EXPERT REVIEWS

Standardization and simplification of vaccination records

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The majority of vaccines are administered during childhood. Vaccination records are important documents to be kept for a lifetime, but the documentation of immunization events is poorly standardized. At the point of care, paper records are often unavailable, making it impossible to obtain accurate vaccination histories. Vaccination records should include batch specifications to allow the tracking of licensed vaccines in cases of recall. The WHO have generated the International Certificate of Vaccination or Prophylaxis for the documentation of childhood and travel vaccinations as well as seasonal and booster immunizations. When moving vaccination records into the digital age, data standards and interoperability need to be considered. The ideal vaccination record should facilitate the interpretation of safety reports and promote a data continuum from pre-licensure trials to post-marketing surveillance. The current article describes which data elements are essential, and how vaccination documentation could be streamlined and simplified.

Keywords: AEFI • certificate of immunization • data interoperability • m-health • electronic health records • harmonization • pharmacovigilance • simplification • standardization • vaccination record

Communicable diseases do not stop at national borders and may pose a threat to human health in different parts of the world. Vaccines are among the most important measures to prevent infectious diseases, saving millions of lives every year [1]. Immunization programs are viable only if vaccination events are monitored vigorously. The monitoring of immunization programs relies on accurate and standardized documentation of vaccination events, as well as the tracking of vaccine transport and logistics. Unfortunately, many healthcare providers and administrative regions are still using inconsistent or poorly interoperable documentation systems.

There are currently very few studies in the published literature investigating completeness of vaccination records or differences between record-keeping by lay people versus medical professionals (see section 'Roles & responsibilities in record-keeping'). In order to enable informed decision-making, for which patients have to understand their own medical documents, clear and intuitive vaccination records are required. New technologies allow different approaches to how and where vaccination data should be stored. As part of this development, a consensus should be reached on the question of who should be responsible for the maintenance and accuracy of vaccination records: the physician, the vaccine recipient or both.

The importance of standardized requirements for complete documentation will be discussed in 'Standardization of vaccination records'. At the end of 'Standardization of vaccination records', we provide a literature review illustrating different views on roles and responsibilities with regards to vaccination records. In 'Simplification of vaccination records', we address the need to simplify standardized vaccination records to improve applicability in all settings, including low-resource environments. The feasibility of digital solutions will also be addressed in 'Simplification of vaccination records'. This interdisciplinary field requires close collaboration between clinicians, public health experts and standards organizations, who would also constitute the target audience for this paper. We therefore include the perspectives of all three parties including a non-profit organization closely involved with data standards for clinical research and electronic health records (EHRs).

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In 'Five-year view', the impact of mobile phone technology on the development of digital and portable vaccination records will be highlighted.

Standardization of vaccination records

The need for universal vaccination records

A patient's vaccination status has important health implications. A comprehensive vaccination record will summarize any diseases the patient should be protected from. This is particularly important in the critical care setting, where the date of the most recent tetanus booster immunization should be assessed as timely as possible [2]. In such situations, portable vaccination records offer a quick reference summarizing any vaccinations recieved to date. Verbal immunization histories obtained from the patient or proxy on the other hand, have been shown to be largely incorrect or incomplete [3,4]. Most written vaccination records involve manual record-keeping. Legibility may pose a challenge in emergency situations, including annotations in different styles of handwriting. Some patients also keep several incomplete vaccination records in parallel. This may complicate the rapid abstraction of vaccination data by the healthcare provider, and vaccine recipients may be confused with respect to their own and their families' vaccination status. As a result, a clear immunization history is often unavailable when needed the most.

Experience with natural disasters, global disease outbreaks and pandemics has shown that vaccination records may be important to public health officials [5]. In times of worldwide travel and migration, vaccination records should be well-designed and highly standardized. In addition, in-flight medical emergencies or those that occur during international travel may pose significant risk, especially if important and potentially life-saving health data are unavailable [6]. International travelers seeking medical care away from home may be asked for evidence of routine childhood vaccinations as well as hepatitis, rabies, polio, typhoid, meningococcal or yellow fever vaccines. The requirement to demonstrate proof of yellow fever immunization when crossing borders from/to high-risk countries might be a key motivation for travelers to obtain an international vaccination record, as proposed by WHO. Despite this important harmonization effort, many different vaccination records are still in use, with different priorities and levels of detail [7].

Examples of vaccination records currently in use

The International Certificate of Vaccination or Prophylaxis (ICVP) represents the official vaccination record/template approved by WHO. WHO records are available in bilingual formats (e.g., English/French) and in trilingual versions (such as English/French/Arabic) [8]. In some countries, the WHO ICVP is used in lieu of a vaccination card, while in other systems, it is used for travel only [7]. In some instances, portable records are used in addition to a national immunization registry, whereas in other settings the paper record may be the only one available [4].

Official WHO records dedicate an entire page to the accurate documentation of yellow fever vaccinations. An additional section is available for the documentation of yellow fever booster immunizations, although recent WHO recommendations claim that yellow fever booster vaccinations are no longer needed [8,9]. This example illustrates the need to adapt vaccination records constantly to changes in immunization recommendations in different parts of the world. As illustrated in Figure 1A, several different versions of the WHO template are currently in circulation, following local adaptation and various renewals.

The WHO ICVP is not restricted to travel vaccines, but contains additional pages for childhood immunizations including diphtheria and mumps–measles–rubella vaccines [9]. In Europe, it is frequently used as the main vaccination record. In other countries, the WHO ICVP has not been adopted for the documentation of childhood immunization, resulting in multiple vaccination records to be maintained in parallel [7]. Most childhood immunizations are still documented in non-standardized records (Figure 1B), or in the mother-baby pass [10]. The situation may be complicated even further when different family members keep different types of vaccination records depending on their respective age (Figure 1C) or place of birth. Even within the same country, vaccination records may differ from region to region. German citizens born prior to reunification may still be utilizing old versions of Eastern or Western German vaccination records [11]. Additional vaccination records may be issued in case of new vaccines becoming available, as was the case during the 2009/10 influenza pandemic [12].

Additional formats for vaccination records have been developed by several other international institutions. For instance, the Immunization Action Coalition supported by the US CDC has provided an 'Immunization Record Card' [13]. As another example, the European Commission is planning to introduce a 'European Vaccination Passport' in order to alleviate difficulties in migration between European countries [14]. The idea of the 'passport' is to simplify migration and relocation within the EU, while reducing the risk of delayed or missed immunizations. Currently, more than 20 national vaccination schedules exist across Europe [15,16].

The activities conducted by WHO, the CDC and the EU to establish an international vaccination record emphasize the need for standardization. However, the existence of different versions also illustrates the need for therapeutic disease area standards for vaccines and vaccine-preventable diseases (VPDs).

One approach would be to merge several existing vaccination records into one single, internationally valid document, which should be durable and provide sufficient space to include all possible vaccination events throughout the lifespan of an individual, for example, annual influenza immunization. Possible formats may include folders or ring binders made of water-repellent materials, or pre-printed forms with checkboxes and sufficient space for stamps and/or adhesive labels. Establishing the vaccination record as a mandatory travel document could

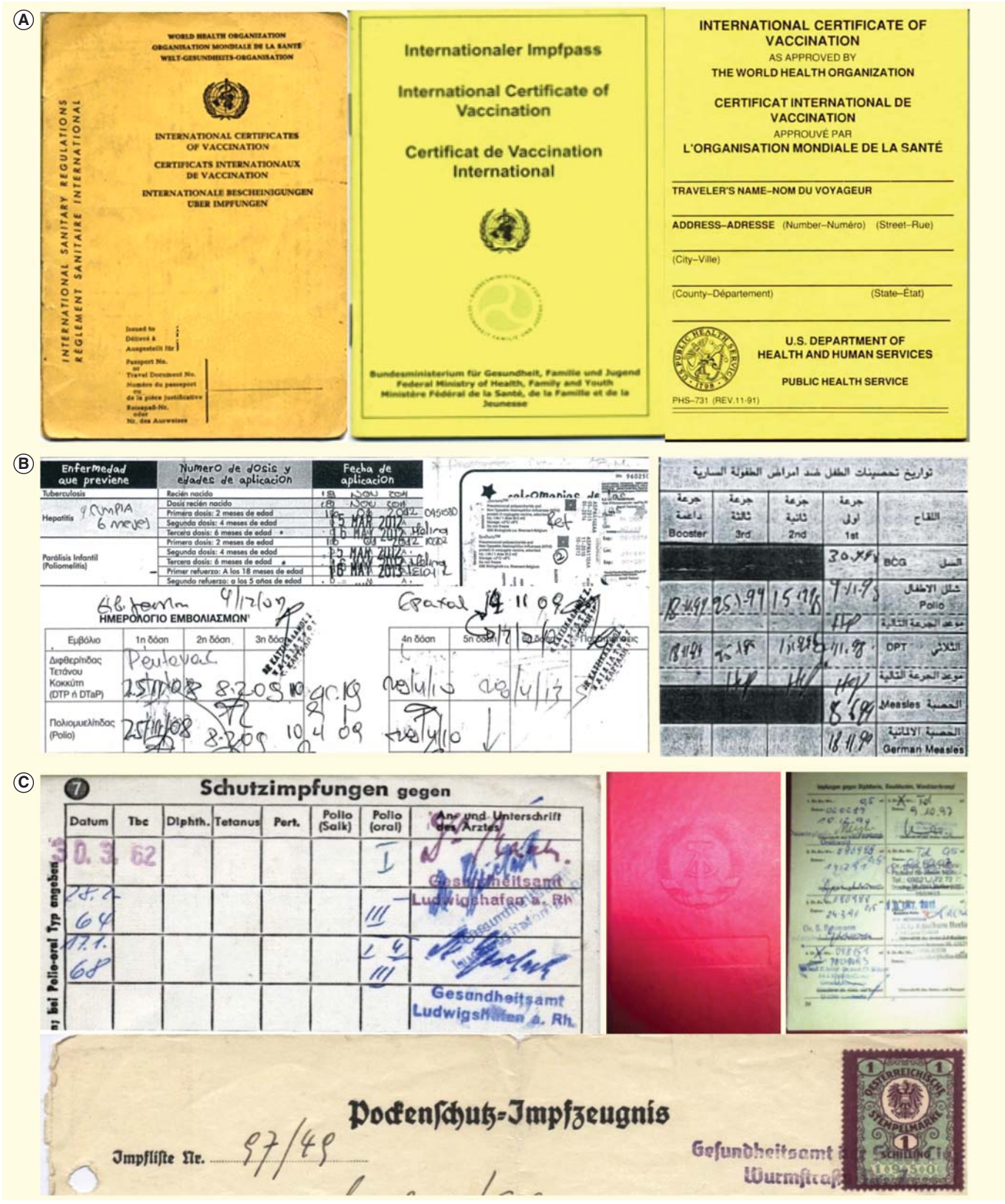

Figure 1. Examples of international vaccination records. (A) Examples of different WHO immunization records. **(B)** Excerpts from national immunization records (Columbia, Syria and Greece). **(C)** German vaccination records representing different birth years (1950, 1970 and 1990). Batch numbers, expiry dates as well as trade names are missing.

Box 1. Required data elements in vaccination records.

To keep track of immunization events, a minimum set of information must be documented [19]. To allow use of vaccination documents in international travel, the record should be completed in English, but other languages may be added. Amendments are only acceptable following the rules of the International Council of Harmonization and Good Clinical Practice [18]:

- Full name and birth date of the vaccine recipient, national or personal identifier, race/ethnicity, BMI, smoking status and concomitant medication use
- Date of administration (day-month-year, e.g., 1 January 2013 [8])
- Adhesive label (including the name of the vaccine, manufacturer, batch number and expiration date)
- Vaccine-preventable disease against which the vaccine was administered
- Route of administration [19]
- Injection site, technique and needle size for injectable vaccines [19]
- Name, signature and stamp/seal of the healthcare provider administering the vaccine, including information where the vaccine was administered
- Special indications, if applicable (such as international travel or risk factors)

enhance the acceptance of standardized documents worldwide, as already demonstrated by the wide distribution of the WHO vaccination record as proof of yellow fever vaccination in high-risk countries.

Essential data elements & standards

A standardized vaccination record should promote and facilitate the intuitive, correct documentation of each vaccination event by collecting a minimum amount of required data (Box 1). As suggested by Bundy *et al.* in 2009, 5 Rs should be followed to avoid errors in immunizations or documentation thereof: The Right Drug, The Right Dose, The Right Route, The Right Time and The Right Patient [17]. These 5 Rs can be supplemented by the right injection technique and the right documentation, as will be explained below [18,19]. A complete vaccination record should contain these 5 Rs, to prevent vaccination errors. International vaccination records should require verification of completeness by healthcare professionals. In case of incomplete or incorrect documentation, previous healthcare providers should be contacted for clarification [19].

Only a few publications provide information on how to report a vaccination event [19]. Ideally, routine documentation of vaccination events should be as detailed as in a clinical trial, allowing full access to necessary data during post-marketing surveillance [20]. Clinical trials are usually not powered sufficiently to detect rare adverse events following immunization (AEFI), thus AEFI assessments will continue throughout the post-licensure phase of a vaccine [21–24]. One way of establishing valid data sources for post-marketing surveillance would be to maintain the same data elements already established during the pre-licensure evaluation of vaccines for better comparability.

Documenting patient demographics

Ensuring correct identification on every page of the vaccination record is vital. This may be important when different family members have similar names (distinguished by name attributes or suffixes such as 'junior', 'senior', 'IIIrd', etc.) or when the first name of a newborn baby has not yet been decided upon. The full name should be added as soon as possible with the next well-child visit. Nevertheless, a recent report of a national error reporting system in the USA revealed that the patient identity was incorrectly documented in 4.1% of cases [17].

Personal identifiers may vary, as in the case of maiden names or marriage-related name changes. Even passport numbers may change throughout a lifetime. In countries such as the USA, only few citizens are holding a passport [25]. Complete identification should thus include the full name, including any previous names and suffixes, the birth date and a permanent personal identifier, such as a social security or national identification number.

Certain characteristics and risk factors in addition to age and gender may influence vaccine immunogenicity as well as the individual risk of adverse events [19]. Therefore, it might be prudent to also document information such as race and/or ethnicity, BMI, smoking status, concomitant medication use and specific risk factors. Certain data elements such as BMI and smoking status, may change over time. Sufficient space for periodic updates or status changes must be available. For children, the inclusion of growth charts may be advisable.

If special vaccinations require information on patient demographics, this can be specified under 'special indications' as outlined in Box 1. For further assessment of potential vaccine risks, the importance of interoperability between vaccination data and medical records cannot be underestimated.

Documenting vaccine information

The exact documentation of detailed vaccine information is key, as vaccine compositions may change over time and different public health goals may be achieved by each one of them. For example, the inactivated poliomyelitis component (IPV) is currently a combination of three inactivated wild-type poliomyelitis viruses (type 1 Mahoney strain, type 2 MEF-1 strain, type 3 Saukett strain) [26]. In the final phase of polio eradication, it may become feasible for the wild-type strain to be substituted by an inactivated Sabin strain vaccine, resulting in different levels of immunogenicity [27]. In this case, it would be important to know which polio strains were administered.

Non-active vaccine ingredients, such as adjuvants or components derived from vaccine production (e.g. egg-proteins), may have an impact on vaccine safety and effectiveness [28,29]. When batch numbers are used to document vaccinations, non-active ingredients in the vaccine will be trackable. In low-resource settings, the risk of re-use of needles and blood-borne infections as well as bacterial or fungal contamination of vaccine multi-

dose vials may be an issue [30,31]. Multi-dose containers may thus contain preservatives, resulting in different safety profiles [32]. In the past, some vaccines and biologicals used to contain plasma-derived human serum albumin. With occurrence of prion-derived diseases such as new-variant Creutzfeldt-Jakob disease, a theoretical risk of infection by human proteins could be hypothesized [33]. Manufacturers switched to recombinant human serum albumin and other stabilizers following recommendations by the EMA and other regulatory agencies, and no such adverse events were observed [34]. Public communication would be more timely, transparent and reassuring, if each vaccine recipient could easily check his/her personal vaccination record whenever changes in vaccine composition are indicated.

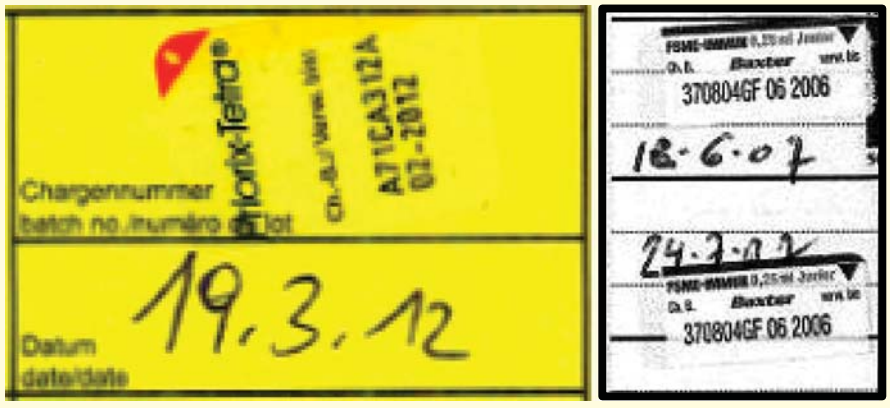

Figure 2. Vaccination records are important documents when expired vaccines have been in use. Expired vaccines must never be administered.

Asides from clinical significance, documentation whether a single-use syringe or a multi-dose vial was used has public health implications as well. In Europe, vaccination rates are often estimated based on sales statistics, so for example a sold 10-dose multi-vial would account for 10 patients immunized [35]. When multi-dose containers are used, remaining vaccine doses have been discarded after the expiration date leading to overestimation of vaccination rates in the population. Parmar *et al.* stated that wastage rates can be calculated from 1 to 10% with single vials, compared approximately to 44% with 10-dose containers [36]. To ensure the quality of the vaccine, the expiration date on the adhesive label, together with the date of immunization, should always be documented in the vaccination record (Figure 2).

A simple way to facilitate the task of record-keeping with respect to vaccine information is the inclusion of adhesive labels in the vaccination record. Adhesive labels can be removed from the vaccine container and typically include the name of the vaccine and manufacturer, batch numbers and expiration dates. Documentation of the batch number adds important information [19]. Adverse events, such as local reactions, could be linked to deviations from the manufacturing process or interruptions of the cold chain. In cases of vaccine recall by regulatory agencies, such as in the case of inadequate vaccine lots, the batch number in the vaccination record may be the only means of tracking vaccine distribution. In such instances, only affected batches have to be withdrawn and recipients can be monitored closely. This happened in 2012, when the distribution of two influenza vaccine batches was stopped due to precipitation events. A deviation in the production process was found and was collated with certain batches, whereas unaffected batches could be made available again [37]. To allow linkage of batch numbers with safety signals, vaccination records should provide sufficient space to document any specific action taken after a recall notice has been released, as well as any adverse events (or absence thereof). In case of insufficiently immunogenic vaccines, similar procedures should be in place to prevent vaccination failure [38].

Criminal acts, such as the production of counterfeit pharmaceuticals, are a problem necessitating real-time surveillance and documentation. For instance, during a drug raid in China in 2007, 10,000 doses of 'rabies vaccine' lacking active ingredients were confiscated [39]. To facilitate the documentation of vaccine administration in real-time, bar (or quick response [QR] or 2D) codes could be included in the label. The label could then be scanned with a QR reader, as currently in use for international flight tickets, and collate vaccine product information with a manufacturing database. If a vaccine is identified as carrying an expired or non-official barcode, or as under observation because of suspected cold chain interruptions, an immediate warning to vaccine providers can be issued [40]. Pilot studies are currently being conducted by the CDC on an Immunization Information Systems with 2D-barcodes [41]. As another example, a start-up project in Ghana is currently using short message services to differentiate between authentic and counterfeit drugs [42].

Documenting vaccine administration

With the addition of new vaccines to childhood immunization schedules, several injections may be administered at the same time. This practice requires accurate documentation of vaccine administration details. This includes the geographic location of where the vaccination was administered as well as the injection site and route of administration (Box 1). According to the German and Austrian vaccination schedules, polyvalent vaccines (e.g., DTaP-HBV-IPV-HIB) are commonly used on the same day with pneumococcal conjugate vaccines, administered on one thigh each. The injection site should be documented, so that in case of a localized reaction the corresponding vaccine can be identified. Another option would be the establishment of Standard Operating Procedures, for example, pneumococcal vaccine to always be administered on the left thigh [19,43,44]. In addition to the vaccine name coding system mentioned in

'Documenting in standardized language', we propose a three-letter lowercase code, which could be used to document the site of administration, as follows: ora: oral; nas: nasal; dml: deltoid muscle/left upper arm; dmr: deltoid muscle/right upper arm; tml: thigh muscle/left; tmr: thigh muscle/right.

To ensure the safe administration of vaccines, it is important to use standardized terminologies also for the route of administration. Standard terms have been published by the Department of Quality in Medicine of the Council of Europe [45] as well as by the International Organization of Standardization [46]. As an example, the term *injection needle* is defined as 'a hollow needle with a locking device intended for the administration of liquid pharmaceutical forms', while a *cannula* is considered an 'administration device, tubular with a conical tip used for the application of semisolid pharmaceutical forms' [45]. Despite these differences, both terms are often used synonymously, resulting in use of incorrect administration techniques. In order to prevent errors in application, labeling and electronic communication, standard terms should be used in accordance with the relevant guidelines such as Summary of Product Characteristics, European Marketing Authorization. In addition, standardized labels may contain universally recognizable symbols or photos of the vaccine container to further increase immunization safety.

Documenting in standardized language

While the core data elements outlined in Box 1 summarize the information to be included in the vaccination record, it is important to recognize that the data language should also be standardized. Figure 1B illustrates vaccination records in different languages and writing styles or alphabets (such as Latin, Cyrillic, Arabic, Greek or Chinese) that may be encountered in routine medical practice. To be valued as international travel documents, vaccination records should always include English language terminology in addition to the respective local language.

The vaccine recipient should be considered a well-informed partner in all aspects of health and physical wellbeing, hence vaccination records can only be considered complete when the owner is able to understand any relevant information provided therein. Therefore in all instances, the record should be completed in the native language of the vaccine recipient. When both healthcare provider and vaccine recipient are informed, a trusting relationship will ensue.

In addition to standardizing the language of vaccination records, a universal vaccine nomenclature using universal coding systems could facilitate communication even further, while limiting potential sources of error or confusion. In many areas of international collaboration and communication, universal coding systems have been established. A well-known example is the 'three-letter code' nomenclature for international airports [47]. As proposed previously, a similar *three-letter code for vaccines* could be used on adhesive labels and in vaccination records, assigning a unique identifier to each vaccine component [48]. For example, the name of the hexavalent vaccine 'diphtheria, tetanus, pertussis (acellular), hepatitis B (rDNA), poliomyelitis (inactivated) and *Haemophilus influenzae* type B conjugate vaccine (adsorbed)' could be condensed into 'DTaP-HBV-IPV-HIB'. By contrast, a hypothetical trade name such as *hexaject* would not reveal any vaccine ingredients. Addressing the same need, the US CDC proposed two- to five-letter codes, taking the many different formulations for pediatric and adult patients into account [49].

Roles & responsibilities in record-keeping

There has been much debate surrounding the topic of patient empowerment with respect to matters of their own health [50]. Vaccination records are no exception [51].

Many healthcare systems use centralized vaccination registries; nevertheless, vaccine recipients should be informed about their own vaccination status. In the absence of national immunization registries, the responsibility to keep track of immunizations rests entirely upon the healthcare provider and/or the vaccine recipients themselves. In case of childhood vaccinations, parents are usually in charge of maintaining vaccination records. Children are barely involved in the decision-making process, even if they might be old enough to comprehend the basic principles of vaccines and immunization [52,53].

Families may have difficulty maintaining vaccination records, especially when multiple family members are involved. In addition, it may be difficult for lay people to comprehend what is written in the vaccination records, and hand-written notations or unfamiliar trade names may complicate the matter [54,55]. When new vaccines are introduced to the immunization schedule, it may be hard for parents to keep track of what constitutes being up-to-date on vaccinations. Parents may also have questions or concerns about VPDs and/or vaccinations referenced in the records, without finding the answers in the record itself.

Last but not least, paper records may always get lost or misplaced. A recent campaign by the German Federal Centre for Health encouraged individuals to take charge of their vaccination records. Large posters were issued with the slogan "Germany is looking for the vaccination record", in an attempt to educate the public about the need for catch-up immunizations against measles [56]. Along with the campaign, detailed instructions on how to determine one's own vaccination status for measles with the help of the WHO ICVP were provided [56].

WHO mandates that each visit to a physician should be used to check the patient's vaccination status and to catch up on missing immunizations, if necessary [57]. For vaccine recipients to be responsible for keeping their vaccinations up-to-date, the record should be as easily comprehensible as possible.

Reliability of self-reports compared to reports by healthcare professionals

One requirement for patient empowerment will be the ability of a lay person to understand and report from their own vaccination record. Several recent studies and meta-analyses have been

comparing parental recall to vaccine data in national or federal registries or medical records kept at the physician's office [3,4]. Very little is known, however, about the parents' ability to correctly interpret the information presented in a vaccination record, or to determine and report the vaccination status accurately.

Comparison of parental reporting to vaccination reporting by healthcare professionals: a literature review

We conducted a systematic review of the literature aiming to assess the reliability of parental or self-reports of vaccination status compared to records interpreted by healthcare professionals.

A MEDLINE search was conducted including studies published between 1 January 1975 and 21 October 2013. Search terms were clustered around different terms describing vaccination records, such as *immunization card* or *shot card*, in combination with terms describing self or parental reporting (Box 2).

Limits were set for 'language' (English), 'humans' and 'full text available'. Studies were included, when self-reporting or reports of vaccination histories by proxy with the vaccination record were compared with medical provider reports as gold standard. Studies using centralized immunization registries or data from insurance networks as gold standard were excluded.

The keyword search resulted in a total number of 180 manuscripts. After screening by abstract and full text, only six studies were found to fit the criteria of this search. Two additional studies were identified from referenced articles (Table 1).

The eight studies [58–65] showed significant differences in rates of agreement between parental reporting and physician reporting, with kappa scores ranging from 0.03 (poor agreement) [66,67] to 0.92 (almost perfect agreement) [58]. Estimated vaccination coverage rates based on self-reporting or report by proxy ranged from a significant underestimation of the number of actual immunizations received [62] to overestimation [67]. The literature review, therefore, revealed that there is a lack of information regarding the accuracy of an immunization status reported by lay people. Any efforts toward standardization of vaccination records should recognize this unique opportunity for patient education and empowerment [51,68,69].

It is concerning that the information provided by parents, even if the vaccination record is available to them, may not always be in agreement with a provider-reported vaccination status for the same individual. Additional studies, analyzing differences between self-report/report by proxy with information from standardized vaccination records, are needed.

The physician's assessment of a vaccination status may be incomplete, as some vaccines might be administered in pharmacies, travel clinics or emergency rooms. The information in a household-held vaccination record may be incomplete if the vaccination record was unavailable at the time of immunization.

We found very little literature on the difficulties parents may be facing when trying to extract specific information from vaccination records [55]. In times of shared decision-making, additional studies are warranted [50,70]. Compliance with booster immunizations may improve if more parents and vaccine recipients are actively involved [56]. Post-marketing surveillance of AEFI may benefit as well [71,72].

Standardized vaccination records may provide a unique opportunity to educate about the benefits of immunizations. When standardized vaccination records are developed, motivational factors should be considered [73]. Interactive medical documents could encourage a constructive dialogue between patients and healthcare providers [74–77]. Additional incentives may be added, such as collectible stickers for completed vaccination records. In case of a ring binder or another expandable record, information cards including graphic images or symbols can be added to the record in a modular approach.

Even if active involvement of the vaccine recipient is desirable, any information provided in the vaccination record should be confirmed by a healthcare professional. A verbal history of a VPD will not replace a documented immunization [78]. Standardized vaccination records may, however, be extended to include the reporting of adverse events or the absence thereof, as well as confirmed cases of vaccination failure, requesting laboratory confirmation of a breakthrough infection [79]. This would enable the accurate monitoring of real-world effectiveness of vaccines. Vaccination records can thus be a valid tool for health education [13].

Simplification of vaccination records

Digitization & backups

The process of standardization is often perceived as complex and labor-intensive. Keeping the data standardization requirements simple and practical should always remain a priority. Digital vaccination records may offer sufficient space to include all relevant vaccination data for a lifetime (Box 1), providing a significant advantage over paper records.

Vaccines are often administered by nurses or pharmacists and in sites other than physician's offices (i.e., in drugstores, schools, hospitals, outpatient clinics or emergency rooms). All documentation of immunization events should adhere to the same standards, but it should also be simple enough and self-explanatory to avoid misinterpretation or inconsistencies. Access to the internet is becoming universal, including in low-resource settings [42,80]. The era of digital innovation and mobile health (m-health) may bring new possibilities for telemedicine and medical documentation, simplifying work processes and ensuring that accurate and up-to-date information is available to both healthcare professionals and vaccine recipients [51].

In the digital age, there are numerous possibilities to facilitate the task of record-keeping. For utmost patient safety, current vaccination data should be retrievable at any time. It may be a misperception that paper records are safe. Indeed, electronic data provide levels of protection and controlled access that cannot be achieved in a paper format.

Well-designed digital records may offer improved access rights and data protection. Even with the most viable and well-designed paper record, there may always be situations

Table 1. Summary of eight studies comparing self-reporting with physician reporting of vaccination histories.

Study (year)	Total (n)	Age range of vaccine recipients	Vaccination record abstracted by	VPD	Gold standard	Vaccination record plus recall of vaccinations compared with the respective gold standard					Vaccination coverage rates according to vaccination record	Vaccination coverage rates according to gold standard	Ref.
						Sensitivity	*Specificity*	*PPV*	*NPV*	*Kappa*			
Dorell *et al.* (2011)	16,483	13–17 y, parental report	Parents (phone)	HBV, MUM, MEA, RUB, VAR, DTP, IPV, MEN, HPV	Provider-reported vaccination histories	62–96	57–97	74–100	16–96	0.22–0.92			[58]
Gareaballah and Loevinsohn (1989)	464	<18 y, parental report	Interviewer	MEA, BCG, OPV, DTP	Vaccination record	87	79	90	74		80		[59]
Grimaldi-Bensouda *et al.* (2013)	7613	≥14 y, self-report or by proxy	Parents (phone)	INF, PNU, HPV	Provider information, health records	81.5 (INF) 49.6 (PNU) 91.6 (HPV)	87.1 (INF) 99.5 (PNU) 98.9 (HPV)	20 (INF) 62 (PNU) 98 (HPV)	99 (INF) 99 (PNU) 94 (HPV)	0.28 (INF) 0.54 (PNU) 0.91 (HPV)	1.2 (PNU) 38.5 (HPV)	1.5 (PNU) 40.7 (HPV)	[60]
Lu *et al.* (2012)	11,164	13–17 y, parental report	Parents (phone)	INF	Provider-reported vaccination status	86.7	86.2	43.1	98.0	0.51	21.7	11.3	[61]
Luman *et al.* (2009)	594	1–6 y, parental report	Interviewer	UTD	Medical records	52.8–58.9	50.7–70.8	79.4–94.3	12.8–31.6	0.03–0.2	51–53	78–91	[62]
Ndirangu *et al.* (2011)	821	12–23 m, parental report	Interviewer	DTP, IPV, HBV, MEA	Medical records	95–97					65–74	48–86	[63]
Suarez *et al.* (1997)	1029	≤24 m, parental report	Interviewer	DTP, OPV, MUM, MEA, RUB, UTD	Provider-reported vaccination status			68.4–84.7	31.0–54.5		55–60	59.1–78.6	[64]
Williams and Dajda (1980)	352	NA, parental report	Parents	DTP	Provider-reported vaccination status	68.1	74.4	29.1	93.8				[65]

BCG: Bacille Calmette–Guérin; DTP: Diphtheria, tetanus, pertussis; INF: Influenza; IPV: Poliovirus inactivated; m: Month; MCV: Meningococcus; MEA: Measles; MUM: Mumps; OPV: Oral poliovirus; PNU: Pneumococcus; RUB: Rubella; UTD: Up-to-date (following national recommendations); VAR: Varicella; VPD: Vaccine-preventable disease; y: Years.

where the paper-based record is not available, for example in case of accidents and medical emergencies. While identity and insurance cards are gradually changed into laminated wallet-sized chip cards including a centralized backup system, there is usually no such retrieval system for lost vaccination records [13].

These issues could be addressed by creating 'digital mirrors'. Safe digital archiving of vaccination records may also be an asset in times of natural disasters, as became evident during mandatory evacuations after Hurricane Katrina hit Louisiana in 2005. Large numbers of vaccination records could later be restored via the Houston-Harris County Immunization Registry, which was connected to the Louisiana Immunization Network for Kids Statewide. This linkage provided immediate access to the vaccination records of children forced to evacuate the affected area [81].

Another format for the storage of vaccination data could include a personal electronic card [82,83]. Magnetic strips or radio-frequency identification such as the chips used in electronic insurance cards could facilitate the safe storage of important health information. This might include allergies and chronic medications. These technologies have also facilitated record-keeping in low-resource settings involving medical bracelets with USB flash drives, or wallet-sized check card formats [84]. A digital record could also be secured and personalized by biometric measures; a combination with chip cards on some passports would be another option. In veterinary medicine, paper-based pet vaccination records have already been replaced by implantable microchips; this approach seems less likely to be adapted in humans for ethical and legal reasons [85], but mobile chip cards could indeed be helpful, especially in urgent care settings [86].

Centralized storage & linkage of immunization data

Digital mirrors may be used as a personal data repository. If data protection can be ensured, vaccination data may be linked to regional or national immunization registries. Linkage with regional or national registries will enhance data consistency, no matter where a vaccine was administered. Separate databases may contain anonymized healthcare data for the remote monitoring of vaccine usage and inventories, thereby reducing vaccine wastage [87]. Policy-makers would benefit from anonymous digital immunization registries in health planning and forecasting at the local and national levels, for uninterrupted vaccine supply.

Digital data repositories may facilitate the surveillance of AEFI [88]. Vaccination records could provide links for spontaneous AEFI reporting to trigger reporting to public health and regulatory authorities, or feed into the Vaccine Safety Datalink in the USA [89]. Similarly, any issues with the safety or efficacy of specific vaccine lots may be identified and addressed rapidly through targeted intervention [90].

Vaccination records could also be linked to EHR systems. EHR systems may support use of electronic entry forms requiring all necessary information. Similarly, missing data could be detected easily. From EHR systems, immunization data could be reported to national immunization registries [91,92]. Reversely, a digital backup would be retrievable by the vaccine recipient. Following the EU e-Health Action Plan, seven European countries are routinely using EHR systems, with implementation planned or under evaluation for all member states [93]. The USA, Canada and Australia have implemented EHR systems on a statewide level or within insurance networks [94–97]. While a comprehensive overview of all EHR systems worldwide is needed, positive examples of successful EHR system implementation are available from Belize [98] and Korea [99].

Box 2. Search strategy.

'immunization record' OR 'immunisation record' OR 'vaccination record' OR 'immunization card' OR 'immunisation card' OR 'vaccination card' OR 'vaccination register' OR 'vaccination registry' OR 'immunization register' OR 'immunisation register' OR 'immunization registry' OR 'immunisation registry' OR 'vaccination schedule' OR 'vaccination coverage' OR 'vaccination status' OR 'shot card'
AND
'recall' OR 'self-report' OR 'self-reported' OR 'parent reported' OR 'parental report'

Innovative electronic health (e-health) systems for vaccination data should be approached carefully, considering local and national characteristics as well as legal and data protection requirements. Across Europe, public perceptions of data protection needs differ from country to country [100]. In Germany, a first attempt to integrate key medical data including vaccination records into the e-health insurance card was withdrawn due to data safety considerations, while other countries such as Estonia have fully implemented a nationwide EHR system [101,102].

According to the European Commission, the European Centre for Disease Prevention and Control (ECDC) is currently developing various web-based immunization resources [93]. Since 2000, Denmark has established a vaccination registry for children and youths up to 18 years [103]; other prominent examples include the Netherlands [104] and Norway [105]. An electronic vaccination record was also launched in Switzerland in 2011 and is available in four languages, with official support by the Federal Office of Public Health [106].

In Australia, childhood immunization registries were established in 1996 recording all immunizations administered to children up to 7 years of age, using health insurance data for identification [88].

Centralized digital vaccination registries may be of particular significance in developing countries, where a limited physician workforce are responsible for large numbers of patients. Access to emergency healthcare may be difficult and vaccination sites may be remote and difficult to access for regulatory agencies. In 2001, a pilot computerized information system to register, schedule and track childhood immunizations was introduced in Rajshahi, Bangladesh [107]. Approximately 84% of the city's population is covered by the system. Center health workers can use lists for home visits to vaccinate children or to remind parents of overdue or missed vaccinations [107].

Enabling data interoperability

Accurate documentation of vaccination events in compliance with international data standards is a prerequisite for the evaluation of vaccine safety and effectiveness in different parts of the world [21]. Digital vaccination records offer the benefit of data standardization at the source. This implies that not only the *content* of a vaccination record may be subject to standardization, but also the *format* in which data are stored and processed. Standardization at the level of data elements is a prerequisite for interoperability, that is, the ability of different datasets to be compared or to interact. Accurate documentation should be part of each medical record. In clinical research, it often becomes evident, how hard it may be to reconstitute past vaccine exposures in trial patients. It would be beneficial if digital vaccination records were interoperable with other types of EHRs as well as clinical trial databases (in those patients enrolled in observational or clinical research studies). From preclinical research throughout Phase I–IV clinical trials, research data are accumulated and aggregated into large-scale databases to create tabulations and analysis datasets for submission to regulatory agencies for review. If the data are not collected in standard formats, mapping into a standard may result in loss of data integrity; conversely, collection of data in standard formats streamlines the preparation of tabulations and analysis datasets and preserves data quality [108].

Several organizations are now aiming to jointly establish generally applicable data standard formats to support a continuum of data elements and data interoperability from pre-marketing clinical trials to post-marketing surveillance. Different standards organizations collaborate to develop a shared understanding of the semantics of clinical research. The Clinical Data Standards Consortium (CDISC) for example, was formed in 1997 as global, neutral, non-profit Standards Developing Organization (SDO) and has developed worldwide data interchange standards for clinical research [108]. The establishment of therapeutic area data standards mapped to standardized terminologies for the meta-analysis of safety and effectiveness data and the linkage between big data sources are important parts of the work of CDISC. There is now a full suite of complementary data standards for safety data to support research from the protocol and case report forms through data aggregation, analysis and regulatory submissions provided on the CDISC website [108]. Future vaccine research and development will require high-quality data analysis capability and the immediate delivery of comprehensible and accurate information. Throughout the lifespan of a vaccine, regulatory authorities are required to process increasing amounts of data resulting from clinical vaccine trials, safety reports, public health authorities, healthcare providers and multiple sites around the globe. Unless data providers 'speak' the same 'data language', it will be next to impossible to make sense of such data.

Another standards organization focused on e-health repositories is Health Level 7 (HL7), founded in 1987, which is a standards-setting organization accredited by the American National Standards Institute (ANSI). It is dedicated to providing a comprehensive framework (XML [109]) and related standards for the exchange, integration, sharing and retrieval of e-health information that supports clinical practice and the management, delivery and evaluation of health services [110,111].

Shared efforts among regulatory stakeholders, standards organizations and research organizations have been established to develop models for semantic interoperability supporting a common understanding of the representation of health data [112].

International data standards are urgently needed. In the absence of accurate documentation of vaccination events, both vaccine safety and effectiveness analyses are equally impossible.

The goal of vaccine development is the provision of effective and safe vaccines. This translates into the absence of VPDs. Unless common data standards and protocols are implemented, the absence of a VPD could either derive from the administration of an effective vaccine or from the fact that no infection has occurred in the first place. Reversely, the presence of a VPD may either signify that a subject has experienced vaccination failure or that the subject has never received the vaccine.

Even greater effort will be needed in vaccine safety analyses, that is, when it becomes essential to prove the absence of AEFI, which are usually rare. Standardized clinical case definitions based on a consensus process of clinical experts, as provided by the Brighton Collaboration, provide an important step into this direction. Without standardized case definitions of AEFI, the prevalence of AEFI could be underestimated [21,113]. Digital vaccination records do not require clinical case definitions. The standardized ascertainment of AEFI, however, is important for the analysis of healthcare databases that may be linked to immunization registries [21,89].

Regulating access to digital vaccination records

Much like any health data, vaccination data are owned by the patient (i.e., vaccine recipient). With the advent of new digital technologies, the rights and responsibilities with respect to personal health data will need to be refined and regulated, including machine-sensible vaccination records or QR-codes. The owner of a personal vaccination record should have read-access at least [51]. This can be done easily for QR-codes, which could be decodable via a QR reader in the vaccine recipient's smartphone. Access to immunization registries could be restricted by personal passwords [51]. For healthcare workers, a secure and encrypted path should be installed for writing access on EHR audit trails, ensuring that sensitive medical data cannot be changed without traceability [114]. Under well-defined circumstances and for public health reasons, national immunization registries may be accessed by national authorities. Personal rights of vaccine recipients however, should always remain a priority. Stringent data protection and privacy rules should be guaranteed in all instances. There are many examples and regulations promoting the safe storage of health data, which apply to vaccination data, as well. In matters of health care, the focus should always rest on patient empowerment and informed decisions, rather than paternalistic approaches or legal obligations [51,115].

Expert commentary

Many different vaccination record systems are currently in use worldwide. The WHO Certificate of Immunization is an important step forward with respect to standardization of vaccination documents, not only for travel vaccines, but also for routine immunizations.

In times of globalization, international travel and migration, each person should hold a personal vaccination record, which is valid and comprehensible all over the world. Healthcare workers should be trained to administer and document vaccinations in a standardized and accurate way. Digital records provide significant advantages over paper records, as they may support multiple languages and remote backup systems. International efforts toward semantic and data interoperability will be supportive of such systems. Linkage of protected data to national immunization registries could facilitate the surveillance of vaccine safety and effectiveness as well as the accurate storage and handling of vaccines.

Five-year view

Mobile phones are used all over the world. M-health and e-health technologies provide a unique opportunity to improve vaccine safety and effectiveness. With the wide distribution of mobile phones and internet access even in remote settings, forward-looking technologies have become accessible, including the short message service (SMS) -based surveillance of counterfeit drugs, telemedicine and e-learning tools and the mapping of natural disasters and disease outbreaks in real-time [42,80]. Mobile phone providers usually have national licenses. One approach could be to issue national electronic vaccination records on mobile phones, protected by personalized access codes, biometric tools or other unique identifiers.

Currently, many different vaccination record applications ('apps') are being developed, often remaining insufficiently standardized and interoperable [116]. Some applications are sponsored by vaccine manufacturers, whereas others are initiated by private initiatives, patient advocacy groups, physicians, NGOs, or health insurance companies. Immunization data are stored in many different places, and it remains to be determined how consumer protection rights will be handled [115]. User-centered vaccination applications will encourage vaccine recipients to take charge of their own vaccination status.

Vaccination record systems benefit from oversight and approval by national and international health authorities promoting interoperability with authorized databases. Vaccination records should always be endorsed by regulatory authorities while remaining neutral and free of any potential conflicts of interest.

Mobile applications may be developed further to enable the spontaneous reporting of adverse events. Reversely, important messages from stakeholders may be submitted through the same system. In case of withdrawal or expiration of specific vaccine lots or batches, vaccine recipients may be informed in real-time via smart phone applications. Anonymized epidemiological and safety data could be transmitted to regulatory authorities for adverse event surveillance and timely signal detection, or to health departments for the monitoring of VPDs. Patient privacy must be protected at all times. Vaccine providers as well as consumer and patient advocacy groups should always be involved in the development of simple standardized vaccination records.

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Key issues

- Standardized vaccination records are needed on a global level.
- Standardized vaccination records should be universal, safe, flexible, durable and available in emergency situations.
- In order to increase accessibility retrieval/backup systems, electronic mirrors of vaccination records or linkage to national registries should be promoted.
- Simplified digital vaccination records provide significant advantage over paper-based systems, including universal access in cases of emergency.
- User-centered vaccination records should empower patients to keep track of their vaccination record and to ask for professional advice, when needed.
- Regulatory agencies and standards organizations should be involved in the development of digital records to ensure semantic interoperability.

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