher-tier option might infer that responsibility for fertility control falls predominantly upon the target user group (i.e. women). Public narratives need

to make the position clear and emphasise that both sexes have a responsibility, including a positive obligation to prevent the spread of STIs.<sup>44</sup>

#### Conflict, bias and personal values

The potential for conflict between HCPs and potential LARC users has been highlighted. <sup>18</sup> Underlying every contraceptive consultation is a power imbalance, although perhaps not as great as in consultations focusing primarily on illness. <sup>34</sup> Conscious separation of the public health element of HCPs' 'dual agent' role from their professional obligation to an individual service user is needed, giving the latter duty a higher priority. <sup>19 34</sup> A greater uptake of LARC would almost certainly result in fewer women having unintended pregnancies, fewer abortions, fewer single mothers and consequential savings to the public purse. <sup>8</sup> However, positioning any method as the first-line choice invites a lack of regard for the preferences of those using contraception. <sup>45</sup> Effectiveness is not the only concern for potential users when choosing a contraceptive method; other personal factors should be taken into account. <sup>18</sup>

Even when HCPs explicitly prioritise patient autonomy, there is a danger of unconscious bias, ill-informed decision-making or the leakage of personal values into clinical consultations to the detriment of patient interests. <sup>46 47</sup> These concerns may be further exacerbated if directed against marginalised or vulnerable individuals. Clearly, education provision is important for combatting outdated or inaccurate opinions about efficacy or effectiveness and to improve the balanced and personalised communication of contraceptive options.

## **Public narratives and state duties**

In this review, we have drawn a distinction between the nature/ type of duties that SSAs and individual HCPs owe to existing and future users of LARC. We do not have space to identify the full range of obligations that SSAs might have in connection with the promotion of general or specific contraceptive options. Certainly, there are likely to be ethical problems associated with the active state promotion of LARC for 'wrong' reasons including the discriminatory targeting of certain groups or individuals. <sup>35 36</sup> Our specific focus concerns the ethical duties associated with the creation and maintenance of a public narrative about LARC. If promoters want to prioritise LARC methods as a higher-tier contraceptive option, they should be transparent and clear about their rationale(s): are they prioritising group interests and goals over the interests of individuals; is one method preferred over another for non-medical reasons etc? The social narratives of 'awareness' and 'promotion' do not necessarily converge. Further, SSAs should be clear and coherent in their narrative on fertility

control – is the message one of respect for patient autonomy or responsible family spacing? The normative messaging may not be the same – the latter emphasising responsible parenting and consequential considerations rather than the enhancement of individual choice.

#### **Timing**

There has been a trend to promote LARC options to women in the immediate postpartum period.<sup>48</sup> There may be an underlying funding reason or beneficent concerns about the risk of a future pregnancy or short inter-pregnancy intervals. However, care needs to be taken to ensure that the woman has the capacity, freedom and information to make these decisions at the material time.<sup>4</sup> Ideally, the issue of contraception should be canvassed in advance of delivery and decisions reaffirmed in the postpartum period.

#### Follow-up

Should HCPs have an ongoing professional obligation to ensure that the chosen LARC option remains suitable for the user over the longer term? Registration of contraceptive prescription/ intervention has been undertaken in the past<sup>49</sup> and periodic user recall should be feasible and impose limited burdens on providers. The regularity of review could be influenced by circumstantial factors, including knowledge of specific vulnerability. Users would retain a personal responsibility for their care (e.g. to report unusual symptoms), and due recognition should be given to the effectiveness of follow-up when allocating finite resources. What might tip the balance ethically is the longer duration of action and the invasive nature of LARC methods. Users could opt out of review, but advance opt-outs should be avoided if the provider is serious about addressing the autonomy concerns as individual user circumstances may change.

### **CONCLUSIONS**

A balanced narrative and information sharing programme that respects the individual interests of each contraceptive user is called for in LARC provision, especially in direct HCP/ user relationships. In areas of conflict, HCPs should privilege the interests of individual contraceptive users over wider public health or population control objectives. We do not say that policymakers should ignore wider resource considerations, but positive promotion and raising awareness are different. Imposing a dual responsibility upon healthcare professionals for raising awareness/ informational exchange and the active promotion of LARC, creates an unnecessary tension and barrier for the delivery of patient-centred care. This has clear ramifications for target setting and the implementation of policy

objectives. It is critical that user interests are heard in policymaking and programme development in this area.

#### ADDITIONAL EDUCATIONAL RESOURCES

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