Comparison of online reporting systems and their compatibility check with respective adverse drug reaction reporting forms

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Abstract:
AIM: Different forms and online tools are available in different countries for spontaneous reporting, one of the most widely used methods of pharmacovigilance. Capturing sufficient information and adequate compatibility of online systems with respective reporting form is highly desirable for appropriate reporting of adverse drug reactions (ADRs). This study was aimed to compare three major online reporting systems (US, UK, and WHO) of the world and also to check their compatibility with the respective ADR reporting form.

MATERIALS AND METHODS: A total of 89 data elements to provide relevant information were found out from above three online reporting systems. All three online systems were compared regarding magnitude of information captured by each of them and scoring was done by providing a score of “1” to each element. Compatibility of ADR reporting forms of India (Red form), US (Form 3500), and UK (Yellow card form) was assessed by comparing the information gathered by them with that can be entered into their respective online reporting systems, namely, “VigiFlow,” “US online reporting,” and “Yellow card online reporting.” Each unmatching item was given a score of “−1”.

RESULTS: VigiFlow scored “74” points, whereas online reporting systems of the US and UK scored “56” and “49,” respectively, regarding magnitude of the information gathered by them. Compatibility score was found to be “0,” “−9,” and “−26” in case of ADR reporting systems of US, UK, and India, respectively.

CONCLUSION: Our study reveals that “VigiFlow” is capable of capturing the maximum amount of information but “Form 3500” and “Online reporting system of US” are maximally compatible to each other among ADR reporting systems of all three countries.

Keywords: Adverse drug reaction reporting forms, compatibility, Form 3500, MedWatch, online reporting system, Red form, VigiFlow, Yellow card online reporting

Introduction
Although drugs are passed through a series of trials to establish their efficacy and safety in human beings before they get marketing approval, not all the adverse effects caused by a drug can be detected in clinical trials, especially uncommon ones and those appear on long-term administration of that drug because clinical trial results are limited by strict inclusion criteria; relatively small sample size (Hanley’s rule of 3) and short study period.[1] Hence, it becomes necessary to have a system that keeps strict vigilance over and is able to disclose such type of adverse drug reaction(s) (ADRs) after marketing approval of drugs. This objective may be brought about by one such system called “pharmacovigilance.” Spontaneous reporting is one of the most widely utilized methods of pharmacovigilance.[2] Different

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strategies are adopted in different countries for spontaneous reporting of ADRs. For example, “Yellow card form” and “Yellow card online reporting” in the UK, “ADR reporting (Red) form” and “VigiFlow” (software provided by the WHO) in India, and “Form 3500” and “US online reporting system” are used in the US for the same.[3,4]

For detailed description and appropriate causality assessment of a suspected adverse event due to a drug, capturing as much worth information related to that ADR as possible is desirable.[5] To identify the near ideal online reporting system, we compared the three major ones, namely, (a) VigiFlow, (b) Yellow card online reporting, and (c) US online reporting system.

In spontaneous reporting system, flow of information related to suspected ADRs occurs through following basic steps (a) information is entered in ADR reporting form by health-care professionals at the site of event, (b) these filled forms are sent to ADR monitoring centers and analyzed, (c) the information from the filled ADR reporting forms (also known as Individual Case Safety Reports [ICSRs]) is entered in the respective online reporting systems and are sent to regulatory authorities, and (d) after due analysis the information is included in a particular database [Figure 1].[6-8] Interference at any of the above levels could compromise the functionality of pharmacovigilance system. For example, to accomplish the third step properly, compatibility between an ADR reporting form and its respective online reporting system is highly desirable. If incompatible, there may be a significant communication gap that may interfere with the proper transfer of ADR-related information to higher centers and in turn its appropriate analysis either because of inability to capture adequate information in ADR reporting form or loss of some information while entering it into the online system.

Data on such incompatibilities are unavailable in literature. To the best of our knowledge, this study is first time aimed to assess the extent of such incompatibility between ADR reporting forms of UK, US, and India (viz., Yellow card form, Form 3500, and Red form, respectively) and their respective online reporting systems, namely, “Yellow card online reporting,” “US online reporting system,” and “VigiFlow,” respectively.

As an effort to sensitize for filling up these lacunae, this study compared the online ADR reporting systems of UK, US, and WHO, namely, “Yellow card online reporting,” “US online reporting system,” and “VigiFlow,” respectively, with regard to the magnitude of information captured by them along with the quantitative assessment of compatibility between above online ADR reporting systems and their respective ADR reporting forms, namely, “Yellow card form” in UK, “Form 3500” in US, and “Red form” in India.

**Materials and Methods**

The format of ADR reporting forms for health-care professionals and online reporting systems of US, UK, and India (WHO) were searched using the search terms “Yellow card online reporting system,” “Yellow card form,” “MedWatch,” “US online reporting system,” “US ADR reporting form,” “Form 3500,” “VigiFlow,” and “Red form” and were accessed through the links given in the references.[9-14] All the data elements from all the three online reporting systems were obtained and arranged in a tabulated form. Each data element was given a score of “one.” The data elements contained in each online reporting system were marked, and the score was calculated [Table 1].

For quantitative assessment of compatibility between ADR reporting form and online reporting system of respective country, data elements contained in these two were matched with each other. Each of the data element that was common between ADR reporting form

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**Figure 1:** A schematic diagram of workflow of adverse drug reaction related information in spontaneous reporting system of pharmacovigilance involving health-care professionals, in US, UK, and India, respectively. Where HCP = Health-care professionals, AERS = Adverse event reporting system database, AMC = Adverse drug reaction monitoring centre, NCC = National coordinating centre
Table 1: Comparison of three major online reporting systems

| Serial number | Data fields                                      | Yellow card online reporting | US online system | VigiFlow |
|---------------|-------------------------------------------------|------------------------------|------------------|---------|
|               | Reporter details                                |                              |                  |         |
| 1             | Reporters' name                                 | 1                            | 1                | 1       |
| 2             | Reporter address                                | 1                            | 1                | 1       |
| 3             | Institution                                     | 1                            | 1                | 1       |
| 4             | Phone                                           | 1                            | 1                | 1       |
| 5             | Email                                           | 1                            | 1                | 1       |
| 6             | Country of reporter                             | 1                            | 0                | 1       |
| 7             | Health professional (yes/no)                    | 1                            | 1                | 1       |
| 8             | Reporter qualification                          | 0                            | 0                | 1       |
|               | About patient                                   |                              |                  |         |
| 9             | Patients' initials                              | 1                            | 1                | 1       |
| 10            | Date of birth                                   | 1                            | 1                | 1       |
| 11            | Patients' age at the time of side effect        | 0                            | 0                | 1       |
|               | Sex (following 4 points)                        |                              |                  |         |
| 12            | Male                                            | 1                            | 1                | 1       |
| 13            | Female                                          | 1                            | 1                | 1       |
| 14            | Transgender                                     | 0                            | 0                | 0       |
| 15            | Unknown                                         | 0                            | 0                | 1       |
| 16            | Weight                                          | 1                            | 1                | 1       |
| 17            | Height                                          | 0                            | 1                | 1       |
| 18            | BSA                                             | 0                            | 0                | 0       |
| 19            | Ethnicity                                       | 1                            | 1                | 0       |
| 20            | Race                                            | 1                            | 0                | 0       |
| 21            | Local patient identification number             | 0                            | 1                | 1       |
| 22            | Age group                                       | 0                            | 0                | 1       |
| 23            | Death-related information                       | 0                            | 0                | 1       |
|               | Describe event, problem or product use error    |                              |                  |         |
| 24            | Date of event                                   | 1                            | 1                | 1       |
| 25            | Relevant tests/laboratory data                  | 1                            | 1                | 1       |
| 26            | suspected reaction                              | 1                            | 1                | 1       |
|               | Reaction (following 4 points)                   |                              |                  |         |
| 27            | Adverse event                                   | 1                            | 1                | 1       |
| 28            | Product use error                               | 1                            | 1                | 0       |
| 29            | Product problem                                 | 1                            | 1                | 0       |
| 30            | Problem with different manufacturer of same medicine | 0                            | 1                | 0       |
| 31            | Reporters' comment                              | 0                            | 0                | 1       |
| 32            | Reaction term                                   | 1                            | 1                | 1       |
| 33            | Reaction/event as reported by primary source    | 0                            | 0                | 1       |
| 34            | Reaction start date                             | 1                            | 1                | 1       |
| 35            | Reaction end date                               | 1                            | 1                | 1       |
| 36            | Reaction duration                               | 1                            | 1                | 1       |
| 37            | Treatment of reaction                           | 1                            | 1                | 1       |
| 38            | Outcome of reaction                             | 1                            | 0                | 1       |
| 39            | Outcome attributed to adverse event if serious  | 0                            | 1                | 1       |
| 40            | Whether the reaction is a result of a mistake made in the prescription, dosing, dispensing, or administration of the medication | 0      | 1    | 0 |
| 41            | Whether the product is available for evaluation (yes/no) | 0 | 1 | 0 |
|               | Drug                                            |                              |                  |         |
| 42            | List of suspected drugs                         | 1                            | 1                | 1       |
| 43            | Drug name                                       | 1                            | 1                | 1       |
| 44            | Characterization                                | 0                            | 0                | 1       |
| 45            | Suspect                                         | 1                            | 1                | 1       |
| 46            | Concomitant                                     | 0                            | 1                | 1       |

Contd...
Table 1: Contd..

| Serial number | Data fields                                      | Yellow card online reporting | US online system | VigiFlow |
|---------------|-------------------------------------------------|-----------------------------|-----------------|----------|
| 47            | Interacting                                      | 0                           | 0               | 1        |
| 48            | Suspected ingredient                             | 0                           | 0               | 1        |
| 49            | Pharmaceutical form                              | 0                           | 0               | 1        |
| 50            | Is product compounded                            | 0                           | 1               | 0        |
| 51            | Indication                                       | 1                           | 1               | 1        |
| 52            | Route of administration                          | 1                           | 1               | 1        |
| 53            | Action taken (drug withdrawal/change in dose)    | 1                           | 0               | 1        |
| 54            | Dechallenge                                       | 0                           | 1               | 1        |
| 55            | Rechallenge                                       | 0                           | 1               | 1        |
| 56            | Is this ADR adequately labeled                   | 1                           | 1               | 1        |
| 57            | Obtained from which country                      | 0                           | 1               | 1        |
| 58            | Batch number                                     | 1                           | 1               | 1        |
| 59            | Authorization number                              | 0                           | 1               | 1        |
| 60            | Authorization country                             | 0                           | 1               | 1        |
| 61            | Authorization holder                              | 0                           | 1               | 1        |
| 62            | Dose                                             | 1                           | 1               | 1        |
| 63            | Dosage regimen                                   | 1                           | 1               | 1        |
| 64            | Start of administration                          | 1                           | 1               | 1        |
| 65            | End of administration                            | 1                           | 1               | 1        |
| 66            | Duration of administration                       | 1                           | 1               | 1        |
| 67            | Source (prescription/pharmacy/another shop/internet/other) | 1                           | 0               | 0        |
| 68            | Additional information about drug                | 1                           | 1               | 1        |

| Serial number | Additional details                                      | Yellow card online reporting | US online system | VigiFlow |
|---------------|---------------------------------------------------------|-----------------------------|-----------------|----------|
| 69            | Fields that must be completed marked with a specific symbol | 1                           | 1               | 1        |
| 70            | Any medication taken by the patient in the last 3 months | 1                           | 0               | 0        |
| 71            | Relevant information about medical history, known allergies | 1                           | 1               | 1        |
| 72            | Detailed information in case of ADR that occurred in a child due to administration of drug by mother during pregnancy | 1                           | 0               | 0        |
| 73            | Where did you hear about us?                          | 1                           | 0               | 0        |
| 74            | Senders’ comments                                     | 0                           | 0               | 1        |
| 75            | Senders’ diagnosis                                    | 0                           | 0               | 1        |
| 76            | References                                            | 0                           | 0               | 1        |
| 77            | Report information                                    | 0                           | 0               | 1        |
| 78            | Report ID                                             | 0                           | 0               | 1        |
| 79            | Report title                                          | 1                           | 1               | 1        |
| 80            | Type of report (serious/not)                          | 1                           | 1               | 1        |
| 81            | Country of occurrence                                | 0                           | 0               | 1        |
| 82            | Country of primary source                             | 0                           | 0               | 1        |
| 83            | Does this case fulfill the local criteria for expedited report | 0                           | 0               | 1        |
| 84            | Additional documents held by sender                   | 0                           | 0               | 1        |
| 85            | Was the case medically confirmed                      | 0                           | 0               | 1        |
| 86            | Information on sender                                 | 0                           | 0               | 1        |
| 87            | Other case identifier in previous transmission        | 0                           | 0               | 1        |
| 88            | Also reported to                                      | 0                           | 1               | 0        |
| 89            | Review and submit                                    | 1                           | 1               | 1        |

Total 89 data fields were identified from “Yellow card online reporting” of UK, “Online reporting system” of US, and “VigiFlow” of WHO (adopted by India also) collectively. 1=Respective field is present, 0=Absent. ADR=Adverse drug reaction(s), BSA=Body surface area.

and online system of a country was given a score of “0,” whereas the data elements that were not common between these two were given a score of “−1” each. The compatibility score was calculated for each of the three countries. The more negative score indicated, the higher incompatibility between ADR reporting form and its respective online reporting system with respect to extent of communication gap, whereas a score of “0”
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Results

Comparison of three online reporting systems

We identified a total of 89 data fields from these three online ADR reporting systems as “relevant” to provide sufficient information and/or to assess the causality [Table 1]. Each data field was given a score of “1.” Where the “VigiFlow” contained the maximum, that is, 74 out of 89 data fields, the “Yellow online system” was at the bottom with a score of 49, whereas the US online system remained somewhere in between with a score of 56 [Table 1]. This means “VigiFlow,” software recommended by the WHO is able to capture maximum (83.15% of the total) information related to an ADR among these three online systems, whereas “Yellow card online reporting” could capture the least (55.06%) information [Figure 2].

Many of the data fields are common among all three online systems, for example, reporter’s name, address, patient’s initials, date of birth, gender (male or female), weight, date of the event, relevant laboratory tests, name of suspected reaction, its description, its start, and end date, etc.

Some of the data fields are exclusively present in “VigiFlow” such as reporter’s qualification, third option regarding patient’s gender, that is, unknown, patient’s age at the time of side effect, death-related information (date, cause, and autopsy comments), reaction as reported by primary source, characterization of drug, interacting drug, suspected ingredient, pharmaceutical form, sender’s comments and diagnosis, references, report ID, country of occurrence, country of primary source, does this case fulfill the local criteria for an expedited report, additional documents held by sender (Yes/No), was case medically confirmed, information on sender, and other case identifier in the previous transmission.

Likewise, few data fields are contained only in the US online system, namely, (a) whether the event was a result of mistake made in prescription, dosing, dispensing, or administration of medication; (b) whether the product is available for evaluation or not; (c) is the product compounded; and (d) event is also reported to.

Other data fields such as (a) race of patient, (b) source of medication (prescription, bought in pharmacy, bought in another shop, internet, etc.), (c) any other medication taken by the patient in the last 3 months (including prescription, over the counter drugs or herbal medicines), (d) detailed obstetric history in case of event in a child due to administration of drug to mother, and (e) where did you hear about us, are given a place by “Yellow card online reporting” only.

Fields which did not get a place in any of these three online systems are (a) transgender regarding patient’s sex, although “VigiFlow” mentions “unknown” as an option and (b) body surface area (BSA) of the patient although height is mentioned in the US online system and “VigiFlow.”

Data fields that are exclusively absent in “VigiFlow” are (a) ethnicity of patient, (b) product use error, and (c) product problem.

Few data fields are not given a place in the US online system but are present in rest of the both online systems, these are (a) country of reporter, (b) outcome of the event (whether it has resolved/recovered completely or with sequel or it is resolving or it is fatal or unknown), and (c) action taken (drug withdrawn, dose reduced, increased or not changed, or unknown).

Out of three online systems, the UK online system did not give place to (a) patient’s height, (b) local patient identification number (additional patient information, e.g. general practitioner record, hospital specialist record, and investigation number), (c) outcome attributed to adverse event if serious (death, life threatening, hospitalization, disability, congenital anomaly, required intervention, others), (d) concomitant drugs, (e) dechallenge, (f) rechallenge, (g) obtained from which country, (h) authorization number, (i) authorization country, and (j) authorization holder.
Compatibility check between online reporting system and respective adverse drug reaction reporting form of each country
A number of fields were found not to be common between online system of a country and its reporting form. Each of such unmatching field (be it absent either in online system or in the form) was given a score of “−1.”

Compatibility check between “VigiFlow” and “Red form”
A total of 26 items were found to be unmatching between the “VigiFlow” and “Red Form.” Thus, the compatibility between these two is the least with a score of “−26,” among the three pairs [Table 2].

Compatibility check between US online system and respective adverse drug reaction reporting form
The online reporting system of US and the respective reporting form were found to be fully compatible with maximum compatibility score, that is, “0” means none of the item is unmatching between these two [Figure 3].

Table 2: Compatibility check between “VigiFlow” and “Red form”

| Serial number | Items that are not matching between “VigiFlow” and “Red form” (India) | Score |
|---------------|------------------------------------------------------------------------|-------|
| 1             | Report title                                                            | −1    |
| 2             | Type of report (serious or not)                                         | −1    |
| 3             | Country of occurrence*                                                  | −1    |
| 4             | Country of primary source*                                              | −1    |
| 5             | Does the case fulfill the local criteria for expedited report*           | −1    |
| 6             | Additional documents held by sender*                                    | −1    |
| 7             | Was case medically confirmed*                                            | −1    |
| 8             | Type of sender*                                                         | −1    |
| 9             | Other case identifiers in previous transmission*                        | −1    |
| 10            | Reporters’ qualification*                                               | −1    |
| 11            | Age group of the patient (as a separate field)*                         | −1    |
| 12            | Height of patient*                                                      | −1    |
| 13            | Death-related information*                                              | −1    |
| 14            | Reporters’ comment*                                                     | −1    |
| 15            | Reaction term                                                           | −1    |
| 16            | Treatment of reaction*                                                  | −1    |
| 17            | Interacting drug*                                                       | −1    |
| 18            | Suspected ingredient*                                                   | −1    |
| 19            | Pharmaceutical form*                                                    | −1    |
| 20            | Is ADR adequately labeled*                                               | −1    |
| 21            | Drug was obtained from which country*                                   | −1    |
| 22            | Authorization number*                                                    | −1    |
| 23            | Authorization country*                                                   | −1    |
| 24            | Senders’ comment*                                                       | −1    |
| 25            | Senders’ diagnosis*                                                     | −1    |
| 26            | References*                                                             | −1    |

Compatibility check between UK online system and adverse drug reaction reporting form
Nine items were found to be unmatching between UK online reporting system and ADR reporting form with a score of “−9” [Table 3].

The results show that the largest magnitude of ADR-related information can be captured by “VigiFlow” and the smallest by UK online system [Figure 2], but US online reporting system and its form (form 3500) are the most compatible with probably the least communication gap while reporting an ADR, whereas “VigiFlow” and “Red form” are the maximally incompatible to each other among all three ADR reporting systems [Figure 3].

Discussion
ADR reporting forms and online reporting systems are integral to spontaneous reporting, one of the most widely used tools of pharmacovigilance.[2] Different countries have adopted different online reporting systems and different formats of ADR reporting forms[3,4] which may differ with each other with regard to type and magnitude of information captured by them. Capturing all the relevant and sufficiently detailed information related to an adverse event is desirable for appropriate understanding of its development and to rightly establish its causality with the suspected drug and its further analysis.[5]
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Table 3: Compatibility check between “Yellow card online reporting system” and “Yellow card form”

| Serial number | Items that did not match between “Yellow card online reporting” and “Yellow card form” | Score |
|---------------|--------------------------------------------------------------------------------------------|-------|
| 1             | Reporters' profession                                                                      | −1    |
| 2             | Reporters' title (Dr./Mr./Mrs.)                                                            | −1    |
| 3             | Patients' height                                                                           | −1    |
| 4             | Action taken with drug (with regard to change in dose, NA, or unknown)                     | −1    |
| 5             | Source of drug (prescription, pharmacy, another shop, internet, and others)                | −1    |
| 6             | Whether medicine was taken by mother during pregnancy                                       | −1    |
| 7             | Specific point in outcome of the event                                                     | −1    |
| 8             | Do you think this reaction occurred as a result of a mistake made in prescription/ doping/dispensing/administration of the medication (yes/no) | −1    |
| 9             | Where did you hear about us?                                                                | −1    |

List of items that are not matching between “Yellow card online reporting” and “Yellow card form.” Each unmatched item is given a score of “−1.” “Under “outcome of the event” field, in the reporting form, the points such as recovered with some lasting effect, getting better, and unknown are not there but the option “others” is definitely provided. NA = Not applicable

This study revealed that the maximum information can be captured by “VigiFlow” an online reporting software provided by the WHO, with a score of 74 out of 89.

Many of the important ADR-related information fields are not given a place in online reporting system of one or other country. Like “patient’s age at the time of side effect” is mentioned in “VigiFlow” only but not in others. This is important to ask specifically “at the time of side effect” because rest of the systems just ask the “age of the patient” which may be interpreted and informed wrongly, especially if there is a huge gap (e.g., years) between the occurrence of the event and its reporting. Similarly, “interacting drug” is exclusively asked about in the “VigiFlow,” it is worth to ask for this because adverse effect may have not been caused by a drug only rather it may occur because of some interaction between 2 or more drugs. Likewise, pharmaceutical form is also not asked in online reporting systems of UK and US which is of importance because the adverse effect might have occurred say, for example, because of local reaction at the site of administration (not related to drug itself) and not due to the systemic effect of the drug per se.

In the similar way, the medication error is asked only in the US online reporting system and not in others. It is required to differentiate medication error from an ADR because adverse event might not have occurred if there were no medication error (e.g., error in prescription, dispensing, administration, etc.). “Is the product available for evaluation,” which is asked only in the US online reporting system, may be important in case the ADR is caused by a drug that could not be identified at the time so if it is available, it can be evaluated chemically to know its composition and character for its identification.

Race of the patient may be important to know because there are some racial differences in drug responses including ADRs which may be attributable to some genetic differences putting a particular race at higher risk than others for a specific type of ADR.[15,16] For example, Caucasian race was found to be at higher risk of developing ADRs of abacavir in a study.[17] Another study demonstrated African-Americans to be more susceptible for experiencing ACE inhibitors-induced angioedema.[17] One study showed that risk of intracranial hemorrhage was higher in people of African ancestry than in others including white, Hispanic or Latino, Asian, East Asian, non-East Asian or Pacific Islander and Native Americans.[16,17]

Two important fields, namely, transgender as sex of the patient, and BSA did not get a place in any of the three online reporting systems. According to 2016 data from William’s Institute, the proportion of transgender population in the US only is 0.6%. [18] Not to include the “transgender” as an option in patients’ sex, seems neither ethical nor logical.

Dose of a number of drugs, particularly anticancer medicines is calculated on the basis of BSA and not on the basis of body weight[19] to reduce the interindividual variability. Although dose calculation according to BSA did not show to reduce interindividual variability in pharmacokinetic parameters for most anticancer drugs and individual dosing techniques are currently being investigated, so it becomes necessary to depend on the BSA-based determination of dose of these drugs.[20] Moreover, with the information of BSA, we can know whether the adverse event is an ADR or it is due to some medication error, for example, overdosing. None of the above three online ADR reporting systems have included “BSA” in patient’s details.

Another important parameter which is not given any place in “Yellow card online reporting” is “outcome of the event if serious such as death, life-threatening, hospital admission or prolongation of admission, congenital anomalies.” Inclusion of dechallenge and rechallenge help to establish the causality of ADRs.[21] For example, alleviation of an adverse event with reduction in dose of or stopping the suspected medication supports the causal relation between these two, whereas negative dechallenge nullifies the causal relationship at least to some extent. These two important parameters are also not included in this online reporting system.

Quantitative assessment of compatibility between online reporting system and its respective reporting form is
worth because the extent of compatibility between these two tools is inversely related to the communication gap during transfer of information from “filled form” to “online reporting.” If an information that is asked in the form but not in the online reporting system, this information (filled in the form) will have no value because ultimately the information has to be incorporated into the database(s) through online reporting only. Hence, unmatching of an information in either way between these two tools will generate a communication gap which is highly undesirable in spontaneous reporting.

The current work shows the maximum compatibility or in other words the minimum incompatibility between ADR form and online system of US, means all the information asked in the “Form 3500” completely matches with that asked in the US “online reporting,” in contrary the “Red form” and “VigiFlow” are maximally incompatible with the score of “−26,” meaning any one of a total of 26 information present in either of these is absent in the other.

This work warrants improving the compatibility between reporting form and online reporting systems to have uniformity in the collection and the transfer of the data related to an ADR from ADR form to the online system.

Although the WHO suggests the ADR reporting form to be short to improve the voluntary reporting by health-care professionals, this might not capture all the relevant, required, and at least the detailed information related to an ADR. Hence, pros and cons of a “short and sweet” reporting form should be weighed against the extent of its compatibility with respective online reporting system and action taken accordingly.

Conclusion

The present effort reveals that although “VigiFlow” is able to accommodate the maximum amount of information related to an ADR, its compatibility with “Red form” is the least, whereas “Yellow card online reporting” captures the minimum information. The spontaneous reporting system of US has minimum communication gap while transferring the information from “Form 3500,” filled voluntarily by health-care professionals, to US “online reporting system.”

To reduce the communication gap while entering information into online reporting, from a filled ADR reporting form (ICSR), the structure of the latter should be such that it complies maximally with its respective online reporting system in terms of compatibility but simultaneously does not interfere with the spontaneous reporting by health-care professionals, by being a time-consuming form.

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Conflicts of interest

There are no conflicts of interest.

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