Development of a quality evaluation framework for consumer generated food consumption data

Date delivered:
M14

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Deliverable lead beneficiaries:
WU

Project	
Project acronym:	RICHFIELDS
Project full title:	Research Infrastructure on Consumer Health and Food Intake for E-science with Linked Data Sharing
Grant agreement no.:	654280
Project start date:	01.10.2015
Document:	
Title:	Development of a quality evaluation framework for consumer generated food consumption data
Deliverable No.:	D7.3
Authors:	Marcus Maringer, Naomi Klepacz, Susanne Ekman, Anne Norman, Monique Raats, Muriel Verain, Anouk Geelen
Reviewer:	Karin Zimmermann – Project Coordinator prof. dr. ir. Pieter van't Veer – Scientific Coordinator
Start date:	1.10.2015
Delivery date:	30.11.2016
Due date of deliverable:	31.07.2016
Dissemination level:	PU
Status:	

Change history:		
Version	Notes	Date
Final		30.11.2016

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Summary

RICHFIELDS is a design project of a research infrastructure (RI) and data platform which aims to collect, integrate, analyse and share food consumption and associated lifestyle data for the better understanding about what people eat and why they make their choices. One important source of data RICHFIELDS is focusing on is data generated by a vast amount of consumers and users of wearables and software applications, which are accessible to the general public. For the design phase of this RI it is crucial to provide an overview and characterization (Deliverable 7.1) and an evaluation (Deliverable 7.5) of consumer generated food consumption and associated lifestyle data. For the creation of these deliverables the current deliverable (Deliverable 7.3) plays a key role. Aim of this deliverable is to define a set of quality criteria which forms the basis of the evaluation of consumer generated food consumption and lifestyle data and which supports the identification of relevant opportunities as well as possible gaps and needs regarding data integration and sharing. In addition, the quality framework created in this deliverable should provide structure and guidance for data collection and characterization, which is needed for the inventory of consumer generated food consumption and lifestyle data collection tools. More specifically the framework will provide operationalisations for each quality criterion in the form of a set of relevant questions that should be answered for each tool included in the inventory of deliverable 7.1. Based on the needs of Phase 3 as they have been identified in the DOA, a quality assessment framework has been created for the evaluation of data in terms of scientific relevance, data management and legal governance. Data quality related to these three dimensions were considered important, because they can provide indications about: 1) what we can learn from such consumer generated data about peoples' food consumption behavior, 2) the legal limitations, organizational restrictions, confidentiality and privacy concerns related to collection, integration and dissemination of consumer generated data and 3) the technical protocols and standards for data access and data processing. A literature search has been conducted and existing quality frameworks of eHealth and mHealth applications have been summarized. Quality criteria related to the dimensions of scientific relevance, data management and legal governance where characterized and based on expert opinions and overall feasibility included in the final quality assessment framework. Since the summarized existing quality frameworks were found to be too unspecific regarding scientific relevance of food consumption and lifestyle data we additionally relied on the current literature on dietary intake assessments and the determinants of food consumption behaviour for the creation of the quality criteria related to the dimension of scientific relevance. Since a large number of quality criteria have been excluded from the quality framework the scope of quality assessment by the current framework will be limited, however, we believe that the selected quality criteria are relevant and comprehensive across the needs and requirements of the various disciplines involved in designing the blueprint of the RI and data platform.

Contents

1. Introduction

1.1 Context

One important aim of RICHFIELDS is to design a research infrastructure (RI) and data platform for the collection, integration, processing and sharing of food consumption and associated lifestyle data generated by tools which are accessible to the general public in the form of eHealth and mHealth software applications (e.g., found in app stores and the world wide web). For the design phase of this research infrastructure it is crucial to assess the quality of such tools and the data they collect in order to identify the opportunities, gaps and needs in terms of data relevance and the collection, integration and dissemination processes.

1.2 eHealth and mHealth applications

An important terminology that has been created outside the scientific domain and which has only later been introduced is "eHealth". The phenomenon eHealth is not easy to pin down, since eHealth refers to a complex and dynamic phenomenon, which is constantly evolving regarding how it is used and regarding the new technical innovations it rapidly brings forward on a fast scale. According to one definition, by the use of the Internet and associated information communication technologies the intention is to deliver health services and related information in a more enhanced, effective and easy to use manner (e.g., Eysenbach, 2001; Handel, 2011).

Like eHealth, mHealth refers to the generation, aggregation, and dissemination of health information using IT solutions, but other than eHealth focuses entirely on using mobile and wireless devices for that matter. mHealth is the most prominent, rapidly growing, widely used and potentially most promising sector within the eHealth domain. In 2012 the number of health-related iPhone apps was around 13,000 applications (Dolan, 2011). In 2015 the number of mHealth apps for the main application platforms Apple and Android has almost ten times the size, which is 103,000 applications with more than 3 billion estimated downloads (Research2Guidance, 2015).

The category of health applications can be divided into several subcategories of applications such as disease and treatment management applications, which also includes medical devices. Such applications might be required to be labelled and certified as medical devices (e.g., CE marking) and need to comply to the quality regulations and standards associated with that status (e.g., The Law Library of Congress, 2014; KNMG, 2016). Our primary aim is not to evaluate whether medical devices comply to those standards. The quality framework developed here will be applied to applications registered as medical devices as well as non-medical health applications. The resulting evaluation of an application on certain quality criteria might differ depending on its status.

In addition to medical and disease management applications another large group of health applications belong to the category of general wellness management applications. Wellness management applications include fitness, lifestyle and stress, and diet and food and nutrition applications (e.g., Institute for Healthcare Informatics, 2015). The purpose of around 7% (ca. 7200) of mHealth applications is related to the category food and nutrition

apps, which include features such as tracking of food intake in the form of vitamins, minerals, calories or fat, monitoring of weight and BMI, goal setting, feedback and coaching or provide some sort of social, biological or economical aspects of diets (e.g., Research2Guidance, 2014.

Although evidence about the validity of such food consumption and lifestyle data is scarce there is some evidence suggesting that some apps are effective and do adhere to evidence informed scientific practices (Breton, Fuemmeler, & Abroms, 2011; Carter, Burley, Nykjaer, & Cade, 2013a; Laing et al., 2014; Wharton, Johnston, Cunningham, & Sterner, 2014). However, evidence of these initial studies is mainly based on practices and effects of weight loss intervention programs. Evidence regarding the validity of the dietary assessment data and procedures applied by these applications is nearly absent (for an exception see Carter, Burley, Nykjaer, & Cade, 2013b).

Since data collected by eHealth and mHealth application systems in general and nutrition and lifestyle applications in particular, might provide scientifically very relevant insights for a better understanding of people's food consumption behaviours, the target of this quality framework will be eHealth and mHealth systems which generate, aggregate, and disseminate diet and associated lifestyle data.

1.3 Relevant dimensions of quality

Pinning down relevant dimensions for the quality assessment of consumer generated food consumption and lifestyle data is not an easy task. The interpretation of quality might vary depending the purpose or the context of the quality assessment. A nutrition epidemiologist might define quality in terms of the applied methods for dietary assessment and their added value to the understanding of the relationship between diet and disease, a data manager might outline the standards of technical protocols and formats for data access and data integration, and a member of an ethical commission board might emphasize quality in terms of informed consent, data disclosure and data usage restriction policies. Designing a research infrastructure data platform on food consumption behaviour is clearly an interdisciplinary endeavour where the requirements, skills and experiences from various scientific backgrounds need to be considered, including human nutrition, behavioural and social sciences, law and computer sciences. Our definitions of quality criteria need to be relevant and comprehensive across the needs and requirements of the various disciplines involved in designing the blueprint of the RI and data platform and we believe that information about data quality related to scientific relevance, legal governance and data management is crucial for developing not only the vision and business model for a sustainable RI but also its vital data governance and data management structure.

1.3.1 Scientific relevance

Since a research infrastructure is mainly about conducting, sharing and excelling research in certain scientific fields, we believe that scientific knowledge and expertise regarding the scientific relevance, the added value of data and its standards and procedures for data collection is crucial for the design of a research infrastructure and basically lies at the heart of the motivation or the "why" of creating it in the first place. Hence for designing a research infrastructure we need to first understand the scientific gaps and gains of integrating, processing and sharing certain types of information on a common data

platform. That is, we need to get a better understanding of the types of data generated and its relevance to the scientific community (see WP5-WP7). The quality dimension scientific relevance should contain criteria which are indicative about what we can learn from consumer generated data about peoples' food consumption behaviour regarding what is consumed, how much was consumed, by who, where, when, how and why.

1.3.2 Data management

One of the main objectives of RICHFIELDS is to design a flexible technical architecture to link individual and experimental data. Hence, in order to develop a roadmap for the technical design of the research infrastructure (see WP11) we need to get a better understanding about the technical protocols and standards for data access and data integration. In WP11, the RI Consumer Data Platform will be designed considering new developments in information and communication technologies for collecting big and open data created by consumers. Criteria affecting the quality of managing such open data are considered vital for the development and execution of plans, policies, and practices that control and enhance the value of the data and information assets. Hence, in addition to knowledge regarding the scientific relevance of the data, it is also crucial that we understand the technical procedures and standards for data management, including data integration, processing and sharing.

1.3.3 Legal governance

In WP13, the use of previously underexplored big data by RICHFIELDS involves the processing and analysis of personal data relating to consumer behaviour gathered from a variety of data sources. The analysis of big data raises a number of key legal questions such as "What is the data used for?" or "Is personal data used for purposes other than those for which they were initially gathered?". The possible "repurposing" of data also raises other questions about whether consent has been obtained for such use and if not how it can be obtained. The use of data in the absence of consent in this circumstance would be in clear breach of the data protection laws (see EU Directive 95/46/EC, 1995). In addition, data collected from various sources usually is owned by various stakeholders and different users might have different restrictions and permissions for data access and usage. One crucial element of an RI is the design of an appropriate governance structure for regulating the legal governance of issues like consent, privacy, ownership and property rights. Hence, the criteria related to legal governance of data is very relevant for the design phase of the RI. Their focus should be on the legal limitations, organizational restrictions, confidentiality and privacy concerns related to collection, integration and dissemination of consumer generated data.

1.4 Aim

The aim of this deliverable is to formulate a set of quality criteria for the evaluation of consumer generated food consumption and associated lifestyle data in terms of its scientific relevance, data management and legal governance. Data quality related to these three areas are important, because they can provide indications about: 1) what we can learn from such consumer generated data about peoples' food consumption behaviour, 2) the legal

limitations, organizational restrictions, confidentiality and privacy concerns related to collection, integration and dissemination of consumer generated data and 3) the technical protocols and standards for data access and data processing. Information about these topics should provide relevant and useful information for the design phase of the research infrastructure and its data governance structure.

In addition to providing a framework for the evaluation of the data, the result of this deliverable should also provide structure and guidance for the data collection process of deliverable 7.1, which is an inventory of consumer generated consumption data tools. More specifically the framework will provide operationalisations for each quality criterion in the form of a set of relevant questions that should be answered for each tool included in the inventory of deliverable 7.1. Aim of the inventory of 7.1 is not to produce an evaluated and validated selection of data collection tools for the possible integration into a research infrastructure, but is rather about capturing the "variety" of data sources out there by profiling a larger and more heterogeneous sample of data collection systems according to certain quality criteria. The main goal should be in, providing the RICHFIELDS design process with the necessary overview of existing food consumption data collection tools and methodologies, and in forming a solid knowledge base for the identification of possible scientific, legal, technical and ethical gaps and needs regarding the use and integration of the data collected by these tools.

Hence the aim of this deliverable is <u>not</u> to create a quality framework for the scientific validation of the data and data collection methodologies. Such scientific validation is of course crucial for the use of such data in scientific research, and needs to be examined in light of the research questions being addressed. Since scientific validity relates to whether measurement accurately corresponds with the real world and research question of interest, and thus whether a tool is "fit for purpose"; we believe that a validation and possible certification procedure should be an integral part of the research infrastructure and should therefore be considered and incorporated in the overall design of the data platform.

2. Procedure

2.1 Existing health application quality frameworks

Due to the lack of knowledge with respect to the quality of eHealth and mHealth tools and the data they produce, great efforts have been undertaken for the development of frameworks and guidelines that help to evaluate health applications (e.g. Brown, Yen, Rojas, & Schnall, 2013; Kumar et al., 2013; Meulendijk, Meulendijks, Jansen, & Numans, 2014; Stoyanov et al., 2015). Private as well as public companies and institutions now offer guidelines, services and infrastructures for reviewing, evaluating and certifying health applications.

In order to create our quality framework a literature search was conducted on the existing quality frameworks of eHealth and mHealth applications and an overview of the applied quality criteria was created (see Appendix A). Quality criteria from that overview were divided over several groups such as criteria referring to the displayed data, the collected data, the functionality of the tool, the aesthetics of the tool and its design, the general use of the tool and criteria regarding the company and its services.

In addition, quality criteria were categorized according to their significance for the current aim regarding the evaluation of consumer generated data along the quality

dimensions 1) scientific relevance 2) legal governance and 3) data management. These three dimensions are not mutually exclusive and hence some quality criteria can be relevant for multiple dimensions. For instance, the timeliness, complexity or interoperability of data can have important consequences for scientific relevance as well as data management. Appendix B provides an overview of the summarized quality criteria and how we categorized them according to their perceived relationship with the three quality criteria scientific relevance, legal governance and data management.

2.2 Literature on dietary intake and its determinants

Since most existing quality frameworks are rather general in nature with respect to scientific relevance and do not focus on specific scientific fields such as food consumption, we also relied on the current literature on dietary intake assessments and the determinants of food consumption behaviour for the creation of the quality criteria related to the dimension of scientific relevance.

2.3 Expert opinions

The authors main field of expertise is human nutrition and food consumption behaviour. For the evaluation of scientific relevance of quality criteria related to that area we trusted our own professional judgment and expertise. In order to evaluate the relevance of our selection of quality criteria which reside outside of our own field of expertise (legal and data management), we contacted experts in the relevant fields of Law[1] and ICT[2] (one distinguished expert for each field of expertise). Based on the experts' opinions the selection of quality criteria was adjusted.

2.4 Feasibility

Finally, the feasibility of the evaluation of the data of a larger number of tools (n >= 100) was discussed for each quality criterion with partners of the consortium. The decisions for inclusion into the final framework was based on whether information regarding the quality criteria was publicly available (e.g., from the tools home page, or app store descriptions), without actively installing and testing the tools and without examining the data structure of the collected data and its data hosting infrastructure (see Appendix B for an overview of quality criteria and their perceived feasibility).

3. Not selected quality criteria

There were two reasons why a quality criterion was not selected. 1) The consortium partners agreed that the criterion was not related to the quality dimensions, scientific

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relevance, legal governance and data management. 2) Although a quality criterion was considered related to the quality dimensions of interest, collecting information about the criterion from the tool was not considered feasible (see above; see Appendix B for an overview of the criteria selection).

3.1 Unrelated quality criteria

One large group of quality criteria was related to the displayed data of health applications including believability of the disseminated information, its credibility, clarity, objectivity, depth or scope. Since our current focus is on the user generated data the tools collects (usually owned by the user) rather than data that is disseminated by the tool vendor (usually owned by the vendor), we concluded that although the disseminated data is very important in terms of the usefulness and relevance of this tools for the user, it is being judged as unrelated to the quality of the collected data.

In addition, a large number of the summarized quality criteria are related to the overall aesthetics and design of the applications. We agreed that although such criteria are very relevant to the quality of the experience during an interaction with a health application, they are unrelated to evaluations regarding scientific relevance, data management and legal governance. The key challenge in this deliverable is to assess whether a quality criterion is relevant to the design of the RI. We believe that the look and feel of tools is primarily relevant to the design of the tool, and not necessarily to the design of the RI.

3.2 Related but unfeasible quality criteria

There is a vast array of quality criteria which are related to the functionality of the tools and user experience such as usability, utility, feasibility, intuitiveness, learnability, efficiency, engagement, and many more which we agreed on to be very important for evaluating the scientific relevance of the generated data. Not only because a more feasible, usable and efficient tool might produce more reliable and valid sets of data, but might also be directly responsible for reaching and engaging the relevant audience and keep them motivated for a prolonged or repeated usage. We came to the conclusion, however, that gathering indications about most quality criteria related to the tools functionality and user experience, would also involve active interactions with the tools, and hence have been discarded due to feasibility reasons. In addition, we believe that similar to the aesthetics of the tool, the tools' usability focuses more on information relevant for the design of the tools rather than the design of the RI.

Various quality criteria related to the collected data were considered to be closely related to the quality dimensions of scientific relevance, legal governance and data management. Criteria within that group for instance focus on data collection accuracy, data processing, data validity, mechanisms for error prevention and quality controls, data completeness, its amount, timeliness and frequency of being updated. Although information related to such criteria was considered very important for scientific relevance as well as data management we agreed that providing information for these quality criteria would be unfeasible because it would involve actively generating, accessing and examining the data in more detail over a longer period of time.

A large portion of criteria focusing on the company who owns an application and the support that it offers were perceived as very relevant for all three quality dimensions, however, criteria such as the company's reputation, professionalism, business models, problem handling or consistency in services were considered to be not feasible. Gathering information on such quality criteria would involve actively interacting with the companies' services and searching for information beyond the companies' websites and tool descriptions.

Finally, there are some quality assessment papers directly related to the field of human nutrition, such as adherence to behavioural change theories in weight loss applications (e.g., Pagoto et al., 2013), a data quality evaluation system for data used in food composition tables (Holden, Bhagwat, & Patterson, 2002) or validations of diet measures captured on smartphones (Carter, Burley, Nykjaer, & Cade, 2013b). We believe all this research offers valuable information regarding criteria for quality of food consumption data collected by health applications. We agreed, however, that providing the relevant information for database quality, validity of dietary assessments or applied behavioural change strategies would require a more elaborated investigation of the tools and would be more suitable for a smaller sample of health applications.

4. Selected quality criteria

4.1 Scientific relevance

Existing quality frameworks define quality regarding data relevance in terms how well the statistical product or data meets the needs of users in terms of the concepts measured, and the populations represented (e.g., Dufty, Bérard, Lefranc, & Signore, 2014). Since most existing quality frameworks are rather general in nature with respect to relevance and do not focus on a specific scientific fields such as food consumption, in addition to existing quality frameworks we also relied on the current literature on dietary intake assessments and the determinants of food consumption behaviour for the creation of the quality criteria related to the dimension of scientific relevance (table 1).

4.1.1 Accessibility

Accessibility is commonly understood as the degree to which the application is available to users (Meulendijk, Meulendijks, Jansen, & Numans, 2014). Hence tool accessibility in this most basic definition is about making sure that the tool is available for the widest possible audience. This starts by the possibility to find and locate the tool (e.g., Cummings, Borycki & Roeher, 2013). The tools we are focusing on in this work package should be accessible (or accessible in the near future) to the general public such as through the world wide web or one of the app stores (e.g., iTunes or Google Play).

Operationalization of the accessibility criteria:

- What is the URL where the tool can be installed or accessed?

4.1.2 Affordability

Affordability is the extent to which a service is reasonably priced considering the set-up and user costs relative to the application capabilities (e.g., Ho, Lee & Armstrong, 2013) or to the amount that the user is able or willing to pay for it (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013).

Operationalization of the affordability criteria:

- How much does the use of the tool cost?
- Does the tool require or offer any additional paid services (e.g., upgrades, in app purchases)?

4.1.3 Purpose

For the assessment of the quality of the tool it is important that the owner or manufacturer of a tool discloses the intended purpose of the tool (e.g., Kim, Eng, Deering, & Maxfield, 1999). According to the Oxford dictionary the term purpose refers to the reason for which something is done or created or for which something exists. Different kinds of tools might have different purposes depending on who the intended user is. The intended purpose assigned to a tool by the manufacturer can also determine its status as medical device such as intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of diseases (e.g., FDA, 2015; KNMG, 2016). Such tools might be required to be labelled and certified as medical devices (e.g., CE marking) and need to comply to the quality regulations and standards associated with that status (e.g., The Law Library of Congress, 2014). On the other hand, tools that are intended for individuals to log, record, track, evaluate, or make decisions or behavioural suggestions related to developing or maintaining general fitness, health or wellness do not have to comply to such regulations (FDA, 2015, KNMG, 2016).

Operationalization of the purpose criteria:
- What is the intended purpose of the tool?
- Is the tool a medical device?

4.1.4 Consumer unit

There are three main levels to assess dietary consumption (FAO/WHO, 1996): 1) Estimations of population food consumption (e.g., domestic food production plus imports and minus exports). 2) Estimations of household food consumption (e.g., food purchases, larder stocks, gifts minus wastage). 3) Estimations of individual food consumption (prospective or retrospective). In this deliverable we will mainly focus on data collected and data collection methodologies at the level of the individual, that is data referring to actual and measurable food consumption or lifestyle activity an individual engaged in. However, since data on the national and household (FAO/WHO, 1996) level may also provide important information about food consumption, population and household level measures such as food purchase and food preparation will be more focused on in Deliverable 5.3 and 6.3 respectively.

Operationalization of the consumer unit criteria:

- What is the consumer unit on which the consumption has been measured?

4.1.5 Dietary assessment

In The Oxford English dictionary consumption is defined as "The action of eating or drinking something". Food is defined as "Any nutritious substance that people or animals eat or drink or that plants absorb in order to maintain life and growth". The assessment of food consumption involves (e.g., Rutishauser & Black, 2002): 1) A report of all food and beverages consumed by an individual (regular and irregular). 2) The identification of the foods and their nutrient compositions. 3) The determination of the frequency or likelihood of consumption. 4) The quantification of the portion sizes consumed.

Food intake data can be analysed in various units of consumption other than by conversion to nutrient compositions. Whether dietary intake is assessed by individual foods, food groups, meal patterns, and eating practices, depends on the questions of interest and the data available (FAO/WHO, 1996).

Operationalization of the dietary assessment criteria:
- Does the tool collect information about what was consumed?
- What is the level of detail or unit the consumptions have been measured?
- Does the tool collect the amount of food consumed?
- Does the tool collect information about when food has been consumed?
- In what units has the time of consumption been measured?

4.1.6 Dietary assessment methodology

There are various methods of assessing dietary intake with each of the methods having its inherent strengths and limitations (e.g., Shriver, Roman-Shriver& Long, 2010). Technology based versions of various methods for dietary assessment exist such as for the 24-hour dietary recall (e.g., Crispim et al., 2011), Food Frequency Questionnaires (e.g., Fallaize et al., 2014) and food diaries or food records (e.g., Lieffers & Hanning, 2012).

In addition, various portion size measures have been used for assessing the amount of consumed food such as weighing food, estimate food portion size with food photograph aids or self-reported portion sizes (e.g., Lee et al., 2012).

Finally, technical developments in dietary assessment methodologies show a clear trend towards the use of technical devices such as wearables and wireless sensors for more autonomous and unobtrusive measures of food consumption (e.g., Zhang, et al., 2009; Sun et al., 2010; Bedri, Verlekar, Thomaz, Avva, & Starner, 2015).

Operationalization of the dietary assessment methodology criteria:
- Which methods have been used to collect what was consumed?
- Which methods have been used to collect how much was consumed?
- Does the tool support external devices to assess dietary intake?
- What type of external devices does the tool support?

4.1.7 Determinants of food consumption

Food consumption is a multifaceted process, which may be influenced by various types of determining factors (for a review see EUFIC, 2005). These determinants include biological determinants (e.g., hunger, appetite, and taste), economic determinants (e.g., cost and income), physical determinants (e.g., location, access, availability, product characteristics), social determinants (e.g., class, culture, social and situational context), psychological determinants (e.g., mood, goals, attitudes, beliefs and knowledge). Understanding these determinants and how they influence food consumption behaviours is the overarching aim of RICHFIELDS and is important given the priority for population dietary change (EUFIC, 2005). Possible criteria for assessing the determinants of tool's collecting consumer generated food consumption data were discussed amongst RICHFIELDS Phase 1 consortium members. The decision was taken to follow a traditional research question framework which would explore questions surrounding the 'what, who, why, how and where' of food consumption (Köster 2009).

In addition to these key determinants of food consumption other related lifestyle patterns such as people's activity, sleep and exercise patterns might also help in better understanding food consumption behaviours (e.g., Jacobs 2006; Vatansever-Ozen, Tiryaki-Sonmez, Bugdayci & Ozen, 2011; Mathiassen & Hollema, 2014).

Similar to dietary assessment methods there is a trend towards assessing all kinds of lifestyle activities and patterns using wearables and wireless sensors (e.g., Evenson, Goto, & Furberg, 2015).

Operationalization of the determinants of food consumption criteria:

- What type of lifestyle data does the tool collect?
- What type of external devices does the tool support to collect lifestyle data?
- Does the tool collect information about the situation of a consumer?
- What type of situational characteristics does the tool collect?
- Does the tool collect information about the characteristics of the product which has been consumed?
- What type of product characteristics does the tool collect?
- Does the tool collect information about where the consumptions took place?
- In what unit has the location of consumptions been measured?
- Does the tool collect information about the occasion of the consumptions?

4.2. Quality criteria related to legal governance

Based on our literature research on existing frameworks for the evaluation of eHealth and mHealth tools we have identified several criteria which are relevant for assessing the quality related to the legal governance of consumer generated data (table 2).

4.2.1 Terms and privacy documents

There is a requirement that all tools cover data ownership and data privacy in their licensing agreement, which the consumer accepts at the time of initial use (e.g., Cummings, Borycki, & Roehrer, 2013; Adhikari, Richards & Scott, 2014; Blenner et al., 2016).

Operationalization of the consent criteria:
- Does the tool provide a terms of use document?
- Does the tool provide a privacy policy document?

4.2.2 Data privacy

According to the HACP Certification Standards (Happtique, 2013), data privacy refers to the disclosure of all data a tool (or any in-app advertiser) collects or accesses on user devices and the applied methods and technology (automatically or manually; see also Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014). This includes collection, storage, and network transmission of user generated data including personal identifiable data and whether the data is securely encrypted during and after those workflows (e.g., Nije, 2013a), and the duration and termination of data storage (e.g., Cummings, Borycki, & Roehrer, 2013).

In addition, data privacy refers to the (secondary) usage of the user generated data such making data accessible to the general public or sharing data with other affiliated or unaffiliated third-parties such as analytics and advertising services, or data brokers (e.g., Nije, 2013b; Cummings, Borycki, & Roehrer, 2013).

Finally, according to the data protection directive of the European Commission personal information collected by businesses and institutions must be processed fairly for specified purposes only and on the basis of the consent of the person concerned. Perceived lack of consent due to data acquisition and usage may undermine public trust (e.g., Dufty, Bérard, Lefranc, & Signore, 2014).

Operationalization of the data privacy criteria:
- Is stored data encrypted?
- Is data encrypted during transmissions over the network?
- Does the tool collect personal identifiable information (e.g., during registration)?
- What types of personal identifiable information does the tool collect?
- Is the user asked permission about collecting personal identifiable information?
- Does the tool create a public profile of the user's personal data?
- Is the user able to configure privacy settings for his or her public profile?
- Does the app collect device data after installation/visit?
- What types of device data does the tool collect?
- Does the homepage/website of the tool store cookies on a user's computer?
- Does the homepage/website of the tool store web beacons to track the online movements of users?
- Will collected personal identifiable data be shared with affiliated third parties (parties with confidentiality agreements)?
- Is the user asked permission about sharing personal identifiable with affiliated third parties?
- Will collected personal identifiable data be shared with unaffiliated third parties (parties without confidentiality agreements)?
- Is the user asked permission about sharing personal identifiable with unaffiliated third parties?

- Is the user able to delete or ask for deletion of his or her personal identifiable information (e.g., after account termination)?
- Does the homepage/website of the tool uses third-parties for advertising and usage analytics?

4.2.3 Data ownership

Data ownership refers to both the possession of and responsibility for information. Ownership implies power as well as control. The control of information includes not just the ability to access, create, modify, package, derive benefit from, sell or remove data, but also the right to assign these access privileges to others (Loshin, 2002). Loshin (2002) identifies a list of parties laying a potential claim to data such as the party that creates or generates the data (e.g., the app user), the enterprise in which the data is created (e.g., the app vendor) or the individual or organization that buys or licenses data (e.g., third parties and business partners).

Operationalization of the data ownership criteria:
- Who holds the ownership of the user generated data?
- Does the tool vendor retain the right to access and exploit the user generated data?

Data privacy and ownership may have a significant influence on the intended use of the data given legal limitations, organizational restrictions, confidentiality and privacy concerns (e.g., Dufty, Bérard, Lefranc, & Signore, 2014).

4.2.4 Data security

Data security refers to the extent to which access to information is restricted appropriately to maintain its security (e.g., by authentication; e.g., Knight & Cowan, 2005; Schulze & Kromker, 2010; Martinez-Perez, de la Torre-Diez, Candelas-Plasencia, & Lopez-Coronado, 2013). Data security can be assessed on several levels such as data-level, application-level, network-level, and host-level security (e.g., Ho, Lee, & Armstrong, 2013). In addition, data security can refer to the data storage such as local storage versus cloud-based storage or the availability of data backup systems (e.g., Ho, Lee, & Armstrong, 2013).

Operationalization of the data security criteria:
- Is data stored on a device?
- Is data stored on a server?
- Does data access require authentication?

4.3 Quality criteria related to data management

Several criteria which are relevant for assessing the quality related to the data management of the consumer generated food consumption data has been identified (table 3). The criteria are inspired by the widely accepted and recommended FAIR data principle (e.g., Wilkinson et. al., 2016). However, due to feasibility reasons (see procedure) we only focus on those FAIR data principles that do not require us to examine the data structure and data access documentations in more detail.

4.3.1 Data accessibility

Accessibility of data refers to how easy it is to access data and metadata (e.g., Dufty, Bérard, Lefranc, & Signore, 2014) including interactions with the technical infrastructure (e.g., Web API) for data access (e.g., Dedeke, 2000) and whether data is retrievable using an open, free, and universally implementable communications protocol (e.g., REST). In addition to a standardized data access, the protocol should also allow for an authentication and authorization procedure (e.g., OAuth 2.0; e.g., Wilkinson et. al., 2016).

Operationalization of the data accessibility criteria:
- Is the data collected by the tool accessible via the tools data infrastructure?
- Can the data be accessed using a commonly used access protocol?
- Which commonly used protocol must be implemented to access the data?
- In which format is accessible data represented?
- Does data access require authentication?
- Does data access require payment?

4.3.2 Interoperability

Data quality increases if data is represented in a formal, accessible, shared, and broadly applicable language (e.g JSON; e.g., Wilkinson et. al., 2016) and if data includes qualified references to other data (e.g., behavioural determinants and lifestyle data).

Operationalization of the data interoperability criteria:
- Can data be integrated with or linked to other data?
- What type of data does the tool integrate from other tools (e.g., partner apps)?

4.3.3 Reusability

An important factor of data reusability is whether data are released with a clear and accessible data usage license (Wilkinson et. al., 2016).

Operationalization of the data reusability criteria:
- Does the tool provide a terms of access document?

In addition to quality criteria inspired by the FAIR data principle we included the following quality criteria in our framework which we think are important for the evaluation of quality related to data management.

4.3.4 Contact and support

In order to increase user-friendliness, it is important that the tool provides assistance for individuals having technical problems or questions regarding the use of the tool and access to the data. Such support includes availability of contact information, contact address, and concise and comprehensive documentation of the tool and data access protocols (e.g., Kim, Eng, Deering & Maxfield, 1999).

Operationalization of the contact and support criteria:
- Does the tool provide data access documentation?
- Does the tool provide a link to a working home page?
- Does the tool provide contact information?

4.3.5 Software portability
Portability refers to the number of operating systems and devices the application supports (e.g., IOS, Android, Windows; e.g., Meulendijk, Meulendijks, Jansen, & Numans, 2014);

Operationalization of the software portability criteria:
- Which operating systems does the tool support?

5. Summary & discussion

An important aim of RICHFIELDS is to design a research infrastructure and data platform for the collection, integration, processing and sharing of food consumption and associated lifestyle data generated by tools which are accessible to the general public. In order to identify the opportunities, gaps and needs in terms of data relevance and the collection, integration and dissemination processes of such consumer generated data we formulated a set of quality criteria for the evaluation of consumer generated food consumption and associated lifestyle data. Due to the RIHFIELDS multi-disciplinary requirements for knowledge and expertise including human nutrition, law and information technology we grouped the quality criteria around the three dimensions 1) scientific relevance, 2) legal governance and 3) data management. The resulting evaluation framework is meant to provide structure and guidance for data collection regarding the inventory of consumer generated food consumption data tools, which is to be created in deliverable 7.1. The framework will provide operationalisations for each quality criterion in the form of a set of relevant questions that should be answered for each tool included in the inventory.

The purpose of selecting and structuring our quality criteria around the dimensions of scientific relevance, data management and legal governance was not to develop a new classification model for health application quality criteria. We belief that probably most of the quality criteria presented here could either be easily categorized in a different way or fit multiple of our described quality dimensions. For instance, the timeliness, complexity or linkeability of data can have important consequences for scientific relevance, data management as well as legal governance. Our purpose for using these quality dimensions as guidelines was to make sure that our set of quality criteria will be relevant and complete across the needs and requirements of the various disciplines involved in the design of the research infrastructure.

Many decisions for selecting a quality criteria were influenced by how feasible we considered locating and collecting data and indications for the quality criteria. Due to the number of applications the inventory is planned to be comprised of, the decisions for including a quality criterion into the final framework was based on whether information regarding the quality criteria was perceived to be publicly available, without actively installing and testing the tools and their hosting infrastructures. This caused us to exclude quite a large number of quality criteria including criteria related to the collected data and the

tool's functionality. Our main focus is on gathering relevant information for the design of the RI and data platform and we believe that the aesthetics, functionality and usability of the tools are more relevant for the design of the tools rather than the design of the RI.

In addition, a large number of criteria was not selected due to their perceived un-relatedness to scientific relevance, legal governance, and data management. We believe that a tools aesthetics and related user experience is crucial for engaging and keeping users engaged in using a tool, and although not directly related such criteria might have indirectly a profound influence on the scientific relevance of the data such a tool collects. Not selecting quality criteria did not mean we consider them irrelevant. We believe that it is important to determine the tools' quality on most of those quality criteria before they actually should be used and recommended in scientific research. We believe that such an elaborate validation and certification procedure should be an integral part of the research infrastructure and should be anchored around the premise whether a tool is "fit for purpose".

The selection and operationalization of the quality criteria related to scientific relevance, legal governance, and data management were the result of an effortful and elaborate collaboration amongst all phase 1 consortium partners including WP4, and consortium partners of Phase 3. The process consisted of summarizing the relevant literature on food consumption and dietary assessment and on existing evaluation frameworks for eHealth and mHealth applications, their collected data and information systems. Another major part of the selection process consisted of deliberate discussions and considerations of the needs, priorities, and resources amongst the partners of the RICHFIELDS consortium. The fact that we excluded a large number of quality criteria, limits the scope of quality the current framework will be able to reveal, we believe, however, that the selected quality criteria are relevant and comprehensive across the needs and requirements of the various disciplines involved in designing the blueprint of the research infrastructure and data platform on consumer generated food consumption data. The current quality framework supports the RICHFIELDS design process by forming a structured and standardized foundation for the inventory data collections in Deliverables 5.1-7.1 and supports the creation of a knowledge base for the identification of possible scientific, legal, technical and ethical gaps and needs regarding the use and integration of the data collected by food consumption and lifestyle tools.

Overview operationalization of quality criteria

Table 1: Scientific relevance quality criteria

Quality criteria	Operationalization
Tool purpose	What is the intended purpose of the tool?
	Is the tool a medical device?
Dietary assessment	Does the tool collect information about what was consumed?
	What is the level of detail or unit the consumptions have been measured?
	Does the tool collect how much was consumed?
Dietary assessment methodology	Which methods have been used to collect what was consumed?
	Which methods have been used to collect how much was consumed?
	Does the tool support external devices to assess dietary intake?
	What type of external devices does the tool support?
Consumer unit	What is the consumer unit the consumptions have been measured?
Determinants of food consumption	What type of lifestyle data does the tool collect?
	What type of external devices does the tool support to collect lifestyle data?
	Does the tool collect information about the situation of a consumer?
	What type of situational characteristics does the tool collect?
	Does the tool collect information about the characteristics of the product which has been consumed?
	What type of product characteristics does the tool collect?
	Does the tool collect information about where the consumptions took place?
	In what unit has the location of consumptions been measured?
	Does the tool collect information about the occasion of the consumptions?

Table 2: Legal governance quality criteria

Quality criteria	Operationalization
Terms and privacy documents	Does the tool provide a terms of use document?
	Does the tool provide a privacy policy document?
Data privacy	Is stored data encrypted?
	Is data encrypted during transmissions over the network?
	Does the tool collect personal identifiable information (e.g., during registration)?
	Is the user asked permission about collecting personal identifiable information?
	What types of personal identifiable information does the tool collect?
	Does the tool create a public profile of the user's personal data?
	Is the user able to configure privacy settings for his or her public profile?
	Does the app collect device data after installation/visit?
	What types of device data does the tool collect?
	Does the homepage/website of the tool store cookies on a user's computer?
	Does the homepage/website of the tool store web beacons to track the online movements of users?
	Will collected personal identifiable data be shared with affiliated third parties (parties with confidentiality agreements)?
	Will collected personal identifiable data be shared with unaffiliated third parties (parties without confidentiality agreements)?
	Is the user able to delete or ask for deletion of his or her personal identifiable information (e.g., after account termination)?
	Does the homepage/website of the tool uses third-parties for advertising and usage analytics?
Data ownership	Who holds the ownership of the user generated data?
	Does the tool vendor retain the right to access and exploit the user generated data?
Data security	Is data stored on a device?
	Is data stored on a server?
	Does data access require authentication?

Table 3: Data management quality criteria

Quality criteria	Operationalization
Data accessibility	Is the data collected by the tool accessible via the tools data infrastructure?
	Can the data be accessed using a commonly used access protocol?
	Which commonly used protocol must be implemented to access the data?
	In which format is accessible data represented?
	Does data access require authentication?
	Does data access require payment?
	Can data be integrated with or linked to other data?
	What type of data does the tool integrate or link to?
Contact and support	Does the tool provide data access documentation?
	Does the tool provide a link to a working home page?
	Does the tool provide contact information?
Software portability	Which operating systems does the tool support?

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