



Department
for Business
Innovation & Skills

Better
Regulation
Delivery Office

Response Form

**Data Sharing for Non-economic
Regulators**

April 2014

Data Sharing for Non-economic Regulators

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The closing date for this consultation is **7 July 2014**

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Please tick a box from the list of options below that best describes you as a respondent. This allows views to be presented by group type.	
<input type="checkbox"/>	Local authority
<input type="checkbox"/>	Professional body or association
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<input type="checkbox"/>	Charity or social enterprise
<input checked="" type="checkbox"/>	Other (please specify) Executive non-departmental public body and non-economic regulator
Does your response apply to England or Wales?	
<input checked="" type="checkbox"/>	England
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Completed responses should be returned to:

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Data Sharing for Non-economic Regulators

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Introduction and background

The Human Tissue Authority (HTA) ensures the safe and ethical use of human organs and tissue through the regulation of activities such as post mortem examinations, transplantation, research, anatomical examinations, human application and public display. We are also responsible for the assessment of living organ donations and the donation of bone marrow and peripheral blood stem cells from children and adults who lack the capacity to consent.

The HTA has responsibilities under four pieces of legislation:

The Human Tissue Act 2004

Human Tissue (Quality and Safety for Human Application) Regulations 2007

The Quality and Safety of Organs for Intended for Transplantation Regulations 2012.

The Human Transplantation (Wales) Act 2013

We also undertake specified functions on behalf of the Scottish Government under the Human Tissue (Scotland) Act 2006.

We have a team of 47 staff based in a single London office, and undertake approximately 180 inspections and assess 1200 cases of living organ donation each year.

Of the 577 establishments we license, 20% are private companies, 20% are universities and 60% are public sector organisations (primarily hospitals). Therefore, while this consultation is aimed at reducing the burden on private businesses, the HTA's response should be considered in the context of the split of establishments we license.

Throughout this response the HTA refers to both the publication of data, for example on our website, and also data sharing between non-economic regulators. There is a difference between these two activities, in the sense that one of the purposes of giving public access to information, is to give the public confidence in the standards within a given sector, as people are able to establish for themselves the outcome of an inspection, for example. Data-sharing ensures that the public are confident that public bodies speak to each other, and that performance is shared and factored into risk modelling. Data-sharing, on occasion, may allow for more information to pass from one regulator to another than is published on a website. For example, the publication of information on an, as yet, un-investigated complaint may cause a business to suffer commercial detriment, when in the longer term it may be established that the complainant was vexatious. However, sharing such data with other regulators in effect puts them on notice that there may be issues at this establishment.

In regard to possible technical challenges, If data is published (for example) as RDF data using agreed definitions for published data then simply publishing data becomes a very effective way of sharing data and organisations can make use of it as they see fit.

It would then be possible for the HTA to present the public with a page for each licensed establishment which also includes links and up to date licensing or regulatory information

from other regulators which gives them a fuller picture and other regulators may in turn do the same thing with HTA data.

The HTA could also make use of this information as part of the application process and query those published data sources for the fact based data about an organisation and use it to pre-populate our application form or append risk scores, for example. It may also be possible to automate the process of drawing together information on a licence, specialist data or risk scores into the HTA's Customer Relationship Management (CRM) system for use in calculating risk scores, for example.

More formal sharing is more complex as it raises the spectre of a centralised database. Again, distributed data feeds but with some form of permission may be preferable with a front end that aggregates data from the various sources and possibly republishes it without storing any data centrally.

The key questions in this area are where the funding would come from and which organisation/s would manage the systems.

Question 1:

Should personal data be shared? If so, for what purpose?

Response:

The HTA holds limited personal data which would be useful to other non-economic regulators.

Under the Human Tissue Act 2004 (the Act), there is a requirement that each establishment licensed under the Act has a named “Designated Individual” (DI) who has specified statutory responsibilities.

Those establishments licensed under the 2007 Regulations are also required to have a DI.

The names of all DIs are accessible currently via the HTA website.

It may be of limited value to other health regulators to know the individual named on the HTA licence, but we cannot imagine the sharing of this data reducing burden in any significant manner. However, we do consider the publication of this data can add to public confidence as it demonstrates a clear commitment to transparency.

There is also the requirement that all establishments licensed under the Act have an identified Licence Holder. The HTA prefers this to be a corporate body, and that a contact name and number is provided for a key individual. On occasion the Licence Holder is an individual.

There may be benefits to sharing personal data to ensure that anyone who had previously abused a position of responsibility was unable to take up another similar role.

The HTA also holds information on professional and education qualifications of DIs, as well as any professional bodies they may be members of, which may provide useful to other regulators. A central register of such information in the health sector could prevent such data having to be provided to multiple bodies, although we would imagine there would be a requirement that this be updated on a regular basis to ensure it is still accurate (for example, annual confirmation that the individual remained a member of a given professional body). Consideration could be given as to whether such updates are provided to employers, who in turn could pass this on to the central register.

Question 2:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which the HTA regulates on data sharing, therefore the HTA would need to consider the Data Protection Act 1998 when deciding whether such information could be shared.

Question 3:

Are there any circumstances in which personal data should not be shared? Do you feel that the Data Protection Act 1998 prevents the sharing of personal data? Please provide detail for your answer.

Response:

The HTA is required to assess all cases of living solid organ donation (with the exception of domino donations) and all cases of bone marrow/peripheral blood stem cell donations where the donor is a child who is not competent or an adult who lacks capacity to consent.

In the course of this work we collect personal data on the donor and recipient. We would not consider it appropriate to share this information as it is both personal and patient data and quite reasonably information which those involved would not expect to be made available to others.

The HTA also, on occasion, becomes aware of personal information through the reporting of reportable events and incidents in a number of the sectors we regulate. It would not be appropriate to share such information as it is patient information.

The HTA stores patient identifiable data from some organisations which have been licensed by us, but are no longer in existence. These records are stored for traceability purposes should there be a serious adverse event or reaction in the future linked to the Licence Holder. It would not normally be appropriate to share the data with third parties other than to contact the individuals potentially affected by the event or reaction. Where another regulator or government body is involved we may decide to share data if that would increase the likelihood of us contacting those affected and consider how this would fit with the 1998 Act.

It is also hard to imagine a circumstance where sharing such information would reduce burden on a business or organisation.

The 1998 Act does prevent the sharing of some personal data, as this is, in part, the intention of the legislation. However, there is scope to share some personal data under the 1998 Act. There may be benefit in a single information sheet being drafted and circulated to all non-economic regulators on what is and is not acceptable under the 1998 Act to help bolster confidence in sharing data amongst both the Executive and Non-Executive teams at non-economic regulators. At present, if the HTA felt a disclosure may not be covered by the 1998 Act and might be in the public interest, we would carefully weigh up the pros and cons of such a disclosure before reaching a decision

Question 4:

Do regulators consider data regarding sole traders to be personal data?

Response:

The HTA does not licence any sole traders. We may hold data about sole traders undertaking work on behalf of a licensed establishment; in most cases we would regard this as personal data but it would depend on the nature of the data. If another regulator sought access to this information we would consider it on a case by case basis.

Question 5a:

Should fact based standard data be shared? If so, for what purpose?

Response:

It is important to reiterate here that many of the establishments the HTA licences are not businesses, but hospitals or other public sector organisations. Therefore the responses below do not primarily concern businesses.

The HTA considers that fact based data could and should be shared.

A system which allowed such data to be stored by one organisation per sector, for example in health a single point of contact would mean a hospital could add and update its details just once and be confident that the HTA, Human Fertilisation and Embryology Authority (HFEA), Care Quality Commission (CQC), Medicines and Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and Monitor all had access to this information.

The purpose of this would be that it would place less of a burden on the establishment and ensure all the regulatory bodies had up-to-date information.

It is the HTA's understanding that in the health sector such a system would benefit more public sector organisations than businesses. However, reducing the burden on tax-payer funded organisations increases value for money.

Question 5b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the publication of such data.

We publish the names of licensed establishments on our website.

Question 5c:

Are there any circumstances in which fact based standard data should not be shared?

Response:

The HTA cannot envisage any circumstances in which fact based standard data should not be shared.

Question 6a:

Should fact based specialist data be shared? If so, for what purpose?

Response:

The HTA holds information as to the activities an establishment carries out under its licence/s. There is no reason easily identifiable why such information should not be shared.

The HTA currently publishes information on the activities undertaken by licensed establishments, and provides information to the EU on activity under the 2007 Regulations.

Question 6b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, the HTA has an obligation to keep certain records relating to donation and transplantation of organs and to publish an annual report on these activities.

Question 6c:

Are there any circumstances in which fact based specialist data should not be shared?

Response:

Not in the HTA's experience.

Question 7a:

Should licence data be shared? If so, for what purpose?

Response:

The HTA holds licence data on over 500 establishments. We publish on our website the name of the licensed premises, the corporate licence holder, the DI, the licence number and the activities for which the establishments is licenced.

The HTA publishes inspection reports and details of any enforcement action where it has imposed conditions on, suspended or revoked a licence.

The HTA considers that this information should be shared. We believe this is particularly useful to those regulators, such as the CQC, which have a very wide remit, and would therefore benefit for being able to see the number of licences a hospital holds, for example. It is also useful for anyone seeking to use the establishment's services.

We also have Memoranda of Understanding (MoU) and Information Sharing Agreements in place with other regulators setting out what additional information we will share, over and above what is included on our website. We believe that this is in the public interest as it ensures that regulators have access to relevant information.

Question 7b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

We have not yet been challenged on the publication.

Question 7c:

Are there any circumstances in which licence data should not be shared?

Response:

Not in the HTA's experience.

Question 8a:

Should this type of compliance data be shared? If so, for what purpose?

Response:

The HTA considers that compliance data that an establishment is required to report should be shared. This would allow other regulators to feed this information into their risk profiling and better understand establishments or sectors which may not be forthcoming with information.

This could be particularly beneficial when investigating Serious Adverse Events and Reactions (SAEARs) within the human application sector which could also have an impact on the MHRA or the HFEA, for example. Each regulator seeks to share as much information as possible. However, as statutory remits vary it is not always the case that the information held by one organisation, is fit for the needs of another.

The HTA collects annual activity data from establishments in the human application sector (and submits this to the EU) and compliance data from the post mortem, research and public displace sectors. This is used to inform our risk profile, and in part published, and there may be the opportunity to share this systematically with other regulators in future if there is demand to do so.

We share information on SAEARs with in the organ donation and transplantation with the special health authority, NHS Blood and Transplant, in order to support the raising of standards, however this is not mandatory.

Question 8b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

However, we are required to collect information on the levels of activity within the human application sector each year and report this to the EU.

Question 8c:

Are there any circumstances in which this type of compliance data should not be shared?

Response:

Not in the HTA's experience.

Question 9a:

Should this type of data be shared? If so, for what purpose?

Response:

Establishments do sometimes provide us with additional compliance data voluntarily and the HTA believes that such information should be shared with other regulators.

Establishments could be encouraged to share more compliance data if they are made aware this will be shared and may lead to less burdensome regulation. There is a caveat, however, in the sense that robust checks would still need to be made by other regulators to ensure standards are being met and there is not solely high performance in one area.

Question 9b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

Question 9c:

Are there any circumstances in this type of data should not be shared?

Response:

Not in the HTA's experience.

Question 10a:

Should inspection results and analysis be shared? If so, for what purpose, and what benefits are might result?

Response:

Since November 2010 we have published all inspection reports on our website. As the HTA's inspection reports are exception based, they only include information on when a standard has not been met. We also collect other information during inspections, perhaps noting where a particularly innovative approach has been taken or where there is excellent practice, and where appropriate share this with other regulatory bodies where they have an interest in that issue. We conduct joint inspections with some regulators and, in those circumstances, the other regulator will have greater access to the information we identify by virtue of being present.

Question 10b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

Question 10c:

Are there any circumstances in which inspection results and analysis should not be shared?

Response:

Not in the HTA's experience.

Question 11a:

Should the existence of ongoing investigations be shared? If so, for what purpose?

Response:

We undertake joint inspections with MHRA, CQC and HFEA and are about to conduct joint inspections with the UK Accreditation Service (UKAS). In all cases we would share any information we have identified during an investigation with the body undertaking the investigation with us where it is relevant to them. It would be unlikely that we could conduct an effective inspection without doing so. Similarly, where we investigate an allegation which may be of interest to another regulator we would share the nature of the investigation with them where it is in the public interest to do so. This will enable us to conduct a joint investigation or inspection where appropriate.

Question 11b:

Should details of ongoing investigations be shared? If so, for what purpose?

Response:

The HTA believes that details should be shared where it is in the public interest to do so and where there is a joint interest in the issue. Where details have been shared, and the other regulator has decided not to participate in the investigation or inspection, the results of the investigation should be shared once they are available.

Question 11c:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

Question 11d:

Are there any circumstances in which the existence and/or details of ongoing investigations should not be shared?

Response:

Not in the HTA's experience.

Question 12a:

Should complaints data be shared? If so, for what purpose?

Response:

The HTA considers the sharing of complaints data to be similar to the sharing of investigations existence/details, as more often than not complaints lead to investigations.

Question 12b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

Question 12c:

Are there any circumstances in which complaints data should not be shared?

Response:

Not in the HTA's experience.

Question 13a:

Should enforcement action data be shared? If so, for what purpose, and how much detail should be shared?

Response:

The HTA considers that enforcement action data should be shared, as a decision has been made that enforcement action is necessary to achieve compliance. We publish details of enforcement action on our website at the point at which the decision becomes effective.

We include the details of the enforcement action and the reasons for it on our website.

Question 13b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

There are no specific provisions within the legislation under which we regulate on the sharing of such data.

Question 13c:

Are there any circumstances in which enforcement action data should not be shared?

Response:

Not in the HTA's experience.

Question 14a:

Other than those listed above, are there any other types of data which regulators could share? If so, for what purpose?

Response:

The HTA is not aware of any other types of data which could be shared.

Question 14b:

Do you have the necessary legal power (vires) to enable you to share this data? If so, does it specify a purpose for which this data is allowed to be shared?

Response:

Not applicable.

Question 14c:

Are there any circumstances in which this information should not be shared?

Response:

Not applicable.

Question 15:

Which regulators currently share data, and how is it shared? What is the purpose of sharing the data, and what benefits does it bring?

Please name the regulators involved, or indicate the type of regulator (for example, national regulator, local authority) and give details as to how the data is shared (for example, by use of a database, on request, etc).

Response:

The HTA shares some data with CQC and some with the HRA.

The MoU between the HTA and CQC can be found [here](#) and includes information on data sharing.

There is information sharing with the National Research Ethics Service (NRES) function of HRA on a regular basis, as required (almost weekly), to support site-related investigations and enquiries. This information flows both ways. This is underpinned by the MoU we have had with the HRA (previously NRES) for many years.

Question 16:

Is there any type(s) of data which regulators need to share, but do not share at the present time? If so, please explain why this data is not shared.

Response:

In the HTA's experience the categories of data discussed in this consultation are not regularly shared between regulatory bodies. Moving to a position where there was confidence that the sharing of such data was within the law, that there was an expectation by those that are subject to regulation that this data would be shared and that systems were in place to make this as straight forward and risk free process as possible, would be a significant step forward.

The HTA believes this would support regulators in the health sector to better focus resources on those establishments where there was the greatest risk of non-compliance.

Question 17:

What are the consequences of this inability to share data? Please give details (for example, wasted time, additional costs).

Response:

It is difficult to assess the consequences of this data not being shared at the present time.

As the HTA has a relatively narrow statutory remit, the data held by other regulators on compliance and related areas would be useful to provide an overview of the establishments approach to regulation. This could be fed into our risk profiling and potentially support a more focused regulatory approach.

However, as we often regulate specific areas within a larger establishment (for example the mortuary within a hospital); the factual data held by other regulators may be of little use to the HTA.

It is difficult to envisage how sharing data would reduce the costs to either the regulated establishment or the HTA. However, it may lead to those establishments that show a high level of compliance with other health regulators, being inspected less frequently and therefore reduce the burden and costs associated with inspection.

Question 18:

What prevents regulators from sharing data? Please be as specific as possible.

Response:

The HTA considers there are five reasons which prevent the sharing of data between regulators.

One

There is general concern that sharing such data is not within the law, and therefore would be subject to a potentially successful challenge.

Two

Linked to the first, is the amount of time and resource which needs to be allocated to the drafting of MoUs to allow the sharing of data, and the impact this has on the regulators ability to undertake their core activity.

Three

There is not an expectation amongst regulated establishments that data will be shared and there is anecdotal evidence that this would not be supported by a number of establishments and actively challenged in some cases. Therefore, the HTA believes there needs to be a cultural change and a management of expectations to transition to a position where the sharing of data is expected by both regulators and the regulated.

Four

The HTA has relatively limited knowledge of what other valuable data is available that could be accessed if required. MoUs do help, but tend to be relatively high level.

Five

There is also a potential challenge in physically gaining access to the data and the mechanisms in place to do so. The amount of time and resource required to access the data needs to be factored in to any future plans.

Question 19:

Is a measure in primary legislation the most appropriate means of encouraging regulators to share data? Please give reasons for your answer.

Response:

The HTA's experience of a formal data sharing agreement involved the development and agreeing of a MoU between the HTA and CQC.

The terms of a MoU often take lengthy discussion, and MoUs create additional work within both organisations.

There is often, understandably, a degree of concern as to how robust a MoU is, and the potential for successful challenge.

Whereas, if such requirements were enshrined in primary legislation, Executives and Non-Executives would have confidence in sharing and it is more likely this would be actively championed.

Question 20:

Is embedding data sharing as best practice the most appropriate means of encouraging regulators to share data? Please give reasons for your answer.

Response:

The HTA considers that embedding data sharing as best practice would go some way to encouraging regulators to act in such a way.

However, it does not give organisations the level of confidence that primary legislation would afford.

Question 21:

Do you have any views as to whether a single point of registration would be desirable?

Response:

The HTA considers a single point of registration, perhaps in each sector rather than across all non-economic regulators, to be key to the success of data sharing in the medium to long term.

There are four health regulators with which the HTA works regularly, and others which we are in contact with less frequently. To draft and maintain MoUs with each organisation would become a significant part of a job role, as would ensuring new and updated data was shared in a timely fashion, with the relevant organisations. This would also be a confusing situation for regulated organisations as they may be unsure of which body they should be providing information.

A clearly defined single point of registration would reduce the burden for both the regulated and the regulators.

Question 22:

Other than the options outlined above, is there any other means by which data sharing could be encouraged?

Response:

The HTA considers a code of conduct may go some way in supporting non-economic regulators in sharing data. However, we are of the view that the gold standard and the action most likely to achieve the aim of a high degree of high-quality data sharing between non-economic regulators would be to enshrine this in primary legislation.

Question 23:

Are there any regulators listed in Annex A which should be excluded or others which should be included? Please give reasons for your answer.

Response:

The HTA is not aware of any other regulators which should be included, nor any on the list which should be excluded.

Question 24:

Is it desirable to allow further regulators to be included in future, if warranted?

Response:

Very desirable, to ensure that the outcome of reducing the burden on regulated organisations is achieved and continues to be achieved.

Question 25:

Under what circumstances would data sharing warrant the inclusion of safeguards, and how could this be achieved?

Response:

The HTA is not in a position to respond to this question.

Question 26:

Under what circumstances would the imposition of sanctions be appropriate?

Response:

The HTA is not in a position to respond to this question.

Question 27:

Should the sharing of data be monitored? If so, to what extent?

Response:

The HTA believes the sharing of data should be monitored to ensure that any framework for sharing is being adhered to and to identify trends and areas where more could be done to reduce the burden on regulated organisations (and possibly regulators, as well).

Monitoring would also support public and professional confidence in the sharing of data.

Question 28:

Who should be responsible for monitoring the sharing of data?

Response:

The HTA is not in a position to respond to this question.

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