Sharing is Caring?

Consideration of the sharing of patient information in line with existing legislation and guidance, and options going forward

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Introduction
A review of Sexual Health and HIV services was identified as a priority by the Minister for Social Services and Public Health in November 2016.

The individual delivery expectations and specific priorities set out in the new Review of Sexual Health & HIV Services in Wales should help to realise the following overarching ambitions for improved sexual health and wellbeing in Wales:

- Everybody has the opportunity to access high-quality sexual health care and services
- People are empowered to look after themselves and support others to prevent sexual ill-health.

A key task identified by the Minister in her Written Statement [1] was to ‘consider issues relating to data confidentiality and medical professional standards in relation to the National Health Service (Venereal Diseases) Regulations 1974’. This document seeks to address this request.

In undertaking this task, a Task & Finish Group was established, which:

1. Considered examples where patient care has been impacted by the lack of information sharing;
2. Looked at perspectives on balancing confidentiality and patient’s rights with clinical concerns over reducing the risk of further harm, and;
3. Considered ways forward for possible options to overcome data sharing concerns.

This work has culminated in this paper being developed, which presents officials with a series of options that could be taken to improve patient care, whilst also seeking to respect confidentiality and maintain trust.

Much of this paper refers to HIV, as this has been the predominant concern in prior discussions leading to the work being undertaken. Nevertheless, there are other chronic conditions, such as viral Hepatitis, that are of equivalent concern, and therefore the Group have considered communicable, chronic conditions throughout this project. Additionally, the Group have considered HIV in all its transmission routes; not just through sexual transmission. The ambition to reduce the risk of unnecessary harm is relevant regardless of transmission route.

Finally, the Group would also like to stress at the outset that we have found no evidence, nor an appetite or need, to remove the increased levels of confidentiality routinely available with regards to the diagnosis or treatment of sexually transmitted infections (STIs), except in relation to the management of chronic conditions which can be sexually transmitted e.g. HIV, hepatitis B and C.
Sharing is Caring?

Background Literature Review

Literature Search Strategy
The following databases were searched for relevant studies: Embase, Medline, PubMed (2007- July 2017). The search strategies used text words and relevant indexing to capture the concept of the sharing of patient information [sexual health] in line with existing legislation and guidance. The studies were limited to English language with no limitation to study design. A web-based grey literature search was conducted to identify key sources and research reports on this topic published by international health agencies.

General Considerations
Concerns around patient confidentiality and sexual health have been key themes in academic literature over many years, regarding HIV and disclosure, the Fraser Guidelines and their implications for service delivery, and on issues related to abortion and fertility. Outside of the sexual health sector though, the complexities around confidentiality and prevention of harm have been a theme within healthcare generally.

The most historical text of all in relation to the subject of confidentiality and ethics is, of course, the Hippocratic Oath [2]. The Oath has been modified and adapted numerous times; in the 1964 adaptation by Louis Lasagna of Tufts University there was the following statement: ‘I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know.’

In the realm of public health, the book Professional Practice in Public Health [3] provides an overview of the Data Protection Act 1998, with an emphasis on the eight principles for processing personal information [3, p.179]. This text also highlights that respecting confidentiality is ‘part of all codes of conduct for health and social care professionals’ [3, p.215]. The editors also consider the earlier work of Downie and Calman [4], who suggested that people with whom information might be shared includes ‘those who must know, those who should know, those who could know and those who should not know.’

Holland, in the introduction to Public Health Ethics [5, p.9], queries ‘which is the important right, the human right to maximal health or the individual right to liberty?’. This text goes on to consider confidentiality in the context of epidemiology [5, p.103], citing a section of John Last’s chapter ‘Professional Standards of Conduct for Epidemiologists’, which appeared in Coughlin and Beauchamp’s Ethics and Epidemiology: ‘The clash between the privacy rights of persons and the need for access to and disclosure of personal health-related information is the most frequent ethical dilemma to confront epidemiologists.’[6] This debate is further expanded in Chapter 16 of The Philosophy of Public Health [7]. In Contagious Disease and Rights, T.M Wilkinson questions whether rights are always absolute, and ‘If the rights may be infringed on, then when and why? An obvious initial answer is: when it would do enough good, or, what I shall take as an equivalent, averting enough harm.’ [7, p.182]

Concerns over power and models of care should also be considered in this context. In a patient-centred model of care, the patient and clinician should reach an understanding on the nature of their illness, and aims for its management, including who is responsible for what. Box 2.2 in Laverack’s Public health: power, empowerment and professional practice [8, p.20] provides a succinct summary...
of ‘The Patient-centered Clinical Method’, adapted from Stewart’s Patient-centered medicine: transforming the clinical method [9]. This model has traditionally involved the clinician directly in discussion with the patient, but in a consultation following a positive test result for a chronic condition, such as HIV, should this consultation consider the important role of other clinicians responsible for the patient’s wider care, such as the patient’s GP? This consideration leads to further questions on the nature of power and control in healthcare – notably around who oversees the patients care, the patient or the clinician? In Sociology of Healthcare, David Armstrong argues that an encounter between patient and clinician is an ‘institution of social control’ [10].

There have been a limited number of journal articles written specifically on the theme of confidentiality and/or the sharing of patient data and sexual health. Gibbs et al. provided a short vignette on the subject in Sexually Transmitted Infections in 2017 [11]. This article argued that the rights of patients to access confidential care is a ‘founding principle of sexual health care in England’, challenging the concept of using confidential identifiers, such as the NHS number, which was introduced as a possibility through the Health and Social Care (Safety and Quality) Act 2015, though acknowledging that this ‘could improve patient journeys across primary and secondary care and allows for more robust surveillance.’

Parker et. al [12] undertook a patient survey across 51 clinics in England regarding the importance of confidentiality in sexual health clinics. Over 4000 patients responded to the survey, with findings including that women valued confidentiality as more important than men did, and that those 25 years of age or older more likely to disagree with possible changes to confidentiality rules. Associations were noted between disagreeing with changes to rules and feeling less likely to attend a service if the laws were changed. In all, over 60% of total respondents supported keeping additional confidentiality and anonymity for STI services, indicating that they would feel less likely to attend services if this was amended. In a subsequent paper, Saxon and Sukthankar [13] challenged the survey design, outlining how their localised repeat of the survey, with amended phrasing and ordering of questions led to a higher number of survey participants disagreeing with the proposed amendments to the regulations regarding confidentiality in a sexual health context.

Kate Adams provided a personal view article to the BMJ in 2014, focussed primarily on routine referral letters sharing clinical data without patients’ consent [14]. This article reflected on discussions at a roundtable on HIV and confidentiality organised by the National AIDS Trust (NAT). In it, Adams reflected on the consensus of the meeting being that there ‘needn’t be a problem with primary and secondary care doctors directly involved in the provision of care sharing a patient’s HIV status; the problem was how some healthcare professionals stigmatise patients with HIV.’ Adams also reflects on two clinical encounters that she has experience in her practice with HIV-infected patients. She states that she ‘tried to persuade the patients that it was in their interest to disclose their HIV status. I feel uneasy not disclosing relevant clinical information to colleagues and worry that instead of normalising such conditions, I might be further stigmatising them by supporting people not to disclose. But respecting patients means respecting their choices, and patients can be harmed in several ways by inappropriate disclosure—by subsequent discrimination and by breach of trust.’ Adams continues by acknowledging that ‘decisions not to disclose relevant clinical information may also have a negative impact on quality of care by healthcare professionals. If patients ask that information is withheld, they need to be informed of the possible consequences.’
**Legislative & Regulatory Context**

The **National Health Service (Venereal Diseases) Regulations 1974** [15] (‘the 1974 Regulations’) covered England and Wales when introduced on 1<sup>st</sup> April 1974. In short, the Regulations exist so that any data or information that may identify a service user who is examined or treated for any ‘venereal disease’ shall not be disclosed other than to a medical practitioner involved in the treatment of the individual, or for the prevention of the spread of the disease. The Regulations state that:

*Every Regional Health Authority and every Area Health Authority shall take all necessary steps to secure that any information capable of identifying an individual obtained by officers of the Authority with respect to persons examined or treated for any sexually transmitted disease shall not be disclosed except—*

(a) for the purpose of communicating that information to a medical practitioner or to a person employed under the direction of a medical practitioner in connection with the treatment of persons suffering from such disease or the prevention of the spread thereof, and

(b) for the purpose of such treatment or prevention.

In England, these Regulations were updated in 1991 with the National Health Service Trusts (Venereal Diseases) Directions 1991, in turn replaced by the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000 [16], which imposed the same obligations on members and employees of NHS trusts and Primary Care Trusts in England, and revoked the 1974 Regulations. Further developments in England have seen the introduction of The Health and Social Care (Safety and Quality) Act 2015 [17], which made provisions about the integration of information relating to users of health and social care services in England and about the sharing of information relating to an individual for the purposes of providing that individual with health or social care services in England, as well as the Health and Social Care (Safety and Quality) Act 2015 (Commencement No 1 and Transitory Provision) Regulations 2015 [18] which set a duty on publicly funded health services and adult social care providers in England to include a “consistent identifier”, such as an NHS number, when processing information about an individual when providing services. Significantly in this context, the supporting regulations regarding ‘consistent identifiers’, The Health and Social Care Act 2012 (Consistent Identifier) Regulations 2015 [19], and in particular its Explanatory Notes [20, pp.1–2] include exceptions where the patient objects to their information being shared, or their NHS Number being used; where the service user ‘receives services anonymously (e.g. sexual health services)’; or where an individual does not have an NHS Number. A succinct summary of Legislation in England on this topic was published as supplementary material to support the Gibbs et al. article in February 2017’s issue of Sexually Transmitted Infections [21].

As it stands currently, the National Health Service (Venereal Diseases) Regulations 1974 remain in force in Wales, with amendments to terminology due to other legislative updates (e.g. other legislation substituting ‘Regional Health Authorities’ with ‘NHS Trusts’) [22].

**Data Protection Act 1998 & General Data Protection Regulation 2018**

A health record is defined by the Data Protection Act [23] as "information relating to someone's physical or mental health that has been made by (or on behalf of) a health professional". The Data Protection Act will protect a health record that falls within this definition whether the record is manual or computerised.
On 25th May 2018, the General Data Protection Regulation (GDPR) [24,25] will come into force. This is an EU Regulation, to which the UK will be party, as it is directly binding, without requiring any enabling legislation within UK Parliament. The implications of this new regulation must be considered in any subsequent decisions arising from this paper.

**Human Rights Act 1998**

The Human Rights Act 1998 [26] provides a guaranteed right to privacy, unless there is an overriding public interest. Article 8 of Schedule 1 of the Act expresses this as ‘Everyone has the right to respect for his private and family life, his home and his correspondence’ and ‘There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.’

In the context of this paper, it could be argued that in certain scenarios in the sexual health context, the ‘protection of health’ exception could override the right to privacy.

**Professional Standards**

Guidance around professional standards from specific professional organisations is provided in the [Existing Guidance] section of this document, and is therefore not repeated here.

**Associated Issues**

**Defining Consent**

The Nuffield Council on Bioethics considered issues related to confidentiality and consent in their report ‘The collection, linking and use of data in biomedical research and health care: ethical issues’ [27, pp.49–52]. In this, they state that ‘Consent sets aside norms and standards, such as the expectation of confidentiality, in specific ways for specific purposes... Valid consent is consent that is freely (autonomously) given: for it to count as valid it cannot be obtained by coercion or deception. Furthermore, the person consenting should be aware of the morally relevant implications of giving consent.’ [27, p.51]

The GMC’s 2008 publication ‘Consent: patients and doctors making decisions together’ [28] considers issues related to consent in depth, with a particular focus on capacity to give consent to treatment and examination. This, and many other medical publications, tends to consider consent in this context, rather than consenting to share information exclusively.

Dame Fiona Caldicott’s *Information: To share or not to share?* provided clear definitions of consent, explicit consent, and implied consent [29, p.36].

A 2008 Welsh Health Circular outlined the principles of consent, looking at case law and relevant legislation [30]. Again, this reference focuses primarily on capacity to give consent.

‘Privacy’ and ‘Confidentiality’ - which, when?

Linked with the Human Rights Act 1998 right to privacy, there can often be misunderstanding of the context in which the terms ‘privacy’ and ‘confidentiality’ are appropriate, and they are often used together, even though they are distinct issues.
To define ‘Privacy’, the Nuffield Council on Bioethics report [27, p.50] states that ‘Privacy concerns the interest people have in others’ access to themselves, their homes and property, or to information about them…Informational privacy is maintained by selectively withholding or allowing access or through establishing limits on acceptable behaviour by others.’

For ‘Confidentiality’, the Nuffield Council on Bioethics report [27, p.50] states ‘Confidentiality concerns the assurance that information provided by a person (or by another body) will not be further disclosed without their permission (except in accordance with certain established laws, norms or expectations about when confidentiality obligations may be set aside).’

**Self-Management**

A patient’s right to self-determinism regarding their medical conditions is considered in some literature, particularly in relation to HIV infection.

The British HIV Association (BHIVA)’s Standards of Care for People Living with HIV consider the concept of self-management, their ninth standard [31, pp.51–54]. This standard highlights that ‘limited health literacy contributes to sub-optimal care, poorer health status of affected individuals and avoidable costs within health systems’ with further explanation that ‘Self-management involves people with HIV developing an understanding of how their condition affects their lives and how to cope with the issues and symptoms which it presents. Effective self-management allows people with HIV to make the many daily decisions that improve their health-related behaviours and outcomes.’

The standard also explains that ‘people with HIV are frequently best placed to know and understand their own needs’, stating that ‘Services that provide care for people with HIV should be delivered in a way that not only supports but also facilitates self-management, and encourages staff to operate a strong self-management philosophy.’

**Caldicott Reviews**

Dame Fiona Caldicott’s review of Information Governance, *Information: To share or not to share?* (otherwise known as Caldicott 2) was published in March 2013 [29]. The report highlighted a ‘culture of anxiety’ amongst health and social care organisations in relation to sharing information, particularly through misguided efforts to protect organisations from possible fines or perceived breaches of data protection laws, leading ‘to a ‘risk-averse’ approach to information sharing’ [29, p.35].

In relation to implied consent, whilst the Review Panel concluded that this is only applicable in instances of direct care, ‘The Review Panel found there was limited awareness of the boundaries of implied consent both among health and social care professionals who rely on it and other staff who feel it may apply to their practices. The Review Panel also found that patients and public generally assumed there was a greater level of sharing to support direct care than was actually happening.’

The Review Panel also found that ‘generally, the practice of sharing personal confidential data between those directly caring for individuals could be better.’

Recommendation 2 arising from this review [29, p.38] was expressed as follows:
‘For the purposes of direct care, relevant personal confidential data should be shared among the registered and regulated health and social care professionals who have a legitimate relationship with the individual.

Health and social care providers should audit their services against NICE Clinical Guideline 138, specifically against those quality statements concerned with sharing information for direct care.’

The subsequent Review of Data Security, Consent and Opt-Outs [32] (otherwise known as ‘Caldicott 3’), published in 2016, looked in detail at ‘Consent/opt-out of information sharing in health and social care’ [32, sect.3]. The evidence gathered for this aspect of the Review ‘emphasised the importance of trust, clarity and purpose’ but, as with the paper as a whole, suggested a move to an ‘opt-out’ model. This review suggested that there was ‘still limited public knowledge about how data is used in health and social care’ and that ‘Both patients and professionals emphasised the need for clarity and clear communications on when and what information professionals can and should share.’ [32, sect.3.1]

The 2016 Review came about in part following a request from the Secretary of State for Health to the National Data Guardian to develop a consent/opt-out model. This model would make it ‘absolutely clear to patients/users of care when health and social care information about them will be used and in what circumstances they can opt out’ [32, sect.3.2]. Section 3.2.3 highlighted that ‘Information is essential for high quality health and social care...to support the running of the health and social care system; to improve the safety and quality of care; [...] to protect public health’ and also stated that ‘Data sharing is essential to identifying poor care. It is clear that more effective data sharing could have enabled some of the recent failures to provide proper care to patients to be identified and tackled earlier.’ [32, sect.3.2.3]

For direct care purposes, section 3.2.5 highlighted that there remains ‘a low level of public awareness and understanding of how health and social care information is used, but an expectation that information is shared for direct care.’ This referred to the new legislation in England (The Health and Social Care (Safety and Quality) Act 2015 [17]) and how this reinforced Caldicott principle 7 (‘the duty to share information can be as important as the duty to protect patient confidentiality’), but as section 3.2.6 stressed, ‘only relevant information about a patient should be shared between health professionals in support of their care.’

Recommendation 11 of the Caldicott 3 review is as follows:

‘There should be a new consent/opt-out model to allow people to opt-out of their personal confidential data being used for purposes beyond their direct care. This would apply unless there is a mandatory legal requirement or an overriding public interest.’ [32, p.29].

The review continues by recommended the implementation of the new model for uses of personal confidential data ‘specifically authorised under law’. [32, sect.3.2.23-3.2.24]
Existing Professional Guidance

British HIV Association (BHIVA)

BHIVA is a UK association representing professionals involved in HIV care, and is a national advisory body. Their 2012 ‘Standards of Care for People Living with HIV’ [31] were written in partnership with a number of other organisations engaged in the care of people living with HIV (PLHIV) and covers 12 main themes seen as the most important issues related to the care of PLHIV. The Standards were devised to provide a framework to inform and support commissioning decisions both within and outside the NHS.

Within the introduction to the Standards is an acknowledgement that ‘HIV stigma and prejudice continue to blight the lives of many people with HIV, making confidentiality of clinical and personal details of paramount importance. However, confidentiality is not the same as anonymity. On balance the clinical benefits of using a single identifier across all health services outweigh the risks and we suggest that the continued practice of not using the NHS number in some HIV services should be reviewed.’ [31, p.7]

Standard 10 is regarding the participation of PLHIV in their care, stating that ‘People living with HIV should have opportunities to be actively involved in decisions about their health care’ [31, p.55]. This re-iterates the GMC ‘Consent’ guidance [28], suggesting that clinicians:

- Listen to patients and respect their views about their health;
- Discuss with patients what their diagnosis, prognosis, treatment and care involve;
- Share with patients the information they want or need in order to make decisions;
- Maximise patients’ opportunities and ability to make decisions for themselves;
- Respect patients’ decisions.

Standard 11 [31, p.62] considers the competencies of those engaged in a PLHIV’s care. This section acknowledges that ‘The complexity of HIV makes it essential that people are managed by a multidisciplinary team (MDT) and that the members of the team have the appropriate competencies to undertake this care safely and effectively’ and also states that ‘people who are HIV positive should experience care that is delivered to the highest standards of confidentiality, privacy and dignity, in line with GMC guidance and national standards’.

Standard 12 considers patient information for surveillance, commissioning, audit and research purposes. Within this Standard is a section on Information Governance, explaining that ‘confidentiality of the personal and clinical details of people with HIV is of paramount importance. Any data collection processes that involve people with HIV must deliver the appropriate level of confidentiality that is required by law, ethics and policy.’ [31, pp.69–73]

Faculty of Sexual & Reproductive Health (FSRH)

FSRH is a faculty of the Royal College of the Obstetricians and Gynaecologists. It was established on the 26th March 1993 as the Faculty of Family Planning and Reproductive Health Care.

Their October 2015 ‘Service Standards on Confidentiality’ [33] stress that ‘It is essential, if the legal requirements are to be met and the trust of patients is to be retained, that the NHS provides, and is
seen to provide, a confidential service’, expressing the particular importance of this to a sexual and reproductive health service.

Chapter 3 of these Standards provides a statement on clients’ rights to confidentiality [33, p.8]. This emphasises that ‘All clients have the right to expect that information about them will be held in confidence. Patients must be properly informed as to how identifiable information about them is used.’ Point 3.5 states that ‘Explicit consent should be sought for the use or disclosure of personal health information, unless it is clearly implied... Specific permission should be sought from the client to sharing any information with anyone outside the service, other than those directly involved in client care, e.g. laboratory staff...’ (This author’s emphasis).

These standards are due to be reviewed in October 2018.

The FSRH’s Service Standards for Sexual and Reproductive Healthcare [34], published in September 2016, reiterate and link back to the October 2015 standards on confidentiality.

**General Medical Council (GMC)**

Doctors are bound by a strict duty of confidentiality, as set out by their regulatory body, the General Medical Council (GMC) [19, 20]. Of note is ‘Confidentiality: good practice in handling patient information’, the latest version of which was published in January 2017, and came into effect on 25th April 2017 [37]. This guidance is also available in Welsh [38]. Available in English-only is an interactive flowchart to support practitioners in their understanding of whether patient information needs to be disclosed, and the justification for doing so [39]. Additionally, in 2008, the GMC published ‘Consent: patients and doctors making decisions together’ [28], which is also available in Welsh [40]. This guidance sets out the principles on which good clinical decisions should be based.

In ‘Confidentiality: disclosing information about serious communicable diseases’ [36], the GMC outlines the relevant aspects of their core guidance related to communicable diseases. This guidance is also available in Welsh [41]. This guidance outlines the fundamental principles of good practice in handling patient information in the context of sexual health and other serious communicable diseases, and should be considered a key point of reference.

Alongside the 2017 updated guidance on confidentiality, a series of case studies were produced, one of which was a two-part scenario related to a Sexual Health Consultant’s dilemma over whether their patients HIV status should be disclosed to their GP [25, 26].

The 2017 Guidance also provides guidance on the limited instances whereby a healthcare professional should provide information in the public interest about a patient in relation to other laws or by a court order.

In 2008’s Consent, advice is provided on sharing information, discussing side effects, complications and other risks, making decisions and issues related to a patient’s capacity to make decisions. An annex to the guidance provides advice on the legislative context of the time. This guidance states that when discussing a patient’s diagnosis, prognosis and treatment options, the clinician should ‘involve other members of the healthcare team in discussions with the patient, if appropriate’ [28, p.13] and that in discussing side effects, complications and other risks, ‘Clear, accurate information about the risks of any proposed investigation or treatment, presented in a way patients can understand, can
help them make informed decisions. The amount of information about risk that you should share with patients will depend on the individual patient and what they want or need to know. Your discussions with patients should focus on their individual situation and the risk to them. ' [28, p.16]

Aside from these two major guidance documents, the GMC has also published a factsheet which outlines the key legislation linked to confidentiality [44]. This looks at legislation linked to accessing patient records, disclosure of reports, safeguarding, mental capacity and mental health, public health and mandatory notification schemes, and legislation regarding the prevention, detection and prosecution of crime. The factsheet is also available in Welsh [45].

**Nursing & Midwifery Council (NMC)**
The Nursing & Midwifery Council’s The Code [46] (also available in Welsh [47]) presents the professional standards that nurses and midwives must uphold in order to be registered to practise in the UK. Item 5 of the code relates to respecting people’s right to privacy and confidentiality. It states:

*As a nurse or midwife, you owe a duty of confidentiality to all those who are receiving care. This includes making sure that they are informed about their care and that information about them is shared appropriately. To achieve this, you must:*

*…5.4 share necessary information with other healthcare professionals and agencies only when the interests of patient safety and public protection override the need for confidentiality. [46, p.6]*

**British Medical Association (BMA)**
The BMA is the trade union and professional body for doctors in the UK. Their ‘Confidentiality and health records toolkit’ [48] features a chapter on ‘Serious communicable diseases’ [49], which considers the legal restrictions on disclosure, as well as looking at scenarios such as whether information can be disclosed to ‘close sexual contacts’ or in incidents where a healthcare worker has suffered a needlestick injury. About disclosing to sexual contacts, the BMA advice includes the following: ‘Patients should also be advised that if they refuse to share the information, the health professional may be obliged to do so.’ The guidance also links back to advice from the GMC: ‘Exceptionally, if patients refuse to modify their behaviour or inform others, doctors are advised by the GMC that they may breach confidentiality and inform a close sexual contact of the patient. Wherever possible, patients should always be told before this step is taken.’

**General Dental Council (GDC)**
The GDC regulates dental professionals in the UK, maintaining standards for the benefit of patients. Dentists operate under ‘The 9 Principles’, with principle 4 entitled ‘Maintain and protect patients’ information’. Section 4.2 of this principle reflects on the duty to protect the confidentiality of patients’ information. Relevant extracts from this guidance include points 4.2.5 and 4.2.6, quoted in full below:

*‘4.2.5 You must explain to patients the circumstances in which you may need to share information with others involved in their healthcare. This includes making sure that they understand:*

  * what information you will be releasing;*
  * why you will be releasing it; and*
  * the likely consequences of you releasing the information.*
You must give your patients the opportunity to withhold their permission to share information in this way unless exceptional circumstances apply. You must record in your patient’s notes whether or not they gave their permission.

4.2.6 If a patient allows you to share information about them, you should ensure that anyone you share it with understands that it is confidential.’ [50]

Notably, the content of this principle relates to a dentist generating information, not being a potential recipient of confidential patient data from another source.

Expanded guidance on this principle, and the other principles, is provided in ‘Standards for the Dental Team’ [51, pp.34–43].

Antenatal Screening Wales (ASW)
Antenatal Screening Wales (ASW) is based within Public Health Wales’ Screening Division. ASW sets Standards for antenatal screening for HIV, syphilis and Hepatitis B, which the Health Boards in Wales then implement and maintain. ASW has developed Antenatal Screening Wales Policy, Standards and Protocols, the latest version of which was published in 2015 [52]. Section 4 of the Policy, Standards and Protocols document covers Antenatal Screening for HIV, Hepatitis B and Syphilis [52, pp.10–27].

There are protocols for giving positive results to women, with Standard C 34, Protocol 5 stating ‘The result should not be given by the maternity staff to the woman’s partner or relatives without the woman’s consent. The result should not be given to the General Practitioner or Health Visitor without the woman’s consent. Discussing these issues should form part of a comprehensive care plan developed with the specialist HIV team’ [52, p.20]. There are similar Standards in relation to Hepatitis B(Standard C 40, Protocol 6) and in relation to Syphilis, (Standard C 50 Protocol 5).

Information for Service Users

British Association for Sexual Health & HIV (BASHH)
BASHH was formed in 2003 through the merger of the Medical Society for the Study of Venereal Diseases (MSSVD; established 1922) and the Association for Genitourinary Medicine (AGUM; established 1992).

BASHH has created posters for sexual health clinics ‘to promote the importance of patient confidentiality as a fundamental aspect of sexual health services’ [53]. These posters were primarily designed for England-based services following the introduction of the Health and Social Care Act 2012.

National AIDS Trust (NAT)
NAT’s Life with HIV website provides a series of articles for PLHIV. One of these articles, under the heading ‘My Care My Voice’, is Confidentiality and Disclosure [54]. This article outlines how the patient’s personal information will be handled by the NHS, and discusses whether the patient should tell their GP that they have been diagnosed with HIV, and if so, whether the GP would tell anyone else in the NHS about the patient’s HIV status.
The article advises that it is ‘a good idea to tell your GP about your HIV diagnosis...It is also important that GPs know what medication you are on so that they don’t prescribe anything that interacts with it.’ Furthermore, the article acknowledges that ‘your HIV status will normally be included in any referrals that your HIV clinic might make on your behalf, for example to a hospital specialist. A copy of these referral letters are normally also sent to your GP, so if you do not want your HIV status disclosed you should make sure your HIV clinic is aware of this.’

Regarding whether a GP would tell anyone else in the NHS about the HIV status of an individual, the article states that ‘GPs normally assume that there is implied patient consent to share relevant medical information with other parts of the NHS, when referring you for other care (e.g. hospital services).

HIV is considered relevant to almost all aspects of your care, so this information would routinely be shared with other parts of the NHS to help ensure your healthcare is safe and of a high standard. This is especially important if you could be prescribed drugs which would interact badly with any HIV medication you are taking... However, if you do not want your GP to share your HIV status with another part of the NHS, you can ask them not to. It is important to have this conversation, so that your GP knows that you don’t consent to have your information shared.’

With the support of BHIVA, NAT produced the guidance Confidence in the NHS: Your Information, Your Rights [55]. This gave service users in England an understanding on how personal, confidential information on HIV is stored, used and shared. In response to the question ‘When will a healthcare worker share my confidential information with someone else in the NHS?’ the guidance explains that ‘A healthcare worker will share your confidential information with someone else who is, or is about to, provide you directly with healthcare to make sure you get the best possible treatment. They will only share information which is relevant to your care in that instance. They will only share this information if you consent.’ [55, p.4] The guidance also outlines definitions of explicit and implied consent, and explains why it is important for healthcare workers to know about HIV status and current treatment.

Furthermore, in relation to whether a GP would be automatically told about a patient’s HIV diagnosis, the guidance explains that this wouldn’t happen automatically, and a HIV clinic would ask for explicit consent before doing so, with it being ‘strongly recommended that you agree to your GP being told about your HIV diagnosis.’ It also states that ‘Once your GP knows about your HIV diagnosis there should be communication between your HIV clinic and your GP at least once a year with information about your health.’ [55, p.7]

**NAM aidsmap**

NAM is a leading provider of information on HIV and AIDS, primarily through its website aidsmap.com. Amongst its resources are articles on confidentiality. In Confidentiality and medical professional standards [56], NAM outline much of the content of this paper, looking at the various sources of professional standards from clinical organisations, whilst also explaining to the service user what the standards mean in practice.

Of particular relevance to this paper is the article on Confidentiality and the venereal diseases regulations [57]. This describes the regulations as ‘often regarded as providing a special, heightened level of confidentiality with respect to STIs’ and continues by providing a history of the regulations, through to their 1974 version and the 2006 Department of Health consultation.
Antenatal Screening Wales (ASW)

ASW provides an information leaflet for women who are HIV positive [58]. In response to the frequently asked question ‘Who needs to know that I am HIV-positive?’ the leaflet answers:

‘For you and your baby to have the best care, it is necessary for you to receive care from a number of specialists – for example, the HIV clinic team, obstetrician (hospital doctor) and paediatrician (baby and child doctor). Your midwife will ask you if they can share information about you with the specialists directly involved in caring for you and your baby. We will not share information with others without your permission.

We will ask you whether you want us to tell your general practitioner (GP) that you have HIV. If you prefer that your GP does not know, we will respect your wishes. However, your GP will be aware of other health issues you may have and medicines you take. If they know that you have HIV, this can avoid interactions between HIV medication and other drugs they may prescribe.’ (This author’s emphasis) [58, p.6]

Information Supplied to the Task and Finish Group

The Task & Finish Group - through the Public Health Wales Sexual Health Programme Lead and the Lead Author of this paper - invited RCGP, BMA Wales, the Welsh Medical Committee and the chairs of each Local Medical Committee to submit examples of when patient care has been impacted through a clinician not knowing the patient’s full medical history in relation to sexually transmitted infections as a result of the 1974 Regulations [59]. This asked for examples to be supplied by GPs to the Sexual Health Review team, and of the four examples received, two of these were considered by the Task and Finish Group as misinterpretations of the 1974 Regulations, with the remaining two being clear examples of where further harm could have been avoided had the GP known about the patient’s full medical history.

Following the first meeting of the Task & Finish Group, the Chair of BASHH Wales emailed a selection of BASHH members in Wales (at least one representative from each NHS Wales Sexual Health Service in Wales; n=16) to gather opinion and further information on some of the issues highlighted at the meeting. Six responses were received, representing five different services. Although this was a small sample size, from this snapshot:

- All felt that <5% of their HIV patients did not consent to GP disclosure;
- The majority of respondents stated that their clinics discussed GP disclosure at first visit following HIV diagnosis, revisiting it at subsequent visits if required;
- Most clinics don’t have a written policy regarding non-disclosure to GPs for HIV patients but strongly advised patients to disclose, explore reasons for non-disclosure and try to find ways around the problem e.g. patients taking their own letters and handing to the GP, HIV doctor phoning GP to discuss;
- All felt that HIV positive patients having non-STI tests taken under their name/hospital number was a good idea;
- Regarding GUM patients, there was a mix of opinions regarding giving patients the option of having STI tests under their name/hospital number instead of a GUM number, but in general...
clinicians did not think it was a good idea and concerns about increasing confusion were expressed.

**Consideration of Options**

When we consider the existing legislative framework and professional guidance, along with acknowledgement of a patient’s expectations of confidentiality, we are left with three principle options going forward:

1. Maintaining status-quo
2. Amending/Repealing existing regulations and replace with new/updated regulations
3. Issuing new guidance to clarify expectations

These options have their own distinct advantages, disadvantages and major considerations, which will be reflected in this chapter.

**Maintaining status-quo**

The Task & Finish Group do not believe that this is a viable option. Whilst examples of avoidable harm caused by application of the Regulations have been few, the Group would concur that one incident is one too many. Furthermore, it is evident that the 1974 Regulations as they stand are misinterpreted, or at the least poorly understand. As the other UK nations have moved, or are in the process, of moving away from these Regulations, retaining them on the Statute book in Wales seems inadvisable. Developments such as ‘Caldicott 2’ and ‘Caldicott 3’ Reviews have provided a modern-day impetus to review information sharing in the whole, and the Group believe that this could be achieved whilst balancing confidentiality and patient’s rights in a manner that is befitting a revision of the current regulations.

Additionally, whilst the Task & Finish Group did not include legal representation, the Group fail to understand how the 1974 Regulations can remain current in law, referring as they do to the ‘Regional Health Authority’, which of course do not remain in existence. Amendments to the 1974 Regulations were made in England to reflect the changing definition of health organisations, therefore the Group fail to see how the 1974 Regulations accurately, and legally, reflect the nature of the health service in Wales. The group would recommend that further legal advice should be sought on this matter should Welsh Government choose to retain the 1974 Regulations as they stand.

**Amending/Repealing existing regulations and replace with new/updated regulations**

The Task & Finish Group strongly supports the amending or repealing of the 1974 Regulations, as these are not fit for purpose, being as they are misunderstood or misinterpreted. They also use outdated terminology (‘venereal diseases’, ‘sexually transmitted diseases’), which again leaves them open to misuse.

A new piece of legislation, possibly along the lines of The Health and Social Care (Safety and Quality) Act 2015 [17] in England could be a consideration going forwards, though the Task & Finish Group would also strongly recommend that any new regulations/legislation differentiate between the diagnosis and management of acute STIs, and the long term management of chronic infections which can be sexually transmitted e.g. HIV. This could negate confusion and uncertainty about when and how the regulations should be enforced. As the principle matter under discussion in this paper is
wider than the initial scope of sexually transmitted infections, consideration should be given to any new legislation or regulations providing a working definition of chronic conditions, to widen their scope beyond just HIV or other STIs and further reduce the risk of unnecessary harm to patients.

Issuing new guidance to clarify expectations
As we have seen, there is a wealth of guidance provided, both to clinicians and service users, on this subject. Whilst issuing new guidance may not seem at face value sensible or necessary given the weight of these existing publications, new guidance from Welsh Government for all healthcare professions and service users may help to clarify expectations around the 1974 Regulations, if they are to remain on the statute book. Some of the clinical guidance is clearer than others, and one overarching guidance document may help reduce the opaqueness of what a clinician, and a service user, can do to promote - or prevent - the sharing of information.

The need for clearer guidance, for both patients and professionals, will become even more essential if the 1974 Regulations are to be repealed or amended.

Commentary
Ensuring patient safety is unquestionably one of the key responsibilities for any clinician. The key matter at hand in this paper – whether patient data should be shared between a Sexual Health clinic and other healthcare providers, principally in relation to the management of chronic infections – arises from concerns around whether the current regulations could be detrimental to patient safety. Nevertheless, concerns around patient safety need to be balanced with the right of the patient to confidentiality, and whether the patient’s right to keeping their condition undisclosed overrides the clinical duty to prevent harm. It is also imperative to acknowledge the value that service users place on the perceived confidentiality of a sexual health clinic - an important protection for the majority of sexual health services users - and any amendments to this need to be carefully considered in this context.

Whilst much of this paper has considered this in the context of HIV infection, the Task & Finish Group also believe that there is scope for these issues to be considered in the context of other communicable diseases, particularly, chronic conditions such as viral hepatitis. An example scenario of pregnant mothers with hepatitis B has been highlighted by the T&F group. If these women are managed by services who do not share test results then essential information may not be available to all involved parties, hindering interventions to minimise the risk of neonatal infection.

If we take the example of patient participation in their HIV care [31, p.55], as highlighted in the Existing Guidance section of this paper, it is clear that balancing standards of care with respecting a patient’s view about their health and empowering them to make decisions for themselves highlights the quandary inherent in this paper – should a sexual health clinician be further empowered to share patient data with all other clinicians connected to the patient’s care, or should the patient be left to disclose their existing medical conditions with other clinicians as appropriate? This is an ethical quandary to which there is no easy answer. It is imperative that guidance continues to dictate that NHS providers within Wales make provision for patients to access testing and treatment for sexually transmitted infections without this being disclosed to other healthcare workers, with the exception of chronic conditions which can be sexually transmitted.
Another dilemma arises when considering the moment where a decision about HIV care becomes a decision about a patient’s care generally. BHIVA’s Standard 11 acknowledges that ‘the complexity of HIV makes it essential that people are managed by a multidisciplinary team (MDT)’ [31, p.62] but does not define ‘multidisciplinary team’. Furthermore, the FSRH Standards outline that specific permission to share information wouldn’t be sought from the client if sharing with those ‘directly involved in client care’, though also state that should a patient withhold consent to disclosure of their information, their wishes should be respected. All things considered, the Task & Finish Group believe it is reasonable to include a General Practitioner as part of a ‘multidisciplinary team’, given their overall care responsibilities for a patient.

If we move towards a position of sharing patient data across clinics and practices, what might be the best approach to doing so whilst maintaining confidentiality to an acceptable standard? One approach was proposed in the BHIVA Standards:

‘On balance the clinical benefits of using a single identifier across all health services outweigh the risks and we suggest that the continued practice of not using the NHS number in some HIV services should be reviewed. In order to satisfy anxieties this may provoke, we therefore recommend a broad and transparent consultation on the use of NHS number in HIV care with the aim of developing clear guidance to help both staff and patients understand the issues involved.’ [31, p.7]

The Task & Finish Group believe that this suggestion may be an appropriate way forward for the consideration of sharing patient data, but this alone will not address the issue of the current legislative framework. In relation to the 1974 Regulations, the Task and Finish Group are unsure as to how these can remain on the statute book as they stand, referring as they do to now-defunct Regional Health Authorities and Area Health Authorities. Further legal advice should be sought on this matter.

Additionally, the Group believe that, if it is agreed that there is an opportunity to introduce enhanced regulations, any new regulations/legislation differentiate between the diagnosis and management of acute STIs, and the long term management of chronic infections which can be sexually transmitted e.g. HIV.– the Group believes that part of the problem with the 1974 Regulations is that they refer to ‘sexually transmitted disease’ without definition. The 1974 Regulations were written before the recognition of a number of chronic conditions which can be sexually transmitted, such as HIV and viral Hepatitis, and therefore do not consider the need for information sharing in this situation. These conditions are not always sexually transmitted, but the concerns illustrated in this paper over the prevention of further potential harm remain regardless of transmission route. Therefore, any new regulations should include greater clarity on what is, and therefore what is not, covered.

As the Information for Service Users section of this paper has highlighted, the HIV charity’s NAT and NAM are already providing strong guidance for service users on confidentiality and their HIV status, outlining why the sharing of their status is important in preventing further harm, whilst also explaining how they can withhold consent to the sharing of their diagnosis information. This guidance should be promoted more widely, particularly if Welsh Government is to amend the current regulations around the sharing of patient information in this context. The principle highlighted in both the Caldicott 2 & 3 Reviews that ‘there should be ‘no surprises’ for the individual about who has had access to information about them’ [32, sect.3.2.9] so the patient information regarding any changes to the
current system will be critical to garnering patient support, and a person should still be able to ask their clinician not to share certain information if desired.

On similar lines, whilst the concept of self-management may not seem entirely relevant to the context of this paper, the author, and the Task & Finish Group, believe that any subsequent amendments arising from this review of the 1974 Regulations should not negate the value of self-management, and instead this review should be an opportunity to enhance health literacy around conditions such as HIV, emphasising the need for the patient to fully understand the condition in order to manage it, and to suitably inform others and the effects that the condition might have.

Our brief literature review has found that discussions and guidance for clinicians in relation to consent tend to be related to a patient’s capacity to consent to treatment or examination, and not particularly detailed around consenting to the sharing of information. The Caldicott Reviews have provided the strongest arguments in support of enhanced information sharing and similarly provide greater commentary around consent issues for this. Caldicott 2 in particular [29] should be a point of reference for any further guidance developed following this paper. It should also be noted that whilst we have made favourable reference to Caldicott 3 in this paper, we are unsure of the current status of the review in Wales. This paper assumes broad acceptance of the recommendations from Caldicott 2 and 3.

Another aspect regarding consent to bear in mind is the forthcoming General Data Protection Regulation (GDPR). The GDPR will apply in the UK from 25 May 2018, and the government has confirmed that the UK’s decision to leave the EU will not affect the commencement of the GDPR [25]. This will intensify the need for organisations to consider consent to sharing and processing data, giving stronger rights to individuals around how their data is used, processed and shared. As the Information Commissioner’s Office states, ‘Consent under the GDPR must be a freely given, specific, informed and unambiguous indication of the individual’s wishes. There must be some form of clear affirmative action – or in other words, a positive opt-in – consent cannot be inferred from silence, pre-ticked boxes or inactivity’ [60]. That said, provisions introduced within the GDPR for lawful bases for processing personal data include article 9(2)(i): ‘Processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of healthcare and of medicinal products or medical devices’ [60]. Article 6 of the GDPR, regarding lawfulness of processing conditions, should also be considered when deciding the next steps for the 1974 Regulations.

This work has touched upon harm prevention in a relatively under-researched context; the prevention of further harm of the self, and whether the right of an individual to privacy trumps the clinical necessity to reduce the risk of further harm. Outside of the field of mental health, the literature in this dimension is lacking, but an argument could be made that this concept is highly relevant in the context of sensitive chronic conditions, and may require further research.
Conclusions and Recommendations

The primary considerations arising from this paper can be expressed succinctly in the following three questions:

- Are issues around a patient’s sexual health a matter purely between the patient and the sexual health clinician, or should these matters involve others, such as General Practice?
- Should a patient’s right to privacy around diagnosis override the duty of a clinician to ‘First, do no harm’?
- If it is considered prudent to share information about a patient’s condition between clinicians, what particular diagnoses should be shared – all chronic infections which may be sexually transmitted or only specific conditions?

The work of the Task & Finish Group leads to a conclusion that, within NHS Wales, in relation to chronic conditions which may be sexually transmitted, we should move towards a default ‘opt-out’ position, whereby routinely sharing patient information between relevant health services and other healthcare professions becomes the standard. Patients would be notified of this duty to share, and clinicians should ensure that patients who refuse disclosure to other healthcare professionals are made fully aware of the potential impact on their care. As the FSRH Standards put it: ‘They need to know that personal information is secure and that it is handled with care and respect by health professionals, but confidentiality does not mean that information cannot be shared. It is paramount that clients understand why and in what circumstances information needs to be passed on to others and whether it will be identifiable or anonymous’ [32, p.7].

Recommendation 2 from Information: To share or not to share? [29, p.38] we find expresses suitably and succinctly the position towards which information sharing in relation to sexually transmitted infections (STIs) should move.

Whilst the Group’s core focus has been on the sharing of patient information between Sexual Health clinics and Primary Care, further work may be required to establish whether it would be appropriate for other healthcare professions (such as dentistry) to notify cases of communicable diseases, and to be able to add content to a patient’s shared medical record. There are potentially barriers in relation to write-permissions on the patient record and confidence of a range of professionals in the ability of dentists (or other healthcare professionals) to diagnose and arrange testing as appropriate.

Read/write permissions for Welsh Clinical Portal were not considered by the Group for inclusion in this paper, but should be factored in as part of any future consultation on the issues raised. Furthermore, as the guidance cited from Antenatal Screening Wales has highlighted, the implications of any changes go beyond the sexual health services seen to be traditionally impacted by the 1974 Regulations, so wide consultation and involvement must be considered before any significant amendments are undertaken.

From the service user perspective, the basic principles of respecting and upholding confidentiality would be expected at all times, and updated patient information will need to be developed should the 1974 Regulations and surrounding guidance be amended or replaced. The literature would also infer that regardless of any changes, and as a general point, literacy around the rules and regulations regarding the use, sharing and processing of patient data would appear to be lacking, so there may be scope for a wider piece of work to improve patient information on this matter.
Whatever option seems the most appealing following due consideration of this paper, the Task & Finish Group highly recommend further engagement with clinicians and service users through a full consultation process. On a wider note, it is also imperative to consider patient consent to process data in the context of the forthcoming General Data Protection Regulation (GDPR), which is due to come into force in May 2018.

To conclude, the Task & Finish Group’s key recommendations can be summarised as follows:

- It is imperative that legislation/regulations continue to dictate that NHS providers within Wales make provision for patients to access testing and treatment for sexually transmitted infections without this being disclosed to other healthcare workers, with the exception of chronic conditions which can be sexually transmitted.
- The Group believe that a General Practitioner should be considered as part of any multidisciplinary team responsible for a patient’s care, and therefore should be informed about ongoing, chronic conditions undergoing treatment where additional prescribing may cause harm.
- For the purposes of direct care, relevant information should be shared among the registered and regulated health care professionals who have a legitimate relationship with the individual, unless the patient refuses disclosure.
- Following consideration of this paper, a full consultation process should be undertaken, involving patients, clinicians and advocacy groups, making the case for change balanced with the duty to respect a patient’s right to privacy. (Note: Should the consultation be conducted after May 2018, a Privacy Impact Assessment would be required; a mandatory requirement under the General Data Protection Regulation).
- Regardless of any change, further clear guidance is essential, for both patients and professionals, to provide clarity on either the current regulations, or any subsequent amendments.

Implication of Our Recommendations for Services
Depending on whether changes are to be made, services will be required to:

- Provide updated patient information, informing patients of any amendments to the Regulations and/or expectations of confidentiality
- Update confidentiality policies according to new and/or revised regulations, in line with other existing confidentiality policies within the Service/Practice (this could be an opportunity for an ‘All Wales’ standardised confidentiality policy, rather than on a Health Board-by-Health Board basis)
References


Sharing is Caring?


59. Couzens Z., Jones A. Re: Sharing of records of treatment and care between Sexual Health Services and General Practice [E-mail attachment]. 2017.