

Developing an international database on long-term health effects of spaceflight

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ABSTRACT

NASA's Lifetime Surveillance for Astronaut Health (LSAH) program collects health/medical data on active and retired U.S. and Canadian crew; to our knowledge, there are no parallel efforts collecting life-long data on the many international retired astronauts and cosmonauts. The long-term goal of this investigative team is to establish a secure data repository for biomedical data from international retired crew. Using current technologies like electronic personal health records (PHR) that enable the individual to collect and transmit his/her own data could contribute to more efficient collection and transmission of biomedical data to such a data repository. This feasibility study had several discrete goals: 1) collection of retired crew and other stakeholder input on issues related to collecting and archiving biomedical data; 2) selection of a candidate off-the-shelf PHR in coordination with an industry consultant and a subsequent evaluation of that PHR by retired crew; and 3) a preliminary assessment of international medical privacy law pertinent to the collection of individual citizen's biomedical data. Initial feedback received from US and international retired crew members we surveyed reflected widespread support for creating a secure database repository to house medical data from non-US/Canadian crew. Working with a health technology industry consultant, a detailed Product Requirement Document (PRD) was developed to guide selection of an off-the-shelf PHR to test with retired crew; preliminary feedback from seven retired crew responding to an evaluation survey, including Cooper-Harper ratings, provided useful feedback towards a more comprehensive evaluation in the future. Our preliminary analysis of international privacy laws identified a few potential legal issues, but likely no substantial legal barriers to collecting and using the required data for the IRC repository operation. Expanding the "n" of those retired space flyers from whom life-long biomedical data are collected is essential for protecting the health and performance of current and future crew members of all nationalities, as well as defining the long-term health consequences for retired crew members across the globe.

1. Introduction

Understanding the long-term human health impact of space exploration missions is exceptionally challenging because relatively few have ever been exposed to the space environment. Moreover, understanding long-term health impacts requires tracking health and medical status for years after a crew member completes his/her mission. This is

particularly true for those "chronic/degenerative" risks, such as malignancies secondary to radiation exposure, which may take decades to reach full expression. Recognizing the value of these data to mitigating health risks for future crew members, NASA established the Longitudinal Study for Astronaut Health in 1989 as a research effort to document incidences of morbidity and mortality of active and retired astronauts with the purpose of determining whether exposure to the spaceflight

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environment is associated with increased morbidity or mortality when compared to a ground-based cohort of matched controls, primarily civilian employees at Johnson Space Center [1]. In 2010, it was reconfigured as an operational program within NASA and renamed the Lifetime Surveillance of Astronaut Health (LSAH); it continues to accumulate medical/health data on active duty and retired U.S. and Canadian Space Agency (CSA) crew members. Many retired crew members voluntarily return for an annual physical exam at NASA's Johnson Space Center (JSC); all data collected at this time are archived with the LSAH database. Further, the LSAH receives and catalogues other retired crew member medical data collected in between the JSC physical exams, such as physician diagnoses or hospital discharge reports.

Despite the important efforts and accomplishments of LSAH, there are several challenges to leveraging longitudinal health data to understand the risks of space travel, which challenges likely apply to international crew as well. First, there is some lack of clarity regarding the existing data system, based on multiple anecdotal reports from U.S. and Canadian crew members. Many American retired astronauts report (personal conversations with one of us [BJD]) they are unaware that LSAH will accept medical data from physician visits or hospital stays generated in between annual physical exams at JSC. Further, there is a lack of clarity on who must provide the information to LSAH (crew member or attending physician) and how that information is to be transmitted, particularly non-digital data such as X-ray images.

Another challenge is posed by the lack of an organized plan to systematically collect valuable end-of-life (autopsy) data that is well publicized with retired US crew. We are not aware of a successful effort by other space agencies on this point. A systematic review of autopsy studies from multiple countries that were published between 1966 and 2002 revealed a median major error rate (misdiagnosis of cause of death) of 23.5% [2]. Given the small number of humans who have been exposed to the space or Lunar environment, it is essential to proactively promote routine autopsies for these individuals to gain more accurate data defining whether exposure to the space environment increases morbidity or mortality. This occupational health model is that strongly recommended two decades ago by the Institute of Medicine report "Safe Passage: Astronaut Care for Exploration Missions" [3]. For example, might there be any pulmonary consequences of Lunar dust exposure for those Apollo crew who spent time on the Lunar surface? Or, is there any correlation between greater exposure to space radiation in during Apollo missions or with multiple spacewalks and earlier/more severe carcinogenesis? Better data on these points are urgently needed by NASA's Chief Health and Medical Officer in judging eligibility of retired U.S. crew for coverage of medical treatment under the To Research, Evaluate, Assess and Treat Astronauts (TREAT) Act, signed into law by Congress in 2017 [4]. Further, with NASA's plans to return humans to the Lunar surface in this decade, these data can inform smart deployment of countermeasures mitigating health risks for active personnel.

An illustration of challenges regarding collection of autopsy data is provided by the case of Apollo astronaut Pete Conrad, who died suddenly after a motorcycle accident in 1999. The California physician who performed his autopsy refused to release the data to a NASA flight surgeon absent a pre-existing formal agreement to do so (personal communication, BJD). Privacy concerns, as regulated by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and a myriad of U.S. state laws [5], no doubt complicate release of such end-of-life data. All this speaks to the need for more comprehensive advance consenting of retired crew from all space agencies and standing agreements with state or province coroner's offices.

Finally, international members compose an increasing proportion of ISS crew; if their health data are not collected, the "n" for future research inquiries on longitudinal health issues in space fliers will remain quite low. A number of international space agencies currently collaborate with NASA as participants on International Space Station, including the Russian Space Agency (RSA), the European Space Agency (ESA), the

Japanese Space Agency (JAXA) and the Canadian Space Agency (CSA). India and especially China have made rapid advances in their human-based space exploration programs in the last two decades. To our knowledge, no other space agency in the world is systematically collecting longitudinal medical data on their retired crew members as does LSAH for NASA.

Given that the total number of humans who have flown in space is just over 500, and that a growing proportion of ISS crews are now international, it is essential to start capturing medical data from international crew. [For this article's purpose, "international" will be used to refer to non-US/Canadian crew.] Normally, epidemiologists study several thousands of individuals to achieve statistical power in their analyses of predictors for morbidity or mortality; at best, U.S. researchers currently have access to health data on several hundreds of former crew members. The feasibility study described in this paper was designed to address these challenges to expanding data collection of individual crew medical data: 1) lack of an automated, simple system for transferring medical data to a secure data repository; 2) (for international crew) no existing central data repository designed to accept their medical data over the long term; 3) hurdles posed by each country's medical data privacy law; and 4) concerns of retired crew about sharing their biomedical data.

Directly addressing this last barrier, a consensus statement from members attending the 2018 meeting of the Association of Space Explorers urging collection of biomedical data from active and retired crew members in support of mitigating health risks for future humans in space garnered unanimous support (see [Supplementary Appendix A](#)). This increases confidence that, were collection and transmission of personal medical data made easy and efficient, such data would be readily volunteered by retired crew from around the world. There is some time urgency to this task. The vast majority (~60%) of surviving crew members are older than 60 years of age, with a significant number (~42) 80 years or older (Fig. 1). Hence, it is critical that we organize now to capture on-going and end-of-life medical data or this valuable information will be lost to posterity. Out of 553 total humans space flyers (as of 10/2019), Americans (n = 339) and Russians (n = 120) comprise 83% of the total and no doubt account for the majority of those older surviving crew.

The explosion of health information technologies, including electronic health record (EHR) and personal health record (PHR) platforms, provides opportunities for innovative solutions to managing data

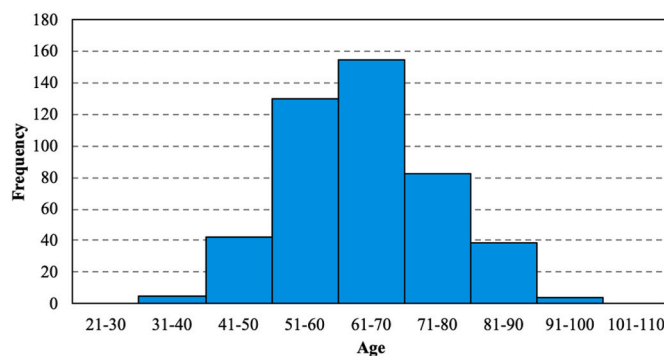


Fig. 1. Numbers of surviving crew members (active and retired) by age group across all space agencies (except China's, for whom public information is not available). The vast majority are above 60 years of age, with 12% of the total 81 years of age or older. Data were collected (and numbers of surviving crew by current age group calculated) from Association of Space Explorers membership rolls and public sources of information on all space flyers, such as Wikipedia, published obituaries, and press releases by family and/or space agencies. Data current as of October 2019. Since these data were collected, four US retired astronauts have passed away (John Young, Owen Garriott, Gerald Carr, Michael Collins) as well as the very first spacewalker, Russian cosmonaut Aleksei Leonov.

collection from retired crew from around the world. Specifically, PHRs have significant potential to enable greater patient engagement in health care, promote better patient-provider communication, and facilitate health self-management [6]. The ASE's unanimous support for data collection suggests that an easy-to-use PHR- or EHR-based solution for collecting and managing their own medical records would be readily adopted by many. An early study indicated that the vast majority (91%) of early PHR adopters were willing to share their health information with researchers [7]. Still, there are notable barriers to PHR adoption and use, including concerns relating to the accuracy of PHR data [6,8] and a generally lower digital literacy of older individuals [9]. Similar barriers exist for use of EHR patient portals. Additionally, patient confidence in EHRs and PHRs is affected by individual concerns about privacy, confidentiality, and security risks, which might be heightened in our target population of former astronauts/cosmonauts. Complex data protection laws that regulate the use and exchange of electronic health information might make addressing these concerns a challenge especially when data sharing crosses jurisdictional and international lines [10,11].

The *long-term goal of this work* is to create an international retired crew (IRC) medical data repository to capture retired astronaut³ data that will otherwise be lost, thereby greatly increasing the “n” for future investigations by qualified researchers beyond that already captured by NASA's LSAH. Ultimately, we envision that data in such a repository would enable a better determination of the long-term health impacts of exposure to the space environment in order to mitigate health risks for current and future crew. Hence, our *short-term goals* included 1) collection of retired crew and other stakeholder input on issues related to collecting medical data; 2) selection of a candidate off-the-shelf PHR or EHR-based product in coordination with an industry consultant and a subsequent evaluation of that PHR or EHR by retired crew; and 3) a preliminary assessment of international medical privacy law pertinent to the collection of individual citizen's biomedical data. Our working hypothesis was that enabling retired crew to manage their own medical/health care data using a convenient application installed on their own smart phone, tablet or laptop would result in a more efficient delivery of such data in the future to a central data repository.

2. Materials and methods

2.1. Surveys for retired crew and stakeholders

In the fall of 2019, pen-and-paper surveys were distributed at the 2019 International Space Medicine Summit (ISMS) at Rice University Baker Institute (September) and at the 2019 Association of Space Explorers (ASE) meeting in Houston (October). ISMS typically attracts retired astronauts and cosmonauts, international space agency managers, flight medicine physicians, and flight medicine researchers from JAXA, ESA, RSA, NASA, and CSA. The 2019 ASE meeting included 125 retired crew delegates from 38 countries.

These surveys were designed by the investigative team to gather feedback from retired crew and other stakeholders about the process of transmitting crew personal medical data, especially that resulting from physician visits or hospital admissions, to existing or future secure data repositories [for US and Canadian crew, this would be the Longitudinal Surveillance of Astronaut Health (LSAH)]. All surveys and procedures involving retired crew and relevant stakeholders were approved by the Texas A&M Institutional Review Board.

³ “Astronauts” throughout this document will be used to refer to crew members of all nationalities, including those typically called “cosmonauts”.

2.2. Creating a product requirement document for a personal health record (PHR) application, with preliminary evaluation

A key element of our project was to work with an industry consultant familiar with EHR and PHR platforms to find an existing product that could be tested for its ability to collect and then transfer personal medical data easily and securely. Our team worked closely with an industry consultant, bPrescient, Inc. (Newton, MA; USA), to develop a detailed Product Requirement Document (PRD) to guide selection of an off-the-shelf product to test with American retired crew for their feedback. Three primary sources of information informed this process: 1) feedback from retired crew and other stakeholders via a focused survey tool; 2) feedback gleaned from in-person conversations with retired crew known to the project PI (BJ Dunbar) and with data scientists/managers of NASA's Lifetime Surveillance of Astronaut Health (LSAH) data repository; and 3) hypothetical case studies discussed with our bPrescient consultant.

The finalized product requirement document included eight sections of requirements, addressing data input, automatic sending of data by sources, output to consumer of data [in this case, a secure data repository], architecture, interoperability, support for application/platform, support services, and security/privacy requirements. The project team ranked all requirements as *mandatory* for the eventual MVP (“shall” in the PRD matrix) versus those that are *highly desirable but not mandatory* (“should” in the matrix), as relevant for the short-term purpose of a preliminary evaluation by volunteer retired crew members. This product requirement document was used by bPrescient, Inc., to recruit interested vendors. Following extensive evaluation of seven finalists that included both EHR and PHR products, the research team selected the personal health record platform MyFHR, created by Care Evolution. The chief reason for this selection was MyFHR's superior functional capabilities enabling the patient/retired crew member to easily ingest personal medical data from health care providers, including the ability to upload pictures/scans of paper-based medical records.

2.3. Evaluating utility of MyFHR

The investigative team constructed a Qualtrix-based survey/evaluation tool in order to document future feedback from retired crew volunteers. The goal will be to document their evaluation of the platform's performance and ease of use, including use of the Cooper-Harper rating scheme that is familiar to all US-based astronauts for rating displays and software applications. A PDF version of the survey can be viewed in [Supplemental Appendix B](#), which also contains a figure explaining the Cooper-Harper rating scale.

2.4. Evaluation of international medical privacy law

For a future IRC repository to be feasible, existing data protection laws must permit retired crew members to acquire and transmit their health data to the repository, and the laws must permit the data repository to collect, disclose, and use the data to understand the health risks of space travel. A preliminary analysis of major data protection laws in six jurisdictions (the European Union, Russia, Japan, China, India, and Canada) was performed by one of the investigators (CS) using traditional legal analysis methods and canons of statutory construction and interpretation [12]. These analyses used English language translations of these laws, from authoritative (i.e., government sources) when available. However, the translated laws from Russia, Japan, China, and India were not official—or binding law—for those jurisdictions. For each jurisdiction, three issues were examined:

- 1) Does the law provide individuals a right to obtain information about them from data holders?
- 2) Does the law permit an individual to send health information in their possession to another country?

- 3) Would the data protection law require an international data repository comply with the law if the data repository contained information pertaining to a citizen of the jurisdiction?

3. Results and discussion

3.1. Retired crew/stakeholder survey result

Quantitative data on responses to the most relevant queries on the retired crew survey (Table 1) highlight several important findings. Responses from US and Canadian retired crew, who regularly report to NASA-Johnson Space Center Flight Medicine for annual physical exams, indicated that collection of personal medical data from primary care providers or hospital stays during the rest of the year might be inconsistent. A sizable minority (25%) of US/Canadian retired crew rated transmission of their own medical data to LSAH as “difficult”, so methods to make this easy and more convenient might improve data flow to LSAH. Responses from international retired crew were consistent with anecdotal feedback to the PI (BJ Dunbar) from ASE members that medical data collection and regular physical exams (as might be conducted by their space agency) are not routine post-retirement. The fact that 90% do not have (or do not know if they have) electronic/digital access to their own medical records might pose a significant challenge to future data collection.

Table 1

Selected survey results from retired crew members. Of the total responses (n = 38), 27 were US retired crew, with 1 Canadian. The 10 international (non-US/Canadian) responses were Russian (n = 5), South Korean (n = 1), and European Union residents (n = 4).

| US/Canadian retired crew responses | % positive responses |
|---|----------------------|
| At my annual JSC Flight Medicine exam, my flight surgeon proactively requests results from PCP exams over the preceding year | 79% |
| Transmitting my medical data directly to LSAH (PCP exam results, medical diagnoses, and hospital visit reports) is difficult | 25% |
| International crew responses | |
| My former space agency provides annual physical exams and/or on-going medical care | 30% |
| My former space agency collects my medical data from annual PCP exams | 50% |
| I have electronic access (via computer/phone) to my own medical data in my home country | 10% |
| I anticipate that legal barriers in my home country (or policy of my former space agency) might prevent me from transmitting my own medical data directly to a secure data repository | 30% |
| Pooled responses from all | |
| I have regular access to the internet via: computer/smart phone/tablet | 97%/91%/59% |
| I am comfortable using my computer/smart phone/tablet for accessing online resources | 100%/72%/61% |
| I can currently access my own medical appointment information and/or medical data via the internet | 63% |
| I can and do transmit my own medical data via the internet | 55% |
| I send my medical data to NASA Flight Medicine or other space agency databases via: paper copies by mail/by FAX/by email or secure digital means | 40%/13%/13% |
| I would be willing to share my “real-world” data collected on wearable devices (Apple Watch/Fibit/Garmins) with a secure data base repository | 70% |
| I would be willing to share personal medical data on a regular* basis if convenient and easy to do so (*72%, with each medical visit; 27%, at least once/year) | 91% |
| I would be willing to sign a prospective consent form to release my autopsy data to a secure database | 93% |
| I believe my family/next-of-kin would also be willing to sign prospective consent to release autopsy data | 79% |

PCP = primary care provider.

Nearly all (97%) retired crew survey respondents indicated willingness to share their personal medical data, including autopsy data (93%), with a secure data repository having the purpose of reducing health risks for future crew. Just over 2/3 of respondents who regularly use wearable technologies (e.g., Fitbits) indicated they would be willing to share those data as well, which creates significant new opportunities to collect “real-world data” (e.g., incidence of atrial fibrillation, heart arrhythmias) as these technologies get more sophisticated over time.

Survey respondents are well-connected with the internet and reasonably comfortable using tablets and smart phones, as well as computers. Although just over 1/3 (37%) of respondents cannot access their medical records online, a slight majority (55%) indicated they are able to transmit their own medical data digitally via internet-connected devices. Nearly as many (45%) cannot transmit their own data electronically or “don’t know” (either if they are able to or there are barriers to doing so). Currently, the majority of respondents (40%) send their personal medical data as paper copies via mail services. Hence, any means of making data transmission easier and more convenient might improve data collection, even in the U.S. An open comment section of this survey yielded three comments that medical data collection and transfer must be easy and pose a “minimum hassle”. Another important comment suggested that any system for collecting retired crew medical data must be proven to be secure.

Results from the survey directed to stakeholders are summarized in Table 2, leading to several conclusions. Collection of personal medical data outside of annual physical exams conducted by the space agency is not as systematic as might be desirable, as greater than 40% of respondents don’t solicit these data at annual exam time. Collection of autopsy data on retired crew appears to be a rare event. The majority (~2/3) of respondents are supportive of enabling retired crew sending their own personal medical data (e.g., hospital discharge notes, important diagnoses from their PCP) directly to a secure data repository. One astute comment raises the very important science question relevant to the ultimate purpose of a secure data repository for international crew: if these data are to determine health risks of spaceflight exposure, we must assure collection of data on family history for disease and lifestyle data, both of which constitute “ground-based” exposures influencing health risks. Notably, most of the respondents work directly with NASA, so these survey data largely reflect experience there rather than with international crew/space agencies. Also, with this small numbers of respondents, we can make only tentative conclusions about stakeholders’ views on these queries.

Table 2

Selected survey results from stakeholders. Of the total responses (n = 12) 4 were biomedical researchers, 2 were space agency managers, 4 were current/former flight surgeons or an Aerospace Medicine resident, and 1 each identified as a contractor for NASA Human Research Program or for LSAH. Of these respondents, 83% work most closely with NASA; the others work with JAXA [2], ESA [1], the Canadian Space Agency [1] or “with NASA and Russia” [1].

| | % positive responses |
|---|----------------------|
| I am directly involved in collecting routine medical data on retired crew members and transfer these data to a secure repository | 58% |
| [Within this subset of respondents] I would rate transfer of those data as “difficult” | 29% |
| [Within this subset of respondents] I actively solicit crew personal medical data related to PCP visits or hospital stays in the preceding year | 57% |
| I have successfully collected autopsy reports on deceased retired crew members | 8% |
| I would lend support to enabling retired crew to send their personal medical data directly to a secure data repository | 68% |
| Note: two more respondents answered “yes, if allowed/ requested by [my] space agency” | (+16%) |

PCP = primary care providers.

Table 3
Summarized findings on international medical privacy law relevant to proposed IRC data repository.

| Jurisdiction and Law | Does the law provide individuals a right to obtain information about them from data holders? | Does the law permit an individual to send health information in their possession to another country? | Would the data protection law require an international data repository comply with the law if the data repository contained information pertaining to a citizen of the jurisdiction? |
|--|--|--|--|
| European Union | | | |
| General Data Protection Regulation (GDPR) | Yes GDPR Art. 15(3) | Yes, but limited exceptions may apply. GDPR Art. 2(2) (c) | Yes GDPR Art. 3(2). |
| Russia | | | |
| Personal Data Act (PDA) | Yes, but limited exceptions may apply. PDA Art. 14(8). | Yes, but limited exceptions may apply. PDA Art. 1(2) [1] | No. No extraterritorial provisions identified |
| Japan | | | |
| Amended Act on the Protection of Personal Information (APPI) | Yes APPI Art 28 | Yes APPI Art 2 | No APPI Art 2 |
| China | | | |
| Cybersecurity Law | No ^a | Yes | No |
| India | | | |
| India's Information Technology Act of 2000 Information Technology Rules of 2011 | No | Yes, but limited exceptions may apply. Information Technology Rules, Rule 7 | No Information Technology Act, Section 1(2) |
| Canada | | | |
| Personal Information Protection and Electronic Documents Act (PIPEDA) | Yes PIPEDA 4.9 | Yes PIPEDA 4.3, 4.3.2. | No. No extraterritorial provisions identified |

^a Pending privacy rules may include a right of access.

3.2. Evaluation of MyFHR personal health record application by U.S. Retired crew

Preliminary testing of MyFHR using our evaluation tool with a convenience sample ($n = 7$) of American retired crew members yielded some valuable lessons before progressing to more comprehensive testing in the near future with our survey tool. This highly educated cohort expressed variable degrees of comfort with the digital skills required by this technology, e.g., taking photos of multi-page reports for uploading or searching for a health care provider within the application. One limitation of MyFHR for this cohort was the lack of alignment of health care providers (HCP's) pre-loaded inside the application with those often used by this population; this includes TriCare, used by the significant proportion of retired crew who came to NASA from the military. A simple means of manually entering one's own HCP would enhance utility of any PHR used for data collection and transmission. Several comments from this cohort reflect that the application's standard privacy notice language, encountered when first logging on, could be a significant deterrent to a population sensitive about sharing their information. This is an issue that must be addressed and may require a customized version of a PHR.

3.3. Preliminary evaluation of international medical privacy law

Data protection laws place limits on the collection, disclosure, and use of information. For a future international retired crew (IRC) biomedical data repository to fulfill the current need, retired crew members must have the capability to acquire and transmit their health information to a future IRC repository. Additionally, a future IRC repository must be able to collect, disclose, and use this information for the purpose of understanding the health risks of space travel. If one or more data protection laws will apply to a future IRC repository, it is important to understand whether the laws individually or collectively act as a barrier for the core functions of the data repository.

Our preliminary analysis of international privacy laws identified a few potential legal issues, but likely no substantial legal barriers to collecting and using the required data for the IRC repository operation (see Table 3). Perhaps most critical of the legal issues, only the China and India data protection laws do not contain an express right of access for individuals, meaning that retired crew members in those countries

cannot compel their health care providers to release their health records under those laws. However, this may change in China where pending privacy rules include a right to access. Additionally, Canada, Russia, Japan and the EU all provide an individual a right to access their health information. All international laws analyzed seem to permit a retired crew member to send their personal health information to a data repository in another country. Of all the laws we analyzed, only the European Union's General Data Protection Regulation (GDPR)—which would apply to any processing of data of IRC residing in the EU—would likely apply to the proposed data repository (in addition to the jurisdictional laws where the data repository would be located). The potential applicability of only two data protection frameworks—the GDPR and the laws of the country hosting the future IRC repository—do not present a substantially complex compliance challenge.

3.4. Limitations

We recognize several important limitations to this work. Given the relatively small number of respondents to the early retired crew and stakeholder surveys, these data should be interpreted conservatively. Notably, the majority (70%) of respondents to the initial survey of crew members were American or Canadian; all those participating in the cohort evaluation of the MyFHR application were retired US crew. It is difficult to predict how well their responses align with those that international crew members might provide, so our conclusions may not be generalizable beyond the US/Canadian crew. However, given the high education and technology literacy of most space agency astronauts and cosmonauts, we believe that the Americans' responses provide valuable insight that might apply to most other retired crew members. Another limitation is posed by the fact that individuals attending International Space Medicine Summit and/or Association of Space Explorer meetings are more likely to be actively engaged in retired crew causes and activities than those not attending these meetings.

The PHR selected by our rigorous screening process, while best fitting the product requirement definition, is not yet able to transmit personal health data from the app to a third party (e.g., an IRC data repository). Further, at the time of this project, Johnson Space Center's Flight Medicine portal for receiving incoming personal health data (which then transmits to the LSAH database) was inactivated. Hence, we were unable to complete even a preliminary trial testing of the selected

PHR application for its ability to both ingest and transmit personal medical data to LSAH. Further work with the PHR firm to ensure the “transmit-out” function and re-establishment of Flight Medicine’s electronic data portal will be required before a more comprehensive evaluation can be attempted.

Lastly, the legal analysis presented is preliminary and the analysis of the issues is sometimes based on unofficial or non-binding English translations of foreign laws. Actual legal limitations or requirements of these international laws might differ considerably from the plain meaning of these English translations. Moreover, other laws not included in this analysis might be relevant to the operation of a future IRC repository. Additionally, governmental actions could create additional barriers, such as restrictions for reasons of state security (e.g., Russia’s Personal Data Act of 2006). Importantly, these findings do not constitute legal advice. Prior to the creation and operation of a future IRC repository, these issues should be examined by appropriate legal counsel.

4. Conclusions

Initial feedback received from US and international retired crew members reflected widespread support for creating a secure database repository to house medical data from non-US/Canadian crew, with the long-term goal of increasing the “n” for future research work by qualified investigators on the long-term health effects of sojourns in the space environment. This is consistent with the Association of Space Explorers’ consensus statement affirming unanimous willingness to share personal health data with an international crew database repository.

The focus of this initial work was on how to harness the power of a commercially available PHR or EHR-based app to streamline medical data collection from individual retired crew members, especially that generated by routine medical visits and hospital admissions. Our working hypothesis was that enabling retired crew to manage their own medical/health care data using a convenient application on their own device would result in a more efficient delivery of such data to a central data repository and, importantly, minimize barriers due to international legal restrictions regarding transmission of medical/health data. Such an application would also have the value-added benefit of enabling retired crew to manage their own health information more effectively and comprehensively.

In this process, we evaluated both EHR and PHR products. To our surprise, some common EHRs fared poorly on some important criteria in our product requirements document in comparison to PHR counterparts. We suspect that this may be due to the different purposes for these products, which address different problems for different populations. EHRs were developed for clinical use for purposes of treatment and payment for health services. In contrast, PHRs were developed for patients as a way to aggregate and control personal health information in an accessible format. Under specific circumstances, some EHR patient portals can meet many of the same patient-centered needs that PHRs address. For example, when patients seek care from providers who all have EHRs that are interoperable and connected to a health information exchange, an EHR patient portal can meet many of the same patient needs that a PHR does. However, these dependencies cannot be assumed for the population of international retired crew, who may have providers without electronic records, come from countries with incompatible EHR technical standards, or lack health information exchange infrastructure between providers. As a specific example, many international retired crew have years’ worth of paper health records that would be relevant to the proposed database repository, but several EHRs we evaluated did not have the ability to upload images (i.e., pdf or jpg) of these paper records or an option to manually enter data as “out-of-the-box” features.

Nevertheless, we did not identify an EHR or PHR product that, straight out of the box, met all of the criteria in our product requirements document. Preliminary feedback received from U.S. retired crew evaluators of our selected personal health record (MyFHR, Care Evolution,

Inc.) indicates that further refinements would be desirable in increasing the number/variety of health care providers pre-loaded on the app, as well as options for uploading pdf versions of documents in addition to taking photographs of paper reports.

The increasingly sophisticated capabilities of wearable technologies that many retired crew members have already adopted presents another unique opportunity for biomedical data collection that could be included in an IRC data repository. The Apple Watch now has capabilities to detect ECG signals from the heart and can correctly detect runs of atrial fibrillation 84% of the time, as validated with subsequent ECG monitoring [13]. A recent study by Kaiser Permanente confirmed that those patients wearing a lead wire-free, single-use ECG monitor who experienced a high proportion of time in atrial fibrillation did indeed experience later a higher incidence of ischemic stroke [14]. Hence, real-world, continuous data collection devices that are being used more and more by the general population also provide a rich source of health-related data on retired crew members and should be explored.

Even once an efficient data transfer technology is refined, there are multiple steps remaining to create an IRC database repository that can receive incoming data from crew members around the world. The physical location of servers housing these data (and/or communicating with cloud-based servers) and the professional staff over-seeing the day-to-day operations of said database repository needs to be determined. Many research-intensive universities offer multiple resources in terms of server management and qualified scientists and professional staff; involvement of data scientists and epidemiologists appears essential. One chief function that must be resolved early on is how medical data deriving from multiple international sources are normalized to a standard language (e.g., English), format (e.g., HL7, FHIR) and units of measurement (e.g., imperial, metric). Standardizing to an established data repository like NASA’s LSAH database would have clear benefits, such as creating interoperability with existing data.

Although our preliminary analysis of international medical privacy law in the chief countries involved in spaceflight endeavors revealed no clear barriers, a more thorough legal analysis on this front should be pursued once the working parameters of an IRC database repository are in place. Finally, the governance structure and long-term funding sources for an IRC database repository must be determined. The relevant ISS Multi-Lateral Control Board, formed decades ago to coordinate issues crossing multiple international space agencies, could play a pivotal advisory role on these points.

Given that there are currently about 120 international retired crew still alive, collecting medical/health data on these crew members has the potential to expand the total “n” for health outcomes in space explorers by 40% (assuming recent count of 306 living US and Canadian retired crew). Enabling our research scientists to work with a more complete database is essential for protecting the health and performance of our current and future crew members, as well as defining the expected long-term health consequences for our retired crew members across the globe.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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